Total Product Affordance Management During Improvement Projects

A Thesis Submitted to Trinity College Dublin, for the Degree of Doctor of Philosophy in the Faculty of Arts, Humanities and Social Sciences

2020
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Abstract

The concept of affordance is linked to external and internal subsystem design aspects. The external subsystem design aspect focuses on product utility and product-user interaction at the interface with a product’s external form. The internal subsystem design aspects focuses on the configuration of component or artefact parts to embody planned utility functions. During development, the external product-user interface communicates an offering of utility which must be consistent with the actual utility functions internally embodied in the product and vice versa.

For Maier and Fadel (2009) such external artefact-to-user affordance emerges as a result of the internal artefact-to-artefact affordance of component parts.

Norman (2013) identified incremental improvement of a standard design as the most successful way of realising useful product affordance designs. Yet, how the development of a relational complementarity between the affordance subsystems (internal and external) and product use scenarios is managed remains an unexplored phenomenon. This research inquired into the management of incremental improvements to the standard design of two established products.

A contribution to theory emerges as a deeper understanding of the process by which relational complementarity with a product’s use environment is enabled through design.

The emergent affordance design management process comprises start points and iterations of the coordinated sequences of actions. They indicate how interactive design dialogue and decision making on internal and external subsystem affordance design considerations are harmonised relative to product use scenarios.
Acknowledgements

Firstly, I would like to express my sincere gratitude to my supervisor Professor Paul Coughlan for the continuous support of my PhD study, for his patience, motivation, and immense knowledge. His guidance helped me in conducting the research and the writing of this thesis. I could not have imagined having a better advisor and mentor for my PhD study.

Besides my supervisor, I would like to thank Professor Joe McDonagh and Dr Katrin Dreyer-Gibney for their insightful comments, but also for their continued support during the entire process.

My sincere thanks to all those in the host organisations that gave their time and provided access to the data necessary to conduct this research.

My sincere thanks to my colleagues in Waterford Institute of Technologies who supported me during the process.

Last but not the least, I would like to thank my family: my parents and to my brothers and sister for supporting me throughout writing this thesis.
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Chapter 1: Introduction to the Thesis

1 Thesis Introduction

Research in the product design and development field is typically conducted from two design perspectives; interaction and engineering design (Norman, 2013). These two perspectives characterise two different but related subsystem aspects of a product’s affordance design; the external “human-using interface” and internal “product-working” features (Kim & Lee, 2010). These design perspectives condition how developers of external or internal subsystem aspects think on improving a product’s affordances. Reviewing the affordances of existing designs can help identify improvable aspects. “The design can then be changed to enhance or reduce the salience of particular action opportunities” (Srivastava & Shu, 2013).

Currently, there is no empirical study or theoretical model that relates to management of the two subsystem aspects of improving a product’s affordance. A challenge for improvement project managers and the focus of this research, is exploration of how the external-internal affordance relationship is managed during improvement projects.

Affordances are form dependent. However, there is a tendency for product affordance research to be conducted from external or internal subsystem perspectives of a product’s form. Neither perspective is independent of the other (Maier & Fadel, 2009). The product’s external form signifies action possibilities and internally structures embodiment of the utility functions implied externally (Maier & Fadel, 2009). Affordance design conceived exclusively from subsystem aspects of a product’s form is misleading and narrow (Ravasi & Stigliani, 2012). Ravasi & Stigliani, (2012) claim “that a different perspective is needed, one that takes into account the entire process”. With improvement team members as the agents of change, an objective of this research is to explore affordance design management from the perspective of a total product’s affordances rather than individual subsystem aspects.

Of interest is how the process of managing the relational design of internal and external subsystem aspects is coordinated during product improvement projects. Maier and Fadel’s (2009, 2007) relational theory for affordance based design defines external and internal subsystem considerations of a total product’s development. In the case of an
artefact designed to be used by people team members are concerned at the external subsystem level with improving the affordances between the artefact and user. At the internal subsystem level, team members are concerned with improving the affordances that exist between the artefact’s parts (Maier & Fadel, 2007). The focus of this research is the “total product affordance” perspective when managing external and internal affordance subsystem improvements. Consequently, the theory of affordance underpins this exploratory research of the total product affordance design management process.

The discrete subsystem focus of product affordance design research has, to date, limited the understanding of product affordance design to “what” external and internal subsystem affordance aspects are, rather than “how” the relationship existing between affordance subsystems is harmoniously integrated as a total product offering.

The two subsystems, if harmoniously integrated within a product’s offering, improve the likelihood of a product’s success in the market (Chen, Huang, Zhang & Xie, 2013). This research proposes the external-internal subsystem relationship as a way of exploring management of a total product’s affordance design during improvement projects (Norman, 2013, Maier & Fadel, 2009).

The unit of analysis is product improvement process.

1.1 Emergence of the Research: Interpretations of Product Development Practice in Hewlett Packard (HP)

“For three decades, HP inkjet technology has set standards for printing in the office, in technical and display graphics, and in commercial high-speed print production by delivering cost-effective, reliable, and high-quality solutions.” (Hewlett-Packard, 2015 p1)

During this three decade period HP has optimised its range of inkjet printer products to meet the demanding requirements of the business office environment. Incremental improvements to three parts, standardised across the range of inkjet printer products, characterises the product development approach adopted by HP. These sub-system part improvements focused on the printer ink, the ink cartridge and print head designs, enabling their range of inkjet printer offerings to perform at the same level as laser jet
technology in terms of print speed, print quality, print durability and printer reliability (Hewlett-Packard, 2013).

Changes made to the design of the standard inkjet cartridge resulted in less bulky and more cost effective printer designs. Changes made to the design of the ink formula (use of pigment over dye) resulted in improved print durability, and changes made to the design of printer heads (page wide sized heads) resulted in faster print speed without compromise to print resolution. Each subsystem part improvement progressively set the basis of subsequent improvement cycles to develop an engineered printer offering that complemented the printer use environment.

In all improvement cycles “chemists on HP’s ink R&D teams collaborate closely with HP color scientists and engineers developing print-heads, writing systems, ink delivery systems, and papers. Working together, these teams manage the design decisions and trade-offs required for the best system-level solution.” (HP Technical White Paper, 2014, p1) Each change project is briefly discussed.

1.1.1 Changes improving the design of the HP Ink Jet Cartridge Part

“Manager Tom Alexander finally grabbed an HP printer and set it on the conference room floor. Then he stood on it, all 200 pounds of him. The point behind his grandstanding? Customers aren’t going to use printers as step stools, so don’t add costs by building them strong enough to withstand the weight of a grown man. Instead, design them to fit in the kitchen and print nice pictures” (Watson, 2003 p.1). Printers are not designed to afford the utility of a step stool. Yet, in doing so, HP released a printer product to the market that was mismatched with market offerings:

- The printer, compared with competitor offerings, was too bulky and heavy for use in a confined space within a room,

- The printer, while offering the same quality of print resolution as competitor offerings, was more expensive due to its unnecessarily robust exterior design.

The printer’s design needed to be more frugal but still offer the same high quality print resolution, if not improve on the current offerings available within the market place. The finished printer product, as a system of interacting parts, had to adequately capture functional requirements (print resolution output) within a form (more compact) that was consistent with market offerings (reasonably priced printing device). Design dialogue started with consideration of the printer’s systems external form. The printer needed to be designed with a physically smaller outer body. With the outer body reduced in size,
design discussions continue to the internal configuration of ink jet printer parts. Parts needs to be reduced in size to fit within the smaller outer body. However, print quality could not be compromised.

Engineers realised that an opportunity lay in consideration of design changes to the parts of the inkjet cartridge. The first change involved halving the size of the silicon chip, the most costly part of the inkjet cartridge. However, this size reduction impacted on the number of inkjet spray nozzles compromising quality of ink output and in turn the print resolution. Two different but related design changes were required to reconcile the impact of the change. First, thinner nozzles enabling an increase in the number of spray holes and secondly, a refinement of the ink viscosity to allow flow consistent with expected resolution quality. Refinement of the ink viscosity was not the only change made to the ink module.

1.1.2 Changes improving the design of the HP Printer Ink Part

Improving “print durability is a key element in HP’s ink and printer development programs” (HP Technical White Paper, 2015 p.1)”. Two issues that impacted print durability was “show through” and “feathering” resulting of the ink formula. Resolution required design changes to the ink formula with chemists focusing design dialogue on analysis of the effect of dye vs pigment based inks. The chemistry of HP pigment inks quickly immobilizes the pigments on or near the paper surface “to produce high color saturation and high black optical density as well as control color bleed, feathering, water-resistance, rub-resistance, and show-through” (Hewlett-Packard, 2015 p3).

However, about 60% of ink is water and a related issue is evaporation, impacting the density, viscosity, and surface tension of the ink form, leading to a plug of viscous fluid that may prevent drop ejection altogether from the print head (HP Technical White Paper, 2014). Engineers realised that resolution required improvements to the printer head, realised by placing caps on the printer’s printer head.

1.1.3 Changes improving the design of the HP Inkjet Printer Head Part

Traditionally, inkjet printers had a small print head that moved across the page impacting time taken to complete the print job. However, in 2013, HP engineers developed page wide fixed inkjet print heads that improved print speed and printing quality in a single pass.

“A common expectation for digital printing is that you can’t have it all: if you need to print faster, then you should expect lower quality; if you need the highest quality, then
you must accept lower productivity.” (Hewlett-Packard, 2015 p.1). Improvements to print head technology overcame these trade-offs.

This HP practice examples suggest that management of improvement in a product’s affordances involves:

1. Design changes that reconcile the design of internal and external subsystems parts of the printer’s design to a specific use environment,
2. Dialogue between cross functional improvement team members in possession of the skillsets required to make the necessary changes.
3. The organisation’s product development process informed improvement dialogue and decisions made.

1.2 Research Question
Management of the external-internal affordance relationship is complex and reflects a practice based phenomenon from which the research question emerges. The research question is:

How is management of action possibilities in external subsystems coordinated with internal subsystems in order to achieve improvements in product affordance and complementarity with a use environment?

This question focuses on identifying the management process used by team members to improve the complementarity of an existing product’s action possibilities to dynamic use environments.

1.3 Research Assumptions
The assumptions behind this research were informed by an overview of insights from product design and development literatures.

A product’s affordances are defined relative to a team member’s assumptions of a product’s use environment (Norman, 1989). A product’s affordances are “considered to be opportunities for action that are provided by an artefact to a human. Team members interpret the perceivable action possibilities required of the artefact to provide a utility to the user within that use environment (Brown & Maier, 2015).
When teams engage in product development projects, they reflect upon two different but related aspects of shaping a product’s action possibilities; the “human-using” and “product-working” features (Kim & Lee, 2010). These two aspects characterise external (human-using features of a product’s external form) and internal (product-working features of a product’s configuration) considerations of a product’s subsystem of affordances.

Opportunities for interaction between a product as an artefact and a user (A-U) or another product/artefact (A-A) are categorised as external subsystem affordance design considerations. Opportunities for interaction between parts within a product (A-A) are categorised as internal subsystem affordance design considerations (Maier & Fadel, 2009). External and internal subsystem considerations of a product’s design reflect a way of backward reasoning and identifying improvable subsystem aspects of an existing product’s affordance design (Srivastava & Shu, 2013).

In product design research, affordances are predominantly discussed from the perspective of the user. This is understandable. After all, it is the user who will perceive action possibilities and interact with the product’s external form. However, the utility implied by action possibilities is dependent upon the interactive arrangement of internal parts that actualise functions within the product’s structural form (Kim & Lee, 2010). As such, the external-internal affordance based relationships represent co-development considerations. Co-development considerations are challenged by the need for management to understand how a product, as a total offering, is developed to complement specific use environment.

1.4 Research Design
The research question explores a product development management phenomenon: improving the relationship between the external and internal subsystems of a product’s affordance design. The research is exploratory and conducted through case work. The contribution is represented by a different way of thinking: retrospective review of product improvements as a way of exploring the approach adopted in practice to managing the external-internal affordances relationship of a total product’s design.
This contribution is theory based through a conceptual model of the external-internal affordance relationship for conducting exploration of management of the external-internal affordance relationship in practice. It is this framework that proposes the relationships to be managed in a total product affordance design context.

1.5 Key Terms
This section presents key terms and insights informing this research.

Use Environment: The unique and dynamic settings within which a product could be used and that defines the context of a product’s design and development to be useful to users in this scenario.

Team member: a person that possesses a specific skillset and is tasked with the creative task of determining the design of a specific aspect (interaction or functional features) of a product. This person is a member of an improvement team, including other members.

Affordances: An intended purpose/ utility. Products are engineered to provide specific utility offerings to the user.

Action Possibilities: Signified opportunities for interface with a product’s form that imply how products and users may interact with the product to experience a utility offering.

Subsystems: A product comprises internal and external parts which form smaller systems within the total product - a larger system.

1.6 Thesis Structure
The thesis is presented through eight chapters. Following this chapter, chapter 1 Introduction, seven additional chapters systematically structure the thesis. These chapters are as follows:

- Chapter 2, Literature Review: This chapter presents a critical review product affordance design literatures to explore what is known and unknown in relation to the research topic. This review includes critical reflection on the contexts of
relational design and product development management and identifies the research gap leading to a refinement of the research question,

- **Chapter 3, Conceptual Framework**: This chapter presents the initial theoretical perspective underpinning the research from which a conceptual framework is constructed. The emerging framework guides the empirical work and forms the basis for the planned theoretical contribution to knowledge in product development management.

- **Chapter 4, Research Design**: this chapter presents the philosophical stance adopted by the researcher in this thesis and the related methodological approach taken in forming the research strategy, the criteria for selecting companies and products for data collection and analysis.

- **Chapter 5, Case 1: Managing affordances for the Sound Reproduction Use Environment**: Pilot case study based upon the relational design of a headphone, revealing the initial empirical observation of management of the external-internal affordance relationship phenomena during phases of improvements to a headphone’s affordance design relative to a use environment within a practice based product development scenario.

- **Chapter 6, Case 2: Managing affordances for the CRM Use Environment**: Second case and final study, building upon case 1 insights, focusing upon management of the external-internal affordance relationship during phases of improvements to a pacemaker’s affordance design relative to a different use environment within a different practice based product development scenario.

- **Chapter 7, Between-Case Analysis, Findings and Discussion**: This chapter presents general observations from each case and consolidates observations between the 3 case studies. Here, an emerging model visualising the process for managing relational design of a product’s representation, through an explicit emphasis on the external-internal affordance relationship, is presented and discussed in detail.

- **Chapter 8, Conclusion and Contribution**: This Chapter presents a response to the research question, proposing how the gap in the literature is closed and contributions to theory, practice and methodology. Limitation of the research, opportunities for future research and a future publications plan are also presented.
Chapter 2: Critical Reflection on Product Affordance Literature

2 Literature Introduction

This chapter lays out the theoretical reflection on the external-internal affordance relationship focus from which the research question originates: How is management of action possibilities in external subsystems coordinated with internal subsystems in order to achieve improvements in product affordance and complementarity with a use environment?

Originating from perceptual psychology, Gibson (1979) coined the concept of affordances, arguing that humans exist in 'systems' or 'ecological' relationships with an environment and that that environment affords various action possibilities (a rigid surface affords support). The concept of affordance has been adopted to conduct “scholarly analysis across multiple fields—including media studies, science and technology studies, communication studies, ecological psychology, and design studies among others” (Davis & Chouinard, 2016 p.241).

Norman (1988) related Gibson’s concept of affordances to product design, identifying the product’s role to communicate, to the user, the utility offering afforded through interface with the object’s design. Maier and Fadel (2003) introduced the concept of affordance to the engineering design field categorising an affordance as comprised of an external and internal system. Maier and Fadel (2009) subsequently defined three affordance subsystem considerations of a product’s development: the external artefact to user (a-u) affordance, the external artefact to artefact (a-a) affordance and the internal artefact to artefact (a-a) affordance. These subsystem aspects structure the external-internal affordance relationship of developing useful product affordance design (Maier & Fadel, 2009).

A product’s use environment is dynamic. In product design, the concept of affordance has been identified as particularly suited to product redesign and the development activities of implementing improvements in the complementarity of existing product designs to specific use environments:

“Most innovation is done as an incremental enhancement of existing products.”
“Because of the century of incremental enhancement, today’s automobiles are much quieter, faster, more efficient, more comfortable, safer, and less expensive.
(adjusted for inflation) than those early vehicles.” “Incremental innovation makes things better.” (Norman, 2013 p. 43, p.280)

“Once a design or a conceptual design is developed, affordances clearly have a role to play in investigating undesirable possible actions, perhaps leading to designs that are safer and easier to use.” (Brown & Blessing, 2005 p. 28)

“Identifying the affordances of existing designs can help improve products. Designers can better understand how users perceive their design, specifically all the potential actions users can envisage performing with their design by listing all its affordances. The design can then be changed to enhance or reduce the salience of particular action opportunities” (Srivastava & Shu, 2013, p.3)

The foundational elements underpinning the concept of affordances in product design and development research represents a way of understanding how improvements in the complementarity of a product’s affordance design to specific use environments is approached (Norman, 2013, Maier & Fadel, 2009). This chapter explores existing product affordance design and development literatures and frameworks towards revealing what is “known” and “unknown” in relation to managing the external-internal affordance relationship.

The research question is divided into four sub questions:

1. What design principles, definitions and terms are used in relation to the relational design of a total product’s affordances?
2. How is the design for internal and external affordance subsystems understood and determined?
3. What is the role of relational design within the development process?
4. What steps are involved in managing the relational design of a product’s internal and external affordances?

These four sub-questions enable an exploration of literature on internal and external affordance design considerations of engineered products. Table 1 presents an overview of the scholarly research on the affordance concept in product design and development research. It is these scholarly insights that underpin the focus of the product affordance design and development literature reviewed within this chapter. It is these literature insights that enable an overview of what is known and useful towards answering the research question to be established. Additionally, what remain unknown and preventing an answer to the question, reveals the gaps and research opportunity going forward.
<table>
<thead>
<tr>
<th>Author</th>
<th>Year</th>
<th>Article Title</th>
<th>Contribution to Product Affordance Literature &amp; Answering the Research Question</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gibson</td>
<td>1977</td>
<td>The Theory of Affordance</td>
<td>Defined an affordance as what the environment provides or furnishes the animal. Affordances, or clues in the environment indicate possibilities for action, and, depending on users’ physical capabilities, are perceived in a direct way. It implies the complementarity of the animal and the environment. Action possibilities result of the relationship between a user and an environment. Perception of the environment inevitably leads to opportunity for action, whether or not the user perceives the opportunity.</td>
</tr>
<tr>
<td>Norman</td>
<td>1988</td>
<td>The Design of Everyday Things</td>
<td>Building upon Gibson’s definition of affordances, Norman introduced the concept of affordance to product design. Norman coined the term “perceivable action possibilities” of artefacts. Product are designed to be complementary to specific use contexts by enabling the perception of opportunity for utility interactions between the designed object and a user.</td>
</tr>
<tr>
<td>Maier &amp; Fadel</td>
<td>2002</td>
<td>Comparing Function and Affordances as Bases for Design</td>
<td>Maier and Fadel (2003) introduced the concept of affordance to the engineering design field proposing the Affordance-Based Design (ABD) approach to overcome the weaknesses of Function-Based Design (a transformative input-output process that does not consider the complex relationship between the designer, user and artefact).</td>
</tr>
<tr>
<td>Maier &amp; Fadel</td>
<td>2007</td>
<td>Identifying Affordances</td>
<td>Presents external and internal affordance systems, discussing their usefulness to conducting backward reasoning focused on redesign and developing improvements.</td>
</tr>
<tr>
<td>Maier &amp; Fadel</td>
<td>2009</td>
<td>Affordance-based Design Methods for Innovative Design, Redesign and Reverse Engineering</td>
<td>Presented the broad view of affordance-based design supporting the ability to documenting affordances, design individual affordances and as basis for reverse engineering and redesign.</td>
</tr>
<tr>
<td>Maier &amp; Fadel</td>
<td>2009</td>
<td>Affordance Based Design: A Relational Theory for Design</td>
<td>Presented the concept of subsystems, the Designer-Artefact- User (DAU) model supported by discussion on the complex relationship between the designer, user and artefact during the development process.</td>
</tr>
<tr>
<td>Norman</td>
<td>2013</td>
<td>The Design of Everyday Things. Revised and Expanded</td>
<td>Reveals the ongoing relevance of the original concept, and introduces new insights from the developer’s perspective: the notion of signifiers and product development perspective of affordances: incremental improvements to existing product designs.</td>
</tr>
</tbody>
</table>

Table 1  Critical Reflection on scholarly product design and development research underpinned by the theory of affordance
Development as an activity and the product development process stand out as being two relevant concerns for mapping out the related areas of literature that resonate with the relational design for affordances research focus (Brown & Maier, 2015). Products are improved relative to two affordance design contexts: the context of consumption and the context of enabling development of complementary product offerings (Kim & Lee, 2010, Gero & Kannengieser, 2008).

Therefore, these two design contexts inform perspectives sought in the literature reviewed:

1. Context of consumption: products are designed relative to the environment within which a product will be used (Gibson, 1979). The use environment defines the physical and functional requirements of affording complementary product designs (Xenakis & Arnellos, 2013; Gero & Kannengiesser, 2014). Complementarity requires a product to be designed to provide action possibilities of delivering specific utility offerings (Hartson, 2003),

2. Context of development: affordance of a utility offering emerges through the development of external human using and internal product working aspects of a product’s utility offering (Kim & Lee, 2010). The complementary of a product’s utility offering is evaluated relative to assumptions of user and product interface requirements (Xenakis & Arnellos, 2013).

Therefore, an exploration of existing design literatures, relative to these two contexts, offers the opportunity to gain insights on product affordance design considerations during the development process. It is these insights that form the substantive detail of this chapter: The literature review. Management is explored relative to the two contexts of a product’s affordance design that inform how a developer thinks and approaches development of improvements in the complementarity of internal and external aspects of a total product’s affordance design.

2.1 Product Affordance

The term affordance refers to the relationship between a physical object and a person. The properties of the object in relation to the person’s past knowledge and experience of interacting with similar objects defines its affordance relationship (Norman, 2013). The
Affordance relationship is communicated by the action possibilities of the object, the opportunity for interaction with the object (Gibson, 1979). An important property of affordances is complementarity (Maier & Fadel, 2009). An affordance is predicated on the complementarity of an object’s action possibilities to the environment. (Burlamaqui & Dong, 2014)

Affordances are useful in product design. Products, referred to as artefacts in affordance design, are used by users. Designers create the affordances of a product according to their assumptions of a user’s utility requirements (Maier & Fadel, 2009). A product’s affordance design points two ways, to the environment and to the user (Maier & Fadel, 2009). Products acquire affordances through the intentional development decisions of designers (Burlamaqui & Dong, 2014). The development decisions of designers are constrained by the environment within which a product is targeted for use and product-user interface requirements of this environment (Norman, 2013).

The relationship between a product’s use environment and the action possibilities required of the artefact itself is complementarity. Capturing complementarity informs designer decisions when developing a product’s affordance design (Burlamaqui & Dong, 2014).

Affordances are form dependent. “By definition, it is the form (i.e. structure) of an artifact that determines what it affords the user” (Maier & Fadel, 2009 p.21). It is the perceivable action possibilities of a product’s form that enables the user interpret the complementarity of a product’s utility offer to their use context. However, there are two perspectives, physical and functional, to the context of developing a product’s affordance design: A physical form that enables perceivable opportunities for interaction with a product and a configuration of parts that embody the technical capabilities that enable utility to be integrated within the product’s form.

2.2 Context of Development: Affordance Design Aspects

A common approach to managing a product’s affordance design is to distinguish between external and internal aspects of a product’s development (Kim & Lee, 2010).
- Designers involved in external design focus on shaping the product’s external form to enable physical product and user interaction opportunities shaping ‘human-using’ features.
- Designers involved in internal design focus on structuring the interactive arrangement of parts that actualise embodiment of ‘product working’ functionality within a finished product’s form.

The external and internal attributes of a product’s design, enables designers assess the complementarity of an existing product’s affordance design to specific product use environments (Gero & Kannengiesser, 2014; Norman, 2013). Management of the product development process enables dialogue and decision making on the consistency of interactions enabled with and within a products design (Xenakis & Arnellos, 2013; Maier & Fadel, 2009; Howard, et al., 2008).

The following sections presents an overview of when (in the product development process), what (external and internal subsystem aspects of a product’s affordance development) and who (a team) is involved in managing the implementation of improvements in a product’s affordance design.

2.2.1 The Product Development Process
The product development process (PDP) defines the procedures and methods that companies use to design products and bring them to the market (Unger & Eppinger, 2012). The development process comprises “the sequence of steps or activities than an enterprise employs to conceive, design, and commercialise a product” (Ulrich & Eppinger, 2012, p12.). There are three types of product development opportunity: new product platforms, derivatives of existing platforms and incremental improvements to existing products. (Trott, 2008) It is within an organisation’s PDP that improvements in the complementarity of a product’s affordance design are coordinated.

Reviewing “the affordances of existing designs can help improve products” (Srivastava & Shu, 2013 p. 3). Artefacts exist in time, and are subject to change (Burlamaqui & Dong, 2014). A user’s mind-set, preferences and technology: all will change redefining the settings of the use environment and the context of developing complementary affordance designs (Norman, 2013, Maier & Fadel, 2009).
A benefit of thinking from an affordances design perspective is product redesign (Srivastava & Shu, 2013). While affordances, as ‘possible actions’, are an important consideration while designing new product designs, it isn’t always easy to reason out what they are, as the search space is large (Maier & Fadel, 2007). However, “once a design or a conceptual design is developed, affordances clearly have a role to play in investigating undesirable possible actions, perhaps leading to designs that are safer and easier to use.” (Brown & Blessing, 2005, p.6).

The affordance design approach supports “backward reasoning” of external and internal aspects, enabling designers reflect on the action possibilities of the existing design with a view to determining ways of improving complementarity (Maier & Fadel, 2007). Backward reasoning enables the nature of an improvement, a human using or product working aspect, to be identified. “The design can then be changed to enhance or reduce the salience of particular action opportunities” (Srivastava & Shu, 2013 p.3).

A commonly used product development system is the Stage-Gate process which envisions businesses as a sequence of work organized around decision points (Summers & Scherpereel, 2008). Depending on the nature of the development project required, there are three different stage gate approaches to inform the implementation of product affordance design improvements:

1. Stage-Gate for big innovation projects,
2. Stage-Gate for smaller projects,
3. Stage-Gate Lite for minor projects.

The stage gate PDP is structured as a series of development stages, from idea screening to launch of a commercial product, with gates as checks between these stages. Each stage is designed to collect specific information to help move the project to the next stage or decision point. Each stage is defined by the activities within it. Activities are cross-functional (not dominated by any single functional area) and are designed to gather information and progressively reduce uncertainty and risk.

Each stage has a deliverable (Cooper, 2008). The improvement team gathers information, through the defined activities of each stage. A review, conducted through an integrated analysis of the activities of that stage, is used to confirm adequacy of the output of a stage against the deliverable (Cooper, 2008). Decisions for proceeding through a gate is dependant upon meeting the deliverables of that stage. The adequacy result of a stage’s
review informs Go/Kill decisions. These decisions determine the ability to proceed through the gates to the next stage or the necessity to end the design project. Stages allowed iterations between activities towards addressing adequacy of its output. Determining adequacy involves a series of build-test-feedback-and-revise loops from the perspective of the customer (Cooper, 2011).

External factors such as government regulations, industry standards, business policies, sales policies, inventory conditions, vendor relationships, and production scheduling, among others impose design requirements that reflect “rules” exhibiting constraints on how component interactions are developed (Cram, et al., 1999). As a result, a product’s development can be viewed as a complex system requiring adaptive management to enable the materialisation of useful product affordances (Holland, 1992).

McCarthy et al., (2006) proposed the Complex Adaptive System (CAS) as a product development framework for facilitating interpretations of the emergence of complex systems such as a product’s development. Emergences are modelled as resulting from iterations in design. During iterations the nature of interactions between parts is assessed by investigating how changes to one component part will affect other component parts, and the behaviour of the product as a whole.

The complementarity of a product’s design to specific use environments is underpinned by the development of perceivable and experience-able action possibilities (Hartson, 2003). A product development process comprises a series of stages with feedback loops that inform the focus of design dialogue which seeks to improve this complementarity. Action possibilities emerge from the dialogue including the interactive arrangement of parts to embody utility functions consistent with that implied by visual reference of a product’s external form (Maier & Fadel, 2009). Therefore, external and internal subsystems of a product’s affordance design reflects a way of approaching management of improvements. Each aspect of a product’s affordance design is discussed in the following sections.

2.2.2 External Aspect of Developing Complementary Product Affordance Design
Norman (1988) introduced the concept of affordances to the design of everyday things. Norman’s concept of affordance “conflates two important but different things—designing the utility of an object and designing the way in which that utility is conveyed
to the user” (Boyle & Cook, 2004 p.296). Presented from a human centred design perspective, Norman (1998) defined affordances as the perceivable action possibilities of a product’s physical design.

Action possibilities refer to the interaction opportunities that a user, resulting of experience of similar products, considers possible of a product’s design. Interaction opportunities inform perceptually guided interactive behaviours between the user and the designed product. Norman made reference to an example of a chair to explain affordances: A chair is designed to be perceived as capable of supporting a weight, inviting the consumer to interpret the affordance to be seated. Norman argues that a chair affords “sitting” because past user experience of a chair supports the sitting action. Norman’s definition of affordances has become widely accepted as a fundamental principle of good product design. The success of a product’s design has been linked to the affordances that a product is developed to enable perception of (Norman, 2013). “Affordances provide strong clues to the operations of things” and “when affordances are taken advantage of, the user knows what to do just by looking” (Norman, 1988 p.9).

“Affordances are of little use if they aren’t visible to the users’, meaning ‘visible’ in both the sensory (detectable or observable) and cognitive sense (understandable)” (Hartson, 2003 p.322). Perceivable action possibilities emerge of decision on a product’s interaction design. According to Norman (2013, p13) interaction designers “have practical problems. They need to know how to design things to make them understandable.” Whilst affordances define what actions are possible, interaction designers adopt use of signifiers to specify how people discover those possibilities. Signifiers of a product’s affordances, perceivable through the attributes of a product’s form, are a visual reference of the opportunity for product-user interactions (Norman, 1988). These interaction attributes enable perception of opportunities for interface with a product (Brown & Maier, 2015, Burlamaqui & Dong, 2014). Signifiers are of importance to interaction designers as signifiers signal product interaction abilities, in particular what actions are possible and how they should be conducted. Therefore, signifiers must be designed to be perceivable; else they fail to function (Norman, 2013). When looking at a door bell, the user perceives the action possibilities of the door bell’s button. The button can be interpreted as affording pushing.
Discovering interaction opportunities requires the user to perceive physical features of a product. The user must be able to recognize that a feature can be associated (i.e., the direct or reasoned out “relationship”) with and invite certain behaviour (i.e., evoking a way of acting) of interaction with an object (Brown & Maier, 2015). For example, a button affords pushing; i.e. the features of the button make it look “push-able”, signifying the interaction opportunity enabling a user, in turn, to perceive and behave by partaking in the “push” action. The aesthetic design of a finished product’s form extends a visual reference of the benefits that the product offers the consumer (Candi & Saemundsson, 2011), including the ability of a product’s design to: “draw attention to the product; foster recognition of product type; generate attraction; support comprehension of function; encourage attribution of qualities; promote personal identification; stimulate emotion; and provoke action” (Crilly, et al., 2004 p.7).

A product’s use environment defines design situated determinants of its form. Interaction designers are tasked with understanding a product’s use environment and the attributes required of an external form to exhibit action possibilities that are complementary (Xenakis & Arnellos, 2013). Interaction designers, applying knowledge from past design experience, make “dynamic presupposition” on the attributes required of a product’s external form to make its action possibilities perceivable (Xenakis & Arnellos, 2013). A product’s external form must be designed to exhibit visual references of the interaction opportunities deemed by interaction designers as necessary to make its action possibilities perceivable (Xenakis & Arnellos, 2013). It is critical that the design of such interactions work toward evoking positive anticipation of utility interactions.

According to Xenakis & Arnellos (2013), aesthetics are held as one of the most crucial decisions in the process of designing interactions. The aesthetic attributes of the product’s form visualises interactions enabled and infers the utility a user can expect to experience of interface with the product (Xenakis & Arnellos, 2013).

A product’s aesthetic attributes (geometry, dimensions, textures, materials, colours, graphics and details) reflect the visual references upon which the user forms cognitive impressions of the engineered product’s offering (Crilly et. al, 2004, 2009). These cognitive impressions are formed through perceivable sensory capabilities (vision, touch,
taste, smell, hearing) of product-user interactions signified by a product’s form (Maier & Fadel, 2009).

The attributes of a product’s external form implies embodiment of a utility offering. Recalling the doorbell example, the user doesn’t press the door bell’s button just because it’s possible. A user presses the button “to accomplish a goal, to achieve a purpose” (Hartson, 2003); to invoke a ringing operation.

The role of affordances does not end with managing development of the physical features of the product’s design (Kaptelinin, 2013). “An action possibility really is an “opportunity”, not a promise” (Brown & Maier, 2015 p4). What is implied as enabled or offered through interface with the product’s form must be delivered upon; perceivable action possibilities also need to be designed to be experience-able (Brown & Maier, 2015 p4). The complementary of a product’s design also requires development of functional affordances. Functional affordances are the purposeful actions that, embodied within the product’s form, underpin delivery of the implied utility offering. Therefore, another challenge is managing the development of an internal configuration that actualises the embodiment of utility functions.

2.2.3 Internal Aspect of Developing Complementary Product Affordance Design

Maier and Fadel (2003) introduced the concept of affordances to engineering design by reconciling function with the affordance concept. However, Maier & Fadel felt that Norman’s concept of affordance design, when viewed from an engineering point of view, stopped “short of incorporating the concept of affordance as fundamental to the design of any artefact” (Maier & Fadel, 2009 p.20).

Brown & Blessing (2005) state “that when an artifact provides a function to a user it has a set of interactions or relationships with the environment (where the environment includes the user) so that those interactions play a desired role for the user”; delivery of a utility offering. Function cannot be fully explained without reference to its physical embodiment. If we characterize the provision of a function as supporting an affordance, then the design of this affordance will of course require the specification of the necessary artefact structure (Hartson, 2003). Prior to Maier and Fadel’s reconciliation of function with the concept of affordances, product affordances were limited to the discrete perspective of external product affordance design considerations. However, Maier &
Fadel’s insights have extended the concept of affordances, enabling product affordances to be characterised by two design considerations: (1) The perceivable human centred interactive design aspect of affordances, introduced by Norman (1988), reflecting an external product design consideration and (2) the engineering design perspective of affordances, introduced by Maier and Fadel (2003), reflecting an internal product design consideration through which human centred interactive opportunities emerge.

“In engineering design, the end goal is the creation of an artifact, product, system, or process that performs a function or functions to fulfill customer need(s)” (Maier & Fadel, 2009, p17). The engineering designer works on the assumption that the developed product must fulfil an intended purpose. Gero’s FBS framework (1990) reflects a general process for mapping the functions of affording an intended purpose. The FBS Model evolved from design thinking reasoning on how humans exist in a natural physical environment and operate in a socio-cultural environment. Functions are the expected actions of a product and actualise the affordance of an intended purpose or utility offering (Gero & Kannengiesser, 2008). The interactive arrangement of a product’s component parts actualisation how functions are embodied within a product’s form. Specifically, function (F) is ascribed to behaviour (B) by establishing a teleological connection between the human’s goals and observable or measurable effects of the object. Behaviour (B) is causally connected to structure (S), i.e. it can be derived from structure using physical laws or heuristics (Gero, 2008).

Problems may arise from the complexity in configuring component systems. The inclusion of one component or sub-system may mandate the inclusion of other sub-systems and components, as well as the exclusion of still other sub-systems and components (Cram, et al., 1999).

Smith & Bahill, (2010) identify attributes as “causes” that imply how functional properties and intended purposes are enabling for integration within the component system. Trade-off dialogue focuses on analysis of component part attributes as a way of achieving consensus of resolution on the finished product’s functional configuration and the affordance realised. “Trade-offs are relationships of attenuation that hold between two or more modelling attributes, or what Levins (1966) called desiderata of model building” (Matthewson & Weisberg, 2009). A Trade Off is a method for evaluating a system of value with regards to what product working features a product should possess,
directly related to a designer’s assumptions of what the customer values and bases their perception and purchase decision against. Trade-off works on the basis that designers assume customers have an order of preference (some feature they accrue meaning to), and this preference has been or is in the process of being translated into characteristics in a systematic way; a system of component parts that, through assembly, aggregate to actualise the expected utility interface features. Therefore trade-off, during a products development, may occur within/across a bill of material level of components or between its levels of component parts. Trade-off thinking resonates with that of the function behaviour structure (FBS) frameworks, a creative process for modelling meaning through the functions of utility expectations.

Howard, et al., (2008) adapted Gero’s Model extending it to include representation of consistency with intended purpose (utility) outputs. Howard, et al., (2008) introduced the inclusion of “Analysis”, “Generation” and “Evaluation” as additional components for inclusion within the existing Gero FBS model. As included, these three components inform creativity of “information transfer” to represent structural fit with intended purpose expectations: that analysis of task (function) to conceptual design (behaviour) to embodiment design (structure) must represent fit with assumptions of the intended purpose of the consumer and not just that of an engineering perspective. The FBS model resonates with the internal product working subsystem aspects of a product’s affordance design. The FBS framework characterises what designers think about when conducting development activities of actualising utility functions underpinning the action possibilities of a product’s affordance design.

2.2.4 Teams in product Development
During the product development process, it is generally accepted that a product’s success is influenced by the creativity of a team (Redelinghuys & Bahill, 2006). During an improvement project teams will be assembled to implement the development activities deemed necessary to improve a product’s complementarity to specific use environments (McCarthy, Tsinopoulos, Allen, Rose-Anderssen, 2006). According to Edmondson & Nembhard (2009) team member are identified by the nature of the development task. Each team member brings the expertise and perspective of his or her own field and the team approach provides a structure that links and integrates diverse skillsets to the collaborative product development task.
Individual members of the team, intentionally develop products to afford a utility offering. The development responsibilities of individual team members characterise two different but related affordance subsystem development concerns: the external and internal aspects of a product’s design (Maier & Fdel, 2009). The integrity of a product’s affordance design is dependent upon the usefulness of its subsystem’s affordance design in specific use environments (Norman, 2013; Kaptelinin, 2013; Maier & Fadel, 2009; Maier & Fadel, 2007; Hartson, 2003). Team members are agents of redesign and make judgements and choices that bridge the gap between the existing product’s design and its specific use environment (Edmondson & Nembhard, 2009, McCarthy, et al., 2006). Internal and external subsystems are the medium through which the improvement team shape a product’s affordance design (Xenakis & Arnellos, 2013) and communicate the message of what a product affords the user. Changes made to internal or external subsystems will impact the affordance emerging. A challenge for improvement team members is management of detailed knowledge such changes infer about the relational complementarity of a product’s affordance to specific use environments (Chen et al., 2013; Maier & Fadel, 2009).

According to Norman (1988) decisions during the development process are made by non-designers, titled silent designers by Gorb & Dumas (1987), such as engineers or, programmers for example. Developing improvements in a product’s affordances design involves the fundamental skill of thinking from different aspects (Gorb & Dumas, 2003). Each member’s skillset defines their design capability and development responsibility within an improvement team. Team members engage in activities that enable them contribute ideas and support dialogue and decisions made during the process of redesigning a product (Ulrich & Eppinger, 2012). Team members possess tacit knowledge informing how the perceptible characteristics of physical objects and embodiment of utility functions are successfully developed. Team members apply future anticipatory thinking on the external human using and internal product working requirements of a product’s design to be complementarity in different product use environments (Xenakis & Arnellos, 2013, Kim & Lee, 2010).

According to Ravasi & Stigliani (2012), a product’s design must be managed in relation to “how the form and function of goods come to be defined during the design activities,
and how they influence and are influenced by social processes in and around organizations” (Ravasi & Stigliani, 2012, p.1). According to Brown (2009), design dialogue and decisions made during the development process must “match human needs with available technical resources within the practical constraints of business”. Consequently, team members make assumptions on the user and product interaction requirements of a product’s external form (Xenakis & Arnellos, 2013) and the interactive arrangement required between parts to improve a product’s affordance design complementarity (Maier & Fadel, 2009; Gero & Kannengiesser, 2008).

2.3 A Total Product’s Design and The External-Internal Affordance Relationship

According to Maier & Fadel (2009), a product’s affordance results of the development of potential behaviours between two or more interacting subsystems within the complex designer-artefact-user system, reflecting 1) the designer(s) of the artefact, 2) the artefact(s) being designed, and 3) the user(s) of the artefact.

They identified two broad categories of interacting product design subsystems requiring management during the development process: artefact to user (A-U) and artefact to artefact (A-A) affordances. Additionally they revealed that these two product design subsystems interacted and reflected three types of affordance based relationships that impact the success of a product’s design:

1. Design of the interactive relationship between an artefact and a user, where a behaviour may occur between the artefact and user that neither the artefact nor user could manifest alone. Maier & Fadel used Norman’s example of the user sitting in a chair, and the need to design the artefact to user (A-U) affordance of enabling “sit-ability” reflecting the usefulness of the artefact to the user.

2. Design of the interactive relationship between an artefact and another artefact where behaviour may occur between two artefacts that could not be manifested by either artefact alone. Using Maier & Fadel’s example of stacking chairs, and the need to design the artefact to artefact (A-A) affordance of enabling the behaviour of “stackability” between two chairs, reflecting the usefulness of the artefact (a product) to another artefact.
3. Design of the internal interactive relationship between an artefact and another artefact where behaviour may emerge through interactions occurring between two artefacts that could not be manifested by either artefact alone and are usually designed in order to fulfil artefact to user affordances. Maier & Fadel use the example of interactions between two gears and the design for or against artefact to artefact affordances of enabling behaviours. In this example, grinding of particles reflects the usefulness of internal artefact to artefact (A-A) behaviours in integrating the utility requirements of the user.

Maier & Fadel (2007) categorised these affordance based relationships as external or internal subsystems.
- The interactive relationship between an artefact and a user and between an artefact and another artefact define external affordance subsystem considerations, useful for informing development of perceivable action possibilities of a product’s form.
- The internal interactive relationship between an artefact and another artefact define internal affordance subsystem consideration, useful for informing development of the technical capabilities that embody utility functions within a product’s structural form.

- The external affordance subsystem resonates with Kim & Lee’s human using design aspect.
- The internal affordance subsystem resonates with resonates with Kim & Lee’s product working aspect.

Both Feijs & Overbeeke (2012) and Kim & Lee (2010) describe the collaboration between designers of internal and external product design aspects as complementary to the success of a product’s affordance design.

Maier and Fadel (2009) present the internal affordance subsystem as underpinning the utility experienced of interaction with a product’s external affordance subsystem. They
state that it is through design decisions on the internal affordance relationship that external affordance relationships emerge.

The “interactions between the designer and the artefact subsystems include specifications of the artefact’s properties that determine its various affordances internally (AAA) and externally (AUA & AAA)” (Maier & Fadel, 2009, p.22).

A product’s “affordances exist (or are nested) in a hierarchy” (McGrenere & Ho, 2000). Subsystems characterise a way of thinking and managing design of that hierarchy and of approaching the development of “useful” product affordance designs (Norman, 2009).

- Shaping and signifying perceivable action possibilities for interface with a product’s external form (Norman, 2013),
- Structuring the embodiment of utility functions within a product’s form (Maier & Fadel, 2009).

Within this nested product hierarchy, external and internal subsystems are related part affordance design considerations that underpin development of useful product affordance designs.

Therefore, the subsystem perspective of the external-internal affordance relationship provides improvement team members with an integrated way of reviewing elemental aspects of a product’s affordance design and assessing complemenatrity in specific use environments.

However, management of improvement in a product’s affordance design is complicated by the dynamic nature of a product’s use environment (Kaptelinin, 2013).

With some improvements evolving through technology changes, and others coming through standardization, the affordances of an engineered product are dependent upon the consistency “designed for” between a product’s functional structure and what it’s structural form enables perception of (Clark & Fujimoto, 1991).
The subsystems that structure the action possibilities of a product’s “affordances clearly have a role to play in investigating undesirable possible actions, perhaps leading to designs that are safer and easier to use.” (Maier & Fadel, 2007 p.2).

The standard design of existing products enables team members to define and assess the action possibilities of interactions with a product’s external form and within the internal configuration of parts.

Backward reasoning on existing subsystem affordances, internal or external aspects, enables team members identify problems and opportunities of the existing product and, in turn, improveable aspects of an existing product’s complementarity.

Chen, Huang, Zhang & Xie (2013), building upon Maier and Fadel’s relational design perspective of affordances, presented the concept of affordances from the perspective of a product’s parts. Chen, et al., (2013) identified parts as contextual knowledge, enabling team members to establish an understanding of the subsystem affordance role provided by or required of parts in existing design. This contextual knowledge establishes design knowledge that is transferrable for use in future design projects. As such, part affordances reflect the “subject” focus for reviewing the internal and external subsystem aspects of existing product’s design.

Chen, et al., (2013) stresses how the complementarity of a product’s affordance design is not just dependent on the development of interactions with the user, but with other engineered artefacts as well. Chen, et al., (2013) classified part affordances as internal or external. They described external part affordances as a way of exploring the perceived interplay relation between a product’s part and other products and users, and an internal part affordance as a way of exploring the perceived interplay relation between a part and another part in the same artefact.

For example, a computer table’s “top” part should facilitate the external affordance of supporting a computer (a different product), while its “leg” part should facilitate the internal affordance of supporting the “top” part. Consequently, team members can identify subsystem parts of implementing improvements in the complementarity of a product’s affordance design.
2.4  A Critical Reflection of the Unknown of the External-Internal Affordance Design Relationship

The preceding sections have, as summarised in table 2\(^1\), presented an overview of product affordance design literature. What is known from the literature is presented in relation to three literature groupings comprising column 1 of table 2: product affordance design principles, product affordance development and the external-internal affordance relationship.

2.4.1  What is Known from the Literature Review in relation to the Research Question

The environment within which a product will be used, a use scenario, defines the context of developing useful product affordance designs. It is the role of team members to make affordances both perceivable and experience-able; else, the design is unsuccessful (Burlamaqui & Dong, 2014).

- Affordances are perceived through the action possibilities, utility interface opportunities, signified by a product’s external form (Xenakis & Arnellos, 2013).
- An affordance is experienced through interface with parts structuring a product’s external form (Chen, et al., 2013).
- It is through the interactive arrangement of internal parts that the action possibilities of an affordance are actualised (Maier & Fadel, 2009).

The complementarity of a product affordance design is assessed relative to its usefulness in specific use scenarios (Gibson, 1979). Action possibilities emerge of interactions enabled with parts and between parts within a product’s design (Gero & Kannengiesser, 2004). Team members are tasked with the development of a product’s action possibilities that complement specific use environments.

These perceivable and experience-able perspectives of a product’s affordance design characterise external and internal subsystem aspects of improving a product’s action possibilities.

Much is known about external and internal subsystem aspects:

- Team members tasked with design of the external subsystem focus efforts on developing a product’s external parts to provide visual clues of a product’s

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\(^1\) References for Overview of Product Affordance Design Literature in Table 2: (1) (Kaptelinin, 2013), (2) (Chen, et al., 2013), (3) (Gero & Kannengiesser, 2014), (4) Kim & Lee, 2010), (5) (Maier & Fadel, 2007), (6) (Maier & Fadel, 2009), (7) (Norman, 2013), (8) (Ravasi & Stiglani, 2012), (9) (Xenakis & Arnellos, 2013), (10) (Burlamaqui & Dong, 2014),
usefulness in specific use environments. It is these visual clues that imply a utility and evoke specific product-user interaction behaviours with the product (Xenakis & Arnellos, 2010; Crilly, Clarkson, Moultrie, 2009, 2004).

- Team members tasked with design of the internal subsystem focus efforts on developing an internal configuration of parts that actualise the functions embodying the implied utility (Chen, Huang, Zhang, Xie, 2013, Gero, 2012).

Team members are tasked with improving the complementarity of external or internal subsystem aspects of a product’s affordances. A product’s “affordances exist (or are nested) in a hierarchy” (McGrenere & Ho, 2000). Subsystems characterise a way of thinking about the hierarchy of interactive parts and of backward reasoning on ways of improving the action possibilities emerging (Srivastava & Shu, 2013; Norman, 2013; Maier & Fadel, 2007).

Team members can modify a product’s affordances to improve users’ experiences by refining opportunities for interaction with the product’s form or resulting of interactions enabled within the product’s structural form (Maier & Fadel, 2009). Changes to the design of interactions enabled with or within a product’s subsystem design represents a way of approaching improvements in the complementarity of a product’s affordance design to specific use environments:

- Design changes to parts shaping and signifying opportunities for interface with parts of a product’s external form (Norman, 2013),
- Design changes to parts actualising the embodiment of utility functions within the product’s structural form (Maier & Fadel, 2009).
<table>
<thead>
<tr>
<th>Research Question</th>
<th>How is management of action possibilities in external subsystems coordinated with internal subsystems in order to achieve improvements in product affordance and complementarity with a use environment?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Literature Groupings</td>
<td>What is Known through Literature</td>
</tr>
<tr>
<td>Perception Action Possibilities</td>
<td>Design Principles, Definitions &amp; Terms</td>
</tr>
<tr>
<td>Use Environment</td>
<td>The use environment defining the context of a product’s consumption. Reveals the properties required of a product form to communicate interaction opportunities compatible with specific use environments.</td>
</tr>
<tr>
<td>Product Development Process</td>
<td>The value adding transformational stage of a product’s design informed through stage-gates &amp; activities. The PDP is comprised of a series of development stages, from idea screening to launch of a commercial product, with each defined by the activities within it.</td>
</tr>
<tr>
<td>External Interactions Opportunities &amp; a Product’s Form</td>
<td>A Signifier of interaction opportunities with external product’s form. Determined via the representational characteristics. Properties of a product.</td>
</tr>
<tr>
<td>Internal Interactive Arrangement &amp; Function Embodiment</td>
<td>Function is embodied within a product’s structure. Action possibilities emerge of interactive arrangement of parts.</td>
</tr>
<tr>
<td>Improvement Teams</td>
<td>A product’s success is influenced by the creativity of an improvement team. Designers, individual members of an improvement team, intentionally develop products to afford a utility offering. The development responsibilities of individual team members characterise two different but related affordance development concerns: the external and internal aspects of a product’s design.</td>
</tr>
<tr>
<td>Total Product Design</td>
<td>Reconciling two different but related design aspects: function and form. It is function embodiment informed but form dependent.</td>
</tr>
<tr>
<td>The Designer’s Intent to Represent</td>
<td>Incremental improvements of existing products through refinements and enhancements to product standards.</td>
</tr>
</tbody>
</table>

Table 2 What is Known and Remains Unknown from the Literature Review
2.4.2 What Remains Unknown from the Literature Review and the Gap in Relation to Answering the Research Question

However, product affordance design literature has shortcomings. A critical reflection on the contexts of consumption and development literature reveals a third context: the context of the designer’s intent to improve a product’s affordances.

The customer experiences a product’s affordances holistically. The nested nature of subsystem parts reveals that action possibilities are underpinned by the development of external and internal subsystem aspects structuring a total product’s affordance design. Therefore, the complementarity of a product’s affordances should be assessed from the total product perspective.

However, the substantive knowledge of product affordance subsystems has resulted from research from the perspectives of interaction and engineering design disciplines, typically conducted in isolation of one another. External and internal affordance subsystem aspects provide an understanding of “what” team members will focus attention on to improve a product’s action possibilities; perceivable interaction opportunities and utility function integration.

External and internal subsystems represent a way of backward reasoning on the complementarity of a product’s action possibilities to specific use environments. Improvements to a total product’s affordance design requires implementing changes to individual subsystem parts that are externally “interacted with” or internally “interacting within” a product’s configuration (Gero & Kannengiesser, 2004). However, improving a product’s affordance design reveals the management challenge: reconciling the complementarity of design changes to external or internal subsystem parts with related part of the total product’s affordance design. (Burlamaqui & Dong, 2014, Crilly, et al., 2009).

Design literature does not provide insight on “how” management of intentional changes to the design of internal or external affordance subsystem aspects are approached or reconciled to improve the complementarity of a product’s action possibilities to specific use environments.
2.5 Looking Forward
Towards exploring and identifying the potential inter-relationship between these design literatures, the following chapter, chapter 3 the conceptual framework, will critically reflect upon the substantive detail of these literature from an external-internal affordance relationship perspective.
This critical reflection informs insights enabling conceptualisation of a framework for informing exploration to close the external-internal affordance relationship management gap. Here, potential inter-relationships will be identified from which opportunity to conduct empirical observations towards forming answers to the research question and making a contribution will be discussed.
Chapter 3: Preliminary Conceptual Framework

3 Introduction to the Conceptual Framework

The research question is: How is management of action possibilities in external subsystems coordinated with internal subsystems in order to achieve improvements in product affordance and complementarity with a use environment? This thesis research is located in the product development management field. The objective of the research is to explore and establish an understanding of the process of managing the external-internal subsystem affordance relationship during improvement projects. The purpose of this chapter is to build upon insights, summarised within table 2, from the literature reviewed in Chapter 2 and to frame a preliminary conceptual framework of the external-internal affordance relationship and the associated management process.

Underpinning the conceptual framework of the external-internal affordance relationship is the theory of affordances. Towards conceptualising the framework informing exploration, the theoretical affordance underpinnings of this research are presented.

The preliminary conceptual framework, as visualised in figure 1, is an illustration of the research question and central to conducting empirical research towards answering the research question. An answer to the research question will close gaps in affordance design literature, and make a contribution to the existing body of knowledge in product development management.

3.1 Product Affordances Theory Underpinning the Research

In product design, an affordance is defined as the real and perceived actions possibilities of a product (Norman, 1988). The migration of the concept of affordances from perceptual psychology to product (interaction and engineering) design introduces two
sub-systems: the external affordance subsystem that characterises Norman’s (2013, 1988) view of product affordance design and the internal affordance subsystem that, building upon Norman’s view, characterises Maier & Fadel (2009) extended relational affordances design considerations.

The development of a product’s affordance is moderated by the environment of a product’s use (Xenakis & Arnellos, 2013, Srinivasan, et al., 2012). Therefore, a product’s affordances requires development of an internal subsystem of parts that actualise utility functions and an external subsystem that signifies utility interface opportunities. Both subsystems are developed to complement specific use environment settings. Maier & Fadel (2009, 2007) present action possibilities as underpinned by the interactive arrangement of parts that structure utility functions within a product’s form. Therefore, action possibilities are dependent upon what the product, as a system of internal and external parts, is designed to enable (Maier & Fadel, 2007).

Product affordance subsystems reveal an integrated relational design approach. The subsystem aspects of the product affordance concept has been identified by many (Burlamaqui & Dong, 2014; Kaptelinin, 2013; Chen, et al., 2013; Maier & Fadel, 2009, 2007) as particularly suited for informing improvements in the complementarity of a product’s action possibilities to specific use environments. User’s experience a product’s affordances holistically. Informed in this way, improvements in a product’s design is managed through reflection on the external and internal sub-system affordance considerations.

The following sections frame the external-internal affordance relationship concept and present the managerial, definitional, and relational perspectives of the conceptual framework. The conceptual framework informs insights from which a propositional model of management of the external-internal affordance relationship is presented to aid exploration of the total product affordance management process.

3.2 Framing the External-Internal Affordance Relationship Concept

This study builds upon knowledge of internal and external aspects of a product’s affordance design and product development management and presents, as visualised in figure 1, a model conceptualising the external-internal affordance relationship.
A product’s design is complicated by the distinction made between the internal and external aspects of a product’s affordances. Improvement team members focused on the external aspects of a product’s design are tasked with developing a product’s utility interface form. Improvement team members focused on the internal aspects of a product’s design are tasked with integrating utility functions within the product’s form (Ulrich & Eppinger, 2012). These two aspects of a product’s design reflect inter-related development considerations (Kim & Lee, 2010) that characterise how a total product’s affordances are realised. User’s experience a product’s utility offering holistically. Therefore, the success of a product’s affordance design is dependent on management of an appropriate balance of both aspects (Von Stamm, 2003). Maier & Fadel (2009, 2003) relate the two design aspects through the notion of affordance subsystems. According to Maier & Fadel (2009), it is through a focus on the internal aspects of a product’s design that the utility offering, implied by the external design aspect, emerges.

The success of a product is proposed as dependent upon management of improvements in the complementarity of the design of external and internal subsystem considerations relative to a product’s use environment (Maier & Fadel, 2009, 2003). Therefore, Maier & Fadel’s (2009, 2003) external-internal affordance subsystems perspective has been adopted as the basis of exploring management of both aspects.

3.2.1 Management of the External-Internal Affordance Relationship
Management of the external-internal affordance relationship involves multidisciplinary improvement team dialogue that is coordinated by the defined stages and activities of an organisation’s product development process (Cooper, 2008). A product’s affordances, the perceivable action possibilities of experiencing a utility offering, are presented as requiring management from the “total product” perspective.

Artefacts exist in time, and are subject to change (Burlamaqui & Dong, 2014). According to Norman (2013), incremental improvements is the best way of approaching the development of successful product affordance designs. Consequently, improvement projects represents a way of exploring management of the external-internal affordance relationship.
Management of the external-internal affordance relationship during phases of improvement is proposed as contributing to the success of a product’s affordances. Changes made to any internal or external subsystem aspect of the product’s design has the potential to improve the relation of (1) part interactions that integrate utility functions within a product’s configuration (Chen et al, 2013) or (2) perceivable interaction opportunities that communicate a utility offering of a product’s form (Crilly et.al, 2008, 2004) to specific use environments.

This suggests a total product affordance design management challenge: coordinating capture of a harmonious balance between related internal and external subsystem aspects of a product’s design during development of product affordance improvements. During improvement phases, improvement team members are tasked with ensuring changes made to interactions enabled with and within the engineered product’s structural form capture complementarity with the use environment.

3.2.2 Definitional Perspective of the Conceptual Framework’s Constructs
Management of the action possibilities during phases of improvement is, as illustrated in figure 1, conceptualised through five constructs; (1) Use Environment, (2) Artefact, (3) Affordance Sub-systems, (4) Action Possibilities, and (5) an Improved Product’s Affordances.

*Use environment*

The settings of the environment within which an artefact, a product, will be used characterises the context of a product’s affordance development (Norman, 2013; Gibson, 1979).

This use environment defines the parameters and benchmarks for design dialogue and of decisions made by team members tasked with engineering product representations to enable utility (Brown & Maier, 2015; Gero & Kannengiesser, 2013) and of improving the utility offering of existing product designs. The adequacy of a product’s affordances are assessed relative to the complementarity of the design of a product’s utility in specific use environments (Norman, 2013, Brown & Maier, 2012).
**Artefact’s design**

An artefact is a product that represents the intent of the members of the product’s improvement team (Ulrich & Eppinger, 2012). Artefacts are intentionally developed to exhibit properties which, denoted by the physical attributes of the product, infer delivery of a utility offering. Physical attributes enable improvement team members evaluate the complementarity of an artefact’s design in specific use environments (Norman, 2013, Crilly et al, 2009, 2004).

An artefact’s affordance design is categorised through subsystem relationships. Subsystem relationships describe two categories of interactions required of the product’s design: external and internal categories. The external category refers to user perceivable opportunities for interactions with the product. External interactions with a product occur between the artefact and a user or another product. The internal category refers to internal arrangement of part interactions that actualises the embodiment of utility within the product. Internal interactions occur between the parts structuring the artefact’s configuration. (Maier and Fadel 2008).

**Affordance subsystems**

Affordance sub-systems characterise two design perspectives deemed by team members as useful in developing physical product offerings; the external subsystem of “human using” features that facilitate a utility interface and the internal subsystem of “product working” features that embody utility functions within a product’s configuration (Maier & Fadel, 2009).

During the product development process, improvement team members identify the attributes required of a product’s form to enable useful external “human using” features (Xenakis & Arnellos, 2013) and of the configuration of internal parts to enable useful “product working” features (Chen, et al., 2013).

**Action possibilities**

Action possibilities, characterised by the external subsystem’s features, are the user perceivable opportunities for signifying and evoking product interactions that infer delivery of a specific utility offering (Xenakis & Arnellos, 2013).

The adequacy of the action possibilities of the external subsystem’s design is dependent upon enabling useful interactions between a user and the artefact, between the artefact
and other artefacts, and between internal artefact parts (Chen et al., 2013, Maier & Fadel, 2009).

There are two different but related design perspective of developing useful interactions:

1. The user’s ability to perceive a product’s action possibilities is dependent upon team members understanding and integrating assumptions on “hard-wired, biological reflexes and habituated responses to recurring stimuli” into the design of a product’s external parts (Kannengiesser & Gero, 2012, p.54). Visual references of the interaction opportunities of a product’s external parts enables team members assess the complementarity of the utility implied as offered in specific use environments (Xenakis & Arnellos, 2010).

2. Utility emerges, in part, of the technical capability of an internal subsystem of parts to actualise the embodiment of utility functions within a product’s structural form (Maier & Fadel, 2009). The technical capabilities unlocked by the internal subsystem of interacting parts enables team members assess the complementarity of the utility offering embodied within in specific use environments (Maier & Fadel, 2009).

_Improved product’s affordances_

A total product’s affordances are characterised by the utility implied as offered by the properties of the external subsystem (Norman, 2013) and underpinned by the technical capabilities of the internal subsystem (Srinivasan et. al, 2012, Maier & Fadel, 2009).

A total product’s affordances are dependent upon integrating the two different but related subsystems considerations that shape the action possibilities to enable a utility:

1. Design of attributes shaping visual references of a product’s external form to communicate opportunities for interact with the engineered product and imply a utility offering (Xenakis & Arnellos, 2013, Crilly et al., 2009, 2004),

2. Design of attributes that structure the ability of an interactive arrangement of internal parts to actualise embodiment of utility functions within the product (Chen et al., 2013, Maier & Fadel, 2009).

The design of an artefact’s action possibilities reflect individual improvement team member’s presuppositions of the product’s market and intentions for how the internal or
external subsystem should be development to improve complementarity to specific use environments (Xenakis & Arnellos, 2013, Kim & Lee, 2010). The attributes of interactions enabled with and within a product enable team member’s assess the complementarity of action possibilities emerging of subsystem’s design improvements (Chen, et al., 2013, Maier & Fadel, 2009).

3.2.3 Relationships between constructs
The external–internal affordance relationship is presented through six relationships potentially existing between the constructs, as illustrated in figure 1. Each relationship is discussed.

Relationship 1: Managing the Relationship between an Artefact’s Standard Design and Improvable Affordance Aspects
There is a product use environment. The properties of the use environment define product use settings and the context of developing a product to afford a utility offering (Norman, 2013, Gibson, 1979). A product’s attributes enable team members determine the complementarity of a product’s affordance design to specific use environments. The settings of a product’s use environment evolve over time (Norman, 2013). Changing settings of a use environment redefine the design benchmark and metrics of a product’s complementarity (Burlamaqui & Dong, 2014). Consequently, existing product designs require refinements that seek to improve complementarity to use environments (Maier & Fadel, 2009, 2007).

Improved product design complementarity is facilitated through review of two subsystem aspects of the product’s design: the external subsystem shaping the human using features of the engineered product’s form and the internal subsystem structuring the product working features of parts that actualise embodiment of utility functions (Kim & Lee, 2010). Each subsystem aspect has the potential to contribute to improving the complementarity of a product’s utility offering to use environments.

Relationship 2: Managing the Relationship between Artefact’s Standard Design and Action Possibilities
The nature of an improvement means a pre-existing product design standard exists. A product’s action possibilities are signified by visual references of opportunities for product and user interactions with the product’s form (Xenakis & Arnellos, 2010, Crilly
et. al, 2009). Improving the complementarity of an existing product’s design requires team members to review the action possibilities enabled by a product’s design (Brown & Maier, 2015, Norman, 2013). The existing design standard enables team members to define the affordance subsystem aspect(s) requiring improving to accommodate changing use settings. Changing use settings reveal the underlying product development challenge. Improvement team members are tasked with reconciling design changes to subsystem aspects of a product’s action possibilities to changing use environments. Action possibilities emerge through interactions between parts structuring utility function within the product’s form (Maier & Fadel, 2009).

**Relationship 3: Managing the Relationship between Improvable Affordance Aspects and Action Possibilities**

Team members skilled in developing specific subsystem aspects are agents of implementing improvements in the complementarity of a product’s action possibilities (Xenakis & Arnellos, 2013; Kim & Lee, 2010). Action possibilities are realised through the design of both the external and internal subsystem features (Maier & Fadel, 2009). Complementarity requires the product’s external subsystem to be developed to communicate action possibilities (opportunities for product and user interactions with the product’s form) that imply a utility offering. Additionally, complementarity requires the product’s internal subsystem to actualise functions of the implied utility offering (Maier & Fadel, 2009). Team members are tasked with identifying ways of improving a product’s action possibilities. Changes to the “human using” and “product working” features of a product’s design represents a way of approaching improvements in the complementarity of a product’s action possibilities to use environment settings (Norman, 2013, Kim & Lee, 2010). Complementary action possibilities requires design changes to part interactions enabled with and/or within a product’s subsystem design. Team members skilled in developing the external subsystem are tasked with improving the external human using interface features that infer delivery of a utility offering (Xenakis & Arnellos, 2010, Kim & Lee, 2010). The utility offering is evaluated through the perceivable opportunities for product and user interactions with a product’s form (Norman, 2013; Maier & Fadel, 2009; Crilly et.al, 2008, 2004). Team members skilled in developing the internal subsystem are tasked with improving the internal product
working features that infer embodiment of utility functions (Chen et al., 2013; Srinivasan et. al, 2012; Maier & Fadel, 2009; Gero, 2008).

**Relationship 4: Managing the Relationship between Interactions With and Interaction Within the Product**

Whilst action possibilities are perceived through the interactions with a product’s external subsystem of parts, action possibilities emerge, in part, of the utility functions embodied within a product’s internal subsystem of parts (Chen et al., 2013, Maier & Fadel, 2009). Improvements in a product’s complementarity is dependent upon ensuring the utility offering embodied within is consistent with that implied by visual references of opportunity for interaction with the product’s form (Norman, 2013). During improvement projects, developers are tasked with maintaining consistency between the utility implied through interactions enabled with a product’s form and the utility functions embodied within a product’s structural form. (Burlamaqui & Dong, 2014).

**Relationship 5: Managing the Relationship between Action Possibilities and an Improved Standard Product Design**

Balancing changes to the design of interactions enabled with and/or within a product represents a way of improving the complementarity of a product’s action possibilities to specific use environments (Burlamaqui & Dong, 2014, Maier & Fadel, 2009). The output of an improved standard product design results of design dialogue that is focused on agreeing trade-offs, a blend of product design compromises, between subsystem design aspects. Changes to any subsystem’s design enables team members assess if the refined subsystem design improves the complementarity of a product’s action possibilities to specific use environment settings (Burlamaqui & Dong, 2014).

**Relationship 6: Managing the Relationship between an Improved Standard Product Design and a Use Environment**

The adequacy of, or need for improvements in a product’s affordance design are assessed relative to the attributes of external and internal subsystem parts of a product design’s to specific use environments (Maier & Fadel, 2009, 2007). The attributes of a product’s external subsystem enables team members assess the compatibility of perceivable artefact to user (a-u) and artefact to artefact (A-A) affordances to use environment settings. The attributes of a product’s internal subsystem enables team members assess the
compatibility of functions actualised by artefact to artefact (A-A) part affordances to use environment settings. When assessed from a total product’s utility interface perspective, the consistency between internal and external subsystems, relative to the changing nature of the use environment, enables team members determine improvable or improved subsystem designs.

The six relationships present two perspective of coordinating management of the external-internal affordance relationship:

1. **Rationale for Informing Complementarity**: Attributes of interactions enabled with and within are the rational for evaluating the complementarity of a product’s affordance design to a use environment. This management perspective is supported by the interplay between relationship 1 and 6,

2. **Rationale for Informing Improvement**: External and internal affordance subsystems are elemental considerations when implementing improvements in the action possibilities of an existing product’s affordance design. This management perspective is supported by the interplay between relationships 2, 3, 4 and 5.

### 3.3 Contribution

The research expects to present new and novel evidence of management of a process that improves internal and external affordance design. A product’s affordance design requires broader thinking. The originality of this research is the “total product affordance” perspective when managing external and internal affordance subsystem improvements. This research is concerned with “theory building”, towards making a contribution to the existing body of knowledge on product development management of improvements in the complementarity of subsystem affordance aspects of a total product’s affordances.

The research, as conceptualised in figure 1, presents the external-internal affordance relationship of managing a total product’s development during improvement phases. Here, management is presented as focused on improving the complementarity of interactions enabled with a product’s form and interactions that integrate utility functions within the product to a specific use environment.
The envisaged contribution is made through closing a gap (discussed at the end of chapter two) in management of relational subsystem affordance design aspects. An expected theoretical contribution lies in explicating the relationships conceptualised between the constructs of the proposed external-internal affordance relationship management process.

The contribution resonates with the way in which the researcher thinks. This thinking is underpinned by an integrated homogeneous view of managing the relational complementarity of product affordance subsystems to use settings.

This research locates the originality and potential contribution in product development management. The complementarity of a total product’s design to specific use environment is proposed as managed through development of product improvements. The research seeks to extend knowledge on the process of managing the external-internal affordance relationship of a total product’s design during improvement projects.

3.4 Conclusion
A preliminary conceptual framework was constructed that integrated insights from relevant product affordance design literatures. This conceptual framework is to guide the exploratory research on the external-internal affordance relationship process during product improvement projects and will be updated to reflect empirical insights. The methodology chosen to conduct this research requires reflection on the ontological and epistemological view taken by the researcher, and is discussed in greater detail in the following chapter.
Chapter 4: Research Design

4 Introduction to Philosophical Foundations

Research philosophy is concerned with the fundamental challenge of adopting an approach to a study that will provide insight into the phenomenon or process of interest (Karlsson, 2009). This chapter begins by examining the researcher’s own philosophical approach in relation to exploring management of the external-internal affordance relationship during improvement projects.

A review of the philosophical literature reveals considerable tension between differing philosophical approaches. From a philosophical perspective, it is vital that the researcher understands this tension and their position within it before beginning any research project. Accounting for the philosophical position adopted, the main research methodologies are reviewed and, the justification of those methods for achieving the objectives of this research discussed. To ensure that the information gathered is consistent with the research objectives, the research design, to which the data collection and analysis phases of the research must be adhered to, will also be reviewed.

4.1 Philosophical Stance Adopted

This research is concerned with determining the process for managing the internal and external subsystem considerations that shape a product’s action possibilities and their complementarity to specific use environments. The research objective is to explore the external-internal affordance relationship phenomena and identify how management of the relationship existing between internal and external subsystem aspects of a product’s action possibilities are coordinated to improve complementarity to a use environment.

There are objective “regulatory” universal laws that govern a product’s internal functional subsystem design. However, there are also social contexts that govern a product’s external utility interface subsystem design.

Using the Burrell and Morgan (1979) framework, as viewed from Kuhn’s (1993) overlapping paradigmatic perspective, the researcher recognised that no paradigm alone sufficiently categorises the theoretical “affordance design” underpinnings of managing the external-internal affordance relationship during product’s improvement projects:
- Originating under the *subjective* interpretivist approach, there is a social context defining external product and user utility interface requirements. These external product utility interface requirements are shaped by an interpretive approach defining action possibilities that imply utility offerings that are complementary to specific product use environments.

- Originating under the *objective* functionalist paradigm, known realities of nature inform the task of structuring the interactive arrangement of internal part that actualise utility functions that are complementary to specific product use environments.

Improving the complementarity of a product’s action possibilities to a use environment, as visualised in figure 2, requires team members to conduct dialogue on the utility interface requirements of the external subsystem and the utility function requirements of the internal subsystem.

![Diagram](image)

**Figure 2** Cross Paradigm DFIA Research Phenomena as Applied to Burrell and Morgan Framework

Management of product affordance improvements occur within the product development process. It was felt that a pragmatic approach was most suited to conducting this research as it entails both epistemic and judgemental relativism opportunity to explore the highly complex contextual nature of improving the complementarity of a product’s affordance design. Therefore, due to the fact, ontologically speaking, that no single paradigm fitted with the theoretical underpinnings of this research’s epistemological view, the researcher, referencing Morgan & Smircich’s (1980) network of assumptions model, adopted, as visualised in figure 3, a “context” based intermediary position for informing the approach.
to explore management of the external-internal affordance relationship. However, the researcher is impartial and focused on objectively observing, rather than participating in, the actions taken during the product affordance improvement process.

This research position decision was justified relative to assumptions on the nature of improving the complementarity of a product’s affordance design: that a product’s use environment context matters. Therefore improvements are context based with management of the external-internal affordance relationship informed relative to two subsystem contexts of implementing an improvement. Here, these subsystem contexts refer to that of external subsystem of perceivable product interaction opportunities and internal subsystem of interacting functional part configurations that complement specific product use environments. This reveals “the ontological assumption on the nature of reality” as dependent upon a contextual field of information where the improvement team, as situated within the context of a changing use environment, use subsystems as a way of improving a product’s standard design to be complementary. This reveals “man as an information processor”, as individual members of the improvement team are challenged with reconcile complementarity by implementing subsystem design changes that match the changing use context. Here, the metaphor of “cybernetics” suitably resonates with the context of inquiry: it is within the product development process that the external-internal affordance relationship is managed. External and internal
subsystem requirements are performance indicators of complementarity and improvements in the complementarity of a product’s action possibilities to specific product use environments.

This stance was informed through review of the differing schools of philosophical thought in relation to many possible approaches to social science in general. The following section presents general discourse in the philosophical domain, where comparable approaches are considered, as background clarification and rationalisation of the chosen stance.

4.2 Philosophical Stances
The grounding of a researcher philosophical stance is dependent on “what is being researched” (Gill & Johnson, 2010). Therefore, to build a firm philosophical foundation for the research project, the research must develop a comprehensive understanding of:

- Philosophy
- Research Focus/Topic

Philosophical tension exists between the older positivist (realist) view and the subsequent post positivist (relativist) view.

Positivist position is derived from that of natural science and is characterised by the testing of hypothesis developed from existing theory (hence deductive or theory testing) through measurement of observable social realities. This position presumes the social world exists objectively and externally, that knowledge is valid only if it is based on observations of this external reality and that universal or general laws exist or that theoretical models can be developed that are generalizable, can explain cause and effect relationships, and which lend themselves to predicting outcomes.

Post positivists argue that there is a fundamental difference between the natural and social sciences. In the social world it is argued that individuals and groups make sense of situations based upon their individual experience, memories and expectations. Meaning therefore is constructed (induced over time) and constantly re-constructed through experience resulting in multiple interpretations that create a social reality in which people act. Therefore, it is seen as important to discover
and understand these meanings and the contextual factors that influence, determine and affect the interpretations reached by different individuals.

A clear distinction can be made between these two in relation to their core assumptions concerning two dimensions: the *nature of society* and the *nature of science* (Burrell & Morgan, 1979).

The first, *nature of society*, dimension involves a choice between two views of society: the regulatory or radical change:

- The regulatory view of society assumes society evolves rationally and is viewed as unified and cohesive.
- The radical change view is in constant conflict as humans struggle to free themselves from societal structures.

These contrasting views are the basis of distinct and often opposing schools of thought: Regulatory society is the basis of modernism (logical or scientific explanation for things, therefore truth exists and can be established) whereas radical change society underlies post-modernism (Everything is relative and therefore never absolute with knowledge claims, as opposed to truth, being established).

The second, *nature of science*, dimension involves either a subjective or objective approach to research, with these two approaches delineated by several core assumptions concerning ontology (nature of reality), epistemology (existence of knowledge), human nature (pre-determined or not) and methodology.

**Ontology** is concerned with the nature of reality from both perspectives. The positivist stance is one of empirical validation – a belief in objective reality with the world external to the individual. What is seen as truth is based upon verification of observable facts derived from valid and reliable tests. Post-positivists have an opposing stance with reality seen as a social construct, dependent on the individual as a participant that attempts to make sense of and provide an interpretation of the research phenomena. Reality consists of subjective knowledge claims that are open to falsification from future research.
Epistemology is described by Blaikie (2000) as “the possible ways of gaining knowledge of social reality” whatever it is understood to be. It is concerned with the approach to how the theory of knowledge that is embedded in the theoretical perspective of the research has been established and is influenced by the ontological views of the researcher. This is emphasised by how Crotty (1998) puts forward three positions under which epistemological concerns are shaped: Objectivism, Subjectivism and Constructivism.

Objectivism: where knowledge exists whether we are conscious of it or not. Regarded as foundational and absolute from which the researcher is concerned with establishing cause and effect explanations. Central to this is theory testing and hypothesis which is contrary to the other two positions which seek to understand and describe rather than explain.

Subjectivism: can be defined as the view where understanding human behaviour requires reconstruction of the understanding of those engaged in such behaviour. Central to this is developing an understanding of what they do (what is the action) and the logic behind this behaviour (why this behavioural response).

Constructivism: concerned with idea that the social context shapes a phenomenon: That this phenomenon is actually an artefact of the social context. Individual/groups create the perceived social reality and will be constantly evolving as a consequence of this context of social interaction.

Methodology is the design of the plan of action or process behind the choice of methods adopted for use in carrying out the research and the rational for the justification of that choice of methods in relation to desired outcomes and replication of the research.

Whatever the researcher’s sociological persuasion, they will find that these assumptions are consequential to each other. That is, their ontological assumptions affect their epistemological persuasion, which in turn affects their view of human nature. Consequently, the choice of methodology logically follows these assumptions that the research has already made.
These philosophical views and their related dimensions of assumptions have had various different labels applied over time: Easterby-Smith et al. (2011) as positivism and phenomenology, Karlsson (2009) as positivism and constructivism, Hughes & Sharrock (1997) as positivism and the interpretive alternative. However these have evolved from the original work by Burrell & Morgan (1979) that expanded upon these two dimensions relating them to four paradigms as “meta-theoretical assumptions which under-write the frame of reference, mode of theorising and modus operandi of the social theorist who operate within them”.

According to Burrell and Morgan (1979), incorporating these two dimensions together “defines four distinct sociological paradigms which can be used for the analysis of a wide range of social theories labelled: Radical Humanism, Radical Structuralism, Interpretive and Functionalist” as visualised in figure 4.

![Figure 4](image)

These four paradigms depict four views of the social world based upon the different meta-theoretical assumptions concerning the nature of society and science. Therefore it is an insightful “tool” for mapping intellectual journeys in social theory (Burrell and Morgan, 1979).

**Radical Humanist:** Reality is a construct of the influence of changing social contexts.

**Radical Structuralist:** Reality is independent of the observer, that causal outcomes are constructed results of the mechanisms working within/under the influence of the world (Regime).
**Interpretive**: Reality is the socially constructed through the management of meaning (Social Contexts).

**Functionalist**: The world exists as a reality independent of the individual (Universal Laws).

The functionalist paradigm approaches academic sociology and the study of the organisation from a perspective grounded in the sociology of regulation whilst adopting an objective point of view. Whereas its diagrammatically opposed counterpart, the interpretive paradigm, adopts the same approach to the nature of society, sociology of regulation, but analyses the world from a subjective point of view.

Objectivists argue that the methods used in natural sciences could be utilised in the social sciences to express the idea that the social world consists of “phenomena which are real, useful, certain, precise, organic, and relative and that knowledge exists in and only in the description of the co-existence and succession of such phenomena” (Bhaskar, 2008). However subjectivists argue that both sciences are disparate and contend that the task of the social scientist is not the search of external causes and fundamental laws to explain behaviour, but rather an understanding and an appreciation of the different constructions and meanings people attribute to their experiences (Easterby-Smith, et al., 2011). Therefore, born from this frustration that the “realist” view of positivism was over-deterministic (in that there is little room for choice due to the causal nature of universal laws) and that the view of post positivism was so totally “relativist”, Bhaskar (2008) put forward the concept of “critical realism” as an approach that takes aspects from both positivist and post-positivist positions. It holds that real structures exist independent of human consciousness, but that actual knowledge is socially created, with Saunders, et al., (2012) contending that our empirical knowledge of reality is a result of social conditioning. Therefore the nature of the relationship between man and the society in which he lives is not free but determined by the external forces in which he is located (Easterby-Smith, et al., 2011).

The publication of Burrell and Morgan’s Sociological Paradigms and organisation analysis (1979) identified a process for theoretical diversity in organisation and management studies. It challenged the dominance of functionalism making a major contribution by opening up alternative forms of analysis within the specialism of management.
However there are shortcomings to the framework. Kuhn (2012) stressed the importance of recognising substantial continuity and overlap between paradigms in the mediation of normal and revolutionary moments of scientific practice. However, Burrell and Morgan explicitly state that there is no synthesis between their four paradigms, that they must remain discrete and developed independently as mutually exclusive “ways of seeing”. According to Willmott (1992), this is an unnecessary constraint upon theory development and excuses burrell and morgan’s dualistic paradigm mentality by regarding it as an important historical device that protected innovative forms of analysis from the dominance of functionalism and a subsequent way of building upon kuhn’s approach; an accumulation of anomalies in existing theories to stimulate plausibility and advancement of alternative theorising by contending that it offers an enlightened theory of continuity as well as incommensurability in the revolutionary process of scientific discovery.

Morgan & Smircich (1980) identified the shortcoming of Burrell and Morgan’s “interpretative and functionalist paradigms” relative to how it “overplays tendency to order and regulation in social affairs, whilst ignoring modes of domination, conflict and radical change”. Building upon Burrell and Morgan’s ideas, Morgan & Smircich identified, in turn, the need for further clarity on the subjective-objective debate within social science and presented a model, as visualised in figure 5, revealing “the network of assumptions characterising the subjective-objective debate within social science”.

<table>
<thead>
<tr>
<th>Core Ontological Assumptions</th>
<th>Subjectivist Approaches to Social Science</th>
<th>Objectivist Approaches to Social Science</th>
</tr>
</thead>
<tbody>
<tr>
<td>reality as a projection of human imagination</td>
<td>reality as a social construction</td>
<td>reality as a contextual field of information</td>
</tr>
<tr>
<td>man as pure spirit, consciousness, being</td>
<td>man as an actor, the symbol creator</td>
<td>man as an information processor</td>
</tr>
<tr>
<td>man as an adaptor</td>
<td>man as a responder</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Basic Epistemological Stance</th>
<th>Some Favored Metaphors</th>
<th>Research Methods</th>
</tr>
</thead>
<tbody>
<tr>
<td>to obtain phenomenological insight, revelation</td>
<td>transcendental, language game, accomplishment, text</td>
<td>exploration of pure subjectivity</td>
</tr>
<tr>
<td>to understand how social reality is created</td>
<td>theater, culture</td>
<td>hermeneutics</td>
</tr>
<tr>
<td>to understand patterns of symbolic discourse</td>
<td>cybernetic</td>
<td>symbolic analysis</td>
</tr>
<tr>
<td>to map contexts</td>
<td>organism</td>
<td>contextual analysis of Gestalts</td>
</tr>
<tr>
<td>to study systems, process, change</td>
<td>machine</td>
<td>historical analysis</td>
</tr>
<tr>
<td>to construct a postpositivist science</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Figure 5 The Network Of Assumptions Characterising The Subjective-Objective Debate Within Social Science
These assumptions about ontology and human nature provide the grounds for defining different epistemological and methodological positions enabling researchers to position the philosophical stance adopted during research in the social sciences.

Whilst critical realism addresses epistemological relativism, it does not, according to Bhaskar (2008), address the key problem of “judgemental relativism”: how can we judge the explanatory power of a theory? Such a judgement must be problematic since our apprehension of the reality the theory purports to explain is, simultaneously, to a greater or lesser extent theoretically determined’. Pragmatism may offer greater insight through its adaptive nature. Pragmatism is a rejection of the idea that the purpose of thought is to describe, represent, or mirror reality. Instead, pragmatists develop their philosophy around the idea that the function of thought is as an instrument or tool for prediction, action, and problem solving. Pragmatists contend that most philosophical topics--such as the nature of knowledge, language, concepts, meaning, belief, and science--are all best viewed in terms of their practical uses and successes rather than in terms of representative accuracy.

Powell (2001) argues that the “pragmatist epistemology stands in contrast to prevailing positivist and anti-positivist views of scientific discovery”. Whereas positivism emphasizes the objective, law-like properties of a brute reality independent of observation (Donaldson, 1992; Wicks and Freeman, 1998), anti-positivism emphasizes the creative role of active, subjective participants, none of whom owns a privileged claim on truth (Burrell and Morgan, 1979; Astley, 1985; Martin, 1990). That “ideas are not ‘out there’ waiting to be discovered, they are social and are tools that people formulate to cope with the world in which they find themselves (Menand, 2003). According to Powell (2001), the mandate of science to a pragmatist is not to find truth or reality, the existence of which are perpetually in dispute, but to facilitate human problem-solving.

Pragmatism rejects positivism, on grounds that no theory can satisfy its demands (objectivity, falsify-ability, the crucial experiment, etc.); and rejects anti-positivism, because virtually any theory would satisfy them. As such, the pragmatist proposes to reorient the assessment of theories around a third criterion: the theory’s capacity to solve human problems (Rorty, 1989; Stich, 1990). To a pragmatist, the mandate of science is not to find truth or reality, the existence of which are perpetually in dispute, but to facilitate human problem-solving.
solving. According to pragmatist philosopher John Dewey, science should overthrow ‘the notion, which has ruled philosophy since the time of the Greeks, that the office of knowledge is to uncover the antecedently real, rather than, as is the case with our practical judgments, to gain the kind of understanding which is necessary to deal with problems as they arise (Powell, 2001, p. 884).

Pragmatism offers, in contrast to objective and subjective approaches, a constructivist approach based, as visualised in table 3, upon:

Pluralism - that there is more than one sound way to conceptualize the world and its content.
Adaptive – trial and error of what works given the situation.
Mimetic – a derivative or representational fit for given contexts: subjective and or objective.

<table>
<thead>
<tr>
<th>Subjective Approach</th>
<th>Inter-Subjectivity</th>
<th>Objective Approach</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Ontology</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Nominalism</td>
<td>Pragmatism</td>
<td>Realism</td>
</tr>
<tr>
<td>Anti-Positivism</td>
<td>Pluralism</td>
<td>Positivism</td>
</tr>
<tr>
<td><strong>Epistemology</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Voluntarism</td>
<td>Adaptive</td>
<td>Determinism</td>
</tr>
<tr>
<td><strong>Human Nature</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Ideographic</td>
<td>Mimetic</td>
<td>Nomothetic</td>
</tr>
<tr>
<td><strong>Methodology</strong></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Table 3  Overview of Philosophical Views

As the researcher has addressed the decision behind the intermediary contextual position adopted, the next step is to examine the methodological choice made as influenced by the philosophical stance adopted: methodological research design.

### 4.3 Methodological Research Design

The following sections describe the research process and methodology pursuant to “demonstrating that a sound approach has been taken” when conducting the research (Remenyi et al., 2000). The methodology section commences with a discussion on the rationale behind the design of the case study to allow an outside audience to judge the credibility, dependability and confirmability of how the research was conducted, analysed and interpreted. Subsequently, the methods of data collections and their
operational details are presented. The chapter concludes with a discussion on the rigour and quality of the present research.

In the literature review chapter, the researcher presented a review of theoretical design literatures and frameworks that relate to the research focus of the external-internal affordance relationship. Building upon insights from these design literatures, the research delved deeper, interpreting what was “know” and what remained “unknown” in relation to the research question and identified contextual internal and external affordance relationships existing within the reviewed literature. These literature based insights directly shaped epistemological views from which methodological decisions, towards answering the research question, were based.

Supporting the literature chapter contents, the philosophy chapter identified the philosophical stances underpinning the epistemic approach taken to the research, presenting the researcher’s adopted stance of a pragmatist (during a product improvement project a product’s use environment context matters and coordinates how improvements in a product’s complementarity to changing use scenarios are realised). This philosophical stance reflects how best the research objectives can be answered through the research design. Guba & Lincoln (2005) imply that the philosophical paradigm within which the researcher has positioned themselves identifies the methodological approach suited to the research. This research is exploratory in nature and a qualitative approach has been adopted as being the most suitable.

The next section discusses the rationale for the research design and details the unit of analysis (product improvement process). The chapter then outlines the reasons for the adoption of the case study method. It also provides an overview of the data collection methods used for the thesis, as well as the means used to analyse the data: coding using NVIVO software. The chapter concludes with sections on the limitations of the research and ethical considerations.

4.3.1 Rationale for the Research Design: Case Research
A case study is an empirical inquiry that investigates a contemporary phenomenon within its real-life context (Yin, 1981). The phenomenon under investigation was the external-internal affordance relationship management process within the operational context of improving a product’s complementarity to specific use environments.
Drawing from insights from Voss (2009), on operations management research methods, the researcher made the decision to adopt a case research approach over other common operations management options such as survey, action research, modelling and simulation. This choice was made on the basis that:

i. Since no model exists of the relationship between internal and external subsystem affordance aspects and management of product affordance improvements, surveys could not be adopted,

ii. Since no specific organisational problem was under study, action research could not be adopted,

iii. Since the external-internal affordance relationship management process under study is yet unknown, modelling and simulation would not be feasible to adopt.

The essence of a case study, the central tendency among all types of case study, is that it tries to illuminate a decision or set of decisions; why they were taken; how there were implemented; and with what results (Schramm, 1971). This section provides a roadmap for how this case research approach was designed, developed and conducted from an operation management research focus.

Voss (2009) states that case research “has consistently been one of the most powerful methods” in operations management especially when it comes to research aiming to contribute with the development of new theory and, in the case of this research, theory building (McCutcheon & Meredith, 1993). Voss (2009) distinguishes operations management from other areas of management research by stating that “it addresses both the physical and human elements of the organisation”. Relating this point to the focus of this research makes it possible to see how it fits with case research: it is the team member’s intent, a human element, to re-design internal and external subsystem aspects of a product’s standard design to improve the complementarity of a product’s action possibilities to specific use environments.

Bebensat et al. (1987) put forward three outstanding strengths of the case research approach:

1) Phenomenon (managing the external-internal affordance relationship), from which meaningful theory (identifying and explaining a process for managing the external-internal affordance relationship) can be generated, are based upon observations (team member’s reflection, on internal and external subsystem design changes relative to examples of decisions made on improving a specific product’s
complementarity to changing product use scenarios) from actual practice (approach applied in two different design organisations) in a natural setting (actual changing use environment and related improvement project examples).

2) Allows for the answering of why, what and how (A “How” question on management of the external-internal affordance relationship during phases of product improvements) questions from an understanding of the nature (different subsystem aspects of improving the action possibilities of affording utility) and complexity (challenge of managing reconciliation of subsystem complementary to a use environment) of the complete phenomenon,

3) Cases lend themselves to exploratory investigations where variables are still unknown and the phenomenon is not understood at all. In product development management theory, affordances are understood from the perspective of perceivable external product interaction opportunities and internal functional part interactions that underpin the complementarity of a product’s action possibilities to a specific product use environment. However, affordances are not understood from the total product perspective and managing the external-internal affordance relationship during improvement projects.

4.3.2 Unit of Analysis
One of the most difficult processes in conducting case research is answering the questions, what the case is? And where does the case leave off? (Yin, 2003; Mason 1996; Miles and Huberman, 1994). Yin (2003) highlights this difficulty in his definition of a case study research “especially when the boundaries between phenomenon and context are not clearly evident”. To overcome this problematic issue, miles and Huberman advise researcher to think about the heart of the study and then build outwardly towards the indeterminate boundary that defines the edge of the case by concentrating on what is not being studied. Noteworthy here is the phrase “indeterminate boundary”. Researchers have to be aware that initial case boundaries are “never quite as solid as a rationalist might hope” (Miles and Huberman, 1994). As is with other facets of research design, discoveries during data collection may result in revising earlier decisions. However in saying that, it is also true that defining a case as early as possible add clarity and direction for the researcher (Mason, 1996).

For Yin (2003), the appropriate unit of analysis occurs when the researcher accurately specifies their research question. He argues that if a researcher is finding the defining of
a unit of analysis confusing, it means that the research questions are probably too vague or too numerous. Table 4 visualises a list of examples of what a unit of analysis may be defined as under three headings.

<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>- Individual</td>
<td>- Event</td>
<td>- Place</td>
</tr>
<tr>
<td>- Role</td>
<td>- Processes</td>
<td>- Space</td>
</tr>
<tr>
<td>- A Small Group</td>
<td>- Episode</td>
<td>- Location</td>
</tr>
<tr>
<td>- An Organisation</td>
<td></td>
<td></td>
</tr>
<tr>
<td>- A Community</td>
<td></td>
<td></td>
</tr>
<tr>
<td>- A Nation</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Table 4 How Cases can be defined as a unit of analysis (Source; Miles and Huberman, 1994; Patton, 1990)

According to Patton (1990), “the key issues in selecting and making decisions about the appropriate unit of analysis is to decide what it is you want to be able to say something about at the end of the study”.

For this thesis, the primary research question posed was; How is management of action possibilities in external subsystems coordinated with internal subsystems in order to achieve improvements in product affordance and complementarity with a use environment?

The objective of the case based research was exploration of the process for managing development of improvement to internal and external subsystem aspects of a product and the complementarity of action possibilities to specific product use environments. Thus, the current study can be defined in terms of management of the external-internal affordance relationship of a total product’s design, where the unit of analysis is the product improvement process.

4.3.3 Case Selection Strategy
Once the general definition of the case study has been established, sampling becomes critical. From the outset, it is important to realise that sampling is not a process that should be solely associated with the logic derived from statistical and mathematical probability (Mason, 1996). Indeed, a case study demands the logic of purposeful sampling as opposed to random sampling. Unlike statistical sampling, where the emphasis is on having a representative sample that is used to substantiate findings to the wider environment, purposeful sampling is concerned with selecting information-rich
cases whose study will illuminate the question under enquiry, hence, the term purposeful sampling (Miles and Huberman, 1994). In general terms, this form of sampling consists of the “procedures used to identify, choose, and gain access to relevant units which will be used for data generation by any method” (Mason, 1996).

The selection of cases represents the first important element of the sampling process. The literature provides a wide range of sampling strategies that researchers could utilise to select their cases (see table 5), however, regardless of whichever strategy is used, “the underlying principle that is common to all these strategies is selecting information rich cases” that will allow them develop theory (Patton, 1990).

<table>
<thead>
<tr>
<th>Type Of Sampling</th>
<th>Purpose</th>
</tr>
</thead>
<tbody>
<tr>
<td>Combination / Mixed Purposeful</td>
<td>Triangulation; flexibility; meets multiple interests and needs</td>
</tr>
<tr>
<td>Confirming &amp; Disconfirming Cases</td>
<td>Elaborating and deepening initial analysis; seeking exceptions; testing for variation</td>
</tr>
<tr>
<td>Convenience</td>
<td>Saves time; money; and effort but at the expense of information and credibility; poorest rationale; yields information-poor cases</td>
</tr>
<tr>
<td>Criterion</td>
<td>Picking all cases that meet some criteria; useful for assuring quality data</td>
</tr>
<tr>
<td>Critical Case</td>
<td>Permits logical generalisation and maximum application of information to other cases because it’s true of this one case it’s likely to be true of all other cases</td>
</tr>
<tr>
<td>Extreme / Deviant Case</td>
<td>Learning from highly unusual manifestations of the phenomenon of interest</td>
</tr>
<tr>
<td>Homogeneous</td>
<td>Focuses; reduces variation; simplifies analysis; facilitates group interviewing</td>
</tr>
<tr>
<td>Intensity</td>
<td>Information-rich cases that manifest the phenomenon intensely, but no extremely</td>
</tr>
<tr>
<td>Maximum Variation</td>
<td>Documents unique or diverse variations that have emerged in adapting to different conditions; identifies important common patterns that cut across variations; purposefully picking a wide range of variation on dimensions of interest</td>
</tr>
<tr>
<td>Opportunistic</td>
<td>Following new leads during fieldwork; taking advantage of the unexpected, flexibility</td>
</tr>
<tr>
<td>Politically Important Cases</td>
<td>Attracts attention to the study (or avoids attracting undesired attention by purposefully eliminating from the sample politically sensitive cases)</td>
</tr>
<tr>
<td>Random Purposeful (Still Small Sample Size)</td>
<td>Adds credibility to sample when potential purposeful sample is larger than one can handle; reduces judgement within a purposeful category; (Not for generalisations or representatives)</td>
</tr>
<tr>
<td>Snowball Or Chain</td>
<td>Identifies cases of interest from people who know people who know people who know what cases are information-rich</td>
</tr>
<tr>
<td>Stratified Purposeful</td>
<td>Illustrates characteristics of particular subgroups of interest; facilitates comparisons</td>
</tr>
<tr>
<td>Theory-Based / Operational Construct</td>
<td>Finding manifestations of a theoretical construct of interest so as to elaborate and examine the construct</td>
</tr>
<tr>
<td>Typical Case</td>
<td>Illustrates or highlights what is typical, normal average</td>
</tr>
</tbody>
</table>

Table 5  Sampling Strategies in Qualitative Research (Source; Miles and Huberman, 1994; Patton, 1990)
In essence, they are cases worthy of in-depth study. The sampling strategy that best fits the purpose of this research, the resources available, the question being asked, and the constraints being face, is criterion sampling. The justification for adopting this sampling approach was grounded in a number of rationales. First, to be sure that each cases was likely to be information rich, it was critical that each case company engaged in product development, had control over the product development process and were open to hosting discussion on the consideration of management of the external-internal affordance relationship within their product’s development process with the researcher.

Second, in order to achieve the objectives of this research, each case company had to have delivered to the market a range of product offerings that were deemed to have successfully afforded, over time, utility requirements of specific product use environments.

Thirdly, each company’s range of product offering were required to be use environment driven product development example, which exhibited specific external product-user interaction requirements and could also be identified as comprising distinct utility functions that were derived of action possibilities that resulted of the internal configuration’s interactive arrangement. Additionally, this range of product offerings had to have been subject to phases of improvement that refined or amended the standard design of the product’s affordance, relative to which a retrospective review of management of the external-internal affordance relationship process could be explored.

Fourth, due to resources and the purpose of the research (multiple site visits required), only companies located in Ireland could be included in the analysis. Obviously, these pre-established criteria have implications for the next sampling issue, that is, how many cases are needed? According to Voss (2009), “the fewer the case study, the greater the opportunity for depth of observation”. Single cases are ideal for longitudinal studies but have limitations such as limited generalizability of the conclusion and misjudgement of a single phenomenon. However, when a phenomenon is compared across cases, it offers a solution to these limitations as it works towards strengthening external validity and attempting to prevent observer bias. Multiple cases are suggested to increase the methodological rigor of the study through "strengthening the precision, the validity and stability of the findings,” (Miles and Huberman, 1994), particularly,
because "evidence from multiple cases is often considered more compelling (Yin, 1994). For this reason, the researcher decided to opt for multiple case studies. Two cases were decided upon as the appropriate number of cases, and a retrospective case approach was taken as retrospective cases allow for more controlled case selection.

According to Voss (2009), theory building through case research requires case selection to be made using replication logic rather than sampling logic: that case selection should predict similar results (a literal replication) or produces contrary results but for predictable reasons (theoretical replication). Yin, (1998) distinguishes between literal replication (where the cases are designed to corroborate each other) and theoretical replication (where the cases are designed to cover different theoretical conditions).

Informing case choice was literal replication based upon Maier & Fadels (2009, 2007) categorisation of affordance subsystems and that defined internal and external contextual focuses of product affordance design.

The rationale behind using a two case study design was twofold. Firstly, as previously mentioned, the criterion of investigating the research phenomenon reflected controlled selections that enabled exploration of how improvements in the complementarity of action possibilities, resulting of the re-design of subsystem aspects (external and internal artefact to use and artefact to artefact interaction requirements) of the existing product’s design, was approached and the realisation of a utility offering deemed complementary to a use environment realised. A minimum of two cases were necessary to collate case observations of the approaches adopted to management of the external-internal affordance relationship, and to support consolidated observations through a compare and contrast of improvement project and process insights across the two cases. Both case’s improvement process examples were conducted on complex products that provided rich insights and represented a saturation of sampling criterion.

Secondly, since the research is pragmatic (due to the contextual nature of improving through subsystem re-design), it has a focus on understanding rather than generalisability (Hirshman, 1986). Thus, the use of two cases is also more applicable for allowing the researcher to give more in-depth and detailed attention to exploring the research phenomenon.
Finally, before leaving this discussion on sampling, it is worth noting, that in practice, decisions regarding the selection of cases and the appropriate number of sample units that are needed, is largely dependent upon practical issues, such as, the possibility of gaining access (de Weer-Nederhof, 2001). Indeed, numerous potential companies were contacted; some refused to participate in the research, while other failed to satisfy the pre-established criteria.

The specific products selected were a headphone and a pacemaker IPG device. Case selection criteria were deemed saturated at the point where the case’s improvement project examples enabled the process to managing the external-internal relationship to be determined through insights on the product re-development actions in two different companies. Table 6 presents an overview of the cases selected. Case 1, a headphone product improvement process and case 2, a pacemaker IPG product improvement process are developed through a total of five improvement project examples and two company perspectives on the process to managing the external-internal relationship.

<table>
<thead>
<tr>
<th>The External-internal Relationship of Managing:</th>
<th>Case 1</th>
<th>Case 2</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of Improvement projects Explored within</td>
<td>Headphone Affordance Improvements</td>
<td>Pacemaker IPG Affordance Improvements</td>
</tr>
<tr>
<td></td>
<td>3</td>
<td>2</td>
</tr>
</tbody>
</table>

Table 6 Sampling Criterion

Case 1 was selected, research was carried out and the case written up before the second case company was selected. To facilitate direct replication, insights from case 1, illustrated within table 7, updated the selection criteria for case 2.

<table>
<thead>
<tr>
<th>Case 1 Insights</th>
<th>Case 1 Company A</th>
<th>Case 1 Insights Shaping Case 2 Selection Criteria</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>External Subsystem Focus</td>
<td>Internal Subsystem Focus</td>
</tr>
<tr>
<td>Improvement Project 1</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Improvement Project 2</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Improvement Project 3</td>
<td>✓</td>
<td>✓</td>
</tr>
</tbody>
</table>

Table 7 Case 1 Insights Shaping Case 2 Selection Criteria

Case 1 provided insights on the process to implementing three improvement project examples. One project provided rich insights on improvements in the complementarity of an external subsystem. The other two improvement projects provided rich insights on improvements in the complementarity of two internal subsystems. A knock-on effect was observed in one improvement project and all three improvement projects resulted in transferrable design data useful in subsequent company A improvement projects.
In addition to the pre-stated selection criteria, the second case company was required to provide insights on the process to improving the complementarity of external and internal subsystems parts, provide insights on how knock-on effects were prevented or resolved and insights on transferrable design data useful in subsequent improvement projects.

As illustrated within table 8, case 2 provided insights through two improvement project examples.

<table>
<thead>
<tr>
<th>Case 2 Insights</th>
<th>External Subsystem Focus</th>
<th>Internal Subsystem Focus</th>
<th>Knock-on Effects</th>
<th>Transferrable for Future Use</th>
</tr>
</thead>
<tbody>
<tr>
<td>Improvement Project 1</td>
<td>✓</td>
<td></td>
<td></td>
<td>✓</td>
</tr>
<tr>
<td>Improvement Project 2</td>
<td></td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
</tbody>
</table>

Table 8 Case 2 Insights supporting Direct Replication with Case 1

One project provided rich insights on the process to implementing improvements in the complementarity of an external subsystem. The other provided rich insights on the process to implementing improvements in the complementarity of an internal subsystem. One improvement project provided insights on how knock-on effects were prevented. Finally, both improvement projects provided insights on transferrable design data useful in subsequent company B improvement projects.

These five improvement project examples enabled exploration of the process to managing the external-internal relationship in both case companies. Consequently, the point of saturation was deemed reached through the five improvement process examples of the two case studies.

4.3.4 Strategy for Data Collection

The discussion thus far on research design has attempted to focus attention on clarifying, what is it that the researcher wants to find out, from whom and why? As Miles and Huberman (1994) puts it “knowing what you want to find out, at least initially, leads inexorably to the question of how you will get that information”. To ensure that this question is answered properly for this research, a research protocol was devised prior to going out into this field (Yin, 2003).

The protocol structures the researchers thinking on decisions relating to how that information is going to be gathered, and so, from the outset sharpens sampling decisions (Yin, 2003). However, there was an additional and even more practical need for such instrumentation in this study. That is, both host companies wanted to know in advance
of the researcher’s entry into the site, what the research entailed? What were the actual research instruments that were going to be used? What was the impact of research instruments on the site going to be? How was the impact going to be minimised? Technical aspects such as how events are to be recorded? Will participant’s anonymity be maintained? Is information confidential? What are the benefits to the informants and to the researcher? What would be a rough estimate of the time span for the investigation? The research protocol contained answers to all these questions and is presented in Appendix A.

For this study the research protocol was an extremely useful mechanism, because it facilitated a discussion between the researcher and the informant(s) on the ground rules for the study and potential access to the site. This ensured that both parties understood what was expected of each other, and in essence, clarified any misunderstandings that existed prior to site visits.

For Yin (2003), a good data collection strategy should possess three critical principles, and when used properly, should help to deal with problems of establishing external validity and reliability of the case study evidence.

**Principle 1: Use multiple sources of evidence:** A case study research methodology relies on multiple sources of evidence to add breadth and depth to data collection, to assist in bringing a richness of data together in an apex of understanding through triangulation, and to contribute to the validity of the research (Yin, 2003). It is generally accepted by most, that findings emanating from a case study should be based on several different sources of information (Yin, 2003; Eisenhardt, 1989). There are a number of reasons for this logic. First, the triangulation of evidence provides a wider scope of coverage, and should produce a more comprehensive picture of the phenomenon under investigation, than would have been achieved with a single source (Bonoma, 1985). Second, the variety of data collection techniques should allow for a greater possibility of discrepancies or anomalies to be notes in research data, and should compensate for any limitations in individual collection techniques (Eisenhardt, 1989). Third, triangulation addresses potential validity concerns in relation to theory development, because multiple lines of enquiry converge towards a particular proposition or conclusion (Yin, 2003).

Keeping the notion of triangulation in mind, the key task that needed to be accomplished for this study, in relation to method, were three fold. Firstly, to decide on the appropriate
methods and data sources. Second, the researcher must develop an understanding of the methodological implication of their choice on method. Third, to create a link between the research question and the methods used (Mason, 1996).

Following the good practice depicted by both Mason (1996) and Yin (2003), the researcher made a list (see table 9) of (i) possible research methods, (ii) data source options, (iii) method justification, (iv) practicalities (such as resources, skills and gaining access), and ethical issues (such as privacy, informed consent, honesty and trust).
<table>
<thead>
<tr>
<th>Research Question</th>
<th>Data Source</th>
<th>Data Collection Method</th>
<th>Justification</th>
<th>Practicalities</th>
<th>Ethical Issues</th>
</tr>
</thead>
<tbody>
<tr>
<td>How is management of action possibilities in external subsystems coordinated with internal subsystems in order to achieve improvements in product affordance and complementarity with a use environment?</td>
<td>Organisation &amp; Public Domain</td>
<td>Documentation: This type of information can take many forms such as letters and other communiques such as emails; agendas, reports, minutes of meetings; Formal Studies; rough notes, progress reports, newspaper clippings, pictures and other internal records.</td>
<td>Documents are unobtrusive in that they are not created as a result of the case study. Documents can provide the formal expression of the interaction that is occurring between the actors. Documents could verify or contradict evidence from other sources. Documents are exact and stable.</td>
<td>Access to full documentation may prove difficult or even be blocked. Thus, retrieve-ability may be low. May not always be accurate. May be lacking in bias.</td>
<td>There are issues over confidentiality, privacy and anonymity.</td>
</tr>
<tr>
<td></td>
<td>Organisation (Cross Functional Design Voices)</td>
<td>Archival Records: Records including computer files, organisational charts and budgets, diary of meetings, names, addresses, phone numbers.</td>
<td>Can provide context to the case study. Can verify or contradict evidence from other sources.</td>
<td>Accessibility may be restricted due to privacy concerns. May not always be accurate.</td>
<td>Issues over privacy have to be addressed</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Interviews: consists of direct face to face communications with the target audience.</td>
<td>The focus is specifically targeted to the problem at hand. Interviews with members of the dyad should provide insights into the dynamics of their interaction. The researcher can probe. The interviews should also clarify issues emerging from other sources.</td>
<td>Time constraint – Interviews to be conducted and transcribed. Scheduling may be problematic. May not always be accurate due to poor recall and reflexivity.</td>
<td>Issues over anonymity need to be addressed</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Direct Observation: Consists of making a field visit to case study site and directly observing the interactions between the actors as they unfold.</td>
<td>Would provide the researcher with a visual account of complex actions that occur during interactions. Events occur in real time.</td>
<td>Issues of bias due to investigators manipulation of events. Events may occur differently because it is being observed.</td>
<td>Issues over privacy, confidentiality would need to be addressed with this issue.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Participant Observation: Demands first hand or direct involvement in the phenomenon under investigation.</td>
<td>Would provide insight into inter-personal behaviours and motives of the interactors. Events occur in real time</td>
<td>Problems in getting the organisation to agree to access may prove difficult. Events may occur differently because it is being observed.</td>
<td>Issues over privacy, confidentiality would need to be addressed with this issue.</td>
</tr>
<tr>
<td></td>
<td>Online Database Repositories</td>
<td>Literature Review: A thorough review of the existing literature on the topic at hand.</td>
<td>Literature review completed in tandem with case research should allow the researcher to see the theory emerging from the data.</td>
<td>Access to literature is paramount. Researcher must expend the time and effort in accomplishing the task</td>
<td>Literatures must be properly recorded.</td>
</tr>
</tbody>
</table>

Table 9  Good Practice relating possible research methods, (ii) data source options, (iii) method justification, (iv) practicalities, and ethical issues
Constructing the chart required the researcher to ask herself fundamental questions such as, How well these methods and sources addressed the research question? And what type of claims they will potentially enable me make? (Mason, 1996). Essentially, these questions required the researcher to consider how and whether study was going to achieve validity, reliability and generalisability with the different research methods and in relation to the research question.

To answer the research question posed by this research, the design organisations are the principle data source. To extract the necessary information, six data collection techniques were identified, their justification for consideration and practicalities of utilising them were considered. With the exception of one technique, participant observation, all others were adopted as sources of evidence for the basis of this research. The rationale for not using participant observation was derived from practical intuition. In essence, retrospective case research was adopted because involvement in one current improvement project would not be guaranteed to provide accurate reflection of the process to implementing improvements in the complementarity of a product’s affordances to specific use environments.

Additionally, it would have proven extremely problematic in getting the organisation to agree to participant observation in what is essentially a very confidential process given the nature of discussions to focus on new concepts and technologies that are innovative and not yet protected by patents and copyright.

Nevertheless, the remaining five methods, documentation, archival records, interviews, direct observation and literature review will provide more than satisfactory evidence for this research.

Principle 2: A strategy for managing collected data: it is without a doubt, a formidable task to manage and analyse a mass of text in multiple forms of data (notes, transcribed conversations, documents, journals etc.). “The researcher is faced by a mass of unwieldy, tangled data and so the first task is to sort and reduce the data to make them more manageable” (Ritchie & Lewis, 2003). As Patton (1990, p297) puts it:

“The data gathered by qualitative methods are voluminous. I have found no way of preparing students for the sheer massive volumes of information with which they will find themselves when data collection has ended. Sitting down to make sense out of pages of interviews and whole field notes can be overwhelming. Dealing with all those pieces of paper seems like an impossible task”.
Researchers need to organise the data into a system, where it can be easily assessed, “converted in analysable text, which then needs to be reduced, displayed and used to draw and verify conclusions” (Miles and Huberman, 1994, p4). Computer software can help, and its role in the process of data management and analysis is essential. The researcher used the NVivo software package to eliminate problems associated with organising data and to make data analysis more manageable. Essentially, it reduced many of the problems associated with organising large amounts of interpretative data. In addition it provided an organised file system so that material could be quickly and easily accessed (Creswell, 1998). The data gathered from interviews, observations, reports, and documents were transcribed and uploaded into NVivo. Each was dated, timed and labelled according to case site and interviewee titles. This forced the researcher to look at the data line by line, to think about the meaning of each sentence and the idea behind it. This software package supported this analysis. In essence the software enabled the researcher to synthesise massive volumes of text through editing, coding, searching and retrieving, annotating, linking data to categories and the use of memos to remove the rigid divisions that existed between ‘data’ and ‘interpretation’ (Richards, 1999).

**Principle 3: Maintain a chain of evidence:** For Yin (2003), to increase the reliability of the information in the case study, the researcher must maintain a clear chain of evidence. The fundamental logic underpinning this principle is that an external auditor should be able to “follow the derivation of any evidence, ranging from initial research questions to ultimate case study conclusions” (Yin, 2003, p96). Indeed, the external auditor should be able to trace the evidence in either direction, that is, conclusion back to research question or from question to conclusions. For this study, the software package NVivo provided an audit trail function that tracked the data collection, analysis and interpretation process. NVivo automatically attached the appropriate identifier to a unit of information, such as titles, dates, creation/ modification times, paragraphs and line numbering. Therefore, whenever a unit of information is utilised in a report, the software package can automatically cite the specific source document, paragraph, or line, for example, from which it originated. In addition, the database, upon inspection, will reveal the actual evidence and indicate the circumstances under which it was collected. In aggregate terms, the audit trail utilised in the research provides the researcher with the ability to “easily move from one part of the case study process to another, with clear cross referencing to methodologic procedures and to the resulting evidence. This is the
ultimate chain of evidence that is desired” (Yin, 2003 p99). The reader is referred to section 4.3.8 (Legitimisation of Research) for a more in-depth discussion on the audit trail and assessment.

4.3.5 Data Analysis Strategy
Although NVivo was essential for data management as the process of analysing contextual research is not quite as neat and tidy as simply using a software programme. NVivo was no substitute for the interpretive skills of the researcher when it came to analysing the data (Easterby-Smith, et al., 2011). NVivo was only a tool, it was up to the researcher to “reduce the volume of information, identify significant patterns and construct a framework for communicating the essence of what the data revealed” (Patton, 2002, p432). The purpose of this section is to outline the strategy utilised in this research for analysis.

In order to categorise and understand the process for managing the relationship between the internal and external affordances of a product to complement a use environment, during the product development process, comparative analysis between the cases was utilised in this research. This analytical model used convergence and divergence to initially identify recurring regularities within the cases, leading to the creation of categories and the development of a classification system, which the cases were then analysed by (Patton, 1980). Discovering the process used to manage the external-internal affordance relationship began with initial observations and preliminary interviews. Further data collection and processes of analysis allowed the researcher to continuously refine these classifications, since these research processes occurred simultaneously with interpretation of the data. Constantly comparing new data with previous events, led to the discovery of new insights, which were then investigated. These in turn led to uncovering the start points and iterations of coordinated sequence of design considerations that reflect the external-internal affordance relationship management process used by team members, focused on improving a product’s complementarity to specific product use environments.

4.3.6 Data Collection Methods
In relation to data collection, all case companies and informants were assured that the information provided by them would be treated with the utmost confidentiality, and that none of the informants or their respective companies would be recognised in any publication from the research. In the case of each of the two case companies a non-
A disclosure agreement was signed and submitted to each company. Hence, all names in this study are fictitious. Data collection continued until theoretical saturation was reached, namely when insights provided by interviews were judged to be insignificant. The five data collection methods utilised in this study will now be discussed in turn, namely, interviews, direct observations, documentation, and literature review.

### 4.3.6.1 Interviews

Interviews were carried out between July 2011 and April 2015. In total 13 interviews were conducted, and table 10 provides an overview of these. All in all, 8 were personal in-depth interviews and 5 were telephone interviews. The personal interviews ranged from one to four hours in length and were not taped.

<table>
<thead>
<tr>
<th>Interviewing Approach</th>
<th>Case 1</th>
<th>Case 2</th>
</tr>
</thead>
<tbody>
<tr>
<td>Preliminary Interview</td>
<td>July 2011</td>
<td>October 2012</td>
</tr>
<tr>
<td>Personal Interviews</td>
<td>4</td>
<td>4</td>
</tr>
<tr>
<td>Telephone Interviews</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td><strong>Interviewee Details</strong></td>
<td><strong>Case Reference</strong></td>
<td><strong>Case Reference</strong></td>
</tr>
<tr>
<td>Product Manager Audiology</td>
<td>PAC1</td>
<td>Principle Mechanical Engineer</td>
</tr>
<tr>
<td>Product Engineering Manager</td>
<td>PEC1</td>
<td>Fellow R&amp;D Engineer</td>
</tr>
<tr>
<td>Product Marketing Manager</td>
<td>PMC1</td>
<td>Process Development Director</td>
</tr>
<tr>
<td>Lead Mechanical Engineer</td>
<td>LMC1</td>
<td>Audiology Engineer</td>
</tr>
<tr>
<td>Info Gathering</td>
<td>Retrospective</td>
<td>Retrospective</td>
</tr>
</tbody>
</table>

Table 10: Overview of Interviews Used for Empirical Data

Due to the confidential nature of a company’s product development process, it was requested that no recording of discussion took place. Note taking was used instead with notes reviewed at a later stage. The telephone interviews lasted on average between 10 to 30 minutes, with the shortest telephone interview merely being aimed at validating the data collected during interviews and at alleviating confusion. Telephone interviews were used subsequent to conducting personal interviews. The interview selection process was relatively simple. Once agreement to participate in the research was obtained from each company, a preliminary interview was conducted. During this meeting, the researcher identified the research objectives and the discussion that followed revealed how the data would be collected within the context of each company and who the informants, in each case, would be. The personal interviews were conducted on a one-to-one basis. However, on occasion, the nature of the data being collected would result in overlaps between informants and small and short handover group meetings occasionally resulted.
By incorporating flexibility into interviews, the researcher was provided with very reliable and valid data, as one informant was confirming what was addressed and set the scene for how the other would continue forward in exploring management of the external-internal affordance relationship during product improvement development. Thus a more comprehensive, richer picture was obtained by the researcher.

For each case, various documents were used to prepare participants for the interviews. In accordance with Perry et al. (1999) and prior to each interview, an interview guide (Appendix B) was presented to each participant setting out the focus of the interview. The number of interviews conducted was dictated by the time taken to collect the data required. This document was used to contain the difficulties associated with selective retrospective bias. Adhering to best practice, as detailed by Doz (1996), the interview guide “challenges interviewees’ memories and cross-checks their ex post data and perceptions”. Nevertheless, the interviews were informal with very little structure or direction placed on the discussion (Carson et al., 2001), except where they were interrupted by the researcher to follow up on some issue. Essentially, the interviewer was a guide, interpreting when it was felt that the interviewee had exhausted the topic of discussion, triggering the move to the next topic listed for discussion in the interview guide. The data collected through semi-structured interviews with the informants outlined in table 10 were supported by discussion on and observations of the product's subsystem parts, manufacturing processes, assembly processes and test procedures. Such observations involved walking the shop floor with the informant and resulted in the informant engaging in short conversations with the shop floor workers involved in some of these tasks.

4.3.6.2 Direct Observation

Direct observation of the production process also contributed to the researchers understanding of affordance relationship considerations and the rationale behind improvement projects. In turn, this provided a greater contextual introduction to the product itself and potential internal and external artefact to user and artefact to artefact considerations requiring management during the product development process. An overview of observational hours carried out per case study was set out in table 11.
Approximately one hour of observations were carried out for each case study. This direct observation was conducted after the preliminary interview but before detailed data collection interviews were conducted. These observations provided clarity to the researcher on many issues that could have posed issues during the subsequent data collection interview process. For example, observations involved walking the shop floor with the informant and resulted in the informant engaging in short conversation with the shop floor workers involved in some of these tasks.

Whilst the informants were discussing the product re-design and development process they also referred to the later production process. Until the researcher had observed the product progressing through manufacturing, assembly and testing activities, it was unclear as to what specific “affordance management” considerations the interviewee was talking about. The direct observations provided the researcher with a greater understanding of the complexity in re-designing a product to complement a use environment. Such observations supported an understanding of how decisions within the improvement process were future anticipatory, revealing the action possibilities requiring improvement and defining the subsystem focus of enabling improved complementarity to be realised. These on-site observations allowed the researcher to gain an insight into knowledge that was hard to communicate without experience and in turn, enriched the researcher’s understanding of the subsystem improvement process aspect that each participant was talking about. Additionally, conversations with informants revealed documents (internal and external) that supported the observations.

### 4.3.6.3 Documentation

Various different types of documents, printed as well as electronic were obtained for the case studies as presented in table 12. In total 18 documents were used between the two case studies.
<table>
<thead>
<tr>
<th></th>
<th>Number of Documents</th>
<th>Case 1</th>
<th>Case 2</th>
</tr>
</thead>
<tbody>
<tr>
<td>Website Articles</td>
<td>3</td>
<td>2</td>
<td>1</td>
</tr>
<tr>
<td>Specialist Company Documents</td>
<td>9</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>Articles in Press &amp; Journals</td>
<td>2</td>
<td>-</td>
<td>2</td>
</tr>
<tr>
<td>Improvement Project Plans &amp; Performance Reviews</td>
<td>4</td>
<td>3</td>
<td>1</td>
</tr>
<tr>
<td>Improvement Project Stage Deliverables</td>
<td>8</td>
<td>3</td>
<td>5</td>
</tr>
</tbody>
</table>

Table 12: Overview of Documents Reviewed for Empirical Data

Whilst the number of document reviewed may sounds relatively small, these documents included detailed reflections of each organisations development process, documentation on the type of products being examined and external regulatory guidelines that constrained how development tasks were to be implemented. Essentially, these documents were referred to during the discussions shaping the interviews and were a reference supporting validation of interpretations of the data as collected for case write up, and analysed for discussion and conclusions drawn between cases. These documents allowed the researcher to obtain sufficient knowledge on the company, the product and the re-design context which was important for understanding and interpreting the case study. Internal documents reviewed included the formal product development process models, product specification drawings before and after improvements, defective parts per million (DPM) data, potential product failure mode reports, reports on customer reported issues, improvement project plans, some of the deliverable documents submitted by team members involved in improvement projects and released company press statements on the improved product offering. Due to the confidential nature of some of these internal documents (deliverable documents) they were not always permitted to be taken off site. However, the case narrative includes discussion informed by such insights. External documents referred to by key informants included independent reviews of the new and improved versions of the product and technical papers on the working principles of related products that often constrained how improvements could be implemented.

4.3.6.4 Archival Records
Various different types of archival documentation were provided to the researcher, as presented in table 13. In total 27 archived records were provided between the two case studies.
<table>
<thead>
<tr>
<th></th>
<th>Number of Documents</th>
<th>Case 1</th>
<th>Case 2</th>
</tr>
</thead>
<tbody>
<tr>
<td>Improvement Project Documents</td>
<td>12</td>
<td>6</td>
<td>6</td>
</tr>
<tr>
<td>Component Drawings and Specifications</td>
<td>2</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Formal Correspondence</td>
<td>13</td>
<td>6</td>
<td>7</td>
</tr>
</tbody>
</table>

Table 13  Overview of Archival Records Used for Empirical Data

For instance, each case company provided the researcher with visuals of their development process. Case company A made reference to archive documents detailing three defining moments in the company’s operational past. These defining moments gave rich insights into the innovative nature of past improvements, defining the company’s ethos to this day. Case company B provided access to archived files that documented project planning and the coordinated activities comprising past product improvement development projects. Both companies conducted formal correspondence through emails. These documents were studied in conjunction with other documentation to provide the researcher with a greater understanding of the design challenges behind the product improvement projects explored within this thesis and that were used as preparation for conducting interviews.

An NVivo screen shot visualising the data sources from the two case organisations used for data analysis is presented in Appendix C. These data sources represented the chain of evidence that supported case write up and enabled data analysis to be conducted to determine an understanding of how the external-internal affordance relationship was managed.

4.3.6.5  Literature Review
As detailed in chapter two, critical reflection on product affordance design literature, an extensive literature review was compiled from a wide range of sources that provided the researcher with valuable insights into the external-internal affordance relationship phenomenon under research.

4.3.7  Analysing and Interpreting Data
As previously mentioned, the research utilised comparative analysis as the strategy for data analysis (Lincoln & Guba, 1985). The purpose of this section was to elaborate on the actual analytical processes that took place, in order to provide the reader with a thorough understanding of how the data collected was analysed and interpreted.
Data analysis was conducted in parallel with data collection, allowing each process to inform the other (Mason, 2002; Lincoln & Guba). Once the data, as collected, was transcribed from handwritten notes taken, the researcher read through the transcript a number of times. This enabled the researcher to become immersed in the details of the case. Contemplative notes, comments and ideas, reflective of what was being read, were entered into the margins of the transcript during reading. This process enabled familiarisation with the data, thus facilitating analytical insight and reflection by the researcher on what was occurring (Miles & Huberman, 1994).

The next step was analysis of the content of the text. This was executed by reducing the data by means of unitising and coding. The transcribed text was broken in categories or units and a code assigned to each. The assigned resulted from keywords or labels used by the research informants to describe the phenomenon being discussed. Each unit was coded according to a source, site, date and label, which enabled fast retrieval of information when required. An NVivo screen shot visualising the nodes and coding of data sources is presented in Appendix D.

Once similarities in categories started to emerge through the coding process, the units of information were placed in provisional category sets that related to the same content (Lincoln & Guba, 1985), and each category was allocated a name that directly related to the information contained within them (di Gregorio, 2000). This process was repeated until the researcher was satisfied that each category set had adequately included the information pertaining to that particular unit of data.

Initially, multiple different categories were created until it was felt that a point of saturation had been reached and no more new categories existed for creation. At that stage, the data contained within each category was thoroughly examined to justify its inclusion. If any piece of data was deemed to have been incorrectly within a category, it was removed and placed within a miscellaneous category or in a newly formed category (Lincoln & Guba, 1985).

The categories were reviewed for overlap and data redundancies (Miles & Huberman, 1994) as well as the existence of relationships between categories. An NVivo screen shot visualising the inter-relationships existing between nodes is presented in Appendix E. Here, several of the initial categories were identified as being subsets of other categories, whilst other categories were further divided. Relationships identified between categories enabled parent and child categories to appear, which enabled the researcher to organise
them into category trees visualising the hierarchical nature of the data (di Gregorio, 2000).

In order to fully understand and correctly interpret the data, the researcher used written case narratives to enable clarify and formulate the data into a coherent description of the phenomenon. As previously mentioned, the researcher presented these written narratives to the informants towards ensuring that the interpretation of the data had been correctly documented and enabling refinements that better documented the phenomenon. By allowing the informant to reflect upon written narratives, the researcher was ensuring that the analysed data was correctly interpreted and fully understood.

4.3.8 Legitimisation of the Data
Legitimisation is the collective term that refers to the validity, reliability and generalisability of the collected data (Easterby-Smith, 1991). The purpose of the section was to establish the trustworthiness of the data and the rigour of the research strategy adopted for this study.

Central to the research design is evolution from Pre-Understanding to Understanding. Pre-understanding is the literature based theoretical (the theory of affordances) underpinnings of the research focus itself setting the scene from which your ontological stance and epistemological understanding shaped the conceptual framework of your research direction. Understanding, however, evolves through how reflection over the period of research between the “definition of the topic and research question, existing literature and your data and its analysis” (Karlsson, 2009) offers greater insight from which more generalized knowledge claim and contribution can be made.

Karlsson (2009) identifies trustworthiness as the general criterion for quality research based upon four requirements: construct validity, internal validity, external validity and reliability.

*Construct validity* is concerned with ensuring that the measures used to research identified constructs will actually measure the concepts that they are intended to measure.
Internal Validity is concerned with causality of demonstrated relationships: that the relationship demonstrated is the result of what was measured and not as a result of any other factor(s).

External Validity is concerned with ensuring that the results are valid in similar settings outside the studied object: knowing whether findings can be generalized beyond the immediate case study.

Reliability is concerned with the extent to which a study can be repeated (Yin, 1994): that another researcher should reach the same conclusion in the same research setting.

Each criterion deserves explicit attention, discussed in relation to the research in the following sections.

4.3.8.1 Construct Validity
The construction of a conceptual framework, developed as a way of visualising the theoretical literature that underpins the objective (management of the integrity of engineered product representations) of the research (Miles and Huberman, 1994), was central to demonstrating the validity and reliability of the research, from which contribution were to be made. The conceptual framework, as visualised in figure 1 of chapter 3, presented and defined five constructs. The validity of each was demonstrated by identifying the operational measures for exploring each. The five constructs and the related operational measures were as follows: (1) use environment, (2) artefact, (3) affordance subsystems, (4) action possibilities, and (5) total product affordances. Toward representing a methodological fit with the research focus, emphasis was placed upon understanding how the relationship between the constructs under investigation supported exploration of management of the external-internal affordance relationship phenomenon: The proposition behind the constructs of the conceptual framework was that the affordances of a product’s design is challenged by the different but related aspects informing managing of a product development to capture complementarity with a use environment.

Three tactics were applied to increase construct validity (Yin, 1994). First, data was collected from multiple sources and different methods were used to to obtain that data. This allowed for the triangulation of evidence on convergent meanings (Yin, 1994). Second, a prolonged engagement with each informant companies enabled a chain of
evidence to be established. Finally, according to Hirschman (1986), the people most capable of evaluating the completeness of the interpretation of that world view are those from whom data originated. Thus, on a regular basis, the gathered data, the interpretations were discussed with the research informants for review to ensure its adequacy and validity in portraying the phenomenon being explored. Upon completion of the findings chapter, the researcher presented each case company with findings pertaining to their company only. Each company was asked to read the findings and verify the validity of the data and the development process that they had participated in. If the company was unhappy with the findings, or if the researchers had missed or had misinterpreted something, the contact enabled these errors to become known to the researcher so that rectifications could be arranged. Company A verified approval through a phone discussion. Appendix F presents an email screen shot visualising the approval of the case write up from case company B’s perspective.

4.3.8.2 Internal Validity
Internal validity only applies to explanatory or causal studies and not descriptive or exploratory studies (Yin, 1994). This research was exploratory in nature. Internal validity was not applicable to this research and therefore was not discussed.

4.3.8.3 External Validity
Critics generally state that single cases offer a poor basis for generalising (Yin, 1994), and that theory must be tested through replications of findings. This research was based upon the multiple case strategy of literal replication, focused on product affordance improvements and the design challenge of managing complementarity of internal and external subsystem design considerations relative to specific product use environments. However, one cannot assume observations are applicable to all products. Generalisation is not automatic (Yin, 1994). The researchers has provided, through observations recorded, rich description that would enable other researchers to assess conclusions drawn and determine whether the study could become “the vehicle for examining other cases” (Yin, 1994).

4.3.8.4 Reliability
According to Yin (1994), a good guideline for doing case studies, is conducting research so that an auditor could repeat the procedures and arrive at the same result. For this study, two tactics were applied to establish reliability.
First, the reliability of findings were addressed by documenting the multiple sources of evidence & triangulation procedures used for data collection and providing a documented audit trail that demonstrated how the exact same same method as applied in case one were also applied in case two.

Second, the theoretical and philosophical basis for the research, along with the process of inquiry, the collected raw data, the findings, interpretations and recommendations were all presented to an auditor (Lincoln & Guba, 1985) or external observer (Yin, 1995) for examination. Yin (1995) argued that the process should be tight enough so that the conclusions obtained be “assuredly the same evidence that was collected at the scene…during the data collection process; conversely, no original evidence should have been lost, through carelessness or bias”. The task of the auditor was to review the quality of the research design and findings to assess the triangulation of evidence and to confirm or disconfirm that the conclusions drawn derived at flowed from the gathered data (Hirschman, 1986; Lincoln & Guba, 1985). To facilitate such an examination, an audit trail from the philosophical, theoretical and methodological backgrounds, to raw data, interview notes and transcripts, to analytical procedures, to interpretations and conclusions were all presented for review.

### 4.3.9 Ethical Considerations

There are many ethical issues that a researcher must consider when conducting research. Communicating benefits and risks, protection of identity, privacy, and obtaining informed consent are some of the ethical issues that need to be considered when conducting research (European Commission, 2007). Bryman and Bell (2007) have noted a lack of informed consent as an ethical issue not widely debated in the academic literature. Karlsson (2009) states that the researcher should implement strict requirements for the procedure on gaining consent for research. This thesis adopted several measures to address such issues and to ensure that this research was conducted in an ethical manner. These measures included:

1) The research was conducted in line with Trinity College Dublin ethical guidelines which states that “Research activities undertaken by staff and students of the College and by others in collaboration with the College shall adhere to the Board-approved Good Research Practice Guidelines” (Trinity College Dublin, 2009, p. 4).
2) For confidentiality reasons, Non Disclosure Agreements (NDA), presented in appendix G, and H, were signed in each host organisation. Terms of Non Disclosure Agreements were discussed and signed in each host organisation prior to being permitted access to assigned research informants and the collection of data. In all cases, organisational identification could not be disclosed.

4.4 Conclusion
This chapter provided a detailed account of the strategy employed for conducting this research and the principles underlying the research methodology adopted towards answering the research question behind this study. The following chapter presents the findings from the first of the two case studies conducted.
Chapter 5: Case 1, Managing Improvements in the Personal Sound Experience Afforded

5 Case One Introduction
The purpose of this chapter is to provide a rich description of case data, which in turn, allows external observers opportunity to assess the researcher’s interpretation of case data in the appropriate context (Klein & Myers, 1999).

Company A is one of the world’s leading electronics manufacturers with a comprehensive audio product portfolio that include headphones, microphones, wireless microphone and monitoring systems, conference and information systems as well as aviation and audiology products.

The organisation’s many product segments maintained strong sales records. However, the “headphone” product segment had been identified as consistently the strongest product across all product markets. Headphone sales had increased year on year, identifying the audio manufacturer, at the time of conducting the case research, as the leader of the headphone market in Europe with a sales volume market share in the region of 23%.

This case study is based upon the headphone product. Key contributors were the product manager of audiology (PAC1), a product engineering manager (PEC1), a product marketing manager (PMC1), a lead mechanical engineer (LMC1) and an audiology engineer (AEC1).

Headphone design, conducted within the organisation’s Irish location, was focused on the premium audio market and design of headphones reflective of the professional requirements and needs of the serious audiophile. An audiophile is a person enthusiastic about high-fidelity sound reproduction and who demands the highest sound quality possible from their audio playback equipment. The audiophile is capable of distinguishing between lower and higher quality sound output by audio equipment, especially when used in music creation use environments. For the serious audiophile, price is not a concern. Company A defined the serious audiophile as expecting headphones that delivered the most advanced and latest in line sound quality technologies, as required for use at different stages of music reproduction (such as audio recording, the audio production process, as well as audio playback).
“All our headphones are created with a singular goal: The pursuit of perfect sound, creating products that exceed expectations and set new benchmarks in audio.” PACI

The headphone is not a new product. Whilst headphones were originally designed for use by the military in the early 1900s, it was 1958 before headphones were designed to deliver a new alternative “personal” sound experience offering to the general consumer. Technological advances during the last five decades have led to the establishment of universal standards for headphone design. Between 1958 and 2011, when case 1 was chosen, the universal concept of a headphone had slowly evolved through a series of improvements made to its standard design.

Company A has been a major contributor to this series of improvements. In company A, enhancements have resulted in improvements to the standard design of their existing headphone offerings. Improvements, driven by their pursuit of perfect sound, were focused on refinements to the external and internal subsystems of headphone parts that underpinned delivery of a personal sound experience. Within this case three improvement projects, each reflecting on refinements to a different subsystem part, are presented. The relative timing of each refinement reflects a different focus that sought to build on the achievement of preceding refinements to the standard design of company A’s headphone offerings. This case explores improvement projects as a basis of understanding how management of the external-internal affordance relationship of a headphone’s development was approached in Company A.

The following sections provide (1) An overview of the standard design considerations of a company A headphone, (2) company A’s headphone development process, (3) the external subsystem of a company A headphone product and (4) the internal subsystem of a company A headphone product. These four sections present a background for understanding (5) inter-related sub-system design considerations of the total headphone product and, using three improvement project examples, exploring company A’s approach to coordinating the external-internal affordance relationship during improvement projects. These company A headphone case based insights inform (6) an analysis of “within case observations” from the perspective of the five constructs emerging from the conceptual framework (illustrated in figure 1 of chapter 3) of the
external-internal affordance relationship and the propositional model (illustrated in figure 2 of chapter 3) of management of the external-internal affordance relationship. The case concludes with an overview of generalised insights emerging from case observations.

5.1 Overview of the Standard Design of a Company A Headphone Product

A headphone is a sound reproduction device that provides the user with an alternative way of experiencing audio. Through connection with an audio device, a headphone’s design enables delivery of a personal sound experience offering.

The company A headphone is a product comprising external and internal subsystem design considerations. The integrity of a company A headphone’s development requires the team to understand two subsystem platform design dependencies of delivering a personal sound experience offering:

1. The external subsystem of parts exhibiting features enabling the user determine the need to connect the headphone with their ear and an audio device,
2. The internal subsystem of parts exhibiting features enabling how sound is reproduced.

An understanding of the anatomy and physiology of the human ear and the working principles and technologies of audio device is necessary to develop headphones that deliver a personal sound experience\(^2\). These considerations characterise settings of the headphone’s use environment and the context of design dialogue and decisions made when developing improvements to the standard design of a company A headphone.

The external subsystem’s design is focused on a headphone’s form and how it is developed to enable coupling with audio source devices and the human ear. The internal subsystem’s design is focused on a headphone’s functional configuration and how it is developed as a system of interacting parts to operationalise the sound reproduction capability, deemed consistent with the physiology of the human ear.

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\(^2\) A background to the headphone product is presented in Appendix I

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The standard design of the company A headphone’s external subsystem, as visualised in figure 6, consists of three external parts; a pair of earpieces, a jack plug and, connecting these, an audio cable.

- The pair of Earpieces (also referred to as cans), each containing a small loudspeaker within, are designed to be coupled with a user's ears through which sound, in the form of a longitudinal wave, is output into the user’s ear,
- The Jack Plug is designed to enable connection with an audio device and source, input in the form of an electrical frequency, the audio to be experienced,
- The Audio Cable is designed to transfer input of the audio source from the jack plug to the earpieces.

![Figure 6  Headphone Product](image)

The standard design of the company A headphone’s internal subsystem, as visualised in figure 7, consists of two levels of parts that structure a headphone’s internal configuration.

- Level one of the internal subsystem’s configuration structures a platform that connects the external parts.
- Level two of the internal subsystem’s configuration embodies the sound reproduction capability, actualising how the personal sound experience is delivered to the user’s ear.

![Figure 7  The Internal Configuration of Component Interactions](image)
External and internal subsystem design considerations represent two different but related design aspects of delivering a personal sound experience.

The standard design of a company A headphone has evolved of decades of changes applied to external and internal subsystems parts. External and internal subsystem design considerations represented aspects of developing improvements in the complementarity of the company A headphone’s to the professional audiophile user’s music creation requirements. Changes, applied to external or internal subsystem parts, represented how improvements in the complementarity of the company A headphone’s offering to the audiophile’s use scenario, was approached.

In company A, improvement projects were coordinated from the perspective of improving the complementarity between subsystem aspects of a headphone's design and the personal sound reproduction requirements of the audiophile user in professional music creation use scenarios. Improvement projects were informed by the activities comprising the defined stages of company A’s formal headphone development process.

5.2 Company A’s Headphone Development Process
In company A, headphone design and development was coordinated, as visualised in figure 8, across seven stages. The development task was defined as a process that applied future anticipatory thinking on the audiophile consumer’s expectations of a company A headphone product.

![Development Stage Diagram](image)

In company A the headphone development process was used for coordinating two different development perspectives:

1. New headphone design projects,
2. Incremental improvements to the standard design of existing headphone product offerings.
This case explores the latter development task; incremental improvements to the standard design of existing headphone product offerings.

The internal and external subsystem headphone design aspects were addressed by the activities, as visualised in figure 9, comprising the first four stages of the development process.

These four stages of activities represented the compilation and consolidation of the different activities, assumed by company A, requiring completion to develop the external and internal subsystem design requirements of an engineered headphone’s design to be complementary to the audiophile users professional music creation use scenarios.

Through these defined stages of activities, the developmental intentions of each stage were enabled and go/ no go decisions, informing movement within and between stages, could be made.

Unlike new product development projects, which required completion of all activities in each stage’s, improvement projects targeted specific activities deemed by the project manager as relevant to implement an improvement. The nature of any improvement project revealed the subsystem focus of an improvement. The specific activities requiring
attention were subsequently identified relative to the subsystem focus of the improvement project.

In company A, improvement projects were conducted by multi-disciplinary improvement teams. The activities requiring attention to implement a subsystem improvement defined the development skillsets required of improvement team members. As visualised in figure 10, the improvement team for improvement projects typically comprised a product engineering manager, a marketing manager, an accounts manager, an R&D engineer, a product engineer, a mechanical engineer, a purchasing manager and a manufacturing engineer.

![Figure 10](Image)

The product engineering manager oversaw all headphone improvement projects in company A.

The project manager held dialogue with “would-be” team members to identify improvement opportunities.

Customer services create monthly reports that summarised per product segment, specific concerns reported through their call centre. These reports are submitted to the marketing manager. The product engineering manager conducted monthly meetings with the marketing manager to identify headphone improvement opportunities from the detail presented within the customer service report.

Additionally, the product engineering manager held weekly meetings with R&D engineers to discuss, amongst other things, new insights and opportunities for implementing improvements across platform of headphone offerings.
Finally, the product engineering manager also held weekly meetings with mechanical and manufacturing engineers to discuss operational activities. During discussions, the identification of inefficiencies (cost and technologies for example) offered insights that revealed other opportunities for improvement.

“Close integration and constructive interaction between our teams – from R&D and manufacturing to marketing, sales and many other departments – form the basis of reviewing the product segment portfolio here. “PEC1

Improvements were implement as informed by the activities comprising the first four development stages. Each stage had a defined purpose that coordinated the focus of dialogue typical of each stage.

5.2.1 Development Process Considerations of Headphone Improvements
Within stage 1, the business concept phase, the product engineering manager conducted dialogue with the marketing manager, focusing discussion on the company’s established assumptions of headphone design requirements of the professional audiophile user. Dialogue focused on the adequacy of the company A headphone offering. Adequacy was assessed relative to reported challenges of the existing headphone standard design (collated through analysis of customer service helpline information) or potential opportunities to incorporate new features (technological advancement or cost savings) as standard features of the company A headphone offering.

Informed by discussions with the marketing manager as well as insights from regular meetings with other company A staff, the product engineering manager may initiate an improvement project. An improvement project, if initiated, started with a “rough business case”. The rough business case detailed subsystem design challenges and or opportunities defining the need for changes to specific subsystems parts of the company A’s standard headphone design. Finally, the product engineering manager would discuss the specific requirements of the improvement project with an accounts manager and requests a “cost estimate” for the “specified improvement project requirements”. The request for a cost estimate typically brought stage 1 to a close.
At the beginning of stage 2, the requirements analysis phase, the project manager would assemble the improvement team deemed to possess the skillset required to address the improvement project requirements emerging from stage 1.

During the requirements analysis phase, the project manager would call a meeting with the entire improvement team. The meeting enabled the project manager present the nature of the improvement project and allocate development responsibilities to improvement team members. Product engineers were tasked with identifying an external headphone architecture that would enable compatible interface with the human ear and high frequency audio device. Mechanical engineers were tasked with identifying a preliminary design for the internal configuration of sound reproducing parts that fit within the constraints of the chosen earpiece style. Depending on the nature of the improvement, R&D engineers may be included to explore inclusion of design alternatives to standard part designs. Finally, the purchasing manager was tasked with creating a preliminary purchasing proposal. The preliminary purchasing proposal identified externally procured headphone part dependencies, constraining external and internal subsystem part improvements. The preliminary purchasing proposal brought stage 2 to a close.

During stage 3, the concept phase, the product engineering manager and the mechanical engineer, reflected upon in-house capabilities and capacities of manufacturing locations. The mechanical engineer was tasked with creating a concept implementation proposal that detailed alternative make or buy situations for external and internal subsystem parts. Finally, the purchasing manager was tasked with creating an updated purchasing proposal, bringing stage 3 to a close.

During stage 4, the development phase, coordinated discussion occurred between the product engineering manager, the mechanical engineer and a manufacturing engineer. Discussion focused on conducting review of documents relating to the developed headphone (component drawings and compliance certification for example) and the detailed specification of the improvements to the headphone subsystem’s design. Additionally, test results reviewing samples from manufacturing processes in proposed production locations were collated and the complementarity of the sound reproduced relative to defined use scenarios verified.
Improvements in the complementarity of a headphones standard design were realised through a focus that implemented changes to the design of external or internal subsystem parts. Headphone design considerations typical of each subsystem aspect are presented in the following subsections.

5.3 The External Subsystem Focus of Improving a Headphone’s Standard Design
In company A “industrial design” describes the development activity tasked with improving the design of a headphone’s external parts. Informed by marketing, the external design of a headphone is focused on identifying the features enabling the user interpret how to interact with external parts of the headphone. The attributes of the headphone’s external parts shape its interface features and imply compatibility of interaction with specific audio devices. These attributes enable the improvement team evaluate the perceivable opportunities required to enable audiophile users and audio devices interact with the headphone.

The product engineering manager of an improvement project, through co-ordinated discussion with marketing and product engineers, identify the attributes of enabling interactions with a headphone’s external subsystem. Interaction opportunities are developed relative to anatomical fit, adjustability and connectivity of external headphone parts:

“Anatomical Fit” is concerned with how the headphone facilitates interaction with the user’s head (support structures), ears (range of coupling styles) and upper body (audio cable interface styles),

“Adjustability” is concerned with how flexibility of fit can be achieved to address interactions relative to different anatomical shapes and sizes (expansion and rotatable characteristics).

“Connectivity” is concerned with interactions facilitating connection with audio source devices.

“All our headphones are tailored to the user’s preferences of being durable and lightweight with an ergonomic design that conforms to the ear and allow maximum freedom of movement” PMCI
Over the last 5 decades, the standard design of a headphone has evolved to include a range of external headphone interface form style options. This range categorises alternative ear piece styles, support structures, audio cable styles and jack plug sizing options for inclusion in a headphone’s offering.

- Earpiece styles are divided into three categories of ear coupling: circum-aural (the earpiece is designed to surround the ear), supra-aural (the earpiece is designed to sit on the ear), and intra-aural (the earpiece is designed to sit in the ear),
- Support structures, are designed to securely position interactions between the ear and the earpiece, included headbands (positioned over the top of the head), neckbands (positioned around the back of the neck), and ear hooks (hook around the back of the ear),
- Audio cable styles can be designed to be symmetrical (two equal cable side lengths) or asymmetrical (one cable side shorter than the other) in appearance,
- The Jack Plug is standardised with connector dimensions of 6.35 mm (1/4 inch) or 3.5 mm (approx. 1/8 inch) size options.

Delivery of the personal sound experience is dependent upon the adequacy of the design of the external subsystem’s parts to exhibit visual references of interaction compatibility with the audio device’s connector dimensions and the anatomy of the ear.

Whilst the interface features of a headphone’s external form enable audio device and user interactions with the headphone, delivery of the personal sound experience is dependent upon the technical capabilities of the internal subsystem of parts.

There is, as visualised in figure 11, a difference between the format of input from an audio device (an electrical audio frequency) and the output format (longitudinal mechanical sound waves) required from the earpiece for compatible with the physiology of the human ear.

“Input from a headphone differs to the output required. An electrical frequency is input from audio source device but sound is a mechanical wave that is propelled
An electro-mechanical conversion is required to enable translation of the electrical frequency input into the required longitudinal sound wave output. It is through the design of the internal subsystem, a configuration of internal parts, located within the headphone, that this conversion process is enabled. Therefore, delivery of a personal sound experience offering is dependent on the technical capability of the internal configuration of parts to establish behaviour states that actualises the electro-mechanical conversion.

5.4 The Internal Subsystem Focus of Improving a Headphone’s Standard Design

In company A, “system design” describes the development activity tasked with improving the technical capability of the internal configuration of parts to facilitate the sound reproduction conversion capability.

The design of the interactive arrangement of parts, located within the earpiece, embody the conversion capability within the headphone. The internal configuration of parts are designed to evoke a chain of reactions that induce the motive force required to convert an electrical frequency into a mechanical sound wave.

*Sound reproduction is the result of an electro-mechanical conversion process that transforms the electrical frequency into a longitudinal mechanical wave. This conversion is facilitated by the configuration of internal driver parts located within each earpiece*”

Sound reproduction is dependent upon the design of the ability of internal configuration of parts to input an electrical frequency from an audio device and to convert this electrical frequency.
frequency into a mechanical sound wave, deemed compatible with the physiology of the human ear.

It is the parts configuring level 2, the driver part, of the headphone’s internal subsystem that actualise the conversion capability underpinning how sound is reproduced.

“The electro-mechanical conversion process requires a component platform, between the three external headphone parts and the internal driver, which will structure the operational conditions of sound reproduction” PEC1

The level 2 driver part is comprised of four parts (diaphragm, voice coil, permanent magnet and housing frame) as visualised in figure 12. When the headphone is connected with an audio device, as assembled, these four parts actualise the functional states required to evoke a motive force:

When an audio frequency is channeled through the voice coil, the coil temporarily became an electro-magnet, alternately being attracted to and repelled by the permanent magnet as the channeling of current start and ends. The voice coil’s movement causes the dome of the diaphragm to move in and out, outwardly propelling sound waves from the earpiece to the user’s ear.

Figure 12  Level 2 Driver Parts Configuration

“Sound reproduction is based on the principle of electromechanical induction. The earpiece is the central platform that structures a conductive connection from jack plug
to the driver. The driver triggers the chain of reactions that convert an electrical frequency into a mechanical sound wave” PEC1

It was essential that driver assembly be designed with a clearance space, as visualised in figure 13, between the voice coil and the permanent magnet. This clearance space allows room for the voice coil to vibrate, from which the resulting motive force would induce and propel the mechanical sound-wave outwardly from the earpiece into the ear.

![Figure 13 Assembly Clearance Space](image)

The form of the earpiece often reflected a constraint as the configuration of internal parts have to be designed to fit within.

“Marketing conducts research on the requirements of the consumer: The type of audio device reflecting the environment of use defines the requirements of the headphone. Then decisions are made on the jack connector and earpiece style. These reflect the parameters against which we develop the configuration of the driver and conversion capability” PEC1

The personal sound experience is dependent upon the adequacy of the design of the internal subsystem’s parts to be compatible with the working principles of audio devices and the physiology of the ear.
Changes to “driver parts” represent the focus in company A of efforts to improve the compatibility of the electro-mechanical conversion capability to working principles of audio devices and the physiology of the ear.

Co-ordinated discussion between the product engineering manager, the lead mechanical engineer and the R&D engineer focused on identifying the functional behaviours required of the configuration of internal parts. It was the configuration of interactions between internal parts that structured the technical capabilities, enabling how the electro-mechanical conversion capability facilitated sound reproduction.

5.5 Coordination of Inter-related Headphone Subsystem Development Considerations during Improvement Phases

The challenge during a headphone improvement project was ensuring the interactions enabled by the design of the external and internal subsystems of the headphone were compatible with the settings of the use scenario.

The coordinated activities of the first four stages of the development process reflected a checklist of requirements for (1) assessing the external and internal subsystem specification of the standard design of a headphone offering, and (2) identifying compromises in the design of any external or internal subsystem part’s specifications to embody a compatible conversion capability.

Improved generations of headphone development had always been driven by the identification of opportunity or necessity for improvements to the headphone’s standard design at any point in time. In the case of the audiophile user, compatibility with high frequency audio devices and sound quality output to a user with a technical knowledge of sound frequency responses represented the use scenario setting of assessing the complementarity of both subsystem’s design specification.

“We only deem a design adequate when we see it as being perfectly adapted to the needs of the given use case scenario”  

AECI
Company A has, over a period of almost 50 years, conducted many in-house headphone improvement projects. The knowledge resulting of these development projects has established the standard design features of a headphone product. The knowledge resulting of these development projects update the library stock, detailed in table 14, of alternative subsystem design attributes.

<table>
<thead>
<tr>
<th>Design Aspect</th>
<th>Part</th>
<th>Attributes</th>
</tr>
</thead>
<tbody>
<tr>
<td>External subsystem Parts</td>
<td>Jack plug</td>
<td>6.35 mm (1/4 inch) or a 3.5 mm (approx. 1/8 in),</td>
</tr>
<tr>
<td></td>
<td>Audio cable</td>
<td>Asymmetrical “J style” or symmetrical “Y” style shape,</td>
</tr>
<tr>
<td></td>
<td></td>
<td>1.2 metre or 3 metre length cable,</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Coiled or Flat.</td>
</tr>
<tr>
<td></td>
<td>Ear Piece</td>
<td>Circum-aural or supra-aural, or intra-aural ear coupling styles</td>
</tr>
<tr>
<td>Internal subsystem Parts</td>
<td>Diaphragm</td>
<td>Intra-aural diaphragms have 12mm diameter &amp; a 1mm depth. Both supra-aural and circum-aural diaphragms have a dimension of 38 millimeters and a depth of 3mm.</td>
</tr>
<tr>
<td></td>
<td>Voice Coil</td>
<td>Layers and windings of wire;</td>
</tr>
<tr>
<td></td>
<td></td>
<td>2.5 layers in intra-aural form and 3.5 in Supra-Aural and Circum-Aural forms</td>
</tr>
<tr>
<td></td>
<td></td>
<td>34 windings in Intra-Aural, 98 in Supra-Aural and Circum-Aural forms</td>
</tr>
<tr>
<td></td>
<td>Magnet</td>
<td>From 5mm to 17mm depending on magnetic force required</td>
</tr>
<tr>
<td></td>
<td>Housing Frame</td>
<td>14mm Intra-Aural &amp; 42mm Supra/ Circum-Aural diameter</td>
</tr>
</tbody>
</table>

Table 14 Alternative external & internal part attribute options

These subsystem design attributes categorise standardised subsystem part features that evolved of improvement projects over the last 50 years of company A’s operational existence.

During improvement projects, complementarity was explored by comparing the compatibility of attributes shaping interactions enabled by a subsystem’s design to enable interface with audio devices (universal jack design standard) and the anatomy of the human ear (average ear dimensions). Audio device and ear interface requirements defined settings constraining decisions on the compatibility of attributes of a headphone’s external and internal subsystem’s parts. Typically, during improvement projects team members refer to the library stock of alternative attributes, identifying problems or opportunity of the existing design of specific parts. Problems and opportunities of specific part’s designs represented how the subsystem focus of an improvement project was identified.
The attributes allocated to each external and internal subsystem part and their compatibility when integrated as a total headphone offering was assessed on an ongoing basis. Assessment reflects upon the complementarity of interactions enabled with external and between internal subsystem part’s, relative to their collective ability of their attributes to establish the operational conditions necessary to deliver a personal sound experience.

For example, the high frequency audio playback devices, typically used in the music creation business scenarios, have quarter inch jack connectors. Therefore, for a headphone to be compatible with such a device, its external subsystem must be defined to include the quarter inch jack plug that facilitate audio device coupling. Additionally, these devices are typically mains powered devices that output a high audio frequency. Therefore, to facilitate the electro-mechanical conversion capability, the configuration of internal parts must be configured to control the powerful audio frequency input by such a device. This design consideration influences decisions made on the number of voice coil windings and layers. Voice coil windings and layers control oscillation timings of inducing the motive force necessary to generate output of a soundwave deemed, by improvement team member, to deliver the sound quality assumed expected by the audiophile user.

Additionally, improvement team members identify incompatible subsystem design scenarios. For example, the intra-aural style earpiece is the smallest of all earpiece styles. There is limited space available within the earpiece; its physical size cannot accommodate the number of voice coil windings and layers required to control high frequency input. Therefore, the quarter inch jack plug can never be included as a wired connection to an intra aural style headphone, as it would impact the quality of sound output. Only the larger quarter inch or 6.35 mm jack plug size can be considered for inclusion with supra-aural and circum-aural styled earpiece styles.

The final test of complementarity of external and internal subsystem parts, relative to use with a specific audio device, is assessed through in-vitro testing using a head and torso simulator (HATS). The head and torso simulator is representative of the “soft pinna” of the human ear and standardised for testing a headphone’s frequency response when interfaced with specific types of audio device (High frequency for example). The head
and torso simulator results enable audio engineers to verify the feasibility of the headphone’s internal mechanical configuration and external coupling structure, supporting the creation of documented evidence of:

- Compliance with acoustic specifications of the International Telecommunication Union (ITU-T Rec. P.58), American National Standards Institute (ANSI S3.36-1985) and International Electro Technical Commission’s IEC 60318-7ITU-T P.57 and IEC60318-4 standards,
- Ergonomics of a headphone’s head and neck supports to structure user interactions.

Improvement projects, limited by the constraints of the defined attributes of existing subsystem parts, often focus on applying changes to the design of subsystem parts. Each change informs updates to the library stock of alternative/replacement attributes of specific parts.

The preceding text has discussed the modern day view of the company A headphone. However, it through improvement projects, conducted over the last 50 years of company A’s operational existence, that this perspective of a headphone has been established. Three company A coordinated improvement projects, representing defining moments in the evolution of their headphone product, are presented.

Improvement projects always started with review of the standard design of an engineered headphone at that point in time, with assessment conducted relative to company A’s assumptions of the needs of the Audiophile consumer.

5.5.1 Improvement Example 1: Advancing the Quality of the Sound Experience

Whilst company A moved into headphone design and manufacturing in 1958, it was 1968 before company A presented their first headphone design improvement, the open headphone design, to the market. This improvement played a major role in improving the personal sound experience of the user.

Company A wanted to improve the quality of the sound experienced by the user and focused their attention on the design of the earpiece as it directly channelled the sound into the user’s ear.

“It was 1968, so naturally I wasn’t involved in this development project. But it was the first innovative development milestone of the company. A legacy of the company’s
innovative headphone development ethos. It features as part of induction for every engineer involved in development projects. It is even displayed on walls around the site as a reminder of its contribution to the headphone division’s success”. LMC1

It was 1968 and headphone development was in its infancy. The company’s engineers felt that the sound output from the standard earpiece’s design of that time was “trapped in the user’s head”. It was believed that sound could be improved and made to feel more life-like, as if they were in the room type of experience; this was defined later as a “wider soundstage feel”.

“The open principle of the X headphone liberated the sound that was up to that point stuck inside the user's head.” AEC1

The earpiece reflected the focus of this first improvement cycle within company A. The outcome of this improvement project became a universally accepted contribution to the standard design of a headphone, not just in Company A but across headphone manufacturing organisations.

An improvement team, comprised of mechanical and audio engineers, was formed and the earpiece identified as the focus of investigation. The internal configuration of sound reproduction parts were examined and deemed adequate at the point in time. Exploration moved to the earpiece’s form. The opportunity to improve the quality of the sound reproduced was deemed dependent on allowing controlled amounts of ambient sound (external noise) to enter the earpiece and interface with the sound reproduced within the earpiece to facilitate the wider soundstage feel.

The earpiece’s back had a hard enclosure. The hard enclosure prevented reproduced sound from escaping out the back of the earpiece. Making a change to the external enclosure of the earpiece, within which the sound reproduction parts were located, represented an opportunity to realise improvements in the personal sound experience. Referred to as the open principle, engineers realised that positioning openings at the back of the earpiece, allowing outside noise and the reproduced sound to meet, would achieve a wider soundstage feel.
“The opening at the back of an earpiece lets some sound out, lessening the impact of music beamed into your head, leading to a personal sound experience that feels more like listening to music in a room. In other words, it sounds more realistic.”

**AEC1**

Initially applied to a supra-aural earpiece form, as visualised in the left of figure 14, company A released a headphone offering with an open back to the earpieces.

![Open vs Closed Back Earpieces](image)

**Figure 14** Closed vs Open Earpiece form

These openings leaked more sound out of the headphone but also let more ambient sounds into the headphone, resulting in a more natural or speaker-like sound and a more spacious "soundstage" giving the perception of distance from the source. 100,000 sets of this open back headphone were sold by the end of 1969, deeming it a success. Additionally, company A patented their open principle technology, but licensed it to Sony for use in its first-generation Walkman headphones.

"We licensed the Open principle technology to Sony for use in its first-generation Walkman headphones.” **PAC1**

The open principle introduced a new feature for consideration during the development of future high-end headphone ear pieces. Whilst the change was made to the back of the earpiece’s external form, this change refined the quality of the sound experience delivered. The open back was added, as visualised in table 15, as an alternative earpiece attribute within the library stock for earpiece parts.
However, the core competence of company A was driver technology. Refinements to the driver part reflected the more commonly adopted focus of headphone improvements in company A.

"Over the years, the focus of our development projects and established competence has evolved to driver technology" LMC1

In stark contrast to the simple example of the refinement to the external form of the earpiece, refinements focused on improving the driver’s conversion capability were more complicated. Improvement team members needed to consider the potential knock-on effect of changes applied to any internal part on the ability of related parts to maintain compatibility with the working principles of audio source devices and the physiology of the human ear.

Improvement example 2 reveals the complex management challenge of ensuring that refinements to the standard design of any part of the driver's configurations did not compromise the ability of related internal and/or external parts of the headphone to deliver the personal sound experience.

5.5.2 Improvement Example 2: Eliminating Operational Inefficiencies of Driver Technology

Company A headphones apply use of the dynamic driver principles. An alternative used in the past was the electrostatic driver technology. In the 90’s, when this improvement project was conducted, the electrostatic driver reflected the standard for a driver part. Dynamic drivers were deemed inferior when considered from the sound quality output.

The product engineering manager starting by focusing attention on establishing an understanding of the failure mode impacting upon the performance of the dynamic driver.
A diaphragm’s intended purpose, within the component structure, was to absorb motive forces and pulsate, extending longitudinal sound waves out to the user’s ear. From discussions with product engineering managers and mechanical engineers, the product engineering manager established that the dynamic driver’s material over-heated during use, distorting the sound wave being output to the user’s ear.

“Previously, diaphragms of the dynamic type had problems with heating at the creases as the driver moved rapidly back and forth with the music. This heating at the folds of the fins would soften the material and change the torsional resistance to bending of the hinge.” PEC1

The product engineering manager decided it was time to find resolution to the diaphragm material’s shortcoming.

“Overheating changed the characteristics of the driver and introduced distortions in the direction of its movements” LMC1

With an understanding of the origin of the problem, the product engineering manager decided to initiate an improvement project, focused on resolving the issue. The product engineering manager determined that resolution required refinements to the diaphragm material’s properties. Consequently, the product engineering manager identified the skillsets required of improvement team members, presented in table 16, to realise the improvement.

With the requirements of the improvement project in his mind, the product engineering manager held a meeting with an accounts manager to establish the funding requirements of the improvement project. With the concept of the improvement project set, the product engineering manager called a meeting with the improvement team members.

Table 16 Improvement Project 2 Improvement team

<table>
<thead>
<tr>
<th>Development Stage:</th>
<th>Design Team Voice:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Stage1: Business Concept Phase</td>
<td>Accounts Manager</td>
</tr>
<tr>
<td>Stage2: Requirement Analysis Phase</td>
<td>R&amp;D Engineer</td>
</tr>
<tr>
<td>Stage3: Concept Phase</td>
<td>Mechanical engineer</td>
</tr>
<tr>
<td>Stage4: Development Phase</td>
<td>Purchasing manager</td>
</tr>
<tr>
<td></td>
<td>Mechanical engineer</td>
</tr>
<tr>
<td></td>
<td>Manufacturing Engineer</td>
</tr>
</tbody>
</table>
The product engineering manager introduced improvement team members to the improvement project.

During the requirements analysis phase, an R&D engineer and a mechanical engineer were tasked with designing a significantly more accurate driver. This was to be realised by developing “a new polymer material that would demonstrate a stable viscosity when heated with flexing, and would deliver predictable and narrow torsion characteristics at the fold” LMCI.

The material needed to be rigid, to prevent uncontrolled dome motions, as well as sufficiently stiff to reduce vibrations continuing after the electrical flow has stopped.

R&D engineers were challenged with identifying materials with properties that could tolerate heat build-up during use. The purchasing manager was tasked with sourcing alternative materials as requested by the R&D engineer.

Multiple material alternatives were ordered in preparation for analysis during the next stage; the concept phase.

During the concept phase, the product engineering manager was adamant that the new diaphragm material was to maintain the same dimensions as the original diaphragm part. Maintaining the same dimension prevented an impact on assembly with related driver parts. This requirement would facilitate easy adoption of the new diaphragm across all families of existing headphone design.

Mechanical engineers were challenged with initially verifying that the materials selected were capable of flexing and absorbing motive forces that facilitated the pulsation necessary to outwardly extend longitudinal sound waves. Additionally, R&D engineers analysed the many materials as polymerized together. The diaphragm’s material had to exhibit dual stiffness and flexibility properties. Of the many materials, a polymer material was identified as most suitable. With analysis completed, the move to the development stage was triggered.
During the development stage the R&D engineers refined the polymer material to tolerate heat build-up during use. The mechanical engineers tested the material’s capability to flex and absorb motive forces at a range of frequency levels. When the materials demonstrated the ability to facilitate the pulsation necessary, the material was deemed ready for testing. A prototype was build and assembled with related driver parts. Further sound frequency test were conducted, including HAT testing for compliance with regulatory standards.

The combined efforts of R&D and mechanical engineers resulted in the successful development of a “duo-foil” material. The lightweight, dual stiffness and flexibility properties of this patented two-layer plastic diaphragm material eliminated heating at the folds of the fins. This material was subsequently patented and adopted in all future headphone offerings.

Consequently, insight from this improvement project transformed the working principle of driver technology and the resulting quality of sound reproduced.

The diaphragm material was successfully developed without requiring change to the dimension of the original diaphragm part, maintaining in turn, compatibility with existing internal subsystem parts.

This subsystem part improvement replaced the original diaphragm material and included, as visualised in table 17, as the standard for the diaphragm part in future headphone designs.

<table>
<thead>
<tr>
<th>External subsystem Parts</th>
<th>Audio cable</th>
<th>Ear Piece</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Asymmetrical “J style” or symmetrical “Y” style shape, 1.3 metre or 3 metre length cable, Coiled or Flat</td>
<td>Circum-aural or supra-aural, or intra-aural ear coupling styles Open vs Closed Back</td>
</tr>
<tr>
<td>Internal subsystem</td>
<td>Diaphragm</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Intra-aural diaphragms have 12mm diameter &amp; a 1mm depth. Both supra-aural and circum-aural diaphragms have a dimension of 38 millimetres and a depth of 3mm. <strong>Duo-Foil Material</strong></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Layers and windings of wire: 2.5 layers in intra-aural form and 3.5 in Supra-Aural and</td>
<td></td>
</tr>
</tbody>
</table>

Table 17  Inclusion of the Duo-Foil material as a Detail in the Library Stock of Subsystem Parts
The development of improvements were complicated by design parameters that imposed restraint on what was and wasn’t possible. The two preceding improvement examples were driven by in-house identified opportunities for technological advancements.

“All our new headphone offerings will incorporate enhancements that build on the formidable achievements of our classic offerings.” PAC1

The two preceding improvement examples also involved design changes that had no knock-on effect on the ability of related subsystem parts (external or internal) to facilitate delivery of the personal sound experience. However, the reality was that this product improvement scenario was not always the case.

In company A improvements were also driven by the identification of evolving features of audio devices and skills of the audiophile user. Audio devices were becoming more powerful and users were becoming more demanding given their skill in recognising sound frequency responses. Additionally, changes to headphone subsystem part designs often have a knock-on effect on the ability of related subsystem parts (external or internal) to, given the attributes of their assembly, facilitate delivery of a personal sound experience.

Improvement example three reflects the complexities of managing improvements. When changes to a subsystem part impacts the capabilities of related parts, improvement team members are challenged with finding solutions that reconcile the compatibility of those related subsystem parts.

5.5.3 Improvement Example 3: The sophisticated Audiophile User & Technological Advancement in Driver Capabilities

During the monthly meeting with the marketing manager, the product engineering manager was made aware of an issue with a specific headphone model targeted for use by production companies in the music, film/TV, and advertising industries.

The product engineering manager decided that an improvement project was warranted. The product engineering manager started by establishing the concept of the improvement project, a business concept phase consideration.
The product engineering manager started by reviewing the standard design relative to the assumptions held by the marketing manager on the audiophile user’s requirements in professional use environments.

The assumption held was that the audiophile users, requiring headphones suitable for use in a professional production environment, typically used high frequency audio source devices.

“A reference class wired headphone that delivered a realistic and natural sound field with minimal resonance when connected with an amplifying device” LMC1

Therefore the requirements of a headphone required for such an audiophile user was defined as needing to be a reference class in wired headphone design that delivered a realistic and natural sound field with minimal resonance when connected with amplified audio devices.

“Our headphones fuse uncompromising sound quality and aesthetic design, containing award winning technical innovations and redefine the audiophile listening experience” PAC1

Another assumption held was that the audiophile user required features that supported portability and built in flexibility for movement during use.

“Audiophile users require an external headphone architecture that includes features that support portability and build in flexibility for movement” PMC1

Therefore the external form of the headphone was designed to include large circum-aural ear cups, comprising aluminium housing and a padded headband.

“The ergonomically designed ear cup frame is crafted of an ultra-lightweight, non-resonant material with titanium like strength that contributes to wearing comfort and acoustic performance” PMC1

The larger circum-aural ear coupling style was adopted as they were central to enabling noise cancellation, assumed critical in professional sound reproduction use environments. The large ear-cups were supported by the design of an adjustable headband that made it easy to achieve the perfect fit.
“A bail/gimbal assembly attaches the headband to the rear of each earpiece, and has two pivot points that allow adequate freedom for the earpiece to tilt and swivel to align with the side of the head for a proper fit”  

Additionally, the headphone was required to include a large quarter inch jack plug connector. Adoption of the large quarter inch jack plug connector was selected to reflect compatibility for interface with the standard jack connector adopted in high frequency audio devices. The large quarter inch jack plug connector was critical to enable sufficient input of audio frequency from high frequency audio source device to the headphone’s internal driver part.

The product engineering manager established that the standard design of the headphone had met all the requirements of the marketing manager. Therefore, the product engineering manager realised that the issue most likely existed in the design of the driver. He needed to speak to someone who could diagnose the origin of the issue.

The product engineering manager requested a meeting with the product engineer. Discussion started with review of the headphone’s internal subsystem’s design.

Typically, the standard internal headphone subsystem driver platform was used as a template for all headphone designs.

“A lot of decisions are made based on experience because forerunner products successfully used certain parameters. Then, the initial research leading to a spec might not be checked again”  

“Our core competence is transducer design.”

The complaints referred to “frequency response” and “harmonic distortion” issues. The high tech equipment used in the professional reproduction environment resulted in a technologically sophisticated user with a greater skill in detecting distortions in frequency response.
An analysis of the complaint from the perspective of the user led the product engineer to speculate that this specific headphone model, if developed using this standard driver platform, exhibited shortcomings when paired with high frequency audio devices.

The product engineering manager defined the headphone improvement project as focused on identifying and eliminating the issues that compromised sound reproduced within this specific headphone model. The improvement team, as visualised in figure 18, was assembled.

The product engineering manager decided that this improvement project was to be managed slightly differently than a normal headphone improvement project. R&D engineers were given a "clean slate" when developing the headphone driver to specifically operate with high frequency audio devices. They were to be unconstrained by the requirement to use the existing platform of driver parts.

“Our product engineers were given a clean slate to develop the world’s best dynamic headphone” PEC1

With the improvement team in place, the project was moved to the requirement analysis stage.

The task at hand was defining the origin of conflict between the technologically savvy audiophile user’s expectations and what the existing headphone design delivered the audiophile user. Product, mechanical and R&D engineers were tasked with revisited the standard headphone platform design and establishing the frequency level that distortions were occurring at.
The engineers established that the standard dome driver, when operating within a specific range of high frequencies, wobbled instead of only moving in and out.

“A problem with the traditional driver design is that at very high frequencies the diaphragm may stop acting like a pure piston, only moving in and out, and may take on additional vibration modes causing the surface to wobble or twist as it moves in and out causing break-up” **PEC1**

The wobble distorted the wave-front and disrupted the direction that the soundwave travelled before being delivered to the ear.

The dome of the driver “produced a strongly curved (spherical section) wave-front that bounced against the outer ear before entering the ear canal to be heard. This type of wave disrupted the psycho-acoustic cues the brain listens to in order to properly localize sound.” **AEC1**

Dialogue needed to focus on “developing a diaphragm driver that would deliver a flatter wave-front as it approached the ear and that would prevent break-up. So, we developed the ring radiator diaphragm in place of the traditional dome diaphragm” **PEC1**

With the requirements of the improvement project identified, the project was moved to the concept phase. During this stage, the product, mechanical and R&D engineers were tasked with conceptualising the solution.

The improved headphone driver’s design, as a system of interacting parts, needed to be capable of converting input of this high frequency range into longitudinal waves consistent with the physiology of the ear. Product, mechanical and R&D engineers were faced with two hurdles:

1) How to resolve the disruptive vibration that distorted the outwardly trajectory of soundwaves,

2) How to design the dome to stop the wave from bouncing off the outer ear before entering the ear canal to be heard.

The solution would be found through consideration of changes to the attributes of the driver and the configuration of internal parts:
1) R&D engineer identified the need to change the shape and diameter of the driver’s diaphragm part.

Sound quality output is proportional to the size of the driver’s diaphragm part: the larger the surface of the diaphragm, the higher the sound quality that is output. However, the disruptive vibration, generated at higher frequencies, occurred as a result of the large surface area of the driver’s diaphragm. This caused a conflict in design objective of affording the high quality sound reproduction requirements of the audiophile consumer.

2) Product and mechanical engineers in response to conversations with audio engineers determined that it was necessary to angle the driver’s positioning within the ear piece so that the resulting outward wave-front did not bounce against the outer ear before entering the ear canal (ideally the soundwave should reach the listener’s ear at an angle of 60 degrees.)

“Angling the transducer slightly forward and closer to the front of the listener’s ears helped deliver a wide and open spatial presentation unlike any other headphone”

LMCI

With the issue defined, the product engineering manager moved the improvement project to the development phase. R&D engineers and mechanical engineers were tasked with developing the solution.

R&D engineers started with a focus on applying design changes to the diaphragm’s design.

The solution involved two changes to the design of the diaphragm part. Firstly, research revealed that removing a portion of the surface area of the diaphragm’s dome, effectively leaving it ring shaped, prevented the occurrence of a wobble. However, secondly, with a portion of the dome removed, R&D engineers were now required to increase the diameter of the diaphragm to realise the required sound response. The increased diameter also required an additional anchor point to control the motive force created during use.
“The patented ring driver was central to the elimination of the wobble. The driver’s diaphragm now has two contact points (instead of one used in traditional dome drivers), at the inside and outside of the ring. Greater surface area coupled with the enhanced control of two contact points prevented the occurrence of vibration modes that caused the surface to wobble and delivered truly exceptional performance”

LMC1

As marketing had identified, during the first stage of the development process, the circum-aural earpiece style was assumed the preference of the audio professional. This design feature revealed another design opportunity. The physically larger size of the circum-aural sized cup enabled product and mechanical engineers to capitalise on the opportunity to build in cost reductions. Attention focused on making changes to the standard material (copper) of the coil part. Aluminium was proposed as an alternative for consideration. Analysis of the suitable of aluminium for adoption in the driver configuration of parts exhibited pros and cons.

“Whilst aluminium was cheaper and lighter, more layers and windings of voice coil wire were required to address the issue that aluminium has about 60 % of the conductivity of copper” PEC1

The increased size of the ring diaphragm’s diameter facilitated the space necessary to enable the inclusion of an extra layer and winding of the voice coil wire within the driver. However, the internal configuration of sound reproduction parts were located within each earpiece. Therefore, a constraint of a headphone’s design was the ability of the internal configuration of sound reproduction parts to fit within the external earpiece’s form.

The new ring driver’s dimensions were too wide to fit within the defined dimensions of a company A circum-aural ear piece. The final challenge was design of a small increase in the earpiece’s external frame to accommodate the new angled driver size. It was noted that the new ring driver was only compatible for fit within circum-aural earpiece styles. The average dimensions of the human ear limited the ability to increase the dimensions of a supra-aural earpiece. It would never be an option for consideration within intra-aural earpieces.
With the solution established, purchasing arranged for supply of the necessary materials. A headphone prototype was created and tested within the previously problematic frequency range. With evidence of the elimination of the wobble issue and improved sound frequency response, the improved headphone was released for sale.

Company A’s analysis of market feedback from audiophile users identified it as a resounding success. As was the case with the previous two improvement projects, updates, as visualised in table 19, were made to detail of alternative subsystem part attributes.

This development project revealed new part attribute details for the diaphragm part (the ring diameter), and the voice coil (aluminium & number of winding and layer required in context of use with the ring diaphragm).

<table>
<thead>
<tr>
<th>Design Aspect</th>
<th>Part</th>
<th>Attributes</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Jack plug</strong></td>
<td></td>
<td>6.35 mm (1.4 inch) or a 3.5 mm (approx. 1.8 in),</td>
</tr>
<tr>
<td><strong>Audio cable</strong></td>
<td></td>
<td>Asymmetrical “Y” style or symmetrical “Y” style shape,</td>
</tr>
<tr>
<td></td>
<td></td>
<td>1.2 metre or 3 metre length cable, Coiled or Flat</td>
</tr>
<tr>
<td><strong>Ear Piece</strong></td>
<td></td>
<td>Circum-aural or supra-aural, or intra-aural ear coupling styles</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Open vs Closed Back</td>
</tr>
<tr>
<td><strong>Diaphragm</strong></td>
<td></td>
<td>Intra-aural diaphragms have 12mm diameter &amp; a 1mm depth.</td>
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<tr>
<td></td>
<td></td>
<td>Both supra-aural and circum-aural diaphragms have a dimension of 38 millimetres and a depth of 3mm.</td>
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<tr>
<td></td>
<td></td>
<td>Duo-foil Material</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Dome vs Open Ring</td>
</tr>
<tr>
<td><strong>Voice Coil</strong></td>
<td></td>
<td>Layers and windings of wire.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>2.5 layers in intra-aural form and 3.5 in Supra-Aural and</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Circum-Aural forms</td>
</tr>
<tr>
<td></td>
<td></td>
<td>34 windings in Intra-Aural, 98 in Supra-Aural and Circum-Aural forms</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Copper vs Aluminium</td>
</tr>
<tr>
<td><strong>Magnet</strong></td>
<td></td>
<td>From 5mm to 17mm depending on magnetic force required</td>
</tr>
<tr>
<td><strong>Housing Frame</strong></td>
<td></td>
<td>14mm Intra-Aural &amp; 22mm Supra/Circum-Aural diameter</td>
</tr>
</tbody>
</table>

Table 19  Inclusion of the Open Ring & Aluminium as two new Details in the Library Stock of Subsystem Parts

5.6 Headphone Affordance Design Improvements: Analysis of the Conceptual Constructs

The preceding sections have presented the background to company A headphone affordance design considerations and three examples of improvements in the complementarity of the affordance design. This section presents a “within case” analysis of case observations building on the Conceptual Framework in chapter 3. Figure 1 of
chapter 3 visualised management of the external-internal affordance relationship. The objective now is to establish an understanding of the approach adopted by company A to managing the external-internal affordance relationship of a headphone during improvement projects. With reference to the five constructs outlined in chapter 3, empirical evidence of the elemental considerations to managing the external-internal affordance relationship in company A is visualised in figure 15 and discussed in the following sections.

5.6.1 A Headphone’s Use Environment

The company A headphone was developed to meet the sound reproduction needs of the audiophile user. Professional music creation defined the use environment of an audiophile user’s headphone. The human ear and high frequency audio devices defined the settings of the company A headphone’s utility. The company A headphone was required to enable sound reproduction that delivered a personal sound experience, suited to the professional music creation tasks of the audiophile user.

Originally, company A’s headphone was designed relative to settings defining the use context of delivering a personal sound experience. The anatomy (structure) and physiology (hearing functionality) of the human ear defined a setting of a headphone’s use environment and a design context of improving the affordances resulting of the design of the headphone’s parts. The nature of a headphone’s utility, as coupled with audio devices, defined the technologies underpinning the working principles of high frequency audio devices as another setting of improving the headphone’s affordances.

The settings of the company A headphone’s use scenarios were subject to change. Overtime, technological advancements in audio devices working principles (more powerful output), as well as the evolution of a more technologically knowledgeable
audiophile user revealed compromises in the headphone’s complementarity in music creation use scenarios.

In company A, headphone improvement projects were used to improve incrementally the sound experience delivered by reconciling the standard design of parts of the headphone to music creation use settings.

5.6.2 The Headphone Artefact’s Design
Company A’s headphone is an established product. The utility interface and technical capabilities of the headphone’s design underpinned the personal sound experience afforded. Company A team members held assumptions of the utility interface and technical requirements of delivering the personal sound experience.

The personal sound experience required a headphone design that enabled direct interface with the human ear and an audio device. The headphone was implied the personal sound experience offering through interface with the earpiece and jack plug parts. Utility interface was dependent upon how headphone parts were developed to facilitate connection with the human ear and audio devices. The attributes of the headphone’s external parts, the earpiece and jack plug, enabled the audiophile user interpret ear and audio device connection compatibility. To deliver a personal sound experience, the headphone was required to enable input of an audio frequency and to generate output of longitudinal sound waves.

The attributes of the headphone’s four internal driver parts structured functional compatibility with the audio device, essential for actualising the sound reproduction capability.

Refinements to utility interface and technical capabilities of the company A headphone enabled improvements in the personal sound experience delivered.

5.6.3 Headphone Affordance sub-systems
A headphone is a complex product. Company A’s headphone offerings were developed from the perspective of two subsystems: its external subsystem and its internal subsystem.
The external system was shaped by the parts of the headphone that enabled direct interface with the audiophile user’s ears and the audio device’s connector.

- The earpiece, audio cable and jack plug parts defined the utility interface capabilities of the *external subsystem* of the company A headphone.

The internal system was structured by the parts of the headphone that enabled audio device input to be output to the user’s ear as a sound wave.

- The driver and its four parts, housing frame, diaphragm, voice coil and permanent magnet, defined the functional capabilities of the *internal subsystem* of the company A headphone.

The specific parts of a headphone, identifiable as either an external or internal subsystem parts, contributed to enabling “human using” and “product working” aspects of a headphone’s design.

The attributes of each external part were shaped to be compatible with the anatomy of the human ear or audio device connector formats:

- The attributes of the earpiece (shape and dimension) were shaped to fit, relative to team member’s assumptions of average ear shapes, angles and dimensions, the human ear,
- The attributes of the audio cable (length and style) were shaped to extend, relative to team member’s assumptions of extension requirements, from the earpiece to an audio device,
- The attributes of the Jack plug (sizing) were shaped to fit, relative to team member’s knowledge of universal jack connector sizing, audio device connector forms.

The attributes of each internal part were structured to collectively embody the technical capabilities to reproduce sound that was compatible with the physiology of the human ear or working principles of audio devices:

- The attributes of the driver (shape, dimensions and dual conductive/non-conductive composition) structured a platform that fit within the earpiece and controlled audio input from the jack plug, as well as output through the earpiece,
The attributes of the four housing parts (dimensions & clearance spaces between each part) structured the assembly of driver parts that would convert the audio frequency input into a sound wave output form.

Design changes to both the human using and product working parts of the headphone’s subsystems represented how company A improved the complementarity of the headphone’s design to music creation use scenarios.

5.6.4 Headphone Action Possibilities

The action possibilities of a headphone were signified by the visual references of the headphone’s external subsystem of parts.

During improvement projects, improvement team members identified, for each external part, features that signified improved opportunities of interaction between the headphone and the user and between the headphone and audio devices. Perceivable opportunities for interaction with headphone parts were defined by:

- Three alternative earpiece styling options that facilitated different user-ear interface opportunities,
- Two alternative audio cable styling options that facilitated different ear to audio device extension opportunities,
- Two alternative jack plug connector sizing options that facilitated fit to different audio device connector formats.

The improvement team members’ assumptions of different audio device and user interface requirements determined the earpiece and audio cable style and jack plug sizing structuring a headphone’s affordance design. Perceivable interaction features were designed to enable the users select the headphone model that would best represent their needs.

The interaction features of the three external subsystem parts represented the “recurring stimuli” of evoking “hard-wired, biological reflexes and habituated responses” of the audiophile user. For example, the jack plug’s size enables the user infer compatibility of connection with different audio devices. During improvement projects, improvement team members improved the design of the recurring stimuli of perceivable interaction
opportunities. The open back circum-aural earpiece style combined with a quarter inch jack plug size represent the recurring stimuli of assessing the compatibility of the company A headphone to music creation use scenarios.

### 5.6.5 Improved Headphone Affordance

Audiophile users experience the headphone holistically. Visual references of the action possibilities of interface with external parts alone did not facilitate delivery of the personal sound experience. The action possibilities of the company A headphone emerged of the functional ability of the internal subsystem of parts to actualise the conversion capability. When a jack plug is connected to an audio device, it is the internal configuration that facilitates input, conversion and output of audio. The internal subsystem of driver parts underpin how the actions possibilities of the headphone’s external subsystem deliver the personal sound experience.

Therefore, the complementarity of the action possibilities of a company A headphone to music creation use environment was dependent upon team members improving external and internal subsystem interactions:

1. Between the headphone’s external subsystem (earpiece) and the user’s ear,
2. Between the headphone’s external subsystem (jack plug) and an audio device,
3. Between the headphone’s internal subsystem of interacting driver parts (within the earpiece).

These three headphone subsystem interaction opportunities structured how the personal sound experience was realised. Each subsystem played a role in accommodating use scenario setting:

- External subsystem parts implied the personal sound experience through visual reference of opportunities for interaction between the headphone’s earpiece and the user’s ear and between the headphone’s jack plug and the audio device.
- Interactions between internal subsystem parts actualised how the conversion capability was embodied.

Whilst each subsystem categorised different headphone design aspects, subsystem represented inter-related development consideration requiring management during any improvement project. Alone, neither subsystem’s design affords the personal sound
experience expected of a headphone. There are interdependencies between external and internal subsystem parts. Neither subsystem could be designed in isolation of the other. The personal sound experience implied as offered by the visual references of external parts interaction opportunities needed to be consistent with the conversion capabilities actualised by the internal subsystem of parts.

- The headphone’s external form should be designed to fit the anatomy of the human ear and specific audio device connector formats,
- The headphone’s internal configuration of sound reproducing parts should be designed to embody a technical capability compatible with the working principles of specific audio devices and human ear physiology.

Improvement projects focused on improving the compatibility of subsystem parts to changing settings of the use scenario.

- The earpiece part should imply a sound stage capable of delivering the personal sound experience,
- The driver part should be capable of converting a range of audio frequency input levels without harmonic distortions being detectable by the knowledgeable audiophile user.

Company A assembled improvement teams to coordinate improvement projects. Improvement team members possess different skillsets.

Team members that focused on design of the earpiece held assumptions on the dimensions of the average ear. These assumptions defined how earpieces dimension of fit were developed.

Team members that focused on design of the internal configuration held knowledge on what sound is and the physiology of the ear. These assumptions defined how individual parts, and as a configuration of interacting parts, were developed to actualise the conversion capability deemed compatible with the working principles of high frequency audio devices.

Improvement team members assessed the compatibility of the attribute of interactions enabled with and within a headphone’s design to settings of the music creation use scenario:

1. Team members tasked with improving the external subsystem parts examined the ability of the headphone’s external subsystem of parts to enable interactions
compatible with the ear’s anatomy and high frequency audio device connector formats,

2. Team members tasked with improving the internal subsystem parts examined the ability of the headphone’s internal subsystem of interacting parts to actualise the conversion capability compatible with the audio frequency input of specific audio devices and the physiology of the human ear.

Compromises in the attributes of any subsystem’s parts informed the need for and subsystem focus of an improvement project. During any improvement projects improvement team members were challenged with ensuring design changes to any part (external or internal) improved the compatible of that part to use scenario settings (ear anatomy or physiology or audio device working principles) and, in turn, the complementarity of the headphone’s utility offering in the music creation use scenario.

The affordances of a company A headphone resulted of the design of its external human using and internal product working subsystem aspects. The total headphone is the perspective of understanding how the external-internal affordance relationship was managed. Of concern was establishing an understanding of how improvements in complementary of a headphone’s design to specific use environment settings of the audiophile user was realised.

5.7 Headphone Affordance Design Improvements: Analysis of the Relationships between Constructs

With reference to the six relationships outlined in chapter 3, empirical evidence of the approach adopted by company A to managing the external-internal affordance relationship is visualised in figure 16 and discussed in the following section.

The headphone was a complex product that evolved through improvements. Design changes to subsystem parts characterised how company A approached the development task during improvement projects. Overtime the headphone’s personal sound experience offering was improved. Improvements projects were initiated and coordinated by a product engineering manager. Each improvement project was driven by the identification of a potentially remediable compromise in the headphone’s design, and sought to improve the sound experience delivered at that point in time.
The product engineering manager determined the skillset required of improvement team members to resolve the identified compromises. During each improvement project, the product engineering manager identified the subsystem part focus of resolving the compromise.

In this case, three improvement projects were presented. Each improvement project represented a phase of company A’s attempts to improve the headphone’s complementarity to its professional music creation use scenario. During each improvement project the headphone’s use scenario defined the benchmark for improving a headphone’s complementarity to professional music creation use scenarios.

**Relationship 1:** Managing the relationship between a headphone’s standard design and improvable audiophile user interface and sound reproduction aspects.

Team members evaluated the adequacy of subsystem aspects of the existing headphone’s standard design relative to settings of the headphone’s use environment. The use environment for the headphone product comprised the human ear and the consumer’s audio device. Each had characteristics which would impact design of headphone interfaces of delivering the personal sound experience.
- The physiology and anatomy of the human ear defined headphone characteristics of enabling perceivable opportunities for interface with the audiophile user.
- The working principles of high frequency audio devices defined headphone characteristics of enabling perceivable opportunities for interface with audio devices used in music creation use scenarios.

The technologies underpinning the working principles of high frequency audio devices and the anatomy and physiology of the human ear defined the benchmark of improving the sound experience of the headphone.

**Relationship 2: Managing the relationship between a headphone’s standard design and action possibilities of the personal sound experience.**

Company A managed the development of improvement to the external-internal affordance relationships by making dynamic assumptions about the audiophile user’s utility requirements. Complementarity was assessed through review of the action possibilities of the external subsystem of human using parts of the headphone’s form. For example, an open earpiece back implies a wider sound stage and a more lifelike personal sound experience. However, the complementarity of a headphone was also dependent upon the ability of the internal subsystem of product working parts to actualise the conversion capability. For example, the larger the surface of the diaphragm, the higher the sound quality that is output. The external and internal subsystems were interrelated affordance design improvement considerations.

The complementarity of the headphone’s affordance design required team members to develop subsystem parts to be compatible with the use setting defining a part. For example:
- The compatibility of the earpiece’s external form was defined relative to the anatomy of the human ear, and the ability of the earpiece to fit the ear,
- The compatibility of the earpiece’s internal configuration was defined relative to the physiology of the human ear, and the ability of any part to actualise the conditions of converting an audio frequency into a soundwave.

Prior to any improvement phase, the headphone had been deemed by the product engineering manager to have a standard design that embodied human using and product working aspects that complemented music creation use scenarios. The identification of
the existence of compromises in the compatibility of any subsystem part of the headphone’s total design was the basis of initiating each improvement project.

The product engineering manager monitored company A product offerings on an ongoing basis for the existence of compromises in any subsystems part’s compatibility. Case observations presented three examples of compromises evident in improvement initiatives:

- The first improvement project example was initiated in the 70’s. The sound output was deemed compromised by how the closed earpiece back limited the sound stage.
- The second improvement project example was initiated in the 90’s. Driver technology was less established and the sound reproduced was deemed compromised as the diaphragm part overheated during use,
- The third improvement project example was initiated in the late 2000’s. The sound reproduced was deemed compromised by how audio devices were becoming more powerful and users were becoming more skilled in recognising sound responses of a headphone.

**Relationship 3:** Managing the *relationship between improvable audiophile user interface and sound reproduction aspects and action possibilities of the personal sound experience.*

The defined development requirements of a headphone device revealed two development aspects and opportunities for team members to improve complementarity:

1. The “human using” features, an external artefact to user affordance subsystem, of enabling the audiophile user connect the earpiece with their ears and the external artefact to artefact affordance subsystem of enabling the jack plug to be connected with an audio device,
2. The “product working” features, an internal artefact to artefact affordance subsystem, of actualising embodiment of the “conversion capability” within the headphone’s configuration of internal driver parts.

Throughout, design dialogue was focused on achieving a complementary set of external artefact-user and external and internal artefact-artefact interactions. Each improvement project started with a subsystem focus. The subsystem focus of each improvement project was a follows:
- Improvement project 1 focused on the external human using aspect of the headphone’s standard design. Changes were to be applied to the external form of the earpiece. This change was required to enable visual reference of an extended sound stage and improve the compatibility of the sound output to the physiology of the user’s ears,

- Improvement project’s 2 and 3 focused on the internal product working aspect of the headphone’s standard design. Changes were to be applied to the technical capabilities of the diaphragm and driver parts. These changes were required to actualise a more efficient and resilient conversion capability and improve compatibility of the internal sound reproduction parts to the working principles of high frequency audio devices.

When compromises were deemed to exist, improvement teams were formed and members within the team were tasked with finding resolutions. Finding resolution required improvement team members to identify the origin of the compromise. Improvement team members considered the “what if” of applying changes to subsystem parts. The “what if” scenario enabled team members assess if such changes accommodated human using and product working requirements whilst improving the complementarity of a headphone’s design to music creation use scenarios.

In Company A, compromises did not result of poor design decisions of earlier development tasks. Rather, compromises emerged of the industry-wide weakness in specialist technical (driver working principles) knowledge, and the evolution of the more “tech savvy” audiophile user.

Compromises reflected dynamic assumptions formed by improvement team members on headphone interface and conversion requirements and the application of future anticipatory thinking on ways to improve the personal sound experience:

- Improvement project 1 was initiated because company A engineers felt the sound reproduced did not feel lifelike and there was opportunity to widen the soundstage and, in turn, the quality of the sound experience.

- Improvement project 2 was initiated because company A engineers felt there was an industry-wide weakness in sound reproduction driver technology. Engineers saw opportunity to develop a more resilient design,
- Improvement project 3 was initiated because company A engineers felt that the audiophile user was becoming more sophisticated and technologically savvy. Engineers recognised the need to advance sound reproduction driver technology.

The origin of each compromise was determined through review of the existing generation of the headphone’s standard design. Reviews enabled improvement team members to locate and map inadequacies of subsystem (human using or product working) part attributes to compromises.

Additionally, the focus (an external or internal subsystem part) of implementing an improvement was defined. Improvement project 1 revealed compromises in the external subsystem’s complementarity. Improvement projects 2 and 3 revealed compromises in the internal subsystem’s complementarity.

- Improvement project 1 identified inadequacies in the earpiece part. The closed back of the ear piece limited the sound stage. A changes to the form of the back of the earpiece (openings) was identified as the solution,
- Improvement project 2 identified inadequacies in the diaphragm part. Changes to make the diaphragm more resilient (a material able to withstand heat build-up) during use was identified as the solution,
- Improvement project 3 identified inadequacies in the driver part. Changes to the diaphragm (new ring shaped & angle of position) part was identified as the solution.

Complementarity of the headphone’s affordances to music creation use environments was dependent upon reconciling the compatibility of design changes to subsystem parts to use scenario settings. Compatibility was realised through the series of design decisions that coordinated how design changes to parts of each subsystem were reconciled to specific settings (ear physiology and anatomy and audio device working principles) of the music creation use scenario.

Improvement to the external subsystem involved improvement team members applying changes to a part that would be directly interacted with by the audiophile user. These changes resulted of team members focusing attention on amending the attributes of the
external part’s design, to signify the improved sound experience resulting of the part’s new design feature:

For example, during improvement project 1, improvement team members focused on the external form of the earpiece, applying openings to the back of the earpiece. These openings providing the audiophile user with a visual reference of a new feature that inferred delivered of a wider soundstage when coupled with their ear.

Improvement to the internal subsystem aspect involved improvement team members applying changes to a part of the headphone’s functional configuration. These changes resulted of team members focusing attention on amending attributes that enabled how the interactive arrangement of sound reproducing parts actualised the conversion capability, underpinning the personal sound experience:

For example, during improvement project 2 and 3, improvement team members focused on making changes to the diaphragm part. Changes were made to the diaphragm’s material, its shape, its dimension and its angle of assembly with other driver parts. These changes amended how sound was reproduction and improved the personal sound experience delivered.

**Relationship 4: Managing the relationship between interactions of parts actualising sound reproduction within and audio devices and human ear interactions with the headphone’s form.**

Company A team members of internal and external aspects could not, independent of one another, definitively inform decisions on improvements in the complementary of a headphone’s personal sound experience to music creation use scenarios. The complementarity of a headphone’s external artefact-user and artefact-artefact interactions was dependent upon the adequacy of the technical design of internal artefact to artefact interactions.

Improvements in the complementarity of a headphone’s design involved considerations of both the human using and product working aspects of the headphone’s design. Each aspect characterised a subsystem defining the context of developing improvements in the headphone’s personal sound experience offering.

- The external human using aspect characterised the development task of improving the perceivable opportunities for useful utility interactions between the
headphone’s external parts and the targeted audiophile user and high frequency audio source devices,

- The internal product working aspect characterised the development task of improving interactions between sound reproducing parts that actualise the conversion capability function within the headphone.

The complementary of the headphone’s personal sound experience was informed relative to the working principles of the audio source device and the physiology of the human ear.

During each improvement project design dialogue focused on maintaining consistency between utility implied by interactions enabled with and utility actualised through interactions enabled within the headphone.

- Consistency between the utility interactions communicated by the headphone’s external form and the technical “conversion” capabilities unlocked within the headphone’s internal driver configuration,

During an improvement project, the coordinated series of considerations that improved a subsystem part revealed another management challenge; reconciliation of design changes with related subsystem parts.

**Relationship 5:** Managing the _relationship between action possibilities of the personal sound experience and an improved standard headphone design._

The resulting headphone was tested before release for compatibility of interactions with the ear (safe sound reproduction noise levels) and with an audio device (adequate sound reproduction response) typical of the profession music creation use scenario. Each improvement project started with a subsystem focus that ultimately applied changes to a part of that subsystem. Improvements in the compatibility of that headphone part had potential to impact the compatibility of related headphone parts to use settings. The affected part(s) could exist within the same or different subsystem aspect to the initial improvement focus. In such situations further iterations of design were initiated to reconcile the complementarity of the total headphone’s design with use environment settings. Complementarity was dependent upon identifying and eliminating all knock-on effects.

Of the three improvement projects only one example of a knock-on effect was observed. Improvement project 3, initially focused on applying changes to the diaphragm part (new
open ring vs dome diaphragm), revealed an example of a knock-on effect. This knock-on effect required improvement team members to apply changes to the driver part’s housing (wider to accommodate the wider ring diaphragm dimensions). Subsequently, this change required improvement team members to also apply changes to the earpiece’s form (internal and external dimensions) to accommodate positioning of the driver within the constraints of the earpiece. Ultimately, improvement project 3 started with a focus on an internal subsystem aspect of a part, and moved through to the requirement for changes to many other parts including a move to the earpieces external form, an external subsystem aspect of enabling the human using feature.

However, the decisions at early stage of the development process can limit the knock-on effect:

In improvement project 2, at the beginning of the concept stage, the product engineering manager made the decisions that design changes to the diaphragm part had to be developed to fit with the existing design of related internal subsystem parts.

**Relationship 6:** Managing the *relationship between an improved standard headphone design and the professional music creation use environment.*

The resulting headphone was reviewed for continuing competitiveness in a dynamic market. The dynamic nature of the electronics industry and market standards, required company A to conduct ongoing reviews of the need for improvement in the headphone’s standard design. The need for improvements were determined relative to evidence of changing use settings and compromises in existing headphone part designs.

The attributes of a headphone’s external parts as well as the attributes of internal sound reproduction parts, and their arrangement, represented a metric of conducting reviews. Reviews enabled improvement team members identify how the internal or external parts, if changed, would eliminate the compromise and improve compatibility with specific settings of the headphone’s use scenario.

Additionally, the attributes of interactions enabled with (product-user utility interface) and within (actualising technical capabilities) the headphone’s design enabled improvement team members determine how solution to knock-on effects were best approached and integrated within and between subsystems. Additionally, the attributes of interactions enabled improvement team member “infer when” complementary headphone affordances were deemed realised.
Reviews examined the compatibility of subsystem parts of the headphone’s affordance design to enable the utility interface requirements of specific audio devices and the human ear. Complementarity assessed the consistency existing between the interactions enabled with the headphone’s external form and the “conversion” functions embodied by the arrangement of parts within the headphone’s internal configuration.

Insights from each improvement updated knowledge of subsystem design aspects. This knowledge was transferrable for use during future improvement projects. Occasionally past improvements became the focus of a new improvement phase.

- During improvement project 3, the open back form resulting of improvement project 1, was a transferrable piece of knowledge considered for adopted when attempting to improve a headphone’s design.
- Driver diaphragm technology of improvement project 2, became the focus of improving the company A headphone’s complementarity in improvement project 3.

5.8 Management Implications for Improving Headphone Complementarity

Analysis of empirical observations in company A yielded three management considerations for improving the headphone’s complementarity to the music creation use scenario:

1. Initiating headphone improvement projects, based on managing relationships 1 and 6,
2. Implementing a headphone subsystem (internal or external) improvement, based on managing relationships 2, 3 and 4,
3. Realising headphone design complementarity to professional music creation use settings, based on managing relationship 5.

Each management consideration is discussed and enables the process coordinating management of the external-internal affordance relationship during improvement projects in company A to emerge.

Initiating improvement projects reflected relationships 1 and 6. During each improvement phase a standard headphone design already existed. The existing headphone, shaped by preceding improvement phases, already embodied an
accommodation between the human using and the product working aspects of the headphone (relationship 6). However, when compared to use environment settings (relationship 1), there was opportunity or need for an improvement in the headphone’s design to be complementary to changing professional music creation use settings.

Implementing a subsystem (internal or external) improvement reflected relationships 2, 3 and 4. Managing relationship 2, the improvement process was coordinated by a truncated version of the regular headphone product development process. Discourse took place within some of the stages of the headphone development process that informed improvement to specific subsystem parts (reflected by considerations of relationships 3 and 4).

Realising complementarity to a headphone’s use environment settings was reflected by relationship 5 and revealed when an improvement to a total headphone’s complementarity was realised. As knock-on effects were identified, improvements required revisiting prior decisions, those of relationships 3 and 4, and associated fits with each subsystem aspect of the headphone’s affordance relationship. The professional music creation use environment settings of the headphone defined the constraints of each improvement phase.

5.8.1 Three Stages to Managing External-Internal Headphone Affordance Relationship Considerations
The emergent management process incorporates three stages for coordinating the external–internal affordance relationship during phases of headphone improvements:

1. *The practical rationale of initiating improvement projects, stage 1*, revealed the *start point* of triggering headphone improvement projects. Improvements were initiated in response to assessment of and identification of compromises in the complementarity of an existing headphone’s design to changing professional music creation use settings.

2. The *challenge of implementing a subsystem (internal or external) improvement, stage 2*, revealed two coordinating series of design considerations of implementing headphone improvement. Each coordinated series of design considerations defined the focus of change to a specific headphone subsystem’s affordance relationship.
3. The **interactive aspects of realising complementarity**, stage 3, involved **iterations** of design changes required so as to reconcile internal and external headphone subsystems to realise affordance design complementarity. Each of the three stages are discussed.

At stage one the pre-existing standard design of this headphone defined the affordance relationship that existed. The complementarity of the standard design was interpreted from the external subsystem perspective, from which opportunities or the need for improvements were identified.

At stage 2 there was “subsystem level” dialogue to be managed with a focus on a specific subsystem. Team members were concerned with realising improvements to a headphone subsystem aspect’s affordance relationship. Improvements were achieved through a focus on redesigning a part within a specific subsystem aspect (human using or product working).

As team members improved the subsystem aspect, they monitored the complementarity of changes to affordance relationship assumptions of stage 1 and engaged in coordinated sequences of dialogue. Dialogue focused on implementing changes to the externally perceivable headphone interaction attributes or changes to the attributes of interacting parts that internally structured the conversion capability.

Improvements resulting from changes applied to subsystems had potential to impact other parts. So, maintaining the complementarity with the stage 1 affordance relationship assumptions required management to extend dialogue to another subsystem aspect, now potentially also requiring attention.

At stage 3 the management act was reconciliation, through discourse, between both subsystem perspectives to resolve conflict with each other. There were defined metrics of enabling the external human using and internal product working subsystem aspects of the affordance relationship. Complementarity required consistency between the sound experience implied by the features communicating interactions enabled with the headphone and the sound experience resulting of parts interacting within the headphone.
Central to the discourse was reconciliation of different perspectives of the affordance relationship through iterations of design. Each iteration required an articulation of subsystem’s affordance relationships, a contextualisation of each subsystem’s affordance relationship aspect and contextualisation of the use environment for inferring complementarity.

There are interdependencies between the three stages:

Stage 1 started each headphone improvement project as a cycle that beginning with a review of the existing headphone’s standard design, the output of a previous improvement phase.

Stage 2 followed with two coordinated series of design considerations for implementing improvements in the compatibility of a subsystems complementarity to the music creation use environment.

Stage 3 reconciled complementarity through iterations of design focused on matching subsystem affordances (internal or external) to their respective music creation use environment settings.

5.8.2 Five Steps to Managing a Headphone’s External-internal Affordance Relationship During Improvements Projects

Within the three stages, there were five steps in the process of managing the external-internal affordance relationship during phases of improvements, as visualised in figure 17. Each of the five steps are presented below.

Step 1: Review of the headphone's Standard Design (the Start Point)
The improvement team started each improvement project by identifying issues (sound reproduction compromises) or opportunities (reduce cost, sound experience effectiveness) for improvement in the affordances of existing headphone offerings.

Step 2: Evaluation of the performance based indicator justifying need to initiate a phase of improvement
Improvement team members examined known indicators and metrics of headphone performance to identify improvable subsystem(s). They assessed the ability of internal
and external subsystem parts of the headphone to deliver the personal sound experience. They defined the origin of "compromises" and need for, or "opportunity for", change to existing subsystems to realise an improvement.

**Step 3: Identification of the Subsystem Focus defining how improvements would be approached**

Once an affordance design compromise was identified, the team identified the subsystem design and related parts that, if changed, could achieve an improvement in complementarity.

**Step 4: Identification of how dialogue and decision made were validated and implementation of improvements were inferred as realised**

The attributes, of interactions enabled with or within the headphone, represented how the product engineering manager determined if an affordance improvement was realised.

**Step 5: Knock-on effect & iterations of subsystem design changes identified as required**

Changes made to any parts of the headphone required exploration of the potential for a knock-on effect of changes made to a subsystem part, on other subsystem parts of the headphone. Iterations of design improvements, through changes to related subsystem parts, may be required to reconcile complementarity with audio device and human ear use environment settings.

Managing these five steps coordinated activities within and between stages of improvement. Stage 1, the start point and the practical rationale for initiating improvements, involved the first two steps. Identifying issues or opportunities for improvement (Step 1) by examining known indicators and metrics of headphone’s performance (step 2) identified subsystem compromises triggering the move to stage 2.

Stage 2, the rationale for implementing a headphone subsystem improvement, involved steps 3 and 4. Identified subsystem aspect and related parts of implementing an improvement (step 3) informed attribute design changes (step 4) for maintaining the complementarity of interactions enabled with or within the headphone. The need to explore knock-on effects, triggers the move to the last management stage, stage 3.
Stage 3, reconciling subsystem designs, involves step 5. Exploration of the potential for a knock-on effect to related subsystem parts defined requirements for iterations of design changes to reconcile subsystem compatibility as a total headphone offering to specific music creation use scenario.
**Stage 1: Start Point**
Practical Rationale for initiating headphone Improvements

**Step 1:** The Start Point of Initiating an Improvement Project via Review of the affordance relationships of the Headphone’s Standard Design

Identification of issues (Compromise in the Sound experience delivered or Audiophile/audio device Interface features) or opportunities (Enhancements to sound experience delivered or Ear Interface features) initiating need for an improvement project.

**Step 2:** Evaluate Known Indicators of Headphones Performance to Identify Improvable Subsystems

Assessed the ability of internal and external subsystem aspects of the Headphone to deliver the personal sound experience, & identified the headphone subsystem to be improved.

**Stage 2: Subsystem Design Change**
Implementing a Subsystem Headphone Improvement

**Step 3:** Identifying the Subsystem Aspect of Driving Improvement to the Personal Sound Experience Offering

The identification of the subsystem aspect of implementing an improvement: change to an external headphone part’s feature OR an internal headphone part’s technical capability to refine the sound experience.

**Step 4:** The rational Basis of dialogue and decisions during the implementation of change to Headphone Subsystem Parts

Identification of the metric informing improvement dialogue & decisions: Attributes of interactions shaped with or within the Engineered Headphone

**Stage 3: Subsystem Reconciliation**
Interactive Headphone Subsystem Considerations

**Step 5**
Knock-on Effect & Capturing Complementarity

Knock-on Effect: Identified if changes to a Headphone part impacted consistency of related parts (internal or external) to be complementary to music creation use environment settings.

Iterations of design were required to reconcile consistency between both headphone subsystem aspects to be complementarity to music creation needs settings.

Figure 17 Company A’s Approach to Managing improvements in the Internal/External Affordance Relationship of the Headphone

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Case insights enabled an opportunity to update the conceptual model of the external-internal affordance relationship, as visualised in figure 18. Figure 18 reveals that the use environment defined the context for (and, so, moderated) the improvement projects. Each improvement project focused on improving the complementarity of the standard design, at that point in time, of internal and external subsystem aspects to specific use environment settings.

Management of the improvement projects was cyclical. The output of each improvement project, an improved standard design, became the focus of future improvement projects. Within each cycle, there were three inter-related stages of management considerations that were coordinated through five steps. The steps in the respective stages comprised a start point, two coordinated series of subsystem changes, and iterations of design changes to reconcile the subsystem aspects with the use environment.

5.9 Case Summary
This case has provided insights on headphone development management of the internal external affordance relationship during phases of improvement to an engineered headphone product’s standard design.
The process of managing the Internal/External affordance relationship during cycles of incremental improvement to a headphone’s standard design.

**Stage 1: Start Point**
Practical Rational of Initiating Improvements

**Step 1**
Review Engineered Headphone’s Standard Design

**Step 2**
Evaluate Performance Indicators of a Headphone’s Complementarity

**Stage 2: Subsystem Design Change**
Implementing a Subsystem Headphone Improvement

**Step 3**
Identify the Subsystem Aspect Driving a Headphone Improvement

**Step 4**
Identify the Metric of Assessing an Improvement in Complementarity

**Stage 3: Subsystem Reconciliation**
Interactive Subsystem Considerations

**Step 5**
Reconcile Potential Headphone subsystem Knock-on effects of changes applied

Figure 18 The process of managing the Internal/External affordance relationship during cycles of incremental improvement to a headphone’s standard design.
Chapter 6: Case 2, Managing Improvements in the Cardiac Rhythm Management Afforded

6 Case Two Introduction
Company B is one of the world’s leading specialist medical manufacturers with a comprehensive product portfolio that includes endoscopy devices, interventional cardiology devices, neuromodulation devices, and cardiac rhythm management (CRM) devices.

The organisation’s Irish operation is involved in the research, development and manufacture of a range of active implantable electronic pace generating (IPG) Cardiac Rhythm Management (CRM) devices that provide lifesaving therapy for patients with heart disease states such as bradycardia, tachycardia, congestive heart failure and those at risk of sudden cardiac death. CRM devices are comprised of three technical component systems (pace sensing/delivery, electrical follow thru & pace generation) that play a technical role in constructing how lifesaving therapy (electrical stimulation to selected chambers of the heart to resolve Cardiac Rhythm disorders) is delivered.

Pacemaker design in the organisation’s Irish location was focused on business to business (B2B) needs and requirements and coordinated from the surgical staff perspective, development of innovative therapy solutions for implant via surgical procedure, potentially simplifying implant surgery and reducing trauma and recovery times for patients.

Therefore, this case study was based upon the pacemaker product that reflected the requirement for the company to design for functional integration between three technical component systems affording CRM; the cardiac lead, the header and the pace generation can systems of an implantable pace generating device. Key contributors were a principle mechanical engineer (PMC2), a fellow R&D engineer (RDC2), and a process development director (PDC2). CRM is dependent upon the electrical follow thru capabilities of the header system and is the designed product focus of this case.

The pacemaker is not a new product. The first pacemaker was developed in 1950. However, it was an external device that was painful when leads were attached to the patient's heart at a skin surface level. It was powered through connection to a wall socket
and put the patient at risk of electrocution during use. It was the early 1960s before the pacemaker was fully implantable.

Company B entered the pacemaker market in 1979 and began partnering with physicians to create less-invasive medical technologies. Company B focused their attention on development and manufacture of the electrical follow thru & pace generation systems of IPG element of delivering CRM.

Over time, as many different manufacturers conducted R&D to improve the weaknesses of the evolving pacemaker design, a range of different pacemaker system parts were being released to the market. Each reflected an improvement but caused confusion to medical practitioners, from the perspective of complementarity of assembled parts, when selecting from the range of pacemaker system parts available. Often, incompatibility of pacemaker system parts impacted, in turn, the success of the pacemaker device when implanted.

It soon became evident within the medical device industry that the three component parts of a pacemaker’s design needed to be standardised. This standardisation was driven from the perspective of the cardiac lead system.

The purpose of standardisation was to ensure that different manufacturer’s designs of pacemaker parts provided safe interchangeability. Standardisation not only defined the dimensions of any pacemaker system but the testing protocols to ensure compatibility of interactions between pacemaker parts of many different manufacturers.

The challenge faced by company B was development of their IPG device to be compatible with international cardiac lead standards.

As a result of standardisation, improvements were often, but not always, driven in-house. This case explores two improvement projects; one externally influenced as a result of changes to cardiac lead technologies and the other internally motivated by the opportunity to refine device resilience and effectivity during implant.

The relative timing of each improvement project reflect a different focus that sought to build on the achievement of preceding refinements to the standard design of company
B’s IPG offerings. This case explores improvement projects as a basis of understanding how management of the external-internal affordance relationship of a pacemaker’s development was approached in Company B.

The following sections provide (1) An overview of the standard design considerations of a company B pacemaker product, (2) Company B’s pacemaker development process, (3) the external subsystem of the company B pacemaker product and (4) the internal subsystem of company B pacemaker. These four sections present a background for understanding (5) inter-related subsystem considerations of the total pacemaker product and, using two improvement project examples, exploring company B’s approach to coordinating the external-internal affordance relationship during improvement phases. These company B pacemaker case based insights inform (6) an analysis of “within case observations” from the perspective of the five constructs emerging from the conceptual framework (illustrated in figure 1 of chapter 3) of the external-internal affordance relationship and, the propositional model (illustrated in figure 2 of chapter 3) of management of the external-internal affordance relationship. The case concludes with an overview of generalised insights emerging from case observations.

6.1 Overview of the Pacemaker Product’s Design
A pacemaker is an implantable electronic biomedical pulse generating (IPG) cardiac rhythm management (CRM) device that can regulate the human heartbeat when it’s naturally latent pace regulating mechanisms break down. What was once latent no longer is. Pacemakers are designed to supplement the heart's own natural controls and to regulate the beating heart when these latent capabilities break down. It is able to do this because it is equipped with sensors that constantly monitor the patient's heart, and a battery that sends electricity, when needed, through lead wires to the heart itself to stimulate the heart to pulse/beat.

The anatomy and physiology of the human heart, defective states of the human heart and the working principles of cardiac leads define the settings of a pacemaker’s use environment. An understanding of the anatomy and physiology of the human heart and the internal environment of the human body, as well as technologies underpinning the working principles of cardiac lead is necessary to develop IPG devices that are
complementary to delivering CRM.\textsuperscript{3} These considerations characterise settings of the pacemaker’s use environment and the context of design dialogue and decisions made when developing improvements to the standard design of a company B IPG device.

There are two different but related contexts of pacemaker use; (1) the surgeon, who will be tasked with implanting the device, and (2) the patient, whose life is dependent upon the built in CRM functionality of the implanted pacemaker device.

- From a surgeon’s perspective, the IPG devices enable life-saving CRM therapy device solutions to be implanted within the human body. Over the years, improvements made to the standard design of IPG devices have simplified implant surgery and safety when implanted,

- From the patient’s perspective, the IPG devices provide a life-saving solution to latent heart defects.

The company B pacemaker device is a product comprising external and internal subsystem design considerations. The integrity of a company B pacemaker device’s development requires an improvement team that understands two subsystem platform design dependencies of delivering a CRM offering:

1. The external subsystem of parts exhibiting features enabling the surgeon infer connection compatibility of the cardiac lead with company B’s pacemaker device and implant within the human body,

2. The internal subsystem of parts exhibiting features enabling how CRM is delivered.

The standard design of a pacemaker, as visualised in figure 19, consists of three external parts or technical systems of a pacemaker; a cardiac lead, a pace generating can and, connecting these, the header.

\textsuperscript{3} A background to the pacemaker product is presented in Appendix J
1. The “Cardiac leads” connect directly to the patient’s heart and enables detection/sensing of the heart's electrical activity or pacing status as well as delivering electrical jolt that stimulates the heart as necessary to sustain life,

2. The “Pace Generating Can” houses the battery and all other electronic and electrical circuits of the pace sensing and generation functionality of a pacemaker device,

3. The “Header” functions as an electrical follow thru system that structures functional interactions between the pace sensing and delivery system of the cardiac Pacing Leads and the pace generating system.

Offering an IPG device to the market requires improvement team members that understand two external interaction design requirements of a pacemaker:

1. How the surgeon will safely assemble company B’s IPG System (header & PG can) with the cardiac lead system to enable deliver of a CRM therapy,

2. How the surgeon will, during implant surgery, connect the cardiac lead to the patient’s heart and position the PG in a subcutaneous pocket to deliver CRM therapy.

Company B focuses their in-house activities on coordinating development and manufacturing of two of the three pacemaker parts, the pace generating (PG) can and the header, referred to in-house as the IPG device. The header and the pace generating can parts are an integrated manufactured piece. It is during the implant procedure that the cardiac leads, as visualised in figure 20, are coupled by the surgeon with the header part, and a total pacemaker device assembled.
This case focuses on improvements to the standard design of a pacemaker, from the perspective of company B’s IPG (header & PG can) hardware.

From a manufacturing perspective these two parts represent, as visualized in figure 21, an integrated element of a total pacemaker’s offering. These two parts are required to be designed to function within the harsh internal conditions of the human body, within which this device will be physically implanted. Implant requires the pacemaker to be “biocompatible” and hermetically sealed (airtight”), and to fit within a sub-cutaneous pocket within the human body.
However, the pacemaker’s pulse generating capability is dependent upon design of the internal subsystem of parts. The internal subsystem configures the standard design of interactions between functional parts of the header and PG can. The standard design of interactions between functional parts are developed to be complementary to the working principles of cardiac pacing lead technologies. Cardiac leads are not a company B developed system. Rather they reflect the development and manufacturing competencies of other organisations, constraining the context of developing company B’s IPG device.

In company B, improvements in the CRM capabilities of the IPG device was approached from a two tiered technical integration development perspective:
- As an Integrated Tier 1 System Requirements: the adequacy of “external implant features” and “internal functional capabilities” of the PG can and header parts as an integrated piece, to facilitate the “electrical follow thru” capability when coupled with cardiac lead technologies,
- As Individual Tier 2 System Requirements: the adequacy of the configuration of each individual part (pace generating can or header) to operationalise conditions (withstand implant conditions, and facilitate pace sensing and generation) of delivering a CRM supplement.

Therefore, Tier 1 and 2 considerations reflected how changes to internal and external subsystem aspects of the standard design of existing IPG devices were integrated to improve delivery of a CRM supplement:
- The external subsystem’s design focused on the form of each IPG Part and how they were developed to enable interface with the cardiac lead and long-term implant within the human body.
- The internal subsystem’s design focused on the functional configuration of the two parts of the IPG and how each was developed as an integrated offering that operationalised the electrical follow thru capability that, consistent with the working principles of the cardiac lead, would supplement the latent defects of the patient’s heart.
External and internal subsystem design considerations represent two different but related design aspects of delivering a CRM supplement.

The standard design of a company B IPG device has evolved of decades of changes applied to external and internal subsystems parts. External and internal subsystem design considerations represented aspects of developing improvements in the complementarity of the company B IPG device’s to facilitate delivery of the CRM supplement defective heart states. Changes, applied to external or internal subsystem parts, represented how improvements in the complementarity of the company B IPG device’s offering to CRM supplement contexts, were approached.

In company B, improvement projects were coordinated from the perspective of improving the complementarity between external and internal subsystem aspects of an IPG device’s design and the electrical follow thru requirements of interactions with the cardiac lead to deliver electrical therapy.

Improvement projects were informed by the activities comprising the defined stages of company B’s formal IPG device development process.

6.2 Company B's Implantable Pace Generating (IPG) Device's Development Process

The development of improvements to IPG device part followed the CRM device/ system life cycle process, as visualised in figure 22.

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![Diagram of Company B's IPG Device Development Process](image)

**Figure 22** Internal Process Used To Develop and Maintain Commercial Devices/Systems
The CRM device/system life cycle process consisted of six stages that began with a proposal and ended with retirement phase. It is through the first four stages (proposal, definition, development and validation and scale up) that improvement projects were coordinated. The lifecycle revealed the internal processes used to develop improvements in an IPG’s internal and external subsystem parts design. This process served as an overview of the activities, as visualised in figure 23, which controlled and coordinated the design dialogue occurring during improvement projects.

![Activities Design Control Process of the Development Lifecycle](image)

During the CRM device/system life cycle process, as visualised in figure 24, stages 1 and stage 4 included technical integration reviews. Technical integration reviews were conducted by external regulatory approval bodies (ISO & FDA) that were tasked with examining the adequacy of design changes to capture complementarity with cardiac lead technologies and realise effectivity and safety requirement expected of delivering a CRM supplement.

![Coordinating Technical Integration & Regulatory Compliance reviews during Improvement phases](image)
The need for improvements were proposed during the proposal phase. Recommendations for improvement projects were presented, as supported by an FMEA report that detailed the specific subsystem part requiring attention, by submission of an improvement project proposal report. Review of the improvement project proposal closed the proposal phase and if deemed worthwhile, subject to approval by external regulatory body approval, a phase of improvement would be triggered. External regulatory body approval triggered the move to the definition stage. Within the definition stage, functional plans were drafted and approved. During the development stage, the detailed design of an improved pacemaker’s IPG part would be determined and reviewed. Prototypes would be created and tested from functional and hazard perspectives.

Prototypes test results indicated readiness for movement to the formal validation and scale up phase. The formal validation and scale up phase focused on review of the adequacy of the improved part’s technical capability from an integrated tier 1 pacemaker perspective. The commercialisation phase integrated the final technical integration review of attaining external clinical /regulatory approval, now concerned with the safety and effectiveness of the manufactured product, and signalled the completion of the formal process of developing an improvement.

In company B, improvement projects were conducted by multi-disciplinary improvement teams. The development activities requiring completion to implement an improvement defined the skillset required of improvement team members.

6.2.1 Improvement team for External & Internal Pacemaker IPG Subsystem Improvements

Design dialogue during improvement projects were informed by input from different but related departments: design, engineering, research and development, supply chain and finance. The voices that form an improvement team include a project director, a process development director, a development manager, a process development engineer, a materials engineer, an R&D Engineer, and a principal mechanical engineer.

Table 20 presents the technical integration procedures of implementing design improvement in company B. These technical integration procedures defined the focus of any improvement project, development stage tasks of implementing change and the
improvement team voice associated with completing design changes that would implement improvements in the standard design of a pacemaker’s IPG device.

These technical integration project procedures reflect the focus of design dialogue and define the deliverables required of each phase of the development process during improvement projects.
**Tier 2 Improvements to a Technical Component System’s Standard Design:**

<table>
<thead>
<tr>
<th>PDP Checklist</th>
<th>Project Director</th>
<th>Functional Plan for “Change”</th>
<th>Process Development Director</th>
<th>Proposal Phase</th>
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</thead>
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<tr>
<td></td>
<td></td>
<td>Process Development Director</td>
<td>System Change Focus &amp; Task List</td>
<td>Definition Phase</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Change System – Component Development Process Review</td>
<td>System Change materials selection and surface preparations</td>
<td>Development Phase</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Development Manager</td>
<td>Ripple Effect Analysis</td>
<td>Validation and scale up</td>
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<td></td>
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<td></td>
<td>Principal Mechanical Engineer</td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>Tier 1 Technical Integration:</th>
<th>Definition Phase</th>
<th>Development Phase</th>
<th>Validation and scale up</th>
<th>Commercialisation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Functional Plan for CRM</td>
<td>CRM Material Review</td>
<td>CRM Functional Effect Analysis</td>
<td>Commercial Approval</td>
<td>FDA</td>
</tr>
<tr>
<td>CRM Component Development Process Review</td>
<td>Hermetic &amp; Biocompatible Review</td>
<td></td>
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</tbody>
</table>

Table 20  Technical Integration Project Procedures & Voices Typically Assigned
Deliverables enabled the activities of the development process, documenting the coordinating integration of changes that would build in improvements, built in transparency. The deliverables of each stages presented the approach taken to implementing design changes. Additionally, deliverables enabled regulatory bodies assess the adequacy of design actions completed during any phase to realise the technical capabilities required of individual subsystem parts (external and/or internal) and as an integrated pacemaker offering to be in compliance with ISO and FDA standards.

“Deliverables reflect the formal documented report that support reviews of the planned design activities and results of design actions conducted at appropriate phases of the technical systems design and development” PDC2

The project director oversaw improvement projects. The project director, a qualified and experienced mechanical engineer, was tasked with the responsibility of monitoring daily defective part per million (DPPM) reports, operational issues reported by staff involved in the pacemaker device’s manufacturing process, supply dependency issues reported by procurement staff and advancements in regulatory standards and competitor offerings.

An analysis of the available data enabled the project director to identify compromises (the potential for as well as actually in effect) in the pacemaker’s ability to provide a CRM supplement. Part of the analysis involved the project director identifying the source of the compromise and to define the context of finding resolution. Ultimately, it was the project director that made the decision on when an improvement project was warranted and the subsystem focus of the improvement project going forward.

When the need for an improvement was recognised, it was also the project director’s responsibility to identify improvement team members and define the checklist of stage deliverables of developing subsystem part improvements and the related technical integration task. The project manager assigned specific improvement team members, deemed to possess the skillset required, the responsibility of completing development stage deliverables.

For example, in the definition phase, two deliverables were identified. Firstly, a functional plan for “change” to a specific pacemaker system, followed by a review of the component development process for realising improvements to a system’s capability. Here, the process development director was assigned the responsibility of delivering a functional plan for implementing “system’s changes”, and the development manager was
assigned the responsibility of conducting the implementation of changes to a technical system’s capabilities. The activities of each phase that followed were similarly coordinated.

The improvement team was predominantly comprised of team members that focus on improving technical aspects of the pace generating and header parts of the CRM supplement.

“The technical system developers ultimately bear responsibility for translating user and/or patient needs into a set of technical integration requirements that can be validated prior to implementation. Technical integration is primarily an engineering function and the participatory role of improvement team members are linked to deliverables expected of each stage and that assure that the design input requirements are complete” PDC2

Improvements in the complementarity of an IPG device’s standard design were realised through a focus on implementing changes to the design of external or internal subsystem aspect of the IPG device. Design considerations typical of internal and external IPG device subsystem aspects are presented in the following subsections.

6.3 The External Subsystem of Improving a Company B’s IPG Pacemaker’s Design

In company B, the external design of the IPG device was focused on identifying the features enabling improvements in how the surgeon interacted with and assembled the external parts of a pacemaker and enabled a safer and more effective CRM supplement.

The attributes of the header and pace generating can’s external parts shaped its interface features. These attributes of each part enables the surgeon to perceive the capability for interface with the IPG and communicates how the cardiac lead can be coupled with the header part.

The project director through co-ordinated discussion with the Process Development Director and the development manager identify the features of improving interactions enabled with an IPG device. Improvements to interaction capabilities focused on anatomical fit, biocompatibility and connectivity of external pacemaker parts:
- “Anatomical Fit” was concerned with how the IPG device facilitated fit for implant within a subcutaneous pocket of the patient’s body,
- “Biocompatibility” was concerned with how both the header and the pace generating can parts maintained a hermetical seal and possessed the tensile strength to withstand the harsh implant environment (the moist and 37°C average internal body temperature) during defined implant periods,
- “Connectivity” was concerned with interactions facilitating connection with the cardiac lead device. Of concern was the visual transparency of the header that guided and enabled the surgeon check the adequacy of coupling with cardiac leads prior to implant.

This discussion involved reasoning on the visual references of the external form of the header systems. Visual references, were vital for enabling the surgeon to infer safe assembly of a pacemaker device. Decisions made focused on:

- The requirement, as visualised in figure 25, of the header to be composed of a transparent material and contain sufficient cylindrical bore holes to facilitate compatibility for a “plug” connection with the cardiac lead pins,
- The requirement of the header and the pace generating can material to be composed of a material that was pharmaceutically inert, non-toxic and, in the case of the housing can, rust resistant.

![Bore Hole](image)

**Figure 25** External Subsystem of Company B’s IPG device

Whilst the external interface features of an IPG’s external form enabled the surgeon perceive how to interact with and assemble the pacemaker, the pacemaker was incapable of enabling delivery of the CRM supplement. Delivery of the CRM supplement was dependent upon the functional capabilities enabling the “electrical follow thru” of pace sensing data and pace generation. “Electrical follow thru” was actualised by the internal subsystem of the IPG device. Therefore, a different but related aspect of an IPG’s design is development of the internal subsystem that actualise embodiment of the CRM
capability. The CRM capability was operationalised by the internal configuration of parts that connected, channelled and induced the electrical stimulation requirements of enabling abnormal heart rhythms to be regulated.

6.4 The Internal Subsystem of Improving a Pacemaker Product’s Design
In company B “the definition phase” reflected the design activity tasked with developing improvement in the internal configuration of the IPG device.

CRM is dependent upon the ability of the IPG part to enable ongoing monitoring of the heart’s pacing activity and determining if electric stimulation is required.

Therefore, the fundamental purpose of the internal configuration of the IPG was to embody the technical capabilities of enabling “electrical follow thru” between the header and pace generating parts of the IPG device. Technologies underpinning the working principles of cardiac lead design constrained how the internal configuration of the IPG was developed.

There are, as visualised in figure 26, three internal subsystem parts to company B’s IPG; the conductive core, the pacing and generating circuitry and the battery. Each is briefly explained:

1. The conductive core channels input of the electrical pacing data received from the cardiac lead. The conductive core subsequently channels output of the electrical energy that, delivered by the cardiac lead, will stimulate the heart,
2. The pacing and generating circuitry consists of a micro controller and some memory. The circuitry facilitates analysis of sensed heart activity and, relative to programmed pulse rates, determines the adaptive electrical rate response required to stimulate the heart muscles regulating cardiac rhythm,
3. The battery is the source of energy for generating electrical jolts necessary to stimulate the heart muscles and regulate cardiac rhythm.
The conductive core, located within the header, is connected to the pacing and generation circuitry, located within the pace generating can. As connected, these two interacting parts establish the operational conditions of enabling input of active heart pacing data and output of the electrical current necessary to stimulate the heart muscles and regulate the electrical conduction system of the heart.

CRM therapy quality is dependent upon the adequacy of the design of the header and pace generating can’s internal subsystem part’s to be complementarity with the technological workings of the cardiac lead.

The internal subsystem’s parts constrained the thickness and height of the external subsystem’s design. Therefore, the external subsystem design of the IPG device, its structural form, resulted of dialogue on the technical design requirements of a pacemaker’s functional parts.

“*The IPG device thickness is defined by the battery package and or the capacitor package constraints. These elements of the active implant have defined the thickness of the device and have driven the aspect ratio of the device*”  

**RDC2**

### 6.5 Coordination of Inter-related Pacemaker Subsystem Development Considerations during Improvement Phases

The internal and external subsystem parts do not operate in isolation of one another. Individual parts operationalised features that as an interacting arrangement of related
parts, a tier 1 integration consideration, established four conditions facilitating the “electrical follow thru” capability, underpinning delivery of CRM.

Firstly, the electrical follow thru capability was dependent upon how a bond surface was facilitated between the pace generating can and header systems. This bond was essential to seal the conductive connections between the header and PG can system and prevent bodily fluid ingress. Bodily fluid ingress would impact safe inward and outward electrical flows (inward electrical heart activity and outward electrical stimulation if/when required).

Secondly, the header’s outer skin positioned electrical conductors and connectors within the IPG device and provided isolation between each conductive connection. This structured how, as visualised in figure 27, the inward channelling capabilities of pacing data from the cardiac lead and outward pace generation from the housing can through the header to the cardiac lead was enabled.

Thirdly, the “pace generating” can housed the battery and all the electrical circuits of monitoring pace sensing data and determining stimulation of the electrical therapy required for delivery of a CRM supplement.

*Finally, one end of the cardiac pacing leads* is connected directly to the patient’s heart and the other end is coupled with the header’s bore holes. The cardiac lead to header
connection enables detection/sensing of the heart's electrical activity and, via the electrical connectors and conductors embedded within the header, transmits this data to the pace generator system within the housing can. If the heart rhythm is interpreted as abnormal, the pace generating circuitry within the PG can will channel an electrical jolt to stimulates the heart as necessary to sustain life.

Changes to any internal or external subsystem part, given their role in integrating the electrical follow thru capability, has the potential to impact the effectivity and safety of the CRM therapy delivered.

Therefore, during improvement projects, improvement team members were tasked with ensuring the tier 2 electrical follow thru and pace generation system capabilities were adequately integrated within company B’s IPG. These capabilities had to be compatible with international cardiac lead design standards.

The preceding text has discussed a modern day view of the company B pacemaker. However, it was through improvement projects that this perspective of a pacemaker has been established. Two improvement projects, one internally motivated from a safety, effectivity and manufacturing efficiency opportunity and the other one externally influenced as a result of changes to the cardiac lead system, are presented in the following two sections. Improvement projects always started with review of the regulated standard design of an engineered pacemakers at that point in time. Assessment was made relative to company B’s assumptions of the needs of the surgeon and the pacemaker patient.

6.5.1 Improvement Example 1: An Improvement in IPG Safety and Effectivity
Traditionally the three pacemaker parts (cardiac leads, header and PG can) were designed and developed by different organisations. Prior to 2009, company B’s core design competence was Pace Generating (PG) cans development.

However, the product output of company B’s manufacturing process is a pacemaker IPG device, resulting of the assembly of their PG can part with an externally procured header part. Assembly involves the mechanical fixation of the purchased header part to the PG
housing can part. Mechanical fixation involved bonding the header part to the top of the PG can part.

The process of bonding the header introduced design inadequacies into the finished pacemaker device. The off the shelf nature of the header complicated how mechanical fixation was facilitated. Mechanical fixation required filing of the PG can’s surface to facilitate grip for multiple layered applications of medical adhesive.

As the project director reviewed DPPM data, a persistent defect was revealed; the observation of contaminants (microscopic air pocket and metal deposits) on the surface of the PG can. The project director, from discussion with the quality manager on the shop floor, realised that the defect resulted of the complicated header to PG can’s assembly process. These two mechanical fixation steps were recognised as having the potential to build in redundancies in the assembly process and impact adhesion properties to the housing.

“The pre-moulded PU header requires multiple applications of the medical adhesive during the insert assembly process. Each application requires cure durations of between thirty minutes to two hours. Void formations (trapped air) can occur during cure impacting on bond strength and durability of the hermetic seal during implant within the body”  

RDC2

During past development processes, improvement team members had permitted, at low levels, the presence of these contaminants on the surface. However, the quality manager stated that, whilst it had never been known to have occurred, he was concerned that even low levels of contaminants risked the bond strength during a typical implant period. If the bond was to weaken as a consequence of these contaminants, there was a risk that pacing data input could be prevented or, a worst case scenario, electrical therapy could be diverted sending electrical stimulation elsewhere in the body.

The quality manager’s concerns led the project director to the conclusion that it would be wise to prevent the risk of header to PG can separation. The project director determined the need for an improvement project, tasked with managing development of a solution.
However, assembly of an improvement team suited to bringing about a solution required the project director to establish a greater understanding of the manufacturing process and the extent of the inherent problem.

The project director, working on the assumption that the adhesive’s viscosity and flow properties were causing the formation of air pockets, spoke with material engineers and procurement to verify/correct his assumptions and gather insights on ways of eliminating the formation of air pockets. Discussion with the material engineer suggested testing alternative supplier adhesives, with different viscosities and flow properties, as a way of eliminating the formation of air pockets. The procurement manager agreed it was the simplest way of finding a solution, however, they noted there was no guarantee that alternative adhesive products would be any different. That it seemed to them that the problem inherently resulted of the assembly process. They suggested developing an adhesive specifically suited to the fixation task at hand might be another alternative. The project director noted consideration of alternative adhesive supplier products as well as developing a customised adhesive product as potential ways of exploring solution.

The project director, working on the assumption that the filing of the PG can surface was leaving the microscopic metal deposits, also spoke with mechanical and manufacturing engineers to verify/correct his assumptions and to gather insight on alternative ways of creating the grip required to fix a header to a PG can.

The mechanical engineered stated that management of a solution was challenged by the integrated nature of the two (header and PG can) technical systems. The manufacturing engineer proposed bringing header manufacturing in-house, suggesting direct moulding of the header to the PG can’s surface. The project director, thinking back to the procurement manager’s comments on a customised adhesive product mentioned the idea to the manufacturing engineer. The manufacturing engineer noted that moulding the header in place would involve the creation of a header material, customised with uniquely developed properties that would, ideally, disperse contaminants off the surface as it was poured into the mould.
The project director had a lot to think about before he could make a decision on the focus of the improvement project.

The project director decided that the improvement project would focus on the development of an integrated header pace generating can part, a tier 2 component system. However, development needed to be managed from context of realising technical integration within tier 1 requirement constraints. The internal subsystem of both the header and PG can parts were functionally sound. This design was to be maintained. However, it was the interactions between the material of the header’s external skin and the adhesive that was the source of the problem. Therefore, the improvement project was challenged with addressing resolution to existing issues compromised by the standard design of the header’s external subsystem.

The project director realised that poor adhesion was compromising the bond strength. To him, bond strength was critical to ensuring isolation of conductive input and output connectors to the pace generating can and to preventing bodily fluid ingress during implant.

“Electrical follow thru requires electrical isolation between the electrical conductors in the header system in addition to a stable fatigue resistance bond to the implantable pulse generators hermetic electronic package”  

The project director decided that the scope of the improvement was to be focused on the development of an “in-house produced” “over-mould” header. Design discussion was to be focused on the development of a material that would structure the header’s outer skin and integrate solutions to issues previously impacting adhesion. Representing a finished IPG’s header design was defined with development priorities in the controlled design for order of (1) therapy quality, (2) reduced manufacturing costs and (3) improved visual appeal.

“Order of priority during development was therapy quality followed by reduced manufacturing costs. Essentially these resulted from technological advancements or our own R&D and have led to less intrusive devices. Whilst not a defined priority, surgeons, on behalf of patients, have identified size reductions as a design requirement”
The project director believed that moulding the outer header skin in place would build in bond strength, eliminate multiple adhesive application redundancies and make it less costly to manufacture. The design was to be applicable for adoption across the range of IPG devices designed and manufactured in the Irish location.

*The goal of redesigning the header system as an over mould design, including the methods and processes are required, was not just for one header system within the therapy group but all the header systems.  PMC2*

With the focus of finding solution determined, the project director initiated the improvement project. The project director kicked off the first stage of the improvement project by creating a checklist of tasks. These tasks would drive the activities of subsequent development stages of realising the improvement.

The first task for the project director was to assemble an improvement team. The project director assigned improvement team members, as visualised in table 21, to specific staged development tasks of the technical integration project procedure table.
### New Technical Component System’s Design:

<table>
<thead>
<tr>
<th>PDP Checklist</th>
<th>Proposal Phase</th>
<th>Definition Phase</th>
<th>Development Phase</th>
<th>Validation and scale up</th>
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<tr>
<td>Project Director</td>
<td>Functional Plan for “Over-moulding”</td>
<td>Process Development Director</td>
<td>Over-mould Core material Selection</td>
<td>Process development engineer</td>
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<td>Over-mould – Component Development Process Review</td>
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<td>Over-mould materials selection and surface preparations</td>
<td>Ripple Effect Analysis</td>
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<td>Core Design/ Bore Hole/ Outer Skin Over-moulding</td>
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<td>Materials Engineer</td>
<td>Principal Mechanical Engineer</td>
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<tr>
<td>R&amp;D Engineer</td>
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### Technical Integration:

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<td>CRM Component Development Process Review</td>
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Table 21 Improvement team members assigned to specific technical integration project 1 procedure
Once the team was assembled, the project director held a preliminary meeting with the entire team. The team member of any stage reported directly to the project director. The responsibilities of each stage was assigned to specific team members. The move to the definition stage was initiated.

The definition stage started with the creation of a functional plan for the design and development of an “over-moulding” solution for the header system. Discussion, now conducted between the project director and the process development manager, was focused on communicating the issues of the current header system and identifying: (1) the functional plan for “over-moulding” the header and (2) a review of the technical capabilities and existing functional configuration integrated within the over-mould part.

The Process Development Director was tasked with creating a functional plan. The functional plan was instrumental to identify the actions required to realise a header design that eliminated past issues but structured integration of the follow thru capability. The header’s design was identified as dependent upon the ability of its moulded form to ensure:

- isolation between the conductive connections that structured connection capabilities with cardiac lead technologies and pace generating capabilities of the housing can,
- visual transparency enabling check of the adequacy of bond during the mould pouring process and guided coupling with cardiac leads during implant procedures.

“The over mould material must be optically clear, form an encapsulation of the core containing conductors and achieve a medical grade bond to the PG Can adherend. Visual transparency of the material is required to confirm trans-venous lead insert at implant”  

RDC2

A review, conducted by the development manager, identified the internal conductive connector core, defining the requirements of the over-moulded header skin. Reflective of the functional role of the inner conductive core, the over-mould’s material composition was required to be developed to be:

- Optically clear, and pourable with a cure speed within two hours,
- Exhibit a pour spread speed that expelled metal contaminants off the PG cans surface, preventing the occurrence of air pocket and isolated electrical connectors,
- Matched the PG can’s material in terms of “stiffness and adhesion”,
- Was pharmacologically inert, nontoxic, and sterilisable,
- Exhibited a modulus elasticity & bond strength compatible within internal body temperatures & conditions.

The functional plan presented an overview of header attributes requiring design for. The functional plan set the referential basis guiding design discussion on the analysis of alternative header materials for consideration within the next stage: Development stage.

Development focused on identifying the over-mould material that would realise integration of electrical isolation of the conductive core’s connectors and bond strength with the PG can. The development manager determined the attributes required to be exhibited by the header material to integrate electrical isolation and bond strength. Following this:

- the process development engineer identified a list of seven alternative materials,
- The materials engineer defined how surface preparations of the housing can to strengthen the adhesive bond during “pour” assembly, justifying the selection of one material,
- An R&D engineer created a jig for positioning the conductor core and the leads bore hole positions when the over-mould header skin would be poured.

Seven alternative materials were assessed: A liquid grade polyurethane resin, a liquid polyurethane/silicone copolymer resin, a UV/Visible light cured Acrylate urethane based adhesive, and four different epoxy resins.

Through coordinated discussion amongst the process development engineer, the materials engineer and the R&D engineer, each of the seven material alternatives were assessed against the operational conditions required to be exhibited by the over-mould material.

“The material must be a simply epoxy chemistry with a secure supply chain, and form a functional cure within two hours eliminating the redundancies of the overly complicated insert header bonding process” RDC2
Design discussion, following engineering feasibilities studies conducted by the materials engineer, slowly eliminated material by material, identifying only one material as suitable for adoption.

The first material was quickly rejected due to supply chain concerns, biocompatible assessment issues and the requirements for new manufacturing processing equipment essential to store, mix and cure the resin. The next was excluded due to poor adhesive bond strength resulting from swelling of the adhesive at the bond interface with the housing can. Another was ruled out because a reliable supply chain could not be established and was excluded from consideration. Only one, an epoxy resin, was selected as suitable as it was:

- Optically clear and exhibited bond strength when cured,
- Survived a standard thermal shock test regime (thermal cyclic shock conditions of -30°C to 60°C) that simulated the shipping conditions an IPG is expected to see prior to arriving at a hospital,
- Comprised a resin’s mix ratio (a 2:1 volume) that simplified the manufacturing process through its ability to be packaged into a standard off the shelf cartridge injection system.

“The over mould material demonstrated a capability of adhering to titanium, the core housing can material, and matched the core material in terms of stiffness, was optically clear to enable confirmation of lead insertion at implant and was capable of withstanding thermals shock test conditions without delaminating/peeling”  

*RDC2*

The over-moulding resin material selected eliminated the need for the layered applications of medical adhesive and cure steps that had previously caused manufacturing redundancies. The adoption of the newly selected epoxy resin, in turn, reduced the cure time for manufacturing of the header from 16 hours to a functional cure time of approximately two hours.

The process for over-moulding the header, injection pouring the epoxy resin in place, required the R&D engineer to provide evidence of the new header form’s ability to facilitate and maintain (during implant period) interactions with the PG can. Additional, the header form had to integrate the operational condition of enabling the electric follow
thru capability to be integrated within. This required consideration of the requirements of the manufacturing process.

“The housing can adherend was positioned at a zero or near zero contact angle prior to being poured, and the viscosity during bonding was relatively low. As a result, air entrapment didn’t occur as the design of the system allowed for the air to escape and to be displaced by the low viscosity resin”  

RDC2

The epoxy resin was required to be injection poured into the jig/mould at a zero or near zero contact angles to prevent air entrapment. Air was displaced by the low viscosity spread of the resin over the housing can’s laser treated surface, further structuring the integration of bond strength.

The final development plan for the over-mould header was assembled and forwarded to the principle mechanical engineer for verification and validation of the technical capability to deliver the “follow thru” capability when integrated as a tier one pacemaker. During the validation and scale up phase, the principle mechanical engineer conducted a ripple effect analysis with reference to how the new over-mould design captured a relational complementarity, as integrated within the tier one system. The ripple effect analysis was the final deliverable that demonstrated objective evidence of the technical capability of the header to withstand implant within the harsh internal environment of the human body and enable functional interactions with the already FDA approved cardiac leads and PG Can systems.

The objective evidence was supported through stress testing results of the over-moulded header. The header form was subjected to testing in an in-vitro environment that simulated implant conditions (heat and pressure) of the internal human body.

“The over moulded test specimens were placed in plastic containers and then filled with PBS (Phosphate-buffered saline) solution and placed into a 55°C oven. The devices were soaked for 10 days in these conditions that mimicked the harsh condition of the internal body. Then the container was removed and allowed to cool for a minimum of 24 hours prior to side load testing. The side load testing applied a lateral force of 3.0 ± 0.5mm to the top of the header”  

PMC2
Comparison of the function requirements of the over-mould design from the definition phase, and the new implant stress test of this phase set the audit basis for final FDA assessment. Once commercial approval was granted, the integrity of the header system was deemed validated and released for mass production.

“Technical integration is dependent upon provision of objective evidence demonstrating attainment of the follow thru capability, implant capability and a cost effective manufacturing process” PDC2

6.5.2 Improvement Example 2: An Improvement in Compliance with New Lead Technology Standards

A new standard (IS-4/DF-4) for the cardiac lead was released in 2010. This new standard reflected changes, as visualised in figure 28, that reduced the number of connector pins in the standard design of a cardiac lead from three to one. This design change improved delivery of the CRM supplement from the perspective of the medical practitioner and the patient.

- From the perspective of the medical practitioner, the new single connector simplified implant surgery (simplifying assembly and eliminating need to test the functioning of three different connector) and reduced, in turn, the time taken to complete the surgery,
- From the perspective of the patient, the new single connector reduced the size of the header and fit within the body.

Figure 28 Visual illustration of the difference between old and new Cardiac Lead

However, these changes in the cardiac lead standard represented a design challenge to organisations of related pacemaker systems, such as company B. The standard design of the existing header and pace generating can parts were incompatible with the new cardiac lead design.
The International Organization for Standardization had directed interchangeability testing using prototypes from three different manufacturers in June 2009. Company B’s prototypes were not involved in these interchangeability tests.

The project director noted that the company B IPG device was only compatible with the preceding lead connectors (IS-1/DF-1) standard. Additionally, because the new lead design simplified assembly, the project director believed that the new single pin connector lead would be the preference of surgeons. An improved IPG device offering, tasked with meeting the new industry standard, was required. Company B needed to respond by amending the standard design of their pacemaker offering to integrate compatibility.

The project director, initiated an improvement project, focused on the integration of the new cardiac lead standard within their range of pacemaker IPG device designs. An improvement team, as visualised in table 22, was assembled and the time for the introductory meeting on the improvement project set.
### New Technical Component System’s Design:

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<td>Integrated Header Connector Circuitry Core</td>
<td>Process development engineer</td>
</tr>
<tr>
<td>Project Director</td>
<td>Process Development Manager</td>
<td>Header materials selection and surface preparations</td>
<td>Connector core Design/ Bore Hole Position/ Outer Skin</td>
<td>Ripple Effect Analysis</td>
</tr>
<tr>
<td>Principal Mechanical Engineer</td>
<td>R&amp;D Engineer</td>
<td>Materials Engineer</td>
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Table 22 Improvement team members assigned to specific technical integration project 2 procedures
This introductory meeting kicked off the proposal phase of the improvement project. The project director introduced the focus of the improvement project.

The first task was to open dialogue focused on establishing how to integrate cardiac lead compatibility.

The project director presented two options: (1) Return to buying an off the shelf IS-4/DF-4 compatible header that would integrate compatibility within the PG Can, or (2) focus attention on making amendments to the internal subsystem of the header parts IPG.

The materials engineer reminded improvement team members of the difficulties associated with assembly of an “off the shelf” header with the pace generating can. Additionally, since the same improvement team had invested time and effort into bringing header development and manufacturing in-house (improvement project 1), the materials engineer questioned the sense of reverting back to an inefficient and costly manufacturing process. After all, company B had now established header development as an in-house competency (FDA approved hermetic seal and biocompatibility stable material established) and adjusted the manufacturing process (injector mould process) to support its adoption.

The R&D engineer agreed with the issue of using an “off the shelf header”. The R&D also added that changes focused on integrating the conductive core in the header to be compatible with the existing circuitry within the PG can was, potentially, a more viable option.

The project director, informed by improvement team member dialogue, determined that the most sensible option was to focus attention on making amendments that integrated the three conductive cores within the header into one conductive core.

The project director assigned improvement team members to specific development stage tasks of this technical integration project, and triggered the move to the definition stage. During the development stage, the process development director was tasked with developing, relative to the technology of the new IS-4/DF-4 single connector cardiac lead standard, a functional plan for integrating the technical capability of isolating pacing input and electrical therapy output within a single connector point.
The development manager was tasked with defining how the conductive core of a single bore was to be developed to embody the electrical follow capability. To integrate functional compliance with trans-venous cardiac lead standards DF4 and IS4, the development manager defined the header’s design as requiring:

1. An embedded single conductive core capability with complementarity to the electrical circuitry of the existing pace generating can,
2. A single bore hole that embodied the conductive core and enabled cardiac lead pin “insert fit”,
3. Elimination of the two redundant external bore holes,

This closed out the definition stage, triggering the move to the development phase.

During the development stage, dialogue was focused on developing compatibility between a single connector header and the PG can.

The output from the development stage had to demonstrate compliance with regulatory standards of the American Society of Testing Materials (ASTM B348 Standard) and the International Standard Dimensional and test requirements of the ISO 27186:2010 IS-4/DF-4.

“New header systems are required to incorporate trans-venous cardiac lead standards DF4 and IS4” RDC2

The members of the improvement team were tasked with documenting details of each stage’s improvement efforts. These documents were deliverables that support technical integration reviews, required to demonstrate compatibility and gain FDA approval and an IS-4/DF-4 cardiac lead interchangeability certification from the International Organization for Standardization.

From a compatibility perspective, the new design required changes to be made to (1) the internal and then external subsystem aspects of the header block (A Tier 2 technical integration consideration) and (2) to ensure compatibility of these changes as a piece for assembly with the pace generating can (Tier 1 technical integration consideration).

The process development engineer focused on the internal subsystem of the header, and the integration of an embedded single conductive core capability within the header.
Integration was complicated by the need for isolation between each connector within the integrated connector point’s circuitry.

The new lead design integrated the conductor points from three lead pin ends within a single pin. The IPG device’s header was comprised of three bore holes, each comprised of a wired conductor making it incompatible with the new cardiac lead standard. The process development engineer was challenged with integrating the three, originally separate, wired conductor within this single bore hole. This new design needed to maintain isolation between the input and output connector points. The single header bore hole was positioned parallel to the PG can surface. Therefore, two of the conductive core connections, previously wired connections to higher bore hole connector points, had to be shortened in size to facilitate relocation to the lower bore hole.

The R&D engineer verified that the connector pins of the existing pace generating can did not require amendment. They could, in their current design, be maintained. It was integration of the conductive core wiring within the single header bore hole that required attention to capture compatibility with the PG can and the cardiac lead standards.

The materials engineer focused on the external subsystem of the header and identified the epoxy material from improvement project 1 as transferrable and suitable for adopted for the header’s outer material. Design for compliance with technical advances in cardiac lead standards DF4 and IS4 eliminated the need for stacking of lead bore holes. The elimination of the two redundant bore homes made the finished IPG shorter and when implanted within the human body, less intrusive.

“The emergence of these new technologies assisted by cutting edge design, IPGs - have been reducing in size. The electrical connectors developed for the new IS4 system has reduced the number of bore holes and resulted in smaller headers on IPG devices.” RDC2

Additionally, the R&D engineer identified the injector mold, from improvement project 1, as suitable for over-mould the header to the PG can. However, the injector mould needed to be adjusted. Originally it was created with three injector points. Two injector points were removed, leaving only one cylindrical bore opening once the material was
poured. Therefore, as visualised in figure 29, instead of three separate bore hole cavities, the new header would result in only one cavity being poured to facilitated fit with the dimensions of the new IS-4/DF-4 lead’s connector pin.

The identification of changes to the internal and external subsystems of the header closed the development stage, and the focus on tier 2 considerations, triggering the move to the validation and scale up stage where tier 1 considerations of complementarity were considered.

During the validation and scale up stage, the principal mechanical engineer completed the final change document, necessary for making an application for an IS-4/DF-4 interchangeability certification from the International Organization for Standardization. Company B received certification of IS-4/DF-4 cardiac lead compatibility in 2014.

6.6 Pacemaker IPG’s Affordance Design Improvements: Analysis of the Conceptual Constructs

The preceding sections have presented the background to company B’s pacemaker IPG device’s affordance design considerations. Two examples of phases of improvements in the complementarity of the pacemaker’s design were presented. This section presents a “within case” analysis of case observations that build on the conceptual framework in chapter 3. Figure 1 of chapter 3 visualised management of the external-internal affordance relationship. The objective now is to establish an understanding of the approach adopted by company B to managing the external-internal affordance relationship of a pacemaker IPG device during improvement projects. With reference to the five constructs outlined in chapter 3, empirical evidence of the elemental
considerations to managing the external-internal affordance relationship in company B is visualised in figure 30 and discussed in the following sections.

Figure 30  Company B perspective of construct and relationships of managing the external-internal affordance relationship

6.6.1  Pacemaker IPG’s Use Environment
Company B’s IPG device is a critical part of a pacemaker. Company B IPG devices are developed to generate the electrical therapy necessary to supplement defective CRM states of the human heart. Implant within the human body to supplement defective CRM heart states defines the use environment of the IPG device. The human heart and cardiac leads defined the settings of the company B IPG device’s utility. The company B IPG device was required to enable the electrical follow thru capability of delivering a CRM supplement suited to implant requirements of the surgeon and defective heart states of the patient.

Originally, company B’s IPG device was designed relative to the settings defining the context of delivering a CRM supplement. The anatomy (structure) and physiology (pumping functionality) of the human heart defined a setting of a pacemaker’s use environment and a design context of improving the affordances resulting of the design of the pacemaker’s IPG parts. The nature of a pacemaker’s utility, as coupled with a cardiac lead, defined the technologies underpinning the working principles of the cardiac lead as another setting of improving the IPG’s CRM affordance.

The settings of the company B IPG device’s use scenarios were subject to change. Technological advancements in the working principles of the cardiac lead as well as complexities in integrating externally procured parts within the IPG configuration compromised the IPG device’s compatibility to supplement defective heart states.
In company B, improvement projects were used to improve incrementally the effectivity and safety of the CRM supplement delivered by reconciling the standard design of IPG device parts to specific settings of defective heart states.

### 6.6.2 Pacemaker IPG Artefact's Design

Company B’s IPG device is an established product. The utility interface and technical capabilities of the IPG device’s design underpinned the CRM supplement provided. Company B team members held assumptions of the technical and utility interface requirements of the IPG device to provide the CRM supplement.

To deliver a CRM supplement, the IPG device was required to be developed to enable input of pace data as well as output the electrical therapy necessary to stimulate CRM. The attributes of the pacemaker’s internal conductive core, electrical circuitry and battery parts structured functional compatibility with the cardiac lead, and was essential for actualising pacing data input and electrical therapy output that would stimulate the heart.

The complementarity of the IPG’s CRM supplement required a design that enabled indirect interface with the human heart and direct interface with cardiac leads. The IPG device was required to be developed to enable the surgeon infer compatibility for IPG to cardiac lead assembly. Interface (direct & indirect) was dependent upon how the IPG was developed to facilitate implant in a subcutaneous pocket within the human body and physical connection with cardiac leads. The attributes of the pacemaker’s external parts, the header and pace generating can, enabled the surgeon interpret implant and lead connection compatibility.

IPG subsystems (internal and external) were developed to integrate the electrical follow thru capability of the delivering the CRM supplement. Refinements to utility interface and technical capabilities of the company B IPG device enabled improvements in the CRM supplement provided.

### 6.6.3 Pacemaker IPG Affordance Subsystems

An IPG is a complex product. Company B’s IPG was developed from the perspective of two subsystem aspects: it’s external subsystem and its internal subsystem.
The external system was shaped by the parts of the IPG device that enabled direct interface with the cardiac leads and the implant pocket within the patient’s body.

- The header and PG can parts defined the utility interface capabilities of the *external subsystem* of the company B IPG device,

The internal system was structured by the configuration of IPG device parts that actualised how electrical therapy was output to the patient’s heart.

- The conductive core, electrical circuitry and battery, defined the functional capabilities of the *internal subsystem* of the company B IPG device.

The specific parts of the IPG device, identifiable as either an external or internal subsystem parts, contributed to enabling “human using” and “product working” aspects of a pacemaker’s design.

The attributes of each external subsystem part were collectively shaped to be compatible with the harsh internal conditions and anatomy of the implant pocket or cardiac lead connector formats:

- The attributes of the header (tensile strength of the material, no. of bore holes and dimensions) were shaped to enable connection with cardiac lead pins and to withstand implant conditions of the human body,

- The attributes of the PG can (tensile strength of the material, and width dimensions matching the header) were shaped to create an airtight seal and to withstand implant conditions of the human body.

The attributes of each internal part were collectively structured to embody an electrical follow thru capabilities that was compatible with the physiology of the human heart and the implant pocket or working principles of cardiac leads:

- The attributes of the conductive core (no of connector points) and electrical circuitry (no of connector points and conductive tracks) were structured to isolate pacing data input and electrical output.

Design changes to both the human using and product working parts of the IPG device’s subsystem represented how company B improved the complementarity of the IPG device’s design to supplement defective heart states.
6.6.4 Pacemaker IPG Action possibilities

The action possibilities of an IPG were signified by the visual references of the IPG device’s external subsystem of parts.

During improvement projects, improvement team members identified, for each external pacemaker part, features that signified improved opportunities of interaction between the IPG device and the surgeon and between the IPG device and the cardiac leads. Perceivable opportunities for interaction with the IPG device defined how a surgeon assembled the IPG with the cardiac lead, prior to implanting the pacemaker:

− The number of header bore holes signified cardiac lead pin to bore hole connection compatibility,
− The header and PG can’s robust materials and hermetic seal signified safe and effective delivery of CRM when implanted.

Whilst the patient with a CRM heart defect is the consumer of a pacemaker, they never directly perceive or make decision on how to interact with the pacemaker. The pacemaker’s action possibilities must be designed to be perceivable by the surgeon. Therefore, improvement team member also identified features that, prior to implant, supported a surgeon’s confidence in the IPG’s assembly with cardiac leads:

− The transparent material of the header enabled the surgeon infer successful cardiac lead to header connection,

The interaction features of the two external subsystem parts were “recurring stimuli” that evoked “hard-wired, biological reflexes and habituated responses” of the surgeon. For example, the number of header connector bore holes and the bore holes dimensions enable the surgeon infer compatibility of connection between cardiac lead and the company B IPG device.

The number of header connector bore holes and the bore holes dimensions represent a recurring stimuli basis of assessing the compatibility of the IPG device to cardiac lead setting of the CRM supplement use scenario.

During improvement projects, improvement team members improved the design of the recurring stimuli of perceivable interaction opportunities.
6.6.5 Improved Pacemaker’s Affordances

Surgeons and patients experience the pacemaker holistically. Visual references of the compatibility of the IPG device’s external parts alone did not facilitate delivery of the CRM supplement.

The action possibilities of the company B IPG device emerged of the technical ability of interactions between parts within the IPG device to actualise the electrical follow thru capability. When a header’s connector is connected to a cardiac lead pin, it is the internal configuration of parts that channel input of pacing data, and output of electrical stimulation. The internal subsystem of header and PG can parts underpinned how the actions possibilities of interface with the pacemaker’s external subsystem safely and effectively delivered the CRM supplement.

Therefore, the complementarity of a company B’s IPG was dependent upon team members improving external and internal subsystem interactions:

1. Between the pacemaker (header & PG can) parts and the subcutaneous pocket within the user’s body,
2. Between the pacemaker (header) and a cardiac lead,
3. Between the configuration of interacting parts within the IPG’s header and PG can parts.

These three IPG subsystems structured how the CRM supplement was realised. Each subsystem played a role in accommodating use scenario settings:

- External subsystem parts implied the electrical follow thru capability through visual reference of opportunities for interaction between the IPG device and the implant pocket and between the IPG’s header and the cardiac lead.
- Interactions between internal subsystem parts actualised how the electrical follow thru (pace sensing & electrical stimulation output) was embodied.

Whilst each subsystem categorised different IPG device design aspects, subsystems represented inter-related development considerations requiring management during any improvement project. Alone, neither subsystem’s design affords the electrical output expected of the IPG device. There are interdependencies between external and internal subsystem parts. Therefore, neither subsystem could be designed in isolation of the other.
The electrical stimulation implied as offered by the visual references of interaction opportunities with the header part needed to be consistent with the electrical follow thru capabilities actualised by the internal subsystem of parts.

- The header’s external form should be designed to fit specific cardiac lead pin connector formats,
- The IPG’s internal configuration of parts should be designed to embody an electrical follow thru capability compatible with the working principles of that specific cardiac leads technologies as well as the implant pocket and heart’s physiology.

Improvement projects focused on improving the compatibility of subsystem parts to changing settings of the use scenario.

- The header part needed to be developed to offer a range of connection formats that were compatible with new cardiac lead technologies,
- The IPG’s internal structure need an air tight seal to be capable of inputting pacing data and to safely and effectively generate output of electrical therapy sufficient to supplement CRM defects.

Company B assembled improvement teams to coordinate improvement projects. Improvement team members possessed different skillsets. Team members that focused on design of the external header and PG can parts held assumptions on the tensile strength of materials compatible with the implant location. These assumptions defined how IPG dimension of fit and suitable materials were developed. Team members that focused on design of the internal configuration held knowledge on the physiology of the heart and the implant locations as well the working principles of cardiac leads. These assumptions defined how individual parts, and as a configuration of interacting parts, were developed to actualise the electrical follow thru deemed compatible with the working principles of cardiac leads and of supplementing defective CRM heart states.

Improvement team members assessed the compatibility of the attribute of interactions enabled with and within an IPG device’s design to settings of providing a CRM supplement:
1. Team members tasked with improving the external subsystem parts examined the ability of the IPG device’s external subsystem of parts, header and PG can, to signify opportunity for interactions between the surgeon and the pacemaker, and between the pacemaker and cardiac lead connector standards.

2. Team members tasked with improving the internal subsystem parts examined the bond strength of the seal required between the IPG device’s internal subsystem parts. This seal was critical to isolate input and output channels that actualise the electrical follow thru capability, deemed compatible with cardiac lead working principles and defective states of the heart’s CRM physiology.

Compromises in the attributes of any subsystem’s parts informed the need for and subsystem focus of an improvement project. During any improvement projects improvement team members were challenged with ensuring design changes to any part (external or internal) improved the compatible of that part to use scenario settings (implant pocket anatomy or physiology or cardiac lead working principles) and, in turn, the complementarity of the IPG device’s utility in defective CRM state use scenario.

The external human using and internal product working subsystem aspects of the company B IPG device shaped the CRM supplement afforded. The total pacemaker/IPG device is the perspective of exploring and establishing an understanding of how the external-internal affordance relationship was managed. Of concern was establishing an understanding of how improvements in the complementary of a pacemaker’s IPG design to specific use environment settings of the surgeon and patient users was realised.

6.7 Pacemaker IPG Affordance Design Improvements: Analysis of the Relationships between Constructs
With reference to the six relationships outlined in chapter 3, empirical evidence of the approach adopted by company B to managing the external-internal affordance relationship is visualised in figure 31 and discussed in the following section.

The IPG was a complex product that evolved through improvements. Design changes to subsystem parts characterised how company B approached the development task during improvement projects.
Overtime the company B IPG’s CRM utility offering was improved. Improvements projects were initiated and coordinated by a project director. Each improvement project was driven by the identification of a potentially remediable compromise in the IPG device’s design, and sought to improve the electrical follow thru capability at that point in time.

The project director determined the skillset required of improvement team members to resolve the identified compromises. During each improvement project, the project director identified the subsystem focus of resolving the compromise.

In this case, two improvement projects were presented. Each improvement project represented a phase of company B’s attempts to improve the IPG device’s complementarity to its defective CRM heart state use scenario. During each improvement project the defective heart state use scenario defined the benchmark for improving an IPG device’s complementarity.

Relationship 1: Managing the relationship between a pacemaker’s standard design and improvable surgeon and patient interface and electrical follow thru aspects.
Team members evaluate the adequacy of subsystem aspects of the existing IPG device’s standard design relative to settings of supplementing a defective heart state. The use environment for the pacemaker product comprised the patient’s heart, an implant pocket and cardiac leads. Each had characteristics which would impact design of pacemaker interfaces of delivering the CRM supplement.

- The physiology and anatomy of the human heart and the subcutaneous implant pocket defined pacemaker characteristics of enabling perceivable opportunities of suitability for implant within the patient’s body.
- The working principles of cardiac leads defined pacemaker characteristics of enabling perceivable opportunities for interface with cardiac leads assembled to the pacemaker prior to the implant surgery.

During each improvement project the settings of a pacemaker’s use scenario defined the benchmark of improving an IPG device’s complementarity to a defective CRM heart states.

CRM was dependent upon the surgeon assembling the pacemaker to cardiac leads prior to implant. The working principles of cardiac leads, the anatomy and physiology of the human heart and the harsh conditions of the subcutaneous pocket, within which the pacemaker will be implanted, defined the benchmark of improving the electrical follow thru capability of the IPG device.

**Relationship 2: Managing the relationship between a pacemaker’s standard design and action possibilities of a cardiac rhythm management supplement.**

Team members managed the development of improvements to the external-internal affordance relationship by making dynamic assumptions about both the pacemaker patient and implant surgeon’s utility requirements. They converted those assumptions into IPG device requirements. Complementarity was assessed through review of the usefulness of the action possibilities of the external subsystem of the IPG device parts to enable interactions with the surgeon user. The transparent nature of the header’s material enabled the surgeon determine effective cardiac lead connection. However, the complementarity of a pacemaker product was also dependent upon the ability of internal subsystem of product working parts to actualise the electrical follow thru capability. Each bore hole linked to a conducted core that input and output electrical data. The external and internal subsystems were interrelated design considerations.
The complementarity of the IPG device’s affordance design required team members to develop subsystem parts to be compatible with the use setting defining each part. For example:

- The compatibility of the header’s external form was defined relative to the technologies underpinning the working principles of the cardiac lead, and the ability of the header to connect with the cardiac lead pins.
- The compatibility of the header’s internal configuration was defined relative to the physiology of the human heart, and the ability of any part within to actualise the conditions of inputting pacing data and outputting the electrical stimulation necessary to supplement the defective CRM heart state.

Prior to any improvement phase, the pacemaker had been deemed by the project director to have a standard design that embodied human using and product working aspects that complemented supplement to defective CRM heart states. The identification of the existence of compromises in the compatibility of any subsystem part of a pacemaker’s total design was the basis of initiating each improvement project.

The project director monitored company B’s product offerings on an ongoing basis for the existence of compromises in any subsystem part’s compatibility. Case observations presented two examples of compromises evident in improvement initiatives:

- The first improvement project was initiated when the manufacturing engineer realised assembling the externally procured header part was compromising the effectivity of the bond with the PG can and safety of isolating electrical flow “into and out” of the pacemaker when implanted.
- The second improvement project was initiated when engineers realised that regulatory approved changes in cardiac lead pin connector standards were incompatible with the existing pacemaker’s design.

**Relationship 3:** *Managing the relationship between improvable surgeon and patient interface and electrical follow-thru aspects and action possibilities of a cardiac rhythm management supplement.*

The defined development requirements of an IPG device revealed two development aspects and opportunities for team members to improve design complementarity:
1. The “human using” features, the external artefact to artefact affordance subsystem of enabling the surgeon connect the pacemaker’s header part with the cardiac lead and the external artefact to user affordance subsystem, of enabling the surgeon implant the pacemaker internally within a subcutaneous pocket of the patient’s body,

2. The “product working” features, an internal artefact to artefact affordance subsystem, of actualising embodiment of the “electrical follow thru” capability within the pacemaker’s configuration of internal header and PG can parts.

Throughout, design dialogue was focused on improving the complementary of external artefact-user and external and internal artefact-artefact interactions.

Each improvement project started with a subsystem focus. The subsystem focus of each improvement project was a follows:

- Improvement project 1 focused on the external human using aspect of the header’s design. Changes were to be applied to the external form of the header. The change was required to enable visual reference of a strengthened bond between the header and PG can parts and improve the compatibility of external header and PG can parts by preventing the risk of disconnect during implant periods,

- Improvement project 2 focused on the internal product working subsystem aspect of the header. Changes were to be applied to the internal functional capabilities of the conductive core part. The change was required to enable embodiment of compatibility with new cardiac lead pin standards.

When compromises were deemed to exist, improvement teams were formed and members within the team were tasked with finding resolutions. Finding resolution required improvement team members to identify the origin of the compromise. Improvement team members considered the “what if” of applying changes to subsystem parts. The “what if” scenario enabled team members assess if such changes accommodated human using and product working requirements whilst improving the complementarity of an IPG device’s design to supplement defective CRM heart states.

In company B, compromises did not result of poor design decisions of earlier development tasks. Rather, compromises emerged of the technological advances of other products (the cardiac lead) and opportunity to implement manufacturing efficiencies.
Compromises reflected dynamic assumptions formed by improvement team members on IPG interface and electrical follow thru requirements and the application of future anticipatory thinking on ways to improve CRM supplement provided.

- Improvement project 1 was initiated because company B engineers felt the need to eliminate the potential impact of manufacturing inefficiencies of the off-the-shelf nature of the header part on bond strength and electrical isolation when assembled with the PG can.
- Improvement project 2 was initiated because company B engineers felt the need to extend their pacemaker design to include an offering that integrated compatibility with technological advances of the cardiac lead.

The origin of each compromise was determined through review of the existing generation of the pacemaker’s standard design. Reviews enabled improvement team members to locate and map inadequacies of subsystem aspects (human using or product working) part attributes to compromises.

Additionally, the focus (an external or internal subsystem part) of implementing an improvement was defined. Improvement projects 1 revealed compromises in the external subsystem’s compatibility. Improvement projects 2 revealed compromises in the internal subsystem’s compatibility:

- Improvement project 1 identifying inadequacies in the header part. The complexity of the insert process compromised external part bond strength during implant periods. A change to the header part (moulded in place) was identified as the solution to strengthening the bond with the PG can part,
- Improvement project 2 identified inadequacies in the conductive core part. The core comprised multiple conductive connector points that were incompatible with new regulatory approved single pin cardiac lead technology. Changes that integrated the conductive core within one connector point, was identified as the solution.

Complementarity of the IPG device’s affordances to supplement defective heart state use scenarios was dependent upon reconciling the compatibility of design changes to subsystem parts to use scenario settings. Compatibility was realised through the series
of design decisions that coordinated how design changes to parts of each subsystem were reconciled to specific settings (heart and implant pocket physiology and anatomy or cardiac lead working principles) of the CRM supplement use scenario.

Improvements to the external subsystem involved improvement team members applying changes to a part that would be directly interacted with by the surgeon. These changes resulted of team members focusing attention on amending the attributes of the external part’s design, to signify the improved electrical follow thru capability resulting of the part’s new design.

  - For example, during improvement project 1, improvement team members focused on the external form of the header and moulded the header form rather than using an externally procured insert piece. This change enabled the internal customer during manufacturing and the surgeon during implant procedures to have confidence in the pacemaker’s ability to deliver a CRM supplement.

Improvements to the internal subsystem involved improvement team members applying changes to a part of the IPG device’s functional configuration. These changes resulted of team members focusing attention on amending attributes that enabled how the interactive arrangement of sensing and generating parts actualised the electrical follow thru capability, underpinning the CRM supplement:

  - For example, during improvement project 2, improvement team members focused on making changes to the conductive core part. These changes enabled sensing and pacing elements of the multiple conductive core parts to be integrated as a single conductive core.

**Relationship 4:** Managing the relationship between interactions of parts actualising the electrical follow thru capability within and audio devices and human ear interactions with the pacemaker.

Team members tasked with improving an internal or external aspects could not, independent of one another, definitively inform decisions on improvements in the complementarity of an IPG device’s electrical follow thru capability to CRM supplement use scenarios.
The complementarity of a pacemaker’s external artefact-user and artefact-artefact interactions were dependent upon the adequacy of the technical design of internal artefact to artefact interactions.

Improvements in the complementarity of a pacemaker’s design involved considerations of both the human using and product working aspects of an IPG’s design.

Each aspect characterised a subsystem defining a context of developing improvements in a pacemaker’s CRM supplement.

- The existing external human using aspect characterised the development task of improving perceivable opportunities for useful utility interactions between the pacemaker and the surgeon, patient’s heart and cardiac leads,
- The internal product working aspect characterised the development task of improving interactions between “electrical follow thru” parts that actualise pace sensing and generation functions within the pacemaker.

The complementary of the IPG device’s “CRM supplement” was evaluated relative to the working principles of the industry standard for cardiac leads. During improvement phases, design dialogue focused on achieving consistency between utility implied by interactions enabled with and utility actualised through interactions enabled within the pacemaker. Of concern was:

- Consistency between the utility interactions communicated by the IPG device’s external form and the technical “electrical follow thru” capabilities unlocked within the IPG device’s internal header and PG can’s configuration,

**Relationship 5: Managing the relationship between action possibilities of a cardiac rhythm management supplement and an improved standard pacemaker design.**

The resulting pacemaker was tested before release for compatibility of indirect interactions with the heart and (CRM effectivity) and direct interaction with the cardiac leads (input output connector standards) and implant pocket (electrical isolation safety) during implant periods. During an improvement project, the coordinated series of considerations that improved a subsystem part revealed another management challenge; reconciliation of design changes with related subsystem parts.

Each improvement project started with a subsystem focus that ultimately applied changes to a part of that subsystem.
Improvements to the compatibility of that pacemaker part had the potential to impact the compatibility of other pacemaker parts to use settings. The affected part(s) could exist within the same or different subsystem aspect to the initial improvement focus. In such situations, further iterations of design were initiated to reconcile the complementarity of the IPG device’s design to the specific use settings of supplementing CRM. Complementarity was dependent upon identifying and eliminating all knock-on effects.

The attributes of the IPG device’s external parts as well as the attributes of internal electrical follow thru parts, and their arrangement, represented a metric of conducting reviews. Reviews enabled improvement team members identify how the internal or external part, if changed, would eliminate the compromise and improve compatibility with settings of the pacemaker’s use scenario.

Additionally, a review of the attributes of interactions enabled with (product-user utility interface) and within (actualising technical capabilities) the pacemaker’s design enabled improvement team members assess if a knock-on effect had occurred.

The two improvement examples explored in company B revealed no examples of a knock-on effect. However, improvement team member did questioned if knock-on effects had occurred. For example, during improvement project 2, team members questioned:

- Did the changes to the conductive core have a knock-on effect on electrical circuitry?
- How to remove two unnecessary bore holes.

However, the integration of connector reduced the number of pins interacting with the electrical circuitry and had no impact on the design of the electrical circuitry as conductive tracks already existed, requiring no further changes. Additionally, the new over-mould manufacturing process of improvement project 1 facilitated the solution to removing two unnecessary bore holes; simply remove two injectors from the manufacturing mould.

Had a knock-on effect occurred, the attributes of interactions enabled between the IPG’s conductive core and electrical circuitry would have enabled improvement team members “infer when” compatibility with the technologies underpinning the working principles of the cardiac lead standard were deemed realised.
Relationship 6:  *Managing the relationship between an improved standard pacemaker IPG design and the defective CRM heart states use environment.*

The resulting IPG device, when released, was reviewed for continuing competitiveness in a dynamic market. The dynamic nature of the medical device industry and regulatory standards, required company B to conduct ongoing reviews of the need for improvements in the complementarity of the standard design of the existing IPG device to changing use environment’s settings. Insights from each improvement updated knowledge of subsystem design aspects. This knowledge was transferrable for use during future improvement projects.

- During improvement project 2 insights from improvement project 1, the over-mould header design, was a transferrable piece of knowledge that would be considered for adopted or exclusion when attempting to improve future pacemaker designs.

### 6.8 Management Implications for Improving Pacemaker IPG Device Complementarity

Analysis of empirical observations in company B yielded three management considerations to improving the IPG device’s complementarity to supplement defective heart states:

1. Initiating pacemaker improvement projects, based on managing relationship 1 and 6,
2. Implementing a pacemaker subsystem (internal or external) improvement, based on managing relationships 2, 3 and 4,
3. Realising pacemaker design complementarity to facilitate CRM supplement use settings, based on managing relationship 5.

Each management consideration is discussed and enables the process coordinating management of the external-internal affordance relationship during improvement projects in company B to emerge.

*Initiating improvement projects* reflected relationship 1 and 6. During each improvement phase a standard IPG device design already existed. The existing IPG device, shaped by preceding improvement phases, already embodied an accommodation between the human using and the product working aspects of the pacemaker (relationship 6).
However, when compared to use environment settings (relationship 1) there was opportunity, or need for, improvements in the complementarity of the IPG device’s design to changing CRM supplement use settings.

Implementing a subsystem (internal or external) improvement reflected relationships 2, 3 and 4. Managing relationship 2, the improvement process was coordinated by a truncated version of the regular pacemaker product development process. Discourse took place within some of the stages in the IPG device development process that informed improvement to specific subsystem parts (informed by considerations of relationships 3 and 4).

Realising complementarity to a pacemaker’s use environment settings reflected relationship 5 and revealed when an improvement to an IPG device’s complementarity was realised. As knock-on effect were identified, improvements required revisiting prior decisions, those of relationships 3 and 4, and associated fits with each subsystem aspect of the pacemaker’s affordance relationship. The CRM supplement use environment settings of the pacemaker defined the constraints of each improvement project.

6.8.1 Three Stages to Managing External-Internal IPG device Affordance Relationship Considerations

The emergent management process incorporates three stages for coordinating the external-internal affordance relationship during phases of IPG device improvements.

1. The practical rationale of initiating improvement projects, stage 1, revealed the start point of triggering pacemaker improvement projects. Improvements were initiated in response to assessment of and identification of compromises in the complementarity of an existing pacemaker’s design to changing CRM supplement use settings.

2. The challenge of implementing a subsystem (internal or external) improvement, stage 2, revealed two coordinating series of design considerations of implementing pacemaker improvement. Each coordinating series of design considerations defined the focus of change to a specific pacemaker subsystem’s affordance relationship,
3. The interactive aspects of realising complementarity, stage 3, involved iterations of design changes required to reconcile internal and external IPG subsystems so as to realise affordance design complementarity.

Each of the three stages are discussed.

At stage one the pre-existing standard design of this pacemaker defined the affordance relationship that existed. The complementarity of the standard design was interpreted from the external subsystem perspective from which opportunities or the need for improvements were identified.

At stage 2 there was “subsystem level” dialogue to be managed with a focused on a specific subsystem. Improvement team members were concerned with realising improvements to a pacemaker subsystem aspect’s affordance relationship. Improvements were achieved through a focus on redesigning a part within the specific subsystem aspect (human using or product working).

As team members improved the subsystem aspect, they monitored the complementarity of changes to affordance relationship assumptions of stage 1 and engaged in coordinated sequences of design dialogue. Dialogue focused on implementing changes to the externally perceivable IPG device interaction attributes or changes to the attributes of interacting parts that internally structured the electrical follow thru capability.

Improvements resulting from changes applied to subsystems had potential to impact other parts. So, maintaining the complementarity with the stage 1 affordance relationship assumptions required management to extend dialogue to another subsystem aspect, now potentially also requiring attention.

At stage 3 the management act was reconciliation, through discourse, between both subsystem perspectives to resolve conflict with each other. There were defined metrics of enabling the external human using and internal product working subsystem aspects of the affordance relationship. Complementarity required consistency between the CRM supplement implied by the interactions enabled with the pacemaker and the CRM supplement resulting of parts interacting within the pacemaker.
Central to the discourse was reconciliation of different perspectives on the affordance relationship. Reconciliation required an articulation of subsystem’s affordance relationships, a contextualisation of each subsystem’s affordance relationship aspect and contextualisation of the use environment for inferring complementarity.

There are interdependencies between the 3 stages.
- Stage 1 started each pacemaker improvement project as a cycle that began with a review of the existing pacemaker’s standard design.
- Stage 2 followed with coordinated series of design considerations for implementing improvement in the compatibility of a subsystem’s complementarity to the CRM supplement use environment.
- Stage 3 involved iterations of design focused on matching subsystem affordances (internal or external) to their respective CRM supplement use environment settings.

6.8.2 Five Steps to Managing a Pacemaker Affordance Improvement Project

Within the three stages there were five steps in the process of managing the external-internal affordance relationship during phases of improvements, as visualised in figure 32. Each of the five steps are presented below.

Step 1: Review of the pacemaker's Standard Design represents (Start Point)
The improvement team started each improvement project by identifying issues (manufacturing inefficiencies that may compromise pacemaker effectivity and design compatibility with new industry standards) and opportunities (reduce cost & integrate latest industry standard within the range of pacemaker offerings) for improvement in the affordances of existing pacemaker offerings.

Step 2: Evaluation of the performance based indicator justifying need to initiate a phase of improvement
Improvement team members examined known indicators and metrics of pacemaker performance to identify improvable subsystem(s). They assessed the ability of internal and external subsystem parts of the pacemaker to deliver the CRM supplement. They defined the origin of "compromises" and the need for, or "opportunity for", change to existing subsystems that would realise improvements.
Step 3: Identification of the Subsystem Focus defining how improvements would be approached
Once an affordance design compromise was identified, the team identified the subsystem and related parts that, if changed, could achieve an improvement in complementarity.

Step 4: Identification of how dialogue and decision made were validated and implementation of improvements were inferred as realised
The attributes, of interactions enabled with or within the pacemaker, represented how the project director determined if an affordance improvement was realised.

Step 5: Knock-on effect & iterations of subsystem design changes identified if required
Changes made to any component parts of the pacemaker required exploration of the potential for knock-on effect of changes made in a subsystem part, on other subsystem parts of the pacemaker. Iterations of design improvements, through changes to related subsystem parts may be required to reconcile complementarity with cardiac lead standards and the CRM physiology of the human heart use settings.
**Stage 1: Start Point**

Practical Rational of Initiating A Pacemaker IPG Device Improvement

- **Step 1:** The Start Point of Initiating an Improvement Project via Review of the affordance relationships of the Pacemaker’s Standard Design
  - Identification of issues (Compromise in the Safety & Effectivity of delivering CRM) or opportunities (Integrate New Standard Compliance & Manufacturing Efficiencies) initiating need for an improvement project

- **Step 2:** Evaluate Known Indicators of a pacemaker’s Performance to Identify Improvable Subsystems
  - Assessed the ability of internal and external subsystem aspects of the Pacemaker to deliver the CRM supplement, & identified the pacemaker subsystem to be improved

**Stage 2: Subsystem Design Change**

Implementing a Subsystem Pacemaker Improvement

- **Step 3:** Identifying the Subsystem Aspect of Driving Improvement to the CRM Supplement Offering
  - The identification of the subsystem aspect of implementing an improvement: change to an external pacemaker part’s features OR an internal pacemaker part’s technical electrical follow thru capability

- **Step 4:** The rational Basis of dialogue and decisions made when approaching implementation of change to Pacemaker Subsystem Part
  - Identification of the metric informing improvement dialogue & decisions: Attributes of interactions shaped with or within the Engineered Pacemaker

**Stage 3: Subsystem Reconciliation**

Interactive Pacemaker Subsystem Considerations

- **Step 5** Potential Knock-on Effect & Capturing Complementarity

  **Knock-on Effect:** Identified if changes to a Pacemaker part impacted consistency of related parts (internal or external) to be complementary to Supplement CRM heart defects environment settings.

  **Iterations of design were required** to reconcile consistency between both pacemaker subsystem aspects to be complementarity to heart defect states settings

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Figure 32  Company B’s Approach to Managing improvements in the Internal/External Affordance Relationship of the Pacemaker device

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Managing the five steps coordinated activities within and between stages of improvements:

Stage 1, the start point and practical rationale for initiating improvements, involved the first two steps. The identification of issues or opportunities for improvement (Step 1) by examining known indicators and metrics of the IPG device’s complementarity (step 2) revealed compromises triggering the move to stage 2.

Stage 2, the rationale for implementing an IPG device subsystem improvement, involved steps 3 and 4. Identified subsystem aspect and related parts of implementing an improvement (step 3) informed attribute design changes (step 4) for maintaining the complementarity of interactions enabled with or within the IPG device. The need to explore knock-on effects, triggers the move to the last management stage, stage 3.

Stage 3, reconciling subsystem designs, involves step 5. Changes made to any subsystem part of the IPG device required exploration (step 5) of the potential for a knock-on effect to parts within the same subsystem or to parts of the other subsystem. The coordinated considerations of steps 3 and 4 defines the focus of any iterations of design changes to reconcile subsystems as a total pacemaker offering to be compatible with setting of defective heart state use scenario.

Case insights enabled an opportunity to update the conceptual model of the external-internal affordance relationship” from the pacemaker IPG perspective, as visualised in figure 33. Figure 33 reveals that the use environment defined the context for (and, so moderated) the improvement projects. Each improvement project focused on improving the complementarity of the standard design at that point in time, of internal and external IPG subsystem aspects to specific use environment settings.

Management of the improvement projects was cyclical. The output of each improvement project, an improved standard design, became the focus of future improvement projects. Within each cycle, there were three inter-related stages of management considerations that were coordinated through five steps. The steps in the stages comprised a start point, two coordinated series of subsystem changes and iterations of design changes to reconcile the subsystem aspects with the use environment.
6.9 Case Summary
This case has provided insights on pacemaker development management of the internal external affordance relationship during phases of improvement to an engineered pacemaker product’s standard design.
Figure 33  The process of managing the Internal/External affordance relationship during cycles of incremental improvement to a pacemaker’s standard design.
Chapter 7: Consolidated Analysis

7 Introduction to the Consolidated Analysis

In chapter 3 the preliminary conceptual framework, visualised in figure 1, identified the constructs and relationships between constructs of managing the external-internal affordance relationship. The relationships embodied the process of managing product affordances during improvement projects. To consolidate an understanding of the emerging framework at the end of the within case analyses, a ‘between case analysis’ follows.

The within case analysis of case 1 observations are discussed in detail in sections 5.6 to 5.9. The within case analysis of case 2 observations are discussed in detail in sections 6.6 to 6.9. Each within case analysis discussed in detail definitional and relational concepts of managing the external-internal affordance relationship in evidence.

This chapter presents a consolidated ‘between case analysis’. This consolidation allows for a more generalised interpretation to inform the construction of an external-internal affordance relationship management model. It is through this model that:

- The theoretical external-internal affordance relationship is presented and explained.
- An answer to the research question is enabled and from which the theoretical contribution to product development management theory will be outlined.

7.1 Consolidated Product Affordance Design Improvements: Analysis of Conceptual Constructs

This section presents a consolidated view of practice-based case observations of management of product affordance improvement. In each case, the use environment defined the settings and development context for improving the affordance of a product’s utility offering. Case observations revealed how team members, tasked with the development of specific subsystems, commonly held specific intentions on the benchmark reference of the product’s affordance design and of ways to improve subsystem complementarity. During improvement phases the team was challenged to manage the process to realise improved complementarity with the product’s use environment. Case observations revealed how reconciling internal and external
subsystems followed a process that iterated towards complementarity to the use environment.

Figure 1 of chapter 3 conceptualised the management process. The following sections present a comparative and consolidated overview of the findings of the two cases in relation to five concepts in the management process, as visualised in figure 34: use environment, artefact’s design, affordance subsystems, action possibilities and an improved product affordance.

![Diagram](image)

Figure 34  Consolidated View of Company perspectives of construct of managing the external-internal affordance relationship

7.1.1 Use Environment

Two affordance improvement cases, a headphone and a pacemaker IPG, were developed in this thesis. From the discussion in sections 5.6.1 and 6.6.1, each product afforded a utility offering. The adequacy of the utility afforded by each product’s design was assessed relative to specific product use scenarios:

- The headphone was developed for use in a professional music creation scenario,
- The IPG device was developed for use in defective CRM heart state scenario.

The settings of each product’s use scenario characterised the context of developing each product’s affordance design (Norman, 2013; Gibson, 1979).

- High frequency audio devices and the anatomy and physiology of the human ear defined the settings of the headphone,
- Cardiac leads and the anatomy and physiology of the human heart and implant pocket defined the settings of the IPG device.
Changing use environment set the parameters and benchmarks of design dialogue and decisions on improving the complementarity of each product’s utility offering. (Burlamaqui & Dong, 2014; Norman, 2013; Maier & Fadel, 2007):

- In the headphone case, audio devices were becoming more powerful, the audiophile user was becoming more technologically knowledgeable and industry-wide weaknesses in driver technology were changing,
- In pacemaker case, perception of safe interchangeability of pacemaker parts and cardiac lead technologies were changing.

As evident in both cases, the complementarity of each product’s utility offering within the specific use scenario settings was the basis for determining the adequacy of the product’s affordance design (Norman, 2013; Brown & Maier, 2012; Maier & Fadel, 2009). Thus, the external-internal affordance relationship concept of the use environment was evident within both cases.

7.1.2 Artefact

From the discussion in sections 5.6.2 and 6.6.2, it was apparent that the headphone and IPG artefacts incorporated established affordance designs that represented the intent of the members of the product’s improvement team (Norman, 2013; Ulrich & Eppinger, 2012).

These artefacts were established products that characterised the integrated thinking of earlier and original development team members. Each product had a standard design that had evolved subsequently through improvement projects to accommodate utility expectations in specific use scenarios:

- Headphone case: The personal sound experience requirement of the audiophile user in music creation use scenarios,
- Pacemaker case: The implant requirements of the surgeon and the supplement requirements of the pacemaker patients in CRM defective heart state use scenarios.

The utility offering of each product, denoted by its physical attributes, enabled improvement team members assess the complementarity of an artefact’s design to settings of a use scenario (Norman, 2013). The team member held assumptions on how
the utility interface and functional attributes of each product’s affordance design could be developed to complement the specific settings of different product use scenarios:

- In the headphone case: The headphone required parts that enabled direct interface with the user’s ears and audio source devices, as well as parts that channelled audio to the user’s ear.
- In the pacemaker case: The affordance design required parts that enabled direct interface with a subcutaneous pocket and cardiac leads, as well as parts that channelled output of electrical therapy.

Both products were designed with features that enabled interaction with the product (between the artefact and a user or another product) and enabled utility to be actualised within the product (between parts of the artefact’s configuration) (Chen et. al, 2013, Maier and Fadel 2009).

In the headphone case:

- The attributes of the headphones jack plug were shaped to be compatible with audio device connectors, essential for sourcing audio. The attributes of the headphones ear piece were shaped to be compatible with the anatomy of the human ear, essential for delivering the sound experience.
- The attributes of the headphone’s four driver parts structured functional compatibility with the audio device, essential for actualising the sound reproduction capability.

In the pacemaker case:

- The attributes of the pacemaker’s header were shaped to be compatible with the anatomy of the implant pocket and cardiac lead connector formats, essential for delivering the CRM supplement,
- The attributes of the pacemaker’s conductive core, electrical circuitry and battery parts structured functional compatibility with the cardiac lead, essential for actualising electrical therapy of supplementing CRM defects.

As evident in both cases, the artefact’s affordance was defined by the design of parts, shaped to be compatible with the settings of specific use scenarios. Thus, the external-internal affordance relationship concept of the artefact was evident within both cases.
7.1.3 Affordance Subsystems

From the discussion in sections 5.6.3 and 6.6.3, it was apparent that the utility afforded by the design of both products was developed from the perspective of the external subsystem and internal subsystem (Maier & Fadel, 2009). The specific parts of a product, identifiable as either an external or internal subsystem part, contributed to enabling “human using” and “product working” aspects of a headphone’s design (Kim & Lee, 2010).

The external subsystem shaped the parts of the product that enabled direct interface with the user’s body and other products:

– The earpiece, audio cable and jack plug parts of the headphone shaped the external subsystem that enabled direct interface with the audiophile user’s ears and the audio device’s connector,

– The header and PG can parts of the IPG device shaped the external subsystem that enabled direct interface with the surgeon and implant within patient’s body.

The internal subsystem was structured by the arrangement of product parts that integrated utility functions within the product.

– The arrangement of the driver, housing frame, diaphragm, voice coil and permanent magnet structured the internal subsystem that integrated the sound reproduction capabilities within company A’s headphone.

The attributes of each external subsystem part shaped compatibility with use settings that enabled human using features to afford utility (Norman, 2013):

In the headphone’s case:

– The attributes of the headphone’s earpiece were shaped to fit team member’s assumptions of the human ear’s anatomy,

– The attributes of the headphone’s Jack plug were shaped to fit with universal jack connector sizing and audio device connector formats.

In the pacemaker’s case:

– The attributes of the header were shaped to enable connection with cardiac lead pins and to withstand implant conditions of the human body,
The attributes of the PG can (tensile strength of the material, and width dimensions matching the header) were shaped to create an airtight seal and to withstand implant conditions of the human body.

The attributes of each internal subsystem part were structured to be compatible with use settings that enabled product working capabilities to afford utility (Maier & Fadel, 2009):

In the headphone’s case:

- The attributes of the driver parts structured a platform that fit converted audio input into a sound wave,

In the pacemaker’s case:

- The attributes of the conductive core and electrical circuitry were structured to isolate electrical input and output.

Design changes to both the human using and product working parts of each product’s subsystems represented how both companies improved the complementarity of their product designs to specific use scenarios.

- In the headphone case, the external earpiece part and the internal driver and diaphragm parts were the focus of improvement projects in company A,
- In the pacemaker case, the external header part and the internal conductive core part were the focus of improvement projects in company B.

Thus, the external-internal affordance relationship concept of affordance subsystems was evident within both cases.

7.1.4 Action Possibilities

From the discussion in sections 5.6.4 and 6.6.4, it was apparent that action possibilities for enabling and evoking product interactions were communicated by the features of external subsystem parts. (Xenakis & Arnellos, 2013). The action possibilities of each product were signified by the visual references of the product’s external subsystem of parts.

During improvement projects, improvement team members identified, for each external part, features that signified improved opportunities for interaction between the product
and the user and between the product and other products. Perceivable opportunities for improved interaction with external subsystem parts were defined by:

- Part features that facilitated different user-product interface opportunities,
- Part features that facilitated different that facilitated interface opportunities with other products,

The improvement team members’ assumptions of different product and user interface requirements determined the features shaping a product’s affordance design. Perceivable interaction features were designed to enable the users select the product design that would best represent their needs.

The design of external subsystem parts represented the “recurring stimuli” of evoking “hard-wired, biological reflexes and habituated responses” of the user. For example,

- In the headphone’s case, the jack plug’s size enabled the user infer compatibility of connection with different audio devices.
- In the pacemaker’s case, the number of header connector bore holes and the bore holes dimensions enabled the surgeon infer compatibility of connection between cardiac lead and the company B IPG device.

During improvement projects, improvement team members improved the design of the recurring stimuli of perceivable interaction opportunities. For example:

- In the headphone case, the open back circum-aural earpiece style combined with a quarter inch jack plug size represent the recurring stimuli of assessing the compatibility of a company A headphone to music creation use scenarios,
- In the pacemaker case, the number of header connector bore holes and the bore holes dimensions represent a recurring stimuli basis of assessing the compatibility of the IPG device to cardiac lead setting of the CRM supplement use scenario.

However, utility emerged of the technical capability of the internal subsystem of parts to actualise the embodiment of utility functions within a product’s structural form (Maier & Fadel, 2009). The technical capabilities unlocked by the internal subsystem of interacting parts underpinned the utility experienced of interaction with the external subsystem (Maier & Fadel, 2009).
Therefore, the action possibilities of a product’s external subsystem was dependent upon the technical capability of the interactive arrangement of internal parts to deliver a utility offering that complemented use environment settings.

- In the headphone case, the personal sound experience was underpinned by complementarity between the physiology of the ear and the conversion capability of the internal configuration of headphone parts. Of concern was the capability of the soundwave, resulting of the arrangement of parts, to be compatible with the physiology of the ear,

- In the pacemaker case, the CRM was underpinned by complementarity between the physiology of the human heart and the electrical follow thru capability of the internal configuration of parts to mimic the CRM physiology of the heart. Of concern was the capability of electrical therapy stimulated to supplement a CRM heart defect.

As evident in both cases, the complementarity of the action possibilities of the external subsystem was dependent upon enabling perceivable interactions opportunities (between a user and the artefact and/or between two artefacts), as well as enabling functional interactions (between internal artefact parts) that underpinned the utility afforded of specific action possibilities (Chen et al., 2013; Maier & Fadel, 2009).

Thus, the external-internal affordance relationship concept of action possibilities was evident within both cases.

### 7.1.5 Improved Product Affordances

From the discussion in sections 5.6.5 and 6.6.5, during improvement projects it was apparent to team members that a total product’s affordances were characterised by the utility implied as offered by the properties of the external subsystem (Norman, 2013) and underpinned by the technical capabilities of the internal subsystem (Srinivasan et. al, 2012, Maier & Fadel, 2009).

Users experience the product holistically. Visual references of the action possibilities of interface with external parts alone did not facilitate affordance of a utility offering. Each product’s action possibilities were underpinned by the technical capabilities of the internal subsystem of parts that actualised the utility offering. For example:
In the headphone case, when a jack plug was connected to an audio device, it was the internal configuration that facilitated input, conversion and output of audio. The internal subsystem of driver parts underpinned how the actions possibilities of the headphone’s external subsystem delivered the personal sound experience.

In the pacemaker case, when a header’s connector was connected to a cardiac lead pin, it was the internal configuration of parts that channelled input of pacing data, and output of electrical stimulation. The internal subsystem of pace sensing and generation parts underpinned how the actions possibilities of the IPG device’s external subsystem delivered electrical therapy.

Therefore, the complementarity of the action possibilities of each product to specific use scenarios was dependent upon team members improving external and internal subsystem interactions (Maier & Fadel, 2009):

- Between the product’s external subsystem parts and the user body or another product,
- Between the product’s internal subsystem of interacting parts.

These product subsystem interaction opportunities structured how the utility offering was afforded (Kaptelinin, 2013; Maier & Fadel, 2009). Each product’s subsystem played a role in accommodating the settings of specific use scenario. For example:

In the headphone’s case:

- External subsystem parts implied the personal sound experience through visual reference of opportunities for interaction between the headphone’s earpiece and the user’s ear and between the headphone’s jack plug and the audio device.
- Interactions between internal subsystem driver parts actualised how the conversion capability was embodied.

In the pacemaker’s case:

- External subsystem parts implied the electrical follow thru capability through visual reference of opportunities for interaction between the IPG device and the implant pocket and between the IPG’s header and the cardiac lead.
- Interactions between internal subsystem parts actualised how the electrical follow thru (pace sensing & electrical stimulation output) was embodied.
Whilst each subsystem categorised different product design aspects, subsystems represented inter-related development consideration requiring management during any improvement project. Alone, neither product subsystem design afforded the utility offering. There were interdependencies between external and internal subsystem parts. Neither subsystem could be designed in isolation of the other. The utility offering implied as offered by the visual references of external parts interaction opportunities needed to be consistent with the functional capabilities actualised by the internal subsystem of parts. For example:

In the headphone’s case:
- The headphone external form should be designed to fit the anatomy of the human ear and specific audio device connector formats,
- The headphone internal configuration of sound reproducing parts should be designed to embody a technical capability compatible with the working principles of specific audio devices and human ear physiology.

In the pacemaker’s case:
- The header external form should be designed to fit specific cardiac lead pin connector formats,
- The IPG internal configuration of parts should be designed to embody an electrical follow thru capability compatible with the working principles of that specific cardiac leads technologies as well as the implant pocket and heart’s physiology.

Improvement projects focused on improving the compatibility of subsystem parts to changing settings of the use scenario. Each company assembled improvement teams to coordinate improvement projects. Improvement team members possess different skillsets.

Team members held assumptions that defined how external and internal parts were developed to be compatibility to specific use settings. For example:

- In the headphone case: Team members that focused on design of the internal configuration held knowledge on what sound was and the physiology of the ear. These assumptions defined how individual parts, and as a configuration of
interacting parts, were developed to actualise the conversion capability deemed compatible with the working principles of high frequency audio devices.

- In the pacemaker case: Team members that focused on design of the internal configuration held knowledge on the physiology of the heart and the implant locations as well the working principles of cardiac leads. These assumptions defined how individual parts, and as a configuration of interacting parts, were developed to actualise the electrical follow thru deemed compatible with the working principles of cardiac leads and of supplementing defective CRM heart states.

Improvement team members assessed the compatibility of the attribute of interactions enabled with and within a product’s design to settings of specific use scenarios (Norman, 2013; Xenakis & Arnellos, 2013; Maier & Fadel, 2009).

In the headphone case:

- Team members tasked with improving external subsystem parts examined the ability of the headphone’s external subsystem of parts to enable interactions compatible with the ear’s anatomy and high frequency audio device connector formats.

- Team members tasked with improving internal subsystem parts examined the ability of the headphone’s internal subsystem of interacting parts to actualise the conversion capability compatible with the audio frequency input of specific audio devices and the physiology of the human ear.

In the pacemaker case:

- Team members tasked with improving external subsystem parts examined the ability of the IPG device’s external subsystem of parts, header and PG can, to signify opportunity for interactions between the surgeon and the pacemaker, and between the pacemaker and cardiac lead connector standards,

- Team members tasked with improving internal subsystem parts examined the bond strength of the seal required between the IPG device’s internal subsystem parts. This seal was critical to isolate input and output channels that actualise the electrical follow thru capability, deemed compatible with cardiac lead working principles and defective states of the heart’s CRM physiology.
Compromises in the attributes of any subsystem’s parts informed the “need for” and defined the “subsystem focus” of each improvement project. During any improvement projects improvement team members were challenged with ensuring design changes to any part (external or internal) improved the compatible of that part to use scenario settings (ear/ heart anatomy and physiology or audio device/ cardiac lead working principles) and, in turn, the complementarity of the product’s utility offering in the specific use scenario (music creation/ defective CRM heart state use scenario).

During improvement projects management of the external-internal affordance relationship was conducted from the total product perspective. In both cases, improvements in the complementarity of the affordances of each engineered product resulted from changes in the design of external human using and internal product working subsystem aspects of a product’s action possibilities. Therefore, the total product was the perspective for understanding how the external-internal affordance relationship was managed and a product’s complementary to specific use environment settings realised. Thus, the external-internal affordance relationship concept of an improved product affordance was evident within both cases.

7.2 A Consolidated Product Affordance Design Improvements: Analysis of the Relationship between Constructs

In section 5.7 and 6.7, the approach adopted by both company A and B to managing the external-internal affordance relationship during phases of improvements was presented. With reference to the six relationships conceptualised in chapter 3, the consolidated overview of the approaches adopted by both company A and B to managing the external-internal affordance relationship is visualised in figure 35 and discussed in the following section.
Relationship 1: Managing the relationship between a product’s standard design and improvable external and internal subsystem affordance aspects.

The products explored in both cases were complex products that evolved of decades of improvements to subsystem aspects. During each product improvement project, the settings of a product’s use scenario defined the benchmark for improving the complementarity of a product’s affordance design. In both cases, each improvement project represented another phase of the company’s attempts to improve the complementarity of the existing product’s design to specific use scenarios.

- In case 1, the headphone’s personal sound experience offering was improved,
- In case 2, the IPG device’s electrical follow thru capability was improved.

Relationship 2: Managing the relationship between the product’s standard design and action possibilities of delivering a specific utility offering.

Both companies managed the development of the external-internal affordance relationships by making assumptions about the consumer’s utility requirements. The complementarity of the utility afforded of either product’s design to specific use scenarios was dependent upon reconciling the compatibility of design changes to subsystem parts to use scenario settings. Compatibility was realised through the series of design decisions that coordinated how design changes to parts of each subsystem were
reconciled to specific settings (ear/physiology and anatomy or working principles of product) of different use scenarios.

Prior to any improvement phase, each product had been deemed by the improvement project manager to have a standard design that embodied human using and product working parts that afforded a utility offering that complemented the settings of different use scenarios. The need for improvement projects was determined by a project manager:

- In company A, the product engineering manager determined the need for improvement projects,
- In company B, the project director determined the need for improvement projects.

Throughout, design dialogue was focused on achieving a complementary set of external artefact-user and external and internal artefact-artefact interactions. Each company’s project manager monitored their product offerings on an ongoing basis for the existence of compromises in the compatibility of subsystem parts to specific use scenario settings. Each improvement project was initiated by the identification of compromises in the compatibility of the design of specific parts to specific product use scenarios settings.

- In case 1, improvement projects were driven by the identification of compromises in the headphone’s design (earpiece’s sound stage, driver’s operational resilience and diaphragm control at specific frequency level), and sought to improve the sound experience delivered by amending the standard design of different parts at different points in time.
- In case 2, driven by the identification of a compromise in the IPG device’s design (effectivity of header bond strength during implant and conductive core compatibility with cardiac lead technologies), and sought to improve the electrical follow thru capability by amending the standard design of different parts at that different points in time.

When compromises were deemed to exist, improvement teams were formed and members within the team were tasked with finding resolutions. The project manager determined the members required of a team to resolve the identified compromises.

- In case 1, company A’s improvement team typically consisted of a product engineering manager, a marketing manager, an accounts manager, an R&D
engineer, a product engineer, a mechanical engineer, a purchasing manager and a manufacturing engineer,

- In case 2, company B’s improvement team typically consisted of a project director, a process development director, a development manager, a process development engineer, a materials engineer, an R&D Engineer, and a principal mechanical engineer.

Improvement team members were tasked with implementing solutions to compromises. Finding resolution required improvement team members to identify the origin of the compromise. Improvement team members considered the “what if” of applying changes to subsystem parts. The “what if” scenario enabled team members assess if such changes inferred ways of accommodating human using and product working requirements whilst improving the complementarity of a product’s utility offering in specific use scenario settings.

- In both companies, improvement team members were challenged with identifying the design changes that would reconcile subsystem part designs to specific use scenario settings.

**Relationship 3: Managing the relationship between improvable product and user interface and functional part requirements and action possibilities of delivering a specific utility offering.**

The defined development requirements of a product revealed two subsystem development aspects and opportunities for improving design complementarity:

1. The “human using” features enabling perception of opportunity to connect external parts of the engineered product with the user (an external artefact to user affordance subsystem consideration) and other engineered artefacts (external artefact to artefact affordance subsystem consideration),

2. The “product working” features (internal artefact to artefact affordance subsystem consideration) of actualising embodiment of the technical capabilities within the engineered product’s configuration of internal parts.

During each improvement project a subsystem was identified as the focus of resolving identified compromises. Between both cases, five improvement projects were presented. The first three improvement projects were company A projects with an overview presented in section 5.7 of case 1, here after referred to as improvement project 1 (IP1),
Improvement project 2 (IP2) and improvement project 3 (IP3). The last two improvement projects were company B projects with an overview presented in section 6.7 of case 2, hereafter referred to as improvement project 4 (IP4) and improvement project 5 (IP5). The subsystem focus of each improvement project was as follows:

- Improvement project 1 focused on the external human using subsystem aspect of the headphone’s standard design. Changes were applied to the external form of the earpiece. This change enabled visual reference of an extended sound stage and improved the compatibility of the sound output to the physiology of the user’s ears,

- Improvement project’s 2 and 3 focused on the internal product working subsystem aspect of the headphone’s standard design. Changes were applied to the technical capabilities of the diaphragm and driver parts. These changes actualised a more efficient and resilient conversion capability and improve compatibility of the internal sound reproduction parts to the working principles of high frequency audio devices.

- Improvement project 4 focused on the external human using aspect of the header’s design. Changes were to be applied to the external form of the header. The change was required to enable visual reference of a strengthened bond between the header and PG can parts and improve the compatibility of external header and PG can parts by preventing the risk of disconnect during implant periods,

- Improvement project 5 focused on the internal product working subsystem aspect of the header. Changes were to be applied to the internal functional capabilities of the conductive core part. The change was required to enable embodiment of compatibility with new cardiac lead pin standards.

Improvement projects 1 and 4 revealed compromises in the compatibility of external subsystem parts. Improvement projects 2, 3 and 5 revealed compromises in the compatibility of internal subsystem parts.

Reviews enabled improvement team members identify how the internal or external part, if changed, would eliminate the compromise and improve compatibility with settings of the product’s use scenario.

A consolidated overview of the development actions taken by improvement team members during improvement projects revealed two coordinated series of design
considerations for reconciling the compatibility of design change to subsystem parts to use scenario settings:

1. Reconciling the compatibility of an external subsystem part resulted of improvement team members applying changes to the parts of the product’s external form. These changes amend the visual reference of the external parts to signify improved compatibility with specific product and user interaction settings,

2. Reconciling the complementarity of an internal subsystem resulted of improvement team members applying changes to the parts of product’s internal functional configuration. These changes amend how the interactive arrangement of parts are structured to actualise the technical capability of functions underpinning a utility offering.

**Relationship 4:** Managing the relationship between interactions of internal parts actualising a technical capability within and external parts of other products and the human body requiring interactions with the product.

Team members tasked with improving an internal or external aspects could not, independent of one another, definitively inform decisions on improvements to the complementarity of the utility afforded of a product’s design to specific use scenarios. The complementarity of a product’s external artefact-user and artefact-artefact interactions were dependent upon the adequacy of the technical design of internal artefact to artefact interactions. Improvements in the complementarity of a product’s design involved review of both the human using and product working parts of a product’s design. Each part characterised a subsystem design consideration, defining a context of improving the compatibility of parts of a product’s standard design to specific use scenarios.

During improvement phases, design dialogue focused on achieving consistency between the utility implied by interactions enabled with and utility actualised of interactions enabled within the product’s form.

Improvement team members explored the consistency between the utility implied of visual references of opportunity for product and user interactions with the product’s external form and the technical capabilities unlocked within the product’s internal configuration.
During an improvement project, the coordinated series of considerations that improved a subsystem part revealed another management challenge; reconciliation of design changes with related subsystem parts.

**Relationship 5:** *Managing the relationship between the action possibilities of delivering a specific utility offering and an improved standard product design.*

The resulting product subsystems were tested before release for compatibility with use environment settings. Complementary explored the extent to which the engineered product’s

- Technical capability integrated the working principles of artefacts the physiology of the user it required interaction with,

- Interface form enabled interactions with other artefacts and the anatomy of the user.

Each improvement project started with a subsystem focus that ultimately applied changes to a part of that subsystem. Improvements in the complementarity of that subsystem part’s design could reveal a knock-on effect that impacted the complementarity of other subsystem parts. The affected part(s) may exist within the same or different subsystem aspect to the initial improvement focus. In such a situation, further iterations of design were initiated to reconcile complementarity with use environment settings. Complementarity was dependent upon identifying and eliminating any knock-on effects on the compatibility of related subsystem parts.

Improvement projects 1, 2, 4 and 5 revealed no knock-on effects or requirement for further iterations of design changes. Improvements were achieved through design changes to one subsystem without compromising the complementarity of the other subsystem’s design. Only improvement project 3 revealed an example of a knock-on effect. Ultimately, improvement project 3 started with a focus on an internal subsystem part. Design changes applied to that part revealed the requirement for changes to be applied to related internal parts (voice coil) as well as an external subsystem part (earpiece width) to capture complementarity.

**Relationship 6:** *Managing the relationship between an improved standard product design and the specific utility settings of the product’s use environment.*
The resulting engineered products, when released, were reviewed for continuing competitiveness in a dynamic market. The dynamic nature of the industry and market standards (electronics & medical devices), required companies to conduct ongoing reviews of a product’s complementarity to changing use environment settings.

The attributes of each external part as well as the attributes of internal part, and their arrangement, represented a metric of conducting reviews. Reviews enable the focus of implementing an improvement, design changes to an external or internal part, to be defined. Additionally, review of the attributes of interactions enabled with (product and user utility interface) and within (actualising technical capabilities) a product’s design enabled improvement team member “infer when” the complementarity of a product’s affordance design was realised.

Insights from each improvement updated knowledge of subsystem design aspects. This knowledge was transferrable for use during future improvement projects.

- Insights from improvement project 1 (IP1), the open back form, was a transferrable piece of knowledge considered for adopted when attempting to improve a headphone’s design.
- Insights from improvement project 4 (IP4), the over-mould header design, was a transferrable piece of knowledge that would be considered for adopted or exclusion when attempting to improve future pacemaker designs,

Additionally, insights from preceding improvement projects became the focus of a new improvement project:

- Diaphragm design changes of improvement project 2 (IP2), became the focus improvement project 3 (IP3).

### 7.3 Consolidated Overview of Managerial Implications for Improving a Product’s Complementarity

Consolidated analysis of both case insights revealed management implications for improving a product’s complementarity to specific use scenarios:

1. Defining a practical rationale for initiating total product improvement projects,
2. Identifying the associated management challenge of implementing a subsystem (internal or external) improvement,
3. Realising the total product design complementarity to facilitate use scenario settings.

Each management implication is discussed

The *practical rationale of initiating improvement projects* was reflected by relationship 1 and 6. During each improvement phase a standard product design already existed. The existing product, shaped by preceding improvement phases, already embodied an accommodation of human using and product working aspects in the product’s design (relationship 6). However, when compared to use environment settings (relationship 1) there was opportunity or need for an improvement in the products design to be complementary to changing use environment settings.

The associated management *challenge of implementing a subsystem (internal or external) improvement* was reflected by relationships 2, 3 and 4. There were parameters of management (relationship 2). The improvement process was coordinated by a truncated version of each organisation’s formal product development process. Discourse took place within some of the stages of the formal development process that informed improvement to specific subsystem aspects (informed by considerations of relationships 3 and 4).

The *interactive aspects of realising complementarity* to a product’s use environment settings was reflected by relationship 5 and revealed when an improvement to a total product’s complementarity was realised. As knock-on effect were identified, improvements required revisiting prior decisions, those of relationships 3 and 4, and associated fits with each subsystem aspect of the product’s affordance relationship. The changing use environment settings of the product defined the constraints of each improvement phase.

**7.3.1 Three Stages of Managing the External-Internal Affordance Relationship Considerations**

Management implications span three stages in coordinating the external-internal affordance relationship during product improvements:
1. The initial stage driven by the practical rationale for initiating improvement projects, stage 1, is the start point for triggering product improvement projects. Improvements were initiated in response to assessment of and identification of compromises in the complementarity of an existing product’s design to changing use environment settings,

2. The analysis stage driven by the practical rationale of implementing a subsystem (internal or external) improvement, stage 2, involved two coordinating series of design considerations defining the focus of change to a specific product subsystem’s affordance relationship,

3. The implementation stage driven by the practical rationale of realising complementarity, stage 3, involved iterations of design changes to reconcile internal and external subsystems so as to realise product affordance design complementarity.

Each of the three stages are discussed. At stage one there is the existing product design. The standard design of this product defined the affordance relationship that existed. The complementarity of the standard design was interpreted from the external subsystem point (interactions enabled between the product and the user and between the product and other products), from which opportunities or the need for improvements were identified.

The complementarity of the product was inferred through comparison of assumptions of improvement team member perspectives of both the user’s requirements in use environment scenarios, and the utility deemed facilitated by the existing product’s standard design. The product was considering from the outside in to identify the subsystem (external or internal) that, if changed, would improve the complementarity of the product’s affordance relationship.

At stage 2 there was “subsystem level” dialogue with a focused on a specific subsystem aspect. Team members were concerned with realising improvements to a product subsystem aspect’s affordance relationship. Improvements were achieved through a focus on redesigning a part within the specific subsystem aspect (human using or product working).
As team members improved the subsystem aspect, they monitored the complementarity of changes to affordance relationship assumptions of stage 1. Two coordinated series of design considerations were revealed.

- The first coordinated series of design considerations represented improvement project dialogue concerned with improvements to external human using subsystem aspects of the product’s affordance relationship.
- The second coordinated series of design considerations represented improvement project dialogue concerned with improvements to internal product working subsystem aspects of the product’s affordance relationship.

Improvements resulting of changes applied to the subsystem aspect had potential to impact the complementarity of other parts. Improvements may be required of parts within the same subsystem or of parts within the other subsystem. Therefore, complementarity with the stage 1 affordance relationship assumptions occasionally required team members to consider moving dialogue to the other subsystem aspect, now potentially also requiring attention.

At stage 3 the management act was reconciliation, through discourse, between both subsystem perspectives to resolve conflict with each other.

There were defined metrics of enabling the external human using and internal product working subsystem aspects of the affordance relationship. The complementarity of the product was dependent upon consistency between the capabilities of interactions enabled with the product and the utility offering resulting of parts interacting within the product.

Central to the discourse was reconciliation of different perspectives of the affordance relationship. Reconciliation required an articulation of subsystem’s affordance relationships, a contextualisation of each subsystem’s affordance relationship aspect and contextualisation of the use environment for inferring complementarity against.

There were interdependencies between the 3 stages.
- Stage 1 reveals each product improvement project as a cycle that started with a review of the existing product’s standard design.
- Stage 2 revealed two potential coordinated series of design considerations for approaching the implementation of improvement to subsystem aspects of a part’s compatibility to changing use settings.
Stage 3 revealed how reconciliation of changed subsystem part designs may require consideration of the need for iterations of design to match related subsystem parts (artefact to user or artefact to artefact) of the total product’s affordance design (internal or external aspects) to changing use environment settings.

7.3.2 Five Steps of Managing a Total Product Affordances during Improvement Projects

From the discussion in sections 5.8.2 and 6.8.2, five steps in the process of managing the external-internal affordance relationship during phases of improvements emerge from insights on managerial implication stages. Each step is visualised in figure 36 and discussed in this section.

**Step 1: Review of the Engineered Product's Standard Design (The Start Point)**

The improvement team started each improvement project by identifying issues or opportunities for improvement in the affordance of an existing product’s design.

**Step 2: Evaluation of the performance based indicators of improvable affordance aspects justifying the need to initiate a phase of improvement**

Improvement team members examined known indicators and metric of a product’s utility performance to identify improvable subsystem(s). Examination assessed the ability of internal and external subsystem parts of the product’s standard design to deliver a utility offering. Assessment defined the origin of "compromises to" or "opportunity for" change to existing subsystems so as to realise improvements in design complementarity.

**Step 3: Identification of the Subsystem Focus defining how an improvement would be approached**

Once an inadequacy and the related affordance design compromise was identified, team members identified the subsystem design aspect and related part that, if changed, represented the focus of achieving improvement in complementarity.
**Stage 1: Start Point**
Practical Rationale of Initiating Product Improvements

<table>
<thead>
<tr>
<th>Step 1</th>
<th>Step 2</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>The Start Point: Initiating an Improvement Project via Review of the affordance relationships</strong></td>
<td><strong>Evaluation of Known Indicators of Product Performance to Identify</strong></td>
</tr>
<tr>
<td>Identification of issues (Compromise in the utility delivered or User Interface features) or opportunities (reduce cost, Enhancements to Utility delivered or Interface features) initiating need for an improvement project</td>
<td>Assessed the ability of internal and external subsystem aspects of the engineered product to deliver the utility offering, &amp; identified the product subsystem to be improved</td>
</tr>
</tbody>
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**Stage 2: Subsystem Design Change**
Implementing a Product Subsystem Improvement

<table>
<thead>
<tr>
<th>Step 3</th>
<th>Step 4</th>
</tr>
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<tbody>
<tr>
<td><strong>Identified the Subsystem Aspect of Driving Improvement to the Utility</strong></td>
<td><strong>The rational Basis of dialogue and decisions made when approaching the</strong></td>
</tr>
<tr>
<td>The identification of the subsystem aspect of implementing an improvement: change to an external part’s feature OR an internal part’s technical capability to refine the utility offering</td>
<td>Identification of the metric informing improvement dialogue &amp; decisions: Attributes of interactions shaped with or within the Engineered Product</td>
</tr>
</tbody>
</table>

**Stage 3: Subsystem Reconciliation**
Interactive Product Subsystem Considerations

**Step 5**
Knock-on Effect & Capturing Complementarity

Knock-on Effect: Identified if changes to a part impacted consistency of related parts (internal or external) to be complementary to use environment settings.

Iterations of design may be required to reconcile consistency between subsystem aspects and complementarity to use environment settings.

*Figure 36* The five steps process of managing the internal/external affordance relationship
Step 4: Identification of how dialogue and decision made were validated and implementation of improvements were inferred as realised

The attributes, of interactions enabled with or within the engineered product’s standard design, enabled team members determine how and if an affordance improvement was realised.

Step 5: Knock-on effect & iterations of subsystem design changes identified as required

Changes made to any part of the product required exploration of the potential for a knock-on effect to another subsystem part of the product. Iterations of design improvements, through changes to related subsystem parts, may be required to reconcile complementarity of interface with the anatomy and physiology of the user and other artificially designed objects to changing the use environment settings.

These five steps coordinated movement within each stage and between the stages. Stage 1, the start point of the practical rational of initiating improvements, involved the first two steps. Identifying issues or opportunities for improvement (Step 1) is achieved by examining known indicators and metrics of a product’s performance (step 2). The identification of compromises from step 2 triggers the move to stage 2.

Stage 2, implementing a product subsystem improvement, involves steps 3 and 4. These two steps define the design considerations coordinating improvements to external or internal subsystem designs. Step three identifies the subsystem design aspect and related parts of implementing an improvement. The improvement is implemented through step four, by applying changes to the design of attributes shaping interactions enabled with or within the product. The need to explore knock-on effects, triggers the move to the last management stage, stage 3.

Stage 3, reconciling subsystem designs, involves step 5. Changes made to any subsystem part of the product required exploration of the potential for a knock-on effect to parts within the same subsystem or to parts of the other subsystem. The coordinated considerations of steps 3 and 4 define the focus of any iterations of design changes to reconcile subsystems as a total product offering to be compatible with setting of the specific use scenario.
The five management steps, related to the three stages of management considerations, enabled the opportunity to update, as visualised in figure 34, the conceptual model of the external-internal affordance relationship” from the total product perspective. Figure 37 reveals that a use environment defines the context for (and, so moderates) improvement projects. Improvement projects are focused on improving the standard design, at a point in time, of an existing product. Management is cyclical. The output of an improvement project is an improved standard design that becomes the focus of a future improvement project. Management involves three inter-related stages of management considerations. Within each stage, five steps reflect how the three inter-related stages of management considerations are coordinated through a start point, two coordinated series of design dialogue and decisions on implementing subsystem improvements and iterations of design changes to reconcile a product’s subsystem aspects to changing use environment settings.

7.4 Consolidated Case Summary
This chapter has presented a consolidated overview of observations on practice based management of the case data and literature based insights of the external-internal affordance relationship. Deductions made allowed for generalised interpretations to inform the construction of a consolidated external-internal affordance subsystem management model. It is through this model that the theoretical affordance subsystem relationship was presented and explained enabling the researcher to conclude this chapter and move to the next chapter: Chapter 8 Conclusion & Contribution. Chapter 8 will provide an answer to the research question from which the theoretical contribution to product development management theory will be made.
Figure 37 Updated Model of Managing the “Conceptualised Concept of Affordances” from Figure 1
Chapter 8 Contribution

8 Contribution Introduction
This final chapter presents a discussion of the research in relation to the objective of exploring management of the external-internal affordance relationship during improvement projects. This chapter describes the contributions that have evolved from a proposed conceptual model of the external-internal affordance relationship through empirical explorations of practice, to the creation of a consolidated model of the external-internal affordance relationship management process, as visualised in figure 38. The resulting interpretations enable an answer to the research question and an outline of key contributions to theory and practice emanating from this research. The chapter concludes with implications for research in the future.

8.1 Outcomes of the Research Relative to Research Objectives
As illustrated in table 2 and discussed in the critical reflection sections of Chapter 2 - the literature review chapter, the existing literature discusses product affordance design from discrete internal or external subsystem perspectives of a product’s utility offering. However, users experience a product’s utility offering holistically through implementing the perceivable action possibilities of a product’s affordance design. This thesis research has explored the “total product affordance” perspective when managing external and internal affordance subsystem improvements. The objective of the research was to establish an understanding of how the concept of the external-internal affordance relationship was managed during improvement projects. Of concern was describing the process of coordinating external and internal subsystems affordance when improving an existing product’s complementarity to specific use environments. The research also explored how product use environment settings moderated management of product improvements in practice.

What has emanated from this research is an understanding of the process of managing the external-internal affordance relationship when implementing improvements in the complementarity of a total product’s affordance design.
Figure 38  Consolidated model of the External-internal Affordance Relationship Management Process
The broad overarching research question posed was “How is management of action possibilities in external subsystems coordinated with internal subsystems in order to achieve improvements in product affordance and complementarity with a use environment?” This research explored the process of managing improvements in the complementarity of existing product designs to specific product use environments. Each product explored comprised a standard design that accommodated human using and product working aspects of being complementary.

The broad overarching research question was answered through insights emerging during the consolidated case analysis of product improvement projects and the associated management process adopted in two different companies. These observations revealed the external-internal affordance relationship process, as visualised in figure 38. This process detailed how the implementation of improvements in the complementarity of each product’s affordance design was approached from a subsystem (external or internal) perspective.

The properties of each product’s use environment defined the use scenario and the settings for evaluating the complementarity of the product’s affordance design. However, the properties of each artefact exist in time, and are subject to change (Burlamaqui & Dong, 2014). “Technology, people, and cultures: all will change” (Norman, 2013 p 285) and will redefine the settings of a product’s use environment. In response, improvement teams were formed, with team members tasked with modifying existing product designs to accommodate the changing circumstances of the affordance relationship. Affordances, assessed through review of the standard design of the external and internal subsystem parts that shape a product’s action possibilities, enabled team members to determine the complementarity of a product’s standard design to specific product use scenarios.

During product improvement projects, internal and external affordance subsystem improvements required inter-related design considerations. The utility experienced through user interactions with a product’s external subsystem parts emerged as a result of the internal subsystem configuration of functional parts. The management challenge during each improvement project was maintaining complementarity of subsystem
affordance designs to changing use environment settings. The visual attributes of the product’s external subsystem parts signified product and user interaction opportunities that implied a specific utility offering. The attributes of a product’s internal subsystem parts actualised the technical capabilities that embodied utility functions consistent with the external interaction opportunities. The management challenge was complicated by the interdependency between the internal and external subsystems that underpin the product’s action possibilities.

This research has concluded that the relationship existing between internal and external subsystems and a product’s complementarity to a specific use environment requires “reconciliation” of subsystem part designs to changing use settings as the management concern during product improvement projects. Reconciliation has management implications for improving a product’s complementarity. There were three inter-related stages during improvement projects where affordance design dialogue was coordinated:

1. The initial stage of an improvement project, driven by the practical rationale for initiating an improvement.

2. The analysis stage, driven by the practical rationale for implementing subsystem improvements requiring two coordinated series of affordance design considerations to the compatibility of subsystem parts.

3. The implementation stage, featuring iterations of subsystem design changes to improve consistency between related subsystem parts and to reconcile the total product complementarity to changing use settings.

From a management perspective, the three stages involved five sequential steps. These steps enabled movement within and between the stages. Each step, located within a stage, defined elemental considerations of the process of implementing improvement in the complementarity of a product’s affordance design to changing use settings.

The challenge of “managing reconciliation” was initiated at the product level by team members identifying compromised subsystem designs and the need for specification changes to maintain compatibility with a use environment. Implementing changes to subsystem part(s) required a series of design considerations for improving the compatibility of individual subsystem designs to changing use settings. However, total product complementarity to the use environment also required team members to consider
the impact of such changes on related subsystem parts. Reconciling knock-on effects required further iterations of design changes to reconcile related subsystem parts to each other and to the changing use environment settings.

In summary, the external-internal affordance relationship management process has emerged as cyclical. The output of an improvement project defines a new affordance design standard, upon which future phases of improvement in complementarity may be initiated.

8.2.1 Closing a Gap in the Literature
The critical reflection of affordance literature revealed gaps in what was known and useful towards answering the research question. The research has enabled these gaps in our understanding of management of the external-internal affordance relationship during improvement projects to be closed.

Firstly, literature on product affordances was characterised by two perspectives of a product’s affordance development, human-using and product-working subsystem aspects (Kim & Lee, 2010). These two perspectives represented “what” required design within a product. Each has an important role. The product-working aspect focuses on actualising the embodiment of a utility function within a product’s configuration. The human-using aspect focuses on shaping the product form to signal user interaction opportunities enabling experience of the embodied utility. Whilst Maier & Fadel’s (2009, 2007) subsystems concept recognises both aspects as inter-related, the literature lacked insight on how the relationship between both subsystem considerations was coordinated for integration as a total product offering.

Secondly, affordances were presented as dependent upon development of a product design that embodied complementarity to specific use environments. Even if a product’s design was deemed to have developed subsystems compatible with use environment settings, Norman (2013) states that people, technology and cultures change. Such changes redefine the settings of a product’s use environment. Consequently, improvements to a product’s affordance design are required to reconcile compromises in the design of subsystem parts to changing use settings. The literature was silent on
management of improvements to the subsystem aspects that reconciled the action possibilities of a total product’s affordance design to changing use environment.

The thesis research has explored examples of incremental improvements to two existing product designs. Harmonious integration of both subsystem aspects within a total product offering required team members to monitor both subsystems’ design compatibility with changing use environment settings. The insights arising from this thesis research includes the five sequential steps which close the literature gap.

8.2.2 Summary Answer to the Research Question
The thesis research has presented case-based insights that answer the research question. The model presented in figure 38, illustrates how the process for managing the external-internal affordance relationship was coordinated to reconcile the complementarity of a product’s action possibilities to changing use settings. These two subsystem considerations require improvement team members to assess and infer if a product’s utility offering is complementarity to specific product use scenarios. During subsequent improvement projects, the design dialogue and decisions seek compatibility of individual subsystem part affordance designs and complementarity towards a total product offering.

A characteristic of affordance design emerged as interdependencies. At the product level, the interdependencies existing between the utility interface, the related functional capabilities and the setting of a product’s use scenario defined compatibility or compromises requiring reconciling. Such interdependencies between human-using and product-working subsystem aspects require design activities to implement the desired improvements. Implementing improvements in a total product’s affordance design had management implications requiring five steps to coordinate the three stages of design activities (start point, series of design consideration and iterations).

8.3 Contributions of this Research
The essence of this thesis is that the process for managing improvements to the external-internal affordance relationship begins with the existing product design and requires reconciling subsystem part specifications to changing use environment settings. Changing use environment settings may reveal compromised subsystem parts. The
implications may dictate a need to initiate an improvement project focused on the redevelopment of specific subsystem part specifications to maintain the complementarity that previously existed. The use environment settings are defined by the utility interaction requirements of other products and the users with the existing product. These settings define, in turn, the context for improving the complementarity of the human-using and product-working subsystem aspects. The management response is contingent and seen across three stages. Each stage comprises inter-related tasks, coordinated through five sequential steps. This conceptualisation of the management process is a contribution in relation to the gaps presented in the earlier literature review. The contribution is divided into two parts: theoretical and practical. The following sections discuss each in turn.

8.3.1 Contribution to Theory
The external-internal affordance relationship is an observable phenomenon in practice that focuses on coordinating improvements in the complementarity of a product’s affordance design to specific product use environments. This thesis research has explored management of the external-internal affordance relationship and built upon existing research on product affordance design in a number of different ways.

First, this research has used the product subsystem affordance concept, defined by Maier & Fadel (2009, 2007), as the conceptual basis. The results emanating from this research provide support for the basic premise of affordances in product design which improvement teams must take into account:

i. The external human-using aspect signifies a utility offering through perceivable interface opportunities with a product’s form. The improvement team’s task is to improve these opportunities.

ii. The product-working aspect actualises utility functions within a product. The improvement team’s task is to improve this actualisation.

As discussed and summarised in table 2 of chapter 2, the theory of affordances lacks insight on the management process coordinating how improvements in complementarity of a product’s affordances are approached. The adequacy of a product’s affordance design requires ongoing monitoring, through review of subsystem parts, of the compatibility of existing external and internal subsystem’s designs with specific settings of the product’s use scenarios. However, as a user’s mindset or technology change, the settings of a
product’s use scenario may require redefinition and compromise in the compatibility of specific subsystem part designs. Therefore, management involves reconciliation of subsystem part designs to the changing use environment settings in order to restore relational complementarity. This is an ongoing product development management challenge. The corresponding aim of team members must be to seek a balance between subsystem design aspects and use environment settings. The external-internal affordance relationship management process model seeks to create an understanding of how this balance is realised.

The management model is presented in figure 38, with three stages of management considerations in the process to improving a product’s affordance complementarity. Each stage, defined by sequential steps, coordinates dialogue informing decisions that improve a product’s complementarity:

- Stage 1 reveals the start point with a review of the standard design of subsystem aspects of an existing product’s affordances, and defines the rationale for initiating a phase of improvement.

- Stage 2 reveals the two coordinated sequences of design consideration - changes to external form or internal functional part specification - when implementing improvement in a subsystem’s complementarity.

- Stage 3 reveals iterations as the basis for reconciling conflicts and the knock-on effects of a changed subsystem part specification towards consistency between internal and external subsystem parts and complementarity of the total product with specific use environments.

Reconciliation of complementarity with changing use scenarios involves management of total product improvement. Of concern is integrating design considerations of both subsystem aspect, addressed through completing the steps of the three management stages.

Second, the results of this research suggest that current conceptions of the external-internal affordance relationship do not correspond with how it is improved in practice. One of the main reasons for this discrepancy in the product affordance design domain is that there is a tendency to undertake research from the perspective of an external or internal subsystem’s affordance requirements. These two perspectives reflect what a product should be designed to afford complementarity; interface with the product or
embodiment of functions within the product’s configuration. However, whilst there are many studies investigating external and internal subsystem perspectives, none have focused on how the external-internal affordance relationship is managed during product improvement projects to maintain complementarity to specific product use environments. This complementarity cannot be improved if dialogue is absent and the redesign of individual subsystem aspects occurs in isolation of one another. This thesis research proposes that improving a product’s affordances is dependent upon multi-disciplinary team dialogue. Thus the theory of product affordances and the processes informing its management are extended through this new understanding of the practices being implemented in practice.

Third, the importance of the role of interdependencies between the process and product is highlighted by the findings. The complementarity of a total product’s design to use environment settings identifies interdependencies to be coordinated, defining how projects focused on improving a subsystem’s compatibility should be approached and complementarity reconciled.

Fourth, existing research has failed to take into account the need for reflection upon the contextual management concerns that exist at the overlap between subsystem affordance perspectives. This thesis research argues that management of a product’s complementarity is contextual and dependent upon understanding and improving the integration of both subsystem’s considerations.

Fifth, this research also contributes a management perspective to the product affordance literature. As summarised in table 2 of chapter 2, most researchers focused on the external or internal subsystem aspect of a product’s affordance design. No attention has been given to an in-depth understanding of the inter-relationship between the different but related subsystem design perspectives or how improvements in a product’s affordances were coordinated. Studies thus neglected establishing an understanding of the complex nature of how the total product affordance relationship process was managed during improvement projects. The external-internal affordance relationship model developed in this research provides researchers with a research-based view of the management process coordinating improvements in a total product’s complementarity to specific use environments.
8.3.2 Contribution to Practice
From this research a number of contributions to practice arise.

A model of the approach to managing improvement of the external-internal affordance relationship in practice is presented. This model emerged from consolidated insight on how two different design organisations successfully improved the complementarity of existing product affordance designs to changing use environment settings. Thus, by revealing the management process for coordinating improvements this model enables decision makers in product development teams to challenge assumptions held on how affordance designs can be approached and improvements to complementarity realised.

Improvements in a product’s complementarity involves use of multi-disciplinary improvement teams. Improvement teams comprise internal and external subsystem developer voices that collectively enact the task of capturing the seen (internal team voices) and silent (external consumer and regulatory voices) views that inform improvements in a total product’s complementarity. Careful planning and coordination of dialogue between improvement team members is paramount to the adequacy of decisions made during an improvement project. During improvement projects multi-disciplinary team dialogue may be coordinated so as to define the improvement focus and set of development tasks for restoring the product’s complementarity to redefined use environment settings.

In addition, the external-internal affordance relationship process may be viewed as a cycle for implementing amendments to subsystem parts of existing product designs. It is through the redesign of subsystem parts that the complementarity of a total product’s design is improved in the changing setting of a product’s use environment. Changing settings define the need for an improvement project to be started, requiring coordination of a series of subsystem design considerations (including subsystem part changes) to restore a product’s relational complementarity. Neglecting to see and use changing use settings as a moderating influence of the need for amendments to subsystem aspects can impact the complementarity of a product’s utility in specific use environments.

Finally, product affordances are incrementally improved over time and require management from a total product perspective. Understanding this integrated total
product perspective is beneficial to education of the next generation of practitioners as it builds awareness of subsystem interdependencies and the broader managerial context for reconciling the complementarity of product affordance designs to changing use environment settings.

### 8.4 Limitation of the research

This section reflects upon the limitations of this thesis research and what remains unexplored. Four limitations are identified relative to the boundaries of the research.

1. This research explored the external-internal affordance relationship process for coordinating improvements in the complementarity of existing product to use environment settings. Two cases were explored, limiting both observations and generalisations.

2. This research explored “physical” products, limiting the applicability of the conclusions to this category.

3. In this research, exploration was limited to “the product’s external and internal subsystem affordance aspects” but excluded other aspects of the total product such as “packaging”, for example. Therefore, observation and conclusions drawn were based upon the development team’s assumptions of the requirements of the primary user and changing settings of the product’s use environment. The research did not take into account the user’s voice or other user considerations such as those of the retailer.

4. The nature of the companies chosen for the research was well defined and focused on large systematic organisations. Additionally the research was conducted retrospectively on successful product designs that evolved over decades of improvements. Therefore, the nature of the companies and the types of product selected for exploration place a limitation on the observations and the generalisations that can be made.

### 8.5 Future research

There are five potential directions for conducting future research on findings from this thesis research.

1. How the external-internal affordance relationship management process findings apply beyond this research project:
A direction that future research could take concerns the conceptual framework developed in this thesis research and whether the findings apply to other established products with the same kind of subsystem affordance design improvement requirements. Other examples of products that have been improved and involved actors knowledgeable in each of the specific subsystem design aspects could be explored. Further research could be conducted to refine, modify or confirm the framework by replicating it in different use case contexts. By studying different product affordance improvement cases, the findings developed in this research could be generalised to a wider context.

2. Role of the External-Internal Affordance Relationship Management Process with Non-Physical Products:
This research focused on interacting external and internal product subsystems, where interdependencies of the process impacted upon interdependencies of the physical product’s affordance design. However, what if the product did not require a physical artefact for specific user or product interactions, as for example a telemetry system with product to software system interface requirements. Further research is needed on subsystem interactions with non-physical products towards clarifying the explicit role of managing the external-internal affordance relationship.

3. Product Selection Criteria
This research used existing physical products with discernible subsystem design aspects, as the product selection criteria. Future research opportunities lie in management of the external-internal affordance improvements such as packaging or from the perspective of the retailer.

4. Design Company Categorisation
The nature of the two design organisations, selected for the thesis research, could be categorised as large organisations exhibiting specific design improvement strategy. Future research could explore the phenomenon in companies such as SMEs with breakthrough products.

5. Management Stages
Three stages of management implications and related steps emerged from case observations. A direction that future research could take concerns the opportunity to
explore how these management implications apply in the improvement of other products with the same kind of subsystem design improvement requirements as well exploration of additional or alternative management stages and related steps.

8.6 Publication Plan
This research reflected upon and established the limits of the known work on the concept of the external-internal affordance relationship. Three peer reviewed academic journals represented the main source of product affordance insights and were particularly useful in establishing an understanding and contextualisation of the management of improvements to the affordance relationship: the Journal of Product Innovation Management (JPIM), the Journal of Design Studies and the Journal of Research in Engineering Design. These three journals are peer-reviewed academic journal and represent the type of journal publication that the researcher is targeting for publications arising from this thesis.
Bibliography


Appendices

Appendix A: Research Protocol

Introduction:
My Name is Patricia Maher and I am a doctoral student in Trinity College Dublin. To complete my PhD I am looking for a case company that engages in product development improvement projects.

Research Objectives:
The general objective of this study is to explore management of the external-internal affordance relationship during product improvement projects. The research aims to determine the process to managing improvements in existing product designs, relative to specific use environments. The external-internal affordance relationship refers to the relationship between two subsystem (external and internal) aspects that shape a product’s utility offering and its complementarity in specific use scenarios. The two subsystems refer to the external human using interface features and internal product working or functional aspects of a product. Subsystems are presented as improvable and useful in exploring how a product’s complementarity in dynamic use environments is maintained. This research has important implications for affordance design theory and product design companies. It aims to provide an understanding of the process for managing overlapping product subsystem development considerations during improvement projects. Currently, product affordance design research has been overly focused on either external or internal subsystem aspects of a product’s design and as a result, design literature fails to take into account that subsystems are overlapping utility affordance considerations. Additionally, product affordance design is not understood from the product improvement perspective. Subsystems enable backward reasoning on the complementarity of interface and functional aspects of existing product designs to specific product use environments. However, there is no model of the external-internal affordance relationship management process during improvement projects.

Case Study Issues:
I am contacting your company because it is known for having developed successful product offerings that have been incrementally improved over time to maintain complementarity to a dynamic use environment. Maintaining complementarity involves re-design of subsystem aspects that compromise the utility afforded. External and internal subsystem aspects of a product’s design are identified as the focus of dialogue during the improvement process and a criteria for selecting products improvement projects for this research. In essence, I am looking to your company for a guide for determining the product improvement process. Essentially, I am looking to explore how your company has implemented product development management of the external-internal affordance relationship during improvement projects.

Benefits to your Company
The findings of the research should prove beneficial to your company because it will devise a model of the process to managing the external-internal affordance relationship. Furthermore, this model will contribute significantly to product development management practice.
Important Issues about Researching In Your Company:
The case study method by which the research will be conducted is designed to cause as little disruption to work as possible. A research schedule will be designed around what best suits your company.
I will respect confidentiality and recognise as private, discussions and observations during the research period. In effect, Research will be conducted in line with Trinity College Dublin ethical guidelines and for confidentiality reasons, Non Disclosure Agreements (NDA) can be signed by myself prior to being permitted access.
A report of the case to be included in will be presented to the company for confirmation that all information is accurate.
Finally, the proposed research should take approximately ten to twelve months to complete.

Data Collection Template:
Data collection will involve interviews, document reviews, observations and archival records. Interviews will be very informal and unstructured and would involve no more than four to five hours per site visit. Three to four site visits may be required depending on the nature of the data gathered from interviewees. Any interviews to your company will be pre-arranged.
Documents related to the product chosen to conduct research on and the product improvement process will be important to this research. Observation of the manufacturing and assembly process of the chosen product as well review of archival record of similar product and processes will be of interest.

Final Comment:
I appreciate the demands that are placed on individuals in a hectic working environment and that there may be concerns over issues such as whether I would interfere or cause disruption to work. If granted the privilege of researching within your company, I will conduct the research in a diligent and professional manner. The research method is designed to facilitate easy access and cause as little disruption as possible to the important work being carried out in your site. This research is innovative and never conducted before. By allowing me to research your company, not only will I be able to complete my doctorate, but we will be significantly contributing to the generation of new knowledge.

I look forward to hearing from you.

Yours Sincerely,

Patricia Maher
Doctoral Research Candidate
Trinity College Dublin
### Appendix B: Interview Guide

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<td>Personal Interview 1</td>
<td>Introductory meeting about the company and product profile, the external-internal affordance relationship research context, the focus on product improvement projects and the objective of establishing the improvement process, understanding the product and selecting product improvement project examples for exploration.</td>
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<td>Personal Interview 2</td>
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<td>Telephone Interview 2</td>
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| Personal Interview 3 | Discussion on:  
  - The product’s environment of use  
  - The external and internal subsystem requirements of the product being used for exploration of the improvement process,  
  - The use context motivating external and internal subsystem development during the product development and improvement projects,  
  - The multi-disciplinary improvement team voices involved in dialogue during staged consideration of the PDP and improvement initiatives, |
| Telephone Interview 3 | Questions to clarify some points made in Interview 2 and arrange Interview 4.                                                                                                                                  |
| Personal Interview 4 | Validation of data collected through review of the written up case narratives and analysis of observations.                                                                                                         |
### Appendix C: NVivo Sources Screenshot

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Appendix D: NVivo Nodes & Coding Screenshot

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### Use Environment
- Subsystems
- External Subsystems
- Improved Product Affordances
- Interactions Enabled With
- Interactions Enabled With

### Coding Density
- Internal Subsystem
- External Subsystem
- Artifacts Design
- Interactions Enabled With
- Action Possibilities

### 3.5.1 Improvement Example 1: An Improvement to PG Effectiveness via Header Form Design

Traditionally for this component systems were designed and developed by different organizations. Prior to 2000, company B’s case design competence was Poor Generating (PG) case development.

*However, company B also manufactured finished IPG devices, resulting in the assembly of their PG can part with an externally mounted header part. Assembly involved the mechanical fixation of the purchased header frame to the housing case.*

Mechanical fixation involved bonding the header from the top of the PG can. The process of bonding the header involved design inadequacies into the finished parameter device. The header was complicated by how assembly of the off-the-shelf nature of the pre-constructed header part exhibited “manufacturing inefficiencies.” The mechanical fixation comprised multiple layered applications of medical adhesives which built in redundancies in the assembly process and still exhibited poor adhesion properties to the housing.

*The pre-assembled PG header requires multiple applications of the medical adhesive during the final assembly process. Each application requires care in the entree to two hours. These steps can cost one or two days, impacting both the lead time and damage risk to the material and equipment within the body. (KDC)*

Issues of how the “off-the-shelf nature” of the header was integrated into the manufacturing and assembly process required company B to manage development of a solution. Management of a solution was challenged by the integrated nature of these two technical devices. Design and development of an “over-molded” rather than an inserted bend between the header and pin generating can was identified as the solution.

This improvement project focused on the development of an integrated Header Replacement can part, a 2 to 3 component system, with development to be managed through context of realizing technical integration within the 3 requirement constraints.

Poor adhesion compromised the bond strength that was critical to ensuring isolation of conductive input and output connectors to the pin generating case and to prevent bulky fluid ingress that would
Appendix E: NVivo Relationships Screenshots

Relationships Created and Used for Analysis in NVivo:

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<th>Type</th>
<th>To Name</th>
<th>To Folder</th>
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<td>Subsystems</td>
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3.5.1 Improvement Example 1: An Improvement to PGM1 Activity via Header Form Development

Traditionally, the three piece-frame systems were designed and developed by different organizations. Prior to 2009, company B’s core design competencies were PGM1 Processing (PGM1) systems development.

However, company B also manufactured finished SPG devices, resulting in the assembly of their PGM1 part with an externally processed header part. Assembly required the mechanical fixture of the purchased header form to the housing can.

Mechanical function involved indexing the header form to the top of the PGM1 can. The process of bonding the header to the header form made up the finished header assembly. The header was assembled by an assembly of the off-the-shelf nature of the pre-assembled header part exhibited “manufacturing efficiencies”. The mechanical function systems comprised multiple layered applications of medical adhesive which had built-in variables in the assembly process and still produced poor adhesion properties in the housing.

The pre-assembled PGM1 header required multiple applications of the medical adhesive during the upper assembly process. Each application requires a series of intervals between applications to dry. Furthermore, the process could not be dried at the same time as bonding to the header form due to the minimal adhesion properties in the housing.

Issues of how the “off-the-shelf nature” of the header was integrated into the manufacturing and assembly process resulted in company B’s inability to manage development of a solution. Management of a solution was challenging by the integration of these technical systems. Design and development of an “off-the-shelf” header was identified as the solution.

This improvement project focused on the development of an improved Header Process Generation can part, a 22 component system, with development to be managed from content of realizing technical integration within a 1 year requirement constraint.

Poor adhesion compromised the bond strength that was critical to ensuring retention of conductive strip and output connectors in the potted generating card and prevent bodily fluid ingress that would cause shorting to occur.
Appendix F: Screenshot of Case Organisation’s email Verification of Case Write-up Validity

Patricia,

Sorry for taking so long to get back to you. We all reviewed the case study and actually met again to finalise all comments before getting back to you. They would probably kill me if they knew that I was only getting back to you now!!!

Overall, there were no major concerns. I know [redacted] had flagged during your last visit that he had concerns about some of the [redacted] content and the confidentiality of it. After reviewing with [redacted] as well, they're happy to go with the existing content.

Thanks,

[redacted]
Appendix G: Case 1 NDA

NON-DISCLOSURE AGREEMENT

between

the Company [redacted]

- hereinafter referred to as "[redacted]" -

and

Patricia Maher
Lecturer, Waterford Institute of Technology, Cork Road, Waterford City
Doctoral Candidate, Trinity College Dublin 2.

- hereinafter referred to as "BB" -
CONTENTS

Preamble

1. Subject Matter

2. Use of Evaluation Material

3. Prohibition of Development / Production / Use

4. Exceptions

5. Employees

6. Liability for Damages

7. Duration

8. Restraint

9. Miscellaneous
In the context of exchange of ideas regarding possible future cooperation with respect to Doctoral Research on Product Affordance Design ("the Project"), both parties are willing to disclose certain information to each other, subject to the following terms and conditions:

1. **Subject Matter**

   Both parties hereby undertake to maintain strictest secrecy and to not make available to third parties any and all information classified as "confidential" which may become known to one or the other or is to be provided to one or the other within the context of the Project (hereinafter referred to as "Evaluation Material" or "Know How").

2. **Use of Evaluation Material**

   Both parties hereby undertake to use the Evaluation Material solely for the purpose of evaluating the Project and the later entry into final contractual arrangements ("Main Contract").

3. **Prohibition of Development / Production / Use**

   Both parties are hereby expressly prohibited from undertaking actions on its own to use the Evaluation Material to develop or produce, or to allow third parties to develop or produce, products or any applications thereof, or to otherwise directly or indirectly economically exploit said Evaluation Material.

4. **Exceptions**

   The duties under this Agreement do not apply in case of:

4.1 Know How already in the rightful possession of the other party;
4.2 Know How already developed by the other party on its own;
4.3 Know How obtained from a third party without that party violating any duties of confidentiality;
4.4 Know How generally available in the public domain;
4.5 Know How becoming publicly available during the duration of this Agreement;
4.6 Know How given by the disclosing party to a third party without a non disclosure agreement;
4.7 Know How disclosed to legal advisors and/or mandatorily disclosed in dispute resolution proceedings and/or mandatorily disclosed as per a governmental body or an administration. The party who is requested to disclose the confidential information of the other party, shall provide the other party with prompt prior written notice of any such request or requirement so that such other party may seek a protective order or other appropriate remedy.
5. Employees

Both parties hereby obligate themselves to impose this duty of confidentiality upon all of their employees, advisors, consultants etc. who, on the basis of their activities, might acquire useful knowledge regarding the Evaluation Material. The duty of confidentiality shall be so implemented as to apply as well following termination of their respective contracts. Each Party may disclose Confidential Information only to those of its employees who have a need to know in connection with the project.

6. Liability for Damages

6.1 In case of a violation of its duty to maintain confidentiality, the party who committed such violation is liable for all damages including consequential damages.

6.2 For each instance of a violation, the party who committed such violation hereby undertakes to pay liquidated damages in the amount of EUR 150,000.00 to the other party, who, in turn, hereby reserves the right to assert higher damage amounts.

7. Duration

7.1 Should the parties enter into a Main Contract, the confidentiality agreement contained therein shall replace this Agreement.

7.2 In the event that a Main Contract is not concluded within the period of twelve (12) months following the signature of this Agreement, each party shall be required to return to the other without its having to make a request, the totality of the Evaluation Material which it has received from the other party up to that point in time. Both parties hereby obligate themselves already now to not retain any copies thereof or any other records containing information which is subject to this Agreement.

7.3 In the event that a Main Contract does not come into existence within the period contained in Section 7.2, the terms of this Non-Disclosure Agreement shall be valid for the period of three years following the signature of this Agreement.

8. Restraint

Both parties and all of their affiliates shall be restrained for a period of five (5) years after the date of this Agreement from entering into a new business relationship with any employees, sales agents, service providers etc., named in the Evaluation Material.
9. **Miscellaneous**

9.1 This Agreement shall replace all oral or written agreements entered into prior to its closing and shall conclusively govern the relationship between the parties.

   Additions to and modifications of this Agreement shall require written form. This also applies to this writing requirement.

9.2 Should one or more of the provisions of this Agreement be invalid or become invalid, the validity of the remainder of this Agreement shall not be affected thereby.

   The invalid provision shall be deemed to be replaced by a valid provision which most closely approximates the economic meaning of the invalid provision.

9.3 German law applies.

9.4 All disputes arising in connection with the present Agreement shall be finally settled by the German court in Hanover.
Title: __________________________

Date: __________________________

(Signature Mr. / Ms. ________________)

Title: __________________________

Date: __________________________

(BB)

Signature Mr. / Ms. ________________

Title: __________________________

Date: __________________________

Place: __________________________
MUTUAL NONDISCLOSURE AGREEMENT

THIS NONDISCLOSURE AGREEMENT ("AGREEMENT") is entered into effective as of the 5th day of April, 2013 ("EFFECTIVE DATE"), by and between [Company Name], a corporation having a principal place of business at [Address], and Patricia Maher, having an address at Waterford Institute of Technology, Cork Rd, Waterford.

WHEREAS, the parties are considering entering into a potential business, research or development collaboration relating to cardiac rhythm management therapies and/or devices, including, but not limited to, [Additional Technologies], and other related technologies (hereinafter the "COLLABORATION");

WHEREAS, the parties each possess certain confidential and proprietary information relating to the potential COLLABORATION (hereinafter the "CONFIDENTIAL INFORMATION"); and

WHEREAS, each party wishes to examine the other party’s CONFIDENTIAL INFORMATION solely for the purpose of considering entering into and furthering the potential COLLABORATION (hereinafter the "PURPOSE"), and each party is willing to disclose its CONFIDENTIAL INFORMATION for the PURPOSE.

NOW, THEREFORE, the parties hereby agree to the following terms and conditions:

1. Each party intends to disclose certain CONFIDENTIAL INFORMATION possessed by it to the other party to enable the receiving party to fully evaluate the same. To be protected hereunder, CONFIDENTIAL INFORMATION must be disclosed in written or other tangible form conspicuously labeled as “Confidential.” Oral or visual disclosures for which protection is sought must be identified at the time of disclosure as being disclosed in confidence, reduced to written or other tangible form, marked as “Confidential” or “Proprietary,” and delivered to the other party within thirty (30) days of such oral or visual disclosure.

For purposes of this AGREEMENT, CONFIDENTIAL INFORMATION shall include, by way of example only, data, know-how, formulae, processes, designs, sketches, photographs, plans, drawings, specifications, samples, reports, studies, findings, inventions and ideas, customer lists, patient information, technical data, marketing and financial plans, and production or purchasing schedules or forecasts.

2. Each party agrees that it will treat the CONFIDENTIAL INFORMATION received from the other party with reasonable care to avoid disclosure of the CONFIDENTIAL INFORMATION to any third party, person, firm or corporation, and each party shall be liable for unauthorized disclosure or failure to exercise such reasonable care. The receiving party will use the same degree of care to avoid disclosure of the other party’s CONFIDENTIAL INFORMATION as it employs with respect to its own proprietary information of like importance. Further, the receiving party shall disclose the other party’s CONFIDENTIAL INFORMATION only to its employees, agents, affiliates or vendors as is reasonably necessary for the PURPOSE and such employees, agents, affiliates and vendors shall be informed of their obligations of confidentiality and restricted use as set forth in this AGREEMENT.

3. Each party further agrees that it shall use the CONFIDENTIAL INFORMATION disclosed to it solely for the PURPOSE as stated above. No additional rights are provided to either party under any patent applications, patents, trade secrets, or other proprietary rights of the other party. Neither party shall be entitled to make any use of CONFIDENTIAL INFORMATION provided by the other, except as explicitly set forth herein as PURPOSE, without separate written agreement to that effect.
4. Neither party shall have any obligation under this AGREEMENT, with respect to the CONFIDENTIAL INFORMATION, or any part thereof, which:
   (a) is already known to the receiving party at the time of the disclosure;
   (b) becomes publicly known without the wrongful act of breach of this AGREEMENT by the receiving party;
   (c) is rightfully received by the receiving party from a third party on a nonconfidential basis;
   (d) is approved for release by written authorization of the disclosing party;
   (e) is subsequently and independently developed by employees of the receiving party without knowledge of the CONFIDENTIAL INFORMATION provided by the other party, or
   (f) is disclosed pursuant to any judicial or government request, requirement or order, provided that the party so disclosing takes reasonable steps to provide the other party sufficient prior notice in order to contest such request, requirement or order.

The burden of proving the existence of facts which would negate the receiving party's obligations of confidentiality and restricted use set forth in this AGREEMENT under this paragraph shall rest with the receiving party.

5. Each party agrees to return to the other all written CONFIDENTIAL INFORMATION received hereunder upon completion of its use or upon request of the party supplying the CONFIDENTIAL INFORMATION; provided, however, one copy of such material may be retained by the receiving party to preserve a record of the same.

6. This AGREEMENT shall terminate twelve (12) months from the EFFECTIVE DATE or earlier upon fifteen (15) days written notice. The non-use and non-disclosure obligations of this AGREEMENT shall expire five (5) years from the first date of receipt of such CONFIDENTIAL INFORMATION, or if such CONFIDENTIAL INFORMATION is not dated, five (5) years from the EFFECTIVE DATE.

7. This AGREEMENT shall be construed under and according to the laws of Ireland.

8. This AGREEMENT shall not be assigned, in whole or in part, by any party hereto without the written consent of the other party. If legal action should be brought to enforce any of the terms of this AGREEMENT, the prevailing party shall be entitled to recover reasonable attorney's fees and costs of the action. The covenants contained in this AGREEMENT may be enforced by either party through court injunction or restraining order granted by an appropriate court of competent jurisdiction, in addition to whatever other remedies are available at law.

IN WITNESS WHEREOF, the parties have caused this AGREEMENT to be executed by their respective duly authorized officers as of the EFFECTIVE DATE.

By: _____________________________
    Patricia Maher
    (Printed Name)
Title: Business Information Systems Lecturer
Date: ____________________________

By: _____________________________
    (Printed Name)
Title: ____________________________
Date: ____________________________
Appendix I: Useful Background Data to Case 1

A headphone’s design is constrained by an understanding of what sound is, the auditory physiology of the human ear, head & ear anatomy and the working principles of audio devices.

Sound is a vibration, a mechanical wave that results of oscillation (repetitive variations) of air pressure. Longitudinal sound waves are produced by these variations in air pressure.

Hearing is the process by which the ear transforms sound vibrations in the external environment into nerve impulses that are conveyed to the brain, where they are interpreted as sounds.

Sounds are produced when vibrating objects, such as a headphone’s internal driver part, produce sound waves.

Every sound that reaches our ears is transferred to the brain in a complex, yet extremely fast, process. We do not consciously experience sound waves as sound until this information reaches our brain. There are 5 parts of the ear which, as visualised in figure A, interact to translate longitudinal sound-waves into a sound experience. These are the pinna, the ear drum, the tympanic cavity, the inner ear and the auditory nerve.

The **pinna** (outer visible part of the ear) collects the longitudinal sound waves and routes them directly to the eardrum. The incoming sound-wave causes the **eardrum** to vibrate which in turn actuates the workings of the **Tympanic Cavity**. The Tympanic Cavity’s hammer, anvil and stirrup are responsible for the playback and amplification of the vibrations by transferring the sound-wave to an area in the **inner ear** that is filled with fluid. Thin hairs cover the basilar membrane in the cochlea of the inner ear. These hairs transform the vibrations of the inner ears fluid into electrical impulses. Once converted into electrical impulses, the sound is transferred to the brain via the **auditory nerve**. The acoustic stimuli that were encrypted as electrical impulses are now sorted and sent to the appropriate parts of the brain. The information from both ears converges in the auditory centre, the auditory cortex, where the brain assigns meaning to the impulses so that we can understand what we have just heard.
A headphone is designed to enable interactions between the headphone and the user’s ear. Delivering sound waves to the ear is dependent upon understanding the external anatomy of the ear and design of interaction features required of a headphone to adequately channel soundwaves into the ear.

Figure B visualises the many points of a user’s head and ear that must be considered towards shaping a headphones earpiece form design. No two people are the same. However, the dimensions of the average head (width of 155mm and height of 215mm) and ear (angle of 40° & 65mm length * width of 35mm) form the basis of decisions on earpiece to ear fit (45° earpiece to ear angle) and headband to head fit.

Audio is sourced from audio devices. Therefore, a headphone is also designed to enable interactions between the headphone and an audio device. Audio devices output electrical audio
frequencies. This output format, as visualised in figure C, is not compatible with the soundwave format required of the human ear. A requirement of a headphone’s design is the technical capability to convert the electrical frequency input from the audio device into a sound wave that realises compatible with the physiology of the human ear.

The internal configuration of functional parts actualises the technical electro-mechanical conversion capability of producing a compatible sound waves output. The working principles of audio devices defines how a headphone’s internal configuration is developed to produce soundwaves deemed compatible with the physiology of the ear. The internal configuration of parts are developed to operationalise functional states that translate the electrical audio frequency into a mechanical wave that propels sound outwardly to the user’s ear.

![Figure C Internal Electro-Mechanical Conversion](image-url)
Appendix J: Useful Background Data to Case 2

Your heart has its own internal electrical system that controls the rate and rhythm of your heartbeat. With each heartbeat, an electrical signal spreads from the top of your heart to the bottom. As the signal travels, it causes the heart to contract and pump blood.

In a normal functioning heart, the pumping action is synchronized by the pacemaker region of the heart, or sinoatrial node, which is located in the right atrium. This is a natural pacemaker that has the ability to create electrical energy. Unfortunately, the natural pacemaker can malfunction, leading to abnormal heartbeats. A pacemaker is required to treat disease states such as bradycardia, tachycardia, congestive heart failure and sudden cardiac death.

A pacemaker, as visualised in figure D, is a small device that’s implanted within the patient’s chest. This device uses electrical pulses to prompt the heart to beat at a normal rate. Pacemakers monitor your heart’s electrical activity and heart rhythm, stimulating delivery of electrical therapy to help control abnormal heart rhythms.

![Implant location for a pacemaker device](image)

The pacemaker is a medical device that is only permitted for release to the market if its design has been approved by ISO and FDA regulatory bodies.

Electrical therapy is generated by the pacemaker but delivered by the cardiac lead. Consequently, cardiac lead technologies represent a constraint on pacemaker development. Cardiac lead have a standard design comprising one or three connector pins. A pacemaker’s design is complicated by the necessity to be developed to be compatible with the cardiac lead’s connector pin design.