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I, Cecilia Arredondo, hereby submit this original work as part of the requirements for the degree of Master of Design in Design.

It is entitled:
Imbued Medical Device Design

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Imbued Medical Device Design

A thesis submitted to the
Graduate School
of the University of Cincinnati
in partial fulfillment of the
requirements for the degree of

Master of Design

In the School of Design of the College of Design,
Architecture, Art and Planning

By

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Abstract

Aesthetics is a branch of philosophy associated with art and beauty (Zhang, 2009). Aesthetic design is directly correlated with imbued design. Imbued design means to evoke a user's feeling or emotion through an object or service. Its process uses analogy to understand functionality and metaphor to translate into aesthetics. Historically, medical device design has been based solely on functionality. Ruled by the principle “form follows function”, aesthetics are left to be applied at the end of the medical device development process. In design, the lack of aesthetics is defined as a lack of communication. Physicians require tools and information that simplify their everyday complex tasks. In order to test this theory, a simple medical device was developed for the purpose of visualizing and removing air bubbles from the arterial lines used in Interventional radiology procedures. This device minimizes time and maximizes accuracy of the task. Three functional prototypes were designed to compare the differences between the perceived conservative, moderately conservative and imbued forms as determined by the users by assessing 2-dimensional representations.

For assessing the user perception of form and usability, fifteen participants from interventional radiology, were asked to take part of the study. The usability performance was assessed based on FDA Draft Human Factors Guidance. The emotional impressions were analyzed using Kansei Engineering Tools which addressed the semantic differential. Semantic Differential measures people's reactions to stimulus words and concepts in terms of ratings on bipolar scales defined with contrasting adjectives.

All sessions were recorded to compared to self-responses in order to assess agreement with participants non-verbals reactions during the interaction. The results of this study conclude that the methodology used to assess imbued design is effective, users' preferences change based on the design communication (2D vs 3D), and an ergonomic fit during usability assessment drives overall preference.
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Acknowledgements:

This thesis is dedicated to my family and my future husband for their love and encouragement.

I can’t find words to express my gratitude to Professor Mary Beth Privitera for all her guidance, honesty and mentorship.

Thanks to Professor Murray and Dr. Ringer for your time and guidance.

And to my classmates “the core” for their total support.
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Chapter 1. Introduction

1.1 Statement of Intent

The purpose of this study is to explore whether or not Imbued Design can be applied in medical device design. By applying this concept to medical devices, the emotional connection between the device and the user, can be improved. In other words, a strong and positive device use experience will be evoked in users.

Hypothesis

By applying Imbued Design to medical device design will improve user's performance and perceptions positively.

1.2 Problem Statement

Historically the development of medical devices has been conservative in overall shape following the idea “form follows function”. This concept has not been challenged and has been defined as a conservative design. This constant variable is embedded in the medical device industry and develops results in shapes which generate ‘a medical appearance.’ A medical appearance can be described as simple lines in shape wherein the overall form of the device is directly correlated to simply shrouding the internal mechanism without much regard to overall aesthetic or ‘cool’ perception.

The medical device industry has focused on the effectiveness of their device with little regard to the product’s aesthetic appearance (i.e.medical appearance). By improving the medical device appeal it is possible to provide an impression of quality that can inspire greater user confidence and even pride of ownership. (Fries, 2001; Weinger, Gardner-Bonneau, & Wiklund, 2011)
While there is considerable conversation between manufacturing companies and physicians regarding clinical efficacy, there isn’t an effective communication regarding aesthetic perception. “Especially in non-professional contexts (consumer products), when design artifacts are noticed and appreciated, it is most often for their aesthetic qualities than their practical or functional ability to solve more or less complex or well-defined problems”. (Folkmann, 2010)

As the known “Maslow hierarchy of needs”, this psychology theory progresses from the basic physiological needs up to the needs of self-actualization. In relation to the medical devices users have different needs.

**First level: Function and ergonomics**

The user just wants the device to perform its intended use. The function is related to effectiveness, performance and safety.

**Second level: Price**

Price is related to quality and volume. This level is the decision making point.

And used is related to the times that devices will be performed.

**Third level: Aesthetic Medical device**

Aesthetic is related to the appearance, form and shape.

Alicia David states that the “aesthetic essentially acts as the bridge between a product and the user’s emotion and feeling. Also, it works as a bridge of communication that can balance the function and aesthetics to increase the value of the product.” “Medical design means introducing design into medicine and utilizing the advantages of good design to please patients. There seems to be no field in which design would be more required or helpful than in...
medicine. Instead of sterile ambiances or cold technological devices, design may help reduce fears and increase acceptance. It will generate more user-friendly products, in some cases demonstrating function of the form. Medical design has a positive psychological effect and helps to improve patient-doctor relationships. Patients feel more comfortable finally leading to better results in health care outcomes.” (L. A. Holzer & Holzer, 2007)

1.3 Introduction to Medical Devices

1.3.1 History of Medical Device

To understand where do the medical device design came from, we need to look backwards on how physicians started the need to develop medical devices in order to solve patient needs. For the purposes of this thesis, there are two periods that are important to analyze with regard to aesthetic design. The first period is the craft evolution in which additional methods were used” (Çetin, 2004) and the second period is the industrialization period.

The medical design process starts with the need physician requiring tools that help them to solve and treat unexpected problems. Physicians communicated their needs to the craftsmen, craftsmen translated this needs into a functional device with aesthetic features give them ornamental look, with small fine details that give a feeling of ownership because was unique.

Figure 2. Silver Syringe 1600-1650 Germany

Figure 3. Steel bone forceps 1650-1750

Figure 4. Stork Forceps 1790-1850 Europe
The innovation and evolution of these devices stayed between the craftman and his pupil. This learn skills and knowledge passed through generation to generations.

The second period is the industrialization period, starting with the industrial revolution, in which the new methods and processes emerged according to the needs of the industry”(Çetin, 2004). The widespread application of mass production, high volume and standardize processes grew to what it is today in medical devices, a 3 billion dollar industry. In reviewing design, aesthetics were lost in the constraint of the form as well of the form language. Giving a feeling of boxing the function.

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(Brought to life. exploring the history of medicine.)
language. Giving a feeling of boxing the function. This uniformity and standardization transition left behind the ornate and unusual craftman aesthetics as a low priority in the medical device design.

Now that trend continues and in the current device development the focus is still mainly on the function. The difference over time is largely the result of the discovery of new materials which are translated to new trends an example of this is the polymers that create a new category named disposable medical devices.

(Brought to life. exploring the history of medicine.)

1.3.2 What is a Medical Device?

The most known definition is given by the United States Food and Drug Administration (FDA), who regulates devices, development, testing, production, distribution and use.

FDA Medical Device definition:

A Medical Device is "an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including a component part, or accessory which is:

Intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or
Intended to affect the structure or any function of the body of man or other animals, and which does not achieve any of its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of any of its primary intended purposes."

### 1.3.3 Medical Device Classification

FDA regulatory classifications of medical devices: Class I, Class II and Class III. The classifications are assigned by the risk the medical device presents to the patient and the level of regulatory control the FDA determines is needed to legally market the device. As the classification level increases, the risk to the patient and FDA regulatory control arises. Accessories to medical devices, devices used with a medical device to support the use of the device, are considered the same classification as the medical device.

<table>
<thead>
<tr>
<th>Class</th>
<th>Description</th>
<th>Risk</th>
<th>Examples</th>
<th>Devices Approved by the FDA</th>
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<tbody>
<tr>
<td>I</td>
<td><strong>CLASS I</strong> have the least amount of regulatory control. They present minimal potential harm to the user. Class I devices are typically simple in design, manufacture and have a history of safe use.</td>
<td>Low risk to a person.</td>
<td>Tongue depressors, arm slings, and stethoscopes</td>
<td>55%</td>
</tr>
<tr>
<td>II</td>
<td><strong>CLASS II</strong> have the potential to pose a mild risk to a patient if used incorrectly. General controls alone are not adequate to assure the safety and effectiveness of the device.</td>
<td>Intermediate risk to a person.</td>
<td>Physiologic monitoring, x-ray systems, gas analyzers, pumps, and surgical drapes</td>
<td>45%</td>
</tr>
<tr>
<td>III</td>
<td><strong>CLASS III</strong> devices usually support or sustain human life, are of substantial importance in preventing impairment of human health, or present a potential unreasonable risk of illness or injury to the patient.</td>
<td>Highest risk to a person.</td>
<td>Pacemakers, replacement heart valves and total joint replacements</td>
<td>5%</td>
</tr>
</tbody>
</table>

Table 1. FDA medical devices classification.
Chapter 2. Imbued design

2.1 The importance of aesthetics

The purpose of this chapter is to discuss the importance of visual appearance of a product which generates a response of the user. This relates to the cognitive response, is the judgment that the user make about the product based to the information that is perceived. The author D. Norman said that “Attractive things work better”. He also describes three levels of processing: Visceral, Behavioral, and Reflective. The visceral level makes rapid judgments of what is good or bad, safe or dangerous, and sends appropriate signals to the muscles (the motor system) and alerts the rest of the brain. (Norman, 2004)

For example, the author Coates studied a daily wear product, the watch. He states that just from the appearance of the watch you can know about it, its designer, its manufacturer, its era, and the person who wears it. Knowing nothing more, the design of a watch alone or of any other product can suggest assumptions about the age, gender, and outlook of the person who wears it, it also conveys the implications about its quality, performance, and worth. (Coates, 2003). The response to aesthetic design is not only influenced by specific design factors (such as form or surface attributes) but may also be modified by characteristics of the individual, such as age, personality, cultural background or gender (Crilly, Moultrie, & Clarkson, 2004). The use of aesthetics is as the use of non-verbal language that can manifest or provoke negative or negative impact.

This table describes the design goals/models, view by different authors’ perspectives, and use of the word aesthetics, to explore with different synonyms as desirable, pleasurable, sensory, hedonic and appealing.
<table>
<thead>
<tr>
<th>Product element</th>
<th>Aesthetics</th>
<th>Interaction</th>
<th>Function</th>
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<tr>
<td><strong>How the product looks and feels.</strong></td>
<td><strong>How the user interacts with the product</strong></td>
<td><strong>What the product does?</strong></td>
<td></td>
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<tr>
<td><strong>Desirable</strong></td>
<td><strong>Usable</strong></td>
<td><strong>Useful</strong></td>
<td></td>
</tr>
<tr>
<td>Aesthetically Appealing</td>
<td>The capacity to be understood learned and utilized</td>
<td>What the product does?</td>
<td></td>
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<table>
<thead>
<tr>
<th>Design goal</th>
<th>Sanders 1992</th>
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<tr>
<td>Desirable</td>
<td>Usable</td>
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<tr>
<td>Aesthetically Appealing</td>
<td>The capacity to be understood learned and utilized</td>
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<tr>
<td>Hedonic</td>
<td>Practical</td>
</tr>
<tr>
<td>Sensory and aesthetic pleasures</td>
<td>Result from the completion of tasks</td>
</tr>
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<th>Types of Appraisals</th>
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<tbody>
<tr>
<td>Objects</td>
<td>Agents</td>
</tr>
<tr>
<td>Does it appeal to my attitudes?</td>
<td>Does it meet my standards?</td>
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<th>Levels of Processing</th>
<th>Norman 2004</th>
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<tbody>
<tr>
<td>Visceral</td>
<td>Behavioral</td>
</tr>
<tr>
<td>Aesthetic and tactile qualities</td>
<td>Effectiveness and ease of use</td>
</tr>
</tbody>
</table>

Table 2. Design goals and emotional design models. (van Gorp, 2012)

Alessi is an Italian design company that uses the aesthetic with integrated function at the same level. Example of this is the corkscrew Anna G. “Is a tongue-in-cheek homage to a real woman.” This corkscrew works as well or better than the standard corkscrew with a handle and appointed metal spiral. But the user isn’t just opening the bottle, rather having a pleasurable experience by interacting with this attractive, functional and fun object. The fact that you can talk about it and this link creates a necessity to repeat the same experience. Anna G corkscrew “Smiling face has become something of a cult figure over the years, giving birth (so to speak) to a rich family of objects for the table and kitchen in a wide range of materials” (Walker art center.).
Aesthetics is a branch of philosophy associated with art and beauty and is concerned with how individuals perceive objects or make judgments based upon information received as five human sensory inputs (Anderson, 2009). By researching the importance of aesthetics in products, in the field of medical device design, the industry can take advantage to integrate aesthetics by building their own form language that can be beneficial by giving more tools to their marketers to impact in the sales. The lack of aesthetics generates a gap between the industry and the user (physicians).

2.2 Imbued Design

Imbued design definition:

Imbued design means to evoke a users feeling or emotion through an object or service. It is the process of design which requires a balance of these two concepts: analogy to understand functionality, and metaphor to translate through aesthetics.
And a similarity between like features of two things, like the analogy between the heart and a pump. This a matter of decontextualizing mechanism. This can allow people to more easily understand a new concept by presenting it in such a way as to suggest an analogy with concepts that are already familiar.

Metaphors help designers to understand unfamiliar design problems by juxtaposing them with known situations. Retrieving concepts from metaphors demands creative thinking (Casakin, 2007). Metaphors can encompass the whole range of similarities in attributes and relationships (Gentner 1989, Tsouka 1993). Metaphors help to make sense of user needs or physical attributes from the source of inspiration.

Products may be compared, not only to other examples from the same product category, but also to other types of product and natural forms. These metaphors may suggest ‘evocative connections between the product and product and memories from our experience. (McCoy, M. Defining new functionalism in design. Innovation: The Journal of the Industrial Designers Society of America Vol. 3 No. 2 (1984) 16-19.)
Metaphor is an unlimited area to explore using figure speech, humor, culture approach, etc. This element became tools to create an intuitive connection with the user.

In this thesis, imbued design is applied in medical device design in order to break the conservative paradigm found in form. In this field, imbued design is not related to transforming medical devices into toys or objects of play rather an intent to improve the overall experience for the user. Imbued design can help find the overall pleasing design. For the purposes of this thesis, the following design definitions will be used:

**Conservative design** follows the parameters of industry and history little regard on the aesthetics, design approach tries to maintain the medical appearance (geometric, simple, clean lines). (Low: aesthetics exploration).

**Moderately conservative design** is the medium point to be innovative and safe. Stay close to the medical appearance parameters. (Medium: aesthetic exploration).
Chapter 3. Bubbler Device Development

For the purposes of understanding form and usability, a small class I medical device for the purpose of visualizing and removing air bubbles from arterial lines was designed.

This device would be used in Interventional radiology procedures as a patient safety device. This concept addresses the needs of the physicians to improve a manual procedure of identifying and removing air from the lines by reducing time and increasing their accuracy. The average time spent throughout and intervention a case can be up to 30 minutes. The current procedure is executed by checking the complete line just by visual inspection. If the bubbles appear, the user must flick with their fingers the line to break the surface tension of the bubble on the line, enabling the bubbles to go up the line.

There is nothing currently available on the market. It is a novel device. By researching in the academic field in the Biomedical Engineering department at the University of Cincinnati developed a mechanism to execute a function of removing the air bubbles. There are two phases of design for this device:

1. Selection process

Through contextual observation, where" Information from semistructured observations is typically synthesized for guiding design inspiration" The steps of the procedure, the user and the context of use was described.

Based on the observations and analyzing the needs of procedure, a set of design requirements were determined and sketching initiated. The ideation was divided in 3 form directions: conservative form, moderate conservative form and imbued form.

In the conservative sketch generation, the intent followed the parameters of the medical appearance, that is translated into simple geometric, kind of wrapping the function. The
moderately conservative is free in form exploration however the intent was to maintain ties to the medical appearance parameters.

In contrast with imbued design, the intent was to apply the metaphor to aesthetics, finding the best concept that match with the purpose of removing the air bubbles from the line. Some metaphors were applied to this concept as fishing for the bubbles, catching the bubbles and scaring the bubbles. For example, translating the ‘scare bubbles’ to the device design, the ghost’s shape semantics were translated to the device aesthetics.

Figure 15. Imbued shape (Ghost example)

Figure 16. Form ideation and 2-Dimensional.
After the ideation, 4 concepts out of the 12 concepts were selected for review with clinical practitioners. A template was created for the initial evaluation. The purpose of this evaluation was to obtain feedback from the users (physicians, nurses, and techs) on their interpretation of the device aesthetic according to their preference and word association. This evaluation was done in the Interventional Neuroradiology suites at the University of Cincinnati Medical Center. Each of the 9 participants were asked to categorize each of the concepts by word and image association. Each category was color code: conservative (orange), moderately conservative (blue) and imbued (purple).

Figure 17. Results' sheet of the primary evaluation
Using the results to provide concept selection direction, the development of functional prototypes was completed for the second phase.

The ergonomic design of each concept follow the recommendations of Human Factors Engineering Design of Medical devices ANSI /AAMI HE75 2009. Each concept works with an
electric circuit that lights up a small LED and produces a vibration which breaks the surface tension of the bubble on the line surface. The vibration is for replacing the flicking finger action. A DC motor generates the vibration. For visualizing and identifying air bubbles a double-convex lens and light (white and blue color led) magnifies the size of the bubble.

To activate the system a 3 position switch, first position is the ON / OFF, second position light is activated and the third position light and led activate. This system is charged with a 12V battery.

![Electric circuit design and Internal mechanical design of functional prototypes.](image)

After the first 3d printing set, some modifications were realized to generate a second set of 3d printing. The importance of the prototyping phase in the secondary evaluation is to get feedback from the users, who can provide a response based on aesthetics, form, interaction and usability. The first set was printed in white plastic material and blue led light. This set includes one prototype of each concept (conservative, moderately conservative).
The characteristic of the 3D printing set is:

The first set was printed in white plastic material and blue LED light. This set includes one prototype of each concept (conservative, moderately conservative).

The second set was printed in bright, energetic and positive colors, the purpose of this is to evaluate the tolerance of colors in this context. The light in these prototypes is white.
Figure 23. White functional prototype set light up.
Chapter 4. Evaluation methods

Using Kansei engineering techniques coupled with medical device industry usability testing methodology the following protocol was developed. This included an assessment on the following participants mood, kansei adjective association, form semantic differential, usability assessment from loading the device with an arterial line through dislodging bubbles, position matrix, and their preferred top 3 designs.

A sketch protocol was developed to follow and visualize all the steps during the evaluation.

This study was approved by the Institutional Review Board at the University of Cincinnati, this study was applied fifteen participants from the medical field who use the device in their daily activities (5 physicians, 5 nurses and 5 technicians).

1. **Mood status**: is a tool that works as an ice breaker, used as an introduction. Allowing the user to be receptive to listening and contributing during the evaluation. The participants’ responses guide the evaluator to conduct the test.
This template was designed to answer the question “How do you feel today?” with the following emotions icons: sick, surprised, angry, worried, sleepy, sad, worried, sleepy.

![Emotions Icons]

Figure 25. Mood status evaluation: users were asked to select two adjectives that described their mood.

2. **Kansei adjective association**: Kansei (affection, emotion or feeling in Japanese) Engineering is a new technology for designers to develop products that satisfy users’ affective needs. One of its main subjects is to study the relationship between product form. A previous study “Multiple Kansei Images on Product Form Design” (Chun-Juei (CJ) Chou, Kuohsiang Chen, 2006). Based on established Kansei tools, users were asked to evaluate the Bubbler product designs and select which best represents the shape and adjective in order to provide a basis of evaluation for the clinical staff. A total of 36 products were introduced with 7 Kansei adjectives described. The adjectives that were used are: cute, traditional, tender, hi-tech, traditional and rational and sporty.
3. **Form semantic differential:** This scale is a linguistic tool designed to measure people’s attitudes toward a topic in order to determine a deeper connotative meaning.

   These Seven pairs polar adjectives were used as: “harmonious and contrasting”, “geometric and biomorphic” and “simple and complex” were used in ranking form elements, “angular and rounded” and “functional and decorative” in ranking detailed treatments and “harmonious and contrasting”, “cool and warm” and “hard and soft” in ranking color. (Chun-Juei (CJ) Chou, Kuohsiang Chen, 2006). This tool helps to the user to ranked and verbalized the thoughts relates to the form. The evaluation 2 and 3 has been constrained just to visualize the concepts.

![Figure 26. Clinical staff filling out semantic differential](image)

4. **Usability test:** users were asked to interact and use the devices based on the best practices guide on usability found in IEC 62366 which is the standard assessment methodology for the medical device industry.

   The usability assessment included a measure on perception using a Likert scale. Likert scales fixed choice response formats and are designed to measure attitudes or opinions
(Bowling 1997, Burns & Grove 1997). Users were able to provide their perception on ease of use, the overall ‘friendliness’ of the device.

The scale measures levels of agreement/disagreement. The users must answer the following questions: 1. I was readily able to attach the device, 2. I was able to access to the light, 3. I was able to access to vibration button, 4. I was able to hold the device comfortable, 5. The device was able to remove the bubbles from the line, 6. Was easy to use it and 7. It is fun to use it. These questions were referred to ergonomics, used and experience.
The second semantic differential evaluation was applied to assess user’s experience. Adjectives, “Easy and difficult”, “friendly and unfriendly”, “relaxed and tense and “serious and fun” were used in ranking interaction, “positive and negative”, “Reliable and unreliable” and “unique and standard” in impact in the context. This tool helps user ranked and verbalized the thoughts relates to form and usability. After finishing evaluating the white set, the color set, was introduced assessing the tolerance of colors.
5. **Position matrix**: Users were asked to relate each product design solution on a positioning matrix that concluded the perception of good-bad aesthetic and functional-non-functional attributes. X axis refer to the function and Y axis refers to aesthetics.

![Position Matrix](image)

Figure 30. Position Matrix

6. **Top 3**: ranked users’ preferences to compared the previous test.
Chapter 5. Results and conclusions

During the study the participants were feeling “sleepy- happy”, “sleepy- worried” and “hungry- worried”. The first word means how the participants felt physically and the second how they felt emotionally.

The participants categorize the concept with the Kansei adjectives:

- Conservative form was defined as a simple and rational.
- Moderately conservative defined as a high technology.
- Imbued defined as cute.

The SD form evaluation was performed based on 7-level rating method, ranking in the first position conservative concept as users’ preference with 61%. (Second column fig.x).

After the participants’ interaction and the usability test, the moderately concept ranked on the Likert scale with the 57% and the conservative form with 61% in the SD interaction evaluation. The position matrix and top 3 assessments raked the moderately form with a high preference of the participants.

Figure 31. Clinical staff completed use scenario within the angiography suite and were able to use both the white and colored prototypes.
In this study, users preferred imbued forms in 2Dimensional representation then switched preferences than post usability study. Since medical devices are largely simple shapes with little color we hypothesize that this may have influenced our intended user group with strong opinions of ‘what shapes are supposed to be present’ in a medical device and the social implications of a playful shape.
Figure 33. Primary results 2D and Secondary results 3D
Conclusion

In this study we can determine that the methodology is valid. However, more study is required to determine if imbued design has a role in medical devices. During this study, the evaluating context and focus of the clinical practitioners were problematic. For example, it was noticed that from the moment, the evaluation started with the participants, in span of 4 to 5 minutes an external variable appears such as cell phone rings, quick look to watch and at that moment the participant starts losing the focus of the evaluation.

In addition, the context affects the perception of the color, bringing the bright and unusual colors to this context can be unfamiliar equally unacceptable. In a further study lighter values should be used in the device design.

The initial evaluation was completed solely with 2D (images) without context or interaction. During this evaluation users preferred the imbued design. Which suggests either a change of opinion most likely due to ergonomics and usability or a lack of appreciation for true 2 dimensional evaluations. As a result, this highlights the importance of the used of prototyping, the design team will receive concrete feedback.

In a novel device, the design team must try to need to build a link of the shape perception and functionality. As a result, users are learning to use the device while evaluating the aesthetic. In the future study, imbued design should be applied to both a novel and an existing device since users will already have experience with the device in order to truly compare the results.
References


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