The Comprehensive Study of Product Criteria on Infant-Wrap (*InfaWrap*) Device: Engineering Perspective

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Mohd Hanafi Abdul Rahim[1], Mohd Azrul Hisham Mohd Adib[1], Nur Hazreen Mohd Hasni[2]

[1]Medical Engineering & Health Intervention Team (MedEHiT), Human Engineering Group, Faculty of Mechanical & Automotive Engineering Technology, Universiti Malaysia Pahang, 26600 Pekan, Pahang, Malaysia.
[2]Family Health Unit, Pahang State Health Department, Jalan IM 4, 25582 Bandar Indera Mahkota, Kuantan, Pahang, Malaysia.

azrul@ump.edu.my

Abstract. Nowadays, most of the parents still monitor their baby's health using a manual oximeter device. However, the existing oximeter device was a hassle for infant and presented the monitoring process difficult. In this paper, two different prototype of the infant-wrap (*InfaWrap*) device is well compared. This *InfaWrap* device is purposely to monitor the SpO2 and heart rate of the baby. The device also easier to use, fast and provides accurate on baby's SpO2 and heart rate. Presently, the main problem was related to the clinical which used of the conventional wrapping concept. Normally, the method involved the movement of the infant's leg which is easier to deprive. This study focuses on the perspective of engineering students on *InfaWrap* device criteria needed from the customer compare between prototype 1 and prototype 2. The results obtained in the perspective study generally shows the prototype 2 is better than the prototype 1 especially on design, safety, comfortability, size, and weight. Finally, by use of this comprehensive study of the product criteria on *InfaWrap* device, we expected to help experienced professional's designers to develop more good products in the future especially on medical devices.

Keywords: Infant, Ankle Wrap, Device, Neonate, Oximeter

1. Introduction

A study conducted by [1,2] was found that 90% of the infant with congenital cyanotic heart disease were detected use of pulse oximeter for screening the patient's SpO2 and heart rate within several hours of birth. This data presented the serious issue related to cyanotic heart disease. The parameter of pulse oximetry was considered abnormal if oxygen saturation at room air or on oxygen therapy measured less than 95% [3]. The Sudden Infant Death Syndrome ("SIDS") also can be related to congenital cyanotic heart disease. The main causes of SIDS maybe difficult to determine [3], many parents do an extraordinary effort and are worried about checking their baby's health. To help parents in this effort, nowadays various products in medical device was developed in order to monitor the health of infants, especially when the baby is sleeping. This existing medical monitoring devices not only developed for adults but also widely available in the market for infant health monitoring. For instance, a non-invasive pulse oximeter is used in a clinical setting to help medical practitioners monitor continuously their patient's blood oxygen saturation level and heart rate. This device has been

acknowledged as the preliminary treatment to quickly assess the oxygen saturation level and provides fast, accurate and reliable readings of patient oxygenation for medical use. The parameter of pulse oximetry was considered abnormal if oxygen saturation at room air or on oxygen therapy measured less than 95% for the infant [4]. Today, reported that the daily routine of parent activities is very tight and they did not have time to bring their children to the clinic or hospital in order to check their kids health condition. Due to this problem, there are many devices were developed to be used to monitor the condition of basic health, but each device is different from the other in terms of accuracy. Currently, in the monitoring system at the hospitals used connections wire, size and power consumption are often too large and not portable [5]. The system becomes unsuitable for the physician in their daily treatment. By applying wireless healthcare technology there are many advantages, one of them is the people who carry the sensing devices can move around freely without the obstacle from complex connecting cables [6]. Presently, two prototypes of *InfaWrap* device have been developed. Both prototypes have difference in the design but same in functions. These both prototypes also remain three parameters value display which are SpO2, heart rate, and temperature.

In this study, we focus on the perspective study of engineering students on *InfaWrap* device criteria compare between prototype 1 and prototype 2. This present *InfaWrap* device is well developed so the clinical checking process can be done easily in a short time. This device also equipped with several sensors such as oximeter MAX30100 and LM35 that can be measured several parameters. Bluetooth HC05 is used to display the parameter result at a smartphone. In addition, the buzzer and display are applied in this system in order to ensure the physician and parent more alert if the parameter at the system indicates a negative value.

2. Methodology

This section describes the comparison of two prototypes *InfaWrap* device. It develops based on criteria derived from the survey. This survey is to identify the criteria of the product based on the engineering perspective.

2.1. Questionnaire

A questionnaire consists with a few elements based on criteria of the product. The questionnaire combined open-ended questions with respondents the possibility to choose and rank among several options or the possibility to grade on a “very disagree” to “very agree” scale. At the end part of the questionnaire, the comments, suggestion and concerns are open which can help us to improve the existing prototypes. This open-ended questions part aim to consider the great importance criteria that can contributes to improving the interpretation of overall results and provides additional suggestions. We adopted a questionnaire technique as part of our data collection procedure as shown in Figure 1 that offers a basic structure to be considered when develop the questionnaire survey.

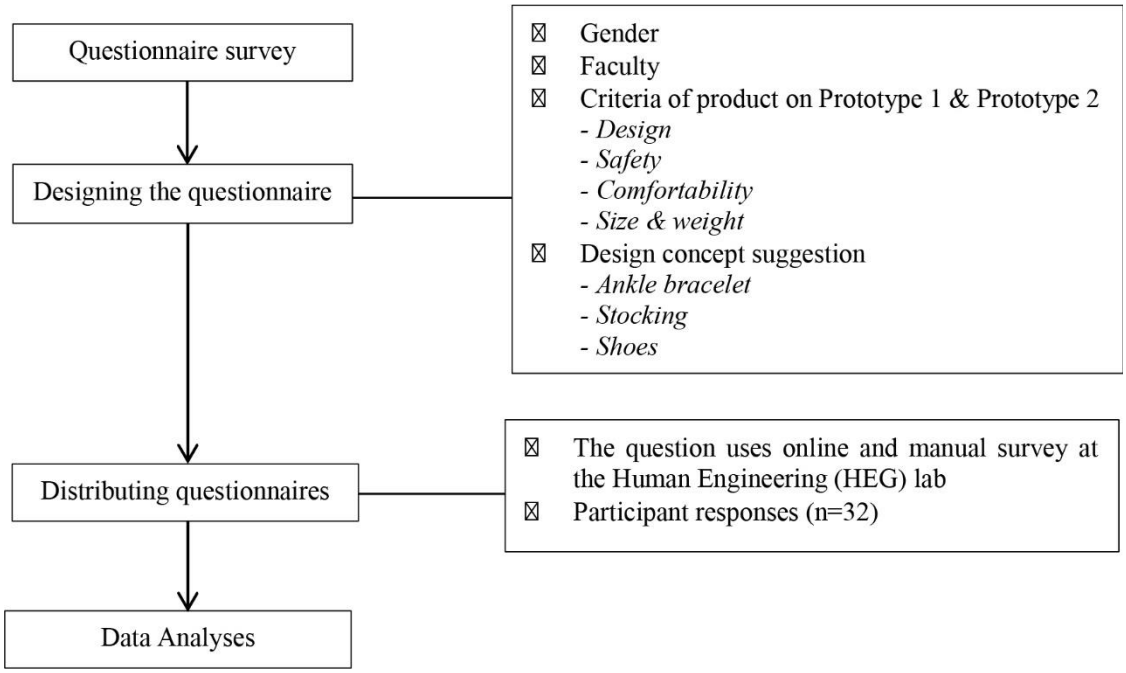

Figure 1. Flow chart of data collection

2.2. Comparison of Prototype 1 and Prototype 2

This study focuses on the perspective view of product criteria needed by the customer compare between prototype 1 and prototype 2. The improvement of the *InfaWrap* device's second series needs to be achieved. Starting with the survey then made the comparison with a new prototype (prototype 2) and old prototype (prototype 1) to identify the criteria problem faced. Actually, prototype 2 is already designed used *3D* CAD software *SolidWorks Version 2016* but still did not yet print using 3D printer. This is because some of the surveys need to be performed to ensure the prototype 2 referred accordingly to the user's wishes. In addition, in terms of design of the prototype 2, the bigger improvements need to achieve and ensure it fits with the size of the baby's foot and not difficult to wrap on the ankle. Figure 1 and Figure 2 shows the prototype 1 and prototype 2 respectively. Full designs for prototype 1 is designed using *3D* CAD software *SolidWorks Version 2016* that allows direct prototyping with 3D printing technology while for the prototype 2 some of parts used the elastic fabric that purpose to be ensured the baby's ankle is comfort. The design concept of both prototypes is slightly different from several improvements but still have same function. To investigate the comparison of these two prototypes *InfaWrap* devices, we have made a satisfaction survey to identify among engineering student’s perspectives about the criteria of the product. The perspective survey more focuses on terms of design improvement and other criteria of the products.

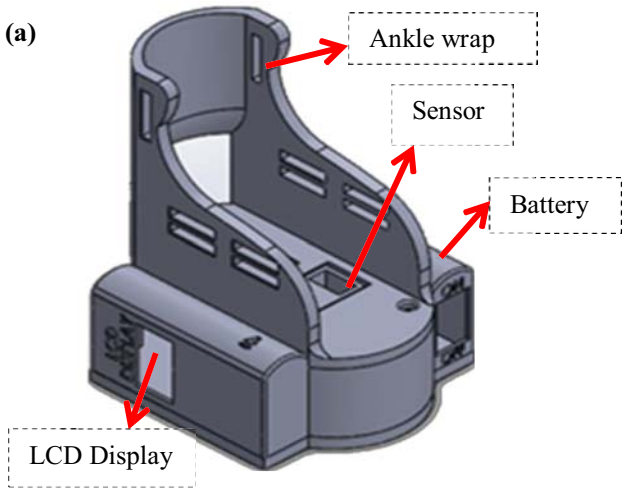

Figure 2. *InfaWrap* device Prototype 1

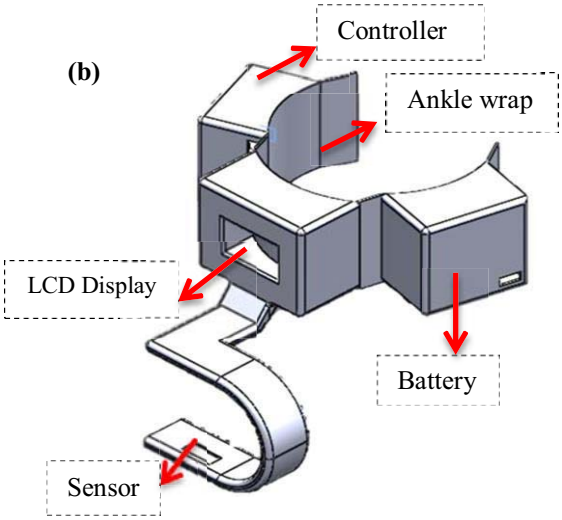

Figure 3. *InfaWrap* device Prototype 2

3. Results

The involvement of users is essential in order to achieve high usability. The influence of users in the evaluation of prototypes can never be neglected [7]. From the table 1, we obtained a few good comments and suggestion from the engineering student's perspective.

Table 1. Comment and Suggestion from Engineering Perspective

No.	Participant	Comment & Suggestion
1	Faculty of Mechanical Engineering	*"reduce the weight of the device"*
2	Faculty of Manufacturing Engineering	*"comfort, design, and weight must be suitable to the baby or patient"*
3	Faculty of Manufacturing Engineering	*"reduce the weight of the Prototype 1 and add move comfortability"*
4	Faculty of Mechanical Engineering	*"the weight must important to baby"*
5	Faculty of Mechanical Engineering	*"use soft material to cover the ankle infant"*
6	Faculty of Mechanical Engineering	*"maybe the weight can be reduced"*
7	Faculty of Manufacturing Engineering	*"should consider the user as baby"*
8	Faculty of Manufacturing Engineering	*"weight should be less not be a burden"*
9	Faculty of Manufacturing Engineering	*"prototype needs to improve on straps and if can reduce the weight"*

This comment is very important for us before further to the design and the development process. The positive feedback is also significant in order to improve and enhance the present prototype with good design and appearance of the product.

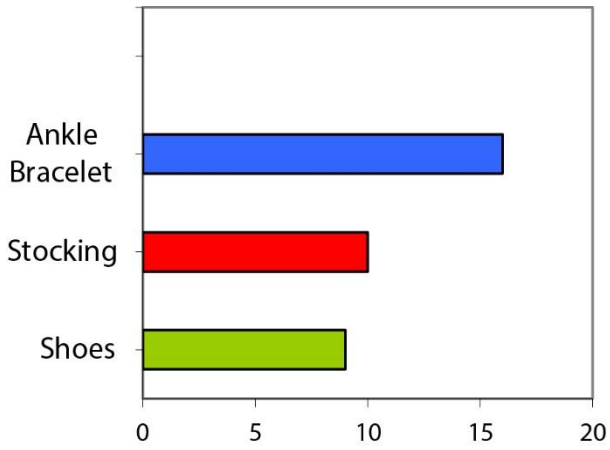

Figure 4. Design concept suggestion

Figure 4 shows the results of the concept design suggestion from the engineering student's perspective. The question also referred to online and manual survey at the Human Engineering (HEG) lab. The participants were given three design concept suggestion. As we see in Figure 3, clearly shows that the majority of participants prefer to choose the design of ankle bracelets with 50% than followed by stocking design 32.2% and shoes design 20%. Only a small minority prefer shoes and stocking concept.

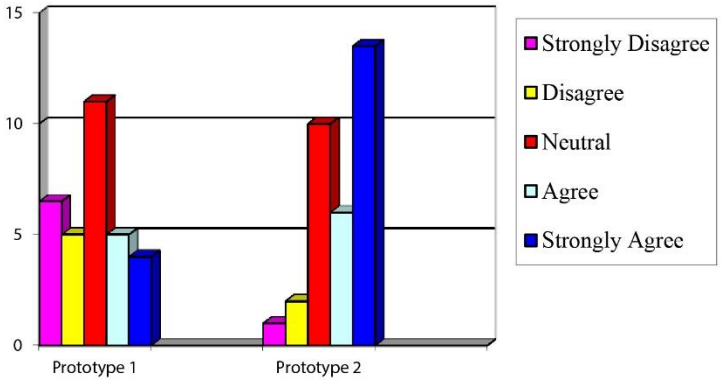

Figure 5. Comparison of design on Prototype 1 and Prototype 2

In medical devices, the development process is more complex [8]. Since the design of a product is the first impression on customer particular product, so we need to design the products that meet and exceed the customer's expectations. Figure 5 shows the comparison between the Prototype 1 and Prototype 2 that was conducted throughout the survey. From the result, most of the participant choose "strongly agree" with Prototype 2 compare to Prototype 1. The graph shows the comparison of the design concept and criteria of the products. A few criteria that stated are to ensure this product can be developed follow by responses especially engineering view perspective before go to the parent's and clinical survey. We also focus in terms of safety to ensure the product developed meet the need of the users. Figure 6 shows the comparison safety of the product between Prototype 1 with Prototype 2.

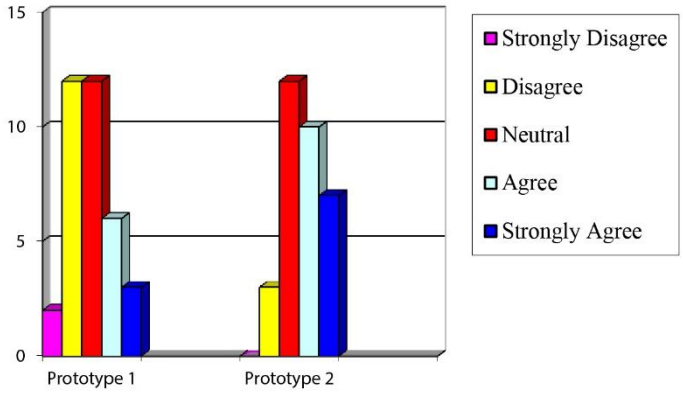

Figure 6. Comparison of safety aspect on Prototype 1 and Prototype 2

Figure 7 shows the result comparison of the comfortability from both prototypes. The comparison of comfort between Prototype 1 and Prototype 2 very noticeable, where Prototype 2 becomes high priority from the user especially on comfortable aspect. To ensure this product is comfort we particularly focus more on design and material selection.

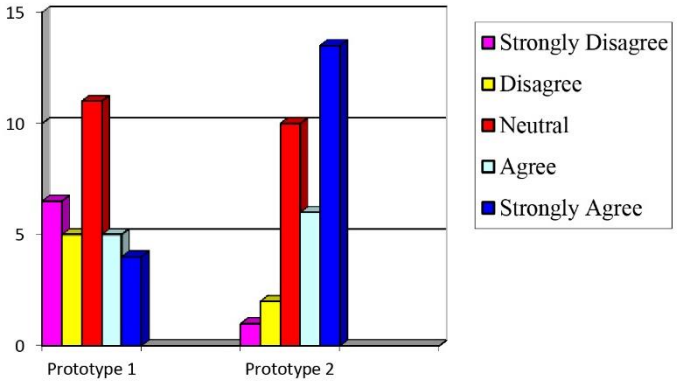

Figure 7. Comparison of comfortability on Prototype 1 and Prototype 2

The main reasons before design the *InfaWrap* device it must relate to the baby's foot size, lightweight and good material used. Figure 8 shows the results on perspective of size and weight between Prototype 1 and Prototype 2. Most of the participants said “strongly agree” and “agree” with the small device and lightweight device.

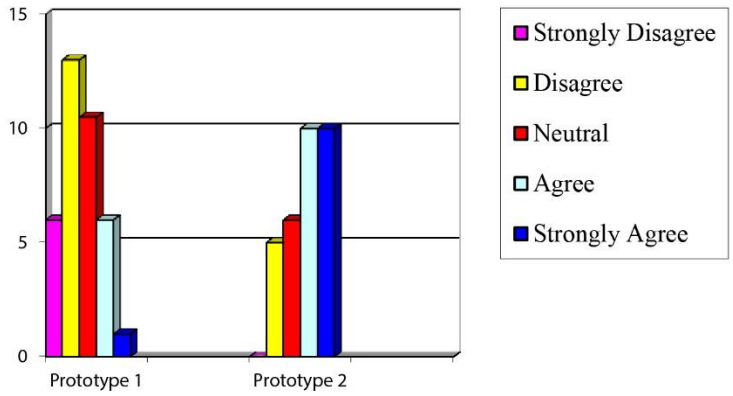

Figure 8. Comparison of size & weight on Prototype 1 and Prototype 2

4. Discussion

4.1. Function

Both prototypes will compare based on engineering perspectives as functions, design, safety, advantages, and disadvantages of the product. In terms of function, both of prototypes are same which is monitoring the heart rate, SpO2, and temperature. This parameter also can monitoring by mobile apps.

4.2. Design

As shown in Figure 2 the design for Prototype 1 is more to the shoes concept. Nevertheless, Prototype 1 have problem to adjust the baby foot size so improvement must be performed. For that purpose, having a good design and the best material for the main parts of the device very important to understand the criteria and perspective of the customer's needed. Details specifications on prototype 1 and prototype 2 shows in Table 2. Firstly, the design concept of both prototypes used different materials. Prototype 2 uses breathable elastic fabric adjustable material while Prototype 1 used fully PLA material. Second, the control system screen for Prototype 2 in suitable position at the front side. However, for the control system and LCD display on Prototype 1 are not suitable position where they are placed right side as shown in Figure 2.

4.3. Safety

The recognition of the role of good design in improved safety has resulted in a number of studies investigating the usability of individual medical devices [9]. Ideally, validation of a device in a clinical trial that compares the performance of the device against the standard medical procedure in clinical practice should provide the strongest evidence for the device's safety and efficacy [10]. For a safe and comfortable product, Prototype 1 has been placed a layer of sponge to protect the skin of the infant from the direct touch to the material as shown in Figure 1. The material used by Prototype 1 is fully PLA. Meanwhile, Prototype 2 is using safe material like elastic fabric to protect the skin and ankle of the baby's and also given position support with the smooth side against skin. Prototype 2 also uses a little bit of PLA material like a box components. The design of Prototype 2 is more suitable to protect and prevent any undesirable injury on the babies.

Table 2. Product Evaluation

Traits	Prototype 1	Prototype 2

Shape	2	2
Adjustment	1	3
Size & Weight	1	3
Comfortability	2	3
Accuracy of sensor	4	4
Net	**10**	**15**
Rank	**1**	**2**

*Responses are indicated as, 1= Poor, 2 = Satisfactory, 3=Good, 4= Very Good

5. Conclusion

This paper is well presented with the perspective study of product criteria on *InfaWrap* devices. As a summary, we concluded that the prototype 2 meets the required from the product criteria selection which is good in design, safety, comfortability, size and weight. This new design of *InfaWrap* device from prototype 2 also presented a better aesthetic value, easier to handle and portable.

Acknowledgments

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