

Redesigning the Incentive Spirometer through Gamification

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On my honor as a University Student, I have neither given nor received unauthorized aid on this assignment as defined by the Honor Guidelines for Thesis-Related Assignments

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Abstract

The incentive spirometer (IS) is a medical device given to patients after lung surgery or to patients suffering from respiratory illnesses like COVID-19. This medical device is extremely helpful in preventing the build-up of fluid in the lungs. However, providers have reported that patient adherence to this device is low and needs to be increased so that patients will have a lower risk of experiencing complications like a collapsed lung or pneumonia. Redesigning the incentive spirometer to have a gamified element is a way to solve this issue and to keep patients more engaged. To do this, our group produced three design candidates: the drink style incentive spirometer, the light up incentive spirometer, and the spiral whirligig incentive spirometer. These designs were made to be possible ways to engage the patient but also be able to hold the same functions as the original incentive spirometer design. Provider feedback was used to find which prototype design would be favorable to increase patient adherence. Using four parameters (Engagement, Creativity, User-Friendliness, and Likelihood of Patient Use), we found that the light up incentive spirometer would be the best design in increasing patient adherence.

Keywords: Incentive Spirometer, Gamification, Respiratory Therapy, Patient Adherence, Medical Device

Introduction

Pulmonary medicine is a specialized area of internal medicine that specifically focuses on the diagnosis, management, and treatment of certain disorders and diseases regarding the respiratory system. The most common way of managing any pulmonary disorder is through respiratory therapy. Respiratory therapy is one way to quantitatively evaluate and monitor heart and lung function of a patient, with the goal of enabling patients to breathe better. To do this, medical devices like the incentive spirometer have been created to improve the lung function of a patient.

Incentive Spirometer

The incentive spirometer (IS) is a simple medical device that plays a critical role in the treatment of lung-related surgeries (post-operative), as well as diseases like cystic fibrosis and COVID-19. The device assists users in taking deep breaths, allowing for the complete filling of the lungs, thereby preventing fluid buildup and improving lung function¹. The risk rate of postoperative pulmonary complications can range from 17% to 88% when a patient undergoes upper abdominal surgery, so patient adherence is important in order to prevent complications like

pneumonia, respiratory failure, and atelectasis. These complications can lead to a higher mortality rate, re-hospitalization, and therefore, a more expensive treatment plan².



Fig. 1. Example of an Incentive Spirometer⁴

The current, standard incentive spirometer is a simple and mass-produced plastic device. It is effective and easy to use, but inexpensive. The device itself consists of a body section with a volumetric tube and a flow rate indicator, along with a detachable mouthpiece. The device also has a wide base and handle to hold or rest the device during use.

An example of this device is shown in Fig. 1. When a patient inhales, the piston inside the volumetric tube rises proportionately to the amount of air inhaled. Additionally, a plastic chip in the flow rate indicator rises in proportion to the rate at which air is being inhaled. Patients will inhale either for a prescribed number of seconds or until the piston rises to the goal level set by the provider³.

Problem Statement

Incentive spirometers are prescribed to a variety of patients in the hospital for reasons ranging from postoperative recovery to respiratory illness. Postoperatively, pulmonary complications are a direct cause of morbidity and mortality, so they require attention from medical professionals⁵. It has been shown that adhering to the IS at the prescribed rate will result in a higher rate of recovery and a lower rate of lung complications from respiratory illness. However, despite the critical role that the IS plays in regulating respiratory health, patient adherence to IS exercises is low. A study of IS users discovered that over one-third of patients prescribed an IS for post-operative care reported not using the device after leaving the hospital¹. A similar study of healthcare providers revealed that more than 86% of providers believe that patients do not use the IS after being discharged⁶. The IS is typically prescribed to be used once an hour with 10 repetitions for every hour the patient is awake. The frequency of this exercise helps to clear the patient's lungs and prevent fluid buildup over time. However, a study shows that despite this prescription, the adherence rate is typically only four times per day on the first postoperative day and ten times per day on the second postoperative day⁷. Failing to use the IS can increase the risk of infections and other complications. Possible severe consequences include a partial to complete collapse of a lung, or pneumonia. Given this critical value of the IS to patient health, it is important that methods are employed to increase adherence to the IS.

To address this problem, we will design a gamified modification to the existing device to create a more engaging version of the IS. Our spirometer will perform the same functions of a traditional IS, but will additionally have enticing, fun elements to drive an increase in patient adherence.

Gamification

Gamification involves integrating game-like features into non-game contexts. Research suggests that gamification can be effective in triggering emotions such as happiness, intrigue, and excitement, leading to increased engagement.

By tapping into people's instinctive curiosity and desire for exploration, gamification has the potential to improve engagement. We aim to leverage the psychological benefits of gamification to improve patients' adherence to the IS. Our theory is that by incorporating gamification as a positive reinforcement and incentive, patients will be more likely to use the IS as recommended by their medical provider.

The incorporation of gamification is an increasingly popular practice in various fields, and analysts have estimated the industry to be worth over 2 billion dollars⁸. Healthcare has also attempted to use gamification, particularly in promoting lifestyle changes, with technologies such as Fitbits, trackers, and smartphone apps shown to be effective at encouraging exercise. A study examining various lifestyle-based interventions for families found that adding gamified elements increased adherence to the device in question⁹. This project aims to apply the same gamification principles to enhance daily usage of the IS.

Prior Art

The current IS device has functional accuracy in measuring inspiration volume and flow rate, but its design is considered uninspiring and lacks motivation. Prior attempts have been made to gamify the IS to increase adherence, such as the ZEPHYRx Gamified Incentive Spirometry¹⁰, which is still being studied, and the Airofit Pro¹¹, which offers personalized settings and data collection but at a high price and with less focus on promoting adherence. Nevertheless, the traditional design of the IS remains the most widely used type in hospitals and clinics.

While there have been some attempts at modifying the design of the IS using gamification to improve adherence, there are still numerous opportunities for alternative modifications. Our project also employs gamification to boost adherence, but our approach is unique, and we are targeting a different patient population. Unlike ZEPHYRx Gamified Incentive Spirometry, which is aimed at patients who have undergone lobectomy or wedge resection, and Airofit Pro, which targets a more active audience, our target audience consists of patients aged 50 years or older.

Results

Resident and Provider Survey Results

The results from the resident/provider survey showed that all eight respondents were under 50 years old, and seven had used an IS before. While their responses may not fully

represent the views of our target demographic, their experience working with that demographic gave us confidence in their valuable insights into patients' perspectives. However, it is important to note that their responses may not fully represent the views of our target demographic.

The original IS design scored an average of 2.375 with a sample standard deviation of 0.91 for engagement (Fig. 2a), an average of 2.125 with a standard deviation of 0.99 for creativity (Fig. 2b), an average of 3.375 with a standard deviation of 1.41 for user-friendliness (Fig. 2c), and an average of 2.5 with a standard deviation of 1.41 for likelihood of use (Fig. 2d). The drink style IS design received an average score of 7.625 with a standard deviation of 0.52 for engagement (Fig. 2a), an average of 8.5 with a standard deviation of 0.53 for creativity (Fig. 2b), an average of 7.125 with a standard deviation of 0.99 for user-friendliness (Fig. 2c), and an average of 7 with a standard deviation of 0.93 for likelihood of use (Fig. 2d). The light up IS design received an average score of 8.75 and a standard deviation of 0.71 for engagement (Fig. 2a), an average of 8.5 with a standard deviation of 0.76 for creativity (Fig. 2b), an average score of 8.25 with a standard deviation of 0.89 for user-friendliness (Fig. 2c), and an average score of 7.75 with a standard deviation of 1.28 for likelihood of use (Figure 2d). The spiral whirligig IS design scored an average of 7.5 and a standard deviation of 1.69 for engagement (Fig. 2a), an average of 7.875 and a standard deviation of 1.46 for creativity (Fig. 2b), an average of 7.625 and a standard deviation of 1.41 for user-friendliness (Fig. 2c), and an average of 7.25 with a standard deviation of 1.39 for likelihood of use (Fig. 2d).

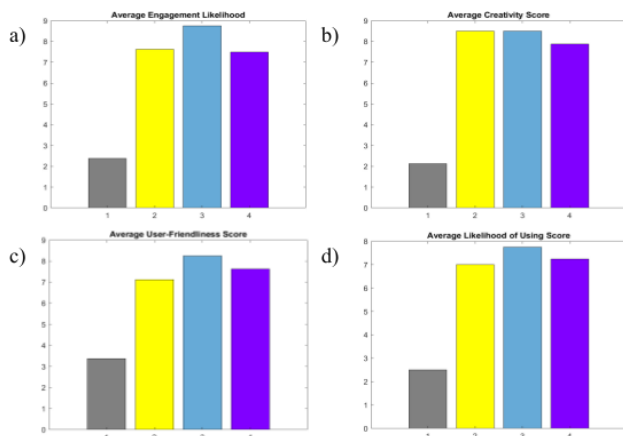


Fig. 2. Average Scores from Provider Survey across Four Metrics: a) Engagement, b) Creativity, c) User-friendliness, d) Likelihood of Use

The average scores of all four metrics for each design were combined, resulting in an average score of 2.59 for the original design, 7.56 for the drink style design, 8.31 for the light up design, and 7.56 for the spiral whirligig design. Based on these results, the light up design was chosen as the final design for our capstone project.

ANOVA Test between Original Design and Redesign

Having selected the light up IS design as our final choice, we sought to demonstrate that there were significant differences in each metric score between the original IS design and the light up design. To do so, we conducted a statistical analysis of our survey results using a one-way ANOVA test. We utilized the anova function in MATLAB to examine the data gathered from our resident/provider survey. The results of the ANOVA test can be found in Fig. 3. Our null hypothesis was that there was no significant difference in scores between the two designs. The ANOVA outcomes revealed that $p = 3.076e-10$ for engagement (Figure 3a), $p = 8.211e-10$ for creativity (Figure 3b), $p = 9.0518e-07$ for user-friendliness (Figure 3c), and $p = 1.8916e-06$ for likelihood of use (Figure 3d). As all p-values were less than 0.05, we can reject the null hypothesis and conclude that there are significant differences between the original design and the light up design in all four metrics. This indicates that the improved design is likely to increase adherence to the IS, as it has received a significantly higher overall perception score.

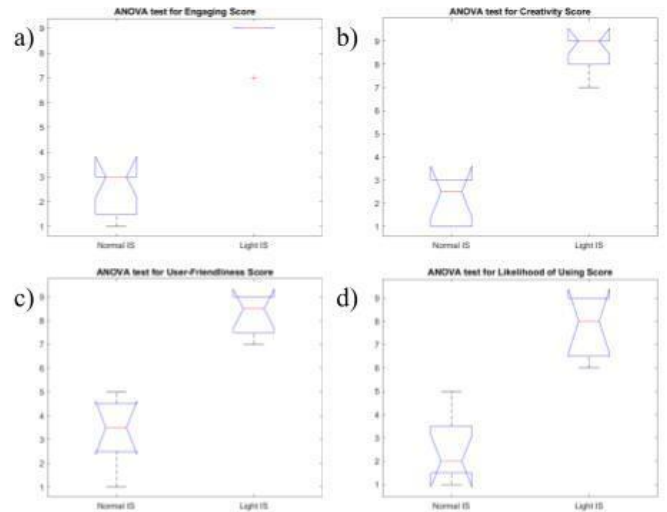


Fig. 3. ANOVA Test Scores Between Light Up IS and Normal IS: a) Engagement, b) Creativity, c) User-friendliness, d) Likelihood of Use

Economic Analysis

Our economic analysis worked to both describe the cost required to create our device and the feasibility of our device in the medical device market. Fig. 4a shows the breakdown of different factors of cost per unit. The total cost to produce one unit would be \$31.25. Materials account for 72% or \$22.44 of the final cost. The materials contributing to this cost are the Printed Circuit Board (\$10)¹², photoresistor sensors (\$7.90)¹³, Light Emitting Diodes (\$0.75)¹⁴, lithium coin cell battery (\$0.39)¹⁵, wires (\$4)¹⁶, and plastic (\$4). The Production of the device accounts for 7% of the total cost or \$2.25. This accounts for the upfront cost of creating an injection mold (\$0.05)¹⁷ and wages (\$2.20). Marketing accounts for 4% of total cost at \$1.10 per unit. This includes using both digital and print advertising for our product. Shipping accounts for 1% of the total cost, mostly because it is assumed that the devices will be shipped in bulk. The remaining 16% or \$5 per unit accounts for overhead. This overhead would include the maintenance of the manufacturing space, salaries of management, and profit. However, it is expected that establishing an effective manufacturing process could potentially reduce some of the material costs.

Fig. 4b shows the predicted sales for the first 5 years after entering the market. In year zero, our device would be used by only the Family Medicine department at UVA’s main hospital. In year one, the device would be used by the entire UVA main hospital¹⁸. In year two, the use would be in all 3 major hospitals in the Charlottesville region^{19, 20}. By year 4, the device would be available in all hospitals in the state of Virginia²¹. In year 5 the device would be in hospitals in Virginia, DC²², and Maryland²³.

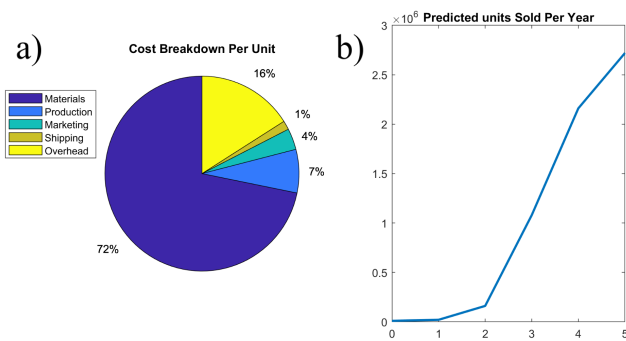


Fig. 4. Economic Analysis: a) Cost Breakdown per Unit, b) Predicted Units Sold per Year

Performance Testing

A summary of the results of the performance testing is shown in Table 1. Our device performed within our

specified standards on 5 metrics: durability, weight, size, gamified element, and cost of production. Durability was assessed by dropping the device from a height of 3ft, to simulate an accidental drop of a hospital bedside table. The device survived that drop, thus it is deemed passing in durability. Weight was tested by measuring the mass of the device on an electronic scale. The mass of the device was 288g, which is within the acceptable range. Size of the device was measured by taking the volume of the body of the device. For our design the volume was approximately 147 in³, which is within our acceptable range. The gamified element was rated by averaging the overall score for each metric from the provider survey. This yielded a score of 8.31 on a scale from 1 to 10, which is within the acceptable range. The cost of production was calculated through the economic analysis described in Figure 4a. The total cost of the device was found to be \$31.25, which falls within the acceptable range. Our device testing was inconclusive on the reusability metric. The device successfully completed a simulated 2-3 day’s worth of usage. The device was still functional at the end of this testing. However, the testing is overall inconclusive due to equipment and time constraints that limited the ability to perform the proposed number of testing cycles.

Table 1. Summary of Performance Testing

Need #	Design Constraint/Metric	Measured Value
1	Reusability	210 cycles
2	Durability	3 ft
3	Lightweight	288 g
4	Portability/Size (Volume of Body)	147 in ³
5	Gamified Element	8.315
6	Cost of Production	\$31.25

Discussion

Societal and Ethical Impact

This project required us to consider many biomedical ethics issues within the medical device field. The areas our project navigated included human testing, patient privacy, affordability and access, use of appropriate materials, gamification, and waste. We chose to address these issues in order to maintain and uphold trust in our device’s development process. As our project moves forward, we will be working within the applicable laws and regulations. This includes the 1974 National Research Act, which institutes Institutional Review Boards²⁴, and the Health Insurance Portability and Accountability Act (HIPAA), which protects patient health data privacy²⁵. It also

includes the important FDA Regulatory pathway, which establishes risk of device use and creates a process to prove safety and effectiveness²⁶. Beyond the positive changes enacted at the federal level to protect patients, a shortcoming we hope to shift is the focus of medical device innovation from being on purely functional metrics to also considering the user experience.

Our project worked to mitigate its ethical impact by planning for potential roadblocks. One key part of this was our choice to do a survey with family medicine providers before doing testing or surveys of the devices using patients. This process was out of respect for the IRB system, which would have taken too long for the time scope of our work. Instead the provider survey gave us key insights into the feasibility of our design in a practical patient care context.

Another important ethical concern that our project considered was the use of gamification. Gamification can be seen as manipulative. However, this concern typically arises from either a mismatch in the understanding of the device's purpose or a gamified design that makes the user feel forced into using it²⁷. We worked to mitigate this concern by having dialogues with providers who would be using this device with patients. Additionally, the finished device would come with a set of instructions detailing how the device, including the gamified element, works.

The final ethical issue we addressed was the waste stream our device could cause. Since the IS isn't meant to be used permanently, there won't be many long-term biomedical issues to address. However, there are concerns over the lifespan of the device. It is expected that the device, or any component of it, could eventually lose accuracy, malfunction, or break down after a longer period of time. Since it's not a vital medical device, the degradation of the device will not have life-threatening or have critical impacts on the user's life. It is also expected that, in most cases, the patients would have recovered by the time the IS reached the end of its lifespan. However, this breakdown of the device may have harmful effects on the environment, especially because of the electronic components of our device. E-waste creates over 50 million tons of waste per year globally²⁸. A solution to this problem would be to find ways to recycle or reuse the electronic components, while also recycling the plastic components. Additionally, our device is designed to withstand a year's worth of use. Therefore, patients using the device long-term or for multiple hospital admissions one device could be used instead of replacing the device on each visit.

Empathy in Design

Empathy and compassion are important factors in the medical device field. Since one of the purposes of medical devices is to improve the quality of life for those with health conditions, we have worked to also consider the emotional and mental well-being of the patients. Redesigning the IS required empathy and compassion because some of the patients using this device have been struggling with various health issues that leave them struggling cognitively in addition to physically. This is a serious concern, which partially led us to giving the survey to clinicians who are familiar with the IS. Additionally, we have to consider the gamification element and ensure that it is appropriate for the patient. Our goal is to increase the compliance rates of the IS by adding a gamified element that promotes happiness and in turn helps the patient with their lung recovery.

Our design is working to be a more empathetic solution to respiratory therapy. We hope that the consideration of patient opinions in the preliminary design process will lead us to a more empathetic solution. Previous designs of the IS have been primarily forced in the device being a functional measurement device and did not consider the patient experience. This likely contributes to the overall low compliance rate⁶. In addition to patient perspectives, we hope to be empathetic in the design process by ensuring the device is cost-effective and easy to use. We were able to achieve, to a certain extent, this price point which we determined through an economic analysis. We hope that as more efficient manufacturing methods are developed the price of the device will be able to decrease even more. The current price of the device is higher than existing models, but still affordable. We assessed the ease of use of our device in the provider survey. Providers gave our device a rating of 7.75 out of 10 on this metric. This leads us to believe that our device is sufficiently easy to use for most patients. Our device is an example of empathetic design in engineering that will make positive changes in patient outcomes.

Future Works

Although we were able to complete our objective of redesigning an IS with a gamified element that is as cheap and portable as the original IS, there are still many ways our prototype can improve, especially if the goal is to market it. A future endeavor would be to find a manufacturer so that an efficient manufacturing process can be obtained. This will allow for mass production of our design. Next, we would get the appropriate IRB approval in order to test the efficacy of the light IS when

patients use it, so that a proper clinical study could be completed. We believe by giving each patient in the study our new design, we would be able to calculate true patient adherence rather than creating a survey that was only for providers. Proving that our redesigned IS is not a danger to the public, another future endeavor would be getting FDA approval and getting a patent for the design.

Conclusions

The objective of our project was to redesign the IS, so that it had a gamified modification, but was as cheap, portable, and functional as the original IS design. Based on our results from the provider survey, ANOVA test, economic analysis, and performance testing, we found that the light IS is the best suited design. We can confidently say that this design can increase patient adherence and be a marketable product within the medical device industry.

Materials and Methods

Design Specifications

To establish the specifications for our design, we engaged in a comprehensive brainstorming session to determine our project's needs and wants. We then ranked these qualities in order of importance to ensure the success of our project. We also reviewed the previous team's design specifications to gain insight into their design needs. From there we researched the current values of the size, weight, and cost of our project to ensure it is as close to the original design as possible. The original IS consists of two parts: a mouthpiece and a body, which can be easily disassembled for cleaning and reassembly. To maintain simplicity, we established a limit of no more than four removable parts. We also set a durability constraint for our device to withstand common accidents, such as being dropped, and survive a drop of at least 7 feet in height. The final design specifications are summarized in Table 2.

Table 2. Design Specifications

Need #	Design Constraint/Metric	Unit of Measure	Marginal (Acceptable)	Ideal Value
1	Reusability	cycles (times used)	800-58,400	58,400
2	Durability	survivable drop height (ft)	3-7	7
3	Lightweight	grams	145-290	200
4	Portability/Size (volume of body)	in ³	120-150	120
5	Gamified Element	average score (scale of 1-10)	6-10	10
6	Cost of Production	dollars	10-50	20

We began by purchasing an IS from Walmart, which had a total mass of 145g and a body dimension of 3 in. x 5 in. x 8 in. We decided to maintain the original design of the

mouthpiece and set our ideal volume constraint for the body at 120 in³ to stay true to the original. Since we expect our gamified element to increase the mass, we increased the ideal mass to 200g. To determine the reusability constraint, we shadowed our advisor, Dr. Morikawa, and visited patients using an IS. Dr. Morikawa informed us that patients typically use the device for 4-5 days, so we set the lower limit at 5 days and the upper limit at 1 year. We calculated the number of cycles based on patients using it 10 times every hour for 16 hours a day, resulting in a lower limit of 800 cycles and an upper limit of 58,400 cycles. To evaluate engagement, we will rank each gamified element internally using a scale from 1-10, with the average score being used to evaluate engagement. Finally, we aim to keep the cost of production under \$20, based on the cost of the device purchased from Walmart for approximately \$10. Our design specifications are summarized in Table 1.

Design Selection

To begin our design process, we brainstormed a range of ideas, then narrowed them down by eliminating ones that did not meet our design constraints (Table 2). From there, we chose our top three favorite designs: the drink style design, the light up design, and the spiral whirligig design. Graphical representations of these designs can be found in Fig. 5. The drink style design was created to resemble a beverage, specifically lemonade, to invoke the feeling of drinking through a straw when the patient inhales through the mouthpiece. The idea was that when the patients inhale through the mouthpiece, it would invoke a feeling of drinking through a straw. In addition, it was hoped that the patients would associate the IS with their favorite drink so they would adhere to the device better. The light up design featured sensors and light-emitting diodes that would activate when the piston moved. The lights will be a visual stimulus that catches the user's attention, and it also provides a visual cue for the user to aim for a target volume or level, and patients can see their progress in real-time, which will hopefully motivate their progress even more. The spiral whirligig design had a spiral placed under the piston so that when the piston rises, the whirligig will unfurl and spin. The spinning motion of the whirligig would create a visual effect that captures the patient's attention and encourages them to use the spirometer more frequently.

To create functional prototypes of these designs, we made modifications to the original designs. The light up prototype was constructed using an Arduino circuit board with photoresistor sensors, light-emitting diodes, resistors, and wires. For the drink style design, we utilized CAD

modeling and 3D printing to create a new mechanism for the volumetric tube to simulate the appearance of the drink going down as the piston rises. The spiral whirligig prototype was created with paper, tape, and thread. Although the prototypes were rough, they were functional and allowed us to test and evaluate the effectiveness of each design.

We presented the prototypes of our top three IS designs at an UVA Family Medicine resident conference and surveyed eight residents/providers for their opinions on the designs. Each design was rated on a scale of 1-10 for four metrics: engagement, creativity, user-friendliness, and likelihood of use. We also requested a rating of the original IS design to use as a control group for comparison with our new designs. Additionally, we asked if the respondents were over 50 years old, which is our target demographic, and if they had used an IS before. We then analyzed the results of the survey to determine which design is our final choice.



Fig. 5. The Top Three Designs Evaluated in the Survey

Performance Testing

After selecting our final design, we will conduct some performance testing to confirm that the new design meets the design constraints we have set. In terms of reusability, we aimed to ensure that the new device could be used up to 800 times without any breakdown or loss of accuracy. This was done by using a vacuum to stimulate the IS by sucking out the air until the piston rises to the top, then letting the piston fall back down and repeat. To test durability, it has to survive a drop height of at least 3 ft but preferably can survive a drop of 7 ft. To pass the lightweight criteria, the new device must have a mass of no more than 290g, which is double the original mass. To test for portability, we measured the approximate volume of the device, mouthpiece excluded, and it cannot be more than 150 cubic inches. To determine the success of the gamified element, the new design must receive a score of over 6 on a scale of 10. We decided to use the average scores from the resident/provider survey. Lastly, the cost of production must be less than 50 dollars.

End Matter

Author Contributions and Notes

M.M.B, C.A.I, and W.L. designed and executed research, created the designs, performed testing, and wrote the paper.

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