

Blind User Accessible Insulin Pump

Design Issues

ECE480: Design Team 4

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Introduction

While planning, fabricating, and testing the Blind User Accessible Insulin Pump, a handful of design issues were formulated. Of these issues, the main priorities were centered on product safety, cost, lifespan, liability, and protection of intellectual property. Some of these issues, such as safety or product lifespan, deal directly with the current prototype model, while others may come into effect as future consumer-based models are created. Since it is a medical device crucial to patient's health, the majority of the issues addressed are focused around creating a safe and reliable product that still has a cost effective appeal. The design team made every effort to address these issues early, in order to avoid any setbacks for future implementation.

Product Lifecycle Management

Within the product lifecycle management, heavy effort was spent during the 'initial design phase' developing a set of specific criteria to optimize the products appeal and functionality. Of these design criteria, the majority of the emphasis was directed towards three key areas: cost, size, and product lifespan.

Going in, cost was the first and foremost of these design criteria. While gathering all the necessary components, every effort was originally spent to find the cheapest parts possible. However, as the design phase progressed, it quickly was realized that the cheapest parts were unlikely to produce the effects necessary for a functional user-friendly device. Therefore, the group learned that a balance must be established between cost and ideal functionality. If too much focus is spent on the cost, the fact that the product doesn't work as intended will greatly overshadow the cheapness of it. Essentially, the end goal was modified towards creating the best product possible at the lowest cost.

Two main issues pertain to advancing the overall lifespan of the unit. The first issue is power supply. The unit must be able to last on a single battery unit for a substantial time length. This will be tested by running the battery unit for an extended period of time, while constantly monitoring its output. The second issue is

durability of materials, specifically the casing piece. This unit will be on the patient 24/7; so it must be able to withstand the normal wear and tear of everyday life, while still being lightweight and comfortable. Currently, the case of this prototype created through 3D printed plastic. This is lightweight, but not very durable, so future models should likely be created with a sturdier type of plastic material.

Lastly, size is an important aspect of the final creation. As mentioned above, the patient will be wearing this device continually during the day. Therefore, the unit must be as small as physically possible as to avoid interfering with the patient's day-to-day activities. Throughout the fabrication process, every intention was made to meet as much of this design criterion as possible. However, in some situations, the standards had to be adjusted to achieve a desired function.

Product Liability

When working with medical devices, there poses more instances compared to other electronic devices where a manufacturer can be liable for any interpreted device errors. As a device developed for those with sight limitations, the add-on for the Asante Snap Insulin Pump aims to deliver insulin pump users the correct information that their pump is presenting to them so that they will operate their device correctly and enter the correct parameters regarding basal and bolus insulin rates. An issue that can develop due to using a digital speech chip is any misinterpretation of the spoken words of the add-on by the user. The user may misinterpret given information and may incorrectly adjust their diets based off of what the add-on is speaking. In future designs, it would be beneficial to add a button or command that allows the pump to repeat any spoken information that is displayed on the LCD screen so that users can adjust their pump settings with more certainty. This will also help improve safety and customer reliability perceptions as well. Medical devices should aim even harder than non-medical electronic devices in producing a product that completely satisfies their users by making the device improve their daily lives.

Also, because this add-on involves significant components from separate manufacturers, there poses the risk of one of these devices failing and causing

damage to one or the other. Since this is the first time that such devices including the MSP430 and V-Stamp Speech Chip have been interfaced with the Snap Pump, there may prove to be long term risks associated with the continued operation of these devices working in tandem.

Another area where product liability could be affected is the operation of the add-on's capacitive touch feature. This capacitive touch feature aims to successfully describe to a blind user what each button's function is before selecting that operation by simply placing their finger on a button. Currently, there is no simple way for a user to disable this feature. During the user's first interactions with the Snap Pump add-on, the capacitive touch feature will help familiarize the user with every available navigation option for each displayed screen. After continuous daily usage, it is assumed that a user will memorize what each of the five Snap Pump buttons does for each screen. The feature may pose as an annoyance after the user has gained total familiarization with the device. A future product will allow for the user to toggle these settings on and off and will allow an experienced user to only use the capacitive touch feature when they encounter pump features that are not often utilized.

Allowing users to have the choice to use only certain features of a product whenever requested is generally an ideal objective in producing any design. When developing this project, the team aimed to demonstrate completely what the device was capable of and did not have adequate time in creating features that were easily switched by the user aside from detaching the Snap Pump from the add-on completely.

Product Safety

For every project, safety is always a main concern. For this project, the team built an add-on for the Asante Snap Insulin Pump for patients to wear every day. Also, the pump will be connected into the user's body to administer insulin. Though the safety issues for this insulin pump add-on are not very obvious, they still exist. Most safety issues for the add-on of insulin pump can be classified as physical issues.

Electrical Issues:

Since the team is using an additional battery to power the add-on, which means there is a possibility of having leakage of current. According to the 'Merck Manuals', the accidental exposure to high voltage causes about 400 deaths each year in United States. Though the current and voltage of the add-on is very small, no patient will want to receive an electric shock while they are having insulin pumped into their bodies. Shocks from the add-on's current and voltage will not kill a user, but it may hurt or startle some.

To improve this kind of safety issue, the team is designing a case for the add-on to package the whole system of electronic components into the case. For the material of the case, the team chose a strong and flexible plastic, because it is a kind of dielectric material. Also, this material can be easily produced by a 3D printer to print the case. This approach not only saves time to produce the case for the add-on, but also improves the safety of the device.

Weight Issues:

The second safety issue of this project is the weight of the add-on's electronics and case. Patients are using this pump while attached to their bodies around 12 hours per day and the pump with add-on is not supposed to negatively affect their daily life. Since the team has chosen to use plastic to be the material of the case, the weight of case has been decreased to be as low as possible. The weight of add-on is the main factor of this safety issue. To build this add-on and achieve the goal of this project, the team has a MSP430G2553 Launchpad microcontroller, a V-stamp digital speech chip, a speaker, and an extra battery. The weight of this add-on is four times heavier than the pump.

To improve the safety of this issue, the team is building the digital speech chip circuit and power supply circuit on the same soldering board. Following this procedure will allow for the weight of the add-on to be reduced to a minimum amount.

Protection of Intellectual Property

Design team four's insulin pump design is easy to copy by rival companies. The design for the blind accessible insulin pump requires a V-Stamp, which contains RC Systems' RC8660, and an MSP430G2553 Launchpad. The V-Stamp has a programmed exception library with recordings by a team member of button and screen labels. The MSP430 Launchpad uses its UART connection to connect the pump and the V-Stamp and regulate the data sent to the V-Stamp. The MSP430 also has additional pins set as inputs for the capacitive touch and is programmed using Energia. The recordings loaded onto the V-Stamp can be downloaded off of the V-Stamp by anyone with access to RCStudio, a program that can be downloaded for free from RC Systems' website. If the recordings cannot be downloaded, it would be easy for someone to rerecord with a new speaker and create their own exception dictionary. The MSP430 code for capacitive touch is easy to recreate and there are multiple examples of capacitive touch with Energia online. Also, the code to read the input from the V-Stamp would be simple to recreate because of online documentation. The entire system the design team has created would be easy to recreate. The materials used in the design are available to everyone, and the programming for the MSP430 and V-Stamp are simple to recreate due to online documentation. The only section of the design created by the team that cannot be recreated is the connector for the pump to the MSP430, which was supplied by Asante Solutions. If rival companies are more concerned with creating a device that allows their insulin pump to speak, then the connection to the Snap pump would not be a concern for them.

In order to stop the design from being recreated by competitors, the design could partner with Texas Instruments or RC Systems to create a microcontroller that only Asante Solutions can use that is specifically made for the Snap insulin pump. The idea of text to speech or digital speech is not new and there are many ways that it can be created, so the best way to protect against a competitor recreating the design is to patent a design in an agreement with RC Systems or Texas Instruments.

Conclusion

A large portion the issues detailed above was formulated early on, during the initial research and planning phase of the project. This way the group could adequately account for, and hopefully eliminate, potential risks or failures that may arise in the final design. Due to this early obstacle detection and planning, the team was able to direct more of their attention to creating the most functional and reliable prototype possible. As the project developed and progressed, the team was also able to identify possible improvements for future models

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