Accessible Insulin Pump

ECE 480
Design Issues
Team 3

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**Introduction**

Insulin pumps are medical devices that deliver insulin 24 hours a day through a catheter placed under the skin. The fact that these devices need to be worn 24 hour a day arises a set of concerns that translate into issues when it comes to its design and fabrication. If we add the need to make these devices visually-impaired-friendly, we encounter an even bigger set of design and manufacturing issues. Among the main design issues we encounter: reliability, since the user’s health depends on these devices; lifespan and safety, these devices are worn 24 hours a day so they must resist any type of condition: bumping, sweating, scratching, dropping, etc. Therefore, we will focus on three main areas of concern: Project lifecycle, product liability, and product safety.

**Project Lifecycle Management (PLM)**

*Design*

During the designing part, a lot of effort was put into selecting electronic devices that when put together would deliver the desired outcome and, at the same time, could fit into a relatively small size case, for a “small” finished product, this is due the fact that the insulin pump must be worn 24/7. It is worth mention that the team is assembling a functional insulin pump, and even though the final design will not, actually pump any insulin, the final product will stimulate insulin being pumped. Moreover, the selected parts needed to be easily assembled and/or programmed, since the team is working on a deadline. In addition to the previously stated requirements, energy efficiency was an important factor on choosing the parts to develop the insulin pump. Once again, the final product is to be worn 24/7, it must consume enough power to process information, do calculation and deliver the insulin, but not so much that the user needs to be changing or recharging the battery every hour.
Another important aspect of the design process was not only finding the parts that would be small enough, have low power consumption, and are reliable enough to be used on medical device, but also are low cost.

Fortunately, the team was able to find all the parts needed for the development of the accessible insulin pump. The parts obtained were: the experimental board MSP-EXP30F5438, this board manufactured by TI posses an integrated five-directional joystick, two buttons, an LCD and a microcontroller (MSP430F5438A). The board has integrated almost all devices needed for the successful completion of the project, it was initially believed by the team members that the experimental board also included a text-to-speech converter, but after receiving the experimental board it was noted the lack of it. The experimental board successfully complies with the low energy consumption, small size, and lightweight standards. The other part obtained was a text-to-speech chip/voice synthesizer. This device was a little harder to obtain than the experimental board as there were some logistic problems, i.e. it took around four weeks for the part to arrive, which caused a delay in the team’s schedule. If the team would have done more research on the experimental board, it could have been noted from the beginning that the experimental board did not include the text-to-speech chip, which may have saved a little time. Along the line of the text-to-speech devices, the team could have researched the supply and demand of the product. The unavailability of the product in the market put the team’s schedule to an unexpected halt. An alternative solution could have been to find a different part to use for the design.

Production
The total manufacturing cost of one unit of the accessible insulin pump is about $500. The most expensive parts are components of the hardware: the experimental board MSP-430F5438 ($175) and the MSP-FET430IUF ($120). For future modifications, parts of equally high quality and lower prices can be used to substitute these two components. The software will be completely developed by the team over a period of 3
months with testing and modification. For the program development, the software has no cost. The team might obtain a copyright for its intellectual property. To house the pump, a design will be constructed via a computer aided design program. This design will be exported to a 3D printer which will manufacture the piece out of polymer. As it will be a high grade polycarbonate, the housing will continue to successfully hold the product for the entirety of the pumps life.

**Distribution**

Distribution will be made at the request of the patient provided a medical prescription. The amount of units will be kept at a minimum so the cost in storage can be saved. Provided that the team decides to sell the final product's rights, its distribution will be managed by the company acquiring the final product. However, shipping cost will be paid by the consumers.

**Consumption**

A representative will go to diabetes centers to teach users how to operate the insulin pump. Written documents will also be available for users to download and a hard copy will be included with each insulin pump order. Video tutorials will also be available on the company webpage. No spare parts are used in this project. If a user needs a refill of insulin, he/she can contact his/her medical provider to be prescribed refills, which can be obtained online or by phone.

**Retirement**

The accessible pump is made out of different electronic/electrical parts, all of which vary in lifespan. Proper care of the device will increase the lifespan of the product, but the outer part of the insulin pump is design to protect the electrical/electronic components of the device helping on situations where a user might drop the device. The device might have contact with water or any other external factor that could affect greatly the lifespan of the device.
**Product liability**

“From 1996 through 2005, the FDA received 1594 reports of adverse events involving insulin pumps in patients between the ages of 12 and 21 years. These adverse events involved injuries in 1038 patients (65.1%), malfunctions in 528 patients (33.1%), “other events” in 15 patients (0.9%), and death in 13 patients (0.8%). The device-related events involved error messages as well as problems with the alarm, catheter, and/or screen display” (Klonoff, 2009) Due to the delicate nature of medical devices, they required a little more precautions while designing and manufacturing them. Millions of people rely on this lifesaving device on a daily basis. That is why, while designing the accessible insulin pump, the team has spent a lot of time looking for a reliable device that could carry the most important features of the insulin pump. The text-to-speech conversion must have no errors in communication between the user and the pump. This feature is a necessity because blind or visually impaired users will rely on what is being spoken, from the insulin pump, to input their basal and/or bolus data. Any error in these values inputted could cause low or high glucose levels that could, eventually, lead to a fatal catastrophe. A “Repeat” button is placed on the insulin pump so that user can repeat what is being displayed on the menu as many time as they need.

The experimental board MSP-430F5438 has not been tested for continuous use, with the text-to-speech/ voice synthesizer attached to it over a long period of time, so long term interferences between devices have not been detected.

Moreover, the device functions are completely controlled by a set of codes downloaded to a microcontroller on the MSP-430F5438. This type of electronic device is susceptible to viruses that can corrupt the source codes completely damaging the device functionality. For further development of the accessible insulin pump, software protection and code encryptions must be implemented, while also leaving sufficient access for simple data extraction, such as usage history.
Product safety

One of the main safety issues concern with this accessible insulin pump is the risk of electric shock. Although the pump is designed to resist the usual wear that comes from a 24/7 usage, there are circumstances for which the pump is not yet to undertake. For example, the accessible insulin pump is not design to operate underwater. If a user would take the device under water, it will result in permanent damage. Although the amount of current feeding the device is not large enough to affect the user, no one would like to be carrying a device that might give them sporadic electric shocks, even if the possibility of them is almost null. That is why the team is using a non conductive material for the device’s case to avoid the risk of voltage/current conduction through the case and on to the patient. Furthermore, the batteries draw such a small current that electric shock from them is virtually impossible.

In addition to the electric shock hazard, weight is a factor to be considered. Due to the constant usage of the insulin pumps, the device must be lightweight. It should be light enough to the point of comfortability, such as a cell phone or a pager. It should be easily accessible and have a firm attachment to the person. The experimental board along the text-to-speech/voice synthesizer are lightweight enough to be carried at least 12 hours without feeling uncomfortable or “heavy”. The housing will have a clip that will allow the user to attach the device around their waste.

Conclusion

Since the design phase of the project the team was well aware of constraints like size, weight, and quality of the voice produced. Before coming with a final design, the team met with a blind insulin pump user to gather information and get the “needs” directly from the source. Due to this fact, the team was able to come up with the most reliable and safe prototype possible. Moving forward towards the completion of the project, the team will identify and strive to fix any design issue encountered.
Resources


http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2771530/