WHERE THE RUBBER MEETS THE ROAD: MAKERS, DIY, AND QUALITY CONTROL

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ABSTRACT

The Maker movement and Do-It-Yourself (DIY) attitude are rapidly growing all over the world. This combined with inexpensive digital fabrication technologies, such as 3D printing, has the potential to turn traditional engineering and manufacturing paradigms upside down. This might be an overstatement, but the fact remains that it has never been easier for a 9 or 90 year old tinkerer to build truly amazing electromechanical devices with little training or money. The Assistive Technology (AT) field is experiencing an influx of these tinkerers, or amateur engineers, with a passion to help individuals with disabilities. The E-nabling Group which helps people 3D print their own prosthetic hands is a great example of this influx, with over 3600 members worldwide. With the growing number of amateur engineers possessing the ability and desire to create AT how does the existing professional establishment embrace this movement? The purpose of this paper is to begin the discussion of this question and how to best assist amateur engineers in producing safe, reliable, and functional AT devices. The included clinical case study will provide a convenient and practical framework for discussing the design considerations differentiating a prototype suitable for tinkering from a device safe and reliable enough to be sent home with a Patient. This case study involves a button pusher developed with the same tools used by Makers, such as 3D printing and open source electronic development platforms. The design considerations offered don't necessarily equate to a product suitable for manufacture, but rather a minimally viable product. A product ready for manufacture would require even further design refinement and is beyond the scope of this paper.

CASE STUDY- BUTTON PUSHER

Many Patients with spinal cord injuries and other neurological disorders have limited ability to interact with their environment. There are an ever growing and changing array of products and systems known as Electronic Aids to Daily Living (EADL) available to give access to televisions, telephones, lights, and many other systems. This area of AT is experiencing a growth boom fueled by the rapidly expanding home automation industry. One item that continues to be difficult, at best, to control is hospital bed power functions. Enabling access to bed functions increases a Patient's independence for bed mobility and positioning while decreasing caregiver burden. Traditionally, to provide this access involves reverse engineering hospital bed hand pendant communication protocols or even modifying these pendants, switch adaption, to enable external control. This tends to be expensive and time consuming.

The practice of switch adaptation is common in the AT field and is acceptable for toys and non-medical equipment as part of clinical practice involving the rehabilitation team. This team includes the physician, therapist, and rehabilitation engineer. The waters become somewhat muddy when an Food and Drug Administration (FDA) regulated medical device is modified. This brings about the potential for liability, legal, and warranty related issues unless cleared with the manufacture or FDA. To provide a more universal and cost effective solution that somewhat side steps the potential for negative liability, legal, or regulatory repercussions a configurable button pusher was built. This design will be discussed in detail in the Approach section.

DESIGN GUIDELINES AND CONSIDERATIONS

Translation of a prototype design into something that will function reliably and safely requires attention to many details not always initially addressed. The following questions are part of responsible engineering design practice. They do represent important concerns when designing and building safe and reliable electromechanical devices. They do not represent a formalized design process guide. The best way to summarize these considerations is to design and build for the worst case scenario. It is better to over engineer than under engineer when related to safety and reliability of AT devices.

Design Considerations

1. Construction and packaging
    a. Is the enclosure strong enough?
    b. Use off-the-shelf project box versus custom 3D printed enclosure?

c. How will the enclosure be mounted or secured?
d. Environmental protection required (i.e. water resistant)?

2. Wire and cabling
    a. Are internal cables secured and attached properly?
    b. If there are external cables are they permanently fixed or attach via connectors?
    c. If connectors are required are the appropriate parts utilized?
        i. Power versus signal connectors,
        ii. Connector coupling rating,
        iii. Locking versus non-locking connectors,
        iv. Keyed versus non-keyed connectors.
    d. Are external wires strain relieved adequately?
    e. Cable strength versus flexibility.
    f. Is cable shielding required?
    g. Is the cable insulation non-toxic?
3. Power
    a. Will battery, wheelchair, or wall power be used?
    b. If battery power, what is the battery life requirement?
    c. Should a rechargeable or primary battery be used?
    d. If primary battery, are they easily replaced by the user.
    e. If user replaceable, what happens when batteries are inserted incorrectly?
    f. If externally powered what happens if the power cord is cut, shorted, or reversed?
    g. Should there be a power button, switch, or no power control?
4. User Interface
    a. Is a user interface required?
    b. What user feedback is required (audible and/or visual)?
    c. How does the user adjust device settings if applicable?
    d. How are improper user settings prevented or mitigated?
5. Moving Parts
    a. What are strength and durability requirements?
    b. What materials should be used for moving parts?
    c. Is any sort of simulation required to verify part design?
6. Appropriate Documentation
    a. Are buttons, connections, and the user interface labeled?
    b. Instruction manual including
        i. Features,
        ii. setup and usage,
        iii. usage guidelines,
        iv. Troubleshooting and support.
7. Support
    a. Who will install or setup device?
    b. Who will provide support?
8. Has catastrophic failure been considered?
    a. What is the worst case scenario of a failure and how could that effect the user?
    b. What measures have been taken to prevent these failures?
    c. What measures have been taken to prevent harm to the user?
    d. Is this documented?
9. When should additional mechanical, electrical, or clinical help be sought out?

<u>Patient Related Considerations</u>

In addition to the mentioned design considerations it is important to begin with the Patient and not let the excitement of creation pull the design process in the wrong direction. The following questions are important to explore in the beginning stages of a design.

1. What is the Patient's goal?
2. What is the caregiver's goal?
3. Do these goals align with the rehabilitation team's goal?
4. Is the design goal based on these goals?
5. Have existing off the shelf solutions been explored?
6. How can the solution be tested in a controlled environment with the Patient to quantitatively verify effectiveness?

APPROACH – CASE STUDY

The button pusher design was intended to allow most wired / wireless remotes or hand pendants to be operated via IR signals emitted from Augmentative and Alternative Communication (AAC) or EADL systems. The remote to be adapted, in this case a bed hand control, is mounted in a frame work of servo motors. These servos are controlled by a simple electronic development platform and positioned over the desired buttons to be pushed. This configuration requires more servos and more mechanical setup than a single robotic arm button pusher, but is an extremely reliable configuration. Infrared (IR) signals received from a universal television remote are converted to servo motions that depress particular buttons. The IR remote is then used to train an AAC or EADL system which is controlled by the Patient. The IR remote can then be used by caregivers to access bed functions if no other control method besides the enclosed hand pendant is available.

Building a working prototype involved 3D printing the adjustable servo mounting hardware, and programming the electronics development platform to control the servos in response to IR commands. Initially the button press duration was hardcoded in the software. The device enclosure housed the bed hand pendant, electronics, and had open holes for an IR receiver and power cable. Once a proof of concept prototype was completed the real work began to transform this device into a reliable product that could be installed by someone other than the designer, and reliably used by the Patient.

Many of the considerations and guidelines mentioned in this paper were addressed at this stage. The button pusher is intended to be mounted to the bed frame or placed on the floor. There is minimal vibration in these environments, but the potential for moisture exposure is likely. Therefore, the enclosure chosen was an off-the-shelf project box rated to be waterproof and extremely durable. The IR receiver was separated from the enclosure so it could be mounted on a wall or near the EADL or AAC device. All connections from inside to outside of the project box were via appropriate power and signal connectors with coupling ratings over 10,000 and voltage ratings 10 times the required voltages. The cable for the bed hand pendant was passed through the enclosure using a split strain relief ring, providing protection to the interior of the enclosure and the cable itself. A power switch or button was not included as this device should be powered at all times. A power switch could be a source of confusion or failure. The power supply used was a simple and safe low voltage fuse protected power converter. In the event of a short circuit the power supply fuse would fail, cutting off power to the device. A simple user interface was included consisting of a light emitting diode (LED) and the universal television IR remote control. The software of the button pusher was modified to include a setup mode to allow for adjusting the button press duration through the IR remote. This allows for customizing button depression time to the given bed function for bed compatibility and ease of use. All internal wire routing was secured with cable ties and the electronics firmly mounted in place using plastic standoffs. The method for entering the setup mode was developed to minimize accidental usage and confusion.

All connections and the LED were labelled on the enclosure externally. Additionally, a contact information label was added for troubleshooting and support. The device was tested with a hospital bed and AAC device to insure reliable and successful operation. To test the longevity of the mechanical and electrical systems a special software version was developed and loaded onto the button pusher which activated each servo every 3 seconds and device was run continuously for 6 hours. This resulted in each servo activating 7200 times which caused a slight temperature increase above ambient temperature in the sealed enclosure, but otherwise left the button pusher functionality unaffected. This concentration of usage far exceeds any potential normal usage.

Currently the button pusher has been used in the hospital setting for short durations, but not been installed permanently or used in the Patient’s home environment. This device has the potential for many other applications where a Patient desires control of medical and / or non-medical equipment, but doesn’t have the ability to use the standard equipment user controls.

DISCUSSION

Case Study

The provided case study illustrates the basics of design refinement related to translation of a prototype to a minimally viable product which is suitable for Patient usage. Additional design modification, testing and documentation are required to make this product appropriate for long term usage by a Patient. Details such as servo selection, electronic protection, enclosure mounting, reliability testing, and user manual development certainly need to be addressed in more depth to create a more robust and mature product.

AT Design Guidelines

The guidelines and questions presented constitute a rough outline of the thought process that should occur when designing and building any product. They become even more essential when a person is relying on this product as an AT device. The button pusher case study illustrates this process in practice. This paper is a starting point in a broader discussion about the Maker community and its relationship to AT professionals and to RESNA itself. Some additional and more general questions surrounding this issue include:

1. What role should RESNA play in this environment?
2. What other organizations should be included in this discussion?

3. How should this information be communicated to the Maker and DIY community?
4. How can an AT organization utilize amateur engineering AT designs or products?
5. How can RESNA be a leader in this new environment?

A powerful opportunity for growth of the AT field exists if RESNA can provide the appropriate guidance to the expanding population of passionate and talented amateur engineers contained in the Maker and DIY movements. Possible paths to this goal could be RESNA producing a position paper, provision guideline, conference presentations, or training series related to electromechanical AT design practices.