Cleaning Indicator for Reusable Medical Equipment

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Abstract

Dr. Scott Springman wishes to have a more reliable mechanism to determine if a machine brought into an operating room is clean and available for use or dirty and needing to be reprocessed. He expects the device to be permanent and adjustable, capable of being thoroughly cleaned and non-hazardous. Thus far we have modeled three designs that meet the design requirements and determined the best prototype. The prototype will be made of a hard plastic, incorporate a gear and knob mechanism, and have a clear acrylic or Plexiglas viewing window. Next, we plan to 3D print the prototype and test it with the client. After thorough testing, multiple indicators will be fabricated using plastic injection molding.

Problem Statement

The problem of determining the cleanliness of a piece of equipment is difficult in the anesthesiology department. There are a limited number of machines available to the anesthesiology department and the machines are always in high demand. Due to time and personnel limitations it is difficult to reprocess a machine every time there is a question of cleanliness in the department; therefore, the washing (reprocessing) of a machine needs to be limited to only when it is necessary.

Often times the machines will be placed in the hallway outside of the departments operating rooms. A machine in the hallway then indicates to other anesthesiologists that the equipment is not in use. Therefore, if another anesthesiologist decides that they may need that piece of equipment he or she will try to determine if it is clean then roll it to their room.

To determine if it is clean there are many different indications to look for. Sometimes it is obvious that it is dirty, and then it is rolled to the reprocessing room. The device may have other clear indications that it has been reprocessed (cleaned). These indications may be tools of the machine in certain places or visual indications of cleaning will be present. An example of this may be a string holding the drawers of a large toolbox together. However, getting accustomed to these little indications of reprocessing is not easy to pick up on for new persons in the department, and the indicating cues are different between departments in the hospital.

The current method of indicating the machines is based on the last user's ability to move the machine to a cleaning area for reprocessing or on flipping a paper sign on a cable. This paper sign method is widely accepted in the department as unreliable and many anesthesiologists and technicians do not bother flipping the sign from clean to dirty after use. This sign method will be described later in more detail. The unreliability of this method results in uncertainty of cleanliness of equipment, and if there is uncertainty the machines get reprocessed.

However, the reprocessing of machines may not always be necessary. Therefore, if the reliability of indication could be standardized throughout the hospital and indicated consistently, the hospital could save time, money and possibly the risk of contaminating another patient.

Background Information

Client Description

Dr. Scott Springman is an anesthesiologist at the University of Wisconsin Hospital. He would like a device that accurately indicates whether anesthesia equipment is clean or if it has been used and requires sterilization. Christina Jordan is an anesthesia services support supervisor that works with Dr. Springman who shares his interest in the development of such a device.

Use of Anesthesia in Medical Procedures

Anesthesia is the process by which feeling and or consciousness is removed during a medical operation in order to eliminate patient pain. This is done with the use of anesthetics; drugs that work to slow the heart rate, cause the onset of drowsiness, and block pain during surgery. Anesthetics can be delivered intravenously or by inhaling a gas (1).

Primary Machines used in Anesthesia

Figure 1: Anesthesia Machine .

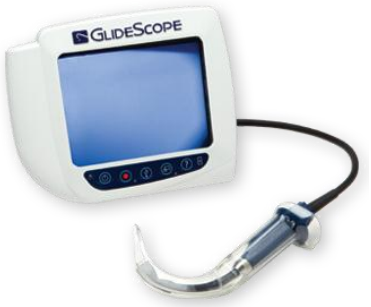

Figure 2: GlideScope.

Anesthesiologists use advanced medical equipment to facilitate the delivery and monitoring of anesthesia. Large anesthetic machines (Figure 1) are used to continuously supply the patient with oxygen and a vaporized anesthetic drug during the course of a procedure in order to keep the patient sleeping and prevent pain (2). GlideScopes (Figure 2) are video laryngoscopes used to place tracheal tubes with the assistance of a live video stream on a monitor (3). Bronchoscopes (Figure 3) are used to monitor the airway during a procedure (4). Jet ventilators, ultrasound machines, and larger video scopes are also used.

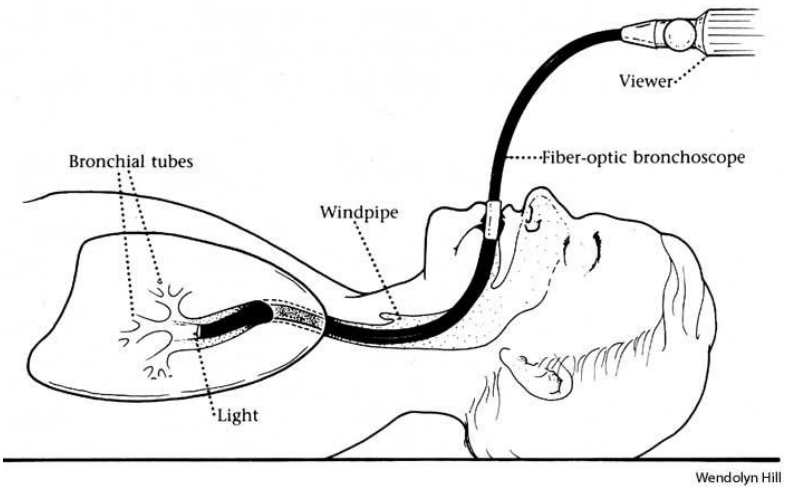

Figure 3: Bronchoscope intubation.

All of these machines are mounted on rolling transport carts, allowing them to be quickly moved throughout the hospital. Bronchoscopes and GlideScopes are mounted on a vertical metal poll with rollers (Figure 4), while the larger equipment is on larger square carts (Figure 5).

Figure 4: Vertical poll cart for bronchoscope.

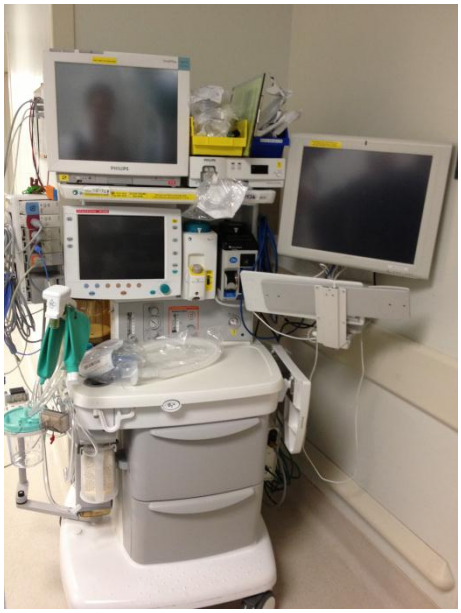

Figure 5: Standard anesthesia delivery cart.

Medical Device Reprocessing

The majority of anesthesia equipment is reusable, allowing it to be used to treat multiple patients. During an operation, the medical instruments that contact the patient become contaminated. In anesthesia, instruments routinely come into contact with bodily fluids as they are inserted into the mouth and throat. This means that everything must be thoroughly sterilized following a procedure before it can be used with another patient. The process by which medical equipment is cleaned after use is called reprocessing (5).

Multiple common sterilization techniques are used to reprocess medical equipment. The technique used depends on the device in question. Smaller instruments, such as bronchoscopes, GlideScopes, and tracheal tubes, are sterilized by autoclave. An autoclave is a sealed chamber that uses a combination of high temperature (250+ degrees F) and pressure (20-30 psi) to sterilize objects with steam (6). It is commonly used in hospitals to clean surgical instruments. For larger anesthesia equipment, including monitors and the transport carts, a quaternary ammonium disinfectant solution is used (Quat). It is applied to a washrag and used to wipe down machines that are not easily autoclaved. In addition to CaviWipes—which serve the same purpose as a Quat soaked rag—the solution used at the UW-Hospital is Neutral Quat Disinfectant Cleaner Concentrate by 3M.

Following a medical procedure, used equipment is brought to the reprocessing room for sterilization. Everything on a cart must be reprocessed, as well as the cart, regardless of whether or not it was all used in the operating room.

Currently Employed Indication Method

Currently, the UW-Hospital uses laminated flip signs to indicate whether a machine is clean or dirty. “Clean” is printed on one side, and “Dirty” is printed on the reverse side (Figure 6). A metal chain is used to hang the signs on anesthesia machines and carts.

Figure 6: Current indication system used by UW-Hospital.

There are several problems with this method. The signs are not permanently attached and have a tendency to fall off when the cart is in transport. It is easy to inadvertently flip the signs when moving a cart or by bumping it. This causes confusion as to whether a machine is actually clean or dirty.

RFID Technology

The UW-Hospital uses Radio Frequency Identification (RFID) devices to wirelessly track the location of machines throughout the hospital. Because carts are moved around to accommodate patients in different operating rooms, they are sometimes temporarily lost if not returned to the reprocessing room after use. The RFID system allows missing machines to be found quickly when they are needed in another area. The hospital uses a device made by AeroScout(7), which is adhered to a flat surface on a cart (such as the side of the cart or the back of a monitor, Figure 7). These devices use a standard WI-FI network to pinpoint their exact location in the hospital.

Figure 7: RFID tag mounted on a portable bronchoscope machine.

Design Requirements and PDS:

The device must function to universally indicate the state of cleanliness of a medical instrument. The device must be cleanable under various conditions and must not pose any biological hazards along with withstanding various operating room conditions. The device must be biologically friendly in that there are no risks to patients in the operating room and also to the user of the device.

The device must be capable of being permanently affixed without interfering with the functionality of equipment, and be able to withstand physical impact and cleaning operations. The indicator must also be capable of bonding to multiple surfaces to fit machines universally, with each machine having its own cleaning indicator.

In addition to the common sterilization practices, the device must also be able to withstand various operating room environments and conditions. These may include exposure to bodily fluids, primarily blood, saliva and vomit. With a risk of contamination with bodily fluids, the materials used to build the device should not be composed of corrosive or biologically abrasive elements. If the device resulted in a torn glove, this may endanger the person performing the operations or contamination of the exposed operating area.

The accuracy and reliability of this device are important considerations in this design. The device must accurately and reliably display the desired state of cleanliness. The device must also remain permanently affixed to the desired piece of equipment that needs indication lasting as long as the medical device it is permanently attached to.

There are ergonomics in this design that need consideration. The indicators must be compact enough to be simply affixed. The device must be quick and easy to adjust by the user, such that the device's mechanical functions are capable of being performed with minimal user precision. The indicator should then be capable of being manipulated with a single, glove-covered hand similar to the conditions expected in the operating rooms. The indicator should have a depth no deeper than 2-3 cm, a length and width no greater than 8 cm by 6 cm. The

device should weigh around 28.35 grams (8 ounces) so that it is easy to attach and manipulate by the technicians and anesthesiologists.

Design #1 (Flipper):

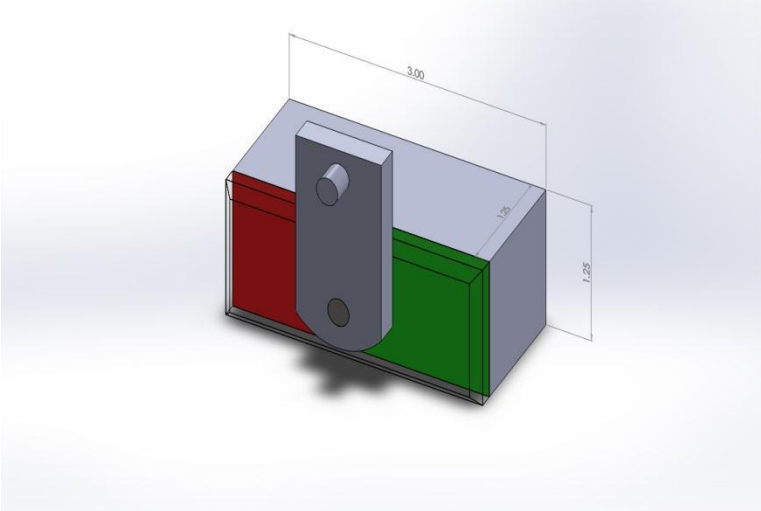

Figure 8: Design #1 – Flipper.

As can be seen from Figure 8, main dimensions of this flipper design are 3.175 cm. (1.25”) X 3.175 cm. (1.25”) X 7.62 cm. (3”); which fall within the specifications of the client. This design has a rather simple flipper mechanism that the operator would pivot around the fixed column to indicate whether or not the machine it is affixed to is clean (red covered) or dirty (green covered. The grey areas in Figure 8 will be made out of plastic. The type of plastic has not been determined yet for a few compounding reasons. First, we hope to 3-D print our prototype which would make our type of plastic dependent upon the printer plastic that is on hand. Second, we hope to eventually have the product made from a plastic injection mold process and the composition of the material will depend on what plastics would be compatible with the plastic molding process. Finally, we need to further meet with a few different contacts within the hospital to determine common types of plastics that are used and would be safe within the hospital and what plastic would allow for us to use the hospitals proprietary adhesive that they normally use to attach items such as RFIDs to the machines. As can be evidenced from Figure 8 there are red and green colors used to indicate the cleanliness of the machine. These colors would be either enamel, such as Rustoleum, or another sort of plastic bonding paint. To protect these colors throughout many wash and sterilization cycles, a clear viewing pane would be used to seal this face. The viewing pane can be machined out acrylic or Plexiglas and adhered with either a bonding agent or stainless steel/ plastic screws, in compliance with many other medical devices. The major downside to this design is that if any biological agents get in between the flipper cover and the viewing pane, it wouldn’t be possible to clean without the flipper being slid from the shaft and the indicator being partially disassembled.

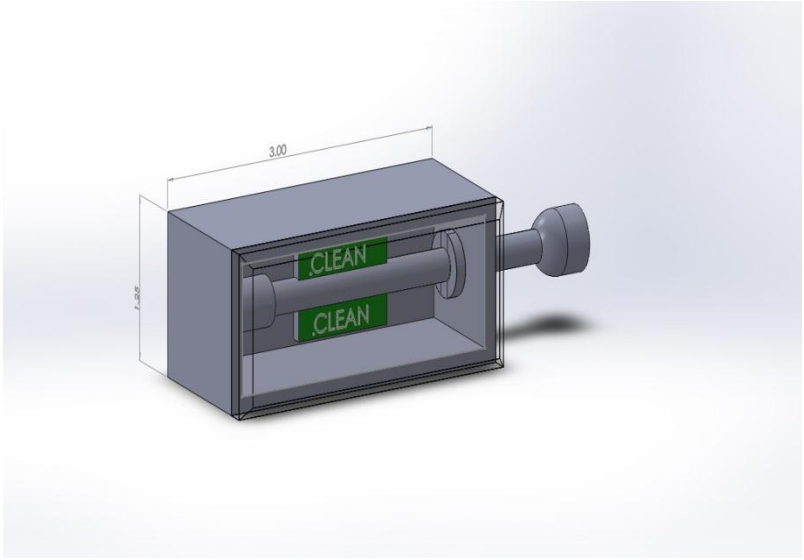

Figure 9: Design #2 – Side Knob.

Design #2 (Side Knob):

The second design allows for a little more complex, but overall more reliable indicator. As can be seen in both Figure 8 and Figure 9 these designs have the same body dimension of 3.175 cm. X 3.175 cm. X 7.62 cm., in accordance with the clients wishes. This knob mechanism was developed to ensure a reliable indicator mechanism. This is achieved through the gear mechanism. Inside the footing that the above rod slides into is a compression spring. When the operator applies pressure to the knob and compresses the spring, the gears will disengage and the user can rotate the rod 180°. This will display the opposite rod face and show red, which indicates the machine needs to be cleaned. Upon relieving the pressure on the knob, the gears will re-engage and the indicator will display whether it is clean or dirty until it is manually changed. This design will be composed of a similar plastic to Design #1, and currently faces the same material decision challenges that Design #1 also does. It will also use an enamel or paint similar to that for Design #1. This design will also have an acrylic or Plexiglas viewing window to protect the mechanism from any biological agents that could enter otherwise. The motivation for the domed cylindrical knob was to provide adequate gripping surface but still allowing for the reprocessing personnel to be able to adequately clean in between the enclosure and the knob.

Design #3 (Front Knob):

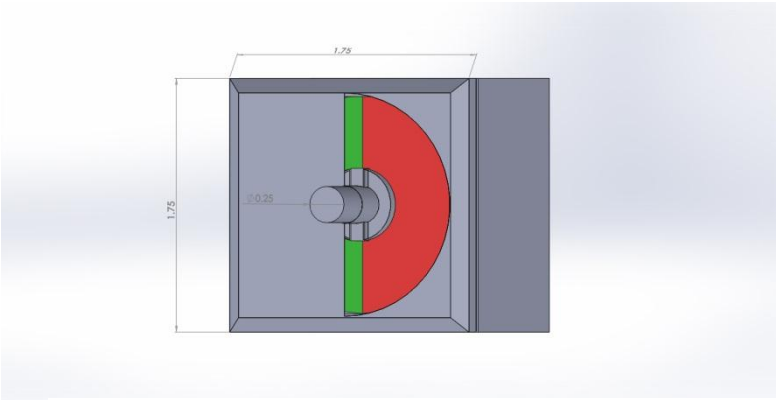

Figure 10: Design #3 – Front Knob

The third design is quite similar to the second design in multiple aspects.

The body dimensions of the third design are 4.445 cm. X 4.445 cm. X 3.81 cm. as shown in Figure 10. The mechanism housed inside the indicator is the same as the one used in Design #2, except that it is positioned with the knob projecting from the face of the projector. It possesses the same reliability factors that are achieved through the use of the gear mechanism, and the ease of cleaning by using the domed cylindrical knob. However, it

presents a more easily accessible knob and may be mounted on a greater variety of surfaces than Design #2 as a result. The square rotating indicator that is mounted on the shaft found in the second design is replaced with a disk, colored into two halves using enamel paint. When the operator applies pressure and rotates the indicator knob, the disk will rotate, bringing either the red or green colored half of the disk into the viewing window indicating whether the medical device requires cleaning. This design will be composed the same plastics as Design #2, and again, it faces the material challenges of Design #1.

Design Matrix

Metric	Weight (1-3)	Flipper	Knob 1 (Side)	Knob 2 (Front)
Indication Reliability	3	2	5	4
Ease of Use	2	5	4	4
Cleaning Accessibility	3	1	5	5
Durability	1	1	5	3
Longevity	2	5	4	4
Size	1	5	3	4
Cost	1	5	3	4
Total		40	57	54

Indication Reliability

The reliability of the device to indicate the proper machine state was given the largest weight because of its importance to the success of the device. The goal of this device is to replace the current indication methods used by the UW Hospital Anesthesiology Department, which have been inaccurate in displaying medical devices sanitation, resulting in wasted time spent sanitizing machines that may be clean. Therefore, the ability of our device to eliminate this problem is crucial. The flipper device received the lowest score because of its low resistance to being changed from ‘dirty’ to ‘clean’ during possible bumpy transits through hospital corridors. The front mounted knob device received the second highest score, primarily as a result of the knobs location on the face of the device. Mounting the knob on the front of the device means that the knob may be bumped and twisted inadvertently, however, the gear mesh mechanism inside still made it more reliable than the flipper. The side mounted knob device received a perfect

score because the knobs location on the device results in a much smaller degree of accidental indication changes. The combination of the gear meshing mechanism and the ideal location of the knob made the Knob 1 (Side) design the best option.

Ease of Use

The ease of use for our device was given the second largest weight due to a fundamental problem seen in previous solutions used. In the past, the indicators used to label each device were different, and were found to be frustrating and unused by medical aids that only spent a short time in each department due to their rotations. As a result, the operation of the indicator must be simple and intuitive. The front and side mounted knob designs scored the same in this area due to the designs identical mechanisms. They both received high scores as well because both devices may be operated with one hand and are relatively simple to use. The fact that you must push in the knob first may confuse some however. The simple flipper design received the highest score in this area, due to the fact that its entire mechanism is evident to the user.

Cleaning Accessibility

The cleaning accessibility of the design also received the largest weight as a result of the environment which it will be used in. The device should be easily sanitized and should possess no unreachable or difficult recesses that may house bio hazardous materials. The flipper mechanism scored very low in this class due to its friction faces in between the flipping slide and the mounted base. Hazardous materials may be smeared on the face of the device, and the flipping of the slide would smear the material behind it into an unreachable location without removing the slide from the mounted base. Both the side and front mounted knob mechanisms received a perfect score in this class, however, due to their knob design and basic shapes, yielding no gaps or spaces for simple sanitation. The tight, slip-fit rod of the mechanism would also restrict any hazardous materials to enter the device.

Durability

The ability for these indicators to handle possible abuse received the least weight in this design. The possible bumping of devices together or misuse by the client should be accounted for in designing a long term solution; however, the faces these devices will be mounted to are usually out of the way and are rarely impacted. The flipper design scored very low in this class, due to the moment that can be created about the pivot point by the slide. If bumped incorrectly, the slide could easily snap the rod in the mechanism. The front mounted knob design received the second highest score, with its easily accessible knob also making it project out from the medical device more and raising the likelihood of it being bumped and snapped off. The side mounted knob design scored the highest in its class once again due to its ideal knob location, minimizing the likelihood of impact with the fragile knob.

Longevity

The long term structural capacity for the indicator received the second largest weight. The device being designed is meant to be used on a variety of machines, and is meant to serve its purpose for the foreseeable future. As a result, it is important that the indicator has the ability to

survive repeated and long term use without significant wear. The flipper received a perfect score in this class because of its simple design. The devices functionality revolves around one simple moving part, ensuring long time use. The front and side mounted knob mechanisms received the same score, with both designs based on the same spring and gear mesh mechanism. The spring or the gear inside these devices may wear and result in inaccurate indications over time.

Size

The dimensions for the indicator received a small weight because of the similar sizes of the three designs. The dimensions of the device have been loosely set by our client so that the device will fit within the allotted space available on each medical device. The side mounted knob mechanism, with its housed rotating label, would require the largest dimensions to accommodate, and as a result it received the lowest score in this class. The front mounted knob design would minimize the volume required to house the spring and gear mechanism, and would require less space for the disk to rotate. However, this design would require a slightly larger surface area on the medical device it is mounted to, giving it the second highest score. The flipper scores the highest in this class though, with its simple design requiring a very small amount of space.

Cost

The cost of the device also received a small weight due to the relative cheapness of all the projected designs. The client's projected budget is sufficient to pursue any of the designs presented. However, on a large scale the costs of each device can be considerable. For manufacturing reasons, the side mounted knob indicator would cost the most to prototype and would be the most difficult to create using 3D printing. For these reasons, Design #2 scored the lowest. Design #3 scored the second highest, bypassing some of the difficulties posed with the manufacturing of Design #2, but requiring the same materials. The flipper once again scored the highest, with its simple design resulting in an extremely cheap and easy production.

Future Work

First, the current final design needs to be 3D printed. The Dimension Elite printer in the ECB Student Shop is preferable because it is free to use but problems have arisen from its limited precision. The device to be printed is roughly 7.62cm x 3.175cm x 3.175cm and the inner mechanisms are smaller still. The Dimension Elite printer can print layers from 0.01778cm to 0.0254cm (.007" to .010"), a range too large for the small and intricate gear and spring mechanisms. To compensate for this, a design alteration has been considered which would change the current gear mechanism to a saddle joint mechanism. A saddle joint mechanism would not need to be as precisely printed and would allow for the same movement limitations as the previous gear design. Another alternative would be to use the Viper si2 printer in the Wisconsin Institute of Discovery to print the device. This printer has a range of 0.00508 to 0.01524 (.002" to .006") but is not free to use. These factors will need to be considered moving forward.

After the final design has been 3D printed the device will be presented to our client along with a review and critique form. The technicians who frequently used the device will be asked to gauge the effectiveness of the prototype and provide feedback on how to improve the device. The direct user feedback will be coupled with the original design considerations and a new design matrix will be created. Using the new design matrix modifications to the final design will be implemented and a new prototype will be 3D printed.

With the final design completed, the indicator will need to be mass produced. Our client has expressed a desire to work with Larry Maier from the UW-Hospital as he has done plastic injection work for them in the past with great results. There are multiple restrictions of plastic injection molding that pertain to the current final design such as: 1) all flat surfaces must have a minimum of 3° of relief; 2) multiple molds must be fabricated to accommodate the different mechanisms within the design; 3) mating components onto different portions of the outer frame may be impossible to cast. All of these restrictions will need to be considered before a final prototype can be submitted for plastic injection molding mass production.

Finally, the assembly and bonding of the different components of the indicator will need to be considered. Currently, an acrylic bonding cement is the bonding agent of choice but that may need to be altered as the design is updated. After all manufacturing considerations have been accumulated and applied to the final design a precise estimate of the cost per indicator manufactured will need to be delivered to the client.

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Appendix

Product Design Specifications

Design of a Cleaning Indicator Device for Medical Equipment

Team Members: Kevin McConnell, David Hintz, Paul Strand, Ross Paulson, Matt Boyer

Date: 10/24/12

Function: A universal indicator device that displays the state of cleanliness of a medical instrument. It will indicate to a user quickly and clearly whether a machine is sterilized and ready for use or if it is contaminated and in need of reprocessing.

Client Requirements

- Device must be able to be easily placed on machine or cart.
- Device must be permanently affixed to machine or cart.
- Device must not interfere with functionality of equipment in any way.
- Device must be capable of withstanding autoclave environments.
- Device must be capable of withstanding chemical cleaning with quaternary ammonium disinfectant solution.
- Device must be biologically friendly (non-hazardous).
- Device must be easy to clean thoroughly on all surfaces.
- Device must require minimal user interaction.

Design Requirements:

1.) Physical and Operational Characteristics

a. *Performance Requirements*: The cleaning indicator must be able to be easily adhered to a machine and must also be permanently affixed. The indicator must be capable of bonding to multiple surfaces to fit multiple machines. The indicator must be adjusted following reprocessing and each time a machine is used.

b. *Safety:* The cleaning indicator must not introduce nor harbor any biological contaminants. For the given method of sterilization, both machine and indicator must be completely exposed to sterilizing agents.
c. *Accuracy and Reliability:* Device must accurately and reliably display the desired state of cleanliness. Device must also remain affixed as long as desired.
d. *Life in Service:* Device must be reusable and capable of being in service 2+ years before replacement is necessary.
e. *Operating Environment:* Must be able to withstand harsh sterilization environments (250 degrees F and 20-30 psi for autoclave) and exposure to various biological elements.
f. *Ergonomics:* Indicators must be compact enough to simply affix and must be quick and easy to adjust.
g. *Size:* Device should not exceed 7.62 cm x 3.175 cm x 3.175 cm (3.0"x 1.25"x 1.25").
h. *Weight:* Device should not exceed 28.35 grams (1 ounce). Selected adhesive must be capable of holding device's weight over the life of the device.
i. *Materials:* Must not be composed of corrosive or biologically abrasive elements. Materials must be capable of withstanding reprocessing environments.
j. *Aesthetics, Appearance, and Finish:* Method of indication must be bold enough to be easily discerned. If colors are used as primary form of indication, a secondary indication method such as symbols must be incorporated to accommodate colorblind users. Any mechanical functions must be capable of being performed with minimal user precision.

2.) Production Characteristics

a. *Quantity:* 35-40, with option for more in future for replacement and to accommodate addition of more equipment.
b. *Target Production Cost:* $100 for prototype development

3.) Miscellaneous

a. *Standards and Specifications:* Due to presence inside of operating room, FDA approval may be required. Medical equipment warranty considerations must also be considered.

Wrap Up

X	Sept				Oct				Nov					Dec	
	7	14	21	28	5	12	19	24	2	9	16	23	30	7	14
Project R&D															
Literature/Patent Search	X	X	X	X	X										
Brainstorming	X	X	X	X	X										
Component Research/Work		X	X	X	X	X									
Drawing/Modeling					X	X	X								
Calculations															
Manufacturing															

Prototyping/Testing																	
Deliverables																	
Progress Report		X		X	X	X	X	X	X								
Mid-Semester Presentation								X	X								
Final Poster/Paper																	
Design Notebooks	X		X		X	X	X	X	X								
Meetings																	
Team		X		X	X	X	X	X	X								
Advisor				X		X	X	X	X								
Client				X		X		X									

Deviations from our proposed timeline include a shorter time drawing and modeling our device, and a difficult time literature searching. We have also not started the SolidWorks testing of deign as we need to determine the types of plastic safe for operating room conditions along with a material strong enough for the device's construction. The drawing and modeling took a shorter time than expected as we met to discuss what exactly we wanted to create and went over the device specifications as a group. This resulted in limited changes in the design and a shorter time modeling. We also had members with a good background in SolidWorks which also reduced modeling time. The literature searching was complicated by the fact that it was not precisely clear until our second client meeting exactly what types of machines needed indicating and to have a full understanding the current indicating problem. Therefore, much of our original literature searching was not helpful for our new interpretation of the problem.

Our budget still remains at 100 dollar. We have not invested any money in production of the prototype, but due expect to use some after SolidWorks testing. By applying different forces we will better understand the material types needed for construction.