Cleaning Indicator for Reusable Medical Equipment

Kevin McConnell – Co-Team Leader
Paul Strand – Co-Team Leader
David Hintz – Team Communicator
Ross Paulson – BWIG
Matt Boyer – BSAC

Dr. Scott Springman – Client
Dr. Chris Brace – Advisor
12/10/2012

Abstract

Dr. Scott Springman is an anesthesiologist at the UW Hospital. He is concerned with the ability of anesthesia machines to display whether they are clean and ready for use in an operation or dirty and in need of reprocessing. Anesthesia machines must be reprocessed following each use to ensure a sterile operating room environment. Time and money is lost when a sterile machine is unnecessarily reprocessed when its status is unclear. The current indication method uses paper signs attached to machines that flip to display "clean" or "dirty". A device is needed that accurately and reliably indicates the reprocessing status of a machine without inadvertently flipping displays. The team has created a locking teeth and spring mechanism, utilizing an external knob to turn an internal indication bar that indicates a machine's state of cleanliness. Multiple prototypes were constructed and tested to analyze a number of important factors including visibility, ease of use, and reprocessing capability.

Table of Contents

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 a 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 gas inhalation (1).

Primary Machines used in Anesthesia

Figure 1: Anesthesia Cart. Large carts like this will have all of the items on them reprocessed if any contamination is expected. An indicator that shows the entire cart is clean will reduce the time when equipment is unavailable due to cleaning.
Image Credit: medicalpointindia.com

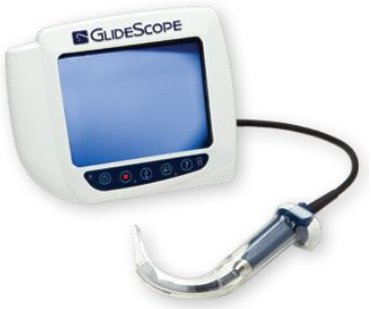


Figure 2: GlideScope—one of the machines which will be reprocessed if cleaning is in doubt. The GlideScope is mounted on a wheeled post and its location is monitored through an RFID tag. The indicator would be placed either directly above or below the monitor screen for easy user manipulation.
Image Credit: verathon.com

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.

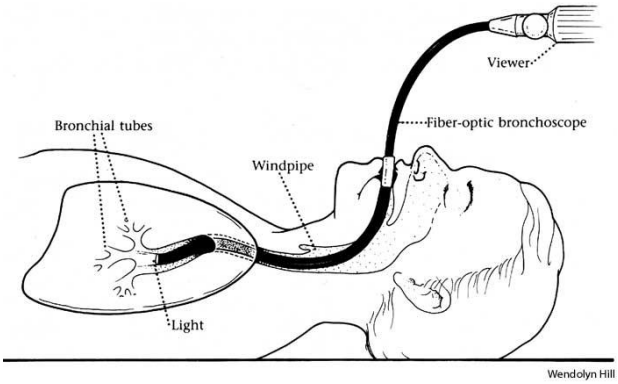


Figure 3: Bronchoscope intubation. Tube inserted into patient's throat during operation allows for viewing of airway. Image Credit: answcdn.com

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. A bronchoscope will be placed in the cylindrical tube on the cart. If this device is left out in a hallway medical personnel will not know if it is ok to be used.

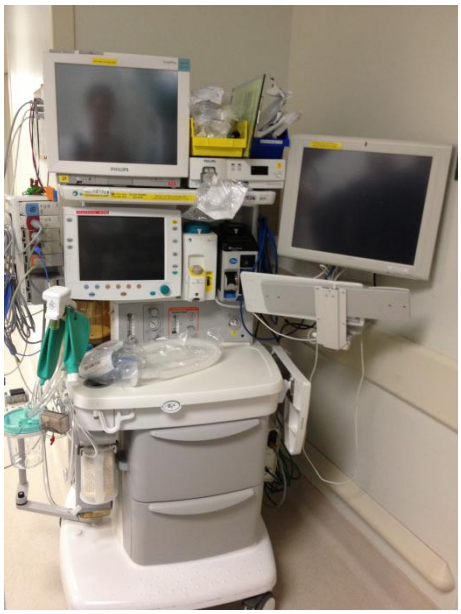


Figure 5: Standard anesthesia delivery cart. The cleaning indicator would indicate if the entire cart needed to be reprocessed.

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 sterilization techniques are commonly 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 a commonly used method 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. The solution used at the UW-Hospital is Neutral Quat Disinfectant Cleaner Concentrate by 3M. This solution consists primarily of water (60-90%), but also contains ammonium chloride, octyldimethylamine oxide, ethylenediaminetetraacetic acid, ethyl alcohol, sodium hydroxide, and d-limonene. It is capable of killing HIV, Methicillin-resistant Staphylococcus aureus (MRSA), vancomycin-resistant enterococcal (VRE), Herpes Simplex I and II, and other pathogens that may be contact medical equipment present in the operating room(7).

Medical device reprocessing is beneficial to hospitals as it significantly reduces operational cost. Hospitals have reported saving between $115,000 and $1 million annually by reusing electrophysiology catheters alone. The same hospitals reported that the cost of

reprocessing is less than 10% the cost of buying new equipment (8). For anesthesiology, the high cost of equipment makes reprocessing a necessity.

Reprocessing carries a slight risk, as it requires equipment to be thoroughly and properly cleaned following each use. Although rare, there have been incidents where non-sterile instruments have been used in operations. In 2005, a Pennsylvania hospital required over 200 people to be tested for hepatitis and HIV after performing procedures with inadequately cleaned instruments (9). Considering the potential for the spread of disease, great care must be taken to ensure equipment is properly sterilized following every use.

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. This precautionary measure is necessary because airborne pathogens can come into contact with an object without direct contact. This further exacerbates the problem because a cart may contain any number of tools, and if its reprocessing status is unknown, it all must be cleaned. This wastes time and money

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. There are several problems with this method. First, the signs are not permanently attached and have a tendency to fall off when the cart is in transport. Second, 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. Finally, the signs are not consistently used by everyone in the anesthesiology department

Figure 6: Current indication system used by UW-Hospital. Laminated paper sign displays "clean" on one side and "dirty" on the reverse side. These signs are unreliable and often neglected.

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(10), 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. RFID tags are used to monitor the location of equipment throughout the hospital. The cleaning indicator will be mounted in a similar fashion as the RFID tags.

Design Requirements and PDS:

The device must universally indicate the status of the machine it is attached to. The device needs to be clear in its status (Clean or Dirty) to anyone who is trained to operate the indicator at a distance no less than 3 meters (~10 feet).

The device must be cleanable using the hospital's standard techniques. The device must be able to withstand the QUAT spray and wash cloth wipe down. The device must be sealed and smooth to be able to remove all infectious agents QUAT is designed to remove.

The device must be durable enough to withstand the environments it is operating in. The device must be able to withstand exposure to bodily fluids with a pH1-8 (vomit, blood, saliva, and pancreatic secretions) (11). The device must be able to withstand the forces of the wipe down with QUAT spray (about 50 N or 10 lbs). Must be able to withstand cleaning up to three times a day every day for its lifespan (~7000 times) (12). Must withstand accidental forces applied from objects being placed on the device (100N or 20lbs). 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 (1 ounce).

The construction of the device must be compatible in the hospital environment. The materials used to build the device should be made of plastic and 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 reliability of the device is crucial as its will be used every day and expected to show the correct indication. The device must accurately and reliably display the desired state of cleanliness set by the user. The device must also remain permanently affixed to the desired piece

of equipment as long as the expected life of medical device it is permanently attached to (4-8 Years) (12).

The ability to use the device easily is important. The user will have many more important things to be considering as they are preparing for an operation. The indicator's mechanical functions must be capable of being performed with one hand. The device must be attached at a height of one meter to be operated easily.

The device attachment is important as the areas for placement of a device on a machine is often restricted. The device must be able to attach all surfaces found on the machine carts (to round, flat, rough, smooth and any combination of these).

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.

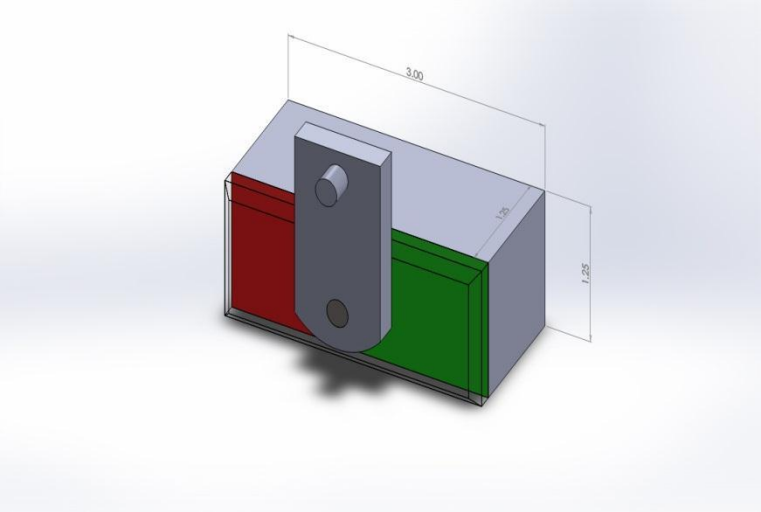


Figure 8: Design #1 – Flipper. This design is 3.175 cm (1.25 in.) X 3.175 cm. (1.25 in.) X 7.62 cm. (3 in.). The flipper will cover the side which indicates the opposite of the current state. For example: if the machine is dirty the flipper bar will cover the green (clean) side and only show the red (dirty) side. This design would be difficult to clean behind and could be inaccurate.

Design #2 (Side Knob):

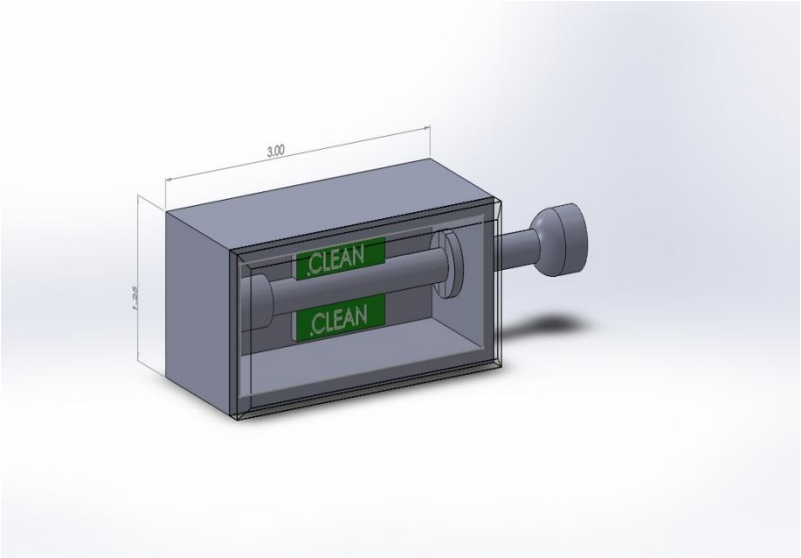
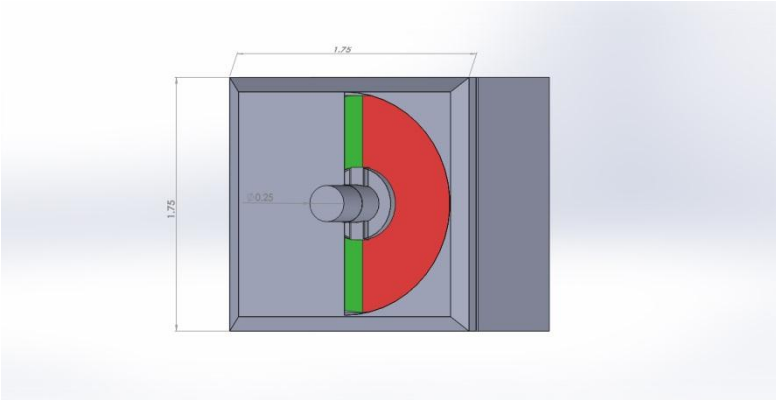


Figure 9: Design #2 – Side Knob. The design is 3.715 cm. X 3.175 cm. X 7.62 cm. This design offers the largest indication panel and should be easier to manipulate than the other designs. The gear mechanism will ensure that the indication choice is locked in.

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):

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.

Figure 10: Design #3 – Front Knob. This design would allow for easy frontal manipulation and could be easier to turn. However, the device likely wouldn't last as long because it is more likely to catch on items and be broken.

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.

Final Design

The final design, design #2, was chosen. It scored the highest in the two most heavily weighted categories and the highest score overall. The design was 3D printed using the Dimension Elite printer in the ECB Student Shop with tolerance for 3/100ths of an inch variance factored in. The gear mechanism was altered to a saddle joint which required less precision in printing. A piece of acyclic was machined to set into the indicator box and provided a clear viewing window for the indicator. A spring with proper stiffness was purchased and the printed

shaft was cut down to allow the proper amount of travel while maintaining strong enough spring resistance to lock the gears in place. This device will be placed on large carts or rolling machines and will serve as an indication for the entire machine. The indicator will be adhered using a foam tape on a flat surface in an easily visible location.

Assembly

After the solid works drawing was successfully printed and the parts were all fitted to ensure proper operation, the indicator was ready to be prepped for painting and assembly. ABS plastic is very porous and was a point of concern as to whether or not it could be successfully painted and glued. Upon meeting with Charles Allhands, the person in charge of 3-D printing, in the College of Engineering Student shop, it was found that ABS is very easy to paint and will adhere with almost any adhesive. To prepare the prototype indicator face for painting, acetone was sprayed on a rag and wiped over the face of the indicator. This process was repeated until there was a smooth, glossy finish to the face. Once this face was achieved, a high grit sand paper (around 400 grit) was used to make micro-scratches in the face to allow for better contact with the primer and paint. After this, the primer, Rustoleum Plastic Primer, was applied and allowed to dry. Once this had dried, the color was applied over and allowed to dry. After everything was painted and dried, the indicator was ready to be assembled. Common superglue was used to affix the knob to the shaft, the box end to the rest of the box and to attach the polycarbonate face to the front of the indicator. This method worked very well, was cheap and the super glue was readily available.

Testing Procedures

Team Testing

The purpose of this study was to find the minimum angle at which the indicator's state can be determined. By determining the minimum viewing angle of the indicator, the visibility and the distance at which the average person could see the indicator at a certain height can be determined.

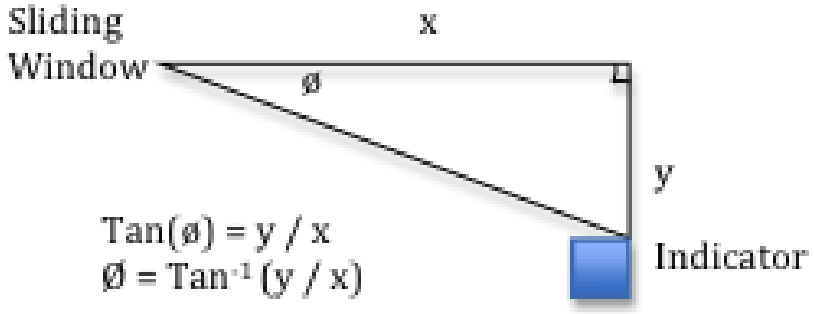
Ten subjects looked into the viewing window (C) that was connected to a caliper (B) and mounted on the viewing stand (D). The caliper was zeroed at a "zero line" (E), where the viewing window would be at the equivalent height of looking horizontally at the indicator's viewing window. At the beginning of each test, the indicator's status would be randomly assigned to either the red, "Dirty" side or the green, "Clean" side. The subjects then slid the calipers up while looking through the viewing window until they were able to determine the indicator's (A) status with confidence. The viewing stand was mounted on a table with optimal lighting so that lighting will not cause a change in visibility determination. The indicator was mounted with the viewing window facing upward at a fixed distance.

After each subject performed the angle test, their minimum viewing height was combined with the other subjects' values in order to find the average viewing height. This average height along with the fixed dimensions of the viewing stand could then be used to calculate the critical viewing angle.

Data Table: Angle of minimum determination

Subject	Caliper Reading (in)
1	1.354
2	1.216
3	1.297
4	2.433
5	2.272
6	1.17
7	1.023
8	1.019
9	.999
10	2.49
Standard Deviation:	.531
Group Average:	1.3775

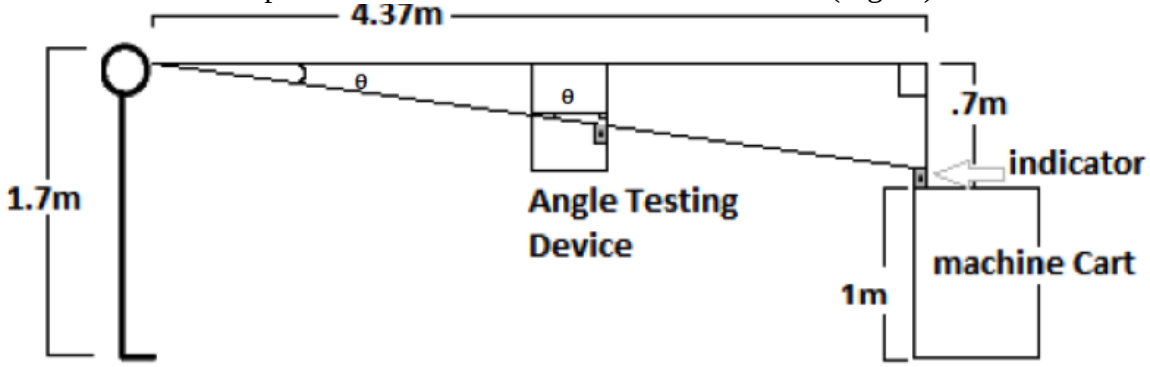
From the data on the average displacement of the sliding window we can determine the angle at which the device is viewable. The average movement of the caliper was 1.3775 inches. This is the distance moved from the line were the calipers was zeroed. The zero line was measured to be .45 inches above the top of the box therefore, .45 inches is added to measured height to obtain the actual distance traveled in the vertical direction (y-value). The distance from the viewing window to the back corner of the box was measured and recorded to be 11.4 inches (x-value). With these two values for x and y, two sides of a right triangle are formed. The angle of minimum determination can be calculated as follows.



The results of this experiment show that the minimum angle above the horizon of the indicator's viewing window at which the indicator is viewable is 9.1 degrees. The calculations are show below.

y = (average recorded height above indicator) + ("distance zero line" is above the indicator) = (1.3775in) + (0.45in) = 1.8275 in
x = 11.4in
Tan^{-1} (y/x) = Tan^{-1} (1.8275in / 11.4in)= 9.1 degrees
Critical Angle = 9.1 °

With the critical angle determined, we can produce the minimum distance at which the average person could observe the status of the indicator in the tested position.
Through the use of trigonometry the angle was determined to be 9.1 °. Using this angle the maximum distance a person could view the indicator is shown in (Figure)



Using the average height of an American male to be 5’ 9.9’’ and female to be 5’ 4.3’’ the average height of 67.1 inches (1.7m) was calculated (13).With the placement of the indicator on the machine cart at about 1 meter this would leave about .7m from the top of the indicator to an imaginary line running horizontally from the person’s eyes. Using the approximate distance of .7m and an angle of 9.1° the distance can be estimated. For an angle of 9.1°, the maximum distance that the person can be away from the indicator horizontally would be about 4.37m or about 14 feet. Using these same methods, the maximum viewing distance can be found for the indicator at different heights.

Submersion Test

One of the primary requirements for the medical indicator’s design was to insure that the indicator would not act as a harbor for bio hazardous material and would be easily cleanable. As a result, one worry with the chosen design was the possibility of material leaking into the indicator’s enclosure, most likely through the through-hole located on the end plate which allows freedom of movement for the indicator’s shaft. Although the main method of cleaning this indicator while it’s attached to the medical carts will be through a QUAT wipe-down with very little liquid pressure applied to this slip fit gasket, it was important to determine how the indicator would fair under the worst case scenario: complete submersion.

To test the waterproofing of the indicator, the device was attached to a weight and underwent a controlled sinking, with the indicator being lowered deeper and deeper into our submersion test chamber via a string with the slip fit gasket directed upward to prevent the internal pressure of the indicator interfering with possible leaks. The submersion test chamber, per se, was a cylindrical container capable of holding 131.9 in3 of liquid and submerging our indicator to a depth of 36 inches. The chamber had labeled measurements down its’ length incremented by .5’’ in order to track just how deep our indicator was before it began to leak. However, the indicator and the slip-fit hole on the end plate proved to be watertight as it succeeded in reaching the maximum depth of the chamber. At 36’’, this is the equivalent of exposing the indicator to 1.085 atm. Knowing that the indicator can handle upwards of 36’’ of submersion, for the conditions that the indicator will be exposed to it will watertight and will not allow leaking of any material into its interior chamber.

Ease of Use Testing

A second factor requiring consideration in the design of the device was the ease of use of the final product. One of the desires of the client was to have a device that required little to no thought to operate. A complex device could discourage user interaction, whereas a simple device would be more likely to be used. To evaluate the ease of use of the design, an efficiency test was conducted.

Subjects were asked to change the indicator status a total of twenty times. This was defined as flipping the indicator from green to red or red to green. A success was defined as disengaging the gears, spinning the rod 180 degrees, and reengaging the gears all in one fluid motion. A failure was noted whenever the gears were not properly locked or additional rotation was required. A total of ten subjects completed the trial.

As can be seen in figure A4 of the appendix, users faired very well in rotating the indicator to the desired state. The average number of successful turns was 19 compared to an average of only one failure. This corresponds to a 95% success rate. Additionally, subjects finished the testing in approximately 30 seconds, meaning to rotate the indicator 180 degrees one time takes less than two seconds. Following testing of the device, subjects were asked to rate the ease of use on a scale of 1-10, with 1 being difficult and 10 being very easy. The average score was 9.2. The high rate of success and small amount of operational time required, as well as subject input following testing, reveals that the indicator is not challenging to operate and is fairly intuitive to use.

Client Testing

The purpose of the client testing was to get feedback from the people that would actually be using the device. This feedback and comments could be used to make changes before the final prototype was presented but most importantly for future work in considering device modifications.

For the client testing, a survey was generated and distributed at the UW-Hospital. To accompany the survey the device was mounted on a flat surface of a small box to simulate the device being attached to a machine and present the people filling out the questionnaires with a reference. The device was mounted with the viewing window perpendicular to the floor (vertical orientation). The surveys were left with the device in a break room at the UW-Hospital and the completed evaluations could be placed in a folder to be collected later for analysis.

The amount of surveys completed was lower than expected. Some of the surveys gave useful information and comments and others gave little to no helpful comments. Days in which the hospital experienced high traffic were more stressful for the hospital's employees than others, which may have affected their attitudes in filling out our survey.

Overall, the results of this survey did not produce as much useful feedback as expected. The number of surveys completed was lower than expected; therefore, no analysis was completed on this study. There were some useful comments that are described in the future work section.

SolidWorks Testing

A SolidWorks analysis was performed on the modified design to determine the most vulnerable area on the device. A situation was simulated where the indicator shaft that sticks out from the indicator body had a 100 N (22.48lb) force dropped upon it. The 100 N force was

selected to simulate a heavy medical device hitting it or someone bumping into the indicator. As can be seen from Figure 11, the green arrows, showing the fixed plane, represent the normal force created by the gear mechanism under this loading. The device was modeled as ABS plastic, which has properties to similar common injection molding plastics. After this test was complete it was determined that there would be considerable stresses at connection point of the knob and the indicating bar. Red shows the most stress in the object and turns to blue in areas with the least amount of stress. The highest amount of stress (the red area) was determined to be 30.954 MPa (4487 lb/in^2), which is less than the yield strength for ABS, which is 65 MPa. Upon this failure stress the maximum displacement is .703994 mm (0.027716 in).

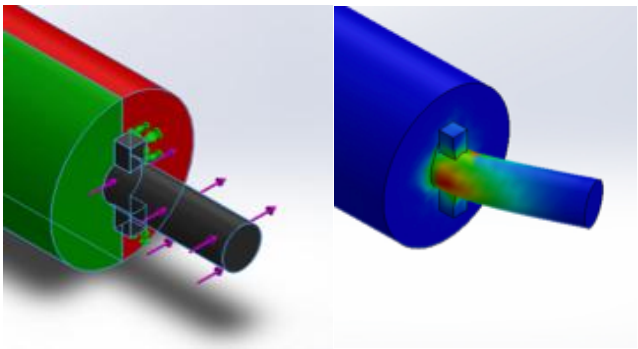


Figure 11: SolidWorks testing of shaft bending under 100 N. The red portion of the stress diagram is the portion of maximum tensile stress. The shaft didn't reach maximum stress and thus didn't break.

Final Design Alterations

The second prototype printed differed significantly from the first prototype. The design was 2.75 in. X 1.25 in. X 1.25 in. and was adjusted due to feedback suggestions from the client, reviews from user testing, and design decisions meant to maximize the functionality of the device. The most frequent criticism from the client was the indicator was too large. The client was concerned whether there was enough space to mount the indicator on the medical equipment and if the indicator itself was large enough to be viewed from a wide range of angles given its deep placement inside of the containing box. This problem was met through three different design alterations.

First, the box was reduced in length by .625 cm. (.25 in.). The shaft of interior rod was also reduced in length to allow for the adjusted box. Then, the in-set panel indicator was adjusted to a thicker panel that was flush with the top of the rod. This allowed the "CLEAN" indication to be printed as one large word

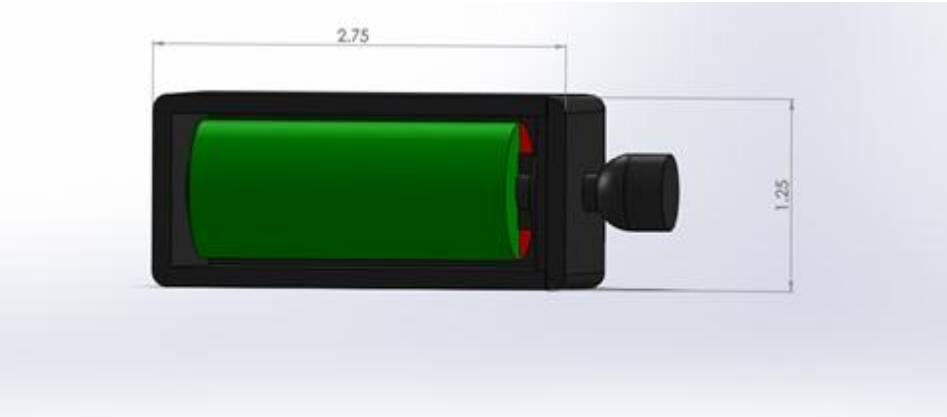


Figure 12: Final Design for prototype #2. The design is .625 cm. (.25 in.) shorter than the previous version. The indication panel was made larger by transforming it into a cylinder. The travel of the gear mechanism was also reduced, improving ease of use.

instead of two smaller words separated by the rod in the middle. Another alteration was then made to the indication panel—transforming it into a hollow cylinder that extended down over the spring holding. Making the indication panel a cylinder effectively maximized the ratio of box size to indication size, as seen by Figure 12. The team determined that these changes adequately addressed the client's concerns regarding the size of the indicator.

Another critique by the client was the gear mechanism was too difficult to align properly and would take too long for technicians to adjust the device. To correct this, two alterations were made. First, the perpendicular angle of the teeth insert was sanded down to allow the tooth to slide into the groove without needing to be perfectly aligned (Figure 13). The gear was also constructed so there was a maximum height at the transition point from one indication to the other and a minimum where the gears were to be locked into place. This allowed the gears to pseudo-slide into correct alignment even if they were not precisely placed. Additionally, the travel of the shaft was reduced so the gears could not displace as far. The team predicted that more consistent and precise gear manipulation would occur if translational movement was possible within the gearing mechanism.

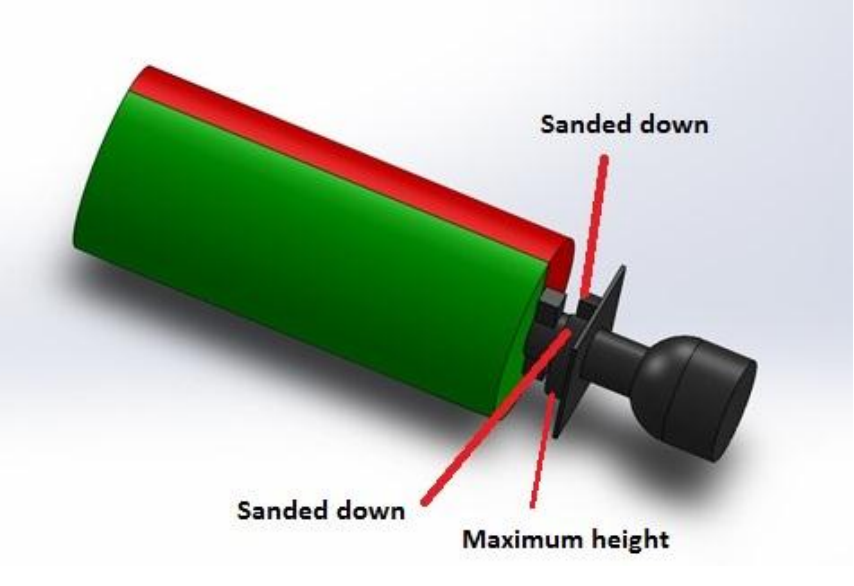


Figure 13: Alterations to be made to prototype 2. The gearing mechanism will be sanded down to allow the gears to slide and lock into place even if not perfectly aligned. Shown above are the regions of the mechanism to be sanded down and the section (labeled maximum height) where no sanding will occur.

Finally, a few aesthetic concerns were addressed in the final prototype. The client expressed that a bold, stand-out color was desired so the prototype was painted black. Black was chosen because many of the machines the indicator would be mounted on were white and black would stand out significantly. Furthermore the corners needed to be rounded so that alteration was also made.

Plastic Injection Molding

Process

Once the design was 3-D printed the group contacted UW Carpentry department. Our client had believed that they were capable of conducting plastic injection molding for us. The group thought plastic injection molding would be a good option to mass produce the indicator due to the wide capabilities of the mold. During plastic injection molding raw plastic material in the form of pellets are loaded into a hopper and melted through mechanical shearing (14). The

plastic is then injected through a reverse screw mechanism and the product is allowed to cool (15). High pressure (typically 15,000 psi.) is used to ensure complete filling of the mold. The mold can be machined to the required specifications with high precision. This option of mass production was preferred but the Carpentry department was unable to provide the service due to a lack of equipment and expertise.

Quotes

In an attempt to get the project moving forward the group contacted multiple prototyping and plastic injection molding companies. The hospital needs about fifty of these indicators that would need to be made up. Upon contacting Zeier Plastic and Engineering Industries, they never responded and a quote from them was never obtained. Midwest Composites, a rapid prototyping and small run plastic injection mold outfit told us that they could not accommodate the small quantity of molds that we would need. NMC, another plastic injection molding company told us that they only really do larger (over 10,000) plastic injection molding runs and recommended using proto mold. Proto mold is a small run plastic injection house. After receiving quotes from their online quote system, completing the project would cost $9,286.30. This price includes all of the tooling and material costs of the molds and all of the parts to assemble fifty indicators. With all of the mold and tooling prices included this comes out to $185.73 per indicator. While just the material cost per indicator is $9.21. This was way out of the proof of concept budget and shocking to the group all around. While the University does not run productions of this size, in comparison, to 3-D print fifty of the indicators it would cost $1950. So as of now there is no real viable option to produce this design on this scale.

Conclusions

The number of indicators desired by the hospital lies in a grey area of mass production. The quantity is too low to plastic injection mold due to the high upfront cost of the mold but is also too high to 3D print. After further research a possible alternative was found. A new technology called Rapid Tooling is starting to take hold in the industry. In Rapid Tooling the mold is created in a way similar to 3D printing (built layer by layer). The process of creating the mold is completely automated but involves multiple layers of aluminum that need to be adhered to each other and friction stir welded (15). The resulting mold has a cheaper upfront cost but is also less precise. Rapid Tooling is designed to provide an economical production option for projects which fall between Rapid Prototyping and Plastic Injection Molding. The prices for Plastic Injection Molding and Rapid Prototyping will be presented to the client along with a summary of options regarding Rapid Tooling.

Final Budget Breakdown

Prototype Component	**Quantity**	**Price**	**Total**
Springs	5	$.62	$3.10
Rustoleum Paint/Primer	3	$3.98	$11.94
$1/16^{th}$ in. screws	4	$.43	$1.70
3D printing	2	$0	$0
Total			$16.74
Project Component			
Poster printing	1		
Total			

The cost of producing two prototypes came in below budget by $83.36. However, production of the number of indicators desired by the client came in at an estimated $9,186.30 over budget. The cost per indicator of $185.73 was even over the entire project budget. Because of these pricing difficulties plastic injection molding almost certainly will not be used to mass produce the indicator. The hospital may deem the cost per indicator acceptable if the depreciation of the medical equipment was reduced extensively enough and the life in use extended long enough to offset the high costs of the indicator.

Future Work

There are a number of design alterations that should be considered before a final prototype is to be used for mass production. First, the entire device should be made lower profile. All of the features should be scaled down to reduce the obstruction caused by the device when mounted on a medical device. As the device is currently sized, indication can be determined from over 60 feet away, a distance that isn't especially practical in a hospital setting. Reducing the size of the device may reduce the detection range but such a reduction should not have a significant impact on the functional performance of the device. Additionally, the outer structure of the device could be altered to a triangular prism or cylinder to allow for a wider range of viewing angles. A device that indicated the state of the machine in every direction of viewing would be ideal. The gearing mechanism could also be altered. Changing it to a self-locking gear would increase usability. Options for vision impaired operators should also be considered.

There are also multiple decisions that will need to be made by the design team in correspondence with the UW Hospital and Dr. Springman. The quotes provided by Protomold will be presented and production decisions will need to be made. Given how far outside the provided budget the quote from Protomold was; alternative production techniques will need to be considered and presented. Those alternatives could include Rapid Prototyping and Rapid Tooling. Cost breakdowns should be determined and presented for each. Another production

consideration to be discussed would be who and where the final indicators would be put together. For each indicator the plastic parts will need to be fit together, the spring inserted, and the face plate adhered. Depending on the quantity of indicators this may need to be performed by an outside company. Finally, the indicators will need to be mounted to their respective machines. They will be adhered with the same bonding material as the RFID tags currently used but someone will need to be responsible for their installation. As new machines are purchased indicators will need to be installed as well. All of these cost, assembly and installation techniques will need to be reviewed.

References

Sites

1. "General Anesthesia: MedlinePlus Medical Encyclopedia." U.S National Library of Medicine. U.S. National Library of Medicine, n.d. Web. 23 Oct. 2012. <http://www.nlm.nih.gov/medlineplus/ency/article/007410.htm>.
2. Couto, Marcelo, and Jim Houts. Molecular Imaging Products Company. Molecular Imaging Products Company, n.d. Web. <http://www.mipcompany.com/princ_anesthesia.pdf>.
3. "GlideScopeÂ® Video Laryngoscope." GlideScope Video Laryngoscope. N.p., n.d. Web. 23 Oct. 2012. <http://verathon.com/products/glidescope-video-laryngoscope>.
4. "Bronchoscopy: MedlinePlus Medical Encyclopedia." U.S National Library of Medicine. U.S. National Library of Medicine, 27 Sept. 2012. Web. 23 Oct. 2012. <http://www.nlm.nih.gov/medlineplus/ency/article/003857.htm>.
5. "Bronchoscopy." Medline Plus. Medline Plus, 27 Sept. 2012. Web. <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/ReprocessingofReusableMedicalDevices/default.htm>.
6. "Steam Sterilization: Autoclaving." Preparing The Equipment for Surgery. N.p., 1998. Web. <http://cal.vet.upenn.edu/projects/surgery/2220.htm>.
7. Material Safety Data Sheet 3M Neutral Quat Disinfectant Cleaner Concentrate. 3M Company. 2012.
8. United States. Cong. Senate. Committee on Health, Education, Labor, and Pensions.*Medical Devices: Reprocessing and Reuse of Devices Labeled Single-Use*. Janet Heinrich. June 27, 2000
9. "HIV Tests Urged for Some Colonoscopy Patients." *Associated Press* 31 Mar. 2005.
10. "Asset Management." WIFI Based RTLS Solutions & Wireless Sensor Technologies by Aeroscout. AeroScout, n.d. Web. 23 Oct. 2012. <http://www.aeroscout.com/>.
11. Boron, Walter, F.; Boulpaep, E.L. *Medical Physiology: A Cellular And Molecular Approaoch*. Elsevier/Saunders. ISBN 1-4160-2328-3. (2004).
12. Steven, S. Liu. "Cost Identification Analysis of Anesthesia Fiberscope Use for Tracheal Intubation." *Journal of Anesthisia & Clinical Research* (2012).
13. Naik, Abhijit. “Average Human Height”. (1/29/2010). BUZZEL http://www.buzzle.com/articles/average-human-height.html
14. Colton, JS. "Injection Molding - Process Description." Manufacturing Processes and Systems. Georgia Institute of Technology. 2009.

15. Karthikeyan, Rajesh Kumar, "Process planning for rapid manufacturing of plastic injection mold for short run production" (2010). *Graduate Theses and Dissertations.* Paper 11761.

Images

1. "Anesthesia Machine RIPE-A." Medical Point. Medical Point, n.d. Web. <http://www.medicalpointindia.com/mech-Anesthesia%20Machine%20RIPE-A.htm>.
2. "Glidescope." Verathon, n.d. Web. <http://verathon.com/portals/0/Uploads/Components/GlideScope/CobaltAVL_ComponentImage_01.png>.
3. "Bronchoscope." Verathon, n.d. Web. <http://content.answcdn.com/main/content/img/medTest/f007001.jpg>.

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

Figure A1:

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	X							
Calculations								X							

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

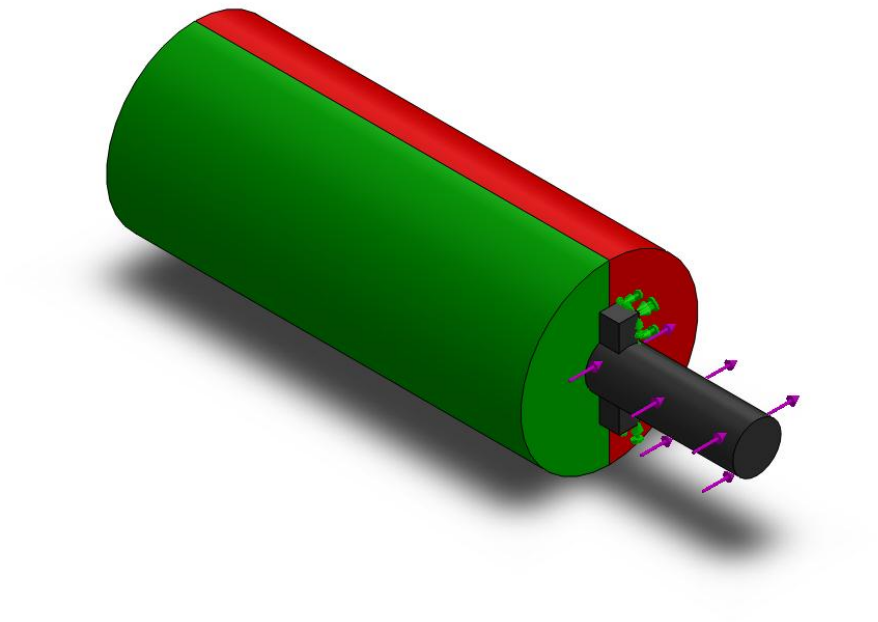
Deviations from our proposed timeline include a shorter time drawing and modeling our device, and a difficult time literature searching. We have also not started the SolidWorks testing of deign as we need to determine the types of plastic safe for operating room conditions along with a material strong 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 dollars. 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.

SolidWorks Analysis Report

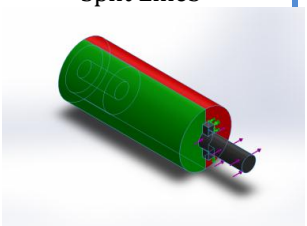
Model Information

Figure A2:



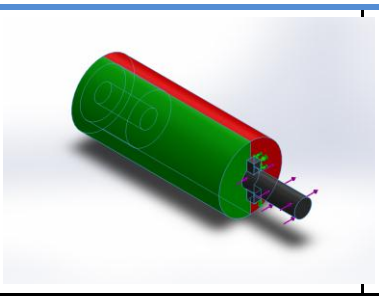
Model name: Knob Design (New Shaft)(3D TOLERANCES)
Current Configuration: Default

Solid Bodies

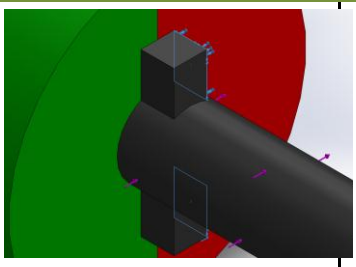
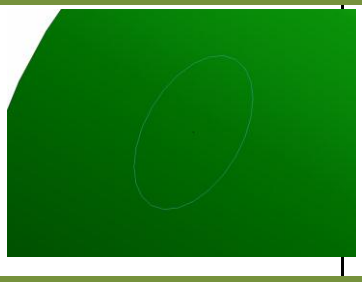
Document Name and Reference	Treated As	Volumetric Properties	Document Path/Date Modified
Split Line5 	Solid Body	Mass:0.0199236 kg Volume:1.9533e-005 m^3 Density:1020 kg/m^3 Weight:0.195251 N	C:\Users\Ross Paulson\Documents\School 2012-2013\BME 200\SolidWorks\Knob Design\Knob Design (New Shaft)(3D TOLERANCES).SLDPRT Dec 02 19:15:27 2012

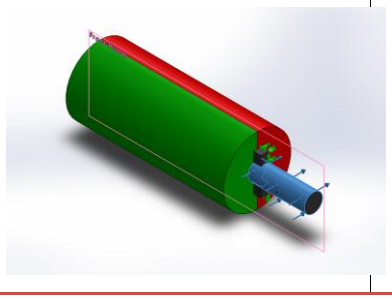
Material Properties

Model Reference	Properties	Components

	Name: **ABS** Model type: **Linear Elastic Isotropic** Default failure criterion: **Unknown** Tensile strength: **3e+007 N/m^2**	**SolidBody 1(Split Line5)(Knob Design (New Shaft)(3D TOLERANCES))**

Loads and Fixtures

Fixture name	Fixture Image	Fixture Details
Fixed-3		**Entities:** **2 face(s)** **Type:** **Fixed Geometry**
Fixed-4		**Entities:** **1 face(s)** **Type:** **Fixed Geometry**

Load name	Load Image	Load Details
Force-1		**Entities:** **1 face(s), 1 plane(s)** **Reference:** **Front Plane** **Type:** **Apply force** **Values:** **---, ---, -100 N**

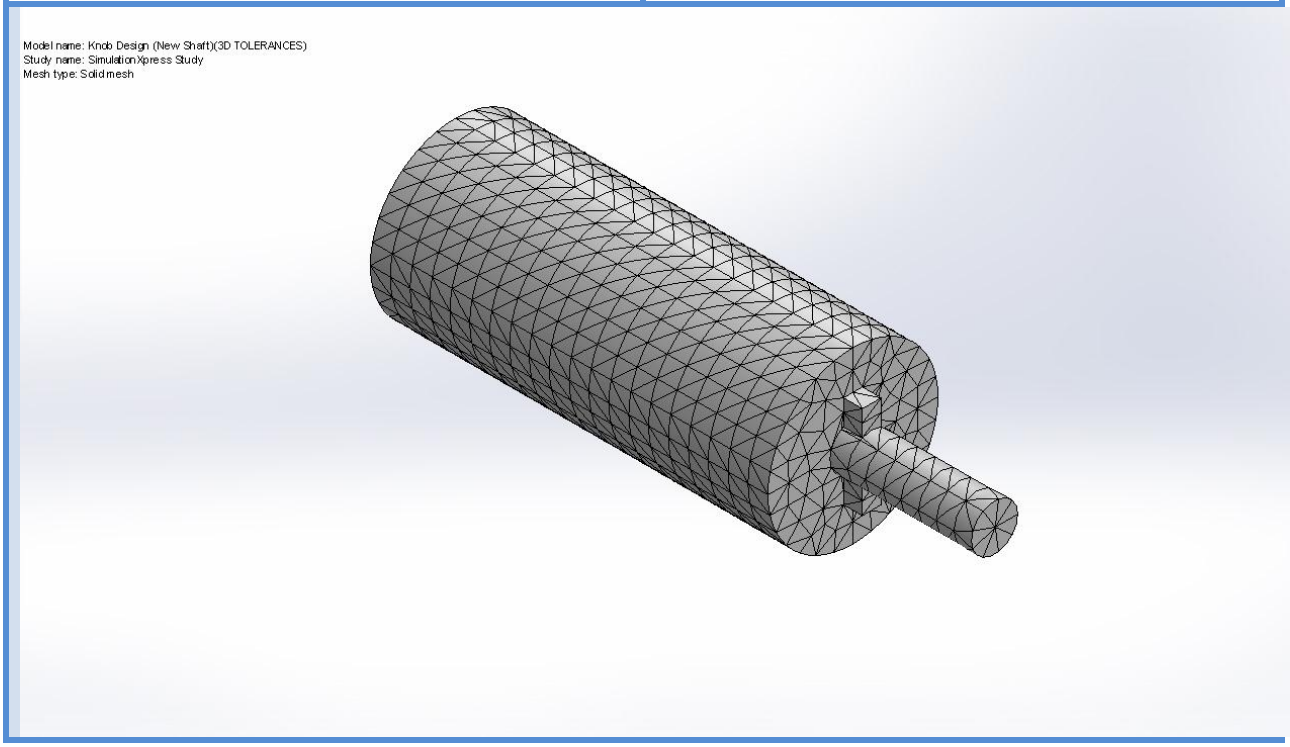
Mesh Information

Mesh type	Solid Mesh
Mesher Used:	Standard mesh

Automatic Transition:	Off
Include Mesh Auto Loops:	Off
Jacobian points	4 Points
Element Size	0.106067 in
Tolerance	0.00530334 in
Mesh Quality	High

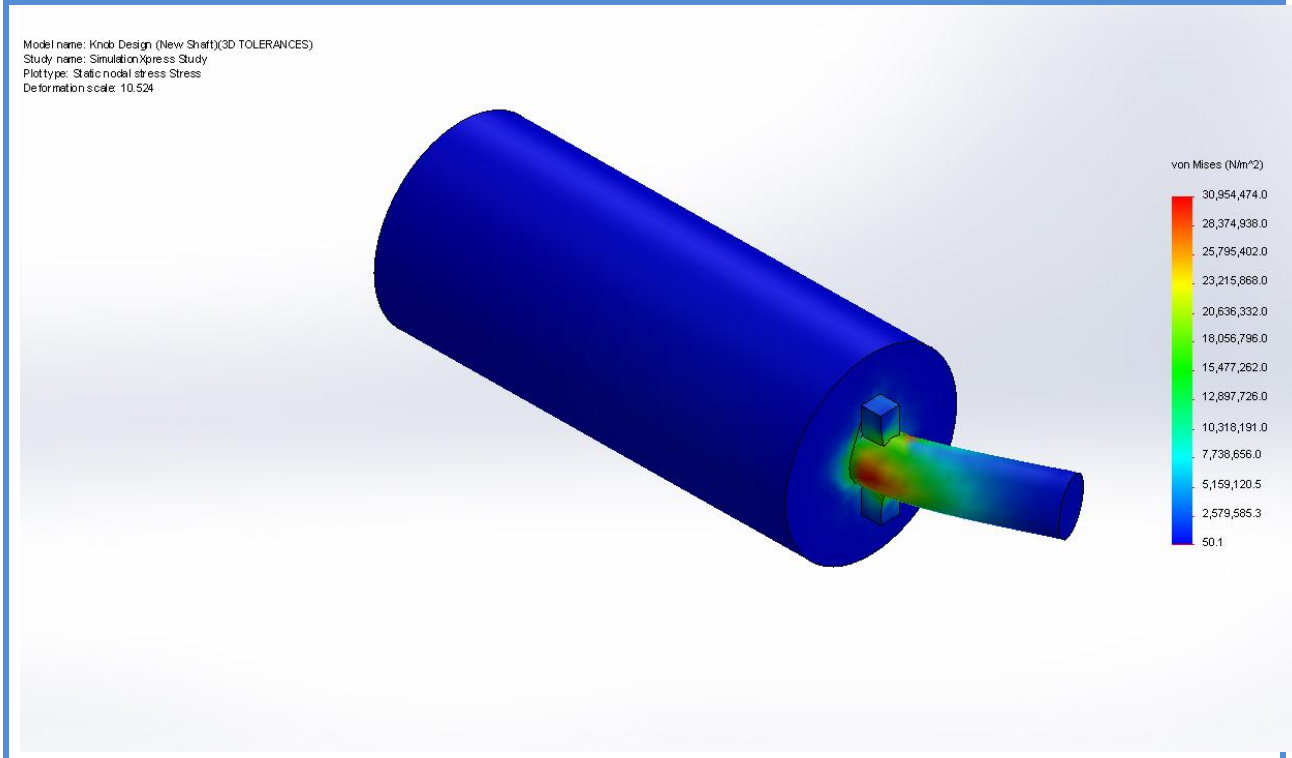
Mesh Information - Details

Total Nodes	12013
Total Elements	7599
Maximum Aspect Ratio	7.542
% of elements with Aspect Ratio < 3	99.6
% of elements with Aspect Ratio > 10	0
% of distorted elements(Jacobian)	0
Time to complete mesh(hh;mm;ss):	00:00:06
Computer name:	RPAULSONXPS



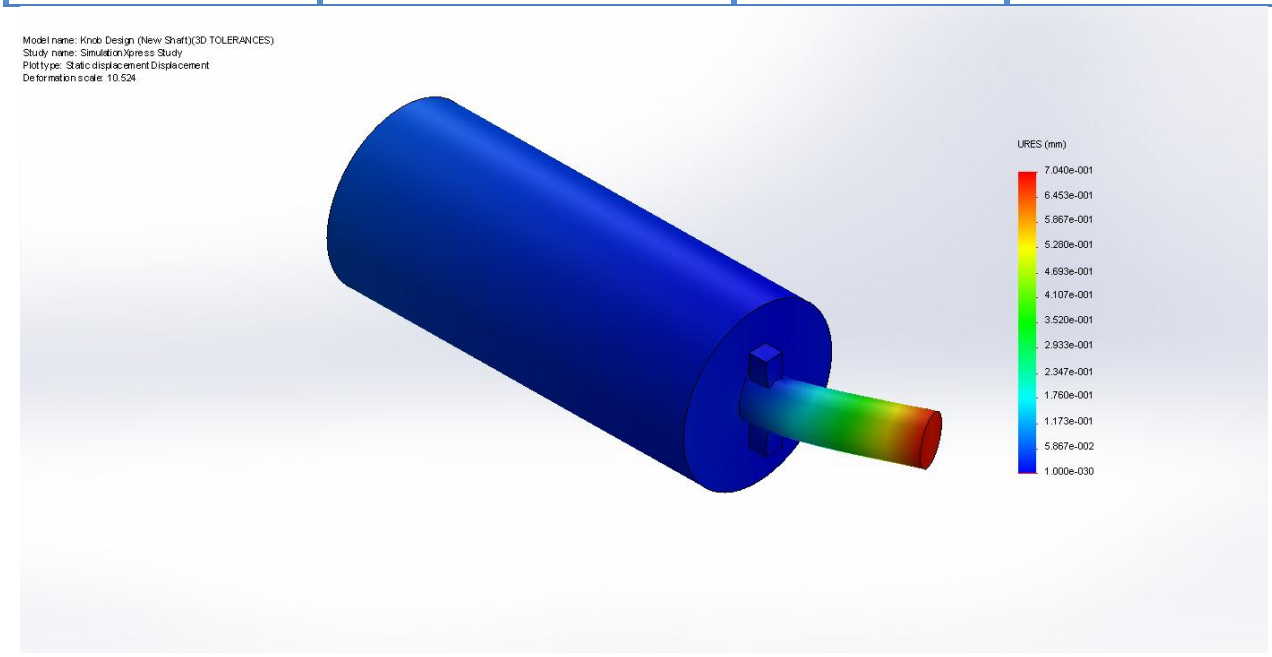
Study Results

Name	Type	Min	Max
Stress	VON: von Mises Stress	50.0899 N/m^2 Node: 145	3.09545e+007 N/m^2 Node: 341



Knob Design (New Shaft)(3D TOLERANCES)-SimulationXpress Study-Stress-Stress

Name	Type	Min	Max
Displacement	URES: Resultant Displacement	0 mm Node: 11	0.703994 mm Node: 9677



Testing Data

Figure A3:

Angle Testing: Determining Minimum Angle of Visibility

Subject	Caliper Height (in)	Height Above Indicator (in)	Angle (rad)	Angle (deg.)
1	1.354	1.804	0.157	8.992
2	1.216	1.666	0.145	8.314
3	1.297	1.747	0.152	8.713
4	1.023	1.473	0.128	7.362
5	1.163	1.613	0.141	8.053
6	1.019	1.469	0.128	7.343
7	0.999	1.449	0.126	7.244
8	2.433	2.883	0.248	14.192
9	2.272	2.722	0.234	13.429
10	0.999	1.449	0.126	7.244
Average	1.3775	1.8275	Average Angle (deg.) =	9.089
SD	0.53062			

Figure A4:

Ease of Use Testing

Subject	Success	Failure	Ease Value(1-10)
1	19	1	9
2	16	4	9
3	20	0	9
4	17	3	7
5	19	1	9
6	20	0	10
7	20	0	10

8	20	0	10
9	20	0	10
10	19	1	9
Averages	19	1	9.2
SD	1.41421		0.91894