DESIGN OF A CLEANING INDICATOR FOR REUSABLE MEDICAL EQUIPMENT

Kevin McConnell, Paul Strand, David Hintz, Matthew Boyer, Ross Paulson
Client: Dr. Scott Springman, University of Wisconsin Hospital Anesthesiology Department
Advisor: Dr. Chris Brace, Department of Biomedical Engineering – University of Wisconsin-Madison

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.

Problem Definition

Motivation

- Maintaining a sterile surgical environment is critical
- Reusable machines must be reprocessed between uses
- Time and money is lost when machines are unnecessarily reprocessed

Current Practice

- Laminated paper signs attached to machines via a chain flip to display "clean" on one side and "dirty" on the reverse side
- These signs tend to flip inadvertently or fall off during machine transport
- Causes confusion as to whether a machine is actually clean or dirty

Right: Machine with paper sign attached

Anesthesia Machines

- Device must interact with variety of machines of different size
- Placed on rolling carts for easy transport

Left: Bronchoscope, Right: Anesthesia Delivery System

Design Criteria

- Easily adhered to machine, permanently affixed
- Ability to bond to multiple surfaces
- Max size: 3" x 1.25" x 1.25"
- Accurately and reliably displays the desired state of cleanliness
- Ability to withstand reprocessing environment (quaternary ammonium disinfectant solution)
- Materials used must not be corrosive or biologically abrasive

Final Design

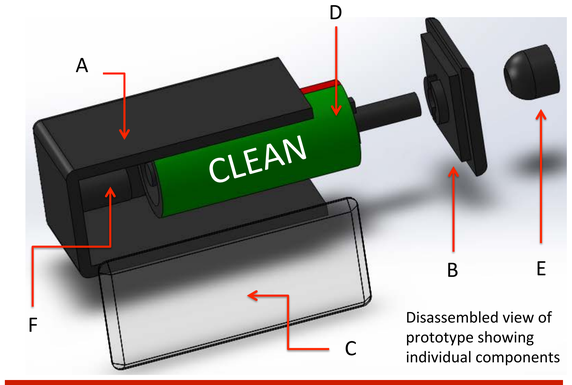
- Materials
  - -Acrylonitrile Butadiene Styrene (housing and internal indicator bar)
  - -Polycarbonate (viewing window)
- Housing
  - -2.75" x 1.25" x 1.25"
  - -rounded corners prevent hang-ups
- Indicator Bar
  - -0.90" diameter, 2.6" length
  - -Rotates 180 degrees to change between two indication states
  - -Cylindrical shape maximizes space efficiency
- External Knob
  - -0.50" diameter
  - - Depresses to disengage locking mechanism
  - - Rotation spins indicator bar to desired setting

- Locking Mechanism
  - -Square gearing mesh prevents inadvertent changes to indicator state
  - -Requires pressure to disengage
- High contrast colors maximize visibility
- Visible text to aid colorblind individuals

Left: Assembled prototype
Right: Close up view of locking mechanism in disengaged state

Parts List

A. External Housing
B. End Cap with Gear Mesh
C. Viewing Window
D. Rod with Indicator Bar
E. Knob
F. Spring Chamber (spring not shown)

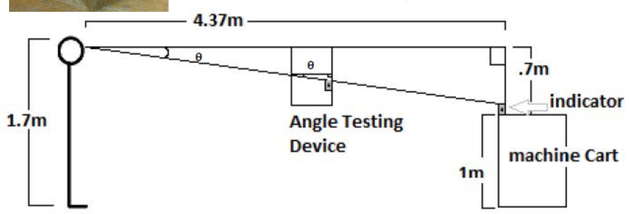


Disassembled view of prototype showing individual components

Testing and Analysis

Angle Visibility Testing

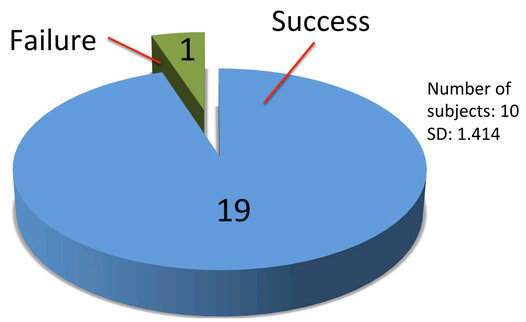
- Looking through eye hole, subjects raise viewing window until indicator status is discernible
- Mean vertical displacement determined **(1.8275"±0.531)**
- Critical angle calculated **(9.1°±2.572)**
- Using mean critical angle, max viewing distance calculated **(4.37 m)** for human of average height (1.7 m) assuming indicator is 1 m off ground



Top: Testing device used to acquire minimum angle of visibility
Bottom: Schematic showing relationship of angles between testing device and person of average height with indicator placed at 1 meter off ground

Ease of Use Testing

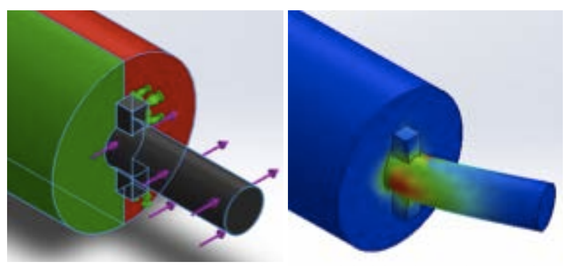
- Subjects asked to change indication state 20 times
- Number of mistakes recorded
- Success defined as having gears lock on first attempt
- 95% success rate



Number of subjects: 10
SD: 1.414

Average number of successful turns out of 20 attempts

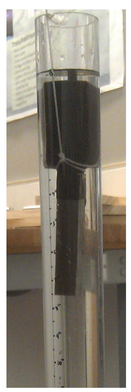
SolidWorks Analysis



SolidWorks testing of shaft bending under 100 N force

- Analysis to determine weakest point of device
- ABS Yield Stress: 65 MPa
- 100 N applied force (dropping 20 pound object on device)
- Stress = **30.954 Mpa**

Pressure Analysis



- Test of worst case scenario during reprocessing: complete submersion
- Most likely leak point: shaft through-hole
- Test chamber: volume= 131.9 in^3
- Indicator submerged to depth of 36"

Result

- No water entered through through-hole
- At max depth: **pressure = 1.085 atm**

Submersion chamber filled with water. Indicator lowered to measurable depth with weight and string

Future Work

Manufacturing

- Gather additional quotes from competing injection molding companies
- Research alternative production methods
- Contact Hospital funds to arrange for mass production

Design Modifications

- Modify profile extrusion to flatten device
- Modify device to alter viewing angle
- Change locking mechanism to a more efficient saddle joint
- Incorporate patterns and/or colors to accommodate users with vision impairments

Research

- Determine ideal bonding agent to mount device to various machine surfaces
- Gather more feedback from client and users on current design

References

1. Colton, JS. "Injection Molding - Process Description." Manufacturing Processes and Systems. Georgia Institute of Technology. 2009.
2. "HIV Tests Urged for Some Colonoscopy Patients." *Associated Press* 31 Mar. 2005.
3. Material Safety Data Sheet 3M Neutral Quat Disinfectant Cleaner Concentrate. 3M Company. 2012.
4."SolidWorks Forum: FEA on ABS Material." *SolidWorks Forum: FEA on ABS Material.*
5. 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.

Acknowledgements

• Dr. Scott Springman
• Professor Chris Brace
• Christina Jordan
• COE Student Shop