

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.