Design of a Cleaning Indicator Device for Medical Equipment

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

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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 (round, flat, rough, smooth and any combination of these). 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. The device must be able to withstand the QUAT spray and washcloth wipe down. The device must be sealed and smooth to allow QUAT to remove infectious agents.

c. *Accuracy and Reliability:* Device must accurately and reliably display the desired state of cleanliness. The device must universally indicate the status of the machine it is attached to.

d. *Life in Service:* Device must be reusable and capable of being in service 5 years before replacement is necessary. Must be able to withstand cleaning up to three times a day every day for its lifespan (~7000 times) (4-8 Years).

e. *Operating Environment:* Must be able to withstand harsh sterilization environments and exposure to various biological elements. The device must be able to withstand exposure to bodily fluids with a pH 1-8 (vomit, blood, saliva, and pancreatic secretions). The device must be able to withstand the forces of the wipe down with QUAT spray (about 50 N or 10 lbs).

f. *Ergonomics:* Indicators must be compact enough to simply affix and must be quick and easy to adjust. The device must be attached at a height of about one meter to be operated easily.

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 be made of plastic and not be composed of corrosive or biologically abrasive elements. Materials must be capable of withstanding reprocessing environments (QUAT).

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. 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). Any mechanical functions must be capable of being performed with minimal user precision (one hand).

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.