Product Design Specification

Last updated: *November 28th, 2008*

Title: *Ethanol Degradable Indicator of Hand Hygiene Quality, Team Hand Hygiene*
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Function:
A topical compound containing a marker characterized by fluorescent properties that will be altered upon contact with ethanol will serve as an indicator of hand hygiene quality. Following development of this compound, a portable fiber-optic spectroflourometer and hand positioner device will be designed to quantitatively measure the effectiveness of hand washing technique utilizing waterless alcohol-based sanitizer.

Client requirements:

- Eliminate current dependency on soap and water as only modality for fluorophore attenuation via Glogerm and blacklight
- Topical agent exhibiting intrinsic fluorescence which must be attenuated or eliminated when exposed to alcohol-based hand cleansers
- Determine if fluorescence spectroscopy can successfully detect attenuation of fluorophore due to alcohol solvent
- Construct rubric to translate quantitative data into qualitative data
- Construct a mobile spectrofluorometer intended for research and clinical setting
- Standardize hand hygiene evaluation method to optimize reproducibility and precision in quantitative data analysis

Design requirements:

1. **Physical and Operational Characteristics**
    a. *Performance requirements*: The overarching goal is for the product to serve as a teaching aid for alcohol-based hand cleansing with the target audience of health care professionals. The elected fluorescent marker will simulate bacteria and should be invisible throughout the visible light spectrum and fluoresce with exposure to UV light. This fluorescence should be attenuated or eliminated following hand cleansing. The product will also include a standardized mechanism for collecting quantitative data.
    b. *Safety*: The fluorescent marker must be safe for application to human skin and should only include substances approved by the U.S. Food and Drug Administration (FDA). The spectrofluorometer and measurement accessories should not put the user at risk at any time.
    c. *Accuracy and Reliability*: As a didactic tool, the marker is required to have a visible change in fluorescence following hand cleansing. However, to ensure a qualitative change, measurable data must be collected to prove a quantitative change in both fluorescence and amount. Every application of

this product must reliably change in fluorescence following hand cleansing to successfully achieve its performance requirements. Spectrofluorometer measurement accessories should decrease variables and increase accuracy with standardized data collection points.

d. *Life in Service*: The shelf life of this product should, at minimum, be comparable to other basic hospital products including alcohol-based hand cleansers and lotions. While fluorescent molecules will exhibit a decay factor, the alteration in fluorescence after hand cleansing must last approximately one hour.
e. *Shelf Life*: The shelf life of the fluorescent marker will be dependent upon the chemical and physical properties of the solution. Ideally, the chemicals should have a shelf life of at least one year. The spectrometer and measurement accessories should have a life span of at least 15 years expecting proper care and maintenance.
f. *Operating Environment*: The initial product will have to be restricted to classroom studies. For testing on the travel of "germs" originating from stationary objects in the hospital setting, FDA approval will be required for patient safety.
g. *Ergonomics*: The marker must be safe for human contact and easily disposable after use. The spectrofluorometer unit should provide means to be easily lifted and moved.
h. *Size*: The marker must be small and not visible without special diction, i.e. spectrometer. The size should mimic the size of typical contaminants that could be found on the hand—approximately 5 microns. The spectrometer and accessories must be small enough to be moved easily and frequently.
i. *Weight*: Weight of the marker should be negligible. The spectrometer should be no greater than 20 lbs.
j. *Materials*: The marker should adhere to FDA regulations and standards, and should not include any hazardous substances.
k. *Aesthetics, Appearance, and Finish*: The marker should blend with the skin tone to minimize its appearance as much as possible. The measurement device should have a professional appearance and match the hospital aesthetic.

2. Production Characteristics

a. *Quantity*: The amount needed for testing should suffice, though mass-production of the device should be considered.
b. *Target Product Cost*: Cost of the identified agent should be minimized to ensure affordable mass-production expenses in the future. Current budget is $10,000, which includes the purchasing of a spectrometer.

3. Miscellaneous

a. *Standards and Specifications*: FDA approval is required if the fluorescent marker or other chemicals used in the design project have not been submitted to the FDA and approved for use on the skin.

b. *Customer*: The fluorescent marker solution should be easy to apply to the hands, non-toxic, have no long-term effects on the skin, have little or no color, and have little or no unpleasant odor. The solution should also have a smooth consistency and not cause any drying of the skin, if possible.
c. *Patient-related concerns*: Since alcohol will be applied to the hands, there is minimal risk of bacterial or viral contamination. The spectrofluorometer measurement accessories will have to be cleaned between patients to keep testing standardized. After testing, patients should be instructed to wash hands again with soap and water to remove the remaining fluorescent marker. Safeguarding of patient data is not necessary.
d. *Competition*: A comprehensive literature and patent search has been done to eliminate the possibility of similar products on the market.