Product Design Specifications

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Title: Interpenetrating Networks for Delivery Systems

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Function: Hand hygiene is an integral part of a health care professional's job, and the single most important infection control procedure in preventing contamination. This design project is focused on achieving a high percent of compliance with hand decontamination when moving from computer keyboard to the patient. The device should expedite the process of hand decontamination while keeping the health care professional and patient safe. It should also be affordable and able to assimilate in to any clinical setting.

Client requirements: Our client, Dr. Carla Alvarado, would like our team to develop an input device that would maintain a clinically-acceptable level of decontamination while also functioning as a means of decontaminating the user's hands. This device would preferably be retro-fitted to an existing input device and it would be implemented for computers on wheels in clinical settings. Key areas to focus on include efficacy of the design, clinical acceptability, the ability to reach a broad market, and to streamline the handwashing process. This project may involve mechanical, chemical, or electronic approaches.

Design requirements:

1. Physical and Operational Characteristics

a. *Performance requirements*

Disinfect user's hands and maintain cleanliness of input device. Must fit seamlessly into the clinical environment. Must increase user's hand washing compliance while increasing efficiency of current methods. Device must be able to be used 20-30 times per clinician, per day. Must be able to sustain significant usage for up to 10 minute intervals per use. Minimally, the device must be able to remain disinfected, but ideally, it should maintain the hand hygiene of the user.

b.*Safety*

Ensure that disinfectant is safe for prolonged exposure to user. Conform to FDA labeling requirements if necessary. Awareness of the device's efficacy over time must be recognized. An indicator of performance levels should be incorporated. Procedure should be streamlined and minimal user training should be required.

c. *Accuracy and Reliability*

The device should be accurate enough to conform to the Spaulding definition of decontamination for both the device and the user's hands. Active ingredient must be evenly distributed throughout the product during its duration of use.

d. *Life in Service*

Product must be able to sustain repeated use for multiple users. Product should be designed to be used for a term of no longer than five years, based on current depreciable value.

e. *Shelf Life*

If chemical modification is incorporated, it will degrade over time with or without use. This must be noted on the device, and testing of this degradation must be performed prior to mass production.

f. *Operating Environment*

Product will be used in a clinical setting. Must be able to withstand normal levels of heat and humidity, dust, and dirt. Must not be susceptible to small levels of shock loading. Must be incorporated onto a mobile device. Possible application in laboratory setting.

g. *Size*

Must fit onto a COW (computer on wheels). Must not impede normal performance in the operating environment.

j. *Materials*

Device should be made from a cost-effective material that is either a modified polymer or a mechanical adaptation. Materials should comply with all FDA regulations and should not contain any common allergens or potentially harmful chemicals.

k. *Aesthetics, Appearance, and Finish*

Input device should maintain standard size and proportions for keyboards. The design should accommodate all ranges of users, and have professional appearance.

l. *Ergonomics*

Product should not impede the user's ability to type nor prevent the user from accessing the keyboard readily. The device cannot interfere with the hand-washing task. Product should be comfortable for positioning of user's hands, and promote proper typing mechanics.

2. Production Characteristics

a. *Quantity*

Only one unit is desired at the present time. Product should be developed with the intent of mass-production.

b. *Target Product Cost*

The price for production for the prototype should be less than $500, however the mass produced final design should be affordable to all hospitals. There are some very underfunded hospitals, however since EMR will soon be required of all care facilities, our device should be cheap enough so that they may also increase hand-washing compliance with our device.

3. Miscellaneous

a. *Standards and Specifications*

FDA approval may be necessary. Product should meet ergonomic standards for keyboards. Product must be able to be easily translated into mass production. Product must increase handwashing compliance in a clinical setting.

b. *Customer*

Institutions with hygienic standards and EMR. This includes but is not limited to hospitals, clinics, and possibly research labs.

c. *Patient-related concerns*

Product should have an indicator for life remaining in service. Product should not interfere with patient-clinician interactions.

d.*Competition*

According to our client, there are no products that fill this niche, but further research must be done. All FDA approved disinfectants are both possible competition, but may also be incorporated into the design. This is a method development design project, so further patent research will have to be performed