Filter Integrity Testing of Reprocessed N95 Masks: A Testing Rig and Quality Assurance Model

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Introduction: The COVID-19 coronavirus pandemic has put a strain on hospital resources across the globe. One notable scarcity among these resources are face masks used to prevent the transmission of airborne viruses and infected water droplets. To address this scarcity, institutions have begun to consider the possibility of reprocessing single-use N95 masks in order to extend their utility. To demonstrate successful reprocessing, masks must be tested to ensure that they maintain functionality criteria, as set by the National Institute for Occupational Safety and Health (NIOSH).

Materials and Methods: The work involved two main arms to meet the immediate need for N95 reprocessing, testing, and quality assurance (QA). First was development of a testing rig suitable to measurement of particle stoppage (>95% of particles >0.3μm) and pressure drop (<35/25 mm of water for inhalation/exhalation) for reprocessed N95 masks. Initial measurements evaluated filter integrity for 3 levels of mask, both pristine and worn. Second was development of a statistical model and user interface (UI) for guiding QA test frequency and sample size / confidence interval estimates for large scale reprocessing and testing programs.

Results and Discussion: As shown in Fig. 1, the testing rig (Fig. 1A) is capable of quantifying particle filtration of various mask types (Fig. 1B) while adhering to primary NIOSH testing criteria. Most notably, the stoppage results acquired from the N95 mask coupons rightly reflected a >95% stoppage of particles with a diameter > 0.3 μm. The average loading of the rig was found to be approximately 0.082 mg/min, suggesting that in order to achieve a proper loading according to NIOSH criteria, a run time of over 200 minutes for a single coupon is required. Such runtimes place steep constraints on the number of masks that can be reasonably tested, further motivating the statistical QA model. The UI (MATLAB) is illustrated in Fig. 1C, providing a sample size calculator for QA testing programs. Based on the total population of reprocessed masks deployed in the field along with user-defined statistical criteria, the required sample size is estimated such that a given confidence interval is achieved on the integrity of the population of masks in the field.

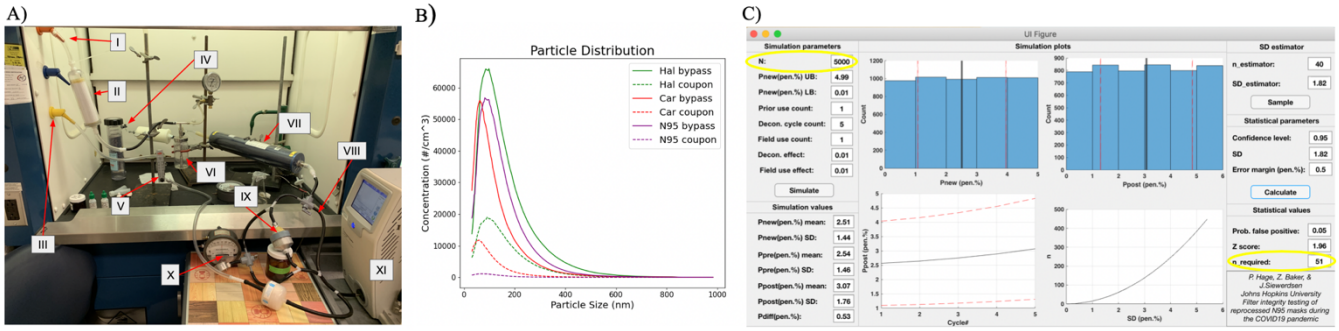

Figure 1. (A) The filter integrity testing rig: (I. House air) (II. HEPA filter) (III. House Vacuum) (IV. Desiccant and HEPA filter) (V. Rotameter) (VI. Collison Nebulizer with NaCl (aq)) (VII. Charge Neutralizer) (VIII. Bypass line) (IX. Mask coupon line) (X. Pressure gauge) and (XI. SPMS Spectrometer 3938). (B) Example particle distribution measurement for various masks (Hal – Halyard; Car – Cardinal; and N95). (C) UI calculator for guidance of QA process, demonstrating the estimated sample size for a population of reprocessed masks (e.g., 51 tests for 5000 masks in the field to achieve 95% CI).

Conclusions: The rapid design and development of a testing rig to measure N95 mask filter integrity was described, and a statistical model for sample size calculation in QA was developed along with a UI suitable for deployment in reprocessing N95 masks at scale. The rig allows in-house testing of filter integrity, and the sample size calculator UI provides a basis for an institutional QA program.