# 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 accross the globe. One notable scarcity are facemasks used to prevent the transmission of airborne viruses and infected water droplets. To address this scarcity, institutions have begun to consider reprocessing single-use N95 masks in order to extend their utility. To demonstrate successfull reprocessing, masks must be tested to ensure that they maintain functionality criteria, as set by the National Institute for Occupational Saftey and Health (NIOSH).

## Methods

This work involved two main arms to meet the immediate need for N95 reprocessing, testing, and quality assurance (QA):

**1. Development of a filter integrity testing rig** suitable to measurement of particle stoppage (>95% of particles >0.3 μm) 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.

**2. Development of a statistical QA model and user interface (UI)** for guiding QA test frequency and sample size / confidence interval estimates for large scale reprocessing and testing programs.

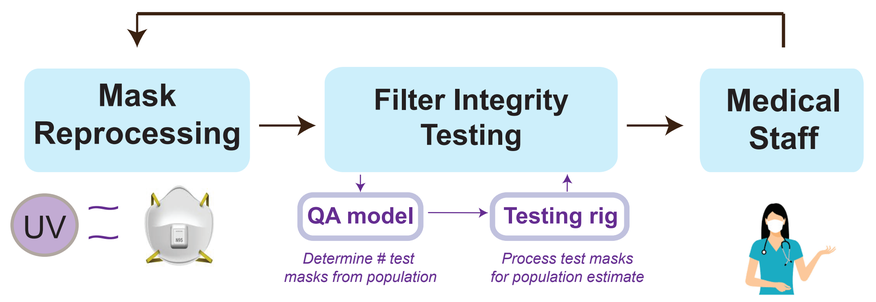


Figure 1. Mask reprocessing pipline

## Results: Filter Integrity Testing Rig

The filter integrity testing rig (Fig. 2A) is capable of quantifying particle filtration of the various mask types while adhering to primary NIOSH testing criteria.
Notably:

- N95 coupon stoppage results rightly reflected a >95% stoppage of particles with a diameter > 0.3 μm (Fig. 2B).
- Average rig loading was found to be 0.082 mg/min for a 47 mm (diameter) N95 coupon.

Steep runtime requirements highlight constraints on the number of masks that can be reasonably tested, motivating a statistical QA model

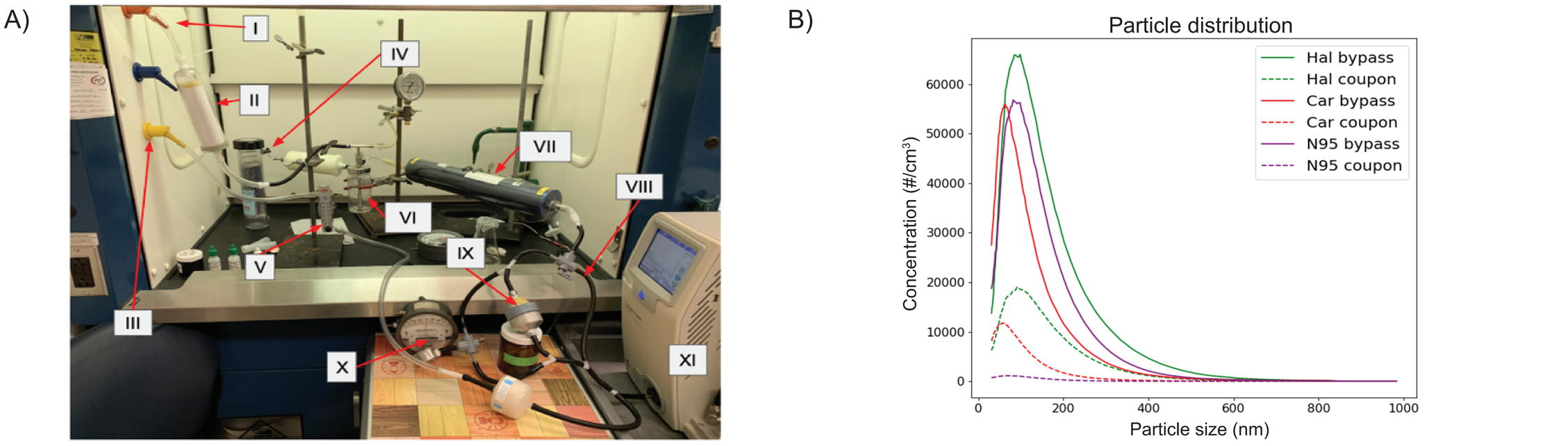


Figure 2. (A) The filter integrity testing rig: (I. House air) (II. HEPA filter) (III. House Vacuum) (IV. Desiccant and HEPA filter) (V. Rotameter) (VI. Collison Nebulizer with NaCl (aq)) (VII. Charge Neutralizer) (VIII. Bypass line) (IX. Maskcoupon line) (X. Pressure gauge) and (XI. SPMS Spectrometer 3938). (B) Example particle distribution measurement for various masks (Hal – Halyard; Car – Cardinal; and N95).

## Results: Statistical QA Model

A statistical model was developed to compute the number of masks that need to be tested in order to provide a given confidence level that masks in circulation meet minimum N95 criteria.

The UI exposing model parameters and calculations is shown in Fig. 3. It provides users with a sample size calculator to guide QA testing programs.

Example: 51 tests for 5000 masks in the field to achieve 95% CI (Fig. 3)

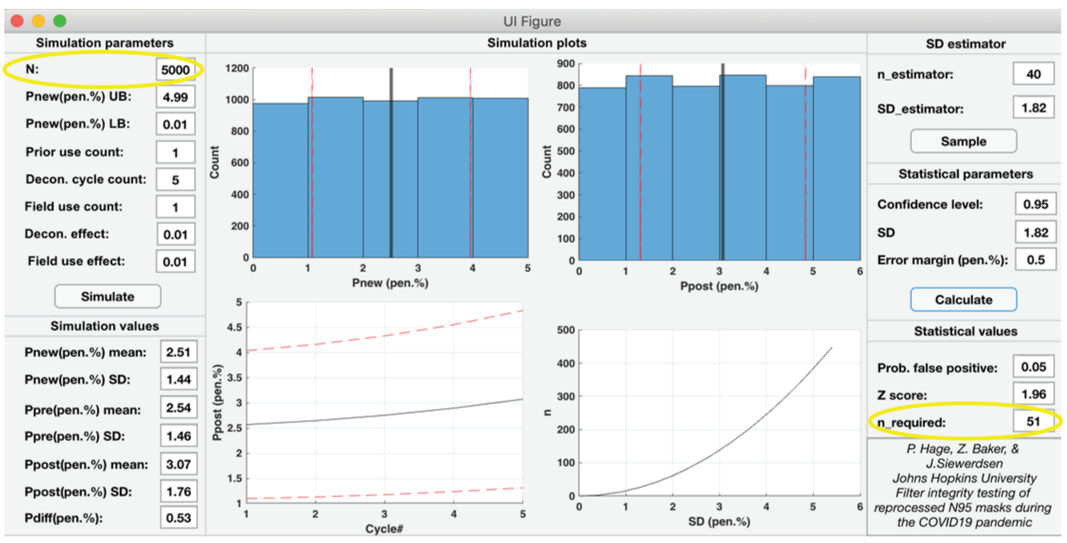


Figure 3. UI of the sample size calculator

## Conclusion

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 suitale 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.

## Acknowledgements

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