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DEVELOPMENT OF A DEVICE FOR ANALYZING THE FUNCTIONALITY OF N95 RESPIRATORS REGARDING THE EFFICIENCY OF THE FILTERING FIBER

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Abstract. *N95 respirators are used to prevent airborne transmission of diseases such as the novel coronavirus (COVID-19), influenza and tuberculosis. Given their scarcity globally amid the COVID-19 crisis, reuse strategies have been advocated. However, there is still no clear evidence regarding how long the N95 respirators retain their filtration ability for particles measuring 0.3 microns (μm), ensuring a minimum efficacy of 95%. The aim of this study is to develop equipment to analyse the filtration efficiency of the material used in N95 respirators. The devices will be fashioned into a circular shape and affixed to a cylindrical tube. NaCl particles with an average size of 0.3μm will be aerosolised within the apparatus, while a vacuum generator will establish the airflow. The concentration of these particles, both before and after passing through the N95 respirator, will be measured to determine the Particle Filtration Efficiency (PFE). Breathability will be evaluated by measuring the pressure differential in the material (ΔP). This will enable the assessment of the efficiency of each filtering element, aiming for a high PFE. Consequently, the duration for which the N95 respirator maintains its baseline filtration efficiency (95%) post-reuse, ensuring the safety of healthcare professionals, will be ascertained.*

Keywords: *N95 respirators, Efficiency of filtering, Test Bench, Equipment Reuse*

1. INTRODUCTION

On March 11, 2020, the World Health Organization (WHO) declared a state of pandemic Organization attributable to the emergence of a novel human coronavirus, Severe Acute Respiratory Syndrome Coronavirus-2 (SARS-CoV-2), the

causative agent of the disease COVID-19 (ZHU et al., 2020). The first instance in Brazil was documented on February 26, 2020. Since then, the spread of the virus and the subsequent mortality rate have been a major concern. Globally, there have been 771,151,224 cases and 6,960,783 deaths, with Brazil ranking second in deaths (704,659), trailing only the United States of America (USA) which has 1,127,152 deaths (WHO, 2023).

In this context, both national and international guidelines advocate for the use of Personal Protective Equipment (PPE), encompassing N95 respirators for healthcare professionals involved in potential aerosol-generating procedures on patients, whether they are confirmed or unconfirmed COVID-19 cases (WHO, 2020; ANVISA, 2022; CDC, 2023). The objective of these guidelines is to mitigate the risks associated with the potential transmission of this highly infectious disease.

These N95 respirators should be designated for single use, followed by proper disposal (CDC, 2023). However, the significant global demand surge during the COVID-19 pandemic resulted in a worldwide shortage of these essential protective devices (Cohen and Rodgers, 2020). Given this scenario, under emergency circumstances, the Centers for Disease Control and Prevention (CDC), along with other health societies and agencies, proposed the reuse of N95 respirators beyond the manufacturer's suggested usage parameters, as long as their integrity, functionality, and structure are maintained. This approach has been referred to as the extended/prolonged use of the N95 respirator, involving its continuous use over several hours while attending to multiple patients, without disposal between appointments (CDC, 2023a). The limited reuse refers to serving multiple patients with the same device, with removal and appropriate storage for future use after each patient interaction (CDC, 2023a).

While this strategy is pivotal for resource optimization, the adoption of this practice poses contamination risks to healthcare professionals due to the potential for self-inoculation from particles that may remain on the outer or inner layers of the equipment, amplified by continuous use and/or improper doffing (Zhang et al., 2021). Furthermore, there is an increased likelihood of direct transmission when a contaminated surface of the respiratory device is touched, followed by touching facial mucous membranes (Fisher, Weber and Wohl, 2015; Zhang et al., 2021).

The reuse of N95 respirators encourages the emergence of mechanical failures, such as loosening of the elastic bands and breaks in the nose clip, resulting in a poor seal between the device and the wearer's face (Duncan et al., 2020). Additionally, data suggest that a maximum of five consecutive donning sessions are allowed to avoid overloading their components and to ensure an effective seal (Vuma et al., 2019).

The premise of safe usage of N95 respirators is predicated on minimal handling, and thus a lower risk of SARS-CoV-2 transmission (CDC, 2023; Zhang et al., 2021). Conversely, prolonged use may lead to structural losses, fostering gaps at the edges of the PPE, potentially compromising their filtering functions, and allowing pathogenic droplet nuclei to penetrate the professional's airways (CDC, 2023; Jung et al., 2021). It must also be considered that during extended use, professionals inevitably need to take breaks, even brief ones, for using the restroom, eating meals, and giving their faces rest. This presupposes increased handling of this PPE, potentially causing alterations and wear to its functionality and integrity in terms of its structure (Fischer, Weber and Wohl, 2015).

With a focus on occupational safety, particularly on its use and risk mitigation of contamination, the appropriate fitting of the N95 respirator to the user's face, as determined by the qualitative fit test, constitutes a fundamental principle for its effectiveness in respiratory protection (Jung et al., 2021; Rivard et al., 2021). However, laboratory studies have demonstrated a high proportion of Fit Test failures due to the extended use or reuse of the N95 respirator, indicating that at least 38% of the participants failed after redonning the device (Jung et al., 2021).

Despite evidence of the loss of functionality in N95 respirators during extended use and reuse, studies that examine the preservation of the integrity and functionality of the N95 respirator, specifically looking at the maintenance of their sealing, filtering, and safe reuse characteristics at varying intervals as proposed by healthcare services, are yet to be found. This gap necessitates, as various authors have pointed out, the evaluation of knowledge from a comprehensive study that encompasses all characteristics of the integrity and functionality of N95 respirators to uphold the occupational safety of professionals (Kirubarajan et al., 2020; Sancho, González-Maria e Abad-Corpa, 2021; Toomey et al., 2020).

Thus, the reuse or extended use of this PPE has been a challenging and complex strategy regarding healthcare professionals' safety, particularly due to the lack of clear and precise recommendations on the potential effects that proposed protocols may have on the functionality and integrity of N95 respirators (Jung et al., 2021).

Given the context, the central question of this study is: what is the efficacy of N95 respirators after prolonged use and/or reuse in terms of functionality, taking into account their filtration efficiency and the safety of healthcare professionals?

In this regard, it is imperative to identify gaps in knowledge related to the safety of reusing and extended use of N95 respirators. Such recognition is essential to establish appropriate protocols ensuring both patient and healthcare professionals receive quality and safe care. Moreover, this understanding aids in the implementation of specific interventions, given that this PPE is widely employed in treating patients infected with airborne pathogens, especially the SARS-CoV-2 virus.

In this sense, the objective of this work will be to construct an equipment in accordance with the standards of the National Institute for Occupational Safety and Health, United States (Certified Under 42 CFR 84) to analyze the functionality of the filtering material of the N95 respirators in terms of the minimum filtration capacity of 95% of airborne particles and quantify their breathability in reuse protocols (seven and 15 days).

2. METHODOLOGY

The collection of N95 respirators will take place in adult Intensive Care Units (ICU) which adopt distinct protocols. In Unit A, professionals are guided to reuse the N95 respirator, provided it remains intact, dry, and clean, for a period of up to seven days or shifts, after which disposal is recommended. In Unit B, the protocol allows for the N95 respirator to be reused for an extended period of up to fifteen days or shifts, with disposal advised at the end of this period.

2.1 Study Population and Sample

The eligible population for the study will be all nursing professionals who provide direct care to patients admitted in the selected units and who agree to participate in the study after signing the Informed Consent Form (ICF), which contains the main information about the research.

This population is justified as they form the largest quantity among the healthcare professional team and spend the most time caring for patients. They also constitute a risk group for respiratory transmission diseases due to direct exposure to infected patients, thus coming into contact with a high viral load.

To select the study population, stratified random sampling will be used, taking into account the roster of professionals.

The sample will consist of N95 respirators after extended use and/or reuse over different time intervals (seven and 15 days) by nurses and nursing technicians who provide direct patient care in an Adult Intensive Care Unit.

All N95 respirators from the nursing professionals will have a certificate of approval (CA) issued by the Ministry of Labour and Employment (MTE), maintaining the protective characteristics and recommendations from health agencies such as CDC, WHO, and ANVISA.

Figure 1A illustrates a model of N95 respirators, and Figure 1B shows a detailed view with its separated layers, divided into synthetic fibres (non-woven): external polypropylene, structural, with electrostatic treatment (filter), and internal polypropylene.

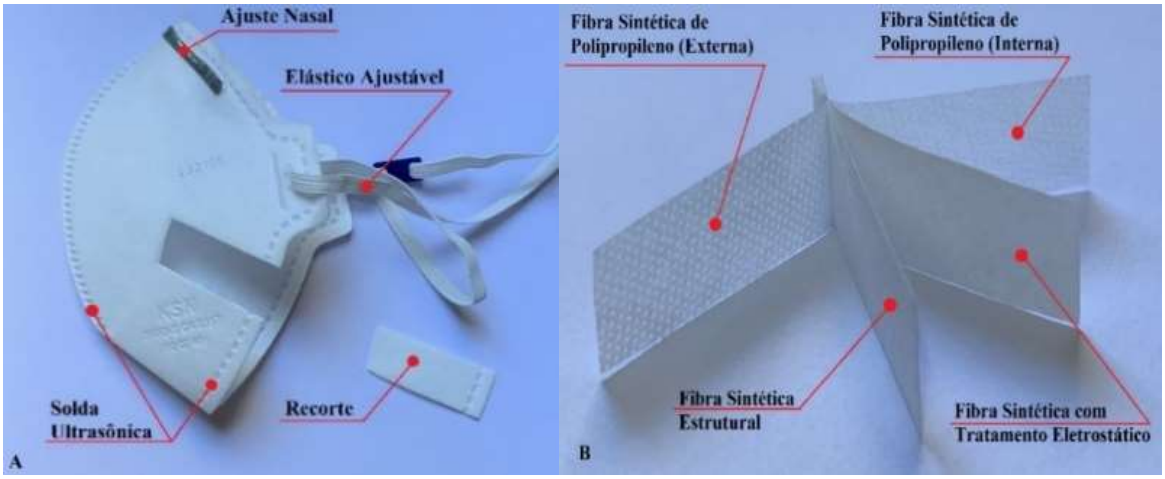


Figure 1. (A) View of a cut-out N95 respirator. (B) Identification of layers for analysis

2.2 Proposed Experiment - Filtration Efficiency Test

The filtration efficiency test will assess the filtration effectiveness and filter material integrity of N95 respirators after extended use and reuse at different time intervals regarding their ability to retain particles up to 0.3 microns, with a minimum filtration efficiency of 95%, through a test bench located in the Laboratory of Bioengineering (LabBio), affiliated with the Department of Mechanical Engineering (Figure 2).

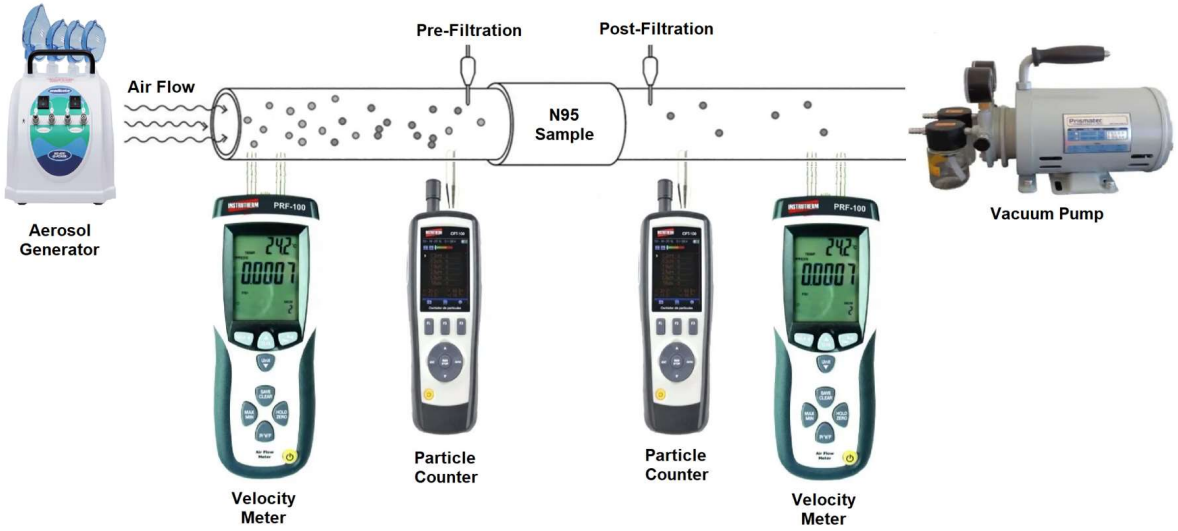


Figure 2. Filtration Efficiency Test Bench.

Samples of the N95 respirators will be cut in a circular shape with an approximate diameter of 5.0 centimeters (cm), subsequently affixed onto a cylindrical tube of corresponding internal diameter. An aerosolized saline solution (0.9% NaCl) will be produced using a nebulizer at one end of the equipment, while a vacuum generator at the other end will be employed to induce suction, hence creating an airflow in the direction specified. The filtration capability of the N95 respirator will be gauged through the utilization of a particle counter both pre and post the sample. A reduced number of particles subsequent to the N95 respirator filter implies superior filtration efficiency, which is expected to be at least 95%.

2.3 Prototype Construction

The project revolves around the application of a wind tunnel to perform filtration tests on an N95 respirator. The test bench prototype uses two acrylic tubes (1), used to increase the visibility of the experimental process (Figure 3). The tubes will be conjoined at the center via flanges (2) secured by a rapid coupling system. An N95 respirator sample will be trimmed and affixed at the center of the two flanges (2). An aerosol generator (3) (nebulizer) will be installed at one extremity, tasked with generating aerosol particles that will be filtered by the N95 respirator sample. At the opposite end, a vacuum pump (4) will be fitted, accountable for generating the pressure difference in the pipe, and consequently, the air flow to simulate human respiration.

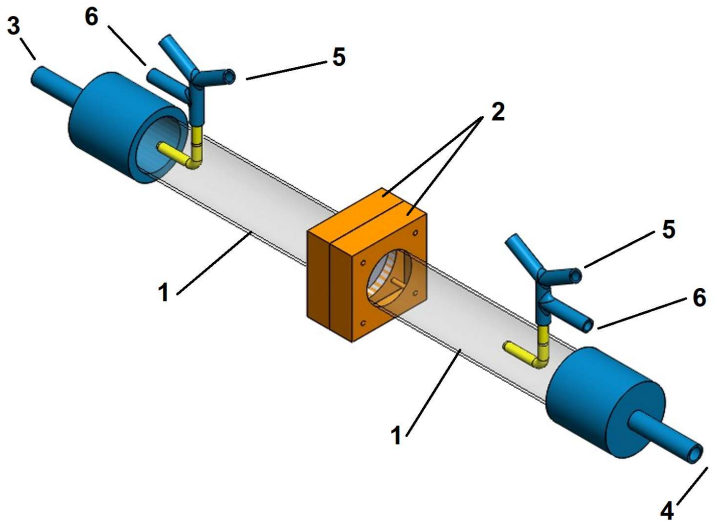


Figure 3. Test bench assembly configuration.

To evaluate filtration efficacy, two particle counters (5) and two pressure gauges (6) will be installed at collection points. The particle counters (5) will be positioned in the tubes upstream of the N95 respirator sample, assigned to measure the quantity of particles in the air before passing through the respirator, and subsequently after the sample to evaluate its filtration efficiency. The pressure gauges (6) will be deployed to ensure pressure constancy throughout the test, guaranteeing consistent parameters for the study. Figure 3 shows a three-dimensional rendering of the test rig assembly configuration.

3. RESULTS AND DISCUSSION

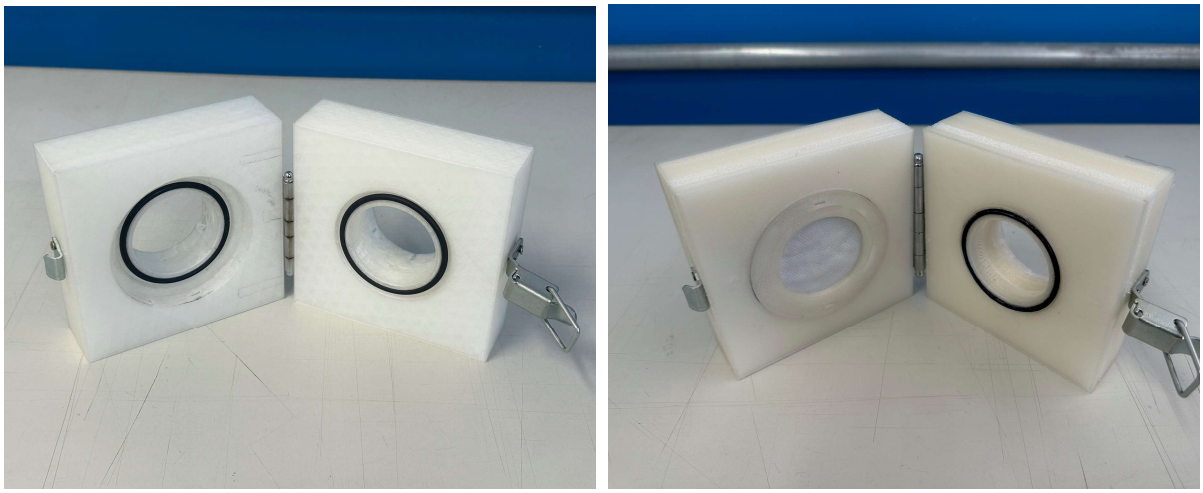
3.1 Fixation of N95 respirator samples

The N95 respirator sample was taken from a region close to the nose and mouth. Two nylon rings are used to allow the sample to be glued and subsequently fixed to the test bench. The internal diameter of the rings is 50 mm, equivalent to the diameter of the acrylic tubes on the bench. Figure 4a shows the preparation of the sample for gluing and Figure 4b shows the sample already glued to the nylon rings.

(a) (b)

Figure 4. (a) Preparation of the sample for gluing to nylon rings; (b) sample already glued to the nylon rings.

The nylon rings containing the N95 respirator sample are positioned on the flanges of the test bench, as illustrated in Figure 5. The flanges are connected by a hinge and on the opposite side a quick lock was installed to allow quick replacement of the N95 respirator test sample. Rubber rings (O-rings) were installed in the internal slot of the flange with the aim of sealing the region and preventing air leaks with the aerosol that must pass completely through the sample. Leaks could cause errors in evaluating the filtration effectiveness of samples using particle counting before and after the aerosol passes through the N95 respirator sample.



(a) (b)

Figure 5. (a) Open flanges for viewing the sealing O-rings and recess for fixing the N95 respirator sample; (b) Flanges with the nylon rings and the N95 respirator sample already fixed to the recess.

3.2 Assembly of the bench test prototype

With regards to the technical specifications of the bench components, the features of each equipment have been evaluated with the objective of replicating suitable conditions to facilitate an accurate evaluation of the filtration efficiency of N95 respirators. The specified aerosol generator should be capable of generating particles ranging in size from 0.3 to 5.0 µm. It is proposed a hospital nebulizer with four outlets (Model D400-BP – Medicate brand), so that the outlets can be utilized in tandem to meet differing air flow requirements within the pipe.

The vacuum pump needs to generate a flow capable of simulating human respiration under various conditions. Considering panting, equivalent to intense exercise, human breathing can reach a flow rate of 90 liters per minute. Such a condition could be encountered in a hospital environment, for example, during a patient's cardiopulmonary resuscitation procedure. The proposed pump (Model VAC29 – ION brand) has a capacity of 128 liters per minute.

The particle counters need to be able to count particles ranging in size from 0.3 to 5.0 µm, to permit evaluation of the filtration efficiency of the N95 respirator. By technical specification, N95 respirators should be capable of filtering 95% of particles up to 0.3 µm in size. The specified model (Model CPT-100 - Instrutherm brand) possesses six channels (0.3 / 0.5 / 1.0 / 2.5 / 5.0 / 10µm).

Lastly, the pressure gauges will be utilized to measure the pressure and speed of the air flow, for control of the human respiration simulation conditions. The specified model (Model PRF-100 – Instrutherm brand) possesses a Pitot tube, a pressure scale of ± 5000Pa, and a maximum pressure of 68,95 kPA.

Figure 6 shows the test bench assembled with the acrylic tubes glued to the flanges. The aerosol generator and the vacuum pump are installed at the respective ends of the tubes. After this assembly, a sealing test was conducted on the pipe connection components, and no leaks were detected. The last step to complete the assembly of the prototype is the installation of the particle counters and the pressure gauges along the acrylic tubes. The purchasing process for these sensors was not completed until the completion of this paper.

Figure 6 – Test bench prototype assembly for N95 respirators.

3.3 Test bench operation

The two pressure gauges will be installed in the tubes of the bench in a region far from the flanges, that is, closer to the connections with the aerosol generator and the vacuum pump. These sensors make it possible to measure the speed of the air flow inside the tube. The measurement will be conducted using pitot tubes, which will be fixed to the acrylic tubes using a system that will allow their positioning to be adjusted to make it possible to measure the speed in at least 5 different points along the diameter of the tube. In this way, the average velocity of the aerosol flow will be calculated and using the cross-sectional area of the tube, the aerosol flow rate inside the acrylic tubing will be calculated.

When the test bench is in operation, the aerosol flow can be controlled by adjusting the vacuum generation of the vacuum pump. This way, it will be possible to vary the flow rate to evaluate the samples by simulating different breathing patterns.

The two particle counters will be installed on the test bench close to the flanges, one on each side, to count particles before and after the aerosol passes through the N95 respirator sample. With the data from the 2 counters, simply perform a calculation to check what percentage of the number of particles were retained by the N95 respirator sample. This will make it possible to evaluate the filtration efficiency of new and used N95 respirators, for the two reuse protocols described previously (seven and fifteen days).

4. CONCLUSION

This study proposed the development and construction of a test bench dedicated to conducting tests on samples of N95 respirators, with the aim of evaluating filtration efficiency after prolonged use and reuse. The project selected all the necessary components for the bench, describing the entire installation and use process of the components and sensors, enabling a detailed analysis of the minimum requirements for conducting the tests.

Despite the dearth of studies in literature regarding the evaluation of N95 respirator efficiency when subjected to protocols of reuse and extended use, it is critical to highlight the considerable relevance of conducting such studies to guarantee the safety of health assistance professionals. These professionals, in their healthcare routines, are consistently subjected to similar protocols worldwide.

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7. RESPONSIBILITY NOTICE

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