PRECISION AIR™

Product Disinfection

WHITE PAPER

PADM Medical™

Address: Unit A - 1595 Buffalo Place Winnipeg, MB R3T 1L9

P: +1 855 500 PADM (7236) **E:** info@padmmedical.com **W:** www.padmmedical.com

Backstory: What is Precision AIR

Precision AIR is a reusable elastomeric half-mask respirator designed specifically for medical environments with easy clean surfaces. PADM Medical recommends using Oxivir® Tb wipes, which can safely be used without personal protective equipment as the disinfectant at dilution is non-corrosive and nonirritating to skin and eyes[5].

Precision ADM Medical Inc. (PADM Medical) developed the Precision AIR reusable elastomeric respirator after a call from the Canadian Government to manufacturers, and produced it with healthcare provider feedback in mind. Precision AIR has successfully been implemented in Canadian hospital systems.

Disinfection processes are newly developed for reusable elastomeric respirators, as the use of elastomeric respirators became more prevalent in healthcare amidst the COVID-19 global pandemic. The test PADM Medical utilized was under GLP-compliant lab controls. These outcomes provide evidence to support the cleaning methodologies adopted by your local organization.

Precision AIR reusable elastomeric respirators are medical devices with two components: the harness system, or head halo, and the respirator body. In addition, there are disposable components: the filter caps and filters, which are not reprocessed.

PADM Medical researchers and engineers utilized evidence from the following sources to inform the third party laboratory testing:

- The Canadian Government has listed Oxivir® as a satisfactory disinfectant for use against SARS-CoV-2
- Diversey, the company that produces Oxivir® Tb wipes, received approval on the label claim for "Kills SARS-CoV-2 (COVID-19 virus) in 1 minute" in Australia
- Efficacy summary for Oxivir® Tb wipes from Diversey
- Journal of International Society for Respiratory Protection performed testing using various disinfectants on reusable respirators. This included Oxivir® (0.5% accelerated hydrogen peroxide) and detergent for disinfecting/cleaning and provided evidence to the testing methods
- EPA Disinfectant is a disinfectant effective against COVID-19

Precision AIR reusable elastomeric half-mask respirator

Outcomes

Please see manufacturer IFUs for reprocessing "Detergent and wipe clean[3]" and "Wipe clean[4]". Both of these cleaning methodologies passed third-party laboratory screening. See detailed outcomes for each data section below.

PADM Medical is submitting wipe clean methodology to Health Canada for inclusion under their existing Interim Order authorization. The updated lab results of wipe clean (May 2021 results) are currently being submitted to Health Canada for approval.

Data

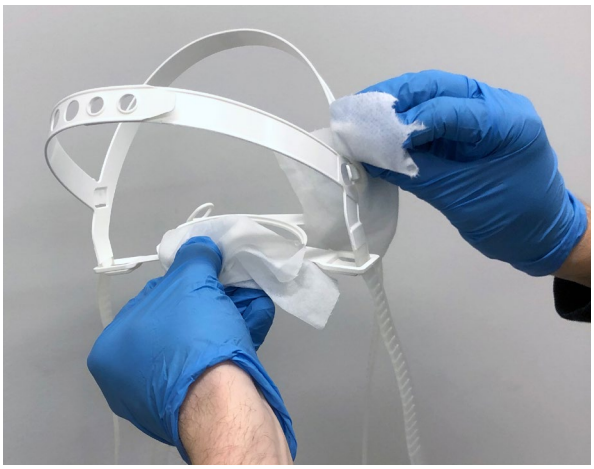
The Food and Drug Administration (FDA) recommends cleaning instructions to be supplied by medical device manufacturers to the end-users of reusable medical devices to ensure proper cleaning.

Wipe Clean[4] Using Cleaning Agent: Diversey Oxivir® Tb Wipes

Hemoglobin and Carbohydrate testing:

The Precision AIR respirator underwent third party laboratory testing. The laboratory examined both methodologies and found no visible soil present on any of the three test replicates performed (and less than 0.1ug/cm2 of carbohydrates, hemoglobin less than 0.5 ug/cm2). Under the six conditions of the laboratory testing, the cleaning methods reduced the level of hemoglobin to less than 2.2 ug/cm2 and carbohydrates 1.8 ug/cm2.

Therefore, the cleaning methods were considered effective. While there is no regulated established benchmark for residual test markers, the normal residue for flexible endoscopes were used which is less than 2.2 ug/cm2 of hemoglobin and less than 1.8 ug/cm2 of carbohydrates.



Wipe cleaning using Oxivir® Tb wipes

Wipe Clean[4] Using Cleaning Agent: Diversey Oxivir® Tb Wipes (continued)

Mycobacterium terrae:

The Precision AIR respirator underwent third party laboratory testing and found intermediate level disinfection was effective (greater than or equal to 3 log reduction) when tested against Mycobacterium terrae, following 2-minute exposure time at room temperature (22.19-22.87C) in presence of 5% Fetal Bovine Serum organic soil load.

Bacterium Testing:

The Precision AIR respirator underwent third party laboratory testing, and found intermediate level disinfection was effective (greater than or equal to) 6 log reduction when tested against Kiebsiella pnumoniae, Staphylcoccus aureus, Escherichia coli and Pseudomonas aeruginosa in presence of 10% Fetal Bovine Serum organic soil load.

Detergent Method (Manual Cleaning)

Hemoglobin and Carbohydrate:

The Precision AIR respirator underwent third party laboratory testing in the worst case scenario of respirator, soiled, dried and cleaned. Getinge High Foam Detergent (prepared at 3.2 mL/L in 39-41C tap water was used). See manufacturer IFU[3].

While there is no regulated established benchmark for residual test markers, the normal residue for flexible endoscopes were used which is less than 2.2 ug/cm2 of hemoglobin and less than 1.8 ug/cm2 of carbohydrates.

The laboratory found no visible soil present on any of the three test replicates performed (and less than 0.1ug/cm2 of carbohydrates, hemoglobin less than 0.5 ug/cm2). Under the six conditions of the laboratory testing, the cleaning methods reduced the level of hemoglobin to less than 2.2 ug/cm2 and carbohydrates 1.8 ug/cm2. Therefore, the cleaning methods were considered effective.

Detergent Plus Wipe[3] Clean Method

Carbohydrates and Hemoglobin:

The Precision AIR respirator underwent third party laboratory testing in the worst case scenario of respirator, soiled, dried and cleaned. Getinge High Foam Detergent (prepared at 3.2 mL/L in 39-41C tap water was used). See manufacturer IFU[3]. The laboratory found no visible soil present on any of the three test replicates performed (and less than 0.1ug/cm2 of carbohydrates, hemoglobin less than 0.5 ug/cm2). Under the six conditions of the laboratory testing, the cleaning methods reduced the level of hemoglobin to less than 2.2 ug/cm2 and carbohydrates 1.8 ug/cm2. Therefore, the cleaning methods were considered effective. While there is no regulated established benchmark for residual test markers, the normal residue for flexible endoscopes were used which is less than 2.2 ug/cm2 of hemoglobin and less than 1.8 ug/cm2 of carbohydrates.

Bacterium testing:

See manufacturer IFU for Wipe Clean plus Detergent[3] (Oxivir® Tb wipes, and Getinge High Foam) using tap water at 41+1C. The Precision AIR respirator, tested by a third party laboratory, was effective for intermediate level disinfection, greater than 6 log reduction when testing with Kiebsiella pneumonia, Staphylococcus aureus, Escherichia coli, and Pseudomonas aeruginosa in presence of 10% fetal bovine serum organic soil load.

Mycobacterium terrae:

See manufacturer IFU for Wipe Clean plus Detergent[3] (Oxivir® Tb wipes, and Getinge High Foam prepared at 3.2mL/L) using tap water at 41+1C. The Precision AIR respirator underwent third party laboratory testing and found intermediate-level disinfection was effective (greater than or equal to 3 log reduction) when tested against Mycobacterium terrae in presence of 10% Fetal Bovine Serum organic soil load.

Recommendation:

Follow the manufacturers IFU for cleaning and reprocessing and develop process into localized organizational procedures. See manufacturer IFUs for donning and doffing instructions, and reprocessing guides.

Skin Safety

Oxivir® Tb wipes are non-corrosive and nonirritating to skin and eyes at dilution, they can be safely used without personal protective equipment, enabling use by visitors or staff in public areas or patient settings[5].

In all six EPA toxicity categories, Oxivir® Tb wipes fall into Category IV, the lowest level of hazard (effective in 1 minute contact time and gentle on people and the environment) and require no safety warnings[5,6].

PRECISION AIR™

References:

1. Precision Air Instructional Donning Video
2. Manufacturer "IFU 20053-IFU-MASK REV 05".
3. Manufacturer "IFU 20053-IFU-REPROCESSING-METHOD1 REV 04".
4. Manufacturer "IFU 20053-IFU-REPROCESSING-METHOD2 REV 04".
5. Diversey: Tough on Pathogens, Not on People
6. Manual Detergent 0872 Safety Data Sheet

For more information, please visit www.padmmedical.com

PADM Medical

Address: Unit A - 1595 Buffalo Place Winnipeg, MB R3T 1L9

P: +1 855 500 PADM (7236) **E:** info@padmmedical.com **W:** www.padmmedical.com