



User Instructions

Health Canada Authorization

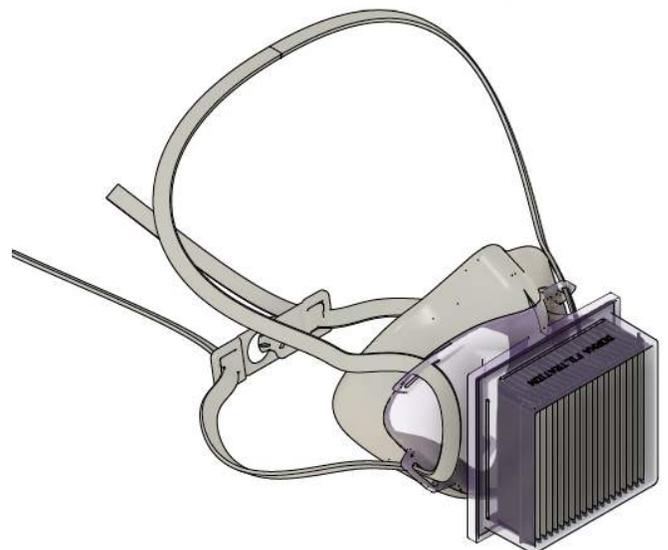
Reference Number: IO315359

Dorma 99

Model: 95SP, 95M, 95LG. For health care: 99SP, 99M, 99LG

99PFE-L3 Respirator

<https://mi-integration.com/en/mi-protection/>



DOCUMENT VERSION: 1
REVISION: April 28, 2021

IMPORTANT: Before use, read these *User Instructions*. Keep these *User Instructions* for reference. Refer to the steps outlined below for instructions on how to properly assemble, don, doff, clean, and reuse the Dorma 99 respirator. Keep these *User Instructions* for reference.

WARNING: This respirator helps protect against certain particulate contaminants but does not eliminate exposure to or the risk of contracting any disease or infection. Misuse may result in sickness or death. For proper use, see supervisor, or *User Instructions*.

NOTE: This product contains no components made from natural rubber latex.

Intended Use

The respirator has at least 99% filtration efficiency against particulate aerosols free of oil.⁺ The Dorma 99 respirator is designed to cover the nose and mouth and is intended to be worn by healthcare professionals to protect the wearer from transfer of microorganisms, body fluids, and particulate material.

As a respirator, it is intended to reduce wearer exposure to certain airborne particles.⁺ For reuse in a healthcare setting, the device is intended to be sterilized using an autoclave (121 degree Celsius cycle) or decontaminated using high-level decontamination procedures, per the Spaulding scale. Complete cleaning (see *User Instructions*, sterilization using an autoclave (121 degree Celsius cycle) or high-level decontamination of the device using a Clean Flow Healthcare Mini or hydrogen peroxide (30%) will eliminate *Geobacillus stearothermophilus* spores from the device surface.[❖] The device is intended to be decontaminated (per *User Instructions*) and reused up to 50 times.* The device must be discarded after the decontamination reuse limit (Table 1). For reuse as a surgical respirator, the Dorma 99 should be sterilized in an autoclave (method A). The Dorma 99 may be sterilized for reuse as a surgical respirator up to 20 times.[◊] The Dorma 99 may not sustain fluid resistance when decontaminated with 30% hydrogen peroxide (method B) for reuse 30 times or the Clean Flow Healthcare Mini (method C) for reuse 50 times.[❖] For non-medical use, the Dorma 99 can be reprocessed and reused up to 100 times.

+ Tested against 0.3 micron particle (mass median aerodynamic diameter) per U.S. 42 CFR 84.

❖ Reuse tested with removal of *geobacillus stearothermophilus* spores using 10% hydrogen peroxide and Clean Flow Healthcare Mini.

*Tested for fit, Particulate Filtration Efficiency after 50 Clean Flow cycles, 30 hydrogen peroxide (30%) decontamination cycles and 20 autoclave cycles. Sustained 99PFE standards at 50 Clean Flow and 30 H₂O₂ (30%) decontamination cycles. Sustained 99PFE-L3 standards at 20 autoclave decontamination cycles.

◊ Exceeds ASTM Level III standards for Fluid Resistance (F1862).

CONTRAINDICATIONS: Not for use with beards or other facial hair that prevents direct contact between the face and the sealing surface of the respirator. Does not protect against gases or vapors. This respirator was not designed to be used by children under 10 years old and must be supervised by an adult.

WARNING: FAILURE TO PROPERLY USE AND MAINTAIN THIS RESPIRATOR RENDERS THE RESPIRATOR INEFFECTIVE AND MAY LEAD TO SICKNESS, INJURY AND/OR DEATH.

Use Instructions

DECONTAMINATE COMPONENTS BEFORE USE

DO NOT USE THE RESPIRATOR OR ANY COMPONENTS IF THERE IS ANY VISIBLE DAMAGE.

1. Before occupational use of this respirator, a written respiratory protection program must be implemented meeting all the local government requirements. In the United States, employers must comply with OSHA 29 CFR 1910.134 which includes medical evaluation, training, and fit testing. Select and use respirator in accordance with all applicable regulations, standards, and professional guidance. Fit testing must be performed while the test subject is wearing any applicable safety equipment that may be worn during actual respirator use which could interfere with respirator fit (e.g. eyewear, face shield). In Canada, CSA standard Z94.4 requirements must be met. Follow all applicable local regulations. This respirator is designed for occupational/professional use by adults who are properly trained in its use and limitations. OSHA and CSA accepted fit test protocols are recommended for fit testing this respirator.
2. All components of filtering facepieces are to be inspected prior to each use to assure that no damage has occurred. Holes resulting in ripped or torn filter or respirator material are considered damage. If dirty, submit for cleaning and get a replacement. If there is any damage, properly dispose of the component and get a replacement.
3. A user seal check **MUST** be completed before use, as specified in *User Instructions*. If you cannot achieve a proper seal, **DO NOT** use the respirator.
4. Leave the contaminated area immediately and contact your supervisor if dizziness, irritation or other distress occurs.
5. The Dorma 99 respirator should be decontaminated or sterilized after every use or if contaminated with blood or bodily fluids (up to reuse limit, Table 1). Follow User Instructions for reprocessing and replacing the respirator. Follow national, provincial/state, local and facility infection control guidance, and policies.
6. If the user has **ANY** reaction to any part of the respirator, discontinue use immediately. Refer to User Instructions for information on use and maintenance of these respirators.

Note: M.I. Protection recommends wearing a face shield over the Dorma 99 Respirator to avoid aesthetic damage (stains) from splash and spray of bodily fluids.

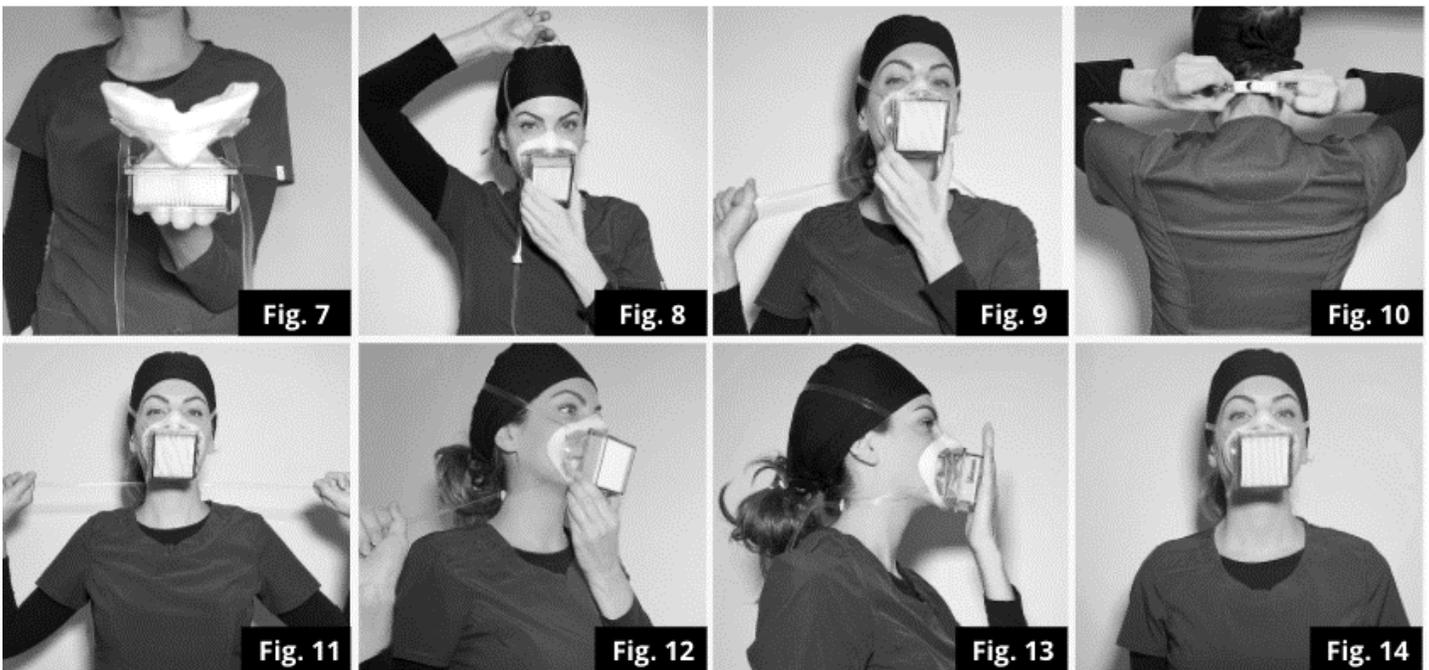
Donning Instructions: Must be followed each time the respirator is worn

ALWAYS PUT ON DECONTAMINATED RESPIRATOR WITH CLEAN HANDS

1. Perform hand hygiene using hand sanitizer or soap and water.
2. Inspect the assembled respirator prior to use to assure there are no holes in the breathing zone and no damage has occurred. Discard and replace if damaged.

3. Cup the respirator in your hand, with the nosepiece at your fingertips, allowing the head strap to hang freely below your hand (Fig. 7).
4. With the nosepiece up, place the respirator over your nose and mouth. Pull the top strap over your head, resting it high at the top back of your head (Fig. 8).
5. Adjust the strap length through the eyelets so that the respirator comfortably covers both your mouth and nose (Fig. 9).
6. Fasten the clips behind your neck (Fig. 10) and pull the loose strap ends to tighten to an appropriate tension (Fig. 11).
7. Perform a user seal check each time you put on the respirator. Use one or both hands to completely cover the respirator filter (Fig. 12), and exhale. The respirator should budge slightly. If air leaks at the respirator edges, reposition the respirator on face (Fig. 13) and/or readjust tension of head strap to eliminate the leakage. Once the seal check is successful, the respirator is ready for use (Fig. 14).

WARNING: If you CANNOT achieve proper seal, DO NOT USE AND SEE YOUR SUPERVISOR.



Use Limitations

DO NOT use the Dorma 99 respirator continuously for more than 8 hours. In heavily contaminated or humid environments the respirator may reach its filtration load more rapidly. The user must be aware of the respirator's filter load throughout use. If breathing becomes difficult, immediately leave the contaminated area and don a new/clean Dorma 99 respirator.

Removal Instructions

EXERCISE HAND HYGIENE BEFORE AND AFTER HANDLING YOUR DORMA 99 RESPIRATOR

1. Perform hand hygiene using hand sanitizer or soap and water.
2. Do not touch the front of the respirator (Fig. 15).
3. Undo the strap clip. Touching only the strap, grasp the top head strap with two hands and bring it carefully over the head (Fig. 16). Pull the respirator away from the face without touching the front of the respirator.
4. Submit the respirator for cleaning and disinfecting, per *User Instructions*.
5. Perform hand hygiene after removing the respirator and before putting it on again when practicing reuse.



Cleaning Instructions

IMPORTANT: To optimize the life of the Dorma 99 respirator, clean the Dorma 99 respirator immediately after use: a maximum time frame of 4-6 hours is recommended. DO NOT allow organic substances (blood, mucus, tissue, etc.) to dry on the Dorma 99 respirator or any of its components.

Gloves should be worn during cleaning as well as other personal protective equipment (PPE) as indicated by internal protocols.

- 1. Disassembly (optional):** Remove and separate strap and clips from the respirator body.
- 2. Inspection:** inspect the respirator components per *User Instructions* to identify any damage or excessive wear:
 - a. Damage to the surfaces of the elastomer, polymer, elastics, clips or filter (barb, curvature, discoloration, etc.);
 - b. Cracks, cuts, lacerations or abrasions;Discard damaged components or the entire respirator as necessary. **CAUTION:** Use of a damaged respirator may result in sickness or death.
- 3. Cleaning for decontamination methods A, B & C)** Failure to remove foreign material can make the decontamination process ineffective.
 - a. Clean the plastic (elastomer and polymer) components and interior/exterior surfaces of the Dorma 99 respirator with a soft bristled brush (Fig.17). DO NOT brush the filter material (Fig. 18). Use a pH-neutral cleaner (without subtilisin) for a minimum of one (1) minute or until

- the Dorma 99 respirator is visibly clean. DO NOT use abrasive cleaners or solvents.
- Rinse the Dorma 99 respirator and its components in water [use critical water where possible] for 1 minute or as required.
 - Inspect the Dorma 99 respirator for any signs of residual organic matter and repeat cleaning steps again if necessary.
 - Dry the Dorma 99 respirator and its components with a clean cloth.

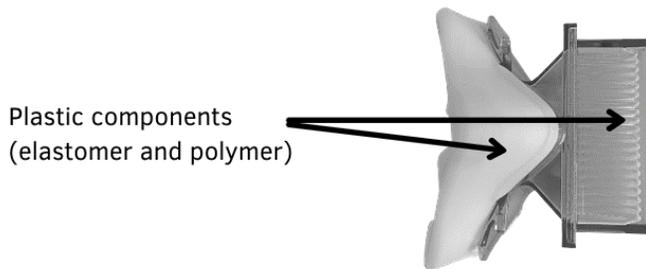


Fig. 17



Fig. 18

4. Sterilization or decontamination: Complete one of the protocols below.

CAUTION: For reuse as a surgical respirator, the Dorma 99 should be sterilized in an autoclave (method A). The Dorma 99 may be sterilized in an autoclave (121-degree cycle) for reuse as a surgical respirator up to 20 times. The Dorma 99 may not sustain fluid resistance when decontaminated with 30% hydrogen peroxide (method B) or Clean Flow Healthcare Mini (method C). The respirator must be dry before it can be sterilized. Interim methods (D,E,F,G)

Decontamination Methods	Reuse Cycle Limit	Tested and recommended by
A. Autoclave	20 uses	Health Canada
B. 30% Hydrogen Peroxide	30 uses	Health Canada
C. Clean Flow Healthcare Mini	50 uses	Health Canada
D. Soaking in Accelerated hydrogen peroxide solution	100 uses	OSHA & MI Protection
E. Soaking in Hypochlorite sodium solution (50 ppm)	100 uses	Guelph University & MI Protection
F. Soap & water or detergent (Antibacterial & hypoallergenic)	100 uses	Guelph University & MI Protection
G. Disinfecting wipe	100 uses	CDC & MI Protection

Table 1

Method A: Autoclave (121-degree Celcius steam cycle):

1. Inspect the Dorma 99 respirator to ensure cleanliness and that the respirator is devoid of any defects and is **dry** (see step 5).
 2. Place the Dorma 99 respirator individually in a permeable autoclave bag measuring at least 10x10 inches;
 3. Position the bag in a single layer in the autoclave to avoid damage to the Dorma 99 respirator. The bag should be positioned with the paper side facing down to facilitate air evacuation (see standard CSA Z314-18);
 4. Add a chemical indicator in each autoclave bag (e.g. 3M Attest chemical integration indicator 1243RE) with a control label;
 5. Select and run gravity cycle: 250°F/121°C, 30 minutes disinfection, 20 minutes drying time.
- or

Method B : 30% hydrogen peroxide:

1. Prepare a bowl containing a 30% hydrogen peroxide solution;
2. Immerse the Dorma 99 respirator and its components in the 30% hydrogen peroxide solution for 30 seconds, ensuring the device is completely submerged;
3. Remove the respirator and its components from the hydrogen peroxide solution;
4. Rinse the Dorma 99 respirator and its components with purified water for 30 seconds;
5. Wipe the Dorma 99 respirator and its components with a clean, dry towel;

Method C: Clean Flow Healthcare Mini: to learn more about the decontamination Dorma 99 Respirator procedure using 10% H2O2 and Clean Flow Healthcare Mini unit.

This procedure may be used for decontaminating Dorma 99 respirators. This procedure is suggested to be used for a maximum of fifty (50) times on Dorma 99 respirators. It consists in the spraying of 10% hydrogen peroxide (H₂O₂) on the respirator followed by a designated cycle through a Clean Flow Healthcare Mini (CFHM) unit, manufactured by Clean Works Inc. (Beamsville, Canada, <https://cleanworkscorp.com/>). Please refer to Clean Works Inc. for details about the CFHM (i.e. the CFHM Manual, the Fact Sheet, the Spec Sheet and the Instructions for Healthcare Facilities, etc).

Decontamination process:

1. Spray Dorma 99 respirator with 10% H₂O₂ solution
2. Process the respirator through 5-minute cycle in the Clean Flow Healthcare Mini unit
3. Wash the Dorma 99 respirator in distilled water for 30 seconds
4. Dry the Dorma 99 respirator

A 6 Log reduction of *Geobacillus Sterothermophilus* was demonstrated after the application of this procedure (report from University of Guelph). For the proper use of the CFHM, operators must follow the instructions provided by Clean Works Corporation (<https://cleanworkscorp.com/>).

Procedure using 10% H2O2 spray followed by CFHM treatment:

IMPORTANT: To optimize the life of the Dorma 99 respirator, clean the Dorma 99 respirator immediately after use: a maximum time frame of 4-6 hours is recommended. DO NOT allow organic substances (blood, mucus, tissue, etc.) to dry on the Dorma 99 respirator or any of its components.

Gloves, protection cloths, protection glasses, and protection masks or other personal protective equipment (PPE) should be worn during cleaning.

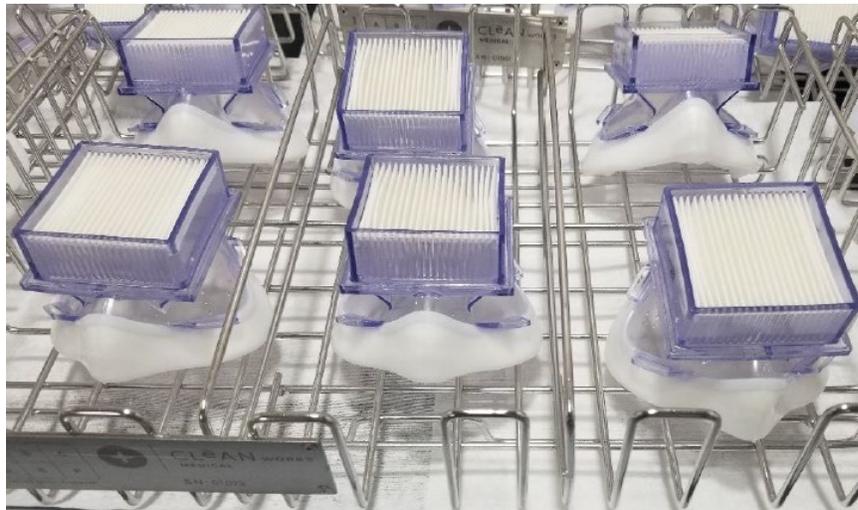
CAUTION: Follow facility protocols concerning the safe use of:

- 10 wt.% H₂O₂ solution
- Clean Flow Healthcare Mini device (UV-C, ozone and H₂O₂). Also refer to manufacturer's instructions.

High-level decontamination using 10 wt.% H₂O₂ and Clean Flow Healthcare Mini unit:

1. Prepare a vaporization bottle of around 1000 ml containing a 10 wt.% H₂O₂ solution
2. Spray the interior and the exterior of the Dorma 99 respirator once, as well as each component;

IMPORTANT: Before using the CFHM unit, READ and UNDERSTAND the CFHM Operator's Manual (CFHM-D001, supplied by Clean Works Corp.) Place the respirators with the filter up in the CFHM's 6 units trays (see below):



3. Place the trays at the entrance of the CFHM unit;
IMPORTANT: Contact Clean Works Corporation if you have questions and to receive training at tel.: 905 630 6247 or by email: info@cleanworkscorp.com
4. Use the CFHM following the method below. The trays will pass through the CFHM reactor for a 5 minutes cycle. **The UV-C and ozone are kept ON while the H₂O₂ mist is switched OFF during treatment.** For the proper cycle, follow these steps:

- a. Check Solution Storage Tank level and refill with Clēan Flow Solution as needed.
 - b. Ensure conveyer belt is clean and clear of all objects.
 - c. Ensure power is in "ON" position.
 - d. If the home screen indicates faults, address faults as necessary, clear faults, and press the reset button twice.
 - e. Press and hold "Start" button for 3 seconds. The green stack light will begin to flash as system "warms up." It will turn to solid green when system is ready for use.
 - f. Check that the Process Temperature Value (labelled as PV on home-screen) is above 19°C.
 - g. Press "Manual" button to check the following values:
 - I. **Ozone Level PPM value is > 2.0 ppm**
 - II. **UV-C Light intensity value is >0.8 mW/cm²**
 - III. **Peroxide Pump Flow – switch it at OFF**
 - h. Check that the cycle time value is five (5) minutes (from internal curtain of infeed to internal curtain of outfeed). To do this:
 - i. Place tray on conveyer belt;
 - b. Using a stopwatch, start timing when tray reaches internal curtain of the infeed;
 - c. Observe through view port. Stop timing when tray reaches internal curtain of the outfeed
 - i. Record Process Temperature, Ozone Level PPM, UV-C Light Intensity, Peroxide Pump Flow is OFF, and Cycle Time is 5 minutes.
10. Use facility specific protocols for indicating number of times respirators have been reprocessed.
 11. Place loaded tray in the centre of conveyer belt at infeed with maximum of six (6) respirators. Respirators must be placed facing up. **Respirators must not overlap, nest or stack.**
 12. Allow loaded tray to pass through the CFHM
 13. Remove tray from "clean" side, following facility specific protocols to avoid recontamination.
 14. Ensure respirators have maintained upright position. If not, respirator must be reprocessed.
 15. Press "Stop" button on touchscreen to end use.

At any time, push the red emergency stop button located below the touchscreen to immediately stop the process*.

*Note: User must clear faults and press the reset button twice on the home-screen before starting the CFHM following the use of the emergency stop button.

- f. Rinse the Dorma 99 respirator and its components with purified water for 30 seconds
- g. Components should be hand dried with a clean, non-abrasive cloth and / or use the drying methods below.

Method D: Soak in accelerated peroxide solution (considered as an interim method) In case of severe contamination or facial oil, a cleaning step should be performed before decontamination. Follow the recommendation of the manufacturer for effective neutralisation time.

1. Rinse components thoroughly in clean, cold water
2. Respirator components should be submerged for 3 minutes in one of the selected disinfectant solutions following the manufacturer's instructions.
3. Rinse the respirator in cold water
4. Components should be hand dried with a clean, non-abrasive cloth and / or use the drying methods below.

Method E: Soak in Hypochlorite solution (considered as an interim method) In case of severe contamination or facial oil, a cleaning step should be performed before decontamination.

1. Rinse components thoroughly in clean, cold water
2. Respirator components should be immersed for two minutes in one of the following:
3. Hypochlorite solution (50 ppm of chlorine) made by adding approximately one milliliter of laundry bleach to one liter of water at 43 deg. C (110 deg. F). (May leave an odor on the filter)
4. Rinse components thoroughly in clean, cold, preferably running water and drain.
5. Components should be hand dried with a clean, non-abrasive cloth and / or use the drying methods below.

Method F: Soak in water & Soap or detergent (antibacterial & hypoallergenic) (considered as an interim method) In case of severe contamination or facial oil, a cleaning step should be performed before decontamination.

1. Rinse respirator in cold water
2. Soak respirator in cold water and soap solution for 2 minutes
3. Rinse respirator in cold water
4. Components should be hand dried with a clean, non-abrasive cloth and / or use the drying methods below.

Method G: Disinfecting wipe (considered as an interim method) If gross contamination or facial oil is present, a cleaning step should be performed before disinfection.

1. Wipe down all components with a disinfecting wipe, including the inside and outside of the mask, strap, clips and cap (if necessary) following the manufacturer's instructions.
2. Rinse the components thoroughly in clean, cold water, preferably running water, and drain.
3. Components should be hand dried with a clean, non-abrasive cloth and / or use the drying methods below.

NOTE: Track decontamination cycles using the unique ID number on the respirator (10-digits, starting with "D").

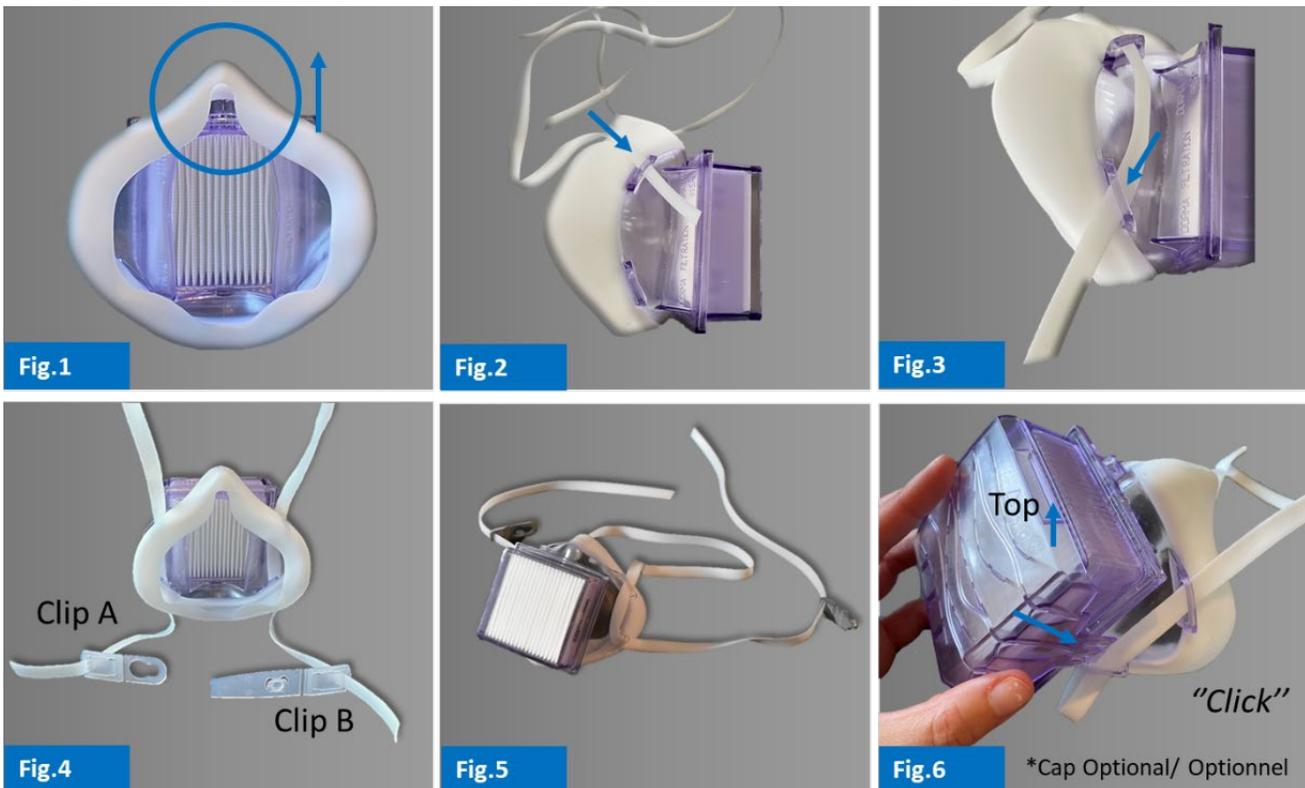
5. Drying (for H2O2 treatment, and as needed): Respirators may be slightly damp after reprocessing. **Reprocessed respirators must not be used until dry.**

Methods	Description	Drying temp	Drying time *
Air dry	Place each respirator in an individual, clean, breathable receptacle to prevent cross contamination. Position the respirator for optimal airflow through the filter.	21 °C	12-48 h
medical dryer	Place the Dorma 99 respirator and its components in a medical dryer	60 °C	2h
Food dehydrator	place on rack of food dehydrator	65 °C	90 h
Desiccant	Place food grade desiccant 100 grams in seal bag	21 °C	4-8 h

*Depend on humidity

6. Assembly (if needed): Once dry, inspect and reassemble the respirator as described in *User Instructions*. Between uses, store dry Dorma 99 in a sealed 10"x10" sterilization bag.

1. Find a clean disinfected environment to work in. Practice hand hygiene using hand sanitizer or soap and water.
2. Don a pair of clean gloves and don a face mask for the assembly process.
3. Inspect the respirator body (including filter), clips and strap, to ensure nothing is damaged or dirty, as above.
4. On the respirator body, identify the nose feature, this will indicate the top part of the respirator (Fig. 1). Select a strap. With the printed lot number facing up, thread the end of the strap under the upper left strap eyelet (Fig. 2) and then through the lower left strap eyelet. Take the other end of the strap, check the strap is not twisted, and thread through the upper right eyelet, then lower right strap eyelet (Fig. 3).
5. Thread the left strap through clip A (Fig. 4). Thread the right strap through clip B (Fig. 4).
6. Do a final inspection of the respirator with all components assembled to ensure everything has been assembled properly.
7. Once final inspection is complete (Fig. 5), this respirator is ready to be used.
8. The installation of the cap is optional (Fig.6).



7. Inspection: Inspect prior to use as described in the User Instructions. The respirator should be stored as described in the User Instructions.

Device Storage & Lifecycle

Before use, store the Dorma 99 respirator in its original packaging, away from contaminated areas, dust, sunlight, extreme temperatures, excessive moisture and damaging chemicals.

Between uses, store the Dorma 99 in a clean, dry environment, free from contaminated areas, dust, sunlight, extreme temperatures, excessive moisture, and damaging chemicals. M.I. Protection recommends storing the clean Dorma 99 respirator in a sealed 10"x10" sterilization bag between uses. The Dorma 99 respirator and its components may be stored and reused according to the facility's infection control policy, up to the decontamination method's reuse cycle limit.

Discard the Dorma 99 after reaching the decontamination method's reuse cycle limit (Table 1), if damaged, or if breathing becomes difficult. Discolouration can be an indication that respirator replacement is needed.

All Dorma 99 components may be recycled.

CAUTIONS AND LIMITATIONS

1. Not for use in atmospheres containing less than 19.5% oxygen.
2. Not for use in atmospheres immediately dangerous to life or health.
3. Do not exceed maximum use concentrations established by regulatory standards.
4. Failure to properly use and maintain this product could result in injury or death.
5. All approved respirators shall be selected, fitted, used, and maintained in accordance with MSHA, OSHA, and other applicable regulations.
6. Never substitute, modify, add, or omit parts. Use only exact replacement parts in the configuration as specified by the manufacturer.
7. Refer to User Instructions and/or maintenance manuals for information on use and maintenance of these respirators.
8. Special or critical User Instructions and/or specific use limitations apply. Refer to *User Instructions* before donning.



M.I.

PROTECTION

DIVISION – M.I. INTEGRATION

For more information:

Visit <https://mi-integration.com/en/mi-protection>

Contact us at 1-888 336-3697 support@mi-protection.com

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MADE IN CANADA

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