

Breezing Med

Simply Breathtaking

Cleaning and Disinfection Protocol

Breezing Med™ Cleaning and Disinfection Procedure

General Note

This procedure has been designed based on a deep review of literature¹⁻⁵, and further optimized based on more recent knowledge related to COVID-19⁶ and related viruses^{2,3}.

General Recommendation

This procedure is applicable to Breezing Med™ and Breezing Pro™, herein referred to as the Breezing device.

The Breezing device should not be used if damaged or improperly cleaned. Inspect the device for any visible damage and consult with Breezing Co. if there are any questions.

One-Time Use Accessories

A new mask and head strap must be used for each new patient, and should be disposed of after the measurement is finished.

Cleaning and Disinfection

Cleaning and disinfection must be performed before every new patient, or if the device is deemed uncleanable, per the facility's risk assessment. The cleaning and disinfection process can be done at room temperature.

Caution: The Breezing device cannot be immersed in liquid. Doing so will damage the electronic components/battery or may cause tubing blockage rendering the device unusable.

Cleaning and Disinfection Procedure

It is recommended to wear personal protection equipment such as eyeglasses, goggles or a face shield, as well as long sleeves and nitrile gloves when cleaning the Breezing device. Defer to any additional guidelines in place at your facility.

1. Mix the cleaning solution with Enzol (or equivalent enzymatic cleaner) per the manufacturer's instructions.

Cleaning Procedure of the device:

2. Apply the Enzol solution over the external surfaces of the device with a clean solution-soaked cloth, ensuring all surfaces are thoroughly moistened. Then, scrub the wet surface vigorously and firmly using a cloth and a soft-bristled brush for a minimum of 30 seconds to ensure the removal of all debris. Reapply the Enzol solution and let soak for 2 minutes. This includes: the internal and external case, display window, sensor cap (top and edges), enclosure mating seams, and power button.

Tight spaces, such as the recessed screws on the back of the device, may require the direct application of the Enzol solution into them using a polyethylene swab while holding the device surface parallel to the floor and allowing the solution to flow into the crevice.

NOTE: please make sure no solution leaks inside the device. This may damage internal device components.





3. After the cleaning, thoroughly wipe the device surface with a cloth made wet with clean water, ensuring all solution and residue are removed. Then, apply a dry cloth to dry the surface.

Cleaning Procedure of the grate and air channel:

4. Remove the grate at the front of the device that covers the air channel by pulling it firmly downward (i.e. away from the display).

Removing the grate

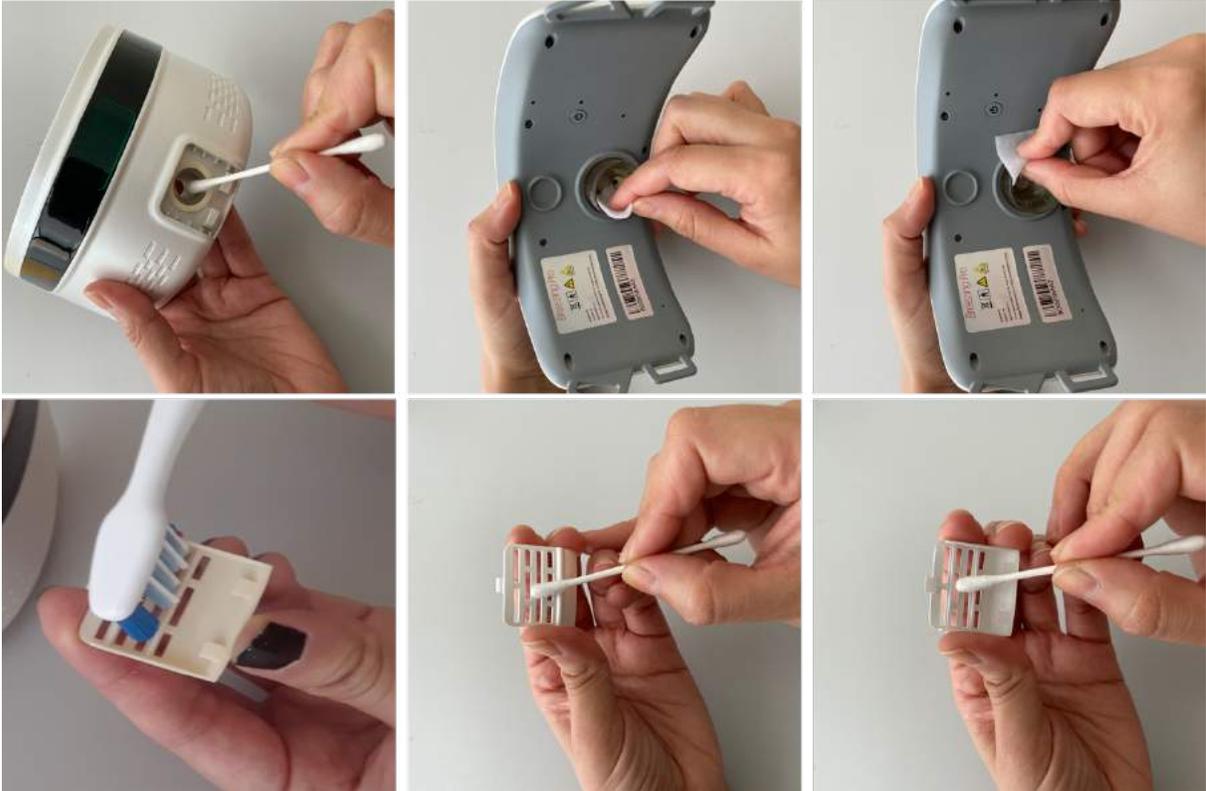


5. Scrub the grate using a soft-bristled brush for 30 seconds and polyethylene swab to ensure the removal of all debris. Let the grate soaked for 2 minutes. Complete the grate cleaning by rinsing in clean water and then drying with a clean cloth.
6. Using an Enzol solution wetted cloth and polyethylene swab, wipe the solution over the surface of the air channel; this includes the interior as well as the exterior surface that mates with the disposable mask. Allow the solution to react for 2 minutes. After the cleaning, thoroughly wipe the device surface with a cloth made wet with clean water, ensuring all solution and residue are removed. Then, apply a dry cloth to dry the surface.

Take care not to allow excessive solution pool in the air channel as that small ports exist that if blocked could prevent the proper functionality of the device.

7. Reattach the grate to the device by aligning in the cavity and sliding upward until a click is heard.

Cleaning grate and air channel



Disinfection of the external device pieces:

8. Use a 70% isopropyl alcohol (IPA) to spray all over the exposed areas of the device, allowing for a minimum of 60 seconds to ensure the soaking of all areas. Afterward, scrub the surface of the Breezing device vigorously and firmly using a soft-bristled brush and a cloth soaked in 70% IPA. Ensure all external pieces of the Breezing device are sprayed with IPS, including (but not limited to): the front and rear case, display window, sensor cap, sensor cavity edges, and power button. Ensure the entire surface is coated with 70% IPA, allow some IPA to flow into the screw recesses using an IPA-soaked polyethylene swab.

Note: IPA should remain on the device surface for at least 60 seconds to assure disinfection, and the device should be fully dried out before any new measurement.

9. Open the sensor cap and ensure the edges of the cap and the outer edges of the cavity are wiped with the cloth soaked in 70% IPA. Ensure the sensor cap edges and sensor cavity edges are wiped thoroughly. Avoid any liquid from going into the sensor slot.

Note: IPA should remain on the device surface for at least 60 seconds to assure disinfection, and the device should be fully dry out before any new measurement.

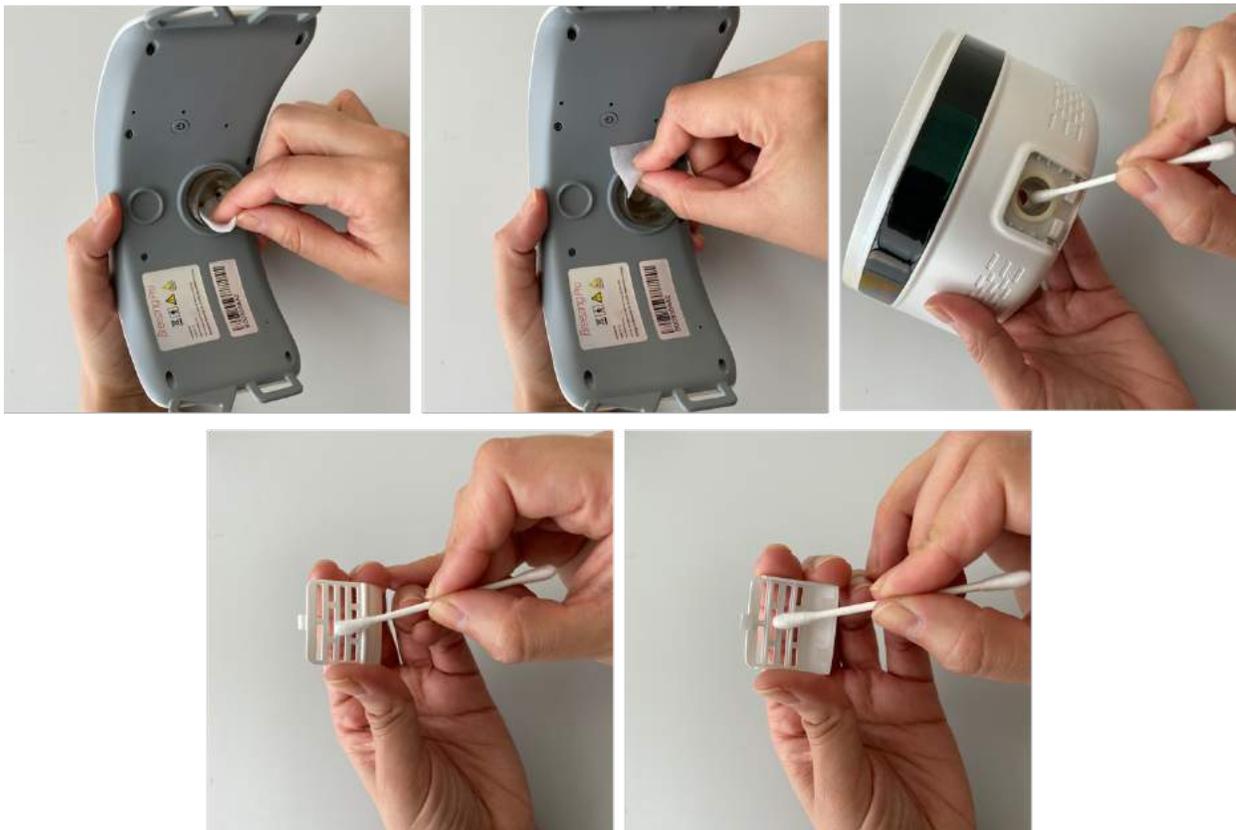
Disinfecting external device pieces



10. **Disinfection of the air channel and grate:** grate is to be immersed in the 70% IPA solution for at least 60 seconds and allowed to thoroughly dry. Afterward, use a 70% IPA-soaked polyethylene swab to wipe firmly and thoroughly the entire air channel and grate. Ensure the entire surface has been soaked with 70% IPA.

Allow the air channel to thoroughly dry in clean air.

Disinfecting air channel and grate



11. Replace the grate by orienting it over the opening and firmly push upward (i.e. toward the display) until a click is heard and the grate is held in place.

Re-installing the grate



12. Close the sensor cap. The Breezing device is ready for use.

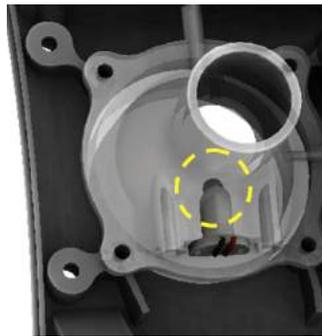
Caution:

Though every measure is taken to ensure all surfaces of the device are clean and disinfected, there exists the potential that material remains. The user must follow the contraindications, utilize new one-time use accessories, and use their training and facility's guidelines to avoid harming the patient.

Always keep the IPA solution away from the face or exposed skin. Do not inhale any of the vapors and wash immediately with running water if liquid comes in contact with the skin.

Avoid scratching the device surface with sharp tools during the cleaning and disinfection process.

Avoid pulling or bending the spherical component located in the air channel on the mask-side part of the constriction. If this component is damaged, contact Breezing Co.



Contraindications

Be aware the following conditions are contraindicated with respect to the maintenance of a clean and disinfected device:

- The device is not to be used if any respiratory impediments, illnesses, or chronic conditions are present.
- The device is not to be used if any infectious agents are present.

References

1. Breezing Co. will provide a Cleaning and Disinfection Validation report upon request (info@breezing.com).
2. William A. Rutala, Ph.D., M.P.H., David J. Weber, M.D., M.P.H., and the Healthcare Infection Control Practices Advisory Committee (HICPAC), Guideline for Disinfection and Sterilization in Healthcare Facilities, 2008 Update: May 2019
Accessible version: <https://www.cdc.gov/infectioncontrol/guidelines/disinfection/>
3. Andrej Trampuz, MD, and Andreas F. Widmer, MD, MS, Hand Hygiene: A Frequently Missed Lifesaving Opportunity During Patient Care, Mayo Clin Proc, January 2004, Vol 79:109-116.
4. Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling Guidance for Industry and Food and Drug Administration Staff. May 2, 2011.
Labeling - Regulatory Requirements for Medical Devices (FDA 89-4203)
5. AAMI TIR30: 2011/(R)2016 A compendium of processes, materials, test methods, and acceptance criteria for cleaning reusable medical devices
6. Annika Kratzel, et al., Efficient inactivation of SARS-CoV-2 by WHO-recommended hand rub formulations and alcohols, bioRxiv preprint, doi: March 10, 2020
Accessible version: <https://www.biorxiv.org/content/10.1101/2020.03.10.986711v1.full.pdf>