

Subject: COVID-19 Ventilation & Mask Cleaning & Disinfection  
Guidance

Date: 24-02-2020

Dear Valued Philips Customer –

Today, as the spread of Coronavirus (COVID-19) persists throughout the global community, Philips is steadfast in its commitment to support health systems and healthcare professionals who entrust us to help them care for their patients. As a leading health technology company, Philips has a broad portfolio of products, services and solutions that can help address the preparation, response and recovery needs for an outbreak of this type of virus.

With the outbreak, we realize the impact of our respiratory care solutions in supporting health systems and care providers, but also the significant concern around the disinfection of our solutions. In this letter, we will provide high-level recommendations on how to optimize NIV treatment and reduce the likelihood of nosocomial transmission of COVID-19 pathogen during NIV therapy, as well as provide you with suggested cleaning and disinfection methods for our ventilators and hospital multi-use patient interface (masks).

### **General Ventilation Recommendations:**

1. Follow the general principles for managing acute hypoxemic respiratory failure when considering ventilator therapy in patients with COVID-19 infection.
2. Adhere to infection control measures, as outlined by your hospital and health department policies, in order to avoid transmission of the COVID-19 virus during therapy. Recommendations from the World Health Organization (WHO) and the Centers for Disease Control and Prevention (CDC) include using negative pressure isolation rooms for patients, and gloves, gowns and masks for caregivers [3-4].
3. If oxygen delivered via high-flow nasal cannula (HFNC) is an option for patients with mild hypoxemic respiratory failure, then provide masks to be worn over the nasal cannula to reduce the potential for airborne virus transmission. Ensure timely endotracheal intubation and positive pressure mechanical ventilation if the patient's clinical status deteriorates [8-9].

4. If continuous positive airway pressure (CPAP) or bilevel positive airway pressure (BiPAP) is considered appropriate in patients with mild hypoxemia and hypercarbia, such as patients with exacerbation of chronic obstructive pulmonary disease (COPD) [8-10] consider the:
  - Use of a well-fitted oro-nasal mask (or helmet, if available). Nasal masks and/or nasal pillows are less desirable.
  - Use of a dual-limb ventilator with filters placed at the ventilator outlets.
  - Use of a Philips Respironics noninvasive patient circuit with expiratory port filter for single-limb application of NIV using the Philips hospital ventilator devices [11].
  - Timely endotracheal intubation and positive pressure mechanical ventilation if the patient’s clinical status deteriorates
5. If patients developing acute respiratory failure with documented or suspected COVID-19 infection fail trials of noninvasive respiratory, they may require endotracheal intubation and positive pressure mechanical ventilation [8-10].

Decisions regarding any specific treatment must be made by the healthcare provider and the patient based on specific clinical conditions and available resources. It is important to note that the recommendations are not meant to replace existing national guidelines or established hospital protocols and follow published guidelines and medical literature.

**General Hospital Mask Guidance:**

1. Given the high transmission rate of COVID-19, we recommend single-patient-use masks.
2. However, if multi-patient-use masks are used on a patient possibly infected with COVID-19, please refer to cleaning and disinfection recommendations below.
3. More importantly, ventilation devices will likely be used on multiple patients and instructions for disinfection are below.

**Ventilation Cleaning and Disinfection Recommendations:**

**Ventilation Cleaning Instructions:**

Apply cleaning agent to a soft lint-free cloth or use a disposable wipe. The cloth or wipe should be saturated but not dripping. Wipe cleaning agent over the entire exterior surface and touchscreen of the ventilator.

**Ventilation Disinfection Instructions:**

Apply disinfecting agent to a soft lint-free cloth or use a disposable wipe. The cloth or wipe should be saturated but not dripping. Wipe disinfecting agent over the entire exterior surface of the ventilator.

Following are approved methods that align with WHO and CDC for each ventilator platform:

	V60/ V60+	Trilogy Evo (Trilogy Evo, OBM / Universal / EV300)	Trilogy (T100 / T200 / T202)	A-Series Refresh (A40 Pro / A40 EFL)	A-Series Legacy (V30 Auto / BiPAP A30 / BiPAP A40)	“DreamStation” - BiPAP ST / BiPAP AVAPS / BiPAP Auto-SV	Cough Assist (E70 / T70)
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<b>Cleaning</b>	Medivators Intercept Detergent, per manufacturer's recommendation at 1/3 oz. (10 mL) per gallon of warm tap water	Mild household detergent	Mild household detergent	Mild household detergent	Mild household detergent		
<b>Disinfection</b>	Solution of 1 part 5% sodium hypochlorite (bleach) diluted in 9 parts deionized water	70% Isopropyl Alcohol  70% Ethyl Alcohol  Chlorine bleach, household, 8.25% sodium hypochlorite, 1 to 10 part reduction with water  Clorox Healthcare® Bleach Germicidal Wipes  Mikrozyd AF Liquid from Schuelke  Bacillol from Bode.	70% Isopropyl Alcohol  Chlorine bleach, household, 8.25% sodium hypochlorite, 1 to 10 part reduction with water	70% Isopropyl Alcohol  Chlorine bleach, household, 8.25% sodium hypochlorite, 1 to 10 part reduction with water	70% Isopropyl Alcohol.  Chlorine bleach, household, 8.25% sodium hypochlorite, 1 to 10 part reduction with water	Chlorine bleach, household, 8.25% sodium hypochlorite, 1 to 10 part reduction with water  DisCide Towelettes / Wipes	70% Isopropyl Alcohol  Chlorine bleach, household, 8.25% sodium hypochlorite, 1 to 10 part reduction with water  DisCide Towelettes / Wipes

### **Hospital Multi-use Mask Cleaning and Disinfection Recommendations:**

The following disinfection methods are validated for following RespiroNics multi-patient use masks in the hospital/ institutional environment: PerformaTrak, PerforMax, PerforMax Pediatric, and Total Face Mask. Headgear for these masks is for single patient use only and should not be used for multiple patients.

### **Hospital Multi-Use Mask Pre-Treatment Cleaning**

Follow all instructions from the manufacturer of the pre-treatment products. Any deviation from these instructions may impact the performance of the product. Review all applicable instructions for additional warnings and cautions.

- Dissassemble the mask according to the **Instructions for Use** included with the product.
- Clean the mask using a soft bristle brush to adequately remove adhering substances from each component while soaking in a commercially available, anionic detergent (Examples: MEDIZIME LF, ANIOSYME DD1\*).
- Extra attention should be given to the crevices and cavities during cleaning.
- If compatible with the manufacturer's instructions, the detergent may be applied within the washer/ disinfection cycle.

- Rinse the mask with 5 liters of water and air dry out of direct sunlight.

## **Hospital Multi-Use Mask High Level Disinfection Instructions:**

The recommended disinfection methods are identified by mask product (below chart) and approved (+) for use on the mask and/or mask parts. See IFU if (-) for details on exceptions or deviations.

It's important to follow all instructions from the manufacturer of the disinfection products. Any deviation from the manufacturer's instructions or use of agents other than those listed in this guide may impact the performance or durability of the product. Review all applicable instructions for additional warnings and cautions.

Prior to disinfection, note the fabric materials (e.g.: headgear, straps) **cannot be disinfected** using the methods listed. The fabric materials **must be replaced before multi-patient use**.

Prior to disinfection, note masks with port caps: **Open or remove the port cap** prior to disinfecting the mask.

Post disinfection inspect all parts for damage or wear; replace any parts that have visibly deteriorated (cracking, crazing, tears, etc.); Rinse thoroughly with water and air dry out of direct sunlight. Make sure the mask is dry before use; And, verify the entrainment valve functions correctly, as outlined in the Instructions for Use included with the product. After disinfection, discoloration and a slight odor is normal.

Following are approved methods that align with WHO and CDC for each Hospital Multi-use Mask:

Product	Thermal					Chemical						Gas Plasma	Autoclave	Max Cycles	Notes (-)
	70° C for 100 minutes	75° C for 30 minutes	80° C for 10 minutes	90° C for 1 minute	93° C for 10 minutes	Cidex	Cidex OPA	Wavicide	Control III	Anioxyde 1000*	Gigasept FF*	Sterrad 100S	121° C for 15 minutes		
PerformaTrak		-		-		-	-	-	-			-		10	Remove the forehead pad from the frame before disinfection. Replace the forehead pad for each patient use.
PerforMax: (Sizes S/L/XL)	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	-	10/5	Mask may be autoclaved using gravity displacement cycle, no sterilization bag (5 cycles max). Mask may be disinfected using all other methods (10 cycle max).
PerforMax Pediatric (Sizes: XXS/XS)	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	-	10/5	The EE elbows should not be disinfected. Replace for each patient use. Mask may be autoclaved using gravity displacement cycle, no sterilization bag (5 cycles max). Mask may be disinfected using all other methods (10 cycle max).
Total Face Mask	-					✓	✓					✓		10	Approved at 70°C for 30 minutes only.

**NOTE:** All Philips reusable masks are available in a single patient use option. Contact your local Philips Representative or distributor for further information.

*Chemical Agent Active Ingredients*

- Cidex - 2.4% glutaraldehyde
- Cidex OPA - 0.55% ortho-phthalaldehyde
- Wavicide - 2.65% glutaraldehyde
- Control III - 10% alkyl dimethyl benzyl ammonium chloride, 10% alkyl dimethyl ethyl benzyl ammonium chloride
- Anioxyde 1000 - 0.15% peracetic acid
- Gigasept FF - 11.0 g succindialdehyde, 3.0 g dimethoxytetrahydrofuran
- \* Anioxyde 1000, Aniosyme DD1, and Gigasept FF are not available for use in the United States.

**COVID-19 Ventilation and Hospital Mask Cleaning & Disinfection Guidance Customer FAQ:**

**Q1: How should the ventilation therapy devices be cleaned and disinfected?**

A1: Follow the “Cleaning and Disinfecting Instructions” in the device’s User Manual. Use only the cleaning and disinfecting agents listed in the manual.

**Q2: Will there be any new recommendations for ventilation therapy devices used on patients with COVID-19 infections?**

A2: No changes are planned at this time, but updates will be provided as needed by new information.

**Q3: What should be done if my hospital’s Infection Control protocols require the use of cleaning and disinfecting agents that are not on the Philips recommended lists?**

A3: Please provide the Philips recommended lists of cleaning and disinfecting agents to the hospital infection control department. Inform healthcare providers that the use of agents not on the Philips recommended lists may damage the plastic, cause cracks to develop, and require device replacement.

**Q4: What should be done if the ventilation therapy is used without installing the proper filters in a person with COVID-19 infection?**

A4: Always use a main flow bacteria filter on the patient gas outlet port in order to prevent patient or ventilator contamination. Do not operate ventilators without installing its appropriate Air Inlet Filter. Filters not approved by Respironics may degrade system performance. Please refer to the Keredusy website for products approved for their disinfection method of airpath: [https://www.medizinservice-sachsen.de/en/files/kr1000\\_liste\\_validate\\_en.pdf](https://www.medizinservice-sachsen.de/en/files/kr1000_liste_validate_en.pdf)

**Q5: How effective is the inspiratory bacteria filter (especially for viral issues like COVID-19)?**

A5: The King Systems Corporation Virobac II® filter has a bacterial/viral filter efficiency rating of greater than 99.99%. However, the filter has not been specifically tested for the COVID-19 pathogen.

**Q6: Will the exhalation filtration ensure 100% protection a patients’ exhaled gas?**

A6: Although it will effectively filter (> 99.99% efficiency) the exhaled gas passing through the exhalation port, most patient interfaces will leak some amount of gas due to an unintended leak where the cushion is in contact with the skin.

**A7: How often should the bacterial filter be replaced?**

A7: The frequency and timing of filter replacement will vary by patient and usage. It is recommended to change the filter between patients and at regular intervals (or as stated by the manufacturer).

**Q8 How should hospital multi-patient use masks be cleaned and disinfected?**

A8: Follow the “Cleaning and Disinfecting Instructions” listed above or in the product Instructions for Use. Use only the cleaning and disinfecting agents listed therein.

**Q9: Will there be any new recommendations for hospital multi-patient use masks used on patients with COVID-19 infections?**

A9: There are no updates planned as of this date.

**Q10: What should be done if my hospital’s Infection Control protocols require the use of cleaning and disinfecting agents that are not on the Philips recommended lists?**

A10: Philips has tested multi-use masks with the agents and disinfection methods listed above, we do not recommend using any other cleaning/disinfection methods. Any deviation from the manufacturer’s instructions, or use of agents other than those listed in this letter/Instructions for Use, may impact the performance or durability of the product.

Please provide the Philips recommended lists of cleaning and disinfecting agents to the hospital Infection Control department. Inform healthcare providers that the use of agents not on the Philips recommended lists may damage the plastic, cause cracks to develop, and require device replacement.

**NOTE:** All Philips reusable masks are available in a single-patient-use option. Contact your local Philips Representative, or Distributor, for further information.

**Q11: Can I use hospital wipes with bleach on Philips/Respironics hospital multi-patient use masks?**

A11: Please read complete Instructions for Use, which state: Do not use bleach, alcohol, cleaning solutions containing bleach or alcohol, or cleaning solutions containing conditioners or moisturizers.

**Q11: Can I reuse the headgear and Capstrap on multiple patients?**

A11: Do not attempt to clean the headgear/straps or foam forehead cushions. Replace the headgear/straps, or mask if the forehead cushions or headgear/straps become soiled, and between patient use.

## References

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