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URGENT Medical Device Correction

Trilogy Evo, Trilogy Evo O_2, Trilogy Evo Universal, Trilogy EV300
Environmental Contamination of Device Sensor

This document contains important information for the continued safe and proper use of your equipment.

Please review the following information with all members of your staff who need to be aware of the contents of this communication. It is important to understand the implications of this communication.

A problem has been identified with the Philips Respironics Trilogy Evo O2, Trilogy Evo Universal, Trilogy EV300, and Trilogy Evo ventilators that could pose a risk for patients if not mitigated. Environmental debris may accumulate on the internal machine flow sensor causing partial occlusion which may impact accurate delivery of pressure, volume, or flow. A malfunction caused by this issue can result in patient harm up to hypoxemia if not addressed by the care provider. Please note, these devices can continue to be safely used in line with the mitigations below as well as in accordance with the Instructions for Use.

1. Description of the issue.

Philips Respironics has detected environmental debris (e.g., external dust and dirt) in the air path of some devices that have been returned from the field. Extended exposure to these environmental debris can lead to buildup of particulate on the internal flow sensor within the device. This may cause the device to inaccurately deliver pressure, volume, or flow.

Using a particulate filter prevents accumulation of environmental debris that can cause a device malfunction.

Philips Respironics has received five hundred forty-two (542) reports of a Trilogy Evo device with some level of environmental debris accumulation on the machine flow sensor. This is a reported incidence rate of less than one percent (1%). Three (3) reports included an allegation of serious injury, where one (1) of these cases reported a patient death which cannot currently be attributed to this issue. This device was returned to Philips Respironics for investigation without an inlet filter or particulate filter installed. Severe contamination of the device airpath and machine flow sensor by environmental debris (e.g., dust and dirt) contributed to degradation of device performance and the device operated as intended where numerous high priority alarms were confirmed.

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2. Potential hazards associated with the issue.

Philips Respironics has assessed the issue and has determined that in the worst case conditions the following hazard could be present for the most vulnerable patient populations that use these devices.

Accumulation of environmental debris on the surface of the machine flow sensor can, over time, reach a point where accuracy of various therapy parameters is impacted. If this happens, the patient may experience barotrauma/volutrauma, hypoventilation, hypercapnia, and if left unaddressed could result in hypoxemia and potentially irreversible harm.

Existing device alarms, configured by the clinician, will alert the user of changes in volume or pressure.

Upon start-up, a *Ventilator Inoperative* alarm condition may be triggered by accumulated environmental contamination, rendering the device inoperative.

3. Affected products and how to identify them.

All Trilogy Evo, Trilogy Evo O2, Trilogy EV300, and Trilogy Evo Universal models could be impacted by this issue. Please refer to attached chart of affected part numbers.

To identify the model, refer to the part number on the bottom of the device with the attached list of impacted part numbers:

4. Actions that must be taken by the user in order to prevent risks for patients.

To help prevent accumulation of debris on the machine flow sensor:

- Use the Philips approved particulate filter which prevents a significant majority of airborne aerosols and particulate from entering the device. This filter must be replaced between patients and monthly as indicated in the Instructions for Use. Using this filter was previously optional. This is now required.
- Use the air-inlet filter as indicated in the Instructions for Use.
- Installation of the particulate filter will not require a change to therapy settings.

To help detect change in therapy:

- Set appropriate alarms based on ventilation mode, such as *Low Tidal Volume*, *Low Minute Ventilation*, *Low Inspiratory Pressure*, and *High Inspiratory Pressure*.
- *Check Proximal Pressure* and *External Flow Sensor Failed* alarms can also alert the user to this issue. These are non-settable alarms.
- The device will issue a low priority *Inlet Filter(s) Blocked* alarm if therapy is reduced due to filter occlusion. The device will continue to function if this occurs, but the user must be aware to rinse the air-inlet filter and replace the particulate filter if this occurs.
- Observe instructions for any alarm, especially *Ventilator Service Required* or *Ventilator Inoperative*. If the situation cannot be resolved, use alternative ventilation equipment.

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- Ensure ventilator-dependent patients have access to alternative ventilation equipment, such as a back-up ventilator or manual resuscitator.

Distribute this notice to all employees in your organization that need to be aware. Train device users within your network to use the air inlet and particulate filters on all patients. Send this notice to any organization an impacted device was sold or distributed to.

5. Actions planned by Philips Respironics to correct the problem.

- Use of a particulate filter is now required for all devices.
- Philips Respironics is updating the Trilogy Evo configurations to include the particulate filter in the device packaging from the factory. Additionally, Philips Respironics will distribute one particulate filter to all Trilogy Evo owners who have previously purchased a device.
- Trilogy Evo O_2, Trilogy EV300, and Trilogy Evo Universal configurations will continue to include the particulate filter with the device from the factory.
- Philips Respironics will replace the machine flow sensor of impacted devices meeting the following criteria:
    - The device was purchased prior to the distribution of this notice.
    - The device has issued a *Ventilator Service Required* or *Ventilator Inoperative* alarm due to accumulation of environmental debris on the machine flow sensor which has been confirmed by the Philips Respironics service network.
    - Philips Respironics is informed of the malfunction within 2023 calendar year.
- Additional filters are available through the standard Philips Respironics ordering process.
- Philips Respironics is investigating the issue further to determine if additional action is required.

Please take the actions above in order to prevent risk for your patients.

If you need any further information or support concerning this issue, please contact your local Philips representative or Philips Respironics Customer Service at 1 (800) 345-6443 for homecare customers or 1 (800) 722-9377 for hospital customers.

This notice has been reported to the appropriate Regulatory Agencies. Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA's MedWatch Adverse Event Reporting program either online, or by regular mail, or by fax.

Philips regrets any inconvenience caused by this change to usage requirements.

Sincerely,

Tom Fallon
Head of Quality – Philips Respironics

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Impacted Devices Models

Model	Description	UDI
DS2000X11B	Trilogy Evo Universal Ventilator	606959052000
DS2100X11B	Trilogy Evo, O2, USA	606959051997
DS2110X11B	Trilogy Evo, USA	606959051942
DS2200X11B	Trilogy Evo, O2, USA EV300	606959052017
IN2100X15B	Trilogy Evo, O2, International	606959054059
IN2110X15B	Trilogy Evo, International	606959051959
IN2200X15B	Trilogy Evo, O2, INTL EV300	606959056497

Replacing or Installing the Air-Inlet Foam Filter

The air-inlet foam filter is the grey foam located on the back panel of the ventilator. It protects the ventilator from dirt and dust.

In the clinical environment, replace monthly and between patients. In the home environment, replace every six months and between patients. Only use Philips Respironics supplied filters. Dispose according to local regulations. Ventilation can continue while you are replacing the filter.

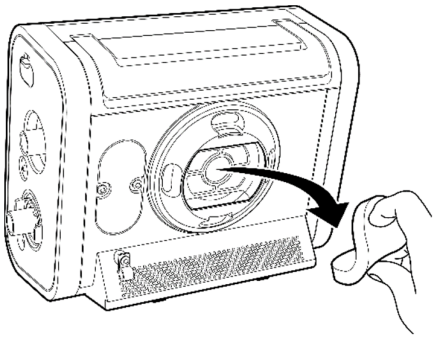
To replace or install the disposable inlet filter:

1. Be sure you have a replacement filter nearby.

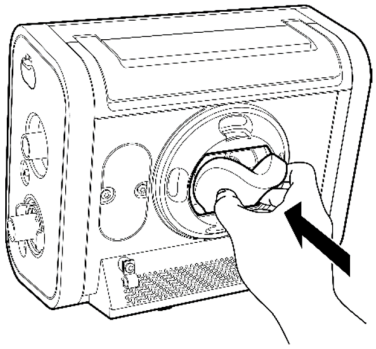
Air-Inlet
Foam Filter

PN 1135260 (single pack: Homecare)
PN 1134591 (10-pack: Hospital)

2. Pinch the filter and pull it out of the filter cover. Rinse the dirty filter in clear water. Inspect the filter for cleanliness and repeat until the filter is clean. Allow the filter to air dry completely before reinstalling.



3. To insert the clean replacement filter, pinch the filter as you press it into the filter cover as shown. Position it securely behind the top and bottom restraints.

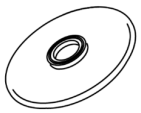


Replacing or Installing the Particulate Filter

The particulate filter protects the ventilator from dirt and dust. Replace the particulate filter monthly and between patients. Ventilation can continue while you replace the filter.

To replace or install the particulate filter:

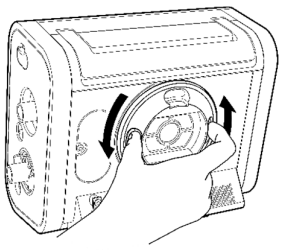
1. Be sure you have a replacement filter nearby.

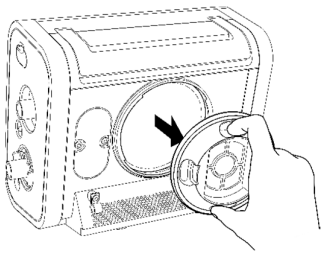


Particulate Filter

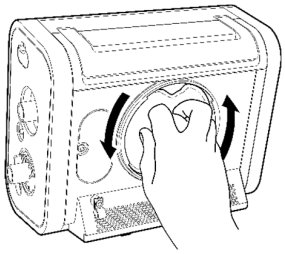
PN 1134430 10/pack

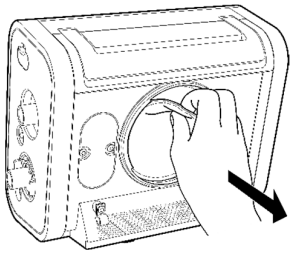
2. Twist the filter cover counterclockwise a quarter of a turn and then pull straight out to remove.



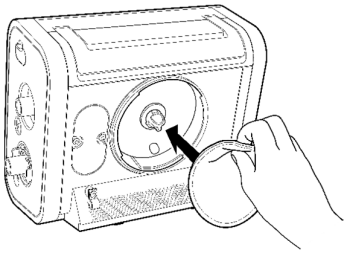


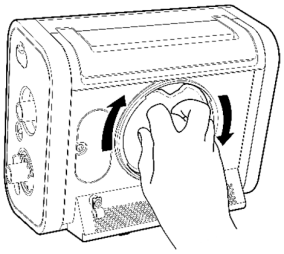
3. Twist the filter counterclockwise a quarter of a turn and pull straight out to remove





4. Place a new filter onto the bayonet mount, then twist the filter clockwise a quarter of a turn while pressing in to secure.





5. Replace the filter cover and turn clockwise to secure.