PHILIPS
RESPIRONICS

Trilogy Evo, Trilogy Evo O2, & Trilogy EV300

Clinical & Caregiver Manual Addendum

This addendum applies to the Trilogy Evo platform (Trilogy Evo, Trilogy Evo O2, and Trilogy EV300) and the Clinical and Caregiver manuals. The following sections are supplemental to or replace information within those manuals. The device operator is responsible for reading and understanding this addendum before use.

Device Usage

Contraindications

If the patient has any of the following conditions, consult the patient's health care professional before using noninvasive ventilation:

- An inability to maintain a patent airway or adequately clear secretions
- At risk to aspirate gastric contents
- Acute sinusitis or otitis media
- Epistaxis, causing pulmonary aspiration of blood
- Hypotension

The AVAPS-AE therapy mode is contraindicated for invasive use and patients less than 10 kg.

The AVAPS feature is contraindicated for patients less than 10 kg.

Users

- (Trilogy Evo and Trilogy Evo O2 only) Properly trained family, and non-professional caregivers.
- Clinical Users of the ventilator include: clinicians (respiratory and non-respiratory) and physicians.
- Service and Maintenance Users of the ventilator include: hospital and service provider technicians.

Warnings

Warning: Use only the cleaning methods outlined in this addendum. Philips is unable to verify the safety or performance of any device if ozone or other unapproved cleaning and disinfection methods are used.

- You must use a Philips Respironics-approved main flow bacteria filter on the patient gas outlet port to prevent patient or device contamination. Filters not approved by Philips Respironics may degrade system performance. For a list of accessories, see your device's accessories guide.
- Move the device away from any potential sources of electromagnetic interference (EMI), including MRI equipment, medical imaging systems, security systems, appliances, wireless communications equipment (such as cellular phones), computers, and televisions.

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- Before placing a patient on the ventilator, perform a clinical assessment. Considerations should include:
  - Choosing alarm settings
  - Whether alternative ventilation equipment is required
  - Whether alternative monitors are required, such as Vte monitoring for Active PAP circuit, pulse oximeter, respiratory monitor with alarm, SpO_2, FiO_2, $EtCO_2$, and pulse rate.
- When using the ActivePAP circuit, CO_2 monitoring is required to measure exhaled carbon dioxide. Be certain that any CO_2 monitoring equipment used complies with ISO 80601-2-55.
- Never use an extension cord with the system. Always operate the device using a properly grounded AC power outlet. If you are unsure whether a power outlet is properly grounded, contact an electrician for assistance.

Notes

- Any serious incident that has occurred in relation to this device should be reported to Philips and the competent authority of the Member State in which the user and/or patient is established.

MRI Safety Information

The ventilation system is MR Unsafe. Keep it outside the MRI scan room (Zone IV). It represents a projectile hazard.

Symbols Glossary

See http://www.symbols.philips.com for a description of the symbols used on this device and its packaging.

Symbol	Definition
	Eject media

How to Contact Philips Respironics

Trilogy Evo, Trilogy Evo O2

Should you experience trouble with this equipment or require assistance, please contact your home care provider. If you need to contact Philips Respironics directly, contact customer service at +1-724-387-4000, or go to www.respironics.com to find your local customer service contact information.

Trilogy EV300

Should you experience trouble with this equipment or require assistance, contact Philips Respironics Customer Service. Visit www.healthcare.philips.com to find your local customer service contact information.

Device Overview

The following section is supplemental to the "About" chapter in your device manual.

Parts of the User Interface

Status Bar

Note: *Features and icons may differ based on software version, product type, and/or market availability.*

Use the status bar to monitor device status and the availability of manual therapeutic actions.

1	Deliver 100% Oxygen	5	Full access indicator
2	100% Oxygen timer	6	Bluetooth
3	Automatic algorithm restart	7	Bluetooth data transfer
4	Nebulizer **Note:** *This icon will be displayed if the Nebulizer option is selected/set to Yes under the Device Options menu.* **Note:** *For more information, refer to the "Adding Nebulization" subsection, located within the "Device Setup (Startup)" section, of this addendum.*	8	Alarm silence
		9	Power sources and their status
		10	Device Actions menu
		11	System time

Therapy Modes & Controls

Therapy Control Settings

Setting Name	Setting Range/Increment
Max Pressure	6-50 cmH_2O, 1 cmH_2O increments (as stated in device manual) ***Note:*** *A maximum pressure setting of less than 40 cmH_2O is recommended for pediatric patients.*
PC Min/Max	A/C-PC AVAPS: 0-40 cmH_2O Increments: 1 cmH_2O
PS Min/Max	PSV AVAPS and AVAPS-AE: 0-40 cmH_2O Increments: 1 cmH_2O

Device Setup

The following section is supplemental to the "Device Setup" chapter in your device manual.

Connecting a Circuit

Leak Compensation

When using a Passive circuit, the ventilator provides leak compensation for intentional leak in the patient circuit and leaks that occur at the patient interface, such as cuff leak or mask leak. There is no leak compensation when the Active PAP, Active Flow, or Dual Limb circuits are used. Refer to the "Device Setup" chapter in your Clinical manual for more information about leak compensation.

Adding Nebulization

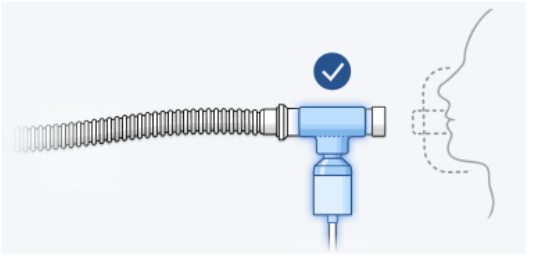
Warning: Do not use a non-pneumatic nebulizer, such as vibrating mesh, with this device. Doing so could degrade device performance, leading to harms such as hypoventilation, low oxygen saturation, and/or dyspnea.

Warning: When using a pneumatic nebulizer, ensure the nebulizer flow rate does not exceed 10 SLPM. Doing so could degrade device performance, leading to harms such as over-inflation of the lung, low oxygen saturation, hypoventilation, and/or delay/absence of therapy.

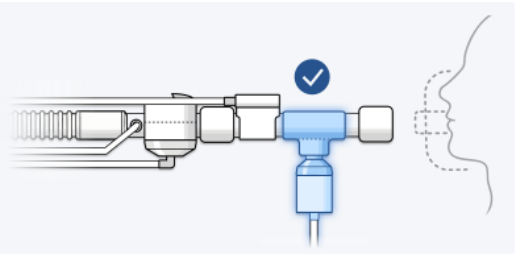
Correct Nebulizer Placement

Warning: Do not connect a pneumatic nebulizer to the ventilator breathing system (VBS) in any position other than as recommended in these instructions. Doing so could degrade device performance, leading to harms such as over-inflation of the lung, low oxygen saturation, hypoventilation, and/or delay/absence of therapy.

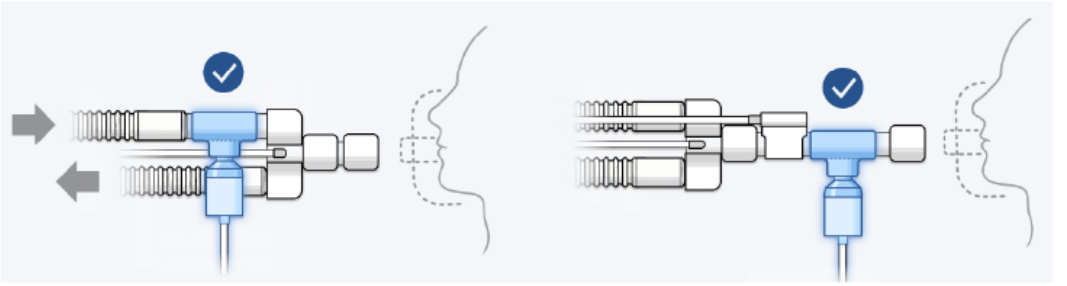
Passive



Active
(external flow sensor shown)



Dual Limb
(before or after wye connector)



If using pneumatic nebulizer treatments with the ventilator:

- The nebulizer should be installed **only** at the end of the patient connection port. For Dual Limb circuits, this could also be at the end of the patient's inspiratory limb, specifically at the input to the wye connector.
- Ensure the nebulizer is placed upright and below the patient tubing.
- Do not place a Heat Moisture Exchanger (HME) between the nebulizer and the patient interface.
- Prior to initiating nebulizer therapy, tap the **Nebulizer** button in the status bar to confirm correct nebulizer placement.

Note: *The icon does not initiate nebulization therapy. Instead, it displays a prompt regarding correct nebulizer placement for the selected circuit type.*

Nebulizer/Circuit Compatibility

Warning: Do **not** use a pneumatic nebulizer with Mouthpiece Ventilation (MPV) circuits. Doing so could degrade device performance, leading to harms such as over-inflation of the lung, low oxygen saturation, hypoventilation, and/or the delay/absence of therapy.

All **heated** circuits are compatible with pneumatic nebulizer use. However, some **non-heated** circuits and tidal volume combinations are not compatible, as described in the table below.

Warning: Do **not** use non-heated circuits in combination with pneumatic nebulizers that are listed as "NOT compatible" in the table below. Doing so could degrade device performance, leading to harms such as over-inflation of the lung, low oxygen saturation, hypoventilation, and/or delay/absence of therapy.

	Pneumatic Nebulizer/Non-Heated Circuit Compatibility	
	Pediatric (14-18 mm)	**Adult (20-22 mm)**
Passive	Only compatible with tidal volume <300 mL	Only compatible with tidal volume <700 mL
Active PAP	NOT compatible	Compatible
Active Flow	NOT compatible	Compatible
Dual Limb	Compatible	Compatible

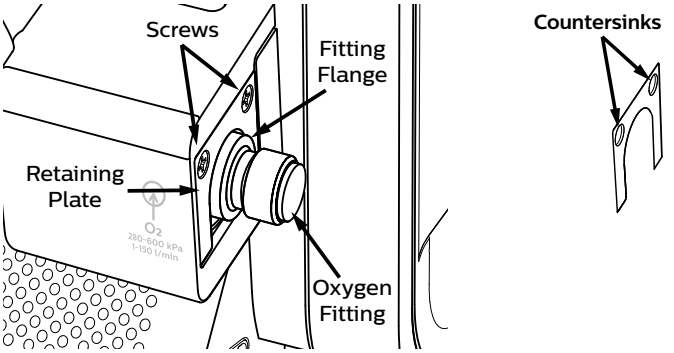
Adding Oxygen

Replacing Oxygen Fitting

The Trilogy Evo Oxygen Blending Module (OBM) is supplied from the factory with a DISS interface to allow connection to an oxygen source. Not all countries or facilities use this interface.

To replace the installed fitting:

1. Remove screws from OBM retaining plate.
2. Remove retaining plate.
3. Firmly pull oxygen fitting straight out of pocket.
4. Insert desired fitting into pocket with flat sides aligned. Fitting flange should be flush with face of pocket after installation.
5. Replace retaining plate with countersinks facing outward.
6. Replace screws to secure retaining plate.



Device Operation

New Patient

1. In the Home window, tap the **New Patient** button. This button clears all existing patient data. For more information about this button, refer to the following sections in your applicable clinical manual: "Setting Up a New Patient" (Trilogy Evo) or "Entering New Patient Information" (Trilogy EV300); and "Preparing the Device for Use by a Different Patient" (both).
2. Follow the prompts on the screen, and select and/or enter information as appropriate.
3. Acknowledge the reminder to ensure both a bacterial/viral filter and a particulate filter are installed.
4. Edit the prescription settings according to the procedure in the "About Prescriptions" (Trilogy Evo) or "About Prescriptions/Settings" (Trilogy EV300) section of your clinical manual.

Alarm & System Messages

Ventilator Inoperative

Priority	High
What to do	Assess the patient and provide an alternate method of ventilation, then contact customer service. If the display screen is not operational, follow these steps: 1. Hold the **Alarm Silence** and the **On/Off (Standby)** buttons for 5 seconds. 2. After 5 seconds, an audible tone will sound. Release both buttons. 3. Press the **On/Off (Standby)** button again. The device will stop delivering therapy and shut down.

Obstruction

Priority	High
Why it occurs	The ventilator detects an obstruction in the patient's inhalation path, exhalation path, or external flow sensor. The ventilator detects that the leak device is missing. ***Note:*** *The Obstruction alarm will not be triggered if there is an obstruction after the exhalation port (passive circuit) or after the active exhalation valve (Active PAP circuit). To detect obstructions after the exhalation port or active exhalation valve, use alternative alarms such as: High Inspiratory Pressure, Circuit Disconnect, Low Tidal Volume, Low Minute Ventilation, Low Respiratory Rate, Leakage, Rebreathing, Apnea, or Low Peak Inspiratory Pressure (volume modes) alarms.*
What to do	Assess the patient, then: • Check the circuit. Is it kinked or pinched? • Check the bacterial/viral filter and/or HME. Is it blocked? • Is the leak device blocked or missing? • Is the external flow sensor blocked?
Device performance	The device activates the obstruction alarm, evaluates the alarm condition until resolution of the obstruction, and continues to attempt to deliver therapy.

Algorithm summary	The obstruction alarm can be triggered in one of the following ways: • Two consecutive breaths have volumes less than a predetermined threshold based on circuit type and therapy settings. • Two consecutive breaths have average flows ≤1 LPM. • The average flow over 4 breath cycles is ≤1 LPM. • The average flow over 60 seconds is ≤1 LPM. Additionally, when the external flow sensor is available: • Two consecutive breaths have an absolute value of the average inspiratory flow ≤1 LPM and a flow span ≤3 LPM. • Flow remains ≤1 LPM for 60 seconds.

Circuit Disconnect

Priority	High
What to do	Assess the patient, then: • Is the circuit connected to the patient? • Is the circuit connected to the ventilator? • Does a large unplanned leak exist? • Is the tracheostomy or endotracheal tube occluded?

High Tidal Volume

Priority	Medium
Why it occurs	*Passive, active flow, or dual limb circuit types*: The estimated exhaled tidal volume is more than or equal to the alarm setting for a number of breaths depending on the therapy mode: • Three consecutive breaths: A/C-PC, CPAP, PSV, S/T, SIMV-VC, SIMV-PC • Six consecutive breaths: A/C-VC When AVAPS or AVAPS-AE mode is enabled, this alarm occurs when the Tidal Volume is more than or equal to the alarm threshold for one minute and Set Inspiratory Pressure is less than or equal to (Set Inspiratory Pressure min + 1 cmH_2O). *Active PAP circuit type*: The delivered tidal volume is more than or equal to the alarm setting for three consecutive breaths.

Low Tidal Volume

Priority	Medium
Why it occurs	*Passive, active flow, or dual limb circuit types*: The estimated exhaled tidal volume is less than or equal to the low tidal volume alarm setting for a number of breaths depending on the therapy mode: • Three consecutive breaths: A/C-PC, CPAP, PSV, S/T, SIMV-VC, SIMV-PC • Six consecutive breaths: A/C-VC When AVAPS or AVAPS-AE mode is enabled, this alarm occurs when the Tidal Volume is less than or equal to the alarm setting for one minute and Set Inspiratory Pressure is greater than or equal to (Set Inspiratory Pressure max - 1 cmH_2O). *Active PAP circuit type*: The delivered tidal volume is less than or equal to the low tidal volume setting.

Inlet Filter(s) Blocked

Priority	Low
Why it occurs	The inlet filter(s) becomes blocked and delivered therapy is reduced.
What to do	• Is the air inlet(s) blocked? • Remove, rinse, and reinstall the air-inlet foam filter. See "Rinsing the Air-Inlet Foam Filter" in your device manual. • Discard and replace the particulate filter.
Device performance	The device continues to function.

Patient-related Alarm Availability by Therapy Mode

Alarm	A/C-PC	A/C-VC	MPV-PC*	MPV-VC*	CPAP	PSV	S/T	SIMV-PC	SIMV-VC	AVAPS-AE
Apnea (requires Backup Ventilation)					•	•		•	•	
High Inspiratory Pressure		•		•					•	
Low Inspiratory Pressure		•		•					•	
No Trigger			•	•						
High SpO_2	•	•	•	•	•	•	•	•	•	•
Low SpO_2	•	•	•	•	•	•	•	•	•	•
High Pulse Rate	•	•	•	•	•	•	•	•	•	•
Low Pulse Rate	•	•	•	•	•	•	•	•	•	•

MPV-PC and MPV-VC available for Trilogy Evo and Trilogy Evo O2 only.

Testing Circuit Obstruction Alarms

The following section is supplemental to the "Testing Circuit Obstruction Alarms" section in your device manual. For ventilator-dependent patients, do not rely on any single alarm to detect when a circuit is obstructed. One or more of the following alarms may indicate an obstructed circuit.

- Obstruction
- High Inspiratory Pressure
- Circuit Disconnected
- Low Tidal Volume
- Low Minute Ventilation
- Low Respiratory Rate
- Low Peak Inspiratory Pressure alarms (settable for volume modes)
- Leakage alarm (Active PAP circuit only)
- Rebreathing Detected

To test that these alarms detect a circuit obstruction, follow these steps.

1. ***For a Passive circuit:*** Remove the leak device, and block the end of the circuit.

   For an Active PAP circuit: Remove the active exhalation valve (AEV), and block the end of the circuit.

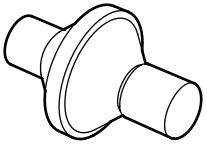
   For an Active Flow or a Dual Limb circuit: Block the end of the circuit.
2. Start ventilation.
3. Confirm that one or more of the alarms listed above activate.
4. Stop ventilation.

Disposal

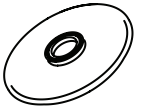
Dispose of this device in accordance with local collections and recycling regulations. For more information, visit www.philips.com/recycling.

Accessories and Replacement Parts

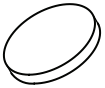
Prior to use, inspect all cords, filters, and circuits for damage or wear. Discard and replace if necessary.



Bacterial/Viral Filter



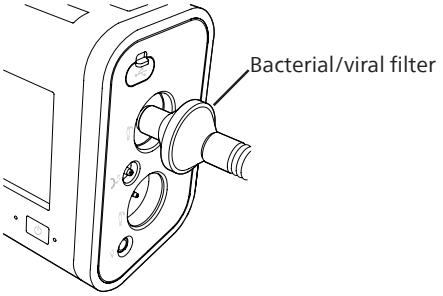
Particulate Filter



Air-Inlet Foam Filter

Bacterial/Viral Filter

The use of a bacterial/viral filter is always required on the patient gas outlet port.



Particulate Filter

The use of the particulate filter is required to protect the device from dirt and dust. For instructions on changing the particulate filter, see Replacing the Particulate Filter in the Service and Maintenance section of this addendum.

- In the hospital setting, replace at least monthly.
- When used outside of the hospital setting, replace at least monthly and between patients.

Note: *The filter is printed with the* ***manufacturing*** *date (FAB [MM/YYYY]); the filter must be used within 5 years of that date.*

External Flow Sensor (Active Flow & Dual Limb Circuits)

Note: *For optimal performance, ensure sensor is always in an upright position (i.e., cap and cable are on top).*

Humidification Accessories

If you are using a humidifier with the ventilator, refer to the instructions provided with the humidifier.

Detachable Battery

- **Warning:** Do not incinerate, disassemble, short circuit or expose to temperatures above 60°C (140°F). Please refer to the instructions for use.
- **Warning:** Do not disassemble, strike, crush or throw into fire. In the event of a serious bout, do not continue to use. Do not place in high temperature environment. Do not use the battery after immersion in water!

FiO_2 Sensor

Calibration

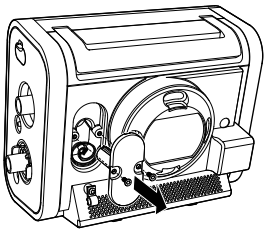
Prior to calibration, the device should be turned on and/or plugged into AC power for a minimum of 15 minutes. Be sure the air-inlet foam filter and the particulate filter are installed in the device. Refer to your device manual for additional information.

Installation

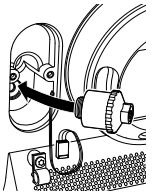
Required: T20 Torx screwdriver

To install a new FiO_2 sensor:

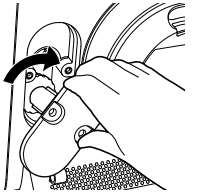
1. Using a T20 Torx screwdriver, unscrew the FiO_2 sensor access panel and set aside. Note that the panel is also the FiO_2 sensor driver, used in step 3.



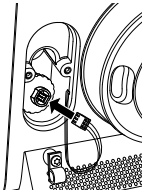
2. Place the sensor in the FiO_2 socket.



3. Place the FiO_2 driver on the sensor and twist clockwise to secure the sensor in the receptacle.



4. Push the connector onto the pins on the sensor. Be sure you have aligned the pins with the receptacles on the connector.



5. Replace the sensor access panel and secure with the screws.

Removal

Required: T20 Torx screwdriver and a slender, pointed tool such as a scratch awl

To remove the FiO_2 sensor:

1. Using a T20 Torx screwdriver, unscrew the FiO_2 sensor access panel and set aside.
2. Use a slender, pointed tool such as a scratch awl to pull the tab lock away from the connector to the unlock position.
3. While holding the tab in the unlock position, pull the white connector straight out. Do not use the wires to pull the connector.
4. Place the FiO_2 driver (sensor access panel) on the sensor and twist counterclockwise to remove the sensor from the device.

USB Flash Drive

The USB flash drive (removable storage) included with your device can be used to import and export data.

Cleaning & Disinfection

Note: *Any damage caused by unapproved ozone cleaning and disinfection methods or other unapproved cleaning and disinfection methods will not be covered by the Philips Limited Warranty.*

Note: *If a home-based device is returned and assigned to a new patient, clean and disinfect the device exterior according to the procedures in this section.*

The following section replaces the information presented in the Cleaning and Disinfection chapter in your device manual.

Warnings

- Because the device is intended for multi-patient use, be sure you follow the cleaning and disinfection instructions in this addendum.
- You must use a Philips Respironics-approved main flow bacteria filter on the patient gas outlet port to prevent patient or device contamination. Filters not approved by Philips Respironics may degrade system performance. For a list of accessories, see your device's accessories guide.
- This product is suitable for use with other patients if a bacteria filter was in use at all times and exchanged between patients.
- There are no approved air path disinfection methods. Use only the cleaning methods outlined in this addendum. Philips is unable to verify the safety or performance of any device if ozone or other unapproved cleaning and disinfection methods are used.

Exterior Cleaning and Disinfection

Warning: To avoid electric shock, do not remove the enclosure cover. Only service personnel should remove the enclosure. After cleaning and disinfecting, be sure the device is completely dry before reattaching accessories and connectors and before reconnecting it to a power source. To avoid electrical shock, always unplug the power cord from the wall outlet before cleaning the ventilator. If the device has been exposed to rain or dampness, dry the device (including the area around the power cord connection) with the power cord disconnected from the device before applying AC power.

Caution: Do not immerse the device or allow liquids into any of the controls or inside the enclosure as the device may be damaged. If this occurs, contact your equipment provider for assistance. Use only the cleaning agents and methods described in this section to clean and disinfect the device.

Cleaning the Exterior

Frequency: Clean the device's exterior surface weekly and between patients.

Requirements:

- Lint-free cloth
- Soft-bristle brush
- Liquid dishwashing detergent solution: 1 teaspoon (5 mL) of liquid dishwashing detergent (such as Dawn Ultra Dishwashing Liquid®) per gallon (3.7 L) of potable water

To clean the exterior, follow these steps:

1. Turn the device off and disconnect it from the power source.
2. Detach all accessories and connectors.
3. Use a lint-free cloth dampened (not dripping) with a liquid dishwashing detergent solution to clean the exterior of the enclosure.
4. Use a soft-bristle brush in the areas around the screen, buttons, and any other areas where soil may be difficult to remove. Ensure you remove all visible soil.
5. Use a lint-free cloth dampened (not dripping) with potable water to remove all detergent residue.

6. Use a lint-free cloth to dry the enclosure.
7. Inspect the device for cleanliness.
8. Repeat the cleaning steps until the surfaces are visibly clean.
9. Inspect the device for damage after cleaning. If any parts are damaged, contact customer service.

Disinfecting the Exterior

Frequency: Disinfect the exterior surface weekly and between patients.

Prerequisite: Before disinfecting the exterior, be sure you have cleaned the device as instructed in the previous section, "Cleaning the Exterior."

Isopropyl Alcohol

Requirement: 70% isopropyl alcohol, lint-free cloth

To disinfect with alcohol, follow these steps:

1. Use a lint-free cloth dampened with alcohol to wipe the alcohol onto the exterior, thoroughly wetting the surfaces.
2. Keep wet 10 minutes.
3. Allow to air dry.
4. Inspect the device for damage after disinfection. If any parts are damaged, contact customer service.

Chlorine Bleach

Requirement: Household chlorine bleach containing 8.25% sodium hypochlorite, lint-free cloth

To disinfect with bleach, follow these steps:

1. Combine 10 parts potable water to 1-part bleach.
2. Use a lint-free cloth dampened with the bleach solution to wipe the bleach solution onto the exterior, thoroughly wetting the surfaces.
3. Keep wet 10 minutes.
4. Allow to air dry.
5. Inspect the device for damage after disinfection. If any parts are damaged, contact customer service.

Air Path Cross Contamination

Warning: You must use a Philips Respironics-approved main flow bacteria filter on the patient gas outlet port to prevent patient or device contamination. Filters not approved by Philips Respironics may degrade system performance.

To manage multiple patients, you can select either the use of a bacteria filter or replacement of the gas pathway components in between patient use.

This product is suitable for multi-patient use when used with a bacteria filter to reduce cross contamination between patients. Ensure the bacteria filter is replaced between patients per the instructions provided with the bacteria filter. If a previous patient has not used a bacteria filter, the next patient must use a bacteria filter, or the gas pathway components must be replaced. For more information about exchanging the gas pathway components, contact Philips Respironics Customer Service at 1-724-387-4000 or visit www.respironics.com for your local customer service number.

> ***Note:*** *The bacteria filter should be disposed of in accordance with the filter instructions for use and between patients.*

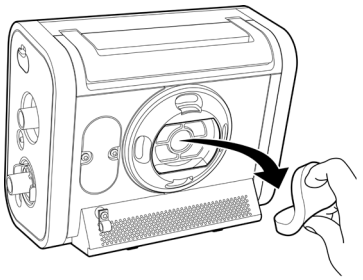
Service and Maintenance

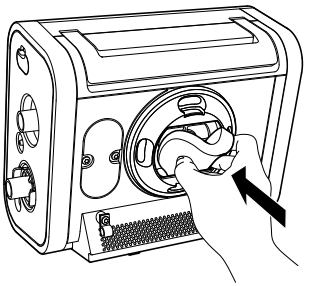
Replacing the Air-Inlet Foam Filter

The air-inlet foam filter is the gray foam located on the back panel. It is required to protect the device from dirt and dust. Replace if it becomes damaged.

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.

Note: *The air-inlet foam filter may be replaced by the user, caregiver, clinician, or service personnel.*





To replace the disposable inlet filter:

1. Be sure you have a replacement filter nearby.
2. Pinch the filter and pull it out of the filter cover.
3. Insert the clean replacement filter into the filter cover. Be sure it is positioned securely.

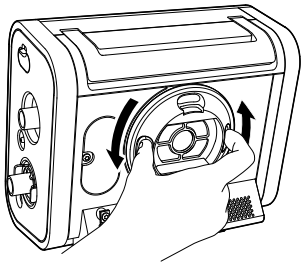
Replacing the Particulate Filter

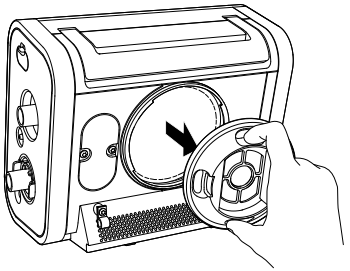
The use of the particulate filter is required to protect the device from dirt and dust. Ventilation can continue while you are replacing the filter.

- In the hospital setting, replace at least monthly.
- When used outside of the hospital setting, replace at least monthly and between patients.

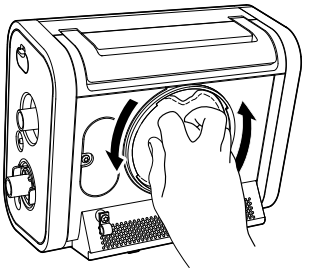
Note: *The particulate filter may be replaced by the user, caregiver, clinician, or service personnel.*

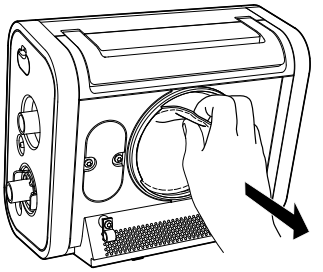
Twist the filter cover counterclockwise a quarter of a turn, and then pull straight out to remove.



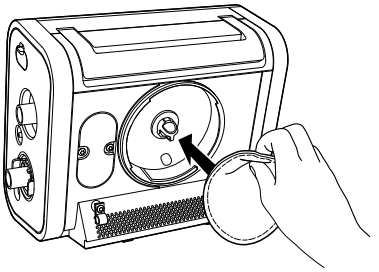


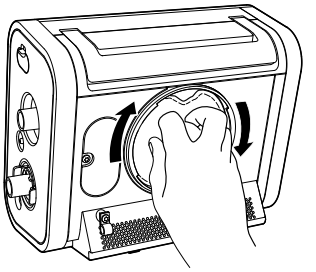
Twist the filter counterclockwise a quarter of a turn, and then pull straight out to remove.





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





Replace the filter cover and turn clockwise to secure.

Technical Data

Measured and Displayed Patient Parameters

Pulse rate with pulse oximeter accessory	Nonin Accessories: 18 to 321 beats per minute in increments of 1 beat per minute Masimo Accessories: 25 to 240 beats per minute in increments of 1 beat per minute See “Pulse Oximeter.”
EPAP	Expiratory positive airway pressure. Displayed parameter in AVAPS-AE mode.

Environmental

Operating	• Temperature: 0°C to 40°C, 32°F to 104°F • Relative humidity: 5% RH to 90% RH, non-condensing • Atmospheric pressure: 62 kPa to 106 kPa • Altitude: Approximately -384 m to 3954 m (-1,253 ft to 12,971 ft) • Battery charging temperature: 5°C to 40°C, 32°F to 104°F

Wireless

NFC	Note: This function is currently not available.
Wi-Fi	Note: This function is currently not available.

Pulse Oximeter

Displayed pulse rate range:	Nonin Accessories: 18 to 321 beats per minute in increments of 1 beat per minute Masimo Accessories: 25 to 240 beats per minute in increments of 1 beat per minute
Data averaging	Nonin Accessories: 4 beat average, updated every second Masimo Accessories: 8 second average, updated every second

Regulatory Information

Wireless Communication

Bluetooth Core Specification version 4.2

Wireless

Hereby, Respironics Inc. declares that this class 1 radio equipment is in compliance with Directive 2014/53/EU. The full text of the EU declaration of conformity is available at the following internet address: http://incenter.medical.philipscom/PMSPublic.

This product meets RF exposure requirements when it is positioned with a separation distance of at least 20 cm away from the body.

> ***Note:*** *The Bluetooth® word mark and logos are registered trademarks owned by Bluetooth SIG, Inc. and any use of such marks by Philips Respironics is under license.*

Limited Warranty

The following information replaces the information presented in the Warranty chapter in the Trilogy Evo, Trilogy Evo O2, and Trilogy EV300 manuals.

Respironics, Inc., a Philips company ("Philips Respironics") provides this non-transferable, limited warranty for Trilogy Evo, Trilogy Evo O2, and Trilogy EV300 ("Product") to the customer who originally purchased the Product directly from Philips Respironics.

What this warranty covers: Philips Respironics warrants each new Product will be free from defects in materials and workmanship and will perform in accordance with the Product specifications under normal and proper use and maintenance in accordance with applicable instructions, subject to the exclusions below.

How long does this warranty last: Two years from the date of shipment by Philips Respironics to the original purchaser (Trilogy Evo, Trilogy Evo O2), or one year from the longer of the date of shipment to the purchaser or date of setup by purchaser for the end user (Trilogy EV300), except:

a. The warranty period for the internal battery included with the Product is 90 days from the date of shipment to the original purchaser.

b. All other accessories and replacement parts are not covered under this warranty.

What this warranty does not cover: This warranty does not apply to any software included with the Product as the software warranty is included in the software license. This warranty does not cover damage or injury whether to the Products, personal property, or persons caused by accident, misuse, abuse, Acts of God, water ingress, unapproved ozone cleaning and disinfection methods, other unapproved cleaning and disinfection methods, repair or alteration by anyone other than Philips Respironics or its authorized service center, failure to operate in accordance with the terms of the operating manual and instructions, lack of reasonable care, the discontinuance of a network (e.g., 2G, 3G, etc.) by a carrier (e.g., ATT, Verizon, etc.), or other defects not related to material or workmanship. This warranty is not transferable. If Philips Respironics finds that a Product returned for service or the issue raised is not covered under this limited warranty, Philips Respironics may charge an evaluation fee and return shipping.

What Philips Respironics will do: If a Product fails to conform to the warranties set forth above during the applicable warranty period, Philips Respironics will repair or replace the Product or refund the original purchase price, in Philips Respironics sole discretion. Philips Respironics may use new or remanufactured assemblies, components, and parts in repair and new or recertified refurbished devices for replacement. The balance of the original warranty period will apply to any Product or component of a Product repaired or replaced under this warranty.

Warranty Disclaimer; Limitation of Liability: EXCEPT AS SET FORTH IN THIS LIMITED WARRANTY, PHILIPS RESPIRONICS MAKES NO WARRANTIES, EXPRESSED OR IMPLIED, STATUTORY OR OTHERWISE, REGARDING THE PRODUCT OR ITS QUALITY OR PERFORMANCE. PHILIPS RESPIRONICS SPECIFICALLY DISCLAIMS THE IMPLIED WARRANTY OF MERCHANTABILITY AND THE IMPLIED WARRANTY OF FITNESS FOR A PARTICULAR PURPOSE. IN NO EVENT WILL PHILIPS RESPIRONICS MAXIMUM LIABILITY UNDER THESE WARRANTIES EXCEED THE ORIGINAL PURCHASE PRICE OR WILL PHILIPS RESPIRONICS BE LIABLE FOR ANY ECONOMIC LOSS, LOSS OF PROFITS, OVERHEAD, OR SPECIAL, INCIDENTAL, OR CONSEQUENTIAL DAMAGES. Repair, replacement, or return of purchase price by Philips Respironics is the original purchaser's sole and exclusive remedy under this warranty.

This warranty gives you specific legal rights, and you may also have other rights that vary from state to state. Some states do not allow the exclusion or limitation of incidental or consequential damages, so the above exclusion and limitations may not apply to you.

How to get warranty support: Patients contact your local authorized Philips Respironics dealer and dealers contact Respironics, Inc. at:

1001 Murry Ridge Lane
Murrysville, Pennsylvania 15668-8550
+1-724-387-4000

Note: For Australian and New Zealand customers, this warranty replaces the warranty included with the user manual.

1. The following statement is provided to a customer who is a consumer under the Australian Consumer Law: Our goods come with guarantees that cannot be excluded under the Australian Consumer Law. You are entitled to a replacement or refund for a major failure and for compensation for any other reasonably foreseeable loss or damage. You are also entitled to have the goods repaired or replaced if the goods fail to be of acceptable quality and the failure does not amount to a major failure. This guarantee applies in addition to other rights and remedies available to the consumer under law.
2. The following statement is provided to a customer who is a consumer under the Consumer Guarantees Act 1993 (NZ): For consumers under the Consumer Guarantees Act 1993 (NZ) who purchase the goods for personal, domestic or household use: Our goods come with guarantees that cannot be excluded under the Consumer Guarantees Act 1993 (NZ).
3. Philips warrants that the products shall be free from defects of workmanship and materials, and will perform in accordance with the product specifications for a period of two (2) years from the date of shipment by Philips Respironics to the original purchaser (Trilogy Evo, Trilogy Evo O2), or one (1) year from the longer of the date of shipment to the purchaser or date of setup by purchaser for the end user (Trilogy EV300). This Warranty covers the replacement or repair at the option of Philips, of any product that has a manufacturing or material defect that is not the result of normal wear and tear, or a natural characteristic of the material used. This Warranty is not transferable and does not cover products used for commercial purposes, and it does not apply to any consumable items (including but not limited to filters, masks, tubes and humidifier chambers).
4. The customer is responsible for returning the product to an authorised Philips Homecare Provider, and for collecting the product from the Homecare Provider after repair or replacement, at its own cost. Philips is responsible only for the freight cost of transporting the product between the Homecare Provider and Philips. Philips reserves the right to charge an evaluation and postage fee for any returned product where no problem is found following evaluation.
5. This Warranty does not cover:
   - products purchased outside of Australia and New Zealand;
   - any damage caused as a result of misuse or abuse, modification, tampering with or alteration of the product, pest infestation, liquid egress into the product, or unapproved ozone cleaning and disinfection methods;
   - contamination due to cigarette, pipe, cigar or other smoke;
   - failure to follow manufacturer's instruction for use as per the user manual;
   - defects that are a consequence of repairs to a product made or attempted by a service provider other than one approved by Philips;
   - products that have been subjected to incorrect electrical supply or inconsistent electrical supply or used with inappropriate accessories.
6. This Warranty is not transferrable in the event of any resale or transfer of products.
7. To make a claim under this Warranty, contact your Homecare Provider or Philips:

AUSTRALIA
Philips Electronics Australia Limited
65 Epping Road, North Ryde
NSW 2113 Australia
Tel: 1300 766 488
Email: repairs-src@philips-easyconnect.com

NEW ZEALAND
Philips New Zealand Commercial Ltd
Level 3, 123 Carlton Gore Road
New Market Auckland 1023 New Zealand
Tel: 0800 251 400
Email: repairs-src@philips-easyconnect.com

Appendix A -- uSpO2 Masimo SET Oximetry Cable, USB

Intended Use

The Masimo SET uSpO2 Pulse Oximetry Cable is indicated for the continuous noninvasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO2) and pulse rate (measured by an SpO2 sensor). The Masimo SET uSpO2 Pulse Oximetry Cable is indicated for use with adult, pediatric and neonatal patients during both motion and no motion conditions, and for patients who are well or poorly perfused in hospitals and hospital-type facilities.

Compatibility

These accessories are compatible with the Trilogy Evo and Trilogy EV300 series of ventilators when used in a hospital environment. They are also compatible with LNCS Adhesive and LNCS Reusable sensors. Refer to the sensor's instructions for accuracy.

Warnings

- The pulse oximeter is to be operated by, or under the supervision of, qualified personnel only. The manual, accessories, directions for use, all precautionary information, and specifications should be read before use.
- Do not start or operate the pulse oximeter unless the setup was verified to be correct.
- Explosion hazard: Do not use the pulse oximeter in the presence of flammable anesthetics or other flammable substance in combination with air, oxygen-enriched environments, or nitrous oxide.
- To ensure safety, avoid stacking multiple devices or placing anything on the device during operation.
- To protect from electric shock, always remove the sensor and completely disconnect the pulse oximeter before bathing the patient.
- If any measurement seems questionable, first check the patient's vital signs by alternate means and then check the pulse oximeter for proper functioning
- The pulse oximeter is not an apnea monitor.
- The pulse oximeter may be used during electrocautery, but this may affect the accuracy or availability of the parameters and measurements.
- The pulse oximeter should not be used for arrhythmia analysis.

Cautions

- Electrical shock and flammability hazard: Before cleaning, always turn off the device and disconnect from any power source.
- Do not place the pulse oximeter on electrical equipment that may affect the device, preventing it from working properly.
- To ensure that alarm limits are appropriate for the patient being monitored, check the limits each time the pulse oximeter is used.
- Variation in measurements may be profound and may be affected by sampling technique as well as the patient's physiological conditions. Any results exhibiting inconsistency withthe patient's clinical status should be repeated and/or supplemented with additional test data. Blood samples should be analyzed by laboratory instruments prior to clinical decision making to completely understand the patient's condition.
- Do not submerge the pulse oximeter in any cleaning solution or attempt to sterilize by autoclave, irradiation, steam, gas, ethylene oxide or any other method. This will seriously damage the pulse oximeter.
- To minimize radio interference, other electrical equipment that emits radio frequency transmissions should not be in close proximity to the pulse oximeter.

Notes

- A functional tester cannot be used to assess the accuracy of the pulse oximeter.

- Do not loop the patient cabling into a tight coil or wrap around the device, as this can damage the patient cabling.
- Additional information specific to the Masimo sensors compatible with the pulse oximeter, including information about parameter/measurement performance during motion and low perfusion, may be found in the sensor's directions for use (DFU).

Instructions for Use

For additional information, warnings, and instructions to use the sensor or cable, see that accessory's instructions for use. To attach the sensor or cable to the ventilator, see the ventilator's instructions for use.

Environmental Specifications

For environmental specifications, see the accessory's instructions for use.

Cleaning

For cleaning instructions, see the accessory's instructions for use.

Disposal

Dispose according to local regulations. If you need help, contact Philips Respironics.

Specifications

Displayed Oxygen Saturation Range (SpO_2):	0 to 100% with a resolution of 1%
Displayed pulse rate range:	25 to 240 beats per minute with a resolution of 1
SpO_2 and pulse rate accuracy:	See the sensor instructions.
Data update period:	Every second
Data averaging:	8 second average, updated every second
Radiant Power at 50 mA pulsed:	≤15 mW

The Masimo SET technology with Masimo sensors has been validated for no motion accuracy in human blood studies on healthy adult male and female volunteers with light to dark skin pigmentation in induced hypoxia studies in the range of 70-100% SpO2 against a laboratory CO-Oximeter and ECG monitor. This variation equals ±1 standard deviation. Plus or minus one standard deviation encompasses 68% of the population.

The Masimo SET technology with Masimo sensors has been validated for motion accuracy in human blood studies on healthy adult male and female volunteers with light to dark skin pigmentation in induced hypoxia studies while performing rubbing and tapping motions, at 2 to 4 Hz at an amplitude of 1 to 2 cm and a non-repetitive motion between 1 to 5 Hz at an amplitude of 2 to 3 cm in induced hypoxia studies in the range of 70-100% SpO2 against a laboratory CO-Oximeter and ECG monitor. This variation equals ±1 standard deviation, which encompasses 68% of the population.

The Masimo SET technology has been validated for low perfusion accuracy in bench top testing against a Biotek Index 2™ simulator and Masimo's simulator with signal strengths of greater than 0.02% and transmission of greater than 5% for saturations ranging from 70 to 100%. This variation equals ±1 standard deviation. Plus or minus one standard deviation encompasses 68% of the population.

The Masimo SET Technology with Masimo Neo sensors has been validated for neonatal motion accuracy in human blood studies on healthy adult male and female volunteers with light to dark skin pigmentation in induced hypoxia studies while performing rubbing and tapping motions, at 2 to 4 Hz at an amplitude of 1 to 2 cm and a non-repetitive motion between 1 to 5 Hz at an amplitude of 2 to 3 cm in induced hypoxia studies in the range of 70-100% SpO2 against a laboratory CO-Oximeter and ECG monitor. This variation equals ±1 standard deviation. Plus or minus one standard deviation encompasses 68% of the population. 1% has been added to the results to account for the effects of fetal hemoglobin present in neonates.

The Masimo SET technology with Masimo sensors has been validated for pulse rate accuracy for the range of 25 -240 bpm in bench top testing against a Biotek Index 2™ simulator. This variation equals ±1 standard deviation. Plus or minus one standard deviation encompasses 68% of the population.

See sensor directions for use (DFU) for complete application information. Unless otherwise indicated, reposition reusable sensors at least every 4 hours and adhesive sensors at least every 8 hours.

Sensor accuracy specified when used with Masimo technology using a Masimo patient cable for LNOP sensors, RD SET sensors, the LNCS sensors, or the M-LNCS sensors. Numbers represent Arms (RMS error compared to the reference). Because pulse oximeter measurements are statistically distributed, only about two-thirds of the measurements can be expected to fall within a range of ± Arms compared to the reference value. Unless otherwise noted, SpO2 accuracy is specified from 70% to 100%. Pulse Rate accuracy is specified from 25 to 240 BPM.

Masimo oximetry sensors use light emitting diodes (LEDs) which operate at the following wavelengths (except TC-I, TF-I, and TFA-1 sensor types as specified in their respective columns below.)

LED	General	TC-I	TF-I	TFA-1
	Nominal Wavelength	Nominal Wavelength	Nominal Wavelength	Nominal Wavelength
Red	660 nm	653 nm	660 nm	653 nm
Infrared	905 nm	880 nm	880 nm	905 nm

EMC Information

Note: *The EMISSIONS characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required) this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment.*

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6. Non-Authorized Accessories. Masimo technology is designed to operate together with Masimo cables, sensors and accessories as an integrated system. When any component of the system is compromised, erroneous measurements can occur. Accordingly, the use of unauthorized sensors or accessories, such as third-party reprocessed or copycat sensors can yield unreliable results when used with a Masimo device. The performance of Masimo technology is not validated when used with any unauthorized sensor or accessory.

7. Transfer Restrictions. The software/firmware is licensed to the Purchaser, and may not be transferred to anyone, except other end-users, without the prior written consent of Philips. In no event may you transfer, assign, rent, lease, sell, or otherwise dispose of the software/firmware or the products on a temporary basis.

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10. Patents. The Masimo technology in this product is covered under one or more patents as set forth at www.masimo.com/patents.htm