PHILIPS
RESPIRONICS

Trilogy Instructions for Use Addendum

Warnings

This is an addendum to the Trilogy manual. The following warnings are in addition to those presented in TrilogyEC, Trilogy100, Trilogy200, and Trilogy202. The operator of the ventilator is responsible to read and understand this addendum and the Trilogy manual before use.

Warnings

Electromagnetic Compatibility (EMC)	Medical Electrical Equipment needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in this addendum to the Trilogy manual. Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally. For more information, contact product support.
	To ensure that you receive safe, effective therapy, use only Philips Respironics accessories. The use of accessories, transducers, and cables other than those specified or provided by Philips Respironics, may result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.
	Portable and Mobile Radio Frequency Communications Equipment can affect Medical Electrical Equipment. See the EMC section of this addendum to the Trilogy manual for distances to observe between RF Generators and the ventilator to avoid interference.
	Do not use this device near active high frequency surgical equipment and the Radio Frequency shielded room of a Medical Electrical system for magnetic resonance imaging, where the intensity of electromagnetic disturbances is high.
	This device is intended for use in the electromagnetic environment specified in this addendum to the Trilogy manual. The user of this device should make sure it is used in a compatible environment.
Bacteria Filter	Any breathing system filter, either incorporated into the ventilator or recommended for use with the ventilator, shall comply with the relevant requirements of ISO 23328-1 and ISO 23328-2.
	Nebulization or humidification can increase the resistance of breathing system filters. Monitor the breathing system filter frequently for increased resistance and blockage.
Nebulizer	Device accuracy may be affected by gas added by use of a nebulizer.

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Patient Circuits (General)	The ventilator system (used with patient circuit accessories, such as patient interface devices, humidifiers, water traps, and circuit tubing) may contain small parts which could result in a choking hazard.
Humidifier	Be certain that if a humidifier is in use, including heated breathing tubes, that they comply with ISO 8185 or ISO 80601-2-74.
Altitude and Temperature Range	Do not use the ventilator at an altitude above the maximum rated altitude or outside the stated temperature range. Using the ventilator outside of this temperature range or above this altitude can affect the ventilator performance which consequently can result in patient death.
Other Safety Notices	Do not use the ventilator in a hyperbaric chamber.
	Do not use the ventilator in the presence of nitrous oxide.
	Do not use the ventilator with helium or in the presence of mixtures in combination with helium.
	Route all cables in a manner to prevent injury to the patient and caregiver (e.g., tripping, strangulation, etc.).
Supplemental Monitoring (Optional)	To ensure accuracy of oxygen administration and to monitor for the presence of contamination (incorrect gas connected), use an external oxygen monitor that complies with ISO 80601-2-61 to verify the oxygen concentration in the delivered gas.
	When the ventilator is used for non-invasive ventilation, measurement of exhaled carbon dioxide concentrations requires CO_2 monitoring in accordance with ISO 80601-2-55.
Remote Alarms	The remote alarm shall be tested daily and after every connection.

Ventilator Alarms

The Ventilator Alarms section in this addendum replaces the information regarding alarms under "Ventilator Alarms" in Chapter 3 of the Trilogy manual. This section describes all of the Patient alarms, System alarms, and Informational messages.

Note: *Alarm settings are restored automatically after power is interrupted for 30 seconds or less.*

Patient Alarms

Check Circuit Alarm

This is a high priority alarm. It occurs when the device detects a problem with the patient circuit, such as pinched or detached tubing, water condensation in the proximal pressure lines, or problems with the active exhalation device.

Low Circuit Leak Alarm

This is a high priority alarm that only occurs with the passive circuit. It occurs when the system detects a problem with the leak device in the passive circuit.

Note: *During Nebulizer Treatment with a Passive circuit, the Low Circuit Leak alarm sensitivity is adjusted for a 20-minute period in order to reduce nuisance alarms. The Low Circuit Leak alarm will still alert the user of potential hazards, such as a blocked exhalation port, but the number of alarms should be significantly reduced.*

High Expiratory Pressure Alarm

This is a high priority alarm. It occurs when the delivered pressure exceeds the target patient pressure during the expiratory phase by 5 cm H_2O. This may be due to pinched tubing or the patient having a fast breath rate. The device continues to operate. The alarm will automatically terminate when the delivered pressure comes within 5 cm H_2O of the target patient pressure during the expiratory phase.

Low Expiratory Pressure Alarm

This is a high priority alarm. It occurs when the delivered pressure is 5 cm H_2O or more below the target patient pressure during the expiratory phase. The device continues to operate. The alarm will automatically terminate when the delivered pressure comes within 5 cm H_2O of the target patient pressure during the expiratory phase.

High Oxygen Flow

This is a high priority alarm. It occurs when the concentration of oxygen from the device is 10% above the FiO_2 set point for more than 30 seconds. This could be caused by a problem with the output of the oxygen source.

Note: *Trilogy202 only.*

Low Oxygen Flow

This is a high priority alarm. It occurs when the concentration of oxygen from the device is 10% below the FiO_2 set point for more than 30 seconds. This could be cause by the oxygen source being disconnected from the device, an occlusion in the tubing from the oxygen source to the device, or a problem with the output of the oxygen source.

Note: *FiO_2 settings of less than 31% result in a Low Oxygen Flow alarm limit corresponding to the amount of oxygen in ambient air (21%). This may cause the alarm to not be generated if oxygen is no longer supplied. An external oxygen monitor to verify the oxygen concentration in the delivered gas is recommended in this instance.*

Note: *Trilogy202 only.*

High Oxygen Inlet Pressure

This is a high priority alarm. It occurs when the pressure of the oxygen from the source measures greater than 87 psi.

Note: *Trilogy202 only.*

Low Oxygen Inlet Pressure

This is a high priority alarm. It occurs when the oxygen source inlet pressure measures less than 40 psi. This could be caused by the oxygen source being disconnected from the device, an occlusion in the tubing from the oxygen source to the device, or a problem with the oxygen source supply system.

Note: *Trilogy202 only.*

Circuit Disconnect Alarm

This is a high priority alarm. It occurs when the breathing circuit is disconnected, has a large leak, or if the patient airway is completely occluded. The device will continue to operate. This alarm will automatically terminate when the circuit is reconnected, the leak is fixed, or when the occlusion in the airway is removed.

Circuit Disconnect (MPV) Alarm

This is a high priority alarm. It occurs when a spontaneous breath has not been initiated within the selected period. This may be useful to alert a caregiver when a patient is unable to connect to the mouthpiece or if the patient has fallen asleep. The device continues to operate. The alarm will automatically terminate when the circuit is reconnected.

Apnea Alarm

This is a high priority alarm. It occurs when the patient has not triggered a breath within the time specified in the apnea alarm setting. The device continues to operate. The alarm will automatically terminate when two consecutive patient breaths are detected that meet the apnea alarm time setting.

High Vte Alarm

This is a high priority alarm. It occurs when the estimated exhaled tidal volume is greater than the High Vte alarm setting for three consecutive breaths. The device continues to operate. The alarm will automatically terminate when a breath occurs in which the exhaled tidal volume does not reach the High Vte alarm setting.

Low Vte Alarm

This is a high priority alarm. It occurs when the estimated exhaled tidal volume is lower than the Low Vte alarm setting for three consecutive breaths. The device continues to operate. The alarm will automatically terminate when a breath occurs in which the exhaled tidal volume exceeds the Low Vte alarm setting.

When AVAPS is on, this alarm will occur when the calculated tidal volume is less than or equal to 90% of the target tidal volume setting for at least 1 minute. The alarm will automatically terminate when the calculated tidal volume exceeds 90% of the target tidal volume for at least 30 seconds.

Note: *When AVAPS is on, the Pressure Support Max limit must be reached to enable this alarm.*

High Vti Alarm

This is a high priority alarm. It occurs when the delivered tidal volume is greater than the High Vti alarm setting for three consecutive breaths. The device continues to operate. The alarm will automatically terminate when a breath occurs in which the delivered tidal volume does not reach the High Vti alarm setting.

Low Vti Alarm

This is a high priority alarm. It occurs when the delivered tidal volume is less than the Low Vti alarm setting for three consecutive breaths. The device continues to operate. The alarm will automatically terminate when a breath occurs in which the delivered tidal volume exceeds the Low Vti alarm setting.

High Respiratory Rate Alarm

This is a high priority alarm. It occurs when the respiratory rate is greater than the High Respiratory Rate alarm setting. The device continues to operate. The alarm will automatically terminate when the measured respiratory rate is less than the High Respiratory Rate alarm setting.

Low Respiratory Rate Alarm

This is a high priority alarm. It occurs when the respiratory rate is less than the Low Respiratory Rate alarm setting. The device continues to operate. The alarm will automatically terminate when the measured respiratory rate is greater than the Low Respiratory Rate alarm setting.

High Inspiratory Pressure Alarm

This alarm occurs in several stages and escalates from an audible beep for the first two occurrences to a high priority alarm if the problem continues. It is detected differently for volume and pressure therapy modes.

For volume modes, the alarm will sound if the measured patient pressure exceeds the High Inspiratory Pressure setting specified by the clinician. The alarm will automatically terminate when the peak inspiratory pressure is less than or equal to the High Inspiratory Pressure alarm setting.

For pressure modes, the alarm occurs when the delivered pressure exceeds the target patient pressure by 5 cm H_2O or more during the inspiratory phase. The device will automatically cycle to the expiratory phase and continue to operate. The alarm will automatically terminate when the delivered pressure falls within 5 cm H_2O of the target patient pressure during the inspiratory phase.

Low Inspiratory Pressure Alarm

This is a high priority alarm. It is detected differently for volume and pressure therapy modes.

For volume modes, the alarm will sound if the measured patient pressure is less than the Low Inspiratory Pressure setting specified by the clinician. The alarm will automatically terminate when the peak pressure at the end of the breath is greater than or equal to the Low Inspiratory Pressure alarm setting.

For pressure modes, the alarm occurs when the delivered pressure is 5 cm H_2O or more below the target patient pressure during the inspiratory phase. The alarm will automatically terminate when the delivered pressure comes within 5 cm H_2O of the target patient pressure during the inspiratory phase.

High Minute Ventilation Alarm

This alarm is a high priority alarm. It occurs when the patient's minute ventilation is greater than the High Minute Ventilation alarm setting. The device continues to operate. The alarm will automatically terminate when the calculated minute ventilation is less than the High Minute Ventilation alarm setting.

Low Minute Ventilation Alarm

This alarm is a high priority alarm. It occurs when the patient's minute ventilation is less than the Low Minute Ventilation alarm setting. The device continues to operate. The alarm will automatically terminate when the calculated minute ventilation is greater than the Low Minute Ventilation alarm setting.

System Alarms

Loss of Power Alarm

This is a technical alarm condition that is treated as a high priority alarm. It may occur when a complete power failure has occurred and power was lost while the device was providing therapy. This may happen if the internal battery was the only power source in use and was completely depleted.

Ventilator Inoperative Alarm

This is a technical alarm condition that is treated as a high priority alarm. It occurs when the ventilator detects an internal error or a condition that may affect therapy. The device will shut down if the cause of the failure indicates that the device cannot deliver therapy safely. If the device can deliver therapy at a limited level, the device will continue to deliver limited therapy.

Ventilator Service Required Alarm

This is a high priority alarm. It occurs when the device cannot perform to specification, a backup safety feature is compromised, or the delivery of therapy is compromised. The device continues to operate (possibly in a reduced capacity mode). If the problem is not corrected, the device will generate a reminder message once per hour until the issue is corrected. Additionally, if therapy is stopped, a reminder message will immediately appear when therapy is turned on again.

High Temperature Alarm

This alarm occurs when the estimated patient airstream temperature or the ventilator internal temperature is too high. The alarm occurs in several stages. The ventilator continues to operate. Internal fans are started when the medium priority alarm is generated. If the condition causing the high temperature is not corrected and the temperature continues to rise, the alarm will escalate to the high priority alarm.

Low Battery Alarm

The Low Battery alarm occurs when the last battery available is low or nearly depleted. This alarm occurs in two stages. When approximately 20 minutes of battery run time remains, a medium priority alarm is generated, and the device continues to operate. If no action is taken and the battery continues to deplete, the alarm escalates to a high priority alarm when approximately 10 minutes of battery run time remains.

Replace Detachable Battery Alarm

The Replace Detachable Battery alarm occurs when the detachable battery is nearing the end of its useful life or a failure in the detachable battery that prevents it from charging or discharging has been detected.

The alarm occurs in several stages, from low to high priority. The device continues to operate when the alarm is the low priority alarm. If the alarm is reset without removing the battery, the alarm will be regenerated once every hour until the detachable battery is removed. The device continues to operate, the detachable battery is not used, and the power source is switched to the next available power source if the alarm is the high priority alarm.

AC Power Disconnected Alarm

This is a medium priority alarm. It occurs when the AC power source was lost, and the device has switched to an alternate power source (either a detachable or external battery, if connected, or the internal battery if no other source is available). The device continues to operate. If AC power returns, the ventilator will beep, but no message will appear on the display.

Keypad Stuck Alarm

This is a low priority alarm. It occurs when a key becomes lodged inside the case of the device.

Informational Messages

Battery Discharging Stopped due to Temperature

This info message occurs when the detachable or internal battery becomes overheated while providing power for the device. The device continues to operate. The battery is not used and the power source is switched to the next available power source.

Battery Not Charging due to Temperature

This info message occurs when the detachable or internal battery becomes too hot while charging or the device was in too cold an environment before charging started. The device continues to operate. Battery charging stops until the battery cools or warms sufficiently.

Battery Not Charging

This info message occurs when the device has detected an error condition with the battery that prevents it from accepting a charge. The device continues to operate. Battery charging stops.

Check External Battery

This info message occurs when a bad connection exists to the external battery or the external battery failed. The device continues to operate using power from the detachable battery, if available, or the internal battery.

Battery Depleted

This info message occurs when the affected battery is fully depleted. The device continues to operate using the next available power source.

External Battery Disconnected

This info message occurs when the external battery power source is lost and the device has switched to an alternate power source (either a detachable battery, if connected, or the internal battery if no other source is available). If external battery power returns, the ventilator will beep, but no message will appear on the display.

Detachable Battery Disconnected

This info message occurs when the detachable battery power source is lost and the device has switched to an alternate power source (the internal battery if no other source is available). If detachable battery power returns, the ventilator will beep, but no message will appear on the display.

Start On Battery

This info message indicates that the ventilator has started on battery power and no AC power is available. The device operator should verify that this is what is wanted.

Card Error

This info message occurs when an unusable SD card is inserted into the ventilator. The device continues to operate but data cannot be logged onto the SD card.

Alarm Summary Table

The Alarm Summary Table in this addendum replaces the information regarding alarms under "Alarm Summary Table" in Chapter 6 of the Trilogy manual. The following tables summarize all of the Patient alarms, System alarms, and Informational messages and what to do if an alarm occurs. There are three types of alarms:

- High Priority – Require immediate response by the operator
- Medium Priority – Require prompt response by the operator
- Low Priority – Require operator awareness. These alarms alert to a change in the ventilator status.

The ventilator also displays informational messages and confirmation alerts that notify the user of conditions that need attention but do not qualify as alarm conditions.

Patient Alarms

Alarm	Priority	Audible	Visual (Alarm Indicator Button and Display)	Device Action	User/Clinician Action
Check Circuit	High	• • • • •	Red flashing button; "Check Circuit" message	Operates	**User**: Press Alarm Indicator/Audio Pause button to silence alarm. Or, press Left (Reset) button to reset alarm. Make certain the circuit type matches what is selected in the Setup Menu. Make sure there is no kinked or pinched tubing. Make sure tubing is properly attached. Make sure all tubing and exhalation devices are clean and free of condensation (refer to the Troubleshooting section - tubing condensation). If using Active PAP or Active Flow Exhalation Device, make sure diaphragm is inserted correctly and is not wrinkled or kinked. If alarm continues, contact your health care professional. **Clinician**: Verify patient status. Verify that breathing circuit setup is correct. Correct any errors. If alarm continues, have device serviced.
Low Circuit Leak	High	• • • • •	Red flashing button; "Low Circuit Leak" message	Operates	**User**: Press Alarm Indicator/Audio Pause button to silence alarm. Or, press Left (Reset) button to reset alarm. Check for occlusions in exhalation devices. Make sure exhalation device is clean and functioning properly. Refer to the Troubleshooting section if Low Circuit Leak alarm is sounding during nebulizer treatments. If alarm continues, contact your health care professional. **Clinician**: Remove obstruction in leak device. If alarm continues, have the device serviced.
High Expiratory Pressure	High	• • • • •	Red flashing button; "High Expiratory Pressure" message	Operates	**User**: Press Alarm Indicator/Audio Pause button to silence alarm. Or, press Left (Reset) button to reset alarm. Make sure tubing is not kinked or pinched. Check patient's breath rate. If alarm continues, contact your health care professional. **Clinician**: Check patient's tubing to make sure it is not kinked or pinched. If alarm continues, have device serviced.
Low Expiratory Pressure	High	• • • • •	Red flashing button; "Low Expiratory Pressure" message	Operates	**User:** Press Alarm Indicator/Audio Pause button to silence alarm. Or, press Left (Reset) button to reset alarm. Make sure tubing is not kinked or pinched. If alarm continues, contact your health care professional. **Clinician**: Check patient's tubing to make sure it is not kinked or pinched. If alarm continues, have device serviced.

Alarm	Priority	Audible	Visual (Alarm Indicator Button and Display)	Device Action	User/Clinician Action
High Oxygen Flow ***Note:*** *Trilogy202 only.*	High	• • • • •	Red flashing button; "High Oxygen Flow" message	Operates	Check hose from oxygen source to device. Check oxygen source. The oxygen source should not restrict flow - nominal up to 175 SLPM. If problem continues, contact Philips Respironics or an authorized service representative. Please have the the device model number and serial number information when you call.
Low Oxygen Flow ***Note:*** *Trilogy202 only.*	High	• • • • •	Red flashing button; "Low Oxygen Flow" message	Operates	Check hose from oxygen source to device. Check oxygen source. The oxygen source should not restrict flow - nominal up to 175 SLPM. If problem continues, contact Philips Respironics or an authorized service representative. Please have the the device model number and serial number information when you call.
High Oxygen Inlet Pressure ***Note:*** *Trilogy202 only.*	High	• • • • •	Red flashing button; "High Oxygen Inlet Pressure" message	Operates	Check oxygen source. The oxygen input must be 40-87 psi. If problem continues, contact Philips Respironics or an authorized service representative. Please have the the device model number and serial number information when you call.
Low Oxygen Inlet Pressure ***Note:*** *Trilogy202 only.*	High	• • • • •	Red flashing button; "Low Oxygen Inlet Pressure" message	Operates	Check hose from oxygen source to device. Check oxygen source. The oxygen input must be 40-87 psi. If problem continues, contact Philips Respironics or an authorized service representative. Please have the the device model number and serial number information when you call.
Circuit Disconnect	High	• • • • •	Red flashing button; "Circuit Disconnect" message	Operates	**User**: Press alarm indicator/audio pause button to silence alarm. Or, press left (reset) button to reset alarm. Check breathing circuit and reconnect it if it has become disconnected, or fix the leak. If it is already connected, check for a possible occlusion in the airway. If alarm continues to occur, contact your healthcare professional. If device will not exit circuit disconnect, switch to an alternate source of ventilation. **Clinician**: Reconnect tubing, fix leak, or clear airway obstruction. If alarm continues, have device serviced.

Alarm	Priority	Audible	Visual (Alarm Indicator Button and Display)	Device Action	User/Clinician Action
Apnea	High	• • • • •	Red flashing button; "Apnea" message	Operates	**User**: Press Alarm Indicator/Audio Pause button to silence alarm. Or, press Left (Reset) button to reset alarm. Continue using device. If using an Active PAP or Active Flow circuit, check proximal pressure line to ensure it is not pinched or has water condensation (refer to the Troubleshooting section – tubing condensation). If alarm continues, contact your health care professional. **Clinician**: Verify patient status.
High Vte	High	• • • • •	Red flashing button; "High Vte" message	Operates	**User**: Press Alarm Indicator/Audio Pause button to silence alarm. Or, press Left (Reset) button to reset alarm. Continue using device. If alarm continues, contact your health care professional. **Clinician**: Verify patient status.
Low Vte	High	• • • • •	Red flashing button; "Low Vte" message	Operates	**User:** Press Alarm Indicator/Audio Pause button to silence alarm. Or, press Left (Reset) button to reset alarm. Continue using device. If alarm continues, contact your health care professional. **Clinician**: Verify patient status.
High Vti	High	• • • • •	Red flashing button; "High Vti" message	Operates	**User:** Press Alarm Indicator/Audio Pause button to silence alarm. Or, press Left (Reset) button to reset alarm. Continue using device. If alarm continues, contact your health care professional. **Clinician**: Verify patient status.
Low Vti	High	• • • • •	Red flashing button; "Low Vti" message	Operates	**User:** Press Alarm Indicator/Audio Pause button to silence alarm. Or, press Left (Reset) button to reset alarm. Continue using device. If alarm continues, contact your health care professional. **Clinician**: Verify patient status.
High Respiratory Rate	High	• • • • •	Red flashing button; "High Respiratory Rate" message	Operates	**User:** Press Alarm Indicator/Audio Pause button to silence alarm. Or, press Left (Reset) button to reset alarm. Continue using device. If alarm continues, contact your health care professional. **Clinician**: Verify patient status.

Alarm	Priority	Audible	Visual (Alarm Indicator Button and Display)	Device Action	User/Clinician Action
Low Respiratory Rate	High	• • • • •	Red flashing button; "Low Respiratory Rate" message	Operates	**User:** Press Alarm Indicator/Audio Pause button to silence alarm. Or, press Left (Reset) button to reset alarm. Continue using device. If alarm continues, contact your health care professional. **Clinician**: Verify patient status.
High Inspiratory Pressure	Escalates from Audible indicator to Medium priority and then High priority	• (for first two consecutive occurrences) • • • (for 3rd consecutive occurrence) • • • • • (for 10th consecutive occurrence)	Peak Pressure symbol turns red. When condition first occurs, a beep will sound. When condition occurs for third time, button flashes yellow and yellow "High Inspiratory Pressure" message appears. When condition occurs for 10th time, button flashes red and red "High Inspiratory Pressure" message appears.	Operates	**User**: Press Alarm Indicator/Audio Pause button to silence alarm. Or, press Left (Reset) button to reset alarm. Make sure tubing is not pinched or blocked. If alarm continues, contact your health care professional. **Clinician**: Verify patient status. If problem continues, have device serviced.
Low Inspiratory Pressure	High	• • • • •	Red flashing button; "Low Inspiratory Pressure" message	Operates	**User**: Press Alarm Indicator/Audio Pause button to silence alarm. Or, press Left (Reset) button to reset alarm. Check patient circuit for leaks or disconnects. If using an Active PAP or Active Flow circuit, check proximal lines to ensure they are not pinched or have water condensation (refer to the Troubleshooting section – tubing condensation). If alarm continues, contact your health care professional. **Clinician**: Verify patient status. If problem continues, have device serviced.
High Minute Ventilation	High	• • • • •	Red flashing button; "High Minute Ventilation" message	Operates	**User**: Press Alarm Indicator/Audio Pause button to silence alarm. Or, press Left (Reset) button to reset alarm. Continue using device. If alarm continues, contact your health care professional. **Clinician**: Verify patient status.
Low Minute Ventilation	High	• • • • •	Red flashing button; "Low Minute Ventilation" message	Operates	**User:** Press Alarm Indicator/Audio Pause button to silence alarm. Or, press Left (Reset) button to reset alarm. Continue using device. If alarm continues, contact your health care professional. **Clinician**: Verify patient status.

System Alarms

Alarm	Priority	Audible	Visual (Alarm Indicator Button and Display)	Device Action	User/Clinician Action
Loss of Power	Technical High	• •	Red flashing button; Blank screen	Shuts down	**User**: Press Start/Stop button and then press Right button to silence alarm. If using AC power, try plugging device into alternate AC power source. If loss of power continues, switch to DC power by connecting a fully charged detachable or external battery to the device. If there is still no power, connect patient to alternate source of ventilation and contact your health care professional. **Clinician**: Restore AC power. If alarm continues, connect a fully charged detachable or external battery to device to restore power. If alarm still continues, have the device serviced.
Ventilator Inoperative	Technical High	[redacted]	Red flashing button; "Ventilator Inoperative" message	Shuts down if can't provide therapy safely. Or, continues to operate at a limited level.	**User**: Press Start/Stop button. If display is operational, Power Off confirmation screen appears. Select Right button to shut off device and silence alarm. Immediately remove patient from ventilator and connect them to alternate source of ventilation. Contact your health care professional for service. **Clinician**: Restore power. If alarm continues, have the device serviced.
Ventilator Service Required	High	• • • • •	Red flashing button; "Ventilator Service Required" message	Operates	**User**: Press Alarm Indicator/Audio Pause button to silence alarm. Or, press Left (Reset) button to reset alarm. The alarm goes away until next reminder appears. Connect patient to alternate source of ventilation and contact your health care professional as soon as possible. **Clinician**: If alarm continues, have the device serviced.
High Temperature	Escalates from Medium to High	• • • for Medium • • • • • for High	Yellow flashing button and yellow "High Temperature" message appears. If condition worsens, button flashes red and red "High Temperature" message appears.	Operates	**User**: Press Alarm Indicator/Audio Pause button to silence alarm. Or, press Left (Reset) button to reset alarm. Make sure device is not close to a heat source. Make sure tubing is not under any bedding. Check inlet filter and clean or replace it if needed. Make sure cooling vents are not blocked. If the ventilator is running off of the internal or detachable battery, move to a cooler location and/or power the device with AC power or a lead-acid battery. If alarm continues, place patient on alternate source of ventilation and contact your health care professional. **Clinician**: If alarm continues after the measures above have been taken, have device serviced.

Alarm	Priority	Audible	Visual (Alarm Indicator Button and Display)	Device Action	User/Clinician Action
Low Battery	Escalates from Medium to High	• • • (Medium - when approx. 20 minutes remains) • • • • • (High - when approx. 10 minutes remains)	Medium Priority-Yellow flashing button. "Low Detachable Battery," "Low External Battery," or "Low Internal Battery" message appears in yellow, On Status Panel, box around battery is yellow High Priority-Red flashing button. "Low Detachable Battery", "Low External Battery," or "Low Internal Battery" message appears in red. On Status panel, box around battery is red	Operates	**User**: Press Alarm Indicator/Audio Pause button to silence alarm. Or, press Left button (Reset) to reset alarm. Switch to an alternate battery. Or, switch to AC power source and recharge low battery. **Clinician**: Switch to alternate battery or AC power while you recharge low battery. If low battery is recharged and alarm continues, replace battery.
Replace Detachable Battery	Low or High, depending on cause of alarm	• • for Low • • • • • for High	"Replace Detachable Battery" message appears. If battery is nearing end of useful life, message appears with yellow background and button is solid yellow. If battery fails, message appears with red background and button flashes red.	Operates	**User**: Press Alarm Indicator/Audio Pause button to silence alarm. Or, press Left button (Reset) to reset alarm. Switch to an alternate battery or AC power source while replacing current detachable battery. **Clinician**: Switch to an alternate battery or AC power source while replacing the current detachable battery.
AC Power Disconnected	Medium	• • •	Yellow flashing button; "AC Power Disconnected" message, and a box appears around battery in use.	Switches to alternate power source	**User**: Press Alarm Indicator/Audio Pause button to silence alarm. Or, press Left (Reset) button to reset alarm. If you were using AC power, check power cord and reconnect it if it has become disconnected. Make sure device is not connected to an overloaded AC circuit. If you were using an external, detachable, or internal battery, recharge the battery. **Clinician**: Check batteries and recharge if necessary. Restore AC power if available.
Keypad Stuck	Low	• •	Solid yellow button; "Keypad Stuck" message.	Operates	**User**: Press Alarm Indicator/Audio Pause button to silence alarm. Or, press Left (Reset) button to reset alarm. Check the keys to determine if they are lodged in the case. If alarm continues, place patient on alternate source of ventilation and contact your health care professional. **Clinician**: Check keys to determine if they are lodged in the case. If alarm continues, place patient on alternate source of ventilation and have device serviced.

Informational Messages

Alarm	Priority	Audible	Visual (Alarm Indicator Button and Display)	Device Action	User/Clinician Action
Battery Discharging Stopped Due to Temperature	Info	•	"Batt Discharge Stopped - Temp." message	Operates	**User**: Press Alarm Indicator/Audio Pause button to silence alarm. Or, press Left (Reset) button to reset alarm. Move device to a cooler location. Make sure device is not close to a heat source. Make sure cooling vents are not blocked. If alarm is detected for internal battery and continues, place patient on alternate source of ventilation and contact your health care professional. **Clinician**: If alarm is detected on the internal battery and continues after the measures above have been taken, place patient on alternate source of ventilation and have device serviced.
Battery Not Charging Due to Temperature	Info	•	"Batt Not Charging - Temp." message	Operates	**User**: Press Alarm Indicator/Audio Pause button to silence alarm. Or, press Left (Reset) button to reset alarm. Make sure device is not close to a heat source. Make sure cooling vents are not blocked. Move device to a cooler location. If device is too cold, allow it to warm up. If alarm continues, place patient on alternate source of ventilation and contact your health care professional. **Clinician**: If alarm continues after the measures above have been taken, place patient on alternate source of ventilation and have device serviced
Battery Not Charging	Info	•	"Detach Battery Not Charging" or "Internal Battery Not Charging" message	Operates	**User**: Press Alarm Indicator/Audio Pause button to silence alarm. Or, press Left (Reset) button to reset alarm. If condition continues for internal battery, place patient on alternate source of ventilation and contact your health care professional. **Clinician**: If condition continues for internal battery, place patient on alternate source of ventilation and have device serviced.
Check External Battery	Info	•	"Check External Battery" message	Operates	**User**: Press Alarm Indicator/Audio Pause button to silence alarm. Or, press Left (Reset) button to reset alarm. Check connection to external battery. Replace external battery with another external battery, if available. If alarm continues, place patient on alternate source of ventilation and contact your health care professional. **Clinician**: If the alarm continues after the measures above have been taken, place patient on alternate source of ventilation and have device serviced.

Alarm	Priority	Audible	Visual (Alarm Indicator Button and Display)	Device Action	User/Clinician Action
Battery Depleted	Info	•	"External Battery Depleted" or "Detachable Battery Depleted" message appears	Operates	**User**: Press Alarm Indicator/Audio Pause button to silence alarm. Or, press Left (Reset) button to reset alarm. Replace depleted battery with another or switch to AC power, if available. **Clinician**: Replace depleted battery with another or switch to AC power.
External Battery Disconnected	Info	•	"External Batt Disconnected" message, and a box appears around battery in use.	Switches to alternate power source	**User**: Check connection of the external battery to ventilator. Check the charge available on external battery and recharge battery if necessary. **Clinician**: Check external battery and recharge if necessary. Restore AC power if available.
Detachable Battery Disconnected	Info	•	"Detachable Batt Disconnected" message, and a box appears around battery in use.	Switches to alternate power source	**User**: Check connection of the detachable battery to ventilator. Check the charge available on detachable battery and recharge battery if necessary. **Clinician**: Check detachable battery and recharge if necessary. Restore AC power if available.
Start On Battery	Info	•	"Start On Battery" message appears.	Operates	**User**: Check battery status and determine how long device can operate on battery power. Find AC power source as soon as possible. **Clinician**: Restore AC power when available. If alarm continues, replace AC power cord to determine if there is a problem with the cord.
Card Error	Info	•	A "Card Error" message appears.	Operates	**User**: Press Alarm Indicator/Audio Pause button to silence alarm. Or, press Left button (Reset) to reset alarm. Remove SD Card and use another card, if available. Check the write-protect switch on the card. If condition persists, contact your health care professional. **Clinician**: Remove SD Card and use another card, if available. Ensure card meets specifications. Check write-protect switch on card. If condition persists, contact an authorized representative of Philips Respironics.

AVAPS-AE Therapy

Information on AVAPS-AE in this addendum replaces information presented in previous Trilogy manual instructions and addendum.

AVAPS-AE is a Bi-level therapy mode that automatically adjusts Expiratory Positive Airway Pressure (EPAP), Pressure Support, and the backup breath rate. AVAPS-AE monitors the resistance in the patient's upper airway and adjusts EPAP automatically to maintain a patent airway. AVAPS-AE mode also monitors delivered tidal volumes and automatically adjusts pressure support to maintain the designated target tidal volume. AVAPS-AE also has the ability to automatically set and maintain a backup breath rate (max 20) based on the patient's own spontaneous breathing rate. AVAPS-AE is intended for non-invasive applications only.

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

AVAPS-AE is enabled in the Settings and Alarms Screen. When in AVAPS-AE mode, the AVAPS feature is always enabled. Similar to AVAPS, AVAPS-AE supports tidal volumes from 50 to 2000 ml (in 5 ml increments).

The following new parameters should be set to ensure appropriate therapy delivery and maximize patient comfort:

- Maximum Pressure: When in AVAPS-AE mode, the Maximum Pressure delivered can be set from 6 to 50 cm H_2O in increments of 1. Settings lower than the maximum setting of 50 cm H_2O may limit other pressure settings.
- Pressure Support Max: When in AVAPS-AE mode, Pressure Support Max can be set from 2 to 40 cm H_2O in increments of 1. This setting may be limited by the Maximum Pressure setting and EPAP Min Pressure setting.
- Pressure Support Min: When in AVAPS-AE mode the minimum pressure support may be set from 2 to 40 cm H_2O in increments of 1. It may not exceed the Pressure Support Max setting. This setting may be limited by the Maximum Pressure or EPAP Max Pressure setting.
- EPAP Max Pressure: When in AVAPS-AE mode, the EPAP Max Pressure can be set from 4 to 25 cm H_2O in increments of 1. This setting cannot be lower than the EPAP Min Pressure and may be limited by the Maximum Pressure setting and Pressure Support Min setting.
- EPAP Min Pressure: When in AVAPS-AE mode, the EPAP Min Pressure can be set from 4 to 25 cm H_2O in increments of 1. This setting cannot exceed EPAP Max Pressure and may be limited by the Maximum Pressure setting and Pressure Support Min setting.
- Breath Rate: When in AVAPS-AE mode, the breath rate can be set from 0 (off) to 60 BPM. The breath rate can also be set to "Auto".

Note: *When "Auto" Breath Rate is selected, the Inspiratory Time will be set by the device and is not user settable.*

AVAPS-AE Troubleshooting

Question: Why can't I increase my Pressure Support Max to the full range of 40 cm H_2O?

Answer: Some settings, such as Pressure Support Max, can be limited by other pressure settings. For example, reducing the Maximum Pressure setting will impose the same reduction on the Pressure Support Max capability of the device. Increasing the EPAP Min Pressure will also reduce the Pressure Support Max that can be applied. You may have to modify one setting in order to extend the range of another setting.

Question: What happens if the device needs to increase EPAP but the Maximum Pressure setting has already been reached?

Answer: The EPAP will increase as high as the EPAP Max Pressure setting. The amount of Pressure Support applied may be reduced in order to reach the EPAP Max setting. Airway patency and hence the EPAP pressure will take precedence over Pressure Support in these situations.

Question: How does the Ramp function work when using AVAPS-AE?

Answer: Ramp: Activation of the Ramp Feature in AVAPS-AE will reset the EPAP setting to the EPAP Min Pressure and restart the Auto EPAP algorithm. Additionally, the Pressure Support will be reduced to the Pressure Support Min level and ramp as high as the Pressure Support Max, as required by the AVAPS algorithm, to allow for a comfortable transition to sleep.

Note: *If using AVAPS, the pressure support capability will ramp from the IPAP Min (or Pressure Support Min) to the IPAP Max (or Pressure Support Max).*

Viewing the Alarm Log

From the Main Menu screen, when you can select Alarm Log to access the Alarm Log screen, the alarm log displays the alarms in chronological order with the most recent events displayed first. Refer to Chapter 5 in the Trilogy manual for more information on viewing the alarm Log. The following notes regarding the Alarm Log are in addition to those presented in the Trilogy manual.

Note: *The alarm log will discard the oldest data when the alarm log becomes full.*

Note: *The contents of the alarm log will be maintained in the event of a total loss of power.*

Battery Function Verification

Test procedures should be performed by the clinician prior to connecting the device to the patient. The following instructions replace "Verify the External Battery Function (If Available)" under Battery Function Verification in Chapter 10 of the Trilogy manual.

2. Verify the External Battery Function (Optional)

A. Connect AC Power to the device and verify that the green AC LED is lit.

B. Connect the external battery cable to the external battery and to the ventilator.

C. Verify that the external battery symbol is shown on the display and some level of charge is present.

D. Disconnect the AC Power source from the device.

- Verify that the AC Power Disconnected alarm message appears on the display and the green AC LED is not lit. Press Reset.
- Verify that the external battery symbol shows the level of charge as noted in the previous step and the device continues to operate.
- Verify that the external battery symbol has a black box around it to indicate that it is in use.

E. Reconnect the AC Power source.

F. Disconnect the external battery from the ventilator.

- Verify the External Batt Disconnect message appears.
- Verify the external battery icon is no longer displayed.

Refer to Chapter 10 in the Trilogy manual for more information on System Checkout Procedures for your device.

Settings and Alarms Tests

Test procedures should be performed by the clinician prior to connecting the device to the patient. The following instructions are in addition to those under Settings and Alarms Tests in Chapter 10 of the Trilogy manual.

7. Low Respiratory Rate Alarm (Optional)

This procedure verifies that the Low Respiratory Rate alarm is working properly. It assumes you have attached the test lung, verified ventilator settings, and turned on ventilator power as described in the Initial Setup section.

A. Modify the Low Respiratory Rate alarm setting to match the value shown below.

Setting	Value
Low Respiratory Rate	15 BPM

B. Verify the Alarm.

Wait up to 40 seconds and verify the follow alarm signals:

- The High Priority audible indicator sounds
- A red light flashes on the Alarm indicator/Audio Pause button
- The Low Respiratory Rate alarm condition appears on the screen, highlighted in red

C. Modify Ventilator Alarm Settings.

Modify the Low Respiratory Rate alarm setting to match the one shown below:

Setting	Value
Low Respiratory Rate	10 BPM

D. Verify Reset.

Wait 40 seconds and verify the following auto-reset conditions:

- The High Priority audible indicator has stopped sounding
- The red light on the Alarm indicator/Audio Pause button has stopped flashing

Refer to Chapter 10 in the Trilogy manual for more information on System Checkout Procedures for your device.

Supplemental Oxygen (Optional)

The following information regarding supplemental oxygen is in addition to information presented in the Trilogy manual. Refer to Chapter 4 in the Trilogy EC, Trilogy100, and Trilogy200 manuals for more information on connecting supplemental oxygen to Trilogy.

Trilogy EC, Trilogy100, and Trilogy200 ventilators are compatible with a low flow oxygen source providing up to 15 l/min.

Note: *The following represents the ventilator response (in seconds) to an increase in oxygen concentration between 21 and 90%.*

Scenario	Time to 90%
500 ml	16.26 seconds
150 ml	16.42 seconds
50 ml	17.52 seconds

Note: *Trilogy202 is equipped with an oxygen blending module which allows oxygen to be delivered to the patient within a range of 21% to 100% concentration within +/- 5% with minimum total flow of 20 l/min.*

Oxygen Blending Module Warnings

The following warnings replace those in the section "Oxygen Blending Module Warnings" under Adding Supplemental Oxygen to the Device in Chapter 9 of the Trilogy202 manual.

- To ensure accuracy of oxygen administration and to monitor for the presence of contamination (incorrect gas connected), use an external oxygen monitor to verify the oxygen concentration in the delivered gas.
- This device is equipped with an oxygen blending module which allows oxygen to be delivered to the patient within a range of 21-100% concentration.
- Contents under pressure. Do not remove O_2 inlet retainer plate or O_2 inlet connecter while still connected to oxygen source.
- FiO_2 settings of less than 31% result in a Low Oxygen Flow alarm limit corresponding to the amount of oxygen in ambient air (21%). This may cause the alarm to not be generated if oxygen is no longer supplied. An external oxygen monitor to verify the oxygen concentration in the delivered gas is recommended in this instance.

Using a Remote Alarm Unit & Using a Nurse Call System

The following warning replaces the first Remote Alarm and Nurse Call warning in the section "Using a Remote Alarm Unit" in Chapter 9 of the Trilogy manual.

The remote alarm and nurse call system shall be tested daily and after each connection. When using a remote alarm, make sure you fully test the remote alarm connector and cable by verifying that:

- Annunciated alarms on the ventilator are also annunciated on the remote alarm.
- Disconnecting the remote alarm cable from the ventilator or from the remote alarm results in an alarm notification at the remote alarm.

Recommended Periodic Device Maintenance

The following information regarding periodic maintenance is in addition to information presented in the Trilogy manual. Refer to Chapter 7 in the Trilogy manual for more information on periodic maintenance for Trilogy.

Time / Hours of Service	Recommended Maintenance
Period of Use	43,800 hours of operation with preventative maintenance.

Electrical

The following specifications replace "AC Voltage Source" under Electrical in Chapter 11 of the Trilogy manual.

AC Voltage Source	100 - 240 VAC, 50/60 Hz, 2.1 - 1.0 A

Declared Dual-Number Noise Emissions Values

The following information is in addition to the Technical Specifications in Chapter 11 of the Trilogy manual.

The A-weighted sound pressure level	Device: 39.7 dB(A) with an uncertainty of 2 dB(A)
The A-weighted sound power level	Device: 47.6 dB(A) with an uncertainty of 2 dB(A)

Note: *Values determined according to noise test code given in ISO 80601-2-12, using the basic standards ISO 3744 and ISO 4871.*

Priority Alarm Sound Level Range Values

The following information is in addition to the Technical Specifications in Chapter 11 of the Trilogy manual.

The A-weighted alarm sound power level range	Medium Priority Alarm: 64.9 dB(A) to 92.9 dB(A) with an uncertainty of 2 dB(A) High Priority Alarm: 65.4 dB(A) to 92.2 dB(A) with an uncertainty of 2 dB(A)
The A-weighted alarm sound pressure level range	Medium Priority Alarm: 57.0 dB(A) to 85.0 dB(A) with an uncertainty of 2 dB(A) High Priority Alarm: 57.3 dB(A) to 84.3 dB(A) with an uncertainty of 2 dB(A)

Note: *Range values determined per IEC 60601-1-8.*

Pressure

The following specifications replace "Maximum Limited Pressure" under Pressure in Chapter 11 of the Trilogy manual.

Maximum Limited Pressure:	80 cm H_2O (Volume Mode)

Control Accuracy

The following information replaces "Pressure Support" and related notations under the Control Accuracy Table in Chapter 11 of the Trilogy manual.

Parameter	Range	Accuracy
Pressure Support	0 to 40 cm H_2O[3]	Greater of 2 cm H_2O or 8% of setting[4]

Note: *Tolerances listed in the Control Accuracy Table here and in the Trilogy manual have a measurement uncertainty of 3.60%.*

[3]The difference between the Inspiratory Pressure and the Expiratory Pressure must never be more than 40 cm H_2O.

[4]Pressure Support and PEEP not to exceed 50 cm H_2O.

Measured Patient Parameter

The following section replaces the table and information under the Measured Patient Parameter Table in Chapter 11 of the Trilogy manual.

Parameter	Range	Accuracy
Vte / Vti	0 to 50 ml > 50 ml to 2000 ml	Greater of 15 ml or 15% of reading +/- (4.0 ml + 15% of the actual delivered volume)
Minute Ventilation	0 to 99 l/min	Calculation based on measured Vte or Vti and Respiratory Rate
Estimated Leak Rate	0 to 200 l/min	N/A
Respiratory Rate	0 to 80 BPM	Greater of 1 BPM or 10% of reading
Peak Inspiratory Flow	0 to 200 l/min	3 l/min plus 15% of reading
Peak Inspiratory Pressure	0 to 99 cm H_2O	+ /- (2 cm H_2O + 4 % of the actual reading)
Mean Airway Pressure	0 to 99 cm H_2O	+ /- (2 cm H_2O + 4 % of the actual reading)
% Patient Triggered Breaths	0 to 100%	N/A
I:E Ratio	9.9 - 1:1 - 9.9	Calculation based on Inspiratory Time and Expiratory Time

Note: *Tolerances listed in the Measured Patient Parameter Table have a measurement uncertainty of 3.60%.*

All flows and volumes are measured at BTPS conditions.

Compliance, Inspiratory and Expiratory Resistance Characteristic Ratings for Standard Patient Circuits

The following table is in addition to the Technical Specifications in Chapter 11 of the Trilogy manual.

	Compliance (ml/cm H_2O)		
	Passive	Active PAP	Active Flow
Range	0.56 – 0.70	0.55 – 0.70	0.61 – 0.72

Flow Set Point (l/min)	Inspiratory Resistance (cm H_2O/l/s)			Expiratory Resistance (cm H_2O/l/s)		
	Passive	Active PAP	Active Flow	Passive	Active PAP	Active Flow
10	0	0	0.23	0	0	0.23
30	0.19	0.23	0.91	0.19	0.23	0.91
60	0.45	0.57	1.60	0.45	0.57	1.60
90	0.76	0.88	1.32	0.76	0.88	1.32
120	1.06	1.27	1.82	1.06	1.27	1.82

Standards Compliance

The following list of standards for compliance replaces information presented in Chapter 11 of the Trilogy manual instructions and previous Trilogy addendum.

- IEC 60601-1: Medical Electrical Equipment – Part 1: General requirements for safety
- IEC 60601-1-2: General Requirements for Safety – Collateral Standard: Electromagnetic compatibility – Requirements and tests
- IEC 60601-1-6: Medical Electrical Equipment – Part 1-6: General requirements for safety and essential performance – Collateral Standard: Usability
- IEC 60601-1-8: General Requirements for Safety – Collateral Standard: Alarm systems in medical electrical equipment and medical electrical systems
- IEC 60601-1-11: General Requirements for Safety and Essential Performance – Collateral Standard: Medical equipment and medical electrical systems used in the home healthcare environment
- IEC 62304: Medical Device Software – Software Lifecycle Processes
- IEC 62366: Medical Devices – Application of Usability Engineering to Medical Devices
- ISO 80601-2-12: Medical Electrical Equipment – Part 2-12: Particular requirements for basic safety and essential performance of critical care ventilators
- ISO 80601-2-61: Medical Electrical Equipment – Part 2-61: Particular requirements for basic safety and essential performance of pulse oximeter equipment
- ISO 80601-2-72: Medical Electrical Equipment – Part 2-72: Particular requirements for basic safety and essential performance of home healthcare environment ventilators for ventilator-dependent patients
- RTCA DO-160G Section 21, Category M; Emission of Radio Frequency Energy

Symbols Glossary

This is an addendum to the Trilogy manual. The following table defines symbols that may appear on this device or its included accessories and may be in addition to those presented elsewhere in this addendum or Trilogy manual. For more information, refer to http://www.symbols.philips.com for a description of the symbols used on this device and its packaging.

Symbol	Title and Meaning
	Refer to the instruction manual To signify that the instruction manual must be read.
	Prescription device Caution: U. S. federal law restricts this device to sale by or on the order of a physician.
	Approved for airline use.
	Non-ionizing electromagnetic radiation Indicates that the equipment includes RF transmitters.
	Catalogue number Indicates the manufacturer's catalogue number so the medical device can be identified.
	Serial number Identifies the manufacturer's serial number for the medical device.
	Batch code Indicates the manufacturer's batch code so that the batch or lot can be identified.
	Humidity limitation Indicates the range of humidity to which the medical device can be safely exposed.
	Temperature limit Indicates the storage temperature limits to which the medical device can be safely exposed.
	Manufacturer Indicates the medical device manufacturer.
	Date of manufacture Indicates the date when the medical device was manufactured.
	Class II equipment (Double Insulated) To identify equipment meeting the safety requirements specified for Class II equipment.
	Type BF applied part To identify a type BF applied part complying with IEC 60601-1.
	DC power (Direct current) Indicate on the rating plate that the equipment is suitable for direct current only; to identify relevant terminals.

Symbol	Title and Meaning
	AC power (Alternating current) Indicates on the rating plate that the equipment is suitable for alternating current only; to identify relevant terminals.
	Therapy on/off (Stand-by) Identifies the button to turn therapy on or off (puts the device in a stand-by condition).
	Unlocking Identifies on a control that a function is not locked
IOIOI	Serial Connection Identifies a connector for a serial data connection.
IP22	Drip Proof Equipment
	Audio Pause Indicates that an auditory alarm system is in the audio paused state.
	Remote Alarm (Loudspeaker) Identifies the connector for the remote alarm (loudspeaker).
	Secure Digital (SD) Card Slot
O_2	Oxygen Inlet To identify an input terminal when it is necessary to distinguish between inputs and outputs.
	Exhalation Valve Port Indicate where the active exhalation valve line connects.

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EMC Information

The following EMC information and its associated tables replace EMC content comtained in Chapter 13 of the Trilogy manual.

Your unit has been designed to meet EMC standards throughout its Service Life without additional maintenance. There is always an opportunity to relocate your device within an environment that contains other devices with their own unknown EMC behavior. If you believe your unit is affected by locating it closer to another device, simply separate the devices to remove the condition.

Pressure and Flow Accuracy

This therapy device is designed to perform within the pressure and flow rate accuracies specified in the user manual. If you suspect that the pressure and/or flow rate accuracy is affected by EMC interference remove power and relocate the device to another area. If performance continues to be affected discontinue use and contact your home care provider.

SpO_2 and Pulse Rate Accuracy

This therapy device is designed to capture the SpO_2 and Pulse Rate oximetry data within the accuracy specification described in the sensor manufacturer's instructions for use. When 4 hours of successful oximetry data have been achieved the device indicates this to the user by displaying "Oximetry: Good Study". If you suspect that your unit is affected by EMC interference remove power and relocate the device to another area. If performance continues to be affected discontinue use and contact your home care provider.

Guidance and Manufacturer's Declaration - Electromagnetic Emissions

This device is intended for use in the electromagnetic environment specified below. The user of this device should make sure it is used in such an environment.

Emissions Test	Compliance	Electromagnetic Environment - Guidance
RF radiated emissions CISPR 11	Group 1 Class B	The device uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Group 1 Class B	The device is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/Flicker emissions IEC 61000-3-3	Complies	
Emission of Radio Frequency Energy RTCA/DO-160G Section 21	Category M	This device is suitable for use onboard commercial airplanes inside passenger cabin.

Guidance and Manufacturer's Declaration - Electromagnetic Immunity

This device is intended for use in the electromagnetic environment specified below. The user of this device should make sure it is used in such an environment.

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment - Guidance
Electrostatic Discharge (ESD) IEC 61000-4-2	±8 kV contact discharges ±2 kV, ±4 kV, ±8 kV, and ±15 kV air discharges	±8 kV contact discharges ±2 kV, ±4 kV, ±8 kV, and ±15 kV air discharges	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 35%.
Electrical fast Transient/burst IEC 61000-4-4	±2 kV for power supply lines and ±1 kV for input-output lines; both at 100 kHz repetition rate.	±2 kV at 100 kHz repetition rate for power supply lines ±1 kV for input-output lines; both at 100 kHz repetition rate.	Mains power quality should be that of a typical home or hospital environment.
Surge IEC 61000-4-5	±1 kV differential mode ±2 kV common mode	±1 kV differential mode N/A - Device is Class 2 and does not have earth connection.	Mains power quality should be that of a typical home or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5% U_T (>95% dip in U_T) for 0.5 cycle at 45 degree increments <5% U_T (>95% dip in U_T) for 1 cycle 70% U_T (30% dip in U_T) for 0.5 seconds <5% U_T (>95% dip in U_T) for 5 seconds	<5% U_T (>95% dip in U_T) for 0.5 cycle at 45 degree increments <5% U_T (>95% dip in U_T) for 1 cycle 70% U_T (30% dip in U_T) for 0.5 seconds <5% U_T (>95% dip in U_T) for 5 seconds	Mains power quality should be that of a typical home or hospital environment. If the user of the device requires continued operation during power mains interruptions, it is recommended that the device be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical hospital or home environment.

NOTE: U_T is the a.c. mains voltage prior to application of the test level.

Guidance and Manufacturer's Declaration - Electromagnetic Immunity

This device is intended for use in the electromagnetic environment specified below. The user of this device should make sure it is used in such an environment.

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment - Guidance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms 150 kHz to 80 MHz	Portable and mobile RF communications equipment should be used no closer to any part of the device, including cables, than the recommended 12 inches (30 cm) separation distance. Interference may occur in the vicinity of equipment marked with the following symbol: 
	6 Vrms Amateur Radio & ISM Bands between 150 kHz and 80 MHz	6 Vrms Amateur Radio & ISM Bands between 150 kHz and 80 MHz	
Radiated RF IEC 61000-4-3	10 V/m 80 MHz to 2.7 GHz	10 V/m	
	Telecommunication frequencies as specified in clause 8.10 of IEC 60601-1-2		
	450, 810, 870, 930, 1720, 1845, 1970, and 2450 MHz at 28 V/m	28 V/m	
	385 MHz at 27 V/m	27 V/m	
	710, 745, 780, 5240, 5500, and 5785 MHz at 9 V/m	9 V/m	

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