NeoPAP Device User Manual

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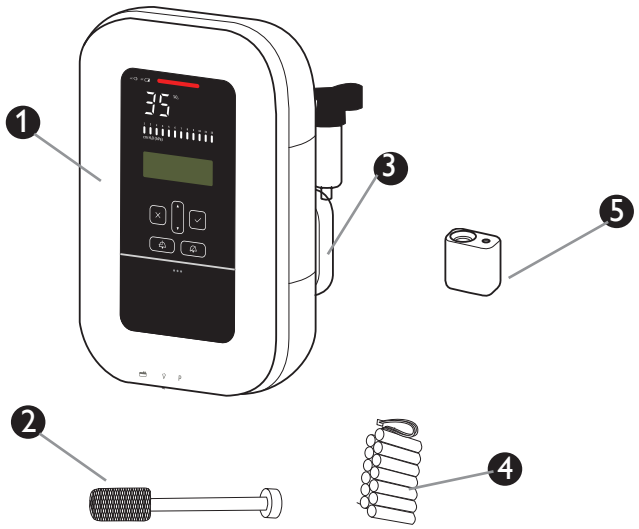
Chapter 1. Introduction

This chapter provides an overview of the NeoPAP device.

Package Contents

The NeoPAP system includes the following components:

1. NeoPAP Device
2. Oxygen sensor removal tool
3. Pole mounting bracket and cover (installed)
4. Internal battery
5. Start-up part
6. User Manual (CD-ROM) (not shown)
7. Fan filters (installed)
8. Quick start guide (not shown)
9. Two allen keys (not shown)
10. 22 mm shim for use with NeoPAP IV Pole (not shown)



The following accessories are required for operation of the system but packaged separately.

1. AC Power cord
2. Air and oxygen hoses and fittings
3. Oxygen sensor (not shown)

The following accessories are available and packaged separately:

1. Remote alarm cables
2. IV Pole

About NeoPAP

The NeoPAP Neonatal CPAP System provides breathing support for infants weighing less than 5 kg.

The NeoPAP Baby-Trak feature actively regulates pressure at all times, eliminating the need for a closely-fitted patient interface that can damage fragile tissues.

The NeoPAP System provides continuous positive airway pressure (CPAP) for use with a nasal cannula or mask. A compact patient interface allows the infant to move with minimal restriction.

The NeoPAP System also offers a constant flow mode and a resuscitation mode for use with resuscitation or hyperinflation bags as well as a stand-by mode to pause therapy to accommodate other patient procedures.

The NeoPAP System alarms when pressure levels or oxygen concentration are above or below alarm limits. The system also detects occlusion, disconnect, or other alarm conditions. The system displays a real-time bar graph that indicates delivered pressure.

The NeoPAP System includes alarm silence and alarm pre-silence features. Battery backup provides up to two hours of backup power in case AC power is not available (for example, during transport within the hospital).

Intended Use

Intended to provide CPAP (Continuous Positive Airway Pressure) for use in hospitals to treat newborns and infants with RDS (Respiratory Distress Syndrome) or who are recovering from RDS.

Symbols

Display and Front Panel

Symbol	Description
AC	AC Power Indicator
DC	DC Battery Indicator
✓	Save/Proceed Button
×	Cancel/Clear Button
	Up/Down Navigation Arrows
	Humidifier Cable Connector (future option)
	Delivery Tube Connector
P	Pressure Line Connector
	Power On/Off (also used to access Standby Mode)
	Resuscitation Button/Resuscitation Connection
	Alarm Reset Button
	Alarm Silence Button
	Alarm Indicator Bar
- / +	Decrease/Increase
	cmH_2O (hPa) display bars
	Heat (future option)

Rear and Side Panels

Symbol	Description
	Serial Interface Connector
	Type BF Applied Part
IPX1	Drip Proof Equipment

Symbol	Description
	Separate collection for electrical and electronic equipment per EC Directive 2002/96/EC
EC REP	European Representative
CE	European Declaration of Conformity
	Canadian/US Certification
	Refer to accompanying instructions for use
O_2	Oxygen Regulator
Air	Air Regulator
DC 	Internal Battery Door
	Oxygen Sensor Door

Patient Interface

Symbol	Description
EC REP	European Representative
	Caution! US federal law restricts this device to sale by or on the order of a physician
LOT	Lot Number
	BPA Free
REF	Reorder Number
CE	European Declaration of Conformity
	Consult Accompanying Instructions for Use
	DEHP Free
	Does not contain natural rubber latex
	Single Patient Use Only

Chapter 2. Warnings, Cautions, and Notes

Before using the Circadiance NeoPAP device on a patient, familiarize yourself with this user manual, particularly the safety considerations listed. This manual is a reference only. It is not intended to supersede your institution's protocol regarding the safe use of CPAP.

WARNING!

A warning indicates the possibility of injury to the user or operator.

CAUTION

A caution indicates the possibility of damage to the device.

NOTE

Emphasizes information of particular importance.

CAUTION! US federal law restricts this device to sale by or on the order of a physician.

General

WARNINGS!

- **For optimal oxygen sensor accuracy and occlusion alarm accuracy, the displayed pressure should be within 50 hPa (37.5 mmHg) of ambient atmospheric pressure. During startup the system displays the atmospheric pressure setting (for example, "Patm : 1010 hPa"). If the setting needs adjusted, use the configuration menu to enter the correct value.**
- **An alternative means of respiratory support should be available whenever the NeoPAP is in use. If a fault is detected in the device, disconnect the patient from it and immediately start respiratory support with such a device. The NeoPAP must be removed from clinical use and serviced by Circadiance authorized service personnel.**
- **All components of the patient interface are intended for single patient use only in a hospital environment; do not attempt to sterilize or reuse on a different patient. Follow all applicable federal and local regulations for disposal or recycling.**
- **This product has been validated under a range of simulated patient conditions for newborns and infants weighing less than 5 kg, and has not been validated for patients weighing more than 5 kg.**
- **Keep any sources of ignition as far as possible from the device when using oxygen-enriched gas.**
- **Be aware of the possibility of contamination from patient exhaled gases being exhausted into the room or incubator through the exhalation port.**
- **To avoid the risk of fire, use this device in a well-ventilated area away from**

flammable anesthetics. Do not use in a hyperbaric chamber or other similarly oxygen-enriched environments.

- **To reduce the risk of electric shock from liquid entering the device, do not put a container filled with a liquid on the NeoPAP device.**
- **The remote alarm should be considered a backup to the primary alarm system.**
- **To ensure that the alarm will be heard, make sure the alarm volume is adequate and avoid blocking the alarm speakers on the NeoPAP device.**
- **This device is not for use with intubated patients.**
- **Medical electrical equipment requires special precautions regarding electromagnetic compatibility (EMC) and must be installed and put into service according to the EMC information provided in this user manual (see Appendix A: EMC Information).**
- **Use only manufacturer-specified cables. Using cables other than those specified by Circadiance may result in increased magnetic emissions and/or decreased electro-magnetic immunity of the NeoPAP System.**
- **Do not use this device close to MRI or high-frequency devices, such as electro surgery or diathermy equipment.**
- **Do not use this device with anesthetic gases.**
- **Do not use flammable disinfectants on or near this device.**
- **Do not use antistatic or conductive hoses or conductive patient tubing with the device.**
- **Before using the NeoPAP System on a patient, allow the device to acclimate to conditions of use following transport or storage.**
- **The NeoPAP CPAP device has been validated for use only with the NeoPAP patient interface and is not compatible for use with patient interfaces from other manufacturers.**
- **The NeoPAP patient interface accessories have been validated for use only with the NeoPAP CPAP device and are not compatible for use with CPAP devices from other manufacturers.**
- **The NeoPAP device and patient interface has been validated for use with the following humidifiers:**
  - **Fisher & Paykel MR850 Humidifier and Fisher & Paykel RT324 Breathing Circuit at NeoPAP CPAP settings of 4 to 10 cmH_2O and NeoPAP Flow mode settings of 5 to 7 L/min.**
  - **Hudson RCI ConchaTherm Neptune Heater Humidifier (REF 385-40) and Universal Neonatal Breathing Circuit (REF 780-01) at NeoPAP CPAP settings of 2 to 10 cmH_2O and NeoPAP Flow mode settings of 3 to 7 L/min.**

CAUTIONS

- Because the device calibrates the oxygen sensor cell on start up, it is important to

power on the device in the ambient operating conditions of use.

- To minimize the risk of overheating the device, do not operate adjacent to heaters.

NOTES

- This product has been validated for patient inspiratory flows of up to 5 L/min.
- Always use a pulse oximeter to monitor patient oxygen saturation when using the NeoPAP System to deliver CPAP therapy to the patient.
- The NeoPAP nasal mask and cannula are shipped clean, ready to use.

Setup

- **WARNINGS!**
- **Connect the NeoPAP to an appropriate medical-grade oxygen source only. The source must be able to deliver 100% oxygen regulated from 276 to 600 kPa (40 to 87 psig).**
- **To reduce the risk of hypoxia, connect only oxygen to the high pressure oxygen connector at the rear of the NeoPAP.**
- **To reduce the risk of fire, do not use a high-pressure oxygen hose that is worn or contaminated with combustible material like grease or oil.**
- **Always check the status of the air and oxygen cylinders before using the NeoPAP during transport.**
- **Do not block or otherwise try to seal the exhalation ports at the delivery circuit/patient interface connection. Rebreathing of exhaled air for longer than several minutes, in some circumstances, may lead to suffocation.**
- **Use only manufacturer-supplied or specified delivery tubes with the patient interface.**
- **Potential side effects of nasal CPAP therapy include pneumothorax, nasal obstruction, gastric distention, nasal necrosis, and necrosis of the nasal septum.**
- **To avoid the possibility of damage to the infant's septum, the infant should be checked regularly to ensure all connections, including the mask and/or prong position, are secure. Ensure that the infant's nose is not pushed upwards, and that the nasal area is clean and dry. Gentle massage may be useful to stimulate circulation to the infant's tissues.**
- **Ensure that the bonnet fits over the infant's forehead, covering the ears, which should lie flat against the infant's head. The infant's eyes should be clearly visible.**
- **To reduce the risk that the patient will aspirate condensed water from the breathing circuit, position any humidifier lower than both the NeoPAP device and the patient.**
- **Only use supplied gas fitting that are connected to the regulators. Do not attempt to remove the fittings.**
- **Only use hoses whose gas fittings correspond to the gas connectors installed on the NeoPAP System.**
- **Any additional accessories in the patient interface may substantially increase flow resistance and impair respiratory support.**
- **To prevent unintentional disconnection of the power cord, always use the correct manufacturer-supplied power cord and lock it into place with the power cord clamp before turning on the NeoPAP. The clamp is designed to**

hold the connector end of the supplied cord securely in place.

- **To reduce the risk of electric shock, regularly inspect the AC power cord and verify that it is not frayed or cracked.**
- **A potential hazard can exist if different alarm presets are used in the same or similar equipment in any single area (e.g., ICU).**
- **To reduce the risk of power failure, monitor the battery's charge level. The battery's operation time is approximate and is affected by NeoPAP settings, discharge and recharge cycles, battery age, and ambient temperature. Battery charge is reduced at low ambient temperatures or in situations where the alarm is continuously sounding.**

CAUTIONS

- Ensure that any pole used to support the NeoPAP System can maintain 6 kg (13.2 lb.) at a height of 1.5 m (59 in.) at a tilt of 10 degrees to the vertical axis.
- To prevent possible damage to the NeoPAP, always secure it to its stand. The NeoPAP System should not be used adjacent to or stacked with other equipment. If adjacent use is necessary, the NeoPAP System should be observed to verify normal operation.

Operation

CAUTION

- Never attempt to disconnect or connect the battery during operation as it has the potential to damage the device.

Alarms and Messages

WARNING! If AC power fails and the backup battery is depleted, an audible and visual alarm annunciates for at least 2 minutes. Immediately discontinue use and use an alternative means of respiratory support.

Care and Maintenance

WARNING! To reduce the risk of fire, explosion, leakage, or other hazard, take these precautions with respect to the battery:

- **Do not attempt to disassemble, open, drop, crush, bend or deform, insert foreign objects into; puncture, or shred the battery pack; modify or remanufacture it; immerse or expose it to water or other liquids; expose it to fire, excessive heat (including soldering irons); or put it in a microwave oven.**
- **Do not attempt to connect incorrectly.**
- **Replace the battery only with another battery specified by the manufacturer.**
- **Follow all instructions for proper use of the battery.**
- **Do not short-circuit the battery or allow metallic or conductive objects to contact the battery connector housing.**
- **Use the battery with the Circadiance NeoPAP only.**

CAUTIONS

- Do not attempt to sterilize or autoclave the NeoPAP.
- To prevent possible damage to the user interface, take care when cleaning it. After cleaning and rinsing, remove all moisture with a dry, soft cloth. Never clean the user interface with an abrasive brush or device, since this will cause irreparable damage.
- To avoid introducing foreign matter into the NeoPAP and to ensure proper system performance, change the air inlet filter at regular intervals. See *Chapter 7: Maintenance.*
- To ensure proper system performance, only use Circadiance-approved fan filters.
- Because some environments cause a quicker collection of lint and dust than others, inspect the filters more often when needed.
- To prevent possible damage to the NeoPAP, always ship it with the original packing material. If the original material is not available, contact Circadiance to order replacements.
- Service, including repair and modification, on this device should only be performed by qualified service technicians. See the *Chapter 7: Maintenance* for user replaceable parts and instructions.

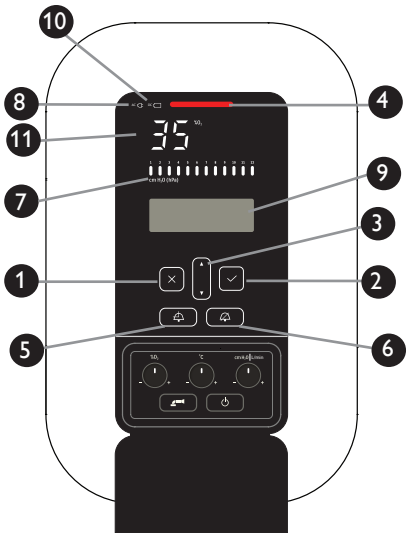
Warnings

- The NeoPAP delivery circuit adapter kit is intended solely for use with the Circadiance NeoPAP Neonatal CPAP System. The NeoPAP delivery circuit adapter kit is intended for single-patient use only in the hospital environment; do not attempt to sterilize or reuse on a different patient.
- Ensure that all gas path connections and the pressure line are secure prior to use on a patient.
- Do not block the inspiratory line safety valve during therapy delivery.
- Use only the NeoPAP patient interface with the delivery circuit adapter.

Chapter 3. System Description

This chapter describes the front, bottom, and rear device controls, connections, and features.

Front Panel Features



WARNING! To avoid damage to the user interface, do not use pens or other sharp objects to change settings.

The front panel contains the control buttons, visual indicators, and display screen.

Display Control Buttons

These buttons are used to navigate the display and change settings.

1. Clear

   Cancels a change that has not been accepted.

2. Accept/Proceed

   Selects a new configuration or proceeds to the next step.

3. Up/Increase and Down/Decrease

   Moves sequentially backward/forward through the items in a screen or increases/decreases a numerical value.

Alarm Indicators and Buttons

4. Alarm Indicator Bar

   Located on the top center of the display, this indicator turns red and flashes when an alarm is active, whether or not alarm silence is in effect.

5. Alarm Reset

   Removes all active and auto reset alarms from display.

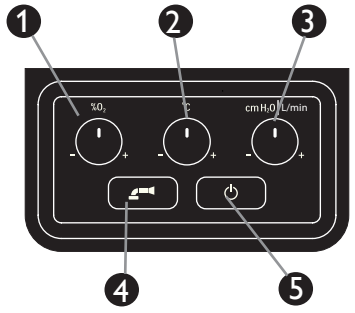
6. Alarm Silence

   Silences the audible portion of an alarm for two minutes.

NOTE: Each press of the SILENCE key restarts the two-minute silence interval. The SILENCE key indicator lights when the silence is active. The SILENCE key is also used for alarm pre-silence, which provides two minutes of silence if pressed when no alarm is active.

Display Features

7. Pressure Bar Graph - Lights to indicate measured patient pressure.
8. AC Power Indicator - Indicates the system is connected to AC power.
9. Message Window - Displays messages, settings, alarms, and prompts.
10. Battery - Indicates the internal battery is installed .
11. $\%O_2$ - Displays the measured $\%O_2$ of delivered gas. During disconnect and occlusion alarm conditions, or when the O_2 sensor is not installed, the $\%O_2$ window displays "- -".



NeoPAP System Setting Controls

1. %O_2 Setting Control

   Adjusts the %O_2 level from 21 to 100% O_2.

2. Temperature Setting Control (future option)

   Adjusts the temperature of the delivered gas from 33 to 41°C, when the NeoPAP is connected to a Circadiance external NeoPAP humidifier (future option).

3. Pressure/Flow Setting Control

   Adjusts the CPAP level from 2 to 10 cmH_2O (2 to 10 hPa) in CPAP mode.

   Adjusts the flow level from 3 L/min to 7 L/min in Flow mode.

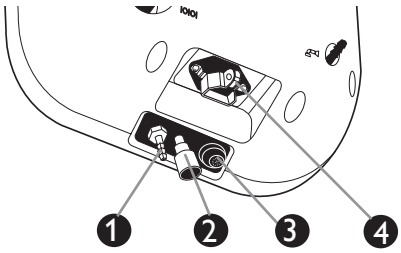
4. Resuscitation Button

   Turns resuscitation mode on and off.

5. Power On/Off and Standby Button

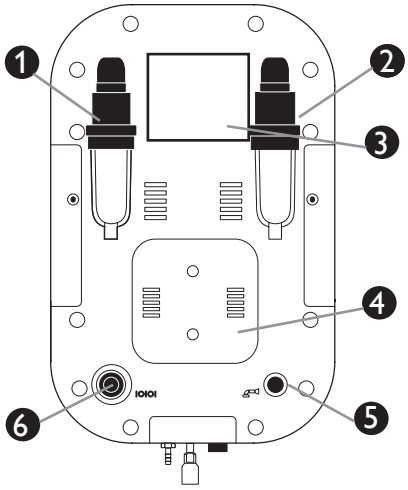
   Turns the system on and off. When pressed during operation, this button allows the user to select stand-by mode or power off the device.

Bottom Panel Features



1. P Pressure line connection.
2. Delivery tube connection.
3. Circadiance external NeoPAP humidifier cable connection (future option).
4. AC Power cord connection with retaining clamp.

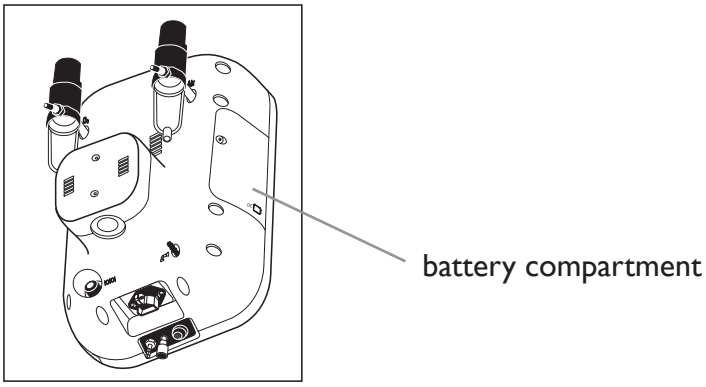
Rear Panel Features



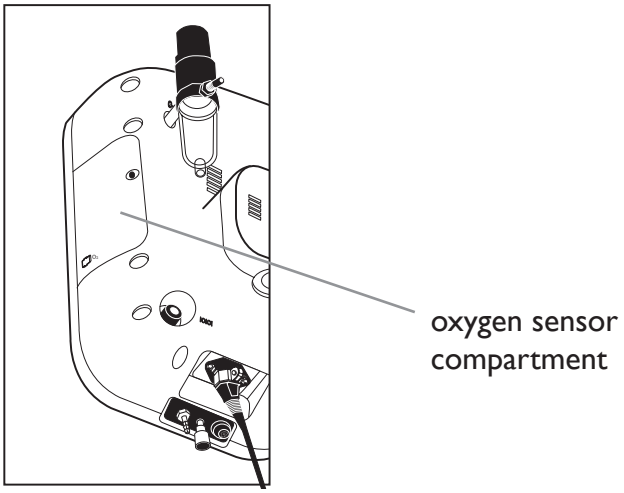
1. Oxygen supply connection (O_2)
2. Air supply connection (Air)
3. Rear Panel Label
4. IV Pole mounting bracket and cover
5. Resuscitation or Hyperinflation bag connection ( )
6. Serial Interface connection, including remote alarm connection (|○|○|)

Side Panel Features

1. Internal battery compartment.



2. Oxygen sensor compartment.



Power Sources

The NeoPAP System can access power from either an AC (wall or mains) power source or the internal battery. The internal battery supplies power to the system for two hours when AC power is not available. See "Connecting to Power" in *Chapter 4: Setup* later in this manual for information.

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Chapter 4. Setup

This chapter provides instructions on how to assemble the NeoPAP System. It includes the following setup information:

- Mounting
- Connecting to power
- Selecting menu items from the configuration menu
- Connecting to air and oxygen supplies
- Connecting a resuscitation or hyperinflation bag
- Connecting start-up part
- Connecting to a humidifier

Warnings

To avoid the risk of personal injury or equipment damage:

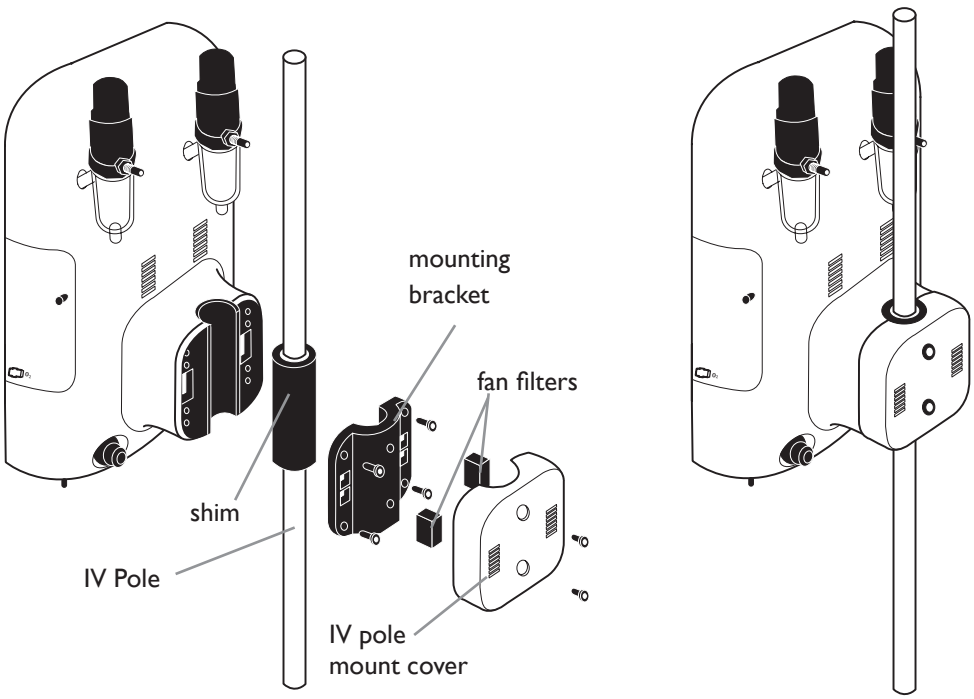
- Set up the device so that tubes, wires, and hoses do not pose a tripping hazard.
- Use proper technique for lifting the device.
- Lower the device on the pole to improve stability during transport.

Unpacking

When unpacking the NeoPAP System, ensure that all parts listed on the packing list are included in the shipment. Inspect all parts for damage before use and immediately report any discrepancies to your Circadiance representative.

Mounting

The NeoPAP device can be mounted to a pole or vertical rail.



1. Remove the IV pole mount cover on the back of the NeoPAP device, by removing the two screws, using one of the allen keys provided.
2. Remove the mounting bracket from the back of the NeoPAP device, by removing the four screws, using one of the allen keys provided.
3. If NeoPAP IV pole (22 mm diameter) is being used, install the 22 mm shim to the pole to ensure proper fit. If the diameter of the pole or vertical rail being used is 24 mm, the 24 mm shim is needed.
4. Place the device in the desired location on the pole or rail.
5. Tighten the four screws to re-install the bracket.
6. Ensure two fan filters are in place and place the pole mount cover over the mounting bracket. Affix two screws and tighten in place.

Connecting to Power

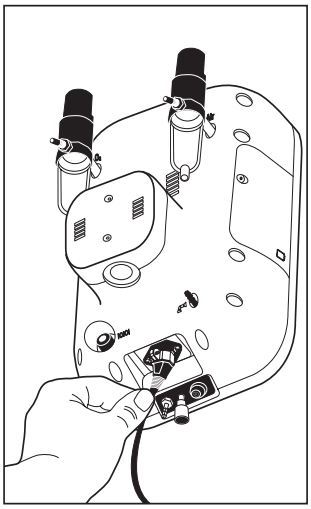
NOTE: When setting up the NeoPAP System for the first time, connect the system to mains power to charge the internal battery. The internal battery will fully charge in 6 hours.

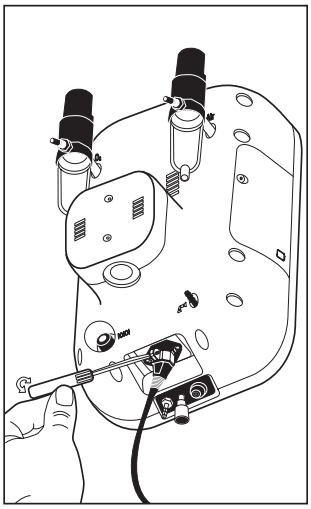
WARNING! To avoid the risk of fire, use only Circadiance-approved batteries. All battery connections are keyed to ensure proper connection: do not attempt to connect a battery incorrectly.

CAUTION: Use only manufacturer-approved power cords with the NeoPAP device.

The NeoPAP System can run on AC (wall or mains) power or internal battery power. The internal battery can run the system for two hours when fully charged.

1. Install the internal battery. For installation instructions, see the "Replacing the Internal Battery" section in *Chapter 7: Maintenance*.
2. Plug the power cord into the bottom of the device, as shown below.
3. Lock the power cord in place by tightening the screw on the power cord clamp.
4. Verify that the AC (AC) indicator is on when the power cord is connected to wall power, that the battery indicator (DC) turns on, and an alarm sounds when the AC power cord is disconnected, and that the system continues to operate normally.





The internal battery recharges when the system is connected to AC Power, whether the system is turned on or off.

When the device is operating on AC power, "AC" will be displayed on the current settings screen. When the device is operating using the internal battery, the battery symbol will appear on the current settings screen.

NOTE: If neither of the power indicators are lit when the system is on, contact a qualified Circadiance service technician.

Selecting Menu Items from the Configuration Menu

You can use the configuration menu to select:

- The time between alarm sound sequences.
- Alarm auto-reset or manual reset.
- Ambient atmospheric pressure (Patm) setting.
- Display/Message window Language.
- Enable/Disable Circadiance (future option)

Warning

For optimal oxygen sensor accuracy and occlusion alarm accuracy, the displayed pressure should be within 50 hPa (37.5 mmHg) of ambient atmospheric pressure. During startup the system displays the atmospheric pressure setting (for example, "Patm : 1010 hPa"). If the setting needs to be adjusted, use the configuration menu to enter the correct value. For recommended settings based on elevation, see *Appendix B. Elevation Settings*.

Follow these steps to use the configuration menu:

1. Hold down the RESET (🔔) key while turning on the NeoPAP System.
2. A message prompts you to disconnect the patient and press ✓ to continue.
3. Use the ▲ and ▼ keys to scroll through the configuration menu, then press ✓ to select the menu item.
4. Once you've selected an item from the menu, press ✓ to change the value or ✕ to return to the configuration menu.
   - Use the ▲ and ▼ keys to scroll through the possible selections.
   - Press ✓ to select a setting, or ✕ to exit the item without making a change.

To resume normal operation after using the configuration menu, turn the system off then back on again.

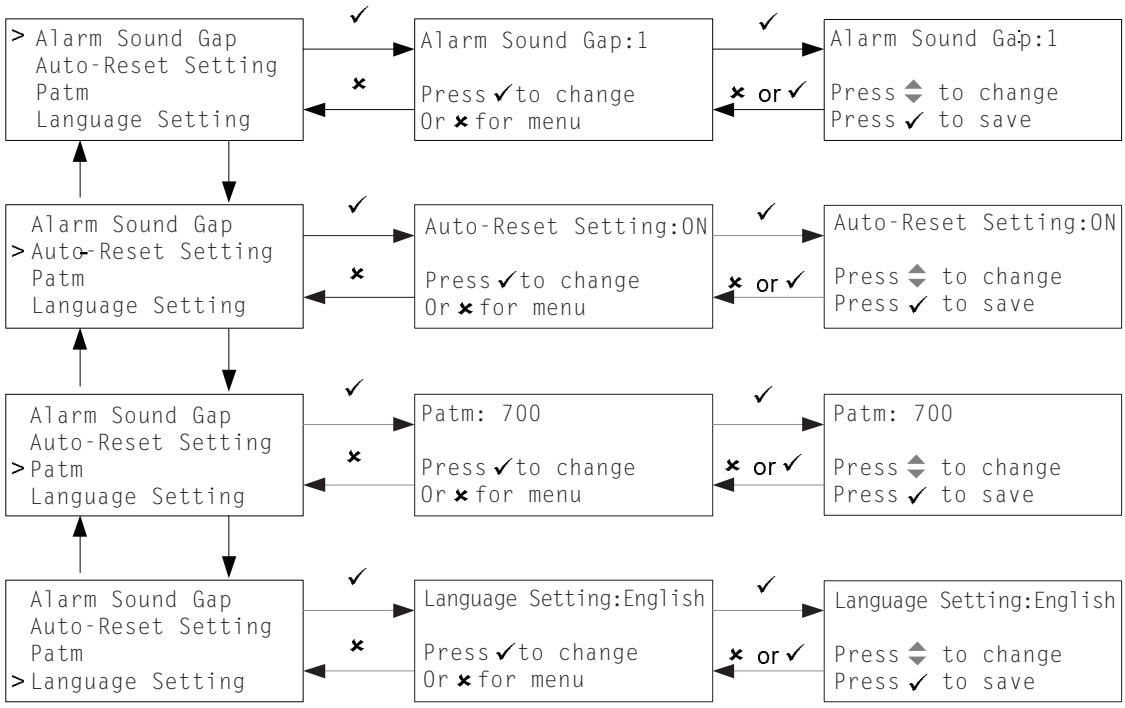
The following summarizes the configuration menu functions:

Menu item	Function
Alarm Sound Gap	Sets the time between alarm sound sequences from 1 to 9 seconds. The default setting is 7 seconds.
Auto-Reset Setting	Selects auto-reset (ON) or manual reset (OFF) for patient pressure, temperature, flow, and oxygen alarms. All other alarms are auto-reset. The default setting is ON.

Menu item	Function
Patm	Selects the ambient atmospheric pressure setting of 800 to 1070 hPa (600 to 802.5 mmHg). The system displays the current Patm setting during startup. This setting allows more accurate oxygen sensor readings and does not affect the $\%O_2$ delivered by the NeoPAP System. For best accuracy, use a local barometric measurement rather than published meteorological pressures, which represent atmospheric pressure at sea level. The default setting is 1010 hPa (757.6 mmHg)
Language Setting	Selects the language. The new selection takes effect when the system is powered off and then back on. The default setting is English.
Humidification	Enables/Disables the Circadiance (future option). This setting should remain in the default Off mode. If the setting is changed to On, the heat icon on the front display will appear but it will have no impact on the safety and efficacy of the device or the external humidifier.

Scrolling through the Configuration Menu

WARNING! To ensure correct gas delivery and avoid the risk of fire, use only correct gas

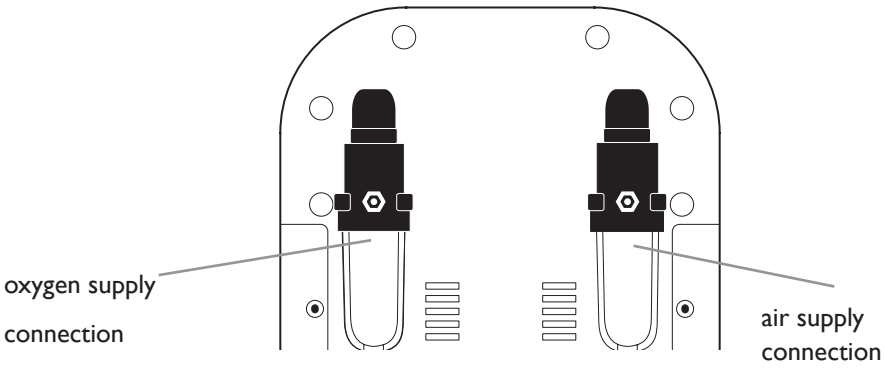


Connecting to Air and Oxygen Supplies

supplies and do not attempt to modify gas supply connections.

WARNING! Do not allow oil or grease to contact air and oxygen supply connectors.

Connect high pressure oxygen and air supplies at the connections shown in the figure below.



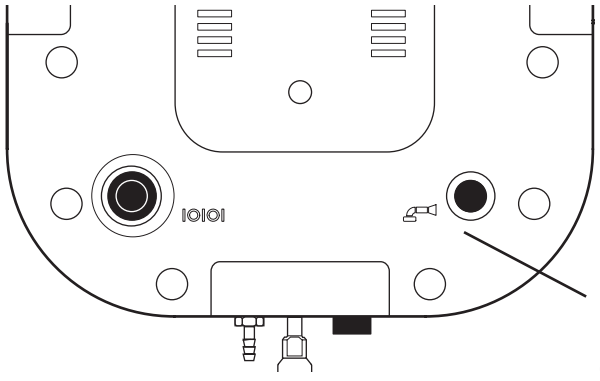
Installing the Oxygen Sensor

The NeoPAP System includes an oxygen sensor, but the sensor does not come installed. When setting up the system for the first time, remove the sticker located inside the oxygen sensor compartment and install the oxygen sensor as described in "Replacing the Oxygen Sensor" in *Chapter7: Maintenance*.

NOTE: Run the system for at least 30 minutes before calibrating the oxygen sensor. This allows sensor calibration at ambient conditions. See "Calibrating the Oxygen Sensor" in *Chapter 7: Maintenance*.

Connecting a Resuscitation or Hyperinflation Bag

To connect a resuscitation or hyperinflation bag, connect the bag's tubing connector to the barb on the back panel.

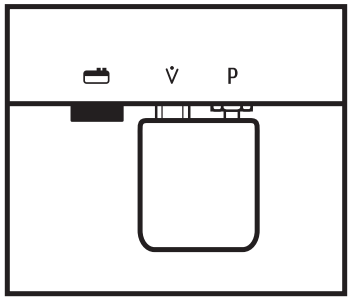


Before beginning the start-up self test, connect the start-up part to the air delivery adapter

Connecting the Start-up Part

and pressure barb.

NOTE: The start-up part is required for the NeoPAP device to complete the start-up self test.



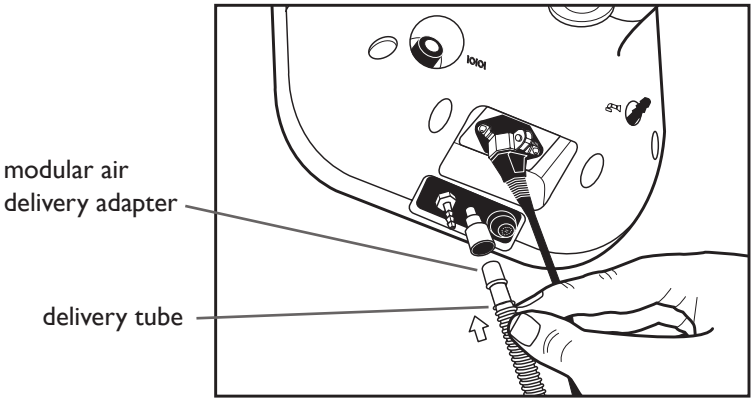
Connecting to a Humidifier

NOTE: Prior to connecting the humidifier circuit to the NeoPAP device, the device must successfully complete the start-up self test.

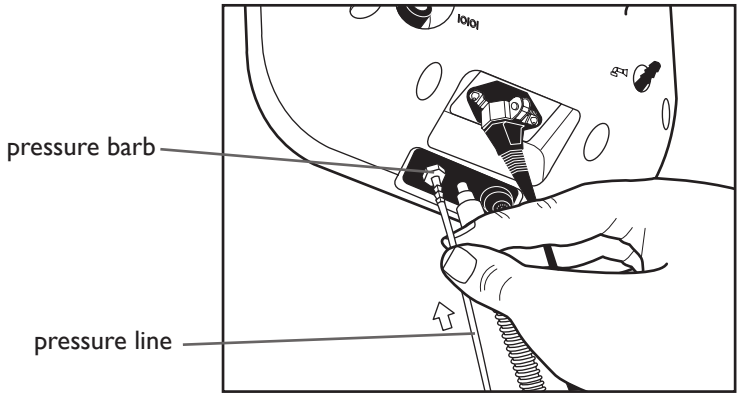
To connect the humidifier to the NeoPAP device you will need the following accessories:

- Delivery circuit adapter with pressure line
- Humidifier and delivery tubing

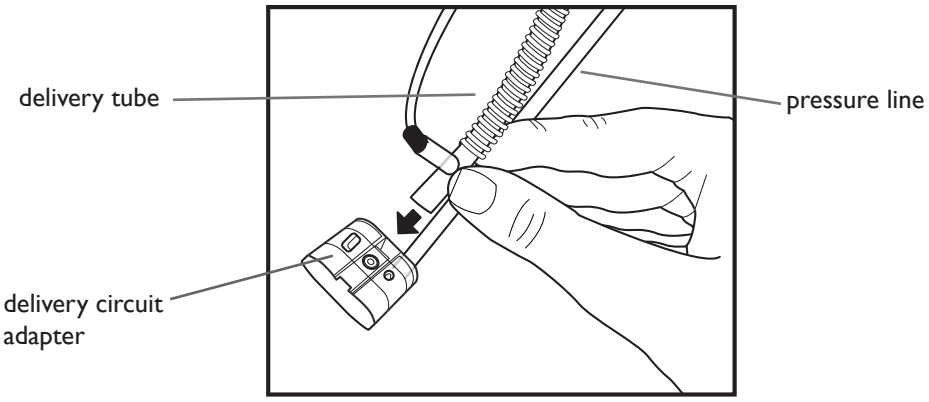
1. Connect the delivery tube, which is connected to the humidifier, to the modular air delivery adapter on the NeoPAP device. The air delivery adapter accepts 15 mm outer diameter tubing fittings.



2. Secure the smaller diameter pressure tube, which is connected to the delivery circuit adapter, to the pressure barb located on the bottom of the NeoPAP device.

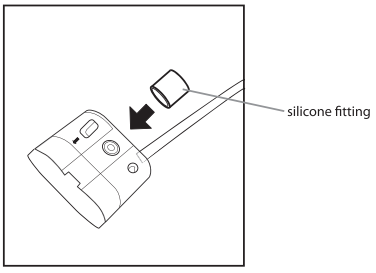


3. Connect the delivery tube to the delivery circuit adapter.

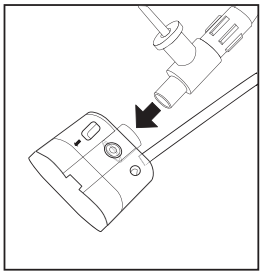


4. To connect the NeoPAP circuit delivery adapter to a Hudson-RCI neonatal breathing circuit. (A.) Place the silicone fitting into the inspiratory line port (center) of the delivery circuit adapter. Ensure that the fitting is securely seated in place. (B.) Connect the Hudson-RCI breathing circuit to the delivery circuit adapter.

A.



B.



5. Connect the patient interface to the delivery circuit adapter. For additional information on connecting the patient interface, see *Chapter 5: Operation*.

NOTE: Do not turn on the humidifier until gas flow has started. See *Chapter 5: Operation* for instructions describing how to connect the patient interface and turn on the NeoPAP device.

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Chapter 5. Operation

This chapter describes how to operate the NeoPAP System and navigate through the settings on the message window screen. It includes the following information:

- Powering the System On
- Connecting the Patient Interface
- Modes of Operation
- Settings

Warnings

- For optimal oxygen sensor accuracy and occlusion alarm accuracy, the displayed pressure should be within 50 hPa of ambient atmospheric pressure. During startup the system displays the atmospheric pressure setting (for example, "Patm : 1010 hPa"). If the setting needs to be adjusted, use the configuration menu to enter the correct value. For more information, see the "Selecting Menu Items from the Configuration Menu" section in *Chapter 4. Setup*.

  NOTE: 1 hPa = 1 mbar = 1.022 cmH_2O.
- Ensure that a patient is **not** connected to the NeoPAP System during start-up self-test.
- Do not operate the NeoPAP without an internal battery or oxygen sensor installed.

NOTE: The NeoPAP System cannot complete its start-up self-test unless the start-up part is correctly installed.

NOTE: Ensure that the internal battery and the oxygen sensor are installed. If the internal battery or oxygen sensor is not installed, STOP! Refer to *Chapter 7: Maintenance* for instructions on installing either of these items before proceeding.

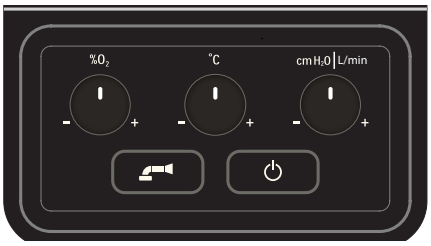
NOTE: The delivery tube connection includes the following:

- Modular air delivery adapter - the delivery circuit tubing from the humidifier connects to the modular air delivery adapter, located on the bottom of the NeoPAP device.
- Delivery circuit tubing - the delivery circuit tubing connects the humidifier to the modular air delivery adapter and connects to the delivery circuit adapter.
- Pressure barb - the pressure line on the delivery circuit adapter connects to the pressure barb, located on the bottom of the NeoPAP device.
- Delivery circuit adapter with pressure line - the delivery circuit adapter connects to the NeoPAP interface. In addition, the delivery circuit tubing connects to the delivery circuit adapter and the pressure line coming from the delivery circuit adapter connects to the pressure barb on the bottom of the NeoPAP device.

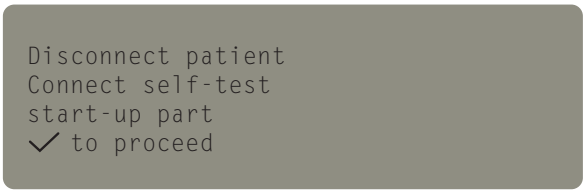
Powering the System On

Once the NeoPAP System is set up, follow these steps to start operation:

1. Open front door on the NeoPAP device and press the Power On/Off button (⏻) to power the system on. During startup, two distinct beeps sound to verify alarm functionality.



2. The message window will show:



3. Connect the start-up part to the air delivery adapter and pressure barb on the bottom of the NeoPAP device, as shown in *Chapter 4: Setup,* and press ✓ to proceed.

WARNING! Ensure that the start-up part is not obstructed during startup.

NOTE: Each time the NeoPAP device is powered off and then back on, the system must complete the start-up self test before the device can deliver gas to the patient. An alternative to shutting down the device is to put the device in Stand-by mode, which does not require the device to go through the start-up self-test.

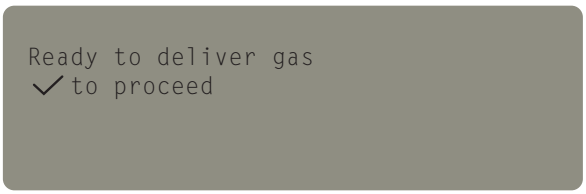
4. The NeoPAP System will then enter a self-test mode. During this self test the device will check for any disconnected gas or power supplies.

   A message will display to alert the user to the items that are disconnected (for example: oxygen supply or AC power). See *Chapter 4: Setup* for instructions on setting up the NeoPAP System before use.

NOTE: Choosing to continue operation without any of these connected will disable alarms specific to the item(s) that is not connected.

   As the device goes through self test, the progress of the steps will be shown on the message window. Once all steps are complete, the device is ready for patient use.

5. Once the system is ready for patient use, this message appears:



6. Disconnect the start-up part from the bottom of the NeoPAP device.

7. Connect the humidifier delivery tube and pressure line to the bottom of the NeoPAP device, as shown in *Chapter 4: Setup*.
8. Connect the patient interface to the delivery circuit.
9. Press ✓ to deliver gas. All alarms are automatically silenced for two minutes to avoid nuisance alarms during patient setup.
10. Turn on the humidifier.
11. The system is now ready to be connected to the patient.

Connecting the NeoPAP Patient Interface

NOTE: Gas therapy should always be started prior to placing the patient interface on the patient.

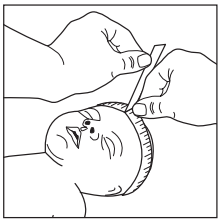
NOTE: The patient interface includes the following:

- Bonnet - specially-sized bonnet allows a secure yet non-constricting fit of the nasal cannula or mask.
- Patient circuit - this circuit includes specially sized cannula or mask, patient tubing, and exhalation body plug.

Selecting Bonnet and Nasal Cannula/Nasal Mask Circuit Size

Bonnet

1. Measure the infant's head circumference at its largest point, using the provided measuring tape.



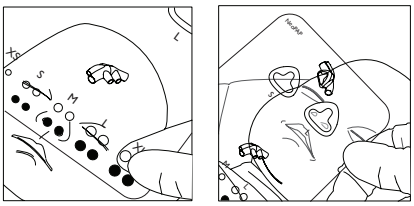
2. Select the appropriate bonnet based on infant's head circumference. The bonnet is available in five sizes. See the sizing chart below.

Size	Head Circumference (cm)	Color
XS	≤ 26 cm	Purple
S	27-29 cm	Teal
M	30-32 cm	Peach
L	33-35 cm	Green
XL	≥ 36 cm	Blue

Patient Circuit

1. Use the measuring gauge, included in the delivery circuit adapter kit, to select the appropriate infant circuit, mask or cannula. The shaded area on the gauge represents the size of the infant's nares and the clear circles and triangles indicate the size of the cannula prongs and masks, respectively. Circuits are available in six nasal prong sizes and two mask sizes.

NOTE: The NeoPAP system features Baby-Trak software, which allows the device to deliver the selected level of CPAP without requiring the patient interface to be fully sealed at the patient's nares or around the nose.



Connecting the Interface

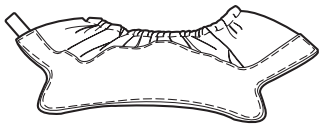
Before connecting the interface, inspect the mask or nasal cannula and replace if it is hardened or torn, or if any parts are broken.

WARNING! To avoid the possibility of damage to the infant's septum, the infant should be checked regularly to ensure all connections, including the mask and/or prong position, are secure. Ensure that the infant's nose is not pushed upwards and that the nasal area is clean and dry. Gentle massage may be useful to stimulate circulation to the infant's tissues.

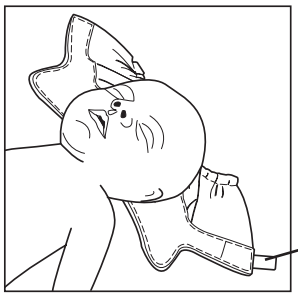
WARNING! Ensure that the bonnet fits over the infant's forehead, covering the ears, which should lie flat against the infant's head. The infant's eyes should be clearly visible.

1. Place the bonnet on the infant.

a. Open the bonnet and place it on the mattress.

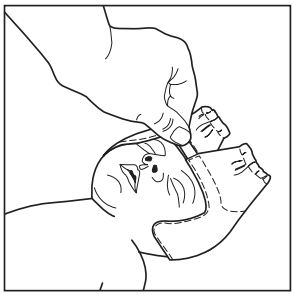


b. Place the infant's head in the center of the open bonnet.

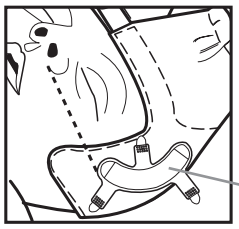


c. Gently close the bonnet by bringing the sides together on the infant's forehead. To fit the bonnet, make sure the infant's ears lie flat. A hook and loop attachment holds the bonnet in place. Make sure there is no exposed portion of hook material touching the infant's skin as this could cause irritation.

NOTE: Do not overtighten the bonnet.

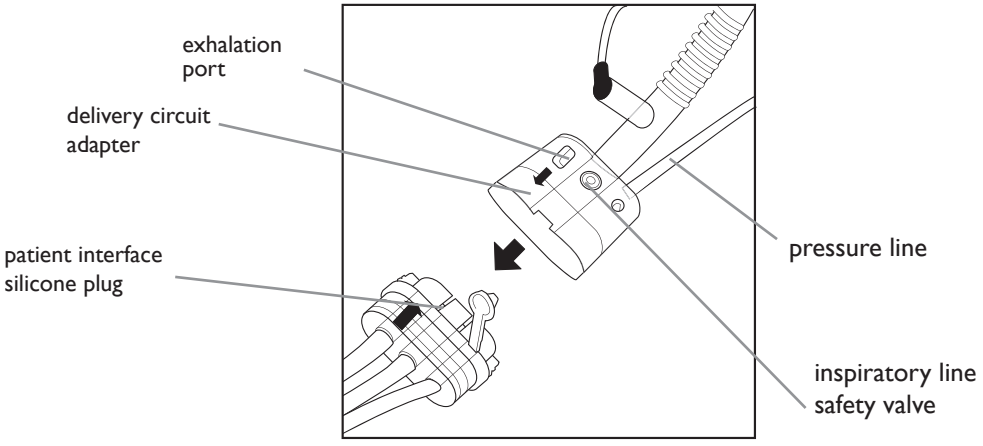


d. Place the bonnet clips in the desired location and orientation on the bonnet, as shown below. For proper orientation of the bonnet clips, the bottom of the clip should be even with the bottom of the infant's nose.

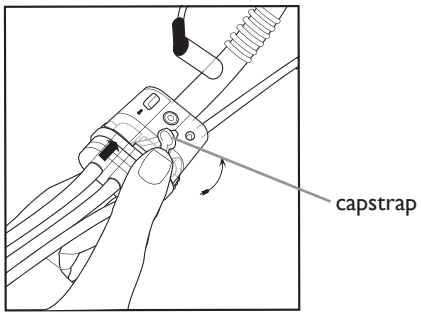


2. Connect the patient interface to the delivery circuit.

a. Push the silicone plug of the patient interface securely on to the end of the delivery circuit adapter. When connecting, ensure that the arrow located below the exhalation port is lined up with the arrow on the silicone plug.



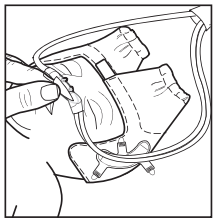
b. **Secure the capstrap, located on the patient interface connection, to the delivery circuit adapter.**

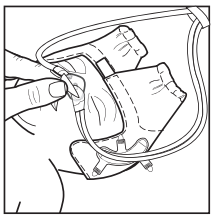


3. Deliver CPAP by pressing the ✓ button on the NeoPAP device. Alarm Silence is automatically engaged for 2 minutes to accommodate patient set-up. After the patient interface is securely affixed to patient, press the Alarm Reset button to cancel the alarm silence.

4. Attach the nasal cannula or mask to the patient.

a. Gently secure the cannula in the nose or mask over the nose.





b. Gently pull the circuit along the face assuring a secure fit without excess tension.

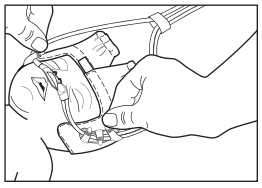
NOTE: The cannula does not require a tight seal. The patient interface should not rest on the infant's nasal septum. Do not overtighten.

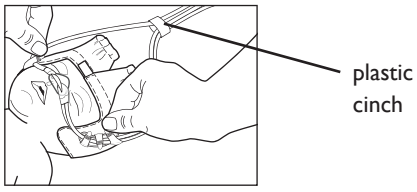
5. Secure the circuit tubing to the bonnet to maintain appropriate positioning at the nose.

a. Using the detachable bonnet clips, secure the circuit to the bonnet while maintaining the appropriate interface position.

b. Reposition the bonnet clips as necessary to provide the best fit.

NOTE: Extra pairs of bonnet clips are available as an accessory part.





c. Pull the plastic cinch towards the patient to secure the patient interface.

6. If water begins to accumulate in the pressure line of the patient circuit, unfasten the capstrap on the delivery circuit adapter until water is pushed out of the pressure line into the adapter. Position the adapter to drain water out of the port. Refasten the capstrap making sure it is securely in place.

Modes of Operation

Normal Operation

The NeoPAP System features these operating modes:

- CPAP mode

  Provides positive pressure through a nasal cannula or nasal mask. The user selects the CPAP level (2 to 10 cmH_2O) and $\%O_2$ (21-100%). Baby-Trak automatic leak compensation is continuously active.

- Flow mode

  Provides a fixed flow of gas through a nasal mask or cannula. The user selects the flow (3 to 7 L/min) and $\%O_2$ (21-100%).

- Resuscitation mode

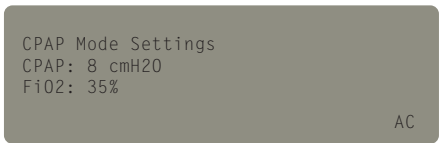
  Provides 10 liters per minute (L/min) of un-humidified, oxygenated air with an FiO_2 value between 21-100% through the resuscitation port, for use with a resuscitation bag or hyperinflation bag. Suspends CPAP or Flow mode and patient pressure until the user presses the resuscitation mode button again.

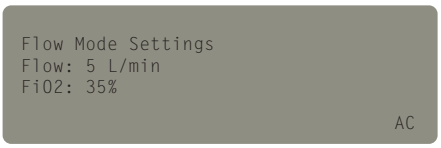
- Standby Mode

  Allows the user to configure the device for a patient prior to patient arrival. In addition, from this mode the user can pause therapy to allow for care procedures that require therapy to be stopped for a period of time. The user can restart therapy with all previous settings by pressing the Standby (Power On/Off) button. While in Standby mode, the user can change CPAP, Flow, and $\%O_2$ settings, and then restart therapy with the new settings by pressing the Standby (Power On/Off) button.

Displays During Normal Operation

The system displays either of these current settings windows during normal operation:



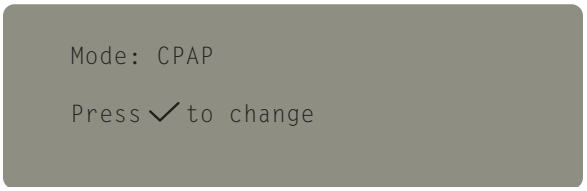


Changing Between CPAP and Flow Mode

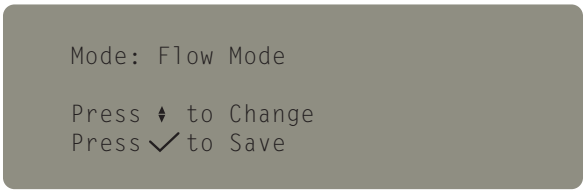
To change between CPAP and Flow mode, follow the steps below.

1. From CPAP mode, the message window will read:

2. Press the ▲ key on the device until the Change Mode screen is displayed.



3. Press ✓ to change mode.
4. Press ▲ until the desired mode is displayed.

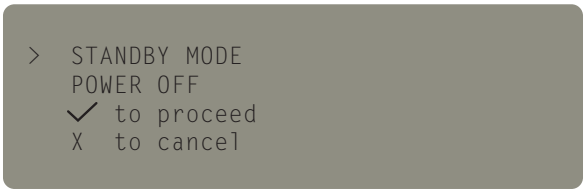


5. Press ✓ to save mode change. The new mode is now active and the message window will show the new mode settings screen.

Entering/Exiting Standby Mode

To temporarily stop CPAP therapy to provide the patient other care procedures, the NeoPAP device can be placed in Standby mode. To enter Standby mode:

1. Open the front door on the NeoPAP device and press the Standby (Power On/Off) button. The message window will show:



2. Press the ✓ to proceed to Standby mode. The device will display:

3. To exit out of Standby mode and resume therapy, press the Standby (Power On/Off) button.

Entering Resuscitation Mode

During normal operation (CPAP or Flow mode), resuscitation mode is available for emergency use.

WARNING! A resuscitation or hyperinflation bag capable of operation with a 10 L/min gas supply must be connected to the NeoPAP System before entering resuscitation mode.

1. To enter resuscitation mode, press the Resuscitation mode button located behind the door on the front of the device. The message window displays this message:

```
Check resus bag
is connected.
✓ to proceed
X  to cancel
```

2. If ✓ is not pressed within 10 seconds, the message window reverts to the current settings screen.

   If proceed (✓) is pressed, CPAP or Flow mode is exited and the system enters Resuscitation mode, and the message window displays this message:

```
RESUSCITATION MODE
Resus key to exit
```

3. During resuscitation mode, the system delivers 10 L/min of un-humidified gas at the current FiO_2 setting through the resuscitation port. CPAP or Flow mode and pressure monitoring is suspended. All alarms except the power and high and low oxygen supply alarms are disabled during resuscitation mode. The system sounds a tone every 10 seconds during resuscitation mode.
4. Check resuscitation mode functionality by entering resuscitation mode and verifying that gas flows into the resuscitation bag.

WARNING! Oxygen should flow through the resuscitation port during resuscitation mode only. Verify that no gas flows through the resuscitation port during CPAP and Flow modes.

5. To exit Resuscitation mode and resume normal operation according to the previous settings, press the Resuscitation mode button again.

Suspension of Operation

Under certain conditions the system suspends operation during system startup or respiratory support. When the system halts, it sounds an audible alarm tone and requires your intervention to resume normal operation. Follow the corrective actions in order until normal operation resumes.

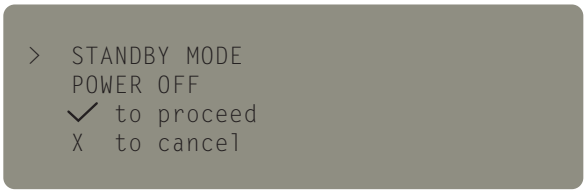
System Halt Conditions

Message	Description	Corrective Action
High Air Supply Pres	Air supply pressure is over 93 psi (641 kPa).	Check air supply connection and ensure that air supply is within specified range of 50-70 psi (345-483 kPa).
High O_2 Supply Pres	Oxygen supply pressure is over 93 psi (641 kPa).	Check oxygen supply connection and ensure that oxygen supply is within specified range of 50-70 psi (345-483 kPa).
System Halted Battery Depleted	Internal battery voltage is depleted. System displays message for 10 seconds, then turns off.	Connect the system to AC power and allow battery to recharge. Replace battery if necessary.
System Halted Connect Delivery Tube	Delivery tube disconnected during operation. Gas delivery and measurement suspended.	Replace/reconnect delivery tube, if necessary.
System Halted Room Temperature Turn unit off and on	Ambient temperature out of range. Gas delivery and measurement suspended.	Move system to a cooler or warmer room. Turn system off and back on.
System Halted Call Service		Provide alternate breathing support and contact customer service.

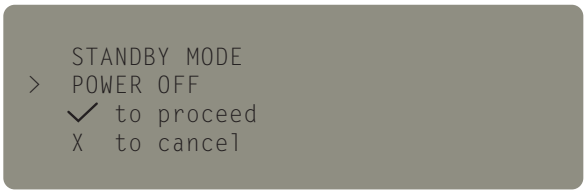
Settings

System Shut Down

1. To turn the system off, press the Power On/Off button. The message window will read:



2. Press the down arrow to select Power Off, and press ✓ to turn off the device.



3. If the system is connected to AC power, the battery recharges. To remove the system from AC power, remove the AC power cord from the wall or the AC receptacle on the bottom of the NeoPAP System.

NOTE: To prolong the life of the oxygen sensor cell, run the system with 21% O_2 before shut down.

CPAP Mode

NOTE: Alarm detection is delayed following setting changes to allow new settings to take effect.

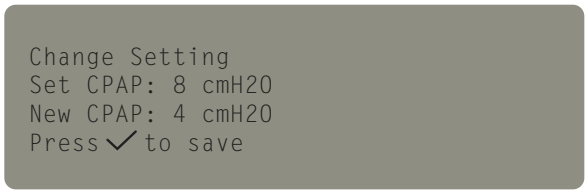
NOTE: When using the knobs to change settings, verify that the correct setting is displayed on the message window.

Changing CPAP level

Follow these steps to change the CPAP level:

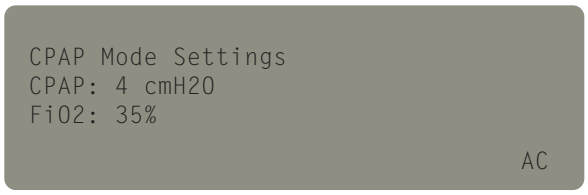
1. Open the front door that covers the settings knobs. The current message window displays:

2. From the current settings screen, turn the cmH_2O / L/min knob to adjust the setting up or down. Turn the knob until the desired value is in the message window, as shown below.



NOTE: The new CPAP setting value will flash and increase or decrease based on the direction in which the knob is moved.

3. After the desired value is selected, press the ✓ key. The new CPAP setting is now active.



4. Close the front door on the device.

NOTE: If the ✓ key is not pressed within 10 seconds of moving the cmH2O / L/min knob, the message window will timeout and return to the previous screen. The new CPAP setting will not be activated.

Changing Leak Sensitivity

Leak sensitivity allows the leak alarm to be set to accommodate the estimated patient circuit leak or variations in a patient's breathing pattern. Adjusting the leak sensitivity setting helps to avoid nuisance alarms.

Readjust leak sensitivity following any settings changes or patient interface adjustments. Since the NeoPAP System automatically compensates for leaks, it is not necessary to tighten the patient interface in order to reduce a leak. It is preferable to adjust the leak sensitivity so that the leak does not cause nuisance alarms.

For example, if the expected flow (for a CPAP setting of 5 cmH_20) is 4 L/min, the actual measured flow of 8 L/min would mean that the leak (or estimated leak) is 4 L/min. A leak sensitivity setting of 5 L/min would mean that the leak alarm would be triggered when the total flow measured is greater than 9 L/min (or 5 L/min above the expected flow for this setting).

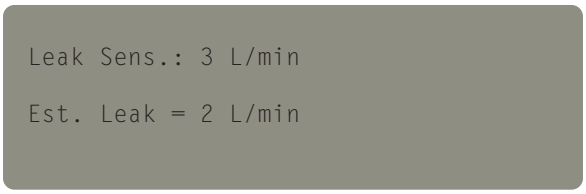
NOTE: The maximum leak sensistivity setting is dependent on the CPAP setting. For more information, see Appendix C.

WARNING! A high leak sensitivity setting can prevent an alarm from occurring when the nasal cannula is disconnected from the patient's nose.

NOTE: When the current leak sensitivity value exceeds the maximum leak sensitivity value for the new CPAP setting, the leak sensitivity value will be reduced to the new maximum value (see Appendix C for the corresponding values).

Follow these steps to change the leak sensitivity (CPAP mode only):

1. From the current settings screen, use the ▲ and ▼ keys to scroll through the screens until Leak Sensitivity is displayed, then press ✓ to ACCEPT.
2. The message window will display this message:



3. Use the ▲ and ▼ keys to change the Leak Sens. value, then press ✓ to Save the new setting.

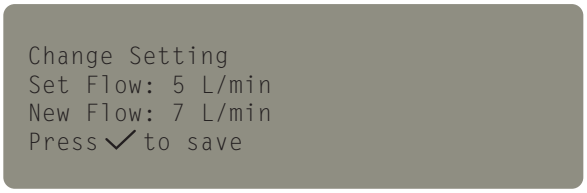
Flow Mode

Changing Flow Level

Follow these steps to change the flow level (Flow mode only):

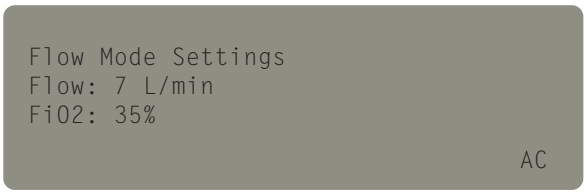
1. Open the front door that covers the settings knobs. The message window will read:

2. From the current settings screen, turn the cmH_2O / L/min knob to adjust the setting up or down. Turn the knob until the desired value is in the message window, as shown below.



NOTE: The new Flow setting value will flash and increase or decrease based on the direction in which the knob is moved.

3. After the desired value is selected, press the ✓ key. The new Flow setting is now active.



4. Close the front door.

NOTE: If the ✓ key is not pressed within 10 seconds of moving the cmH2O / L/min knob, the message window will timeout and return to the previous screen. The new Flow setting will not be activated.

Changing Flow Low Pressure (LP) and Flow High Pressure (HP)

The Flow LP and Flow HP settings allow high and low pressure alarms to be set when the device is in flow mode. This is different from CPAP mode where a pressure is set and an alarm is banded around the set pressure.

1. From the current settings screen, use the ▲ and ▼ keys to scroll through the screens until Flow LP or Flow HP is displayed, then press ✓ to proceed.
2. Use the ▲ and ▼ keys to adjust the value, then press ✓ to save and put the new setting into effect.

Additional Menu Options

From both CPAP and Flow Mode, the following menu setting can be selected and changed:

- Sound Volume - select this option to change the sound volume from 1-3, with 3 being the loudest.
- Light Level - select this option to set the message window to either Bright or Dim.
- Alarm Settings - The following table lists the CPAP mode menu functions. To view and/or change these settings, scroll to the View Alarm Settings menu and press ✓ to change a setting.

Menu Item	Function
Leak Delay	Selects the number of seconds (3 to 12 seconds) that the leak must exceed the leak sensitivity setting before a leak alarm is activated.
HP Delay Setting	Selects the number of seconds a high patient pressure condition must exist before an alarm is activated (0 to 10 seconds; 0 = no delay).
LP Delay Setting	Selects the number of seconds a low patient pressure condition must exist before an alarm is activated (0 to 10 seconds; 0 = no delay).
Pressure Alarm Band	Selects the tolerance above or below the selected CPAP level (2 to 4 cmH_2O or 2 to 4 hPa), beyond which a pressure alarm is activated.
FiO_2 Band	Selects the tolerance above or below the selected FiO_2 (5 to 10%), beyond which an FiO_2 alarm is activated.
Temp Band	Future Option

Changing FiO_2

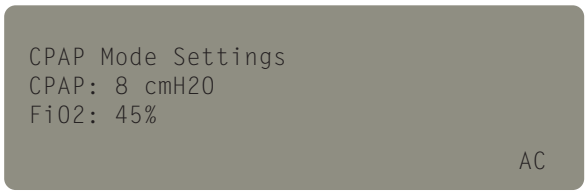
To change the FiO_2 setting, follow the steps below.

1. Open the front door that covers the settings knobs. The message window will read:

2. Turn the $\%O_2$ knob to adjust the setting up or down until the desired value is displayed.

NOTE: The new FiO_2 setting will flash and increase or decrease based on the direction in which the knob is moved.

3. After the desired value is selected, press ✓. The new FiO_2 setting is now active.



4. Close the front door of the device.

NOTE: If the ✓ key is not pressed within 10 seconds of moving the $\%O_2$ knob, the message window will timeout and return to the previous screen. The new FiO_2 setting will not be activated.

NOTE: When the $\%O_2$ knob is adjusted, or after an occlusion alarm is reset, an extended delay of one minute will be set to allow the oxygen to settle at the new setting.

Changing FiO_2 Setting from Resuscitation Mode

1. Open the front door that covers the setting knobs. The display will read:

2. Turn the $\%O_2$ knob to adjust the setting up or down until the desired value is displayed.

NOTE: The new FiO_2 setting will flash and increase or decrease based on the direction in which the knob is moved.

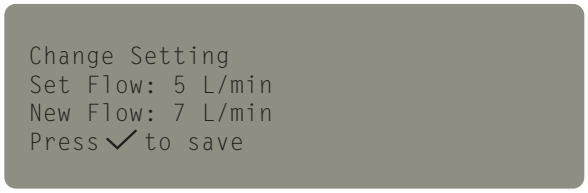
3. After the desired value is selected, press ✓. The new FiO_2 setting is now active and will remain active when Resuscitation mode is exited.

NOTE: If the ✓ key is not pressed within 10 seconds of moving the $\%O_2$ knob, the message window will timeout and return to the previous screen. The new FiO_2 setting will not be activated.

Changing Settings in Standby Mode

To change settings during Standby mode, follow the steps below.

1. While in Standby mode, turn the cmH_2O / L/min or $\%O_2$ knob. The message window will show the current CPAP or Flow and FiO_2 settings. For example, if the device was in Flow mode prior to Stand-by mode and the user wants to change the Flow settings, they would turn the cmH_2O / L/min knob until the desired value appears, as shown in the following graphic.



2. After the desired value is selected, press the ✓ key. The new Flow setting will be active when the device exits Standby mode.

NOTE: If the ✓ key is not pressed within 10 seconds of moving the knob, the message window will timeout and return to the Standby mode screen.

Power Supplies During Normal Operation

If AC power is available, the NeoPAP System runs on AC power. During AC power operation, the system recharges the internal battery.

- If the system is turned on with AC power connected, AC appears on the message window.
- If the system is turned off with AC power connected, a battery filling icon appears on the message window indicating that charging is in progress. When charging is complete a full battery icon is displayed.
- If the internal battery has not successfully charged after 6 hours, a Replace Battery alarm occurs and the battery icon flashes.

If AC power is not available, the NeoPAP System runs on battery power.

NOTE: A beep will sound every 10 seconds when the NeoPAP System is running on battery power.

The system will alarm approximately 2 minutes before full battery depletion. If the battery voltage is fully depleted and AC power is not available, gas delivery stops, and then the system displays a shutdown message for 10 seconds before turning off.

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Chapter 6: Alarms

All alarms that occur with the NeoPAP system are treated as high-priority alarms. Whenever an alarm occurs, an audible alarm sounds, the message window displays the alarm, and the alarm bar at the top front panel of the device will flash red.

The message window can display up to three alarm messages at a time, listed in descending order of priority. The table below shows the priority order, starting with highest. If an alarm occurs with higher priority than the three being displayed on the message window, it is inserted on the display and the lowest priority alarm is removed (until space becomes available again).

When more than one corrective action is listed, follow them in order until the alarm is resolved. If the suggested corrective actions do not resolve the problem, provide alternate breathing support and contact a qualified service technician.

Alarm Message	Description	Corrective Action	Audio/Visual Indicator
Any alarm not listed here		**Provide alternate breathing support and contact customer service.**	• Audible Alarm • Message window • Flashing red alarm bar at top of device
Unexpected Restart	Internal fault, or system connection to AC power without internal battery, or internal battery disconnected then reconnected.	1. Verify internal battery connection, then cycle power. 2. If alarm persists, provide alternate breathing support and contact service.	• Audible Alarm • Message window • Flashing red alarm bar at top of device
Low Battery	Less than 2 minutes of battery power remain.	1. Connect the system to AC power and allow battery to recharge. 2. Replace battery if necessary.	• Audible Alarm • Message window • Flashing red alarm bar at top of device

Alarm Message	Description	Corrective Action	Audio/Visual Indicator
Occlusion	Possible blocked delivery circuit or patient interface. Gas delivery stops until alarm condition is cleared. $\%O_2$ measurement is not displayed. The system will automatically resume normal gas delivery after the condition that caused the occlusion alarm is cleared.	1. Check delivery circuit and patient interface tubing for kinks or occlusions. 2. Verify that the atmospheric pressure (Patm) setting in the configuration menu is within 50 hPa of ambient pressure. 3. Replace delivery circuit or patient interface if necessary. 4. The alarm reoccurs and gas delivery is halted if the alarm condition continues.	• Audible Alarm • Message window • Flashing red alarm bar at top of device
High Pressure	Measured patient pressure is above the pressure alarm setting. (Alarm tolerance and delay are selected in the View Alarm Settings menu).	1. Check patient settings. Verify that delivery tube or nasal cannula is not covered or obstructed. 2. Check nasal cannula or mask tubing for water.	• Audible Alarm • Message window • Flashing red alarm bar at top of device • Pressure bar graph turns red

Alarm Message	Description	Corrective Action	Audio/Visual Indicator
Leak	Delivery circuit or patient interface disconnected. $\%O_2$ is displayed. (Select leak delay in the View Alarm Settings menu).	1. Check patient and reconnect tubing or nasal cannula/ nasal mask. 2. Verify that size of nasal cannula/ nasal mask is appropriate to avoid excessive leakage. 3. Adjust leak sensitivity setting to make alarm less sensitive. See "Changing Leak Sensitivity (CPAP mode only)" in *Chapter 5: Operation*. 4. Verify that the atmospheric pressure (Patm) setting in the configuration menu is within 50 hPa (37.5 mmHg) of ambient pressure.	• Audible Alarm • Message window • Flashing red alarm bar at top of device
Low Pressure	Measured patient pressure is below the pressure alarm setting. (Alarm tolerance and delay are selected in the View Alarm Settings menu).	1. Check the nasal cannula or nasal mask fit for excessive leaks. 2. Check that delivery tube circuit is properly connected.	• Audible Alarm • Message window • Flashing red alarm bar at top of device • Pressure bar graph turns red
High Flow *(Flow mode only)*	Measured flow rate is 2 L/min above the flow setting.	Provide alternative breathing support and contact service.	• Audible Alarm • Message window • Flashing red alarm bar at top of device

Alarm Message	Description	Corrective Action	Audio/Visual Indicator
Low Flow *(Flow mode only)*	Measured flow rate is 2 L/min below the flow setting.	Check gas supply.	• Audible Alarm • Message window • Flashing red alarm bar at top of device
No O_2 Sensor	Oxygen sensor disconnected or depleted.	1. Press RESET to resume normal operation without oxygen sensor ($\%O_2$ display shows "---"). 2. Check oxygen sensor connection. 3. If necessary, replace and recalibrate.	• Audible Alarm • Message window • Flashing red alarm bar at top of device
Low O_2 Supply Pres	Oxygen supply pressure is below 30 psi (207 kPa). Disabled if operator chooses to power up without oxygen supply connected.	Check oxygen supply connection and ensure that oxygen supply is within specified range of 50-70 psi (345-483 kPa).	• Audible Alarm • Message window • Flashing red alarm bar at top of device
High O_2 Supply Pres	Oxygen supply pressure is over 58 psi (400 kPa).	Check oxygen supply connection and ensure that oxygen supply pressure is within specified range of 50-70 psi (345-483 kPa).	• Audible Alarm • Message window • Flashing red alarm bar at top of device
Low Air Supply Pres	Air supply pressure is below 30 psi (207 kPa). Disabled if operator chooses to turn on without air supply connected.	Check air supply connection and ensure that air supply pressure is within specified range of 50-70 psi (345-483 kPa).	• Audible Alarm • Message window • Flashing red alarm bar at top of device
High Air Supply Pres	Air supply pressure is over 58 psi (400 kPa)	Check air supply connection and ensure that air supply is with in specified range of 50-70 psi (345-483 kPa).	• Audible Alarm • Message window • Flashing red alarm bar at top of device

Alarm Message	Description	Corrective Action	Audio/Visual Indicator
Pressure Unstable Check Tube for Water *(CPAP mode only)*	Circuit conditions may cause instability in the level of delivered CPAP.	1. Check patient settings. Verify that delivery tube or nasal cannula is not covered or obstructed. 2. Check nasal cannula or mask tubing for water.	• Audible Alarm • Message window • Flashing red alarm bar at top of device • Pressure bar graph turns red
High FiO_2	Measured $\%O_2$ is above the $\%O_2$ setting. (Alarm tolerance is selected in the View Alarm Settings menu.)	1. Check that air and oxygen supplies are functional. 2. Verify that the atmospheric pressure (Patm) setting in the configuration menu is within 50 hPa 37.5 mmHg) of ambient pressure. 3. Recalibrate oxygen sensor. 4. Replace oxygen sensor if necessary (see *Chapter 7: Maintenance*).	• Audible Alarm • Message window • Flashing red alarm bar at top of device • FiO_2 LED display turns red

Alarm Message	Description	Corrective Action	Audio/Visual Indicator
Low FIO_2	Measured $\%O_2$ is below the $\%O_2$ alarm setting. Disabled if operator chooses to turn on without oxygen sensor connected. (Alarm tolerance is selected in the View Alarm Settings menu).	1. Check that air and oxygen supplies are functional. 2. Verify that the atmospheric pressure (Patm) setting in the configuration menu is within 50 hPa of ambient pressure. 3. Recalibrate oxygen sensor. 4. Replace oxygen sensor if necessary (see *Chapter 7: Maintenance*).	• Audible Alarm • Message window • Flashing red alarm bar at top of device • FiO_2 LED display turns red
No internal battery	Internal battery may not be connected. The battery icon flashes to indicate a battery fault.	Check internal battery connection. Replace battery.	• Audible Alarm • Message window • Flashing red alarm bar at top of device
No AC Power	AC (mains) power has just been lost.	Check connection to AC power and ensure that AC power is functional.	• Audible Alarm • Message window • Battery icon illuminates at top of device and the AC icon disappears
Replace Battery	Internal battery voltage depleted and cannot be recharged.	Replace internal battery.	• Audible Alarm • Message window • Flashing red alarm bar at top of device

Active Alarm

When an alarm is active:

- The alarm indicator bar flashes,
- The alarm message flashes on the message window, and
- The system sounds a repeating sequence of beeps.

The configuration menu allows you to select alarm volume and time between each sequence of beeps. If an alarm auto-resets, the ALARM indicator remains steadily lit and the alarm message is steadily displayed on the alarm screen to indicate that the alarm occurred.

The message window can display up to three alarm messages at a time, listed in order of priority. Alarm messages are not displayed on the screen if you are in the process of changing settings, but audible and visual alarm indicators continue their normal operation.

Alarm Reset

Press (RESET) to clear audible and visual alarm indicators. Pressing RESET cancels an alarm silence.

Alarm Silence

The (SILENCE) key silences the audible portion of an alarm for two minutes. Pressing the SILENCE key again restarts the two-minute timer. The SILENCE key has no effect on the visual ALARM indicator. The SILENCE key turns red when alarm silence is active. The alarm silence time remaining is displayed in the message window.

Alarm Pre-silence

Press the key when no alarms are active to silence any alarm that may occur in the two minutes following the key press. Alarm pre-silence is useful for avoiding nuisance alarms during certain procedures. The alarm pre-silence time remaining can be viewed by pressing the ▲.

Press the key when alarm pre-silence is no longer required.

Serial Interface Connection

The serial interface connection allows the NeoPAP system to connect to a remote alarm monitoring station. The connector also includes serial communications output for service purposes.

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Chapter 7. Maintenance

The following section contains instructions for user replaceable parts. Any other service, including repair and modification, on this device should only be performed by qualified service technicians. When returning parts for service, only return the part that requires servicing.

Maintenance

WARNING! To ensure correct operation, perform all maintenance at the recommended intervals.

WARNING! Before opening the device to perform maintenance, ensure the device is turned off and the AC power cord is disconnected.

Part	Interval	Procedure
Air and oxygen supply inlet filters	Every year or as needed.	Replace.
Fan filters	Every year or as needed.	Replace.
Internal battery	Every year or if the Replace Battery alarm occurs.	Replace.
Oxygen sensor	Every year or as needed.	Replace and calibrate.
Device exterior	As needed.	For external cleaning/disinfection between uses, wipe with a cloth or damp sponge, using one of the following cleaning agents: • Water • Hydrogen Peroxide (3%) • Soapy water or mild detergent • 10% bleach solution (10% bleach, 90% water) • 91% Isopropyl Alcohol Do not spray or immerse in water. Do not allow liquid to penetrate the system. WARNING! Do not use any cleaning agents other than those listed above.
Patient Interface Exterior	As needed.	For external cleaning/disinfection between uses, wipe with a cloth or damp sponge, using one of the following cleaning agents: • Water • 10% bleach solution (10% bleach, 90% water) • Vinegar, 5% acetic acid by volume WARNING! Do not use any cleaning agents other than those listed above.

Recharging the Battery

To recharge the internal battery, connect the system to AC power (the system can be on or off) for 6 hours.

Recharge the internal battery approximately every 3 months when storing the system for extended periods.

Replacing the Gas Supply Inlet Filters

WARNING! It is important to inspect and replace the gas supply inlet filters at the recommended intervals to avoid introducing foreign matter into the patient interface.

WARNING! Do not disconnect the threaded adapters that are connected to the NeoPAP device as it could allow foreign matter to enter into the patient interface.

Inspect the gas supply inlet filters, and replace every year, following the instructions below.

1. Disconnect the hose from the gas supply connection.
2. Press the manual drain button at the bottom of the bowl to drain any water that may have accumulated in the bowl.
3. Unscrew the bowl from the connection.
4. Unscrew and remove the old filter, then screw in the replacement filter.
5. Screw the bowl back into place.
6. Reconnect the gas supply connection.

Replacing the Fan Filters

CAUTION: Because some environments cause a quicker collection of lint and dust than others, inspect the filters more often when needed.

CAUTION: To ensure proper system performance, only use Circadiance-approved fan filters.

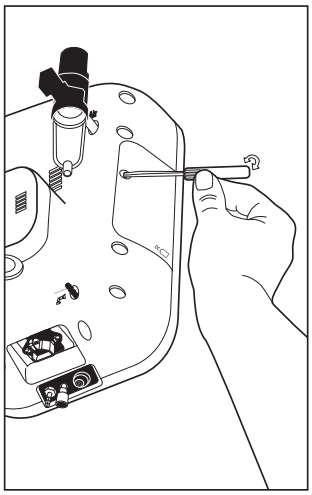
1. Turn the system off and disconnect AC power cord.
2. Remove the two screws that connect the IV pole mount cover to the back of the NeoPAP.
3. Remove the IV pole mount cover from the back of the device to provide access to the fan filters.
4. Remove the old fan filters and replace with new filters.
5. Place the IV pole mount cover on the back of the NeoPAP device. Affix the two screws and tighten in place.

Replacing the Internal Battery

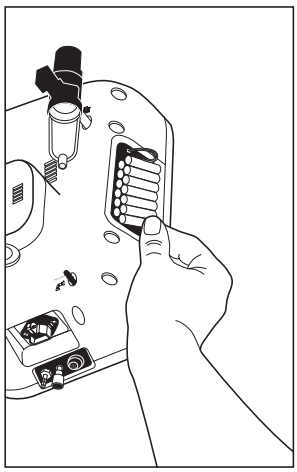
CAUTION: Never attempt to disconnect or connect the battery during operation as it has the potential to damage the device.

Replace the battery pack every year or when battery voltage remains low after recharge.

1. Turn the system off and disconnect AC power cord.
2. Loosen the screw, using a screwdriver, to remove the left side panel (when facing the front panel) from the system.



3. Carefully unplug the battery cable and lift the old battery.
4. Insert a new battery, and plug the battery cable into its connector.



5. Replace the side panel and tighten the screw to secure.
6. Reconnect the AC power cord.
7. Verify that the Battery icon appears on the message display window indicating that the battery was installed properly.

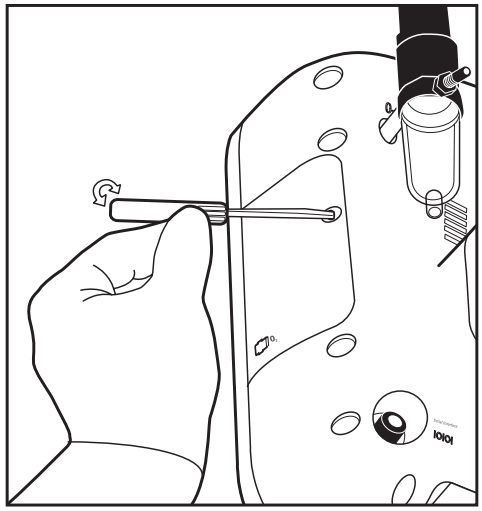
Replacing the Oxygen Sensor

Replace the oxygen sensor every year or as needed.

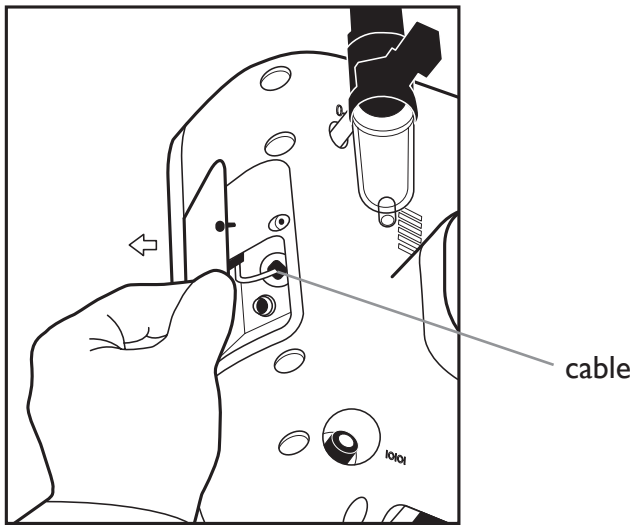
CAUTION: Use only manufacturer-supplied oxygen sensors.

NOTE: Gloves should be worn when replacing the oxygen sensor.

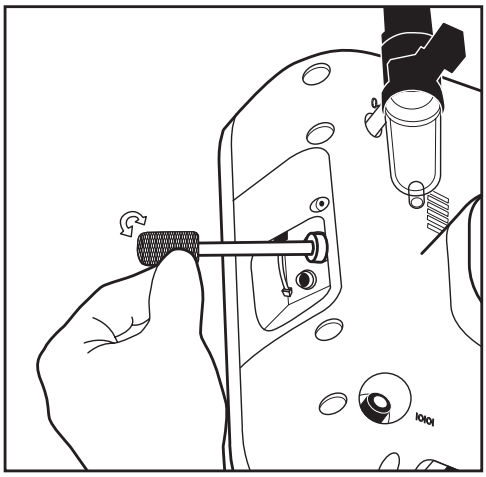
1. Turn the system off and disconnect AC power cord.
2. Loosen the screw, using a screwdriver, to remove the right side panel (when facing the front panel) from the system.



3. Disconnect the cable from the oxygen sensor.



4. Insert the oxygen sensor tool into the top of the oxygen sensor. Use the marker notch and arrow marker etching on the tool to determine the proper orientation. Remove the oxygen sensor from the socket by rotating counterclockwise.



5. Insert a new oxygen sensor into the socket, secure the sensor using the oxygen sensor tool, and plug the cable into its connector.
6. Replace the side panel and tighten the screw to secure.
7. Calibrate the oxygen sensor (see "Calibrating the Oxygen Sensor" later in this section).

Calibrating the Oxygen Sensor

NOTE: Before calibrating the Oxygen Sensor, reference the atmospheric pressure specifications in *Chapter 8: Specifications*.

Calibrate the oxygen sensor whenever a new sensor is installed, or as required.

CAUTION! Always run the unit for 30 minutes prior to performing calibration.

NOTE: The system may alarm during warm-up when a new oxygen sensor has been installed, but has not yet been calibrated.

1. Ensure that the air and oxygen gas supplies are connected, and that start-up part is connected to the system.
2. To enter service mode, turn the system on while holding down the ✕ key.
3. When you see this message:

```
SERVICE MODE

Disconnect Patient
```

Press ✓ to confirm that no patient is connected.

4. At the service mode menu, select Calibrate O_2 Sensor, then press ✓ to start the calibration.
5. During the calibration (which takes three minutes), do not disconnect the air or oxygen gas supplies.
6. When the calibration is complete, this message appears (in addition to technical information on the sensor):

7. Turn the system off then on to resume normal operation.

NOTE: The NeoPAP System checks oxygen sensor calibration every time the system turns on. To perform an additional check of oxygen sensor calibration: set $\%O_2$ to 100, then disconnect the air supply from the system. The $\%O_2$ window should show a value from 97 to 100% O_2.

Cleaning Delivery Circuit Adapter

To clean the external surface of the delivery circuit adapter between uses:

If the delivery circuit adapter becomes lightly soiled during use, clean the external surface of the delivery circuit adapter, following the steps below:

1. Disconnect the delivery circuit adapter from the patient interface and delivery tube.
2. Wipe the external surface of the delivery circuit adapter with a cloth or damp sponge, using one of the following cleaning agents:
   - Water
   - 10% bleach solution (10% bleach, 90% water)
   - Vinegar, 5% acetic acid by volume
3. Allow the delivery circuit adapter to air dry.

WARNING! Do not use any cleaning agents other than those listed above.

Cleaning The Patient Interface

If the patient interface becomes lightly soiled during use, clean the external surface of the patient interface, following the steps below:

1. Disconnect the patient interface from the delivery tube and the bonnet.
2. Wipe the external surface of the patient interface with a cloth or damp sponge, using one of the following cleaning agents:
   - Water
   - 10% bleach solution (10% bleach, 90% water)
   - Vinegar, 5% acetic acid by volume
3. Allow the patient interface to air dry before putting it back on the infant.

WARNING! Do not use any cleaning agents other than those listed above.

NOTE: If the patient interface is heavily soiled, discard it and use a new patient interface.

NOTE: Do not attempt to clean the bonnet or foam liner. Replace the bonnet as necessary if it becomes soiled.

Chapter 8. Technical Specifications

Environmental

	Operating	Storage
Temperature	5-35° C	-20 to 60° C
Relative Humidity	15-95%	15-95%
Atmospheric Pressure	815 to 1100 cmH_2O (800 to 1070 hPa)	

Physical

Dimensions	35 x 23 x 18.5 cm
Weight	Approximately 5.05 kg
Pressure at patient connection	A mechanical pop-off valve opens during fully occulded exhalation tube condition. Patient pressure will never exceed 40 cmH_2O (39.2 hPa).
Mounting	Pole or rail mount (accomodates diameter of 22 to 24 mm with use of shim)
Gas supply connections	Determined by country and configuration
Gas supply input pressures	50 to 70 psi (345-483 kPa)
Resuscitation mode output flow	10 L/min

Electrical

Input range	100-240 V~, 50/60 Hz, 2A (480VA)
Internal battery backup	Provides up to two hour of operation. System automatically recharges internal battery when connected to AC power.
Remote alarm relay	Rated current: 0.5 A. Rated voltage: 250 V.
Fuse type	2.5A, 250V (Antisurge)
Type of Protection Against Electric Shock:	Class I/Internally Powered Equipment
Degree of Protection Against Electric Shock:	Type BF Applied Part
Degree of Protection Against Ingress of Water	Drip Proof, IPX1
Mode of Operation	Continuous

Standards Compliance

This device is designed to conform to the following standards:

IEC 60601-1: 3rd Edition: Medical electrical equipment - Part 1: General requirements for safety

IEC 60601-1-2: 2nd Edition: General requirements for safety - Collateral standard: Electromagnetic compatibility - Requirements and tests

Pressure

Output: 2 to 10 cmH_2O

Control Accuracy

Parameter	Range	Resolution	Accuracy
CPAP	2-10 cmH_2O	1 cmH_2O	± 1.5 cmH_2O for peak inspiratory flow < 3L/min ± 2.3 cmH_2O for peak inspiratory flow ≥ 3L/min
FiO_2	21-100%	1%	± 2% FiO_2
Flow Rate	3-7 SLPM	1 SLPM	± 0.5 SLPM

Measured Patient Parameters

Parameter	Range	Resolution	Accuracy
CPAP	0-12 cmH_2O	1 cmH_2O	± 1cmH_2O
FiO_2	10-100%	1%	± 3% FIO_2 in CPAP mode ± 5% FIO_2 in flow mode

Alarm Tolerances

Parameter	Range	Resolution	Default
Patient Pressure Alarm	± 2-4 cmH_2O (2-4 hPa) around set CPAP to a minimum of 1 cm H_2O in CPAP mode as selected by the user. ± 0-5 cmH_2O (low pressure), 6-15 cmH_2O) (high pressure) in flow mode	1 cmH_2O	2 cmH_2O 2 cmH_2O (low pressure) in Flow Mode 8 cmH_2O (high pressure) in Flow Mode
Delivered FiO_2 Alarm	± 5-10% around set $\%O_2$	1%	5%
Gas Temperature Alarm (future option)	± 2-5 around set temperature, up to a maximum of 42° C	1° C	2° C
Flow Alarm	± 2 L/min	Fixed at ± 2 L/min	± 2 L/min
Gas Supply Alarms	Activated when input gas pressure is below 30 psi (207 kPa) or above 58 psi (400 kPa).		

Disposal

If you are subject to the WEEE/RoHS directives, refer to www.circadiance.com for the passport for recycling this product.

Chapter 9. Accessories

Use the NeoPAP System with the following Circadiance accessories. Please contact your local Circadiance representative before using other accessories with the NeoPAP System.

Description	Item Number
NeoPAP Neonatal CPAP System - Europe	1079410
NeoPAP Neonatal CPAP System - Australia	1079412
NeoPAP Neonatal CPAP System - USA	1076378
NeoPAP Neonatal CPAP System - Canada	1079411
Bonnet Extra Small	1074083
Bonnet Small	1074084
Bonnet Medium	1074085
Bonnet Large	1074086
Bonnet Extra Large	1074117
Nasal Cannula Extra Extra Small	101436
Nasal Cannula Extra Small	1074119
Nasal Cannula Small	1074120
Nasal Cannula Medium	1074121
Nasal Cannula Large	1074123
Nasal Cannula Extra Large	1074124
Mask Circuit Small	1074125
Mask Circuit Large	1074127
Delivery Circuit Adapter and Sizing Kit	1074128
NeoPAP Patient Interface Customer Trial Pack	1078602
UK/Ireland Power Cord	1076702
EU Power Cord	1077067
Denmark Power Cord	1077070
Australia/New Zealand Power Cord	1077069
India/South Africa Power Cord	1077071
Italy Power Cord	1077072
Argentina Power Cord	1079104
Switzerland Power Cord	1077073
IV Pole Kit	1079302
NeoPAP IV Pole Shim (22mm)	1080810
NeoPAP IV Pole Shim (24mm)	1080811
Utility Basket for IV Pole	1079722
Air Hose - NIST x DIN - Germany	1079713
Air Hose -NIST x UNI - Italy	1079714
Air Hose -NIST x AFNOR - France	1079715
Air Hose -NIST x NIST - EU	1079716
Air Hose -NIST x BS - UK	1079717
Air Hose -F DISS x M DISS DV - Canada	1079718
Air Hose -DISS HT x DISS HT (U.S.A & Others)	1079719
Air Hose -NIST x AGA - Scandanavia	1079712
Air Hose - SIS x SIS - Australia	1079720
Oxygen Hose - SIS X SIS - Australia	1079721
Oxygen Hose - NIST X AGA - Scandanavia	1080373

Description	Item Number
Oxygen Hose - NIST X DIN - Germany	1080374
Oxygen Hose - NIST X UNI - Italy	1080375
Oxygen Hose - NIST X AFNOR - France	1080376
Oxygen Hose - NIST X NIST - EU	1080577
Oxygen Hose - NIST X BS - UK	1080578
Oxygen Hose - F DISS X MALE DISS DV - Canada	1080579
Oxygen Hose - DISS HT X DISS HT (U.S.A. & Others)	1080580
Fan Filter Replacement Kit	1080800
Regulator Filter, Replacement	1098394
Internal Battery	1080802
Oxygen Sensor	1080801
Oxygen Sensor Tool	1080812
Remote Alarm Cable - Normally Closed (NC)	1076195
Remote Alarm Cable - Normally Open (NO)	1076194
Remote Alarm Cable - Open Platform (OP)	1078409
Oxygen Sensor Door	1080809
Internal Battery Door	1080808
Start-up Part	1084541

Circadiance continues to develop accessories for the NeoPAP System. Contact your local representative for the latest accessories list.

Appendix A. EMC Information

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 emissions CISPR 11	Group 1	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	Class A	The device is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/Flicker emissions IEC 61000-3-3	Complies	

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	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical Fast Transient/ Burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input-output lines	±2 kV for supply mains ±1 kV for input/output lines	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 ±2 kV for common mode	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 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5 sec	<5% U_T (>95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5 sec	Mains power quality should be that of a typical home or hospital environment.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 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 Radiated RF IEC 61000-4-3	3 Vrms 150 kHz to 80 MHz 3 V/m 80 MHz to 2.5 GHz	3 Vrms 3 V/m	Portable and mobile RF communications equipment should be used no closer to any part of the device, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance:** $d = 1.2 \sqrt{P}$ 150 kHz to 80 MHz $d = 1.2 \sqrt{P}$ 80 MHz to 800 MHz $d = 2.3 \sqrt{P}$ 800 MHz to 2.5 GHz Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey **a**, should be less than the compliance level in each frequency range **b**. Interference may occur in the vicinity of equipment marked with the following symbol: 

NOTE 1: At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

a: Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the device is used exceeds the applicable RF compliance level above, the device should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the device.

b: Over the frequency range 150 kHz to 80 MHz, the field strengths should be less than 3 V/m.

Recommended Separation Distances between Portable and Mobile RF Communications Equipment and this Device

The device is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of this device can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and this device as recommended below, according to the maximum output power of the communications equipment.

Rated Maximum Power Output of Transmitter (W)	Separation Distance According to Frequency of Transmitter (m)		
	150 kHz to 80 MHz $d = 1.2\sqrt{P}$	80 MHz to 800 MHz $d = 1.2\sqrt{P}$	800 MHz to 2.5 GHz $d = 2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance *d* in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

Note 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

Appendix B. Elevation Settings

The table below lists the recommended device settings based on elevation.

Elevation (meters)	Recommended Setting (hPa)	Recommended Setting (mmHg)
-500	1070	803
-400	1060	795
-300	1050	788
-200	1040	780
-100	1030	773
0	1010	758
100	1000	750
200	990	743
300	980	735
400	970	728
500	950	713
600	940	705
700	930	698
800	920	690
900	910	683
1000	900	675
1100	890	668
1200	880	660
1300	870	653
1400	860	645
1500	850	638
1600	840	630
1700	830	623
1800	810	608
1900	800	600

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Appendix C. Maximum Leak Sensitivity Setting by CPAP Setting

CPAP Setting (cmH_20)	Maximum Leak Sensitivity Setting (L/min)	XXS Cannula Maximum Leak Sensitivity Setting
2	5	4
3	7	5
4	9	5
5	11	6
6	13	6
7	15	7
8	14	7
9	13	8
10	12	9

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Appendix D. Warranty

Circadiance, LLC warrants the NeoPAP System to be free from defects in material and workmanship for a period of 12 months from the date of purchase, provided that the unit is operated under conditions of normal use as described in this manual. At its discretion, Circadiance, LLC will make replacements, repairs, or issue credits for equipment or parts that are found to be defective.

The warranty set forth above is the sole and exclusive warranty with respect to the product and Circadiance, LLC does not make, and hereby specifically disclaims, all other warranties, express or implied, including without limitation, any implied warranty of merchantability or implied warranty of fitness for a particular purpose. The repair, replacement or credit remedy set forth above will be the sole remedy for breach of warranty. In no event shall Circadiance, LLC be liable for lost profits, loss of good will, or incidental or consequential damages even if Circadiance, LLC has been advised of the possibility of the same.

Exclusions

This warranty does not apply to any unit or individual parts which have been repaired or altered in any way that in Circadiance, LLC's judgment, affect its ability or reliability, or which has been subjected to misuse, negligence, abuse, or accident.

Unauthorized service and/or failure to perform periodic maintenance may void this warranty.

This warranty does not cover damage that may occur in shipment.

To exercise your rights under this warranty, contact Circadiance, LLC at

the addresses below:

Circadiance LLC
1300 Rodi Road
Turtle Creek, PA 15145 USA
www.circadiance.com

Warranty

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