VAPOTHERM®

Oxygen Assist Module

for use with Vapotherm Precision Flow®

Instructions for Use

Table of Contents

Symbols

	Attention: Consult Manual
	Warning: Instructions for Use must be read
	Alternating Current
	Single Patient Use
	Protective Earth
	Do not cover
	Type BF Class 1
	This symbol indicates that the waste of electrical and electronic equipment must not be disposed as an unsorted municipal waste and must be collected separately. Please contact an authorized representative of the manufacturer for information concerning the decommissioning of your equipment.
	Device On/Off
	Alarm Silence/Suspend
	Alarm Silenced
	Battery Charge
	USB Connected
	Electronic Medical Record Connection Receptacle
	SpO_2 Patient Cable Connection Receptacle
	USB Connection Receptacle
	Ethernet Connection Receptacle
	Nurse Call Connection Receptacle
	Precision Flow Connection Receptacle
	Reserved Connection Receptacle

Section 1 Indications, Warnings and Cautions

Primary Indications

The Oxygen Assist Module is an optional module used only with the Vapotherm Precision Flow and is indicated for on-demand titration of oxygen into warm humidified breathing gases delivered to spontaneously breathing patients based on continuous non-invasive monitoring of blood oxygen saturation.

The Oxygen Assist Module is intended to treat pediatric (including neonatal) and adult patients in monitored clinical environments.

Warnings and Cautions

- A Warning indicates that a situation may occur which is potentially harmful to the patient or user.
- A Caution indicates a condition that may lead to equipment damage, malfunction or inaccurate operation.
- A Note indicates a point of emphasis to make operation more efficient or convenient.

Please take the time to familiarize yourself with the warnings, cautions, and notes listed in these Instructions for Use and in the Precision Flow Instructions for Use.

The user of this product shall have sole responsibility for any malfunction due to operation or maintenance performed by anyone not trained by Vapotherm staff or official training documentation.

When handling any part of the Precision Flow system, always follow hospital infection control guidelines and standard precautions. Vapotherm also recommends that users follow the Center for Disease Control (CDC) publications Guidelines for Maintenance of In-Use Respiratory Therapy Equipment and Guidelines for Prevention of Nosocomial Pneumonia. For more information, see the Precision Flow Instructions for Use.

General Warnings

Federal Law (U.S.) restricts the use of this device to, or by the order of a physician. This device should be used only by clinical staff who are trained on use and operation of the Oxygen Assist Module and the Precision Flow.

Service on the device should only be performed by qualified, certified service technicians.

If the device is damaged or not working properly, do not use. Contact your authorized clinical trial study coordinator.

Do not operate if power cord is damaged. Do not use any cord except the one provided. Do not use extension cords.

WARNING: Do not modify this equipment without authorization of the manufacturer. Failure to follow this warning may result in device failure or patient harm.

For use only in a clinical setting with standard of care patient monitoring. Operator shall remain close enough to hear alarms.

For use only on spontaneously breathing patients. The Precision Flow® with or without the Oxygen Assist Module is not life supporting.

Incorporation of SpO_2 into the Precision Flow® with the Oxygen Assist Module does not eliminate the need for separate and independent patient monitoring indicated by the Precision Flow® system labeling. Patients on high velocity nasal insufflation receiving supplemental oxygen are acute and appropriate clinical vigilance should be observed by the care team. Additional patient monitoring including pulse oximetry is necessary if the Precision Flow® is used to give supplementary oxygen.

Do not initiate automatic oxygen delivery with the Oxygen Assist Module until the patient's SpO_2 is stable.

Section 1 Indications, Warnings and Cautions

For more information, see the Precision Flow Instructions for Use.

Masimo® Warnings, Cautions and Notes

General:

- The Oxygen Assist Module is to be operated by, or under the supervision of, qualified personnel only. The manual, accessories, directions for use, all precautionary information, and specifications should be read before use.

Warnings:

- As with all medical equipment, carefully route patient cabling to reduce the possibility of patient entanglement or strangulation.
- Do not place the Oxygen Assist Module or accessories in any position that might cause it to fall on the patient.
- Do not start or operate the Oxygen Assist Module unless the setup was verified to be correct.
- Do not use the Oxygen Assist Module during magnetic resonance imaging (MRI) or in an MRI environment.
- Do not use the Oxygen Assist Module if it appears or is suspected to be damaged.
- Explosion hazard: Do not use the Oxygen Assist Module in the presence of flammable anesthetics or other flammable substance in combination with air, oxygen-enriched environments, or nitrous oxide.
- To ensure safety, avoid stacking multiple devices or placing anything on the device during operation.
- To protect against injury, follow the directions below:
  - Avoid placing the device on surfaces with visible liquid spills.
  - Do not soak or immerse the device in liquids.
  - Do not attempt to sterilize the device.
  - Use cleaning solutions only as instructed in this Instructions for Use.
  - Do not attempt to clean the device while attached to a patient.
- To protect from electric shock, always remove the SpO_2 sensor and completely disconnect the Oxygen Assist Module from the patient before bathing the patient.
- If the SpO_2 measurement seems questionable, first check the patient's vital signs by alternate means and then check the Oxygen Assist Module for proper functioning.
- Inaccurate SpO_2 readings may be caused by:
  - Improper sensor application and placement
  - Elevated levels of COHb or MetHb: High levels of COHb or MetHb may occur with a seemingly normal SpO_2. When elevated levels of COHb or MetHb are suspected, laboratory analysis (CO-Oximetry) of a blood sample should be performed.
  - Elevated levels of bilirubin
  - Elevated levels of dyshemoglobin
  - Vasospastic disease, such as Raynaud's, and peripheral vascular disease
  - Hemoglobinopathies and synthesis disorders such as thalassemias, Hb s, Hb c, sickle cell, etc.
  - Hypocapnic or hypercapnic conditions
  - Severe anemia

- Very low arterial perfusion
- Extreme motion artifact
- Abnormal venous pulsation or venous constriction
- Severe vasoconstriction or hypothermia
- Arterial catheters and intra-aortic balloon
- Intravascular dyes, such as indocyanine green or methylene blue
- Externally applied coloring and texture, such as nail polish, acrylic nails, glitter, etc.
- Birthmark(s), tattoos, skin discolorations, moisture on skin, deformed or abnormal fingers. etc.
- Skin color disorders

- Interfering Substances: Dyes or any substance containing dyes that change usual blood pigmentation may cause erroneous readings.
- The Oxygen Assist Module should not be used as the sole basis for medical decisions. It must be used in conjunction with clinical signs and symptoms
- The SpO_2 measurement on the Oxygen Assist Module is not a measure of apnea.
- The Oxygen Assist Module may be used during defibrillation but this may affect the accuracy or availability of the SpO_2 measurement.
- The Oxygen Assist Module may be used during electrocautery, but this may affect the accuracy or availability of the SpO_2 measurement.
- The SpO_2 measurement on the Oxygen Assist Module should not be used for arrhythmia analysis.
- SpO_2 is empirically calibrated in healthy adult volunteers with normal levels of carboxyhemoglobin (COHb) and methemoglobin (MetHb).
- Do not adjust, repair, open, disassemble, or modify the Oxygen Assist Module or accessories. Injury to personnel or equipment damage could occur. Return the Oxygen Assist Module for servicing if necessary.

Cautions:

- Do not place the Oxygen Assist Module where the controls can be changed by the patient.
- Electrical shock and flammability hazard: Before cleaning, always turn off the device and disconnect from any power source.
- When patients are undergoing photodynamic therapy they may be sensitive to light sources. Pulse oximetry may be used only under careful clinical supervision for short time periods to minimize interference with photodynamic therapy.
- Do not place the Oxygen Assist Module on electrical equipment that may affect the device, preventing it from working properly.
- If SpO_2 values indicate hypoxemia, a laboratory blood sample should be taken to confirm the patient's condition.
- If the Low Perfusion message is frequently displayed, find a better perfused monitoring site. In the interim, assess the patient and, if indicated, verify oxygenation status through other means.
- Change the application site or replace the SpO_2 sensor and/or patient cable when a "Replace sensor" and/or "Replace patient cable", or a persistent poor signal quality message (such as "Low SIQ") is displayed. These messages may indicate that patient monitoring time is exhausted on the patient cable or sensor.

Section 1 Indications, Warnings and Cautions

- If using the Oxygen Assist Module during full body irradiation, keep the SpO_2 sensor out of the radiation field. If the sensor is exposed to the radiation, the reading might be inaccurate or the device might read zero for the duration of the active irradiation period.
- Variation in measurements may be profound and may be affected by sampling technique as well as the patient's physiological conditions. Any results exhibiting inconsistency with the patient's clinical status should be repeated and/or supplemented with additional test data. Blood samples should be analyzed by laboratory instruments prior to clinical decision making to completely understand the patient's condition.
- Do not submerge the Oxygen Assist Module or any associated accessories in any cleaning solution or attempt to sterilize by autoclave, irradiation, steam, gas, ethylene oxide or any other method. This will seriously damage the device.
- Electrical Shock Hazard: Carry out periodic tests to verify that leakage currents of patient-applied circuits and the system are within acceptable limits as specified by the applicable safety standards. The summation of leakage currents must be checked and in compliance with IEC 60601-1 and UL60601-1. The system leakage current must be checked when connecting external equipment to the system. When an event such as a component drop of approximately 1 meter or greater or a spillage of blood or other liquids occurs, retest before further use. Injury to personnel could occur.
- Disposal of product - Comply with local laws in the disposal of the device and/or its accessories.
- To minimize radio interference, other electrical equipment that emits radio frequency transmissions should not be in close proximity to the Oxygen Assist Module.
- Replace the SpO_2 cable or sensor when a replace sensor or when a low SIQ message is consistently displayed while monitoring consecutive patients after completing troubleshooting steps listed in this manual.

Notes:

- A functional tester cannot be used to assess the accuracy of the SpO_2 measurement on the Oxygen Assist Module.
- High-intensity extreme lights (such as pulsating strobe lights) directed on the SpO_2 sensor, may not allow the Oxygen Assist Module to obtain an accurate reading.
- Do not loop the SpO_2 patient cabling into a tight coil or wrap around the device, as this can damage the patient cabling.
- Additional information specific to the Masimo sensors compatible with the Oxygen Assist Module, including information about parameter/measurement performance during motion and low perfusion, may be found in the sensor's directions for use (DFU).
- SpO_2 cables and sensors are provided with X-Cal™ technology to minimize the risk of inaccurate readings and unanticipated loss of patient monitoring. Refer to the Cable or Sensor DFU for the specified duration of the patient monitoring time.

This device is covered under one or more patents as set forth at: www.masimo.com/patents.htm

NO IMPLIED LICENSE: Possession or purchase of this device does not convey any express or implied license to use the device with unauthorized sensors or cables which would, alone or in combination with this device, fall within the scope of one or more of the patents relating to this device.

Section 2 Principles of Operation

The Vapotherm Oxygen Assist Module is designed to work with the Precision Flow system to manage oxygen delivery based on patient clinical need as reflected in their SpO_2 reading. This automatic control system uses a proprietary feedback control algorithm to track a patient's oxygen saturation and automatically adjust the oxygen concentration delivered through their respiratory support.

Vapotherm Oxygen Assist Module

Vapotherm Precision Flow

The Vapotherm Oxygen Assist Module uses proven pulse oximetry and Precision Flow gas delivery technologies and a proprietary algorithm that increases or decreases the $\%O_2$ setting in an effort to maintain a target SpO_2 value. The clinician sets the target SpO_2 and the system uses the algorithm that combines analysis of real-time measurements and trending to choose the appropriate $\%O_2$ delivery. The use of smart averaging and hysteresis algorithms by the Masimo SET™ SpO_2 monitor protects the system from artifacts that could cause too rapid cycling of O_2 delivery. Oxygen Assist Module is designed for use with the Precision Flow System, which controls the $\%O_2$ delivery based on a setting sent from Oxygen Assist Module or being set on the Precision Flow itself manually.

The Oxygen Assist Module communicates with the Precision Flow through the serial interface port located on the back of the Precision Flow unit.

NOTE: Some clinicians may find the peak wavelengths and radiant power of the light emitting diodes employed in the SpO_2 probe useful. Masimo's sensors use Red and Infrared light emitting diodes. These diodes emit at 660nm and 905nm respectively and have a radiant power of less than 15mW.

Section 3 Components

The Vapotherm Oxygen Assist Module consists of the following parts:

- The Oxygen Assist Module
- Pole Mount Assembly
- Power Supply
- Masimo SpO_2 Patient Cable

WARNING: The provided power adapter is the only adapter approved for use with the Oxygen Assist Module and provides 12VDC to the Oxygen Assist Module. Contact Vapotherm if you believe your power adapter to not be functional or you need a replacement. Only use power adapter as provided by Vapotherm.

Masimo sensors are available separately. Approved Masimo sensor models include the following:

- LNCS® Adhesive Sensors
- LNCS® Neo-3 Adhesive Sensors
- RD SET™ Sensors

WARNING: Applied parts that may be used with the Oxygen Assist Module are the Masimo SpO_2 probes referenced above. Please consult Masimo accompanying documents for details.

Section 4 Assembly and Connections

System Assembly

1. Affix the Oxygen Assist Module to the Pole Mount Assembly.
2. Mount the Oxygen Assist Module to the Vapotherm approved roll stand as shown.
3. Remove the silicone plug in the oxygen sensor cover on the back of the Precision Flow.
4. Plug the communication cable into the Oxygen Assist Module and tighten the two thumb screws.
5. Connect the communication cable from the Oxygen Assist Module into the Precision Flow's interface port.
6. Plug the Oxygen Assist Module Power Supply into the Oxygen Assist Module and into an electrical outlet marked "Hospital Grade" or "Hospital Only."

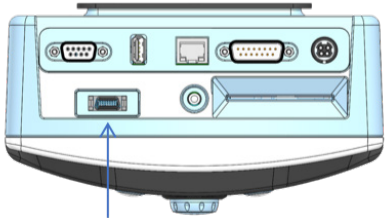
   NOTE: Ensure proper orientation on Power Supply connector when inserting into the Oxygen Assist Module.

   WARNING: Do not position the Oxygen Assist Module so that it is difficult to disconnect the device.

Sensor Connection

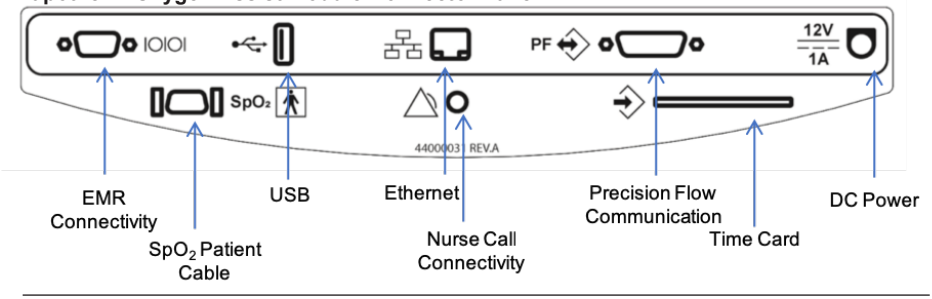
- Connect the SpO_2 patient cable to the SpO_2 receptacle on the connector panel of the Oxygen Assist Module. Please consult Attaching the Sensor to the Patient Cable in the Masimo *DIRECTIONS FOR USE* to learn how to connect the sensor.

Oxygen Assist Module mounted and plugged into the Precision Flow and Power



SpO_2 Patient Cable

Vapotherm Oxygen Assist Module Connector Panel



Section 5 Controls and Display

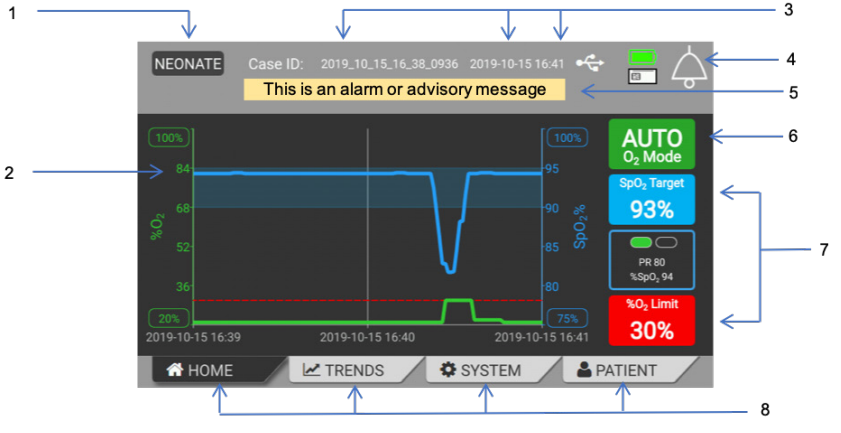
The Oxygen Assist Module is controlled via two fixed keys (On/Off; Alarm Silence), a settings control knob, and a touch screen. When connected to the Precision Flow and to the patient via an SpO_2 sensor, the Oxygen Assist Module delivers manual control (Manual Mode) or automatic control (Auto Mode) delivery of oxygen.

Using Menus

- To call up a menu, press the desired menu tab. Alternately, parameter boxes will redirect to the associated menu.

  Notes:

  Unless otherwise stated, the change to settings takes effect when you press the key.



1 Patient Type Indicator
2 Trend Display
3 Patient ID, Time and Date Display
4 Alarm Silence Indicator (crossed when silenced)
5 Message Display
6 $\%O_2$ Mode (Auto; Manual)
7 Parameter Boxes (press to call up menus)
8 Menu Keys

Note: The Oxygen Assist Module is calibrated to display functional oxygen saturation. Both SpO_2 and $\%O_2$ displayed values on the trend display are normalized as percentages.

Section 6 Power Up and Basic Setup

System Setup

1. Set up the Precision Flow according to Precision Flow Instructions for use. Connect oxygen and air supply hoses to correct inlets, then connect them to wall outlets. Connect power cord.
2. Plug the Oxygen Assist Module unit into power. The “Splash Screen” will be shown while the system powers up. The On/Off Key is used to turn on the device when plugged into power. Select the System Menu. Set TIME and DATE to their correct values.
3. Set the Auto Mode Override to the desired setting. Options are: Exit Auto Mode, 120, 90, 60, 30, 15, or 5 seconds. “Auto Mode Override” establishes how the Oxygen Assist Module will respond to a manual change of the $\%O_2$ delivery using the Precision Flow when the Oxygen Assist Module is in Auto Mode. A manual change in $\%O_2$ on the Precision Flow with “Exit Auto Mode” selected will immediately place the Oxygen Assist Module in Manual $\%O_2$ Mode. A manual change in $\%O_2$ on the Precision Flow with “120/90/60/30/15/5” seconds selected will suppress Auto Mode $\%O_2$ titration for that period of time before the Oxygen Assist Module restarts auto $\%O_2$ titration.
4. Set preferred speaker volume and screen brightness.

System Access

PINs are required to access Software Updates, Case Data, and Institutional Defaults.

Default PINs:

Software Update - 1234

Manage Case Data - 5678

Institutional Defaults - 0987

PINs can be changed on the System screen by using the Access Tab.

Alarm Indications

Section 7 Patient Admission

The Patient menu allows the selection of the patient type and patient specific settings, as well as starting a new case and switching between Auto and Manual $\%O_2$ Mode.

1. Set the Patient Type (Neonate), $\%SpO_2$ Target, $\%SpO_2$ Upper and Lower Range, Backup $\%O_2$, and $\%O_2$ Alarm Limit.
2. Press Start Case. When a new case is started, the Oxygen Assist Module creates a new Patient ID consisting of a date and time stamp. This Patient ID is displayed at the top of all screens.

Section 8 Alarm Setup

The Oxygen Assist Module announces 1 level of alarm:

- Medium Priority Alarm: Flashing amber; burst of 3 beeps.

The Oxygen Assist Module displays silent advisory messages in the message area.

Notes:

Before starting a new case, with the patient sensor disconnected, confirm that the alarm system is functional by observing that an alarm is generated stating "No Sensor Connected".

Alarm messages cycle in the message area.

For a list of alarm messages and required action, please see the section Alarm and Status Messages.

For alarm indications of the Precision Flow, please see the Precision Flow Instructions for Use.

Alarm Silence/Suspend

- Press the Alarm Silence fixed key to mute all alarms for 2 minutes.

Note: If alarms are muted, a crossed bell icon appears in the upper right-hand corner of the screen.

Warnings:

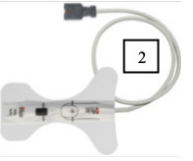
If alarms are silenced for 2 minutes, a subsequent alarm of the same alarm priority will not be announced during the 2-minute alarm silence period.

Section 9 SpO_2 Setup

Sensor Selection and Placement

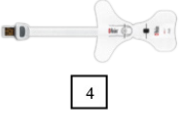
When selecting a sensor, consider the following:

- Patient weight
- Patient activity level
- Patient perfusion levels
- Available sensor sites
- Anticipated duration of SpO_2 monitoring



Masimo sensor models include the following:

- LNCS® Reusable Sensors (1)
- LNCS® Adhesive Sensors (2)
- LNCS® Neo-3 Adhesive Sensors (3)
- RD SET Sensors (4)



Apply the sensor as follows:

1. Clean application site. Remove nail polish, if necessary.
2. Select an appropriate sensor and apply as directed in the sensor documentation.
3. If there is bright ambient light, cover the application site with opaque material. (Direct sunlight, surgical and fluorescent lights, bilirubin lamps, and infrared heating lamps can interfere with sensor performance.

For more information on application of the sensor, consult Site Selection in the Masimo DIRECTIONS FOR USE.

Warnings:

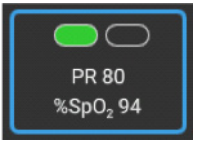
- Use only approved Masimo oximetry sensors for SpO_2 measurements. Other sensors may cause incorrect SpO_2 readings.
- Before using the sensor, carefully read the sensor documentation, including all warnings, cautions and instructions.
- The accuracy of pulse oximetry readings can be adversely affected by ambient conditions, sensor application errors, and patient movement.
- Do not use the sensor on an extremity with a blood pressure cuff, arterial catheter or intravascular line.
- Significant levels of dysfunctional hemoglobin (HbCO or MetHb) can cause inaccurate readings.
- Do not use a damaged sensor or damaged patient cables.
- Do not use a sensor with exposed optical components.
- Do not use sensors in MR environments. Conducted current could cause burns.
- Use of the sensor during defibrillation may cause incorrect readings.
- Incorrect application and prolonged use of the sensor can cause tissue damage. Inspect the application site frequently to ensure that correct sensor positioning is maintained, and to detect any skin irritation.
- Do not wrap the sensor too tightly.
- Do not apply excessive tension to sensor cables.
- Do not immerse the sensor or patient cables in water, solvents, or cleaning solutions. Sensor, connectors and patient cables are not waterproof.

Section 9 SpO_2 Setup

- Do not sterilize the sensor or patient cables by irradiation, steam, or ethylene oxide. Consult the cleaning and sterilization instructions in the documentation for reusable pulse oximetry sensors and patient cables.

  Note: The sensors used with this device can be categorized as surface devices contacting skin for a limited period of time. The sensors have passed the recommended biocompatibility testing and are therefore in compliance with ISO 10993–1.

SpO_2 Parameter Box Display



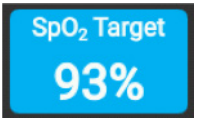
Note: The indicator lights provide information on Signal IQ. Green denotes Signal IQ values of equal to or greater than 0.3%. Red denotes Signal IQ values of less than 0.3%.

The SpO_2 display range is from 1-100%. A value of "---" indicates that no measurement is available. The pulse rate display range is from 1-240 bpm. A value of "---" indicates that no measurement is available.

Note: The SpO_2, pulse rate, and Signal IQ are updated once per second.

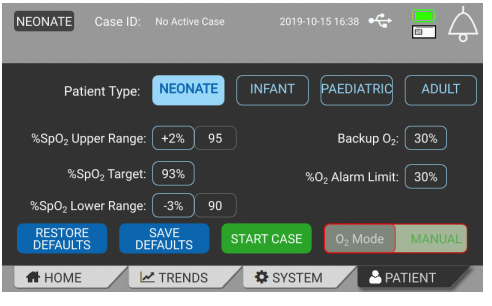
SpO_2 Target Setup

1. Press the SpO_2 Target Box on the Home screen or select the Patient menu to set the SpO_2 target.



2. Press the %SpO_2 Target parameter box on the touch screen, and set the patient's target SpO_2 using the settings control knob.
3. Set the Target Range by pressing the %SpO_2 Upper and Lower Range parameter boxes on the touch screen, and set the percent difference from the %SpO_2 Target using the settings control knob.

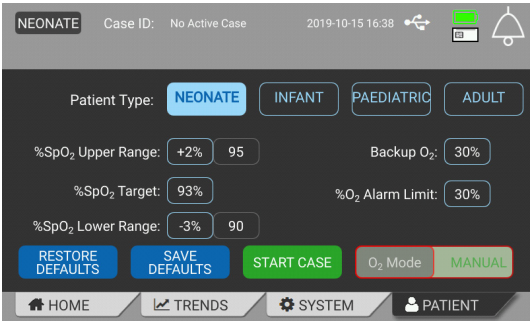
   NOTE: Setting the Target Range does not change the SpO_2 Target. This setting only adjusts the time in range calculation when reviewing trends.



Section 10 $\%O_2$ Setup

Goal and purpose: The automatic $\%O_2$ control system uses the patient's measured SpO_2 values to control the delivery of $\%O_2$ based on patient need. When the automatic $\%O_2$ control mode is enabled, the system tries to maintain the patient's SpO_2 level at or near a preconfigured SpO_2 target (see also Further Reading).

1. Select the **Patient** menu to set the $\%O_2$ Mode.



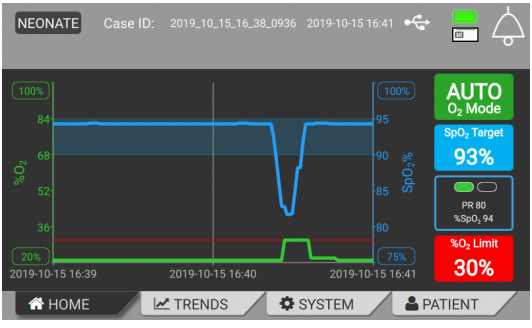
2. Press the Backup $\%O_2$ parameter box on the touch screen, and set the patient's Backup $\%O_2$ using the settings control knob.

   Note: See description of Fallback $\%O_2$ Functionality on the following page for more information.

3. Insert Oxygen Assist Module Time Card and Press Start Case. When the patient is stable, press the O_2 Mode AUTO button to put the device into Auto Mode (default is Manual).

   Note: To enable Auto $\%O_2$ Mode, there must be a time card inserted and a patient case started on the Oxygen Assist Module.

4. The Home screen will now display AUTO mode and the Oxygen Assist Module will begin auto $\%O_2$ titration based on the patient's SpO_2 level and the set $\%SpO_2$ Target. $\%O_2$ delivered by the Precision Flow can range from 21-100%, unless a $\%O_2$ Limit is set. Delivered $\%O_2$ can be seen on the Precision Flow display, or on the Oxygen Assist Module Home Screen graphical trend display.



Section 10 $\%O_2$ Setup

Fallback $\%O_2$ Functionality

For short instances of invalid or unreliable SpO_2 readings, an error message is displayed that reflects the error condition and the Oxygen Assist Module will continue to deliver the calculated $\%O_2$ until the SpO_2 reading becomes valid and reliable.

While the SpO_2 signal is invalid or unreliable, the $\%O_2$ delivery is set to the greater of the following:

- The Backup $\%O_2$ setting.
- The Baseline $\%O_2$ setting, algorithm calculated as the value needed to keep the patient at SpO_2 set point during the period the Oxygen Assist Module was in Auto $\%O_2$ Mode.
- The median value of the last three Auto $\%O_2$ values delivered prior to the SpO_2 failure.

The Oxygen Assist Module automatically exits the Auto mode under the following circumstances:

- Clinical staff changes $\%O_2$ settings at the Precision Flow. The Oxygen Assist Module behaves according to Auto Mode Override setting.
- The Oxygen Assist Module detects invalid or unreliable SpO_2 reading as described above for more than 2 minutes.

If the Oxygen Assist Module has exited the Auto mode, check the patient, sensor placement, connections and settings. When clinically indicated, place the Oxygen Assist Module back into Auto mode in the **Patient** menu.

Section 11 System Shutdown

System Shutdown

1. On the **Patient** menu, select End Case.
2. To power down the Oxygen Assist Module, press the On/Off button to turn off the device, then remove the provided AC power adapter from the AC wall receptacle.

Section 12 Graphical Trend Display

Trend data is displayed on the Home screen. It shows SpO_2 (blue) and $\%O_2$ (green) trended values, with the latest values on the right hand side of the display and oldest to the left. $\%O_2$ Alarm Limit is shown by the dashed red line. The trend display is updated every second. The trend data can also be viewed on the **Trend** screen, where the trend display time can be adjusted.

On the **Trend** screen, the trend data can be viewed and display can be modified using the navigation buttons.

Section 13 Logging of Variables

The following variables are logged at one second intervals and stored indefinitely in non-volatile memory. The non-volatile memory retains its settings even after a loss of power or the system has been turned off.

- Time stamp
- SpO_2
- $\%O_2$
- Auto/Manual Mode

Section 14 Cleaning and Disinfecting

The Oxygen Assist Module must always be cleaned and disinfected between patients. Follow the steps below to ensure a clean and disinfected device.

- Wipe down the main unit with Super Sani-Cloth®.
- Examine for visible soil. If visible soil is present, use a brush (e.g. Spectrum M16 brush) to remove visible soil.
- Wet the module with another Super Sani-Cloth®. Keep the surface wet for at least six minutes. Use additional Super Sani-Cloth® if needed.

  Caution: Do not use bleach, organic solvents or abrasive cleaners.

For cleaning and disinfecting instructions for the Precision Flow, see the Precision Flow Instructions for Use.

For cleaning and disinfecting instructions for the SpO_2 sensor and patient cable, see the instructions provided with the sensor.

Section 15 Data Download

1. Insert USB Drive into the Oxygen Assist Module.
2. On the System screen, select Case Data and enter PIN.
3. Choose which Case file or files to download and press Download button.

   NOTE: Downloading multiple large case files may take several minutes to complete.
4. Once data is saved, press OK and remove USB Drive.
5. As needed, delete Case files to clear Local Storage.

Section 16 Software Updates

1. Insert USB Drive with software file into the Oxygen Assist Module.
2. On the System screen, select Updates and enter PIN.
3. Select Update Software.

   NOTE: System will reboot throughout the Software Update Process

Section 17 Referenced Documentation

Precision Flow Instructions for Use can be found at our website www.vapotherm.com

Section 18 Troubleshooting and Support

General

If you need assistance with the Oxygen Assist Module of Vapotherm system, please contact Vapotherm Technical Support at TS@vtherm.com.

The Oxygen Assist Module has a user-replaceable battery. Remove the mounting plate on the back of the Oxygen Assist Module to access battery compartment. Remove old battery and replace with new battery (Contact Vapotherm Technical Support at TS@vtherm.com).

Prior to use, perform a visual inspection of the display, casing, and wires to confirm there is no visible damage.

Troubleshooting: SpO_2

Condition	Probable Cause	Action
No signal: SpO_2 and PR at 0	Clinical (patient condition).	Check patient.
	Sensor not connected.	Check sensor and cable connections.
	Sensor off patient.	Check sensor application.
	Sensor or cables damaged.	Check sensor and cables. Replace, if necessary.
	Excessive patient movement or electrosurgical interference.	If possible, keep patient still. Check sensor and sensor application. Move sensor to a different site or use a sensor that tolerates more motion.
Inaccurate SpO_2 values	Clinical (patient condition).	Check patient.
	Excessive ambient light.	Check sensor. Cover sensor with opaque material.
	Excessive movement.	If possible, keep patient still. Check sensor and sensor application. Move sensor to a different site or use a sensor that tolerates more motion.
	Nail polish at application site.	Remove nail polish.
	Sensor is applied on an extremity that has a blood pressure cuff, arterial catheter or intravascular line.	Move sensor to a different site.

Section 19 Specifications

Physical Characteristics

Dimensions:	Height 9", width 9", depth 4"
Weight:	4.1 lbs.
Mounting:	VESA Oxygen Assist Module Pole Mount Assembly
Connections:	Via Oxygen Assist Module communication cable to Precision Flow
System Requirements	
Power:	Included 12VDC power supply operates over 100-240VAC, 18W, 47-63Hz This power adapter provides magnetic isolation of the Oxygen Assist Module to the mains supply.
Battery:	Li-ion, 34-37 Wh, internal
External Battery Charger:	N/A
Environment	
Operation:	Ambient Temperature: 18-30°C
	Ambient Relative Humidity: 20-90% RH non-condensing
	Ambient Pressure: Standard atmospheric (not to be used in hyperbaric cond.)
Storage and Shipping:	Ambient Temperature: -10- +50°C
	Ambient Relative Humidity: 20-90% RH
Contact with Patient:	Indirectly via SpO_2 sensor and Precision Flow O_2 cannula
Liquid Ingress Protection:	IPX2 – Drip-proof
Alarm Sound Pressure	Medium Priority Alarm 65dBA maximum at volume setting 10
Operating Altitude	2000 meters
Inputs	
Sensors:	SpO_2 connector for Masimo patient interface cable
External Device Communication:	Connection to Precision Flow via the Oxygen Assist Module communication cable
Outputs	
RJ45 Connection:	**WARNING: This connection is not intended for network connectivity. It is for Vapotherm use only.**

NOTE: The Oxygen Assist Module system is comprised of the Oxygen Assist Module and the provided AC power adapter. The provided AC power adapter is protection Class I device.

WARNING: To avoid the risk of electric shock, this equipment must only be connected to a supply mains with protective earth.

Section 19 Specifications

Standards	
IEC 60601-1:2005 (Third Edition) + CORR. 1:2006 + CORR. 2:2007 + A1:2012 (or IEC 60601-1: 2012 reprint)	Medical Electrical Equipment – Part 1: General Requirements for Basic Safety and Essential Performance
IEC 60601-1-10:2007, AMD1:2013 for use in conjunction with IEC 60601-1:2005, COR1:2006, COR2:2007, AMD1:2012	Medical Electrical Equipment – Part 1-10: General requirements for basic safety and essential performance – Collateral standard: Requirements for the development of Physiologic Closed-loop Controllers (FDA Consensus Standard FR Recognition Number 19-9)
IEC 60601-1-6:2010, AMD1:2013 for use in conjunction with IEC 62366:2007, AMD1:2014 and IEC 60601-1:2005, COR1:2006, COR2:2007, AMD1: 2012 or equivalent consolidated version IEC 60601-1:2012 (Edition 3.1)	Medical Electrical Equipment – Part 1-6: General requirements for basic safety and essential performance – Collateral Standard: Usability
IEC 60601-1- 8: 2006 (Second Edition) + Am.1: 2012 for use in conjunction with IEC 60601-1: 2005 (Third Edition) + Am.1: 2012	Part 1-8: General requirements for basic safety and essential performance – Collateral standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems
IEC 60601-1-2. Ed. 4.0 (2014-02)	General requirements for safety – Collateral standard: Electromagnetic Compatibility – Requirements and tests
ISO 80601-2-61:2017, COR1:2018 for use IEC 60601-1:2005, COR1:2006, COR2:2007, AMD1:2012	Medical electrical equipment – Part 2-61: Particular requirements for basic safety and essential performance of pulse oximeter equipment
IEC 62304:2006 (First Edition) + A1:2015 (or IEC 62304:2015 CSV)	Medical device software: Software Life cycle processes
IEC 62366-1:2015	Medical devices – Part 1: Application of usability engineering to medical devices

Section 19 Specifications

Masimo SET® Accuracy Specifications

Saturation (% SpO_2) – During No Motion Conditions1

Adults, Pediatrics	70% - 100% ± 2 digits
	0% - 69% unspecified
Neonates	70% - 100% ± 3 digits
	0% - 69% unspecified

Saturation (% SpO_2) – During No Motion Conditions2,3

Adults, Pediatrics	70% - 100% ± 3 digits
	0% - 69% unspecified
Neonates	70% - 100% ± 3 digits
	0% - 69% unspecified

Pulse Rate (bpm) – During No Motion Conditions1

Adults, Pediatric, Neonates	25 to 240 ± 3 digits

Pulse Rate (bpm) – During Motion Conditions2,3

Adults, Pediatric, Neonates	25 to 240 ± 5 digits

1 The Masimo SET technology with Masimo sensors has been validated for no motion accuracy in human blood studies on healthy adult male and female volunteers with light to dark skin pigmentation in induced hypoxia studies in the range of 70-100% SpO_2 against a laboratory CO-Oximeter and ECG monitor. This variation equals ±1standard deviation. Plus or minus one standard deviation encompasses 68% of the population.
2 The Masimo SET technology with Masimo sensors has been validated for motion accuracy in human blood studies on healthy adult male and female volunteers with light to dark skin pigmentation in induced hypoxia studies while performing rubbing and tapping motions, at 2 to 4 Hz at an amplitude of 1 to 2 cm and a non-repetitive motion between 1 to 5 Hz at an amplitude of 2 to 3 cm in induced hypoxia studies in the range of 70-100% SpO_2 against a laboratory CO-Oximeter and ECG monitor. This variation equals ±1 standard deviation, which encompasses
3 The Masimo SET technology has been validated for low perfusion accuracy in bench top testing against a Biotek Index 2™ simulator and Masimo's simulator with signal strengths of greater than 0.02% and transmission of greater than 5% for saturations ranging from 70 to 100%. This variation equals ±1 standard deviation. Plus or minus one standard deviation encompasses 68% of the population.
4 The Masimo SET Technology with Masimo Neo sensors has been validated for neonatal motion accuracy in human blood studies on healthy adult male and female volunteers with light to dark skin pigmentation in induced hypoxia studies while performing rubbing and tapping motions, at 2 to 4 Hz at an amplitude of 1 to 2 cm and a non-repetitive motion between 1 to 5 Hz at an amplitude of 2 to 3 cm in induced hypoxia studies in the range of 70-100% SpO_2 against a laboratory CO-Oximeter and ECG monitor. This variation equals ±1 standard deviation. Plus or minus one standard deviation encompasses 68% of the population. 1% has been added to the results to account for the effects of fetal hemoglobin present in neonates.
5 The Masimo SET technology with Masimo sensors has been validated for pulse rate accuracy for the range of 25 -240 bpm in bench top testing against a Biotek Index 2™ simulator. This variation equals ±1 standard deviation. Plus or minus one standard deviation encompasses 68% of the population.
6 See sensor directions for use (DFU) for complete application information. Unless otherwise indicated, reposition reusable sensors at least every 4 hours and adhesive sensors at least every 8 hours.
11 Sensor accuracy specified when used with Masimo technology using a Masimo patient cable for LNOP sensors, RD SET sensors, the LNCS sensors, or the M-LNCS sensors. Numbers represent Arms (RMS error compared to the reference). Because pulse oximeter measurements are statistically distributed, only about two-thirds of the measurements can be expected to fall within a range of ± Arms compared to the reference value. Unless otherwise noted, SpO_2 accuracy is specified from 70% to 100%. Pulse Rate accuracy is specified from 25 to 240 bpm.
12 Masimo M-LNCS, LNOP, RD SET, and LNCS sensors types have the same optical and electrical properties and may differ only in application type (adhesive/non-adhesive/hook & loop), cable lengths, optical component locations (top or bottom of sensor as aligned with cable), adhesive material type/size, and connector type (LNOP 8 pin modular plug, RD 15 pin modular plug, LNCS 9 pin, cable based, and M-LNCS 15 pin, cable based). All sensor accuracy information and sensor application instructions are provided with the associated sensor directions for use.

References

For Vapotherm Precision Flow specifications, see the Precision Flow Instructions for Use.

For SpO_2 sensor specification, see the documentation provided with the sensor.

Section 20 Alarm and Advisory Messages

The essential performance of the device consists of proper delivery of appropriate FiO_2 based on patient clinical need as reflected in their SpO_2 reading. The User needs to appropriately respond to alarms to ensure the essential performance of the device is maintained.

The Oxygen Assist Module does not provide SpO_2 alarms. Separate and independent patient monitoring must be used.

The alarm condition delay is the time between the patient event and to when the Oxygen Assist Module detects the issue. The alarm signal generation delay is the time between when the Oxygen Assist Module detects the issue and when the Alarm is generated. The maximum delay is approximately 1 second.

The below Alarm and Advisory Messages will be displayed when a Case is Active and when the Oxygen Assist Module is in Auto Mode. Fallback $\%O_2$ will be delivered when SpO_2 signal is missing.

Medium Priority Alarm Message	**Action and Troubleshooting**
Battery Low - Shutdown Imminent	Plug Oxygen Assist Module into external power
Check SpO_2 - Adhesive Sensor Expired	Replace sensor, enter MANUAL Mode, or End Case
Check SpO_2 - Defective Adhesive Sensor	Replace sensor, enter MANUAL Mode, or End Case
Check SpO_2 - Defective Cable	Replace cable, enter MANUAL Mode, or End Case
Check SpO_2 - Defective Sensor	Replace sensor, enter MANUAL Mode, or End Case
Check SpO_2 - Incompatible Adhesive Sensor	Replace sensor, enter MANUAL Mode, or End Case
Check SpO_2 - Incompatible Cable	Replace cable, enter MANUAL Mode, or End Case
Check SpO_2 - Incompatible Sensor	Replace sensor, enter MANUAL Mode, or End Case
Check SpO_2 - No Adhesive Sensor Connected	Reconnect sensor with good signal, enter MANUAL Mode, or End Case
Check SpO_2 - No Cable Connected	Reconnect cable with good signal, enter MANUAL Mode, or End Case
Check SpO_2 - No Sensor Connected	Reconnect sensor with good signal, enter MANUAL Mode, or End Case
Check SpO_2 - Sensor Expired	Replace sensor, enter MANUAL Mode, or End Case
Check SpO_2 - Unrecognized Adhesive Sensor	Replace sensor, enter MANUAL Mode, or End Case
Check SpO_2 - Unrecognized Cable	Replace cable, enter MANUAL Mode, or End Case
Check SpO_2 - Unrecognized Sensor	Replace sensor, enter MANUAL Mode, or End Case
Insert Time Card or End Case	Time Card expired or removed. Insert Time Card or End Case
Precision Flow Communication Error	Restore Precision Flow Connection, enter MANUAL Mode, or End Case
Precision Flow Invalid Software Version	Restore Precision Flow Connection, or End Case and Update Precision Flow Software
SpO_2 Communication Error	Alert self-corrects, enter MANUAL Mode, or End Case
System Reset - Check Settings	Check settings. Press any key, touch screen or turn settings control knob

Section 20 Alarm and Advisory Messages

Silent Advisory Message	Action and Troubleshooting
$\%O_2$ at user set $\%O_2$ limit*	Increase $\%O_2$ Alarm Limit, or enter MANUAL mode
Battery Backup In Use	Oxygen Assist Module is in Battery Mode. When external power is lost, the module will automatically switch to Battery Mode.
Battery Low	Plug the Oxygen Assist Module into external power
Check Precision Flow	Clear Precision Flow alarm and ensure it is in Run Mode with both Air and O_2 sources present
Check SpO_2 - Adhesive Sensor Near Expiration	Replace SpO_2 Adhesive Sensor
Check SpO_2 - Cable Expired*	Replace Patient Cable
Check SpO_2 - Cable Near Expiration	Replace SpO_2 Patient Cable
Check SpO_2 - Check Sensor Connection*	Reconnect sensor with good signal
Check SpO_2 - Demo Mode*	Reconnect sensor with good signal
Check SpO_2 - Interference Detected*	Reconnect sensor with good signal
Check SpO_2 - Low Perfusion Index*	Reconnect sensor with good signal
Check SpO_2 - Low Signal IQ*	Reconnect sensor with good signal
Check SpO_2 - Pulse Search*	Reconnect sensor with good signal
Check SpO_2 - Sensor Fault*	Reconnect sensor with good signal
Check SpO_2 - Sensor Initializing*	Reconnect sensor with good signal
Check SpO_2 - Sensor Near Expiration	Replace SpO_2 Sensor
Check SpO_2 - Sensor Off Patient*	Reconnect sensor with good signal
Check SpO_2 - SpO_2 Only Mode*	Reconnect sensor with good signal
Local Storage is Low	Delete Previous Case Data Files from Local Storage
Local Storage is Full	Delete Previous Case Data Files from Local Storage
SpO_2 Target > 95%	Change SpO_2 Target to 95% or Below
SpO_2 Target < 85%	Change SpO_2 Target to 85% or Above
Time Near Expiration	Insert new Time Card before time expires or End Case

* These Silent Advisory Messages will become Medium Priority Alarms if not corrected after 2 minutes.

Section 21 Terminology

Terminology and Acronyms

Dyspnea	Shortness of breath or air hunger
COPD	Chronic Obstructive Pulmonary Disease
Pi	Perfusion Index
APOD	Adaptive Probe-Off Detection (see Further Reading)
Normoxemia	Normal levels of oxygen in blood
Hypoxemia	Low levels of oxygen in blood
Hyperoxemia	Excessively high levels of oxygen in blood / acidity of blood
PID controller	Proportional-integral-derivative controller

Section 22 Further Reading

Perfusion Index

The Perfusion Index (Pi) is a relative assessment of the pulse strength at the monitoring site, expressed as a numerical value that ranges from 0.02% to 20%, where the lower values indicate weak pulse strength, and the higher values indicate strong pulse strength. This index represents the ratio of pulsatile to non-pulsatile components of the blood at a particular site, with a higher number indicating a higher proportion of pulsatile blood. The Pi is used to assess the relative effectiveness of different application sites, and to alert the clinician to changes in the physiological condition of the patient. Clinically, it is often used to help choose the best body site for pulse oximetry, with clinicians choosing the site in which the Pi (and thus pulse strength) is highest.

Automatic FiO_2 Control

The automatic FiO_2 control system uses the patient's measured SpO_2 values to control the delivery of FiO_2 based on patient need. The system tries to maintain the patient's SpO_2 level at or near a preconfigured SpO_2 target by continuously titrating delivered FiO_2 based on the measured SpO_2. The system responds to both transient changes in SpO_2, as well as to long-term changes in the patient's FiO_2 requirements.

The control algorithm creates a feedback loop within the gas delivery system. It compares the patient's SpO_2 reading to that of the preconfigured SpO_2 target and sets the FiO_2 delivery rate accordingly. The algorithm makes near immediate adjustments (within 10 seconds) to changes in SpO_2 readings, learns from past changes, and anticipates short-term changes, thus, acting as what is called a proportional-integral-derivative controller (PID controller).

For example, the algorithm can make the following automatic FiO_2 delivery adjustments:

- During periods of normoxia when the SpO_2 reading is stable and remains above the preconfigured SpO_2 target, the algorithm initiates a gradual weaning/reduction of FiO_2 delivery. Once SpO_2 readings fall below the preconfigured SpO_2 target, no further weaning takes place.
- During periods of hypoxemia (SpO_2 reading < SpO_2 target set-point), the algorithm initiates an increase in FiO_2 delivery, within 10 seconds of detection of hypoxemia. FiO_2 delivery then continuously rises while hypoxemia persists. The rate of FiO_2 increase is proportionate to the severity of hypoxemia.
- During periods of hyperoxemia (SpO_2 reading > SpO_2 target set-point), the algorithm initiates a reduction of FiO_2 delivery. Depending on the severity of hyperoxemia, reduction starts within 10 seconds, leading to an increased and sustained reduction as long as the patient remains in a state of hyperoxemia.

Appendix A

Electromagnetic Compatibility (EMC)

WARNINGS:

- Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the Precision Flow® with Oxygen Assist Module System, including cables specified by Vapotherm. Otherwise, degradation of the performance of this equipment could result.
- Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.
- Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.
- Do not use any cables not provided by the manufacturer of this equipment.

Guidance and manufacturer's declaration – electromagnetic emissions		
The Oxygen Assist Module is intended for use in the electromagnetic environment specified below. The customer or the user of the Oxygen Assist Module should assure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment – guidance**
RF emissions CISPR 11	Group 1	The Oxygen Assist Module 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 Oxygen Assist Module is suitable for use in all establishments other than domestic, and may be used in domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes, provided the following warning is heeded: **Warning:** This equipment/system is intended for use by healthcare professionals only. This equipment/ system may cause radio interference or may disrupt the operation of nearby equipment. It may be necessary to take mitigation measures, such as re-orienting or relocating the Oxygen Assist Module or shielding the location.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

Appendix A

Guidance and manufacturer's declaration – electromagnetic immunity			
The Oxygen Assist Module is intended for use in the electromagnetic environment specified below. The customer or the user of the Oxygen Assist Module should assure that it is used in such an environment.			
IMMUNITY test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment – guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	± 8 kV contact ± 2, 4, 8, and 15 kV air	± 8 kV ± 2, 4, 8, and 15 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 %. 10 second wait time between discharges.
Electrical fast transient/burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/output lines 100 kHz repetition rate	± 2 kV ± 1 kV 100 kHz repetition rate	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 0.5, 1 and 2 kV Line(s) to Ground ± 1 kV line(s) to Line(s)	± 0.5, 1, and 2 kV ± 1 kV	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5 % U_T (>95 % dip in U_T) for 0,5 cycle at phase angle 0°, 45°, 90°, 135°, 180°, 225°, 270°, and 315° 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 s	Per Standard	Mains power quality should be that of a typical commercial or hospital environment. If the user of the Oxygen Assist Module requires continued operation during power mains interruptions, it is recommended that the Oxygen Assist Module be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE U_T is the a.c. mains voltage prior to application of the test level.			

Appendix A

Guidance and manufacturer's declaration – electromagnetic immunity			
The Oxygen Assist Module is intended for use in the electromagnetic environment specified below. The customer or the user of the Oxygen Assist Module should assure that it is used in such an environment.			
IMMUNITY test	**IEC 60601 TEST LEVEL**	**Compliance level**	**Electromagnetic environment – guidance**
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz 6 Vrms in ISM bands	3Vrms 6 Vrms in ISM bands	Portable and mobile RF communications equipment should be used no closer to any part of the [ME EQUIPMENT or ME SYSTEM], including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance** $d = 1.2\sqrt{P}$ $d = 1.2\sqrt{P}$ 80 MHz to 800 MHz $d = 2.3\sqrt{P}$ 800 MHz to 2.3 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).
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.7 GHz	3V/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 Oxygen Assist Module is used exceeds the applicable RF compliance level above, the Oxygen Assist Module should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the Oxygen Assist Module. [b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than [V1] V/m.			

Appendix A

Recommended separation distances between portable and mobile RF communications equipment and the Oxygen Assist Module

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

Rated maximum output power of transmitter W	**Separation distance according to frequency of transmitter** m		
	50 kHz to 80 MHz outside ISM bands $d = 1.2\sqrt{P}$	**150 kHz to 80 MHz in ISM bands** $d = 1.2\sqrt{P}$	**800 MHz to 2.5 GHz** $d = 2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.34	0.34	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.

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