FreeO$_2$

Automated Oxygen Therapy Device

User Manual

Models:
FO2-110-00, adult and pediatric - STD

OxyNov

CE 0459

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User Manual, FO2-OMP-02 (English)
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1 Typographic Conventions, Alerts, and Symbols

This chapter presents the conventions used to present information as well as the warning symbols.

1.1 Typographic Conventions

In a procedure, the steps that the user must follow are numbered 1, 2, 3 ... Lower case letters (a, b, c ...) are used to indicate substeps for a complex procedure.

Small capitals are used to identify a term marked on the unit, such as connector names, buttons, indicator lights, etc.

All terms used in the software interface, such as command names and text boxes are in bold.

1.2 Alerts

This section presents the alert symbols and words that indicate critical information to be aware of before using the FreeO_2.

Warning
Indicates that you must be extremely careful when executing these instructions. Not complying with these warnings can cause serious injury or even death.

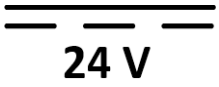
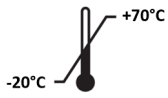
Caution
Indicates that you must be careful when executing these instructions. Not complying with these caution directives can cause minor injury or equipment damage.

IMPORTANT: Indicates information that should be taken into consideration.

NOTE: Indicates additional information about using FreeO_2.

1.3 Symbols

This section presents the symbols used with regard to this medical device.

Symbol	Label	Symbol	Label
	Manufacturer Manufacturing date		Oxygen
	Authorized representative in the European Community		CE mark (made in compliance with 93/42EEC Directive on class IIA or IIB medical devices)
	Serial number		Refer to the instruction manual or booklet
	Catalogue number		Non-ionizing electromagnetic radiation
	Quantity		DC power
	Medical Device		Not for general waste
	Unique Device Identifier		Do not use if the package is damaged
	Type BF applied part		Bell, temporarily canceled
	Temperature limits		USB connection

2 Indications for Use

The FreeO_2 Automated Oxygen Therapy Device provides oxygen therapy on demand, based on continuous, non-invasive monitoring of oxygen saturation.

The FreeO_2 Automated Oxygen Therapy Device is intended to deliver a titrated (self-adjusting) flow of oxygen to maintain the patients within predetermined oxygen saturation levels, as set by the user and monitored by the system via an oximeter.

The FreeO_2 Automated Oxygen Therapy Device is indicated for use under the direction of a physician in a clinical or hospital environment, on spontaneously breathing pediatric, and adult patients who are prescribed supplemental oxygen via a nasal cannula or oxygen mask.

This chapter presents the indications and contraindications for using the FreeO_2.

2.1 Indications

The FreeO_2 device is an automated oxygen regulator intended to be:

- Operated by trained personnel.
- Used under the direction of a physician in a clinical or hospital setting.
- Used to titrate the oxygen flow.
- Used to maintain a target SpO_2 level, set by clinicians, for spontaneously breathing patients older than 1 month.

2.2 Contraindications

- The FreeO_2 device is not intended to be used simultaneously on multiple patients.
- Do not use the FreeO_2 on a patient:
  - That is less than 1 month old.
  - For whom the SpO_2 is not stable.
  - With CO poisoning.
  - That is not spontaneously breathing.
  - Who is incapable to keep airways clear or free of secretions.

NOTE: For additional contraindication, warning, and caution indications, refer to the applicable sensor instructions for use.

3 Description

This chapter presents the components of the FreeO$_2$.

The FreeO$_2$ is an automated oxygen regulator intended to be operated by trained personnel, under the direction of a physician in a clinical or hospital environment, to titrate the oxygen flow, based on a pulse oximetry signal, and to maintain a target SpO$_2$ level on spontaneously breathing patients.

It automatically delivers, through standard devices (nasal cannula, face mask), the necessary oxygen flow rate according to the oxygenation level defined by the clinician and the dynamic response of each patient type.

It works in a closed loop and adapts, every seconds, the oxygen flow rate administered, between 0 and 20 l/min in increments of 0.1 l/min, according to the values read of the oxygen saturation (SpO$_2$) in the blood, provided by a pulse oximeter installed on the patient.

> **IMPORTANT:** The FreeO$_2$ may only be used by trained personnel, according to directions of a physician, and only for patients that are spontaneously breathing.

Figure 3-1 presents the components of the FreeO$_2$ front and back panels.

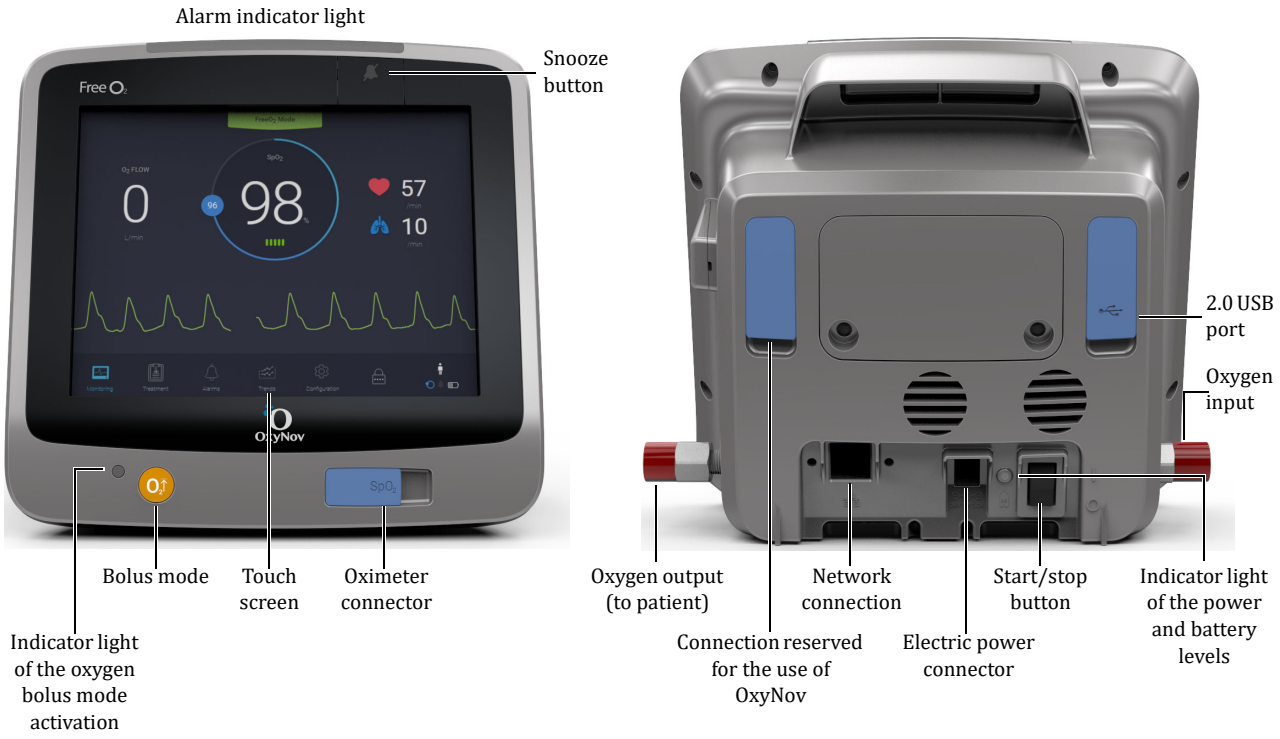


Figure 3-1 Front panel (*left*) and back panel (*right*)

Bolus mode (see Figure 3-1 left)

The bolus mode administers a fixed oxygen flow rate for 2 minutes then returns to the mode previously selected either: **FreeO$_2$**, **CONSTANT FLOW**, or **ACQUISITION**. Press the yellow button "Bolus mode" to activate it. It is possible to deactivate the Bolus mode before the end of the 2 minutes, by pressing the button again.

This mode is used when a quick oxygen boost is needed without having to reconfigure the FreeO$_2$.

Oxygen flow rate:

- Pediatric, 5 L/min
- Adult, 10 L/min

NOTE: If no patient type is selected, Bolus mode is 2 L/min.

Indicator light of the power and battery level (see Figure 3-1 right)

The indicator light of the power and battery levels is green when the unit is connected to a power source and the batteries are fully charged. While charging, the indicator is yellow. When the unit is used with the batteries, the indicator is off. In addition, when the unit is operating on batteries, the indication "BATTERY-OPERATED" appears on the monitoring screen (Figure 3-3).

When the indicator light flashes yellow, it indicates a potential problem with the batteries. Check the battery icon on the screen (Figure 4-8) and if the screen does not represent a full battery even though the equipment has been plugged into the wall for at least 5 hours, this indicates that the batteries might need to be changed and the FreeO2 device should be sent to an authorized service center for evaluation.

Snooze button (see Figure 3-1 left)

During an alarm, tapping this button stops the alarm for a period of 2 minutes after which the alarm restarts. If you tap the button before the end of the 2-minute period, the alarm restarts.

Figure 3-2 presents the components of the FreeO$_2$ left and right panels.

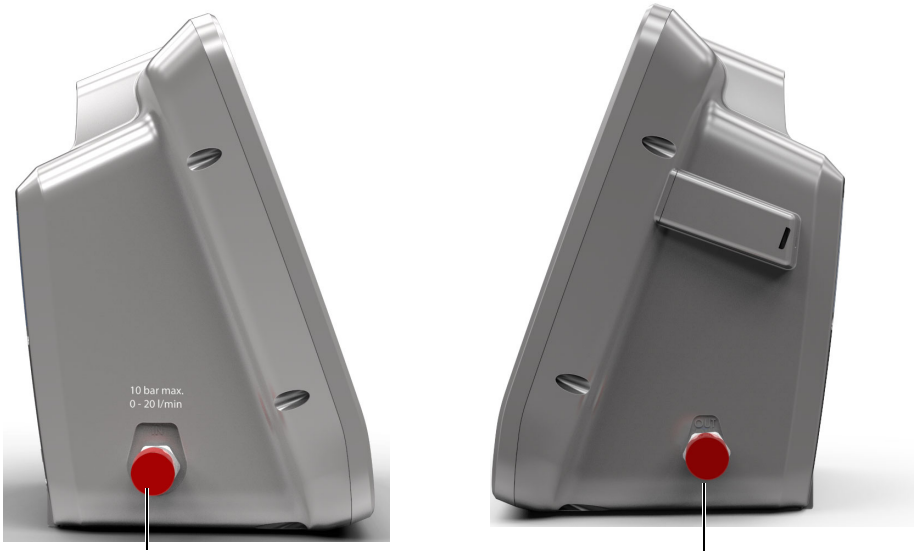


Figure 3-2 Left side (*left*) and right side (*right*)

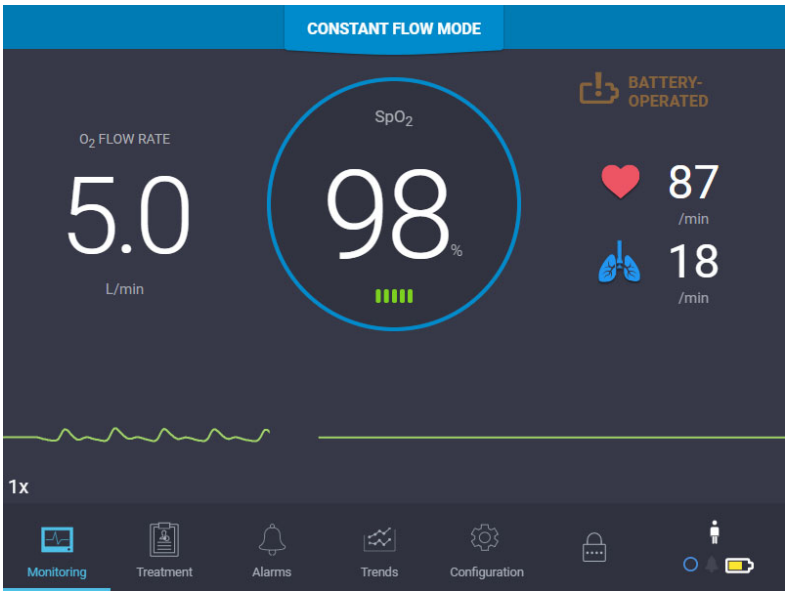


Figure 3-3 Battery operated indication

4 Installation

The FreeO$_2$ should be used connected to an electrical outlet; however, there are lithium-ion batteries that keep the power going in case of a power failure or should the unit get disconnected. The FreeO$_2$ has a battery-life of about 3 hours. If the unit is reconnected after the batteries have been discharged and the unit is still on, the FreeO$_2$ will restart and you can choose to pursue the treatment.

4.1 Installing the FreeO$_2$

In order to adapt to the different clinical contexts and meet the mobility needs of the unit, the FreeO$_2$ is equipped with bosshead clamp to install the unit on a rolling stand or on a wall rail. It is also possible to place it on a bedside table.

To install the FreeO$_2$:

1 Connect the AC power adapter into the wall outlet then connect the power supply to the FreeO$_2$.

NOTE: In order to adapt to different wall outlets, your distributor will provide you with the appropriate power cable, please connect it to the power adapter.

Warning
Only use the AC power adapter provided by OxyNov. Any other cord may interfere with the proper operation of the unit.

Caution
Inspect the power cord regularly and make sure it is free of cuts, tears, damage, etc. A damaged cord should be replaced rather than repaired.
Always position the unit so that it is easy to disconnect the power supply.

Warning
Never touch the signal input, output, or other connectors, and the patient simultaneously.

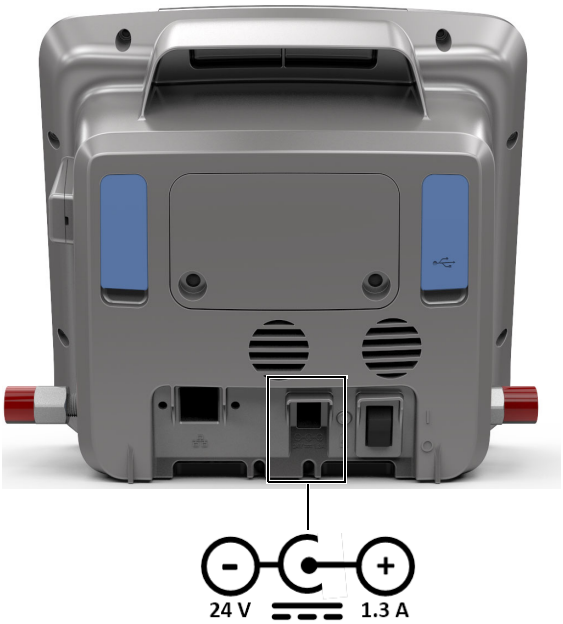


Figure 4-1 Electric power connector

2 Connect the oxygen tube to the oxygen input of the $FreeO_2$ then connect it to the medical grade oxygen source.

The $FreeO_2$ supports all types of oxygen sources, high or low pressure, using the adapted connector of the oxygen input. The high pressure output can be a wall outlet directly connected to the distribution system of the health care establishment or to oxygen cylinders.

Warning
The $FreeO_2$ has to be used with medical grade oxygen exclusively. It can never be used in an explosive atmosphere or in the presence of flammable anesthetics or gases.

Figure 4-2 Oxygen input

3 Start the FreeO_2 by pressing the start/stop button.

The startup takes a certain time, refer to section 4.2.

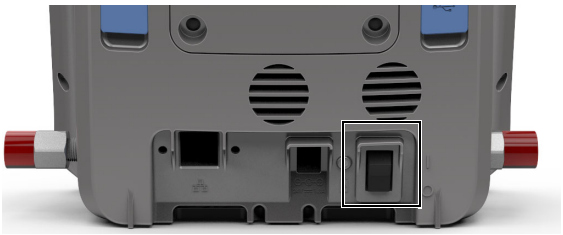


Figure 4-3 Start/stop button

Make sure that the oxygen is properly connected: listen for leaks, if there are none, set the unit to the fixed flow rate of 2 L/min. If there is no alarm and there is O_2 coming out of the oxygen output, the connection is correct.

4 Install the pulse oximeter on the patient, as recommended by the manufacturer, then connect it to the FreeO_2.

IMPORTANT: Make sure to read and understand the warnings and cautions for the oximeter use in chapter 5 “Oximeter Warnings and Cautions” on page 17.

5 Wait until the SpO_2 reading is displayed on the FreeO_2 screen before readjusting the oximeter.

The FreeO_2 supports wired connections only.

Caution
Make sure that the patient is not wearing nail polish or any other product that could produce erroneous readings of the oximeter.

NOTE: The oximeter reading takes 1 to 2 minutes to appear. Wait a little before readjusting the oximeter on the patient.

6 Place the oxygen administration device (nasal cannula, face mask), as recommended by the manufacturer, on the patient then connect it to the oxygen output connector of the FreeO_2.

NOTE: When choosing the oxygen administration device, take into account the maximum flow rate allowed by this interface device. Adding extra tubing increases resistance and may impact the maximum flowrate of the chosen interface. When the interface flow rate limit is reached, an alarm "Patient Interface Obstructed" may occur.

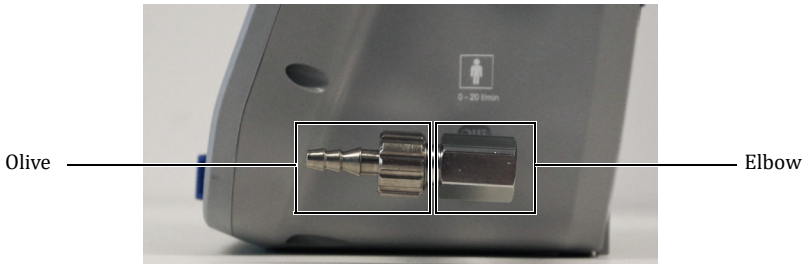


Figure 4-4 Oxygen output

Warning
Never use petroleum-based products on the patient during the administration of oxygen. This can cause severe burns.
In case of nasal dryness, use a lubricant recommended by the health care personnel. It is also possible to use a humidification system (refer to section 4.1.1).

Warning
It is strictly forbidden to smoke during treatment. This can inflict serious injuries.

NOTE: If you want to use the FreeO_2 in the ACQUISITION mode only (continuous oximetry), you do not need to use the oxygen administration device (refer to section 6.4 "Treatment" on page 22).

4.1.1 Humidification System

To install a pharmaceutical grade sterile water bottle for inhalation to moisten the oxygen administered to the patient, remove the olive present at the oxygen outlet of the device, turn the elbow 45˚ downwards and install the bottle directly on the elbow. Refer to Figure 4-5.

Figure 4-5 Humidification System

4.2 Startup

After pressing the start/stop button, the startup sequence takes about 1 minute 15 seconds. Two startup screens open one after the other then the screen to select the usage mode opens (startup screen). You can select the same patient (**CONTINUE**) to use the already established parameters or start a treatment for a new patient (**NEW PATIENT**).

Once startup is completed, on the touch screen, tap **CONTINUE** or **NEW PATIENT**.

NOTE: When you select **NEW PATIENT**, a new data file is created and the trends start over.

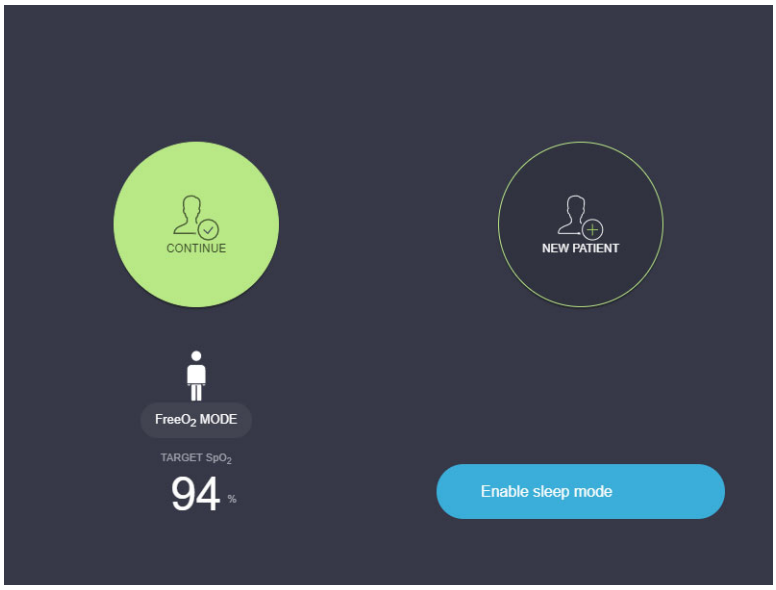


Figure 4-6 Startup screen

The sleep mode allows the device to be placed in standby so that a new patient can start their treatment more quickly. In this mode, the screen is turned off and electricity consumption is reduced. To deactivate sleep mode, just touch the screen, or press the snooze or bolus buttons. In sleep mode, the Bolus function is still available and the delivered flow rate is 2 L/min.

When using the unit for the first time, the **CONTINUE** option is available but the parameters are default settings from the factory.

When selecting **CONTINUE**, the monitoring screen opens. In this screen you can see the usage mode and the target to be reached.

Figure 4-7 Monitoring screen

4.3 Shutdown

You shutdown the FreeO_2 by pressing the start/stop button. No data will be lost since the unit records everything in real time.

Before unplugging the device, turn off the oxygen source. Disconnect the oxygen tubing from the oxygen source and then disconnect it from the device.

4.4 Changing the Oxygen Source During Treatment

It is possible that you may have to change the oxygen source during a treatment. The following is the procedure to change the oxygen source.

IMPORTANT: When changing the oxygen source, the treatment must suspended.

To change the oxygen source:

1 On the main screen tap **Treatment** and tap **Suspend Treatment**.

2 Turn off the oxygen source and disconnect the hose from that oxygen source.

3 Connect the hose to the new source of oxygen and turn on the latter.

4 On the main screen tap **CONTINUE**.

4.5 Description of icons

Refer to Figure 4-7 for the description of the icons located at the bottom right of the screen.

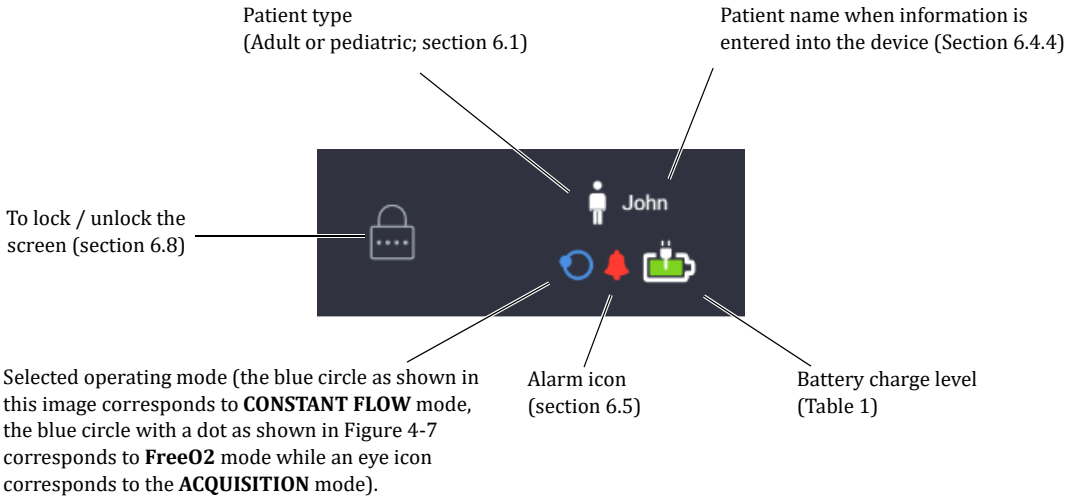


Figure 4-8 Description of icons

Table 1 Description of battery icons

Icon	Description
	The batteries are fully charged and the device is plugged into a wall outlet.
	The batteries are being recharged.
	The batteries are fully charged and the device is currently in battery-operated mode.
	The battery charge level is approximately 3/4 and the device is currently in battery-operated mode.
	The battery charge level is approximately 1/2 and the device is currently in battery-operated mode.
	The battery charge level is approximately 1/4 and the device is currently in battery-operated mode.
	The batteries are practically empty, the device must be plugged as soon as possible.

5 Oximeter Warnings and Cautions

This chapter presents the precaution to take before using the $FreeO_2$. The $FreeO_2$ is equipped with the OEM III module from Nonin®. Nonin® recommends that these instructions are understood and followed.

5.1 Oximeter Warnings

- Use only with Nonin® PureLight® pulse oximeter sensors. These sensors are manufactured to meet the accuracy specifications for Nonin® pulse oximeters. Using other manufacturers' sensors can result in inaccurate pulse oximeter performance.
- Loss of monitoring can result if any object hinders the pulse measurement. Make sure that no blood flow restrictor (for example, blood pressure cuff) hinders the pulse measurements.
- Carefully route cables and connections to reduce the possibility of entanglement or strangulation.
- Operating this module below the minimum amplitude of 0.3% modulation may cause inaccurate results.
- Using accessories, sensors, and cables other than those specified by Nonin® may result in an increased emission and/or decreased immunity of the $FreeO_2$.
- Do not use a damaged sensor.

5.2 Oximeter Cautions

- The accuracy of the SpO_2 measurement may be affected if the total sensor cable length (including extension cables) is greater than 4 meters.
- Follow local, state, or national governing ordinances and recycling instructions regarding disposal or recycling of the unit and unit components.
- In compliance with the European Directive on Waste Electrical and Electronic Equipment (WEEE) 2002/96/EC, do not dispose of this product as unsorted municipal waste. This device contains WEEE materials; please contact your distributor regarding take-back or recycling of the $FreeO_2$.
- The $FreeO_2$ is designed to determine the percentage of arterial oxygen saturation of functional hemoglobin. Significant levels of dysfunctional hemoglobin, such as methemoglobin, might affect the accuracy of the measurement. Factors that may degrade pulse oximeter performance or affect the accuracy of the measurement include the following: excessive ambient light, excessive motion, electrosurgical interference, blood flow restrictors (arterial catheters, blood pressure cuffs, infusing lines, etc.), moisture in the sensor, improperly applied sensor, incorrect sensor type, poor pulse quality, venous pulsations, anemia or low hemoglobin concentrations, cardiogreen or other intravascular dyes, carboxyhemoglobin, methemoglobin, dysfunctional hemoglobin, artificial nails or fingernail polish, or a sensor not at heart level.
- The $FreeO_2$ has motion tolerant software that minimizes the likelihood of motion artifact being misinterpreted as good pulse quality. However, in some circumstances, this device may still interpret motion as good pulse quality. This covers all available outputs (that is, SpO_2, HR, plethysmograph (PLETH), photoplethysmography (PPG)).
- Inspect the sensor application site at least every 4 hours to ensure correct sensor alignment and skin integrity. Patient’s sensitivity may vary due to medical status or skin condition. Discontinue use of adhesive tape strips if the patient exhibits an allergic reaction to the adhesive material.
- Oximeter readings may be affected by the use of an electrosurgical unit (ESU).
- The oximeter sensor may not work on cold extremities due to reduced circulation. Warm or rub the finger to increase circulation, or reposition the sensor.
- A functional tester cannot be used to assess the accuracy of a pulse oximeter monitor or sensor.

6 Operation

This chapter presents the operation of the FreeO$_2$.

6.1 Selecting a Patient

The screen to select the patient, after selecting **NEW PATIENT** (see Figure 4-6), allows you to select the patient type: **Pediatric**, **Adult**.

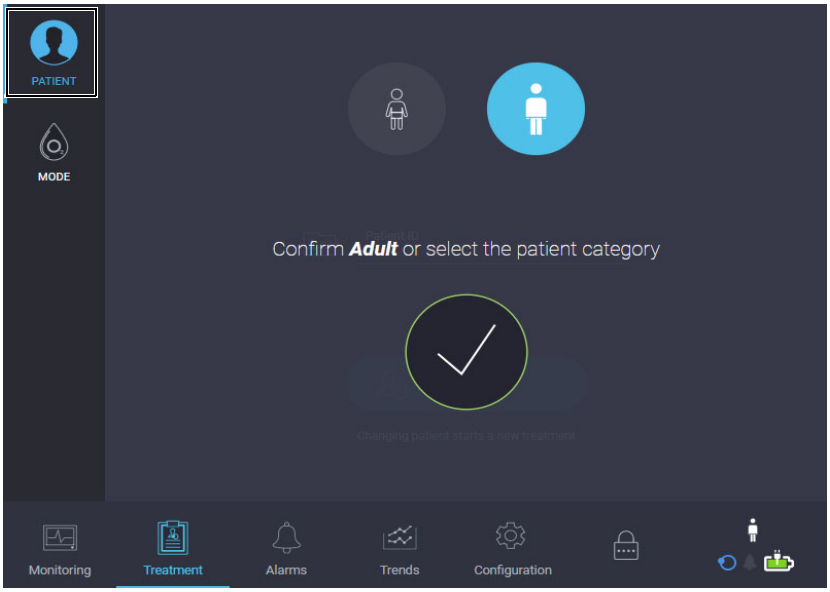


Figure 6-1 Patient selection

NOTE: For **Adult** patient type, the maximum oxygen flow rate that can be delivered is 20L / min. For **Pediatric** patient type, the maximum oxygen flow that can be delivered is 10L / min. Refer to Appendix A.4 for default values and limits for these two types of patients.

To select a patient:

1 On the touch screen, on the left side, tap **PATIENT**.

2 At the top of the screen, tap the selection that corresponds to your patient's type and tap the confirmation button.

The screen to select the treatment opens.

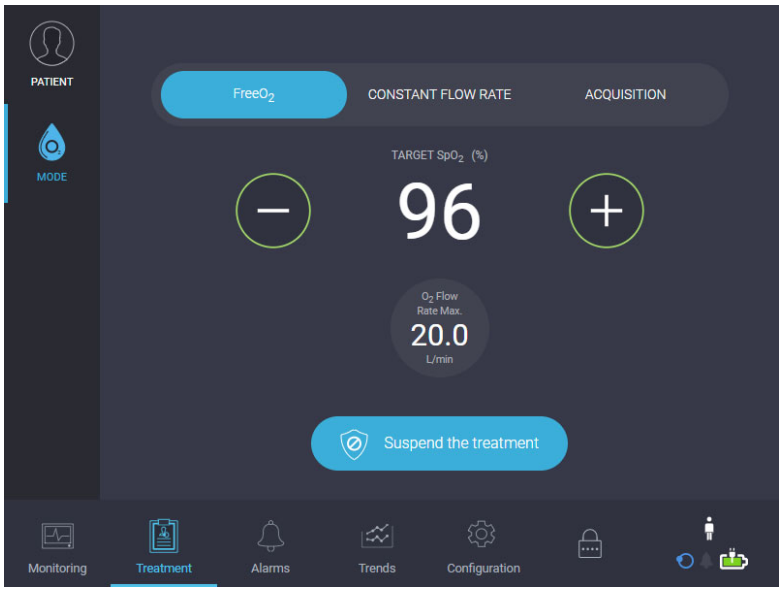


Figure 6-2 Treatment selection

6.2 Continuing the Treatment

When selecting **CONTINUE** (see Figure 4-6), the monitoring screen opens.

Figure 6-3 Monitoring screen

NOTE: When installing or readjusting the pulse oximeter on the patient, a few seconds are necessary before the oximeter signal appears on the FreeO$_2$ monitoring screen.

6.3 Monitoring

The Monitoring screen is the default screen which FreeO$_2$ returns to automatically when no user activity has been detected after a certain amount of time.

In this mode, the screen shows:

- The usage mode.
- Alarms (physiological alarms at top left and technical alarms at top right).
- The oxygen flow rate which corresponds to the flow rate actually being administered to the patient when the FreeO$_2$ mode is being used. If the device is used in Constant Flow mode, the flow rate shown corresponds to the flow rate set in the Treatment screen.
- The target oxygen saturation (circle with blue background) set in the Treatment screen and the patient's actual saturation level as measured by the SpO$_2$ sensor and whose value is updated every 2 seconds.
- Heart rate on the right of the screen.
- Respiratory frequency, calculated from the analysis of variations in the plethysmograph signal.
- The plethysmograph signal, whose scale is adjusted automatically depending on the amplitude of the measured signal.

Figure 6-4 Monitoring screen

Five small bars appear under the SpO$_2$ reading in the center of the screen, they represent the quality level of the signal. A red bar means that the signal from the oximeter is too weak.

> **NOTE:** It is recommended to verify the position of the oximeter on the patient's finger at least once every four hours or in case of loss or sudden change in the saturation signal.

6.4 Treatment

The treatment screen allows you to select the operation mode: **FreeO$_2$**, **CONSTANT FLOW**, and **ACQUISITION** as well as proceeding with the patient identification if it is not already done.

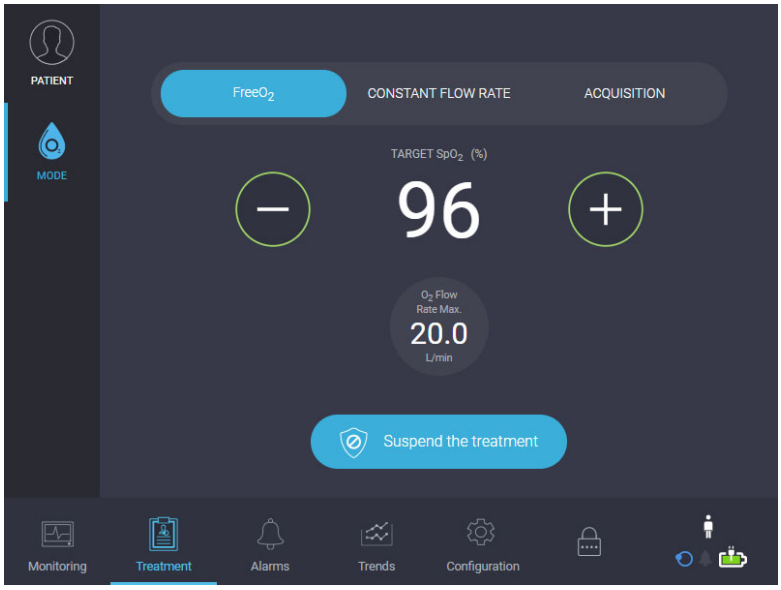
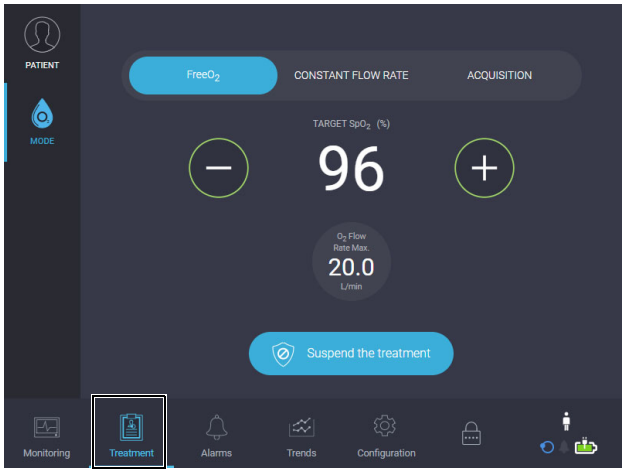


Figure 6-5 Screen of the treatment selection

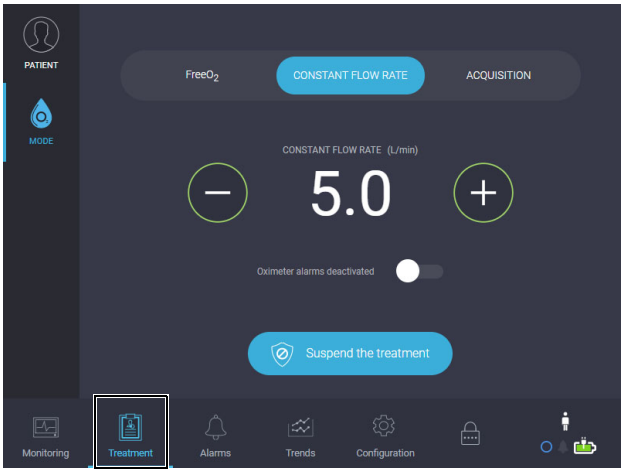
To access the treatment screen:

1 At the bottom of the screen tap the **Treatment** button.
The **MODE** icon (at the left of the screen) is selected by default.

2 Select one of the three modes by tapping **FreeO$_2$**, **CONSTANT FLOW**, or **ACQUISITION**.



FreeO$_2$



CONSTANT FLOW

Figure 6-6 Treatment button

6.4.1 FreeO_2 Mode

FreeO_2 mode is the automated oxygen therapy mode in which FreeO_2 automatically adjusts the oxygen flow administered to the patient in order to maintain the defined target SpO_2. Press the **SpO_2 TARGET** button and then adjust the target oxygen saturation using the **-** and **+** buttons according to clinical recommendations

In addition to being able to limit the administered flow rate according to the type of patient (10 L/min for children and 20 L/min for adults), you can also limit the flow rate that FreeO_2 can deliver to any value whatsoever in order to suit a specific clinical situation. Press the **Max. O_2 Flow** button and then, using the **-** and **+** buttons, set the maximum flow that cannot be exceeded.

When the SpO_2 signal is of too poor quality, if the sensor used is not correctly positioned on the patient or during a major technical error, the FreeO_2 device uses the last valid SpO_2 measurement during the first 10 seconds.

After these 10 seconds, it switches to safety mode and delivers a flow rate based on the analysis of the last 15 minutes of treatment.

6.4.2 Constant Flow Mode

In this mode, just like with a conventional flow meter, the user adjusts the oxygen flow to be administered to the patient at any time without any automatic adjustment from FreeO_2.

6.4.3 Acquisition Mode

This mode allows you to use the FreeO_2 solely as an oximeter in order to evaluate the patient's oxygenation before defining the SpO_2 target.

> **NOTE:** In this mode, no oxygen is administered.

6.4.4 Patient Identification

The patient's identification is done using the keypad that opens on screen.

> **NOTE:** The patient's identification is not required for the good operation of the unit. This procedure can be skipped.

To identify the patient:

1 At the top left of the screen, tap the **PATIENT** icon.

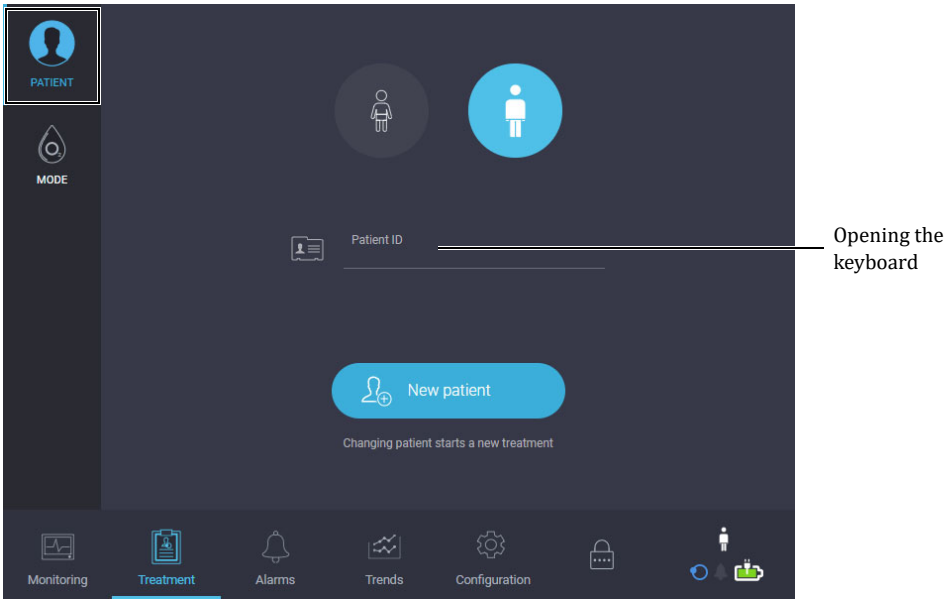


Figure 6-7 PATIENT icon

2 In the center of the screen, tap **Patient**.

The keyboard opens.

3 Tap the keyboard keys, then tap the confirmation button. The patient identifier is limited to 12 alphanumeric characters.

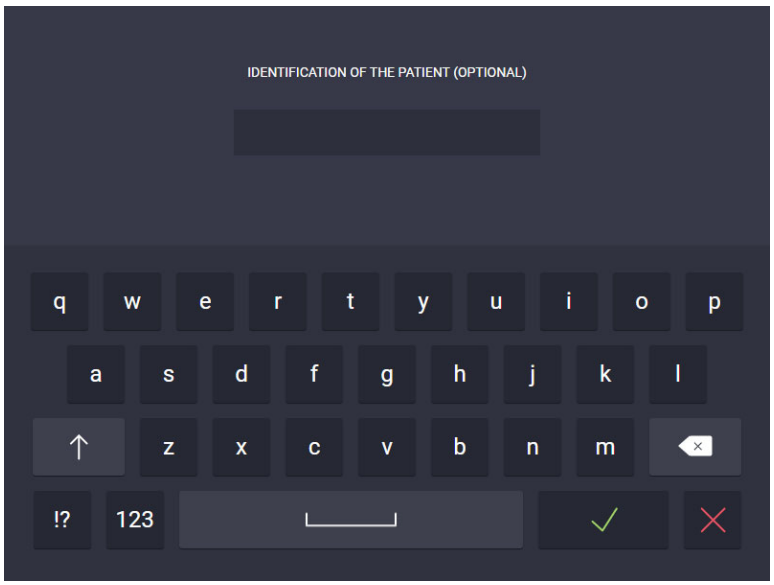


Figure 6-8 Patient identification

6.5 Alarms

The alarm screen allows you to determine at what levels (maximum and minimum) the unit will indicate a problem for the functions detected by the oximeter. These functions are: **SpO_2**, **O_2Flow**, **HR** (Heart rate per minute) and **RR** (Respiratory Rate per minute). Tap one of these buttons then, using the **-** and **+** buttons, adjust the level.

Figure 6-9 Alarm screen

When an alarm is triggered, the alarm icon turns red. Once the alarm is no longer active, the icon turns gray.

The alarm sound volume is adjustable to adapt to various clinical environments. When you use the FreeO_2, always make sure that the alarm sound can be heard above the ambient noise level.

⚠	**Warning** Always respond promptly to any alarm condition. Make sure that the current alarm preset is appropriate before treating each patient. Setting physiological alarm limits to extreme values can render the patient alarm monitoring useless. A potential hazard can exist if different alarm monitoring settings are used for the same or similar equipment in any single patient care unit.

IMPORTANT: Alarm indications are provided within seconds of the detected condition.

Physiological alarms can be tested by placing the oximeter sensor on a finger and then set an individual SpO_2 alarm limit at 99% and 80%.

If a problem with the alarm tone or messaging system is suspected, the FreeO_2 device must be sent to authorized service personnel for evaluation.

Many events can trigger an alarm. When an alarm is triggered, the alarm indicator light turns on. There are three alarm levels:

- Yellow = Low
- Blinking yellow = Medium
- Blinking red = Critical

Figure 6-10 Alarm indicator light

The following table presents the events that can trigger an alarm.

The alarms are visual and audible.

- Blinking red:10 beeps repeated every 7 seconds
- Blinking yellow: 3 beeps repeated every 10 seconds
- Yellow: 1 beep repeated every 5 minutes

Table 1 Alarm description

Event	Indicator	Description	Solution
Batteries	Blinking red	The batteries levels are too low. At 15%, you get a critical battery-life warning.	Connect the power adapter as soon as possible.
	Blinking yellow	The batteries levels are low. At 25% you get a low battery-life warning.	Connect the power adapter.
	Blinking red	There are no batteries.	The FreeO$_2$ must be sent for repairs.
	Blinking red	The batteries need maintenance.	The FreeO$_2$ must be sent for repairs.
	Blinking red	Charging error	Connect the power adapter. If this does not work, send the FreeO$_2$ for repairs.
	Blinking red	The batteries levels are critical, the SBC will shut down. At 5% the FreeO$_2$ enters the sleep mode (the screen turns off, the main processor turns off, and the internal security starts).	Connect the power adapter immediately.
	Blinking red	The charge level between the SBC and the MCU is different. System error #10008	The FreeO$_2$ must be sent for repairs.

Table 1 Alarm description (*continued*)

Event	Indicator	Description	Solution
$FreeO_2$	Blinking red	Charging error, maintenance required. System error #10006	The $FreeO_2$ must be sent for repairs.
	Blinking red	The available space of the internal memory is critical.	The $FreeO_2$ must be sent for repairs.
	Blinking yellow	The available space of the internal memory is low.	The $FreeO_2$ must be sent for repairs.
	Blinking red	Communication with the valve is not working. System error #18001	The $FreeO_2$ must be sent for repairs.
	Blinking red	Communcation error of the valve. System error #18003	The $FreeO_2$ must be sent for repairs.
	Blinking red	Communication error. System error #18002	The $FreeO_2$ must be sent for repairs.
	Blinking red	The MCU has been reset.	The $FreeO_2$ must be sent for repairs.
	Blinking red	The SBC has been reset.	The $FreeO_2$ must be sent for repairs.
	Blinking red	A software error occurred. System error #20001	The $FreeO_2$ must be sent for repairs.
	Blinking red	Parameters are no longer valid. System error #22001	The $FreeO_2$ must be sent for repairs.
	Blinking red	No new data is being sent to the MCU over a period of time. System error #24006	The $FreeO_2$ must be sent for repairs.
	Blinking red	The MCU has stopped receiving data over a period of time. System error #15004	The $FreeO_2$ must be sent for repairs.
	Blinking red	The order of the oximeter data is incorrect. System error #15005	The $FreeO_2$ must be sent for repairs.
	Blinking yellow	Time not set.	Adjust the time; in the configuration screen, in the **BIOMED** page.
Heart rate	Blinking yellow	Too high	Verify the patient condition. Reset alarm limits if indicated.
	Blinking yellow	Too low	Verify the patient condition. Reset alarm limits if indicated.
Respiratory rate	Blinking yellow	Too high	Verify the patient condition. Reset alarm limits if indicated.
	Blinking yellow	Too low	Verify the patient condition. Reset alarm limits if indicated.

Table 1 Alarm description (*continued*)

Event	Indicator	Description	Solution
O_2	Blinking red	Oxygen flow rate high.	Verify nasal cannula or face mask. Reset alarm limits if indicated.
	Blinking red	Delivered oxygen flow rate is incorrect.	Verify the O_2 connection at the input and output or the nasal cannula or face mask.
	Blinking red	Oxygen flow rate is incorrect.	Verify the O_2 connection at the input and output or the nasal cannula or face mask.
	Blinking red	An inconsistency is detected about the requested O_2. Security error FreeO_2 #24001	Restart the treatment.
	Blinking red	The O_2 requested is too high. Security error FreeO_2 #24002	Restart the treatment.
	Blinking red	The O_2 requested is too high for a certain period of time. Security error FreeO_2 #24003	Restart the treatment.
	Blinking red	The O_2 requested is too different from the prior one for a certain period of time. Security error FreeO_2 #24004	Restart the treatment.
	Blinking red	The O_2 requested is too high from the prior one for a certain period of time.	Security error Restart the treatment.
SpO_2	Blinking yellow	Too high	Verify the patient condition. Reset alarm limits if indicated.
	Blinking red	Too low	Verify the patient condition. Reset alarm limits if indicated.
Oximeter	Blinking red	Communication with the wired oximeter is not working. System error #15001	The FreeO_2 must be sent for repairs.
	Blinking red	The wired oximeter is not connected.	Connect the wired oximeter sensor to FreeO_2.
	Yellow	The sensor is not on the finger.	1- Reinstall the sensor on the patient. 2- Verify that the sensor is in the proper position.

6.6 Trend Measurement

The trend screen provides a record of data collected for the last hours. You have a choice of hour range from 1 to 72. The hour range is divided in segments.

You can display 2 trends at a time. You have 4 choices of trend display for each of the 2 trends: SpO_2 including the SpO_2 target data, O_2 flow rate, and HR (Heart Rate per minute) and RR (Respiratory Rate per minute).

A one-off statement can be displayed at a specific time of the treatment period.

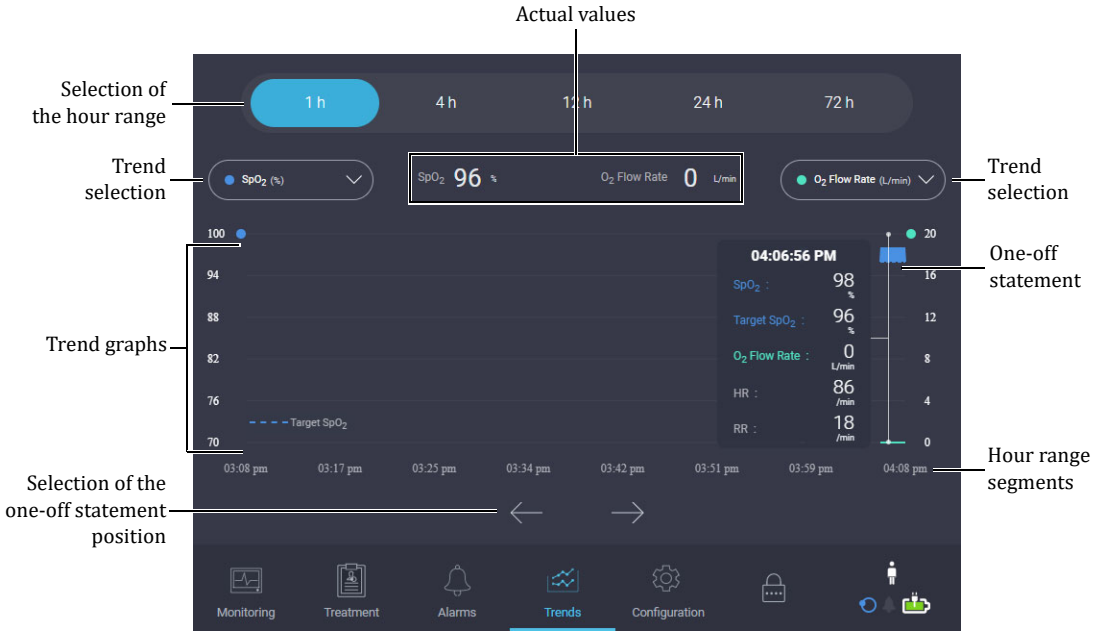


Figure 6-11 Trend screen

According to the choice of trends to display, the trend graphs use different colors. Scales on the left and right change and a color dot indicates the type of scale.

For the example in Figure 6-11:

- The blue line indicates the patient's response to the treatment according to the SpO_2 target (dotted line).
- The green line indicates the requested treatment with regards to the patient's SpO_2.

The one-off statements can be displayed at precise moments of the treatment. When you tap on a specific point of the trend graph, the one-off statement opens. The one-off statement can be moved over the trend graph by tapping the selection arrows of the statement position. To close the statement, tap on it.

The hour range segment starts (to the right) at the minute you enter the trend screen. Segments are adjusted and displayed according to the selected range.

6.7 Configuration

The configuration screen gives you access to many configuration parameters.

6.7.1 General

This page allows you to select the language, the alarm sound level, the screen brightness as well as determine how long to press on the padlock icon to lock and unlock the screen.

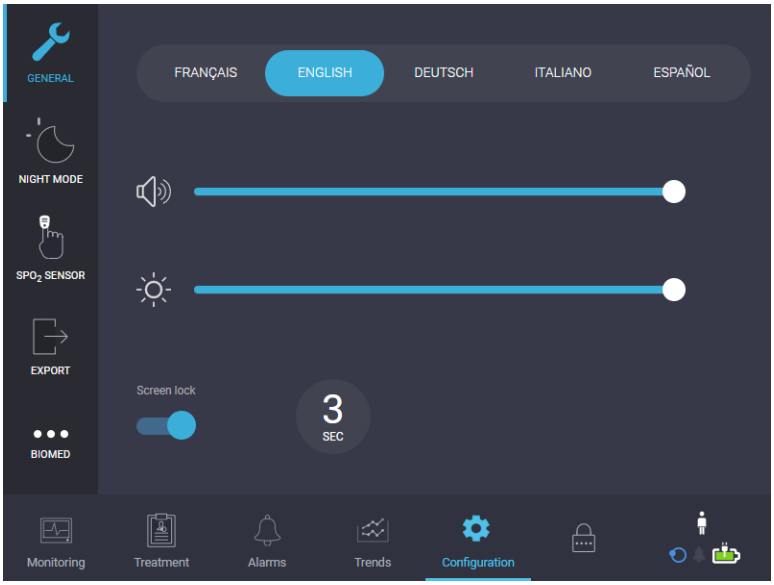


Figure 6-12 Configuration screen, GENERAL page

6.7.2 Night Mode

This page allows you to lower the sound and brightness levels of the unit in order not to inconvenience the patient during the night.

Tap the **NIGHT MODE** button to activate or deactivate the mode.

Press and drag the cursor to select the desired level.

Tap the **Start time** and **End time** buttons and use the **-** and **+** buttons to set the time.

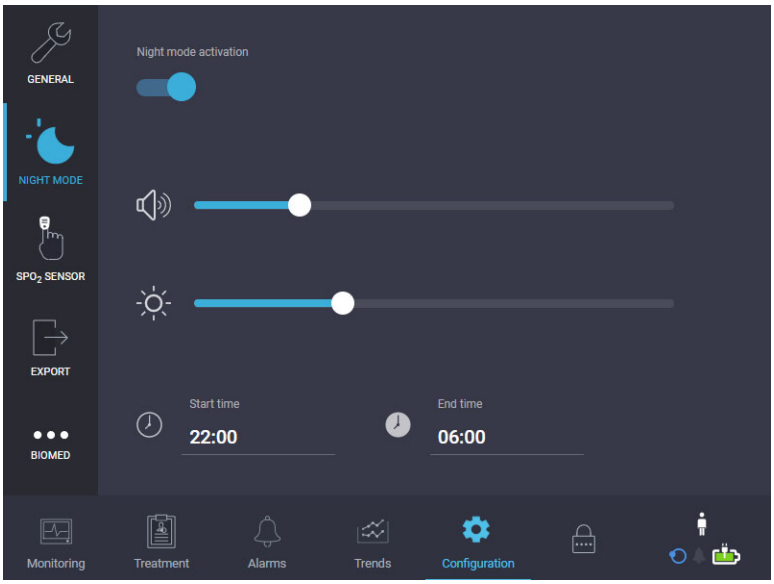


Figure 6-13 Configuration screen, NIGHT MODE page

6.7.3 SpO_2 Sensor

This page allows you to select a wired or Bluetooth oximeter sensor. When selecting a sensor, if no patient is linked to an oximeter, an alarm goes off.

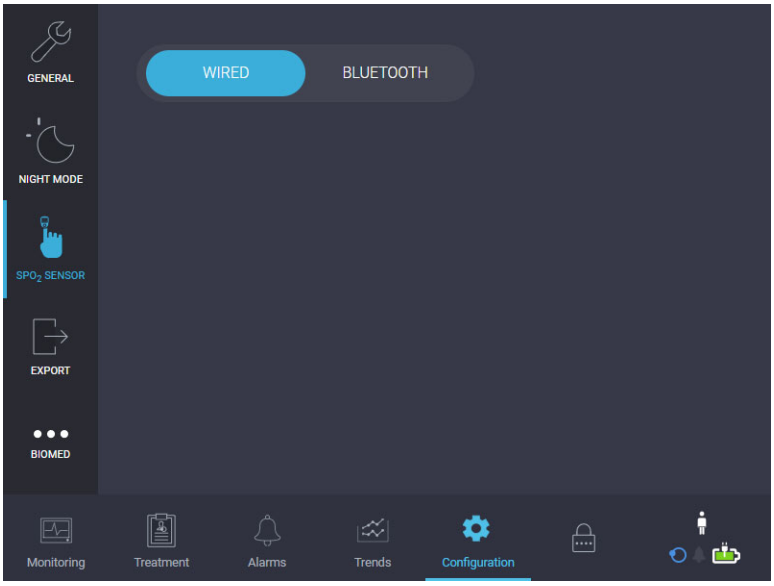


Figure 6-14 Configuration screen, SPO_2 SENSOR page

The oximeter sensors used with the $FreeO_2$ must be of the Nonin® type listed in appendix A.5 on page 53. Only use a Nonin® PureLight® pulse oximeter sensor.

6.7.4 Export Data

This page allows you to export data of the last three patients to a USB key which you connect to the USB port of the unit (see Figure 3-1 on page 5). The USB key must previously be formatted to FAT32.

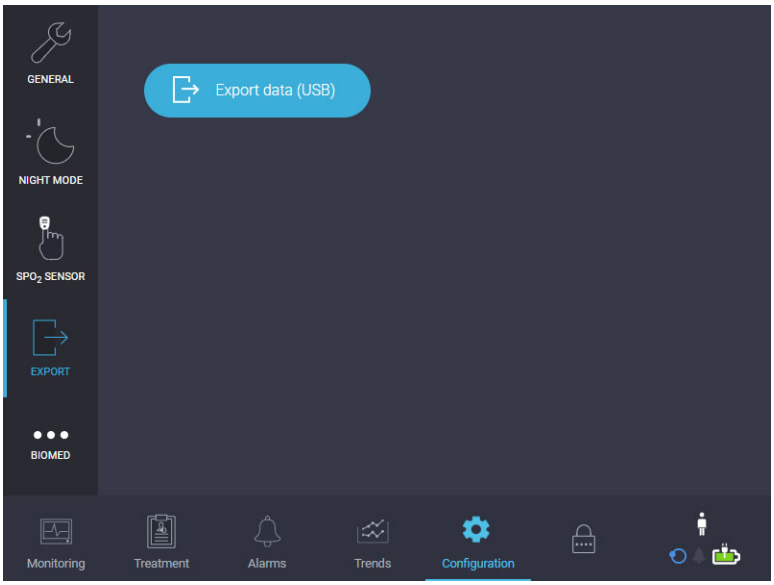


Figure 6-15 Configuration screen, EXPORT page

The FreeO_2 always stores the data of the last three patients even after you have transferred them to a USB key. You can still access them from the unit if necessary.

When exporting to the USB key, a directory is created (treatment, date, hour). This directory contains a .zip file containing records of each process (logs.zip) to be recovered should a problem occur. It also contains .zip files for the ongoing treatment (current.zip) and the archived treatments (for the last 3 patients). In each treatment files (ongoing and archived), there are directories containing data collected every second.

The Delivery folder contains the time in the Unix format, and in the date and hour format (YYYY-MM-DD HH:MM). It also contains the SpO_2, the SpO_2signal quality, the SpO_2 target, the SpO_2 error, the heart rate, the respiratory rate, the O_2 administration rate, and the O_2 current administration.

The PPG file contains the time in the Unix format, a unique number for the current second (from 0 through 74), and the PPG value.

The alarms.csv file contains all information about the alarm triggering. It contains the time in the Unix format, and in the date and hour format (YYYY-MM-DD HH:MM). There is also the alarm identifier, the alarm type, its severity, its priority, and if it was started or stopped. If there is a power loss, the alarm file is still saved.

The events.csv file contains all the important events that occurred during a treatment, a configuration modification, a treatment modification, the alarms, the errors, and some of the communications between processes. The columns contain the time in the Unix format, the event type, and an argument if applicable.

The information.csv file contains useful information for the treatment. In it you find the treatment number, the time at which the treatment has started, the patient number, the patient type, the unit serial number, the material serial number, the software version, the firmware version, the material revision, and the valve firmware version.

6.7.5 Biomed

This page gives an access to the maintenance functions of the FreeO_2 (refer to the maintenance manual).

Make sure to periodically verify that the firmware/software version is up to date; go to the **Support** section of our Web site at www.oxynov.com.

6.8 Screen Locking

Locking the screen prevents any unwanted setting changes; for example, when cleaning the unit.

To lock the screen:

1 At the bottom of the screen, press the padlock icon for the number of seconds defined in the general parameters (see section 6.7 "Configuration" on page 30).

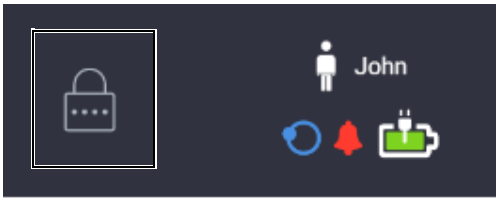


Figure 6-16 Padlock icon

To unlock the screen:

1 At the bottom of the screen, press the padlock icon for the number of seconds defined in the general parameters (see section 6.7 "Configuration" on page 30).

7 Electromagnetic Emissions and Immunity

This chapter presents the emission and immunity tests, and compliance of the FreeO_2.

7.1 Electromagnetic Emissions

The FreeO_2 oxygen therapy optimization device is intended to be used in an electromagnetic environment as specified in Table 1. Users must make sure that the unit is used in such an environment.

Table 1 Emission tests and guidance

Test	Compliance	Guidance
RF emissions CISPR 11	Group 1	The FreeO_2 oxygen therapy optimization device uses radio frequencies (RF) in its internal functions. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11 • With or without USB adapter • With or without oximeter adapter	Class A	The FreeO_2 oxygen therapy optimization device can be used in any health care establishment, as well as domestic establishments and those directly connected to a low-voltage network.
Harmonic emissions IEC 61000-3-2 with or without accessories	Class A	The FreeO_2 oxygen therapy optimization 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.
Voltage fluctuations/ Flicker emissions IEC 61000-3-3 with or without accessories	Complies	

Warning

- The unit should not be used adjacent to other equipment. If it needs to be used very close to other devices, the user should verify that the FreeO_2 operates normally in that configuration.
- The use of accessories other than those specified is not recommended. This could create an increase of emissions or decrease the immunity of the unit.
- The use of portable and mobile radio frequency (RF) communications equipment can affect the operation of the FreeO_2.
- The FreeO_2 needs to be installed and put into service according to the EMC information provided in sections 7.2 and 7.3. Portable and mobile RF communications equipment can affect medical electrical equipment. The device may be interfered by other equipment with CISPR emission requirements.
- Additional equipment connected to medical electrical equipment must comply with the respective IEC or ISO standards (for example, IEC 60950 for data processing equipment). All installation configurations must comply with the requirements for medical electrical systems (that is, IEC 60601-1-1 or clause 16 of the 3rd edition. of IEC 60601-1, respectively). Anybody connecting additional equipment to the medical electrical equipment is responsible to make sure that the system complies with the requirements for medical electrical systems. Local laws have priority over the above mentioned requirements therefore, if in doubt, contact your local representative or the technical service department.
- This equipment has been tested and found to comply with the limits for medical devices to the EN 60601-1-2: 2007. These limits are designed to provide reasonable protection against harmful interference in a typical medical installation. This equipment generates, uses, and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to other devices in the vicinity. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to other devices, which can be determined by turning the equipment off and on, the user should try to correct the interference by performing one or more of the following:
  - Reorient or relocate the FreeO_2.
  - Increase the distance between the FreeO_2 and the other equipment.
  - Contact OxyNov for help.

7.2 Electromagnetic Immunity

The FreeO_2 oxygen therapy optimization device is intended to be used in an electromagnetic environment as specified in Table 2. Users must make sure that the unit is used in such an environment.

Table 2 Immunity tests and guidance

Test	IEC60601-1-2 Test Level	Compliance	Guidance
Electrostatic discharge IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floors should be wood, concrete, or ceramic. If they are covered with a 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 power supply lines ±1 kV for input/ output lines	Main power quality should be of a typical commercial or health care environment.
Surge: IEC 61000-4-5	±1 kV differential mode ±2 kV common mode	±1 kV differential mode ±2 kV common mode	Main power quality should be of a typical commercial or health care environment.
Voltage dips, short interruptions, and voltage variations of power supply input IEC 61000-4-11	<5% Ut (>95% dip in Ut) for 0.5 cycle 40% Ut (60% dip in Ut) for 5 cycles 70% Ut (30% dip in Ut) for 25 cycles <5% Ut (>95% dip in Ut) for 5 s	<5% Ut (>95% dip in Ut) for 0.5 cycle 40% Ut (60% dip in Ut) for 5 cycles 70% Ut (30% dip in Ut) for 25 cycles <5% Ut (>95% dip in Ut) for 5 s	Main power quality should be of a typical commercial or health care environment. If the user of the FreeO_2 oxygen therapy optimization device requires continued operation during power main interruptions, it is recommended that the FreeO_2 be powered from an uninterruptible power supply or batteries. NOTE: UT is the a.c. main voltage prior to application of the test level.
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 commercial or health care environment.

Table 2 Immunity tests and guidance (*continued*)

Test	IEC60601-1-2 Test Level	Compliance	Guidance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms	Portable and mobile RF communication equipment should not be used closer to any part of the $FreeO_2$ oxygen therapy optimization device, (including cables), than the recommended distance calculated from the equation applicable to the frequency of the transmitter.
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	Recommended distances: $d = \left[\frac{3.5}{V_1}\right]\sqrt{P}$ $d = \left[\frac{3.5}{E_1}\right]\sqrt{P}$ 80 MHz to 800 MHz $d = \left[\frac{7}{E_1}\right]\sqrt{P}$ 800 MHz to 2.5 GHz Where P is the maximum output power rating of the transmitter in watts according to the transmitter manufacturer and d is the recommended distance in meters. Field strength from fixed RF transmitters, as determined by an electromagnetic site survey, should be less than the compliance level in each frequency range[a]. Interference may occur when close to equipment bearing the (((•))) symbol[b].

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 and cordless telephones, land mobile radios, amateur radio, AM and FM radio broadcast, and television broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to RF transmitters, an electromagnetic site survey should be considered. If the measured field strength, in which the $FreeO_2$ oxygen therapy optimization device is used, exceeds the applicable RF compliance level above, the $FreeO_2$ oxygen therapy optimization device should be monitored to verify its normal operation. If the performance is abnormal, additional measures may be necessary, such as reorienting or relocating the $FreeO_2$ oxygen therapy optimization device.

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

Table 3 Transmitter

Bluetooth compliance	Version 4.0
Operating frequency	2.402 to 2.480 GHz
Output power	2 dBm
Operating range	Indoor radius of 5 meters (16 feet)
Network topology	Point-to-Point
Operation	Master
Antenna type	Internal
Modulation type	Frequency-shift keying Frequency-hopping spread spectrum
Bandwidth	1 MHz
Transmitter module FCC ID	A8TBM77SPPSYC2A

7.3 Distances between RF Communication Equipment and the FreeO_2

The FreeO_2 is intended to be used in an electromagnetic environment where RF disturbances are controlled. The user can prevent electromagnetic interferences by maintaining a minimum distance between RF communication equipment and the unit as specified in Table 4, according to the maximum output power of the communication equipment.

Table 4 Distances according to the transmitter frequency

Rated Maximum Output Power of Transmitter (W)	150 kHz to 80 MHz $d = \left[\frac{3.5}{V_1}\right]\sqrt{P}$	80 MHz to 800 MHz $d = \left[\frac{3.5}{E_1}\right]\sqrt{P}$	800 MHz to 2.5 GHz $d = \left[\frac{7}{E_1}\right]\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.37	0.37	0.74
1	1.17	1.17	2.33
10	3.69	3.69	7.38
100	11.67	11.67	23.33

NOTE: All distances shown in table 4 are in meters (m).

NOTE: 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.

At 80 MHz and 800 MHz, the distance for the higher frequency range applies.

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

8 Maintenance

This chapter presents the instructions for cleaning and calibrating the FreeO_2.

8.1 Cleaning

This section explains how to clean the FreeO_2 and the precautions to be taken.

Warning
Do not perform any cleaning operation while a patient is connected to the FreeO_2.
Always disconnect the equipment from the AC power before performing any cleaning, disinfection, or maintenance. To avoid an electrical hazard, never immerse any part of the system in any cleaning agent nor attempt to clean it with liquid cleaning agents.

Clean the FreeO_2 exterior surface after each use.

Use a soft cloth or a damp paper towel. You can use a disinfectant or a mild, non-abrasive detergent; make sure to dilute them in water. You can also use isopropylic alcohol to clean the exterior of the unit.

IMPORTANT: Do not use solvent or abrasive cleaners as they will damage the FreeO_2.

Caution
Regularly vacuum the air input and output of the FreeO_2 to remove dust and lint. If this is not done, the unit may overheat.

8.2 Calibration

The pulse oximeter performs all critical computations; therefore, there are no critical parts to drift, no recalibration is usually required during the life of the FreeO_2.

It is recommended to perform an accuracy check of the built-in oximeter once a year.

Batteries replacement may be required (refer to section 8.4 for more information).

8.3 SpO_2 Testing

OxyNov recommends testing the oximeter with a pulse oximetry simulator once a year. There are many commercially available simulators manufactured by third parties. OxyNov recommends the models presented in Table 1.

Table 1 Pulse oximetry simulators

Manufacturer	Simulator Name	Type	Settings	Simulates	User Programmable
Datrend	Oxitest Plus 7	Optical	Nonin number 63 and 65	5 preset SpO_2 levels from 70 to 97% 20-250 BPM 0 to 100% pulse amplitude in 1% increments 4 preset artifact conditions 9 preset patient conditions	Yes
Fluke	SPOT Light SpO_2	Optical	Nonin	8 preset SpO_2 levels from 80 to 100% 30 to 245 BPM Perfusion rate, 0.2%, 2%, 10% 2 preset artifact conditions	No
Nonin	8000S	Non-optical	-	1 preset SpO_2 level, 1 HR level	No

To perform the test, place the sensor on the simulator, configure the simulator to obtain SpO_2 (±1%) and heart rate (±2 BPM) values. Validate that you get the same values with the $FreeO_2$. If the values do not correspond, send the unit for a technical verification.

Warning
No modification of the equipment is allowed.

8.4 Batteries

The $FreeO_2$ is equipped with lithium-ion batteries that keep the power going in case of a power failure or should the unit get disconnected.

Do not charge the batteries at a temperature of 0 °C (32 °F) or less as this may result in significantly reducing the battery life.

The life of the batteries is about 2 years. If the unit does not provide a battery life of 2 hrs, the batteries must be replaced. In normal use it is recommended to change the batteries every 2 years.

The $FreeO_2$ device is also equipped with a non-rechargeable lithium battery that keeps the date and time. The lifespan of this battery is approximately 3 years.

Warning

The batteries are made of rechargeable cells and are integrated into the unit. They can only be replaced by qualified personnel.

Replacement by an unqualified person could result in excessive temperature, fire, or explosion.

Use only OxyNov-approved batteries.

Caution

The batteries should be adequately charged to ensure the backup power in case of an interruption.

9 Warranty and Contact

This chapter presents the warranty terms of the FreeO_2 and the OxyNov contact information.

9.1 Warranty

OxyNov Inc. (OxyNov) warrants this product against material and workmanship defects for a period of one year from the original date of shipping. OxyNov also warrants that this product will comply with the specifications applicable to normal use.

During the warranty period, OxyNov commits, at its own discretion, to repair, replace, or issue a credit for any defective product, as well as verify and adjust the product if would be the case.

IMPORTANT: The guarantee may become null and void if:

- The unit has been altered or repaired by unauthorized persons or personal other than OxyNov's.
- The case screws, other than those specified in this manual, have been removed.
- The unit serial number has been altered, erased, or removed.
- The unit has been misused, neglected, or accidentally damaged.

THIS WARRANTY REPLACES ALL OTHER WARRANTIES, EXPRESS, IMPLIED, OR STATUTORY, BUT WITHOUT LIMITING TO IT, THE WARRANTIES OF MERCHANTABILITY AND APPLICATION FOR A PARTICULAR PURPOSE. IN NO EVENT WILL OxyNov BE LIABLE FOR ANY SPECIAL, INCIDENTAL, OR INDIRECT DAMAGES.

9.1.1 Responsibility

OxyNov cannot be held liable for damages resulting from the product use nor responsible for any performance failure of the other elements to which the product is connected.

OxyNov will not be liable for damages resulting from misuse or an unauthorized modification of the product, its accessories, and software.

9.1.2 Exclusions

OxyNov reserves the right to bring changes to the design or the construction to one of its products at any time without incurring the obligation of making these modifications on products previously sold. Accessories, including but not limited to, batteries, power cord, and oxygen supply tube.

This warranty excludes all failures resulting from: misuse or wrong installation, normal wear, accidents, abuse, neglect, damage caused by fire, water, lightning, or other natural disasters, external causes to the product, or other factors outside the control of OxyNov.

9.2 Contact

For information, please contact:

Your local distributor

OR

Technical service

OxyNov France SARL
135, rue Claude Chappe, Technopôle Brest Iroise, 29280, Plouzane, France
Telephone: +33 (0)2 29 00 15 87 | Fax: +33 (0)2 57 40 02 17
service.techniques@oxynov.com

OR

Visit the **Contact us** section under **Contact us** of our Web site www.oxynov.com.

9.2.1 Manufacturer

OxyNov
725, boulevard Lebourgneuf, suite 109/111
Québec, Qc Canada G2J 0C4

9.2.2 Authorized Representative

CEpartner4U BV
Esdoornlaan 13
3951 DB Maarn, Netherlands

9.3 Training

Training is available, please contact the Technical service or your OxyNov distributor.

> **NOTE:** If a serious incident occurs in connection with the use of the device, it should be reported to the manufacturer and to regulatory authorities.

Appendix A Specifications

This chapter presents the specifications for the FreeO_2, the SpO_2 sensors, and the power supply.

Appendix A.1 FreeO_2

The following tables present the FreeO_2 specifications.

Table 1 Performances

SpO_2 reading	70% to 100% ±2 digits
Heart rate	40 to 190 BPM ±5 digits
Respiratory rate	4 to 70 RR/min
Generated O_2 flow	0 to 20 l/min, in increments of 0.1
Input pressure	10 bar max.

Table 2 Alarms (visible and audible)

SpO_2	Min. and max.
Heart rate	Min. and max.
Respiratory rate	Min. and max.
O_2 flow	Max.
Low battery	Yes
Audible alarm snooze button	Yes
High alarm volume	56 dB
Low alarm volume	33 dB
Alarm delay	<5 s

Table 3 Electrical

Root	
Main	100-240 VAC, 50-60 Hz
DC input	24 VDC, 1.33 A, AC adapter
Power consumption	15 W
Main Batteries	
Type	Lithium ion
Capacity	3 hours
Maximum charging time	3 hours
RTC Batteries	
Type	Lithium
Capacity	1 Ah (3 years)
Not rechargeable	

Table 4 Environmental

Operating temperature	10 °C to 40 °C
Operating humidity	10% to 90% non-condensing
Operating altitude	70 kPa to 106 kPa
Storage temperature	-20 °C to 70 °C
Storage humidity	10% to 90% non-condensing

Table 5 Equipment classifications (according to IEC 60601-1)

Type of protection	Class II (AC Adapter, externally power)
Degree of protection	Type BF - Applied Part
Enclosure degree of ingress protection against harmful ingress of water	IP22
Mode of operation	Continuous

NOTE: The FreeO_2 is suitable for use within the patient environment.

Table 6 Physical characteristics

Weight	3000 g
Dimension	21 cm x 20 cm x 14 cm
Display	
Type	Backlit Active Matrix TFT LCD
Resolution	800 x 600 pixels
Color	24 bit RGB
Size	8 in. (20.32 cm) diagonal
Touchscreen	
Type	Resistive

Table 7 Connectivity

Connector	
SpO_2	DB9
USB	USB 2.0

Table 8 Applied part

SpO_2 sensor	Not supplied by OxyNov Refer to appendix A.5 "SpO_2 Sensors"
Nasal cannula, face mask	Not supplied by OxyNov Follow the clinician instructions

Appendix A.2 $FreeO_2$ Response Time

The following presents the $FreeO_2$ response to the patient.s data. If the signal from the sensor is inadequate, the measure shows dashes instead of numbers.

Table 9 Response

SpO2	Response	Latency
Fast average SpO_2	1.5 s	2 beats
Pulse Rate Value		
Fast average SpO_2	1.5 s	2 beats

Table 10 Delay

Display update	1.5 to 2.5 s[a]
Alarm signal generation	<5 s

a. In all configurations, the display update delay is typically less than 2 seconds.

NOTE: The $FreeO_2$ closed-loop controller does not react the same way for all patients. The oxygen flow, to improve the oxygenation level and the time to reach equilibrium, differs from patient to patient. Depending on the severity of the respiratory disease, the oxygen intake rate, the heart rate, and the respiratory rate the patient's response will be different and the $FreeO_2$ device will adjust the flow rate based on the new SpO_2 readings provided by the oximeter.

Appendix A.3 Example of the SpO_2 Exponential Averaging

This section presents an example of the SpO_2 averaging by the Nonin oximeter.

The SpO_2 decreases 0.75% per second (7.5% over 10 seconds). The pulse rate being 75 BPM. The $FreeO_2$ is configured for an average of 4 beats.

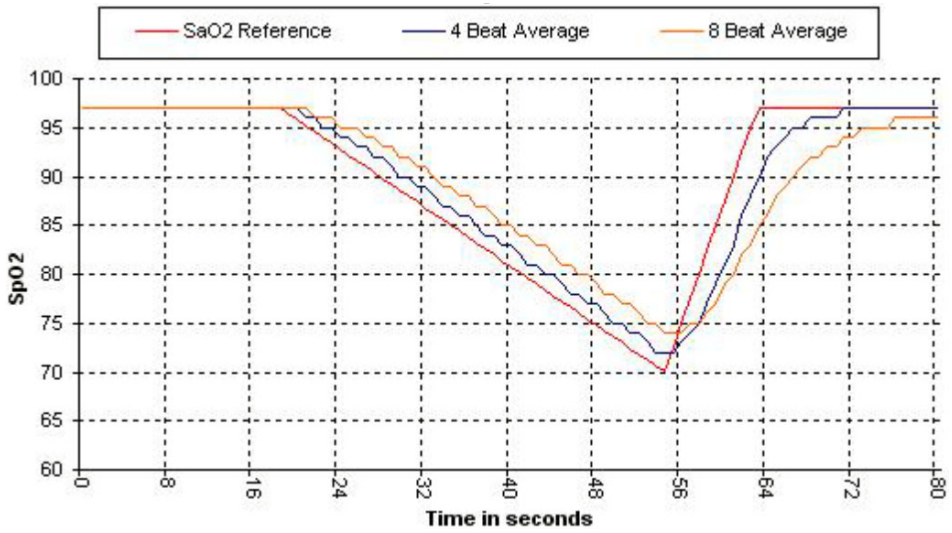


Figure A-1 SpO_2 averaging

Appendix A.4 Default Values and Limits

This section presents a list of default values and limits to be validated for the configuration.

A.4.1 Configuration/Treatment

Table 11 General

Language	English
Sound level	100%
Brightness level	100%
Screen lock	Enabled, 3 seconds
Night mode	Disabled, level at 50%, 22H00 to 6H00
Factory default patient type	Adult
Factory default mode	FreeO_2

Table 12 Factory default SpO_2 target

Type	Default	Minimum Limit	Maximum Limit
Pediatric	94%	88%	96%
Adult	94%	88%	98%

Table 13 Factory default O_2 flow rate maximum (FreeO_2 mode)

Type	Maximum O_2 Flow
Pediatric	10 L/min
Adult	20 L/min

Table 14 Constant flow mode

Type	Default	Minimum Limit	Maximum Limit
Pediatric	5 L/min	0 L/min	10 L/min
Adult	5 L/min	0 L/min	20 L/min

A.4.2 Alarm Panel

Table 15 Absolute limits (all patient types)

Type	Minimum Limit	Maximum Limit
SpO_2	70%	100%
Flow rate	0 L/min	20 L/min
HR	40	190
RR	4	70

Table 16 Pediatric range

Type	Low Default Configuration	High Default Configuration
SpO_2	Defined according to the SpO_2 target, refer to Table 18.	96%
Flow rate	N/A	According to the following calculation: **Max. O2 Flow.** programmed x 80%.
HR	70	150
RR	15	40

Table 17 Adult range

Type	Low Default Configuration	High Default Configuration
SpO_2	Defined according to the SpO_2 target, refer to Table 18.	98%
Flow rate	N/A	According to the following calculation: **Max. O2 Flow.** programmed x 80%.
HR	55	120
RR	8	25

Table 18 Low Default SpO_2 Alarm

Targetted SpO_2	Low SpO_2 alarm - Adult	Low SpO_2 alarm - Pediatric
98	88 %	S.O.
97	88 %	S.O.
96	88 %	89 %
95	88 %	89 %
94	88 %	89 %
93	86 %	88 %
92	86 %	88 %
91	86 %	86 %
90	85 %	86 %
89	85 %	86 %
88	85 %	86 %

Tone intervals: All mid-values, mute disabled

Time zone: UTC -4:00, 24H display enabled

Snooze delay: 2 minutes

Bolus mode: 2 minutes

Appendix A.5 SpO_2 Sensors

This section presents the list of SpO_2 sensors compatible with the $FreeO_2$.

Warning
Using any other sensor may result in false readings, patients' injury, and $FreeO_2$ malfunction.

6000CA - Cloth adult box of 24; 3 feet (1 meter)
6000CI - Cloth infant box of 24; 3 feet (1 meter)
6000CP - Cloth pediatric box of 24; 3 feet (1 meter)
7000A - Flexi-Form III adult disposable box of 24; 3 feet (1 meter)
7000I - Flexi-Form III infant disposable box of 24; 3 feet (1 meter)
7000P - Flexi-Form III pediatric disposable box of 24; 3 feet (1 meter)
8000AA - Adult articulated internal spring finger clip; 3 feet (1 meter)
8000AA-2M - Adult articulated internal spring finger clip; 6 feet (2 meters)
8000AA-3M - Adult articulated internal spring finger clip; 9 feet (3 meters)
8000AP - Pediatric external spring finger clip; 3 feet (1 meter)
8000AP-3M - Pediatric external spring finger clip; 9 feet (3 meters)
8000J - Adult flex sensor, w/25 FlexiWrap®; 3 feet (1 meter)
8000J-3M - Adult flex sensor, w/25 FlexiWrap®, 9 feet (3 meters)
8000Q - Ear clip sensor; 3 feet (1 meter)
8000SL - Soft sensor large; 3 feet (1 meter)
8000SM - Soft sensor medium; 3 feet (1 meter)
8000SS - Soft sensor small; 3 feet (1 meter)
8008J - Infant flex sensor w/25 FlexiWrap®; 3 feet (1 meter)
8008JFW - FlexiWrap® - Infant, bag of 25

Appendix A.6 Power Supply

ME30A2403B01 - SL Power Electronics
ME30A2403F01 - SL Power Electronics

Appendix B Testing Summary

The SpO_2 accuracy, motion, and low perfusion testing were conducted by Nonin® Medical Incorporated.

Appendix B.1 SpO_2 Accuracy Testing

The SpO_2 accuracy testing was conducted during induced hypoxia studies on healthy, non-smoking, light-to-dark- skinned subjects during motion and no-motion conditions in an independent research laboratory. The measured arterial hemoglobin saturation value (SpO_2) of the sensors is compared to arterial hemoglobin oxygen (SaO_2) value, determined from blood samples with a laboratory co-oximeter. The accuracy of the sensors in comparison to the co-oximeter samples measured over the SpO_2 range of 70 to 100%. The accuracy data is calculated using the root-mean-squared (A_{rms} value) for all subjects, per ISO 9919:2005, Standard Specification for Pulse Oximeters for Accuracy.

Appendix B.2 Heart Rate Motion Testing

This test measures heart rate accuracy with motion artifact simulation introduced by a pulse oximeter tester. This test determines whether the oximeter meets the criteria of ISO 9919:2005 for heart rate simulated movement, tremor, and spike motion.

Appendix B.3 Low Perfusion Testing

This test uses an SpO_2 simulator to provide a simulated heart rate, with an adjustable amplitude setting at various SpO_2 levels. The module must maintain an accuracy in accordance with ISO 9919:2005 for heart rate at the lowest obtainable pulse amplitude (0.3% modulation).

Appendix B.4 Test Results

The following tables show the results of the oximeter accuracy.

NOTE:
Reusable group

Finger clip sensors: 8000AA, 8000AA-3M, 8000AP, 8000AP-3M
Flex sensors: 8000J, 8000J-3M, 8008J, 8001J
Soft sensors: 8000SS, 8000SM, 8000SL

NOTE:
Disposable group

Flexi-Form® II sensors (7000 series): 7000A, 7000P, 7000I, 7000N
6000 sensors series: 6000CA, 6000CI, 6000CN, 6000CP

Table 1 SpO2 accuracy (A_{rms}[a])

		Adult/Pediatric (70 to 100%)
No motion		
Reusable	Finger clip	±2 digits
	Flex	±3 digits
	Soft sensor	±2 digits
	8000Q	±4 digits
Disposable	6000 series	±2 digits
	7000 series	±3 digits
Motion		
Reusable	Finger clip	±2 digits
	Flex	±3 digits
	Soft sensor	±3 digits
Low perfusion	All sensors	±2 digits

a. ±1 A_{rms} represents approximately 68% of measurements.

Table 2 Heart rate accuracy

		Adult/Pediatric
No motion (18 to 300 BPM)		
Reusable	Finger clip	±3 digits
	Flex	±3 digits
	Soft sensor	±3 digits
	8000Q	±3 digits
Disposable	6000 series	±3 digits
	7000 series	±3 digits
Motion (40 to 240 BPM)		
Reusable	Finger clip	±5 digits
	Flex	±5 digits
	Soft sensor	±5 digits
Low perfusion	All sensors	±3 digits