O2matic

User Manual

OMC PC-100 / PRO 100

Instructions for use

Software: ver 1.7

2024.02.12

O2matic

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READ FIRST

Disclaimer

O2matic PRO 100 uses pulse oximetry to automatically adjust oxygen flow to the patient which can help reduce manual intervention of oxygen flow to the patient. When providing oxygen treatment with PRO 100, a desired SpO2 range as well as a flow range must be defined for each individual patient. It is paramount that these ranges are chosen carefully by responsible healthcare staff. Failure to actively assess the acceptable SpO2 range and tolerable flow range for patients can lead to severe injuries and potentially fatal outcomes.

Defining the flow range

When defining a flow range for a patient using PRO 100, it is important to consider the patient's ability to tolerate oxygen. It is crucial that patients diagnosed with type 2 respiratory failure or risk of hypercapnia and acidosis doesn't receive a flow above the tolerated level, regardless of the SpO2 level of the patient. The max O2 flow in PRO 100 must not be higher than what the patient can tolerate.

Relying on pulse oximetry

When defining the patients SpO2 range on PRO 100 consider that falsely low readings may be caused by hypoperfusion of the extremity being used for monitoring; incorrect sensor application; highly calloused skin; and movement (such as shivering), especially during hypoperfusion. Falsely high or falsely low readings will occur when hemoglobin is bound to something other than oxygen. In cases of carbon monoxide poisoning, the falsely high reading may delay the recognition of hypoxemia (low blood oxygen level). Methemoglobinemia characteristically causes pulse oximetry readings in the mid-80s. Cyanide poisoning can also give a high reading because it reduces oxygen extraction from arterial blood (the reading is not false, as arterial blood oxygen is indeed high in early cyanide poisoning). In some conditions such as undrained pneumothorax, cluster headaches and sickle cell crisis a high oxygen flow might be warranted according to guidelines, irrespective of SpO2 readings.

1 Introduction, General Warnings and Cautions.

PRO 100 is a medical device with the ability to assist medical staff in hospitals and respiratory clinics with oxygen supplementation to secure a stable oxygenation of the blood. PRO 100 will do this by continuously adjusting the flow of oxygen to the patient based on the actual oxygen saturation in the blood, which is measured by standard pulse oximetry.

PRO 100 is suitable for use in hospitals except near active HF surgical equipment and the RF shielded room of a medical electrical system for magnetic resonance imaging, where the intensity of electromagnetic disturbances is high.

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

To avoid adverse events to the patient due to electromagnetic disturbances, the patient shall be assessed by medical staff at regular intervals, determined based on the condition of the patient.

1.1 Intended purpose

PRO 100 is an electro/mechanical medical device, intended for oxygen therapy optimization at all hospital departments and units that administer oxygen therapy. PRO 100 is for short term continuous use at hospital for not more than 30 days. The regulation of oxygen is managed by a software algorithm.

1.2 Contraindications

- Do not use on multiple patients simultaneously.
- PRO 100 must not be used with devices which deliver a fixed fraction of oxygen (FiO_2) regardless of oxygen flow, such as the Venturi masks, as PRO 100 would not be able to increase FiO_2 in response to a low SpO_2 with such systems.

Do not use this unit on a patient:

- Less than 18 years old
- In the Automatic mode with suspected CO poisoning
- That is not spontaneously breathing
- Who is incapable to keep airways free of secretions
- For whom the SpO_2-signal is not stable
- With increased methemoglobin
- With Cyanide poisoning
- With Cluster headaches
- With Undrained pneumothorax
- With sickle cell crisis

Intended patient population/medical indication

- Acute hypoxemia without risk of hypercapnia
- Acute hypoxemia with risk of hypercapnia
- Worsening hypoxemia during activity

Intended Users for operation of PRO 100

- Medical staff
- System administrator
- Service provider
- Cleaning personal
- The indirect user group

Medical staff can be doctors and nurses. They are the primary users and will have to setup the profiles / saturation targets. They will have to process every data output from the device.

Administrators will have access to some of the backend functions such as paring devices with pulse oximeters, changing a mac address, export data from the device or perform a basic functionality test on the device.

Service provider will have to perform support and service on the device. This covers phone support or performing physical tests on the PRO 100 if there are reasons to doubt functionality, I.E. the PRO 100 has dropped from a high but there is no sign of physical damage.

Cleaning personal are not users of the devices but have some requirements on how to clean the device.

Patients are not considered as a user, but has some requirements for disturbance, comfort, and safety.

Intended use environment

PRO 100 is intended for use at all hospital departments with oxygen treatment. The device is installed on the wall rack, or a pole stand and connected to the hospitals existing oxygen supplies, such as central oxygen supply, oxygen cylinders or concentrators. The device is also connected to the power supply.

Included in box

Item	UDI-DI/GTIN-14
O2matic PRO 100 incl. power adapter, power connectors and user manual	05715081101014
8000AA-3 - Adult articulated internal spring finger clip	0 0833166 000191
Oxygen outlet	1 4026704 65740 4

1.3 Warnings

Warning

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

Do not use in an explosive atmosphere or in the presence of flammable anesthetics or gases.
Use only Nonin Purelight pulse oximetry sensors, as other sensors might not meet the same accuracy criteria required by PRO 100.
Refer to the applicable sensor instructions for use for additional warnings and cautions.
Regularly check the battery indicator. If lit, See section 7.3 for battery instructions.
PRO 100 is only to be used with pure oxygen.
Use of this equipment adjacent to or stacked with other equipment should be voided 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 device could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.
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 O2matic PRO device, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.
PRO 100 shall never be used as a substitute for personal and qualified observations by medical and nursing staff, as PRO 100 only monitors oxygenation of the blood and pulse rate, and other parameters and patient condition can deteriorate if personal observation is inadequate.

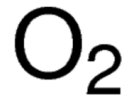
For additional information refer to IEC 60601-1

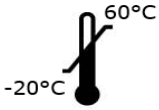
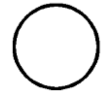
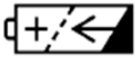
1.4 Cautions

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

Do not place PRO 100 in a corner, as it can be difficult to connect and disconnect accessories.
The accuracy of the SpO_2 measurement may be affected if the total sensor length (including extension cables) is greater than 3 meters.
Pulse oximetry sensors may have reading troubles when used on patients with cold extremities due to reduced blood circulation. For more information please contact your local distributor.
Follow local or national recycling instructions regarding disposal of device and accessories.
In compliance with the European Directive on Waste Electrical and Electronic Equipment (WEEE) 2012/19/EU, do not dispose of this product as unsorted municipal waste. This device contains WEEE materials. Contact your distributor regarding take-back or recycling of PRO 100.

1.5 Symbols

	Refer to instruction manual/booklet. Follow instructions for use		Direct current: 12 VDC
	Manufacturer	 0123	CE mark: Made in compliance with all relevant directives
	Manufacturing date		Serial number
	Do not use if the package is damaged		Bell can be temporarily cancelled
	Not for general waste		For use in oxygen rich environtm-ent
	Alternating current		Type BF Applied part

	Storage Temperature limits		POWER
	“ON”		“OFF”
	Class II equipment	IPX0	Ingress protection from dust and water
	Equipment shall only be used with rechargeable battery.		WARNING

1.6 Essential performance

The essential performance of PRO 100 is to measure pulse and SpO_2, to maintain or adjust oxygen flow to the patient in response to changes to measured values according to the user defined target values and range thresholds. If the measured values are outside the user specified limits, PRO 100 shall trigger the relevant alarms.

1.7 Operators and safety

PRO 100 should only be used by medical staff, with basic experience in the use of pulse oximeters and treatment of patients in need of oxygen therapy. It is recommended that each hospital appoints administrators responsible for setting up the device metadata, i.e. standard profiles and alarm delays. These should normally be physicians.

PRO 100 has a failsafe rechargeable battery that keeps the device running upon short power breaks. The device has two power related buttons, **Main power** and

Power button, for the purpose of distinguishing between a power break and a proper shutdown. Once the device has been turned on, a proper shut down is needed for the device not to trigger any alarms. To shut down PRO 100 press and hold  **(A)** for 3 seconds.

Note: The **Main power** switch, on the back, can be used to isolate the device from the supply mains.

1.8 Button functionality

When navigating through settings and information screens in PRO 100, only the four navigation buttons on the front of PRO 100 are used. They are used to move the marker up and down inside a menu but also to select, enter, undo or go back a level as well as to increase or decrease values. This is possible due to the dynamic functionality that is built in, so that the function descriptions on the screen change, based on the marker position. Navigation buttons are physically lid, when active and having a function in the active screen.

If the device is not interacted with it will eventually display the pause screen. To disable or change the time before the pause screen is shown or which information is shown on it, choose “Admin” followed by “Settings” and finally “Pause Screen”.

2 Installation and Setup

Before starting any patient treatment, PRO 100 must be installed and set up accordingly as described in this chapter.

2.1 Overview

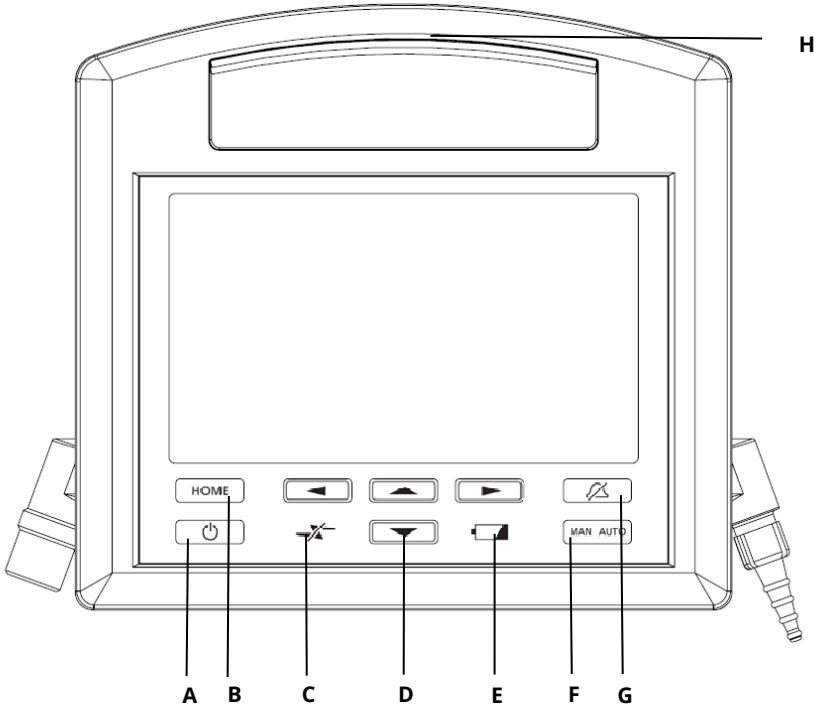


Figure 1: PRO 100 from the front

Front Buttons	
A: Power	E: Battery indicator
B: Home	F: (Manual / Automatic) Mode
C: Power warning	G: Mute (alarms)
D: Navigation	H: Handle

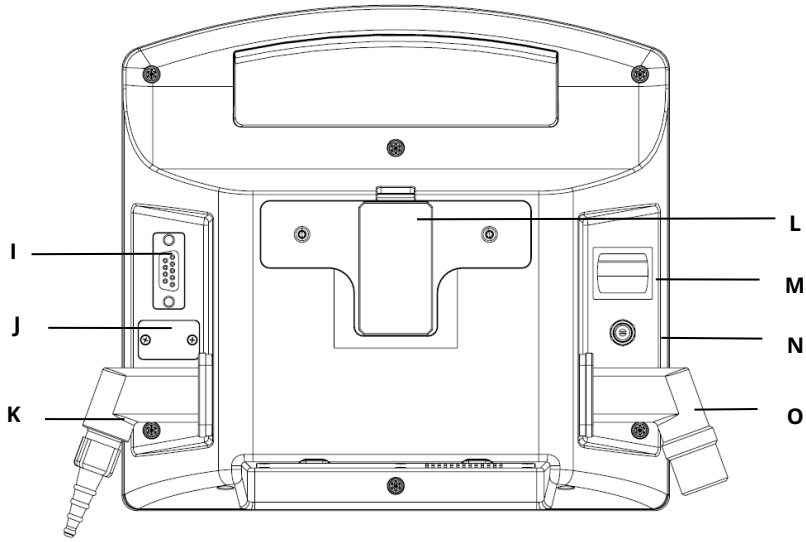


Figure 2: PRO 100 from behind

Back & Bottom Buttons	
I: Pulse oximeter connection	M: Power switch
J: USB connection hatch	N: Power connection
K: Oxygen output connection	O: Oxygen input connection
L: Slider	P: Battery / ventilation hatch

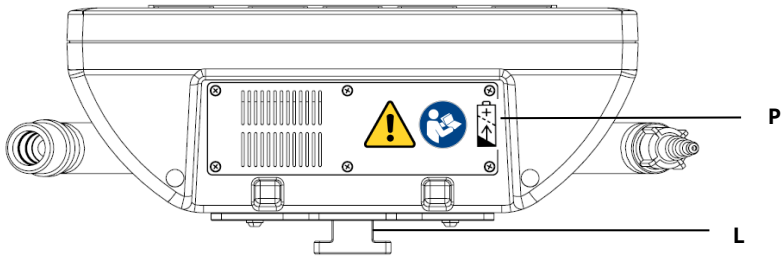


Figure 3: Bottom of PRO 100

2.2 Installation

PRO 100 must be installed near the patient, either on a rail or other fittings matching the standard slide on the back of PRO 100. To install PRO 100:

Slide your regions corresponding power plug into the AC adapter.
Connect the AC power to the wall outlet and to PRO 100 power supply. For safety reasons, the connector is a screw-lock mechanism.

	**Warning** Only use the AC power adaptor provided by O2matic. Any other power supply may interfere with the proper operation of the device.

Connect the oxygen hose to the source of oxygen in the wall or an oxygen cylinder. Then connect oxygen hose to the oxygen input connection (O) of PRO 100.

	**Warning** PRO 100 is only to be used with pure oxygen.

Flick power switch (M) to “I” on the back of PRO 100.

Turn on PRO 100 by pressing  (A) for 2 seconds.

PRO 100 should now be on and the Home Screen appears.

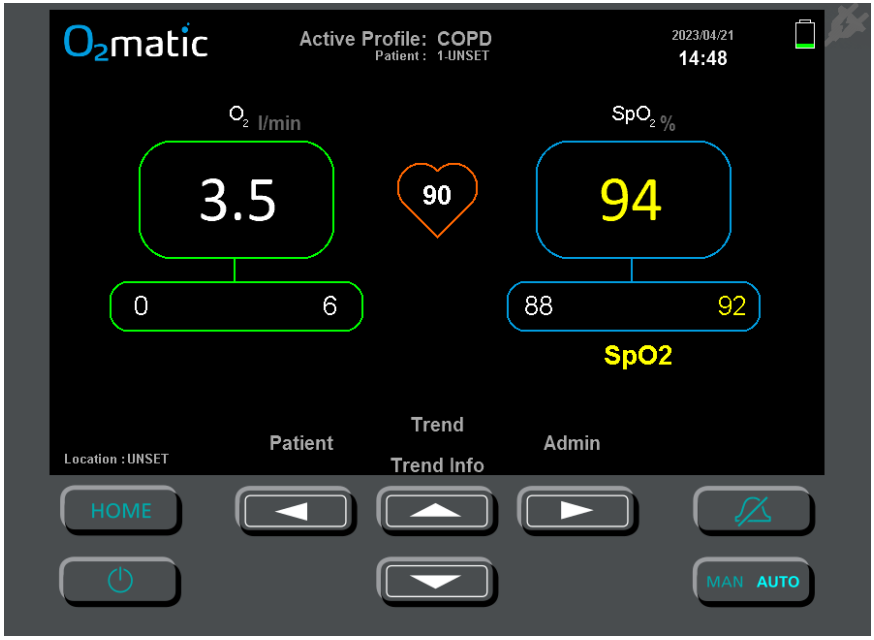


Figure 4: User interface PRO 100 (Home Screen)

PRO 100 will by default actively provide treatment when turned on. Because of this, the device “expects” input signal from the pulse oximeter sensor, worn by the patient. Without a signal from the pulse oximeter PRO 100 will start an alarm after 5 minutes (adjustable). A notification will read “No signal” in yellow font at first and if ignored for a certain period of time (see Signal alarm-table, page 49) will switch to red font when the audible alarm is initiated. To mute the alarm, press the Mute button (G), and the alarm will be muted for 2 minutes. The duration of the muted state is indicated in the bottom right of the screen which will show when the muted state is deactivated. In addition, the light on the physical mute button will also be lit to indicate that it is muted.

Note: Audible alarms are disabled when the patient or admin page is opened. When these pages are opened PRO 100 automatically returns to home screen after 1 minute of inactivity.

Note: If above steps have been followed correctly and there is no visible home screen, see the **Service and Support** section.

Note: PRO 100 goes in to pause screen mode after 30 min. The timing for the pause screen can be adjusted. Press any button to get back to the home screen.

2.3 Setting up the device

All setup functionality in PRO 100 is gathered in the **Admin Menu**. From the **Home Screen** press ► to enter the **Admin Menu** shown below.

Figure 5: PRO 100 Admin menu

Setting up a new profile:

1. From the home screen select Admin and select Profiles
2. Move to New Profile and select Create.
3. Enter the profile name by using the ▲ and ▼ buttons.
   When finished, press ► to save and continue.
4. Navigate to the desired parameters and adjust them as needed.

Return to home screen by pressing HOME (B).

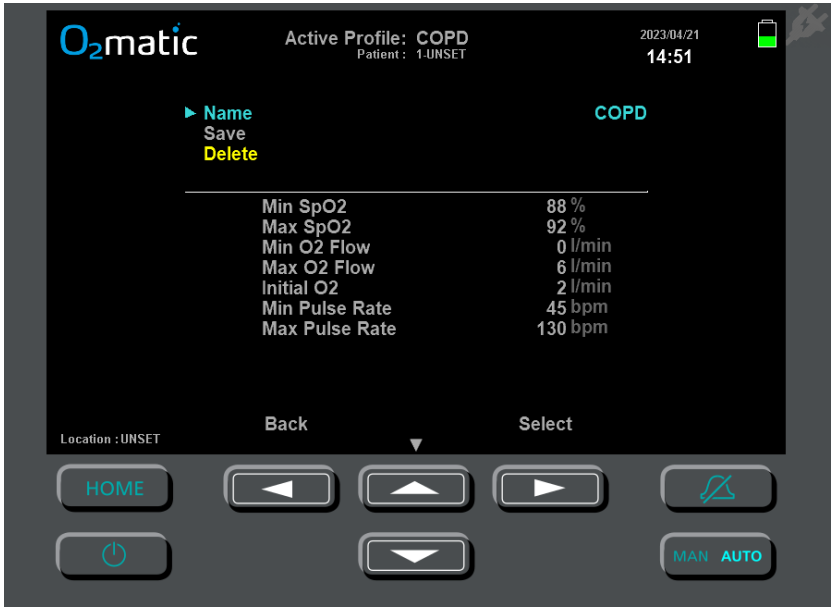


Figure 6: PRO 100 Profile settings

	Warning Setting up profile limits to extreme values can render warnings and alarms meaningless.

NOTE: PRO 100 has built in input validation, to protect against unintended user input. See **appendix A** for a list of input ranges.

Editing an existing profile:

1. From the home screen select Admin and choose Profiles.
2. Move to the desired profile and press Select.
3. Navigate to the desired parameters and adjust them as needed.
4. Save the adjustment.

Return to home screen by pressing HOME (B).

Figures 7 and 8: PRO 100 Edit Profile menu (COPD)

NOTE: Profiles have a parameter named flow response, which will dampen or quicken the flow response rate. If a patient is very unstable and responds very quickly or slowly to changes in flow rate, this parameter can increase comfort for the patient. See **appendix A** for further info.

PRO 100 has built in alarms and warnings that indicate the patient's health status. Warnings are issued when the patient's pulse/SpO_2 moves slightly outside desired level without being critical.

2.4 Importing settings

If you have multiple PRO 100s and you want a specific set of settings on all the devices this can be done easily by importing the same profiles file to all the devices. This minimizes the risk of inconsistency between devices.

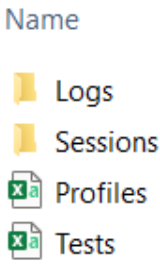
NOTE: PRO 100 complies with the EU directive 95/46/EC from and GDPR from 2018 (General Data Protection Regulation) hence, all access to data logs and settings are protected by physical as well as software related barriers. To gain access to the USB flash on the device you must have the relevant physical tools, and the USB pin code. For more information about the physical tool, visit contact us at info@o2matic.com.

	**Warning** The exported files should only be edited by an administrator that has extensive knowledge of the device. Ignoring this can result in dangerous situations for the patient.

To import settings or profiles:

Remove the screws from the USB hatch
Connect your device to a computer/laptop via a USB 1.0 – 2.0 cable with Type A to Type B connectors
Enter the device's USB pin code on the device to unlock the USB port
Check device connections on your computer. It should be showing up like any other USB device
Enter the USB drive

You will see the following files:



Note: For information about how to export a file see the section 7.2 – exporting data.

2.5 Changing codes and resetting

It is possible to change the USB pin code for the device.

To change the USB pin code:

Enter the admin menu.
Select Settings.
Select Security.
Select Set PIN (default is 1111)
Input the old USB pin.
Press Submit.
Input the new USB pin.
Press Submit.

Note: It is recommended to change the default USB pin code when installing the device.

Resetting

It is possible to reset the USB pin code if it is lost. It is also possible to reset the device to factory defaults. This will bring back all factory default profiles and settings. To reset the USB pin code, you will need the master pin code which can be found on a label on the User manual delivered with the device. To reset the device to factory defaults you will need the USB pin code, which is set to 1111 by default.

Note: The Master pin code is different for each machine. If it is lost, contact your local distributor.

To reset the USB pin code:

a) Enter the admin menu
b) Select Settings
c) Select Security
d) Select Reset USB pin
e) Input the master pin code
f) Press Submit

To reset to factory default:

a) Enter the admin menu
b) Select Settings
a) Select Security
b) Select Reset
c) Input USB pin code
d) Press submit

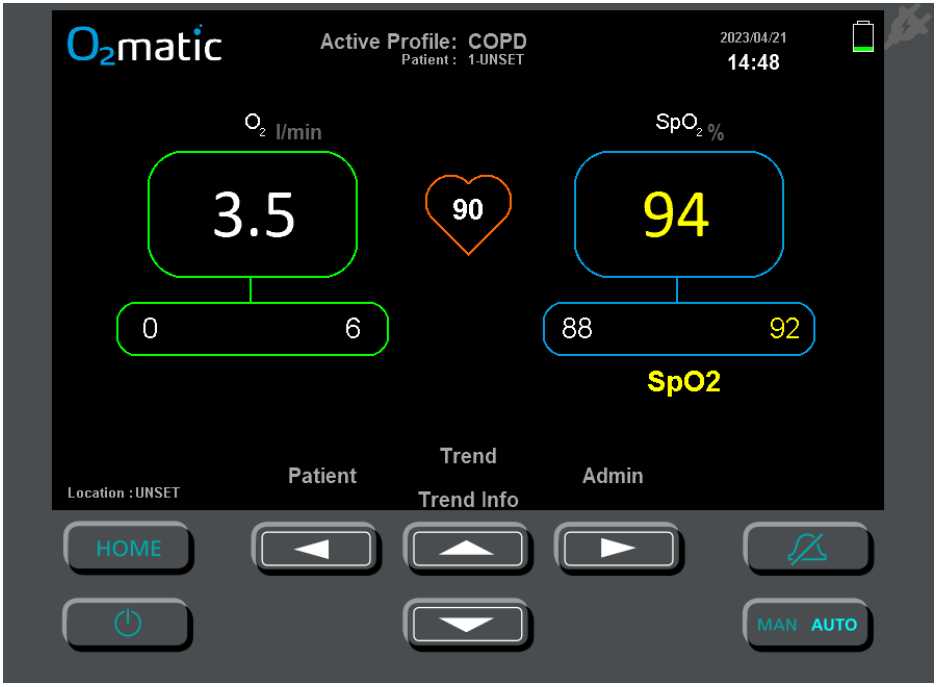
After confirming the device will begin to reset all settings and data on the device. Do not turn off the device while the device is displaying the “Formatting” or “Clearing” messages on the home screen.

3 Starting Treatment

Turn on PRO 100 by pressing ⏻ (A). After turning on the device the Home Screen will appear.

PRO 100 is designed to be as simple as possible and for maximum safety, the device always starts up in the “Automatic Mode” (see section 4.1). Thus, the device is already in treatment mode and an alarm will start immediately if there is no signal from a pulse oximeter sensor. To mute the alarm, press 🔕 **(G)**, and the alarm will be muted for 2 minutes. The button is lit to indicate that it is muted. Entering any menu will also mute the alarms.

Upon startup the device resumes in the latest selected profile. If the device was switched off while in Manual mode, it will regardless, for safety reasons, start up in Automatic mode.



Figures 9: PRO 100 Home Screen

3.1 Assign a new patient to device

To assign a new patient to the device enter the Patient menu. From the HOME (B) screen Select ◄ Patient.
Select New patient.

Figures 10: Patient Screen

When assigning a new patient, the operator needs to complete the instructions seen below:

Change the patient ID.

This can be done either by incrementing the patient ID by 1 **OR** by typing a specific patient ID to accommodate for a hospital's existing ID system.

Selecting “Accept” to increment patient ID by 1.

OR

Select “Edit” and use ▲ and ▼ buttons to manually enter desired ID.

You can select “Clear” to clear the patient ID if needed.

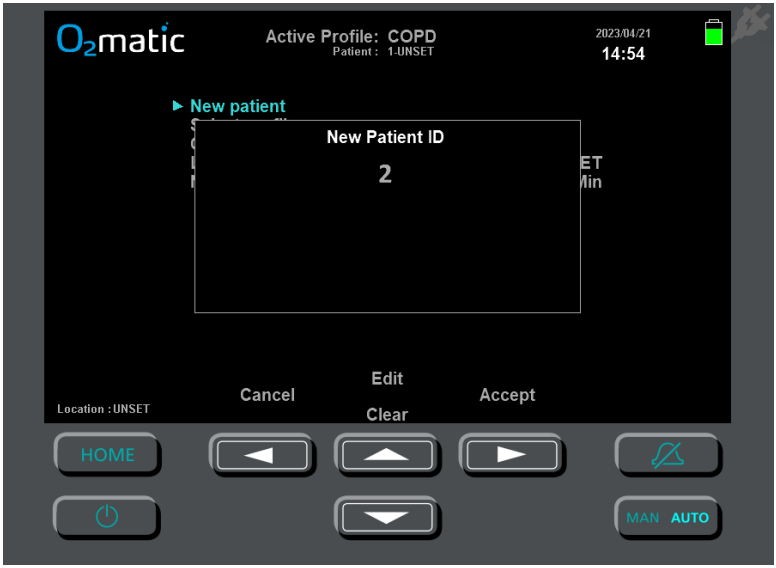


Figure 11: Patient ID change

Input patient name

Select “Edit” and use ▲ and ▼ buttons to manually select each letter for the name.

Press ► to continue to the next letter.

Press ► once more to save the name and continue to the next step.

Input the location.

Select “Edit” and use ▲ and ▼ buttons to manually select each letter for the location.

Press ► to continue to the next letter.

Press ► once more to save the name and continue to the next step.

Set a desired Alarm Delay for losing signal on the pulse oximeter sensor.

This is to accommodate differences in patient mobility. Some patients are very immobile and in critical condition, where a low alarm delay is necessary, while others can be moving around a lot, thus more suited for a higher delay.

Select a profile

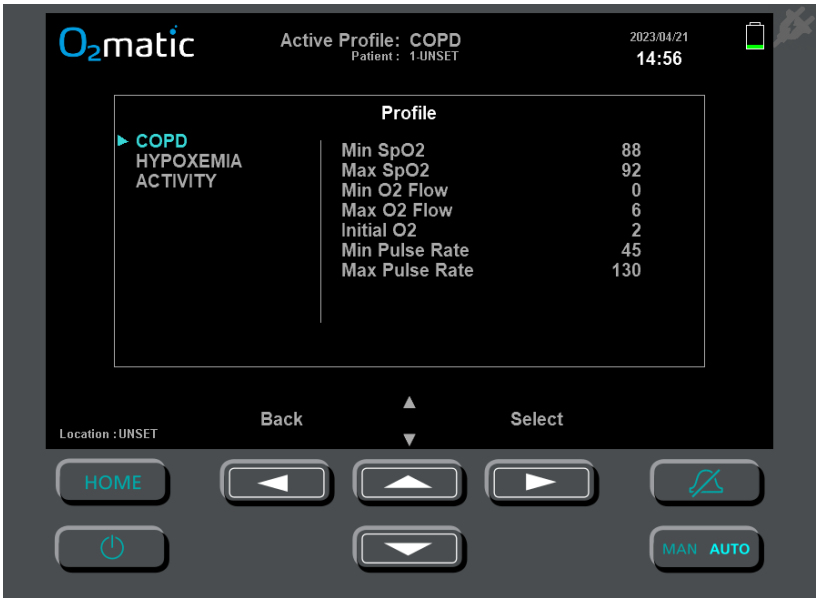


Figure 12: Profile selection

Profiles are a set of parameters tied together to avoid repetitive patient setups. Standard profiles can be set up in the administrator menu and selected in the patient menu. However, the active profile can also be customized if needed. The actual active profile is stated at the top of the screen.

Note: Table A.4 in appendix A shows default factory set profiles.

Once the patient is set up and the device has been installed correctly:

- Place the sensor on the patient's finger
- Apply a nasal catheter or an oxygen mask to the patient.

	**Warning** Only use oximetry sensors listed in this manual. Any other sensor may interfere with the proper operation of the device.

NOTE: It may take up to 10 seconds before a clear signal from the pulse oximetry sensor is established.

NOTE: Nail polish can cause impaired reading functionality of the pulse oximetry sensor.

	**Warning** Never smoke during treatment. This can inflict serious injuries.

	**Warning** Never use any flammable products on the patient as this can cause serious injuries.

4 Treatment and Operation

This section describes the normal operational modes for PRO 100.

4.1 Treatment modes

PRO 100 has two distinct modes for treatment. An “Automatic Mode” and a “Manual Mode”. To switch between modes, press the 

(F) button.

Automatic mode

The “Automatic Mode” is a controlled mode where PRO 100 adjusts the oxygen dosage based on the monitored patient parameters, such as SpO_2 and current oxygen flow. PRO 100 acts within the specified interval of oxygen set in the active profile, as well as the SpO_2 threshold.

NOTE: In the “Automatic mode” PRO 100 is automatically weaning the patient down from oxygen, by giving the optimal oxygen flow necessary to the patient, within the defined SpO_2 interval.

Upon slight exceedance of the interval, PRO 100 triggers a warning by changing the font to yellow and adjusting accordingly. Upon a longer or steeper exceedance of the lower interval, PRO 100 triggers a visual alarm by changing the font to red as well as an audible alarm. See Section 5 for description of warnings and alarms.

If connection to the sensor or signal is lost, PRO 100 will continue with the oxygen flow provided when the signal was lost.

Manual mode

The manual mode works like a standard digital flow meter, where the oxygen flow can be controlled via  and  buttons, while the SpO_2 is still displayed.

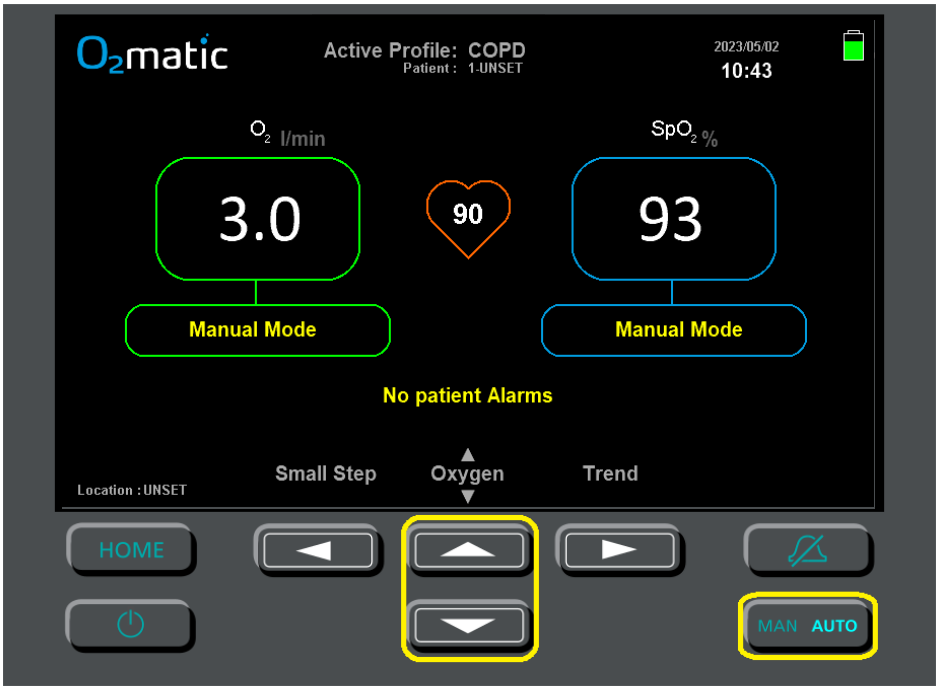


Figure 13: PRO 100 manual mode

When increasing and decreasing the oxygen flow in the manual mode, the incrementation rate changes to match the flow range:

Flow range	**Increments**
0 – 5 l/min	0,1 OR 0,5 l/min
5 – 10 l/min	0,5 l/min
10 – 15 l/min	1 l/min
15 – 15+ l/min	Fully open valve

	Warning No patient related alarms are active in the Manual Mode

4.2 Patient assessment

PRO 100 has two distinct information screens to support better patient assessment. From the HOME (B) screen use ▲ and ▼ cycle through them.

Trend screen Once the patient is set up and the device has been installed correctly:

The Trend Screen shows charts related to the SpO_2, pulse, and oxygen dosage. It is possible to "zoom" in and out on the chart to view trends from the last 12 minutes – last 24 hours, with ◄ and ►.

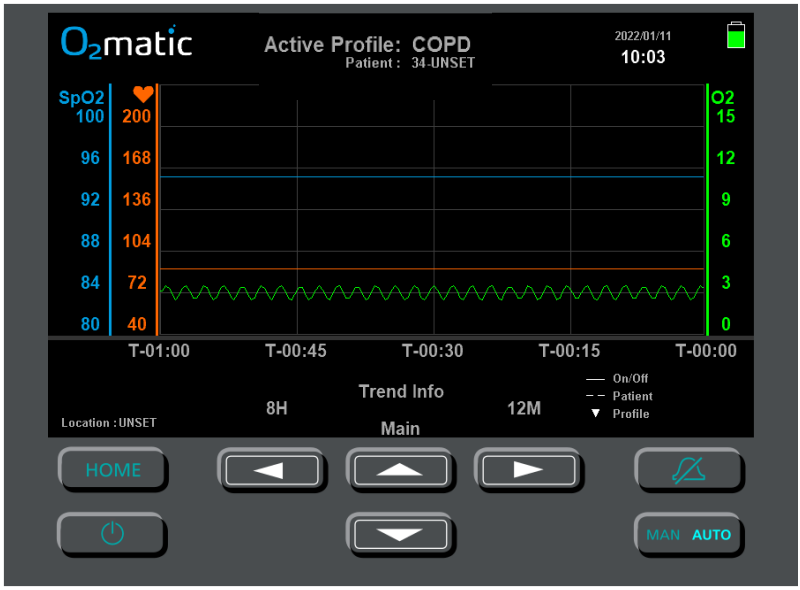


Figure 14: PRO 100 trend screen – last hour

Legends on screen

Legends are illustrating either, if a reboot of the device has occurred, the profiled has been changed/modified or a new patient has been paired with the device.

In Figure 15, the trend screen is shown with legends in the lower right corner. Legends can comprise of different compositions. Either it can be a solid vertical line, a dotted vertical line, a downward facing triangle or a combination of the lines and triangle. The solid vertical line indicates that the device has been rebooted or turned off and on. The dotted vertical line indicates that the patient has been altered or changed.

The downward facing triangle indicates that the profile has been altered or changed to another profile.

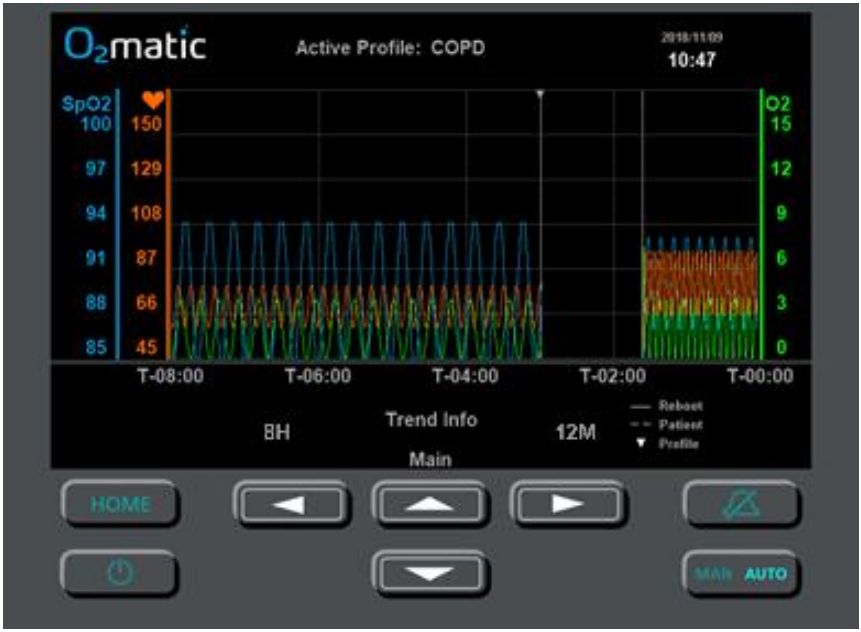


Figure 15: Extract from figure 14 focusing on the legends

Info screen

The Trend Info screen shows average SpO_2, O_2 and pulse rate data for the last 24 hours, as well as minimum (MIN) and maximum (MAX) for each of them. The T-HH:MM at MIN and MAX show how long ago the MIN or MAX occurred. For example, in the below info screen, the lowest O_2 supply of 2 liters per minute occurred at T-00:18 that is 18 minutes ago.

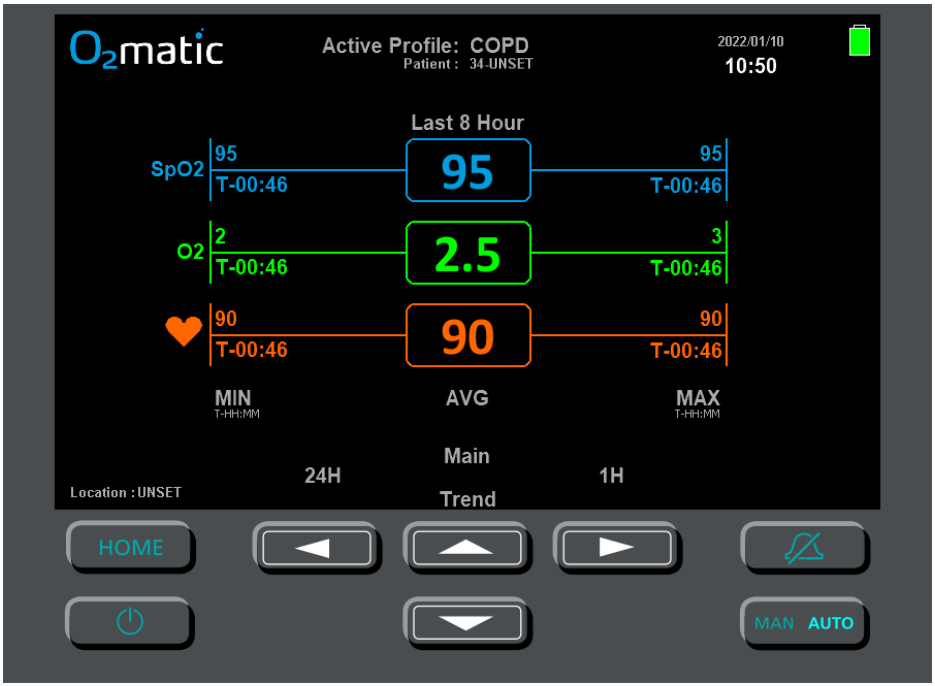


Figure 16: PRO 100 info screen

4.3 Critical profiles

The lowest possible SpO2 saturation value in a Test- or Patient profile is 80%. A profile with a SpO2 value below 85%, a pulse value over 200 or under 40, is termed a Critical Profile.

When the user edits a SpO2 value below 85% and try to select the value, the user is prompted for a decision with "! SpO2 outside safe range !". If confirmed, the name of the profile will appear in an orange font and can go below 85%, but not under 80%. If cancelled, the value stays at 85%.

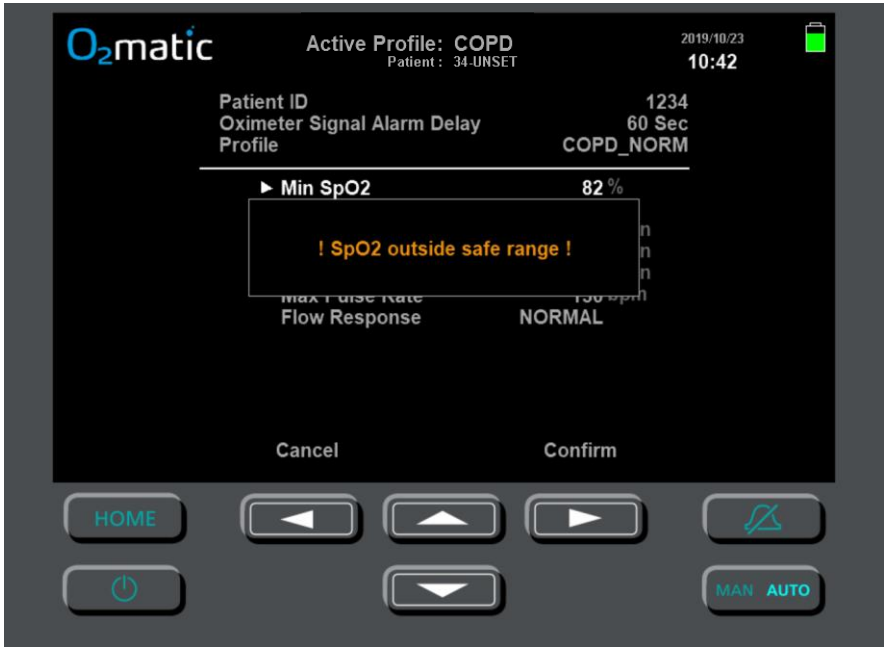


Figure 17 - SpO2 outside safe range prompt

When the user activates a Critical Profile, the user is prompted for a decision “Chosen profile is risky. Continue?”.

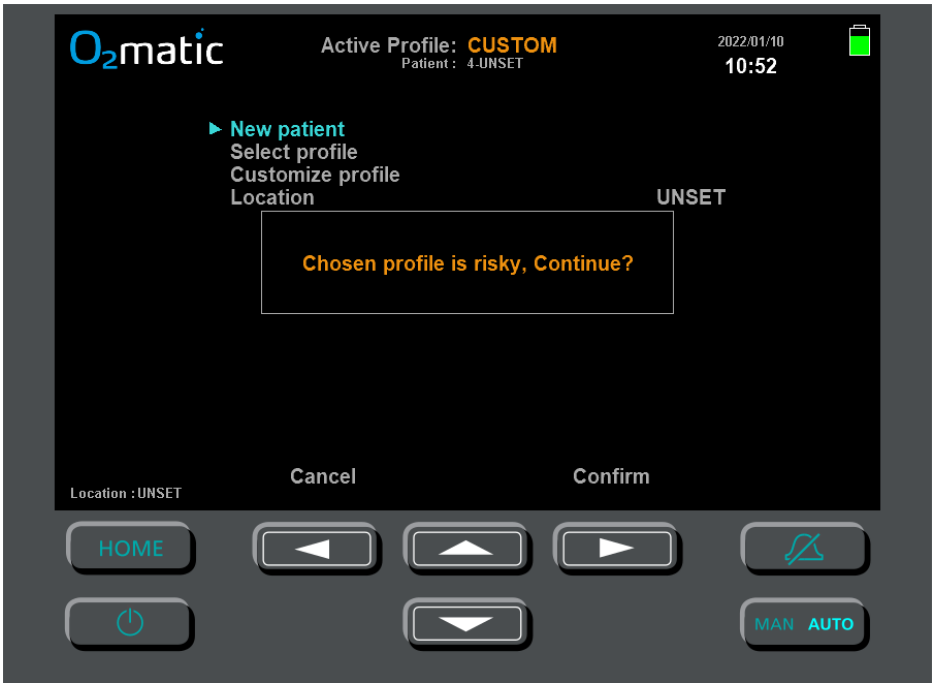


Figure 18 - Critical Profile prompt

If confirmed, the Active Profile name will appear in orange font on the Home screen.

The user is also prompted in the same way when the device is turned on with a Critical Profile set from before the device was turned off.

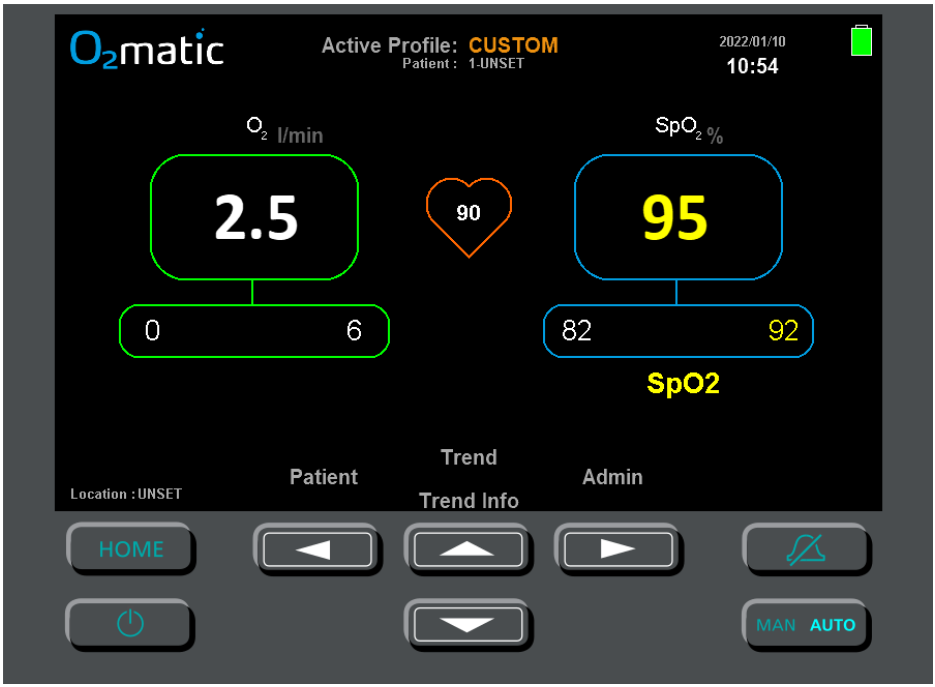


Figure 19 - Critical Profile active

If the user makes changes to or create a new profile via Admin into Profiles screen, and it becomes a Critical Profile, then the name will still appear in orange but keep its profile name.

4.4 Walking tests

PRO 100 can perform both pre-defined Walking Tests and user defined tests. A log file of the tests performed are stored on the device. Test results can be seen on the screen or reviewed by extracting logs.

	**Warning** Tests should only be done with a fully charged battery. Ignoring this and doing tests with a less than fully charged battery may result in power down before test conclusion.

	**Caution** Tests should only be performed under supervision by medical staff.

NOTE: By factory default the device come with three tests:

- Six Minute Walking Test (6_MWT)
- Incremental Shuttle Walk Test (ISWT)
- Endurance Shuttle Walk Test (ESWT)

Each of these tests can be customised by the user. It is also possible for the user to create additional tests. (see chapter 7.2)

Running a test:

A walking tests consists of three phases

- Warm-up – shown as START IN
- Actual test – shown as test name and TIME LEFT
- Recovery – shown as RECOVERY

To see a '6-minute walking test':

1. From the Home Screen select Admin Screen.
2. Select Tests.
3. Select "6_MWT".

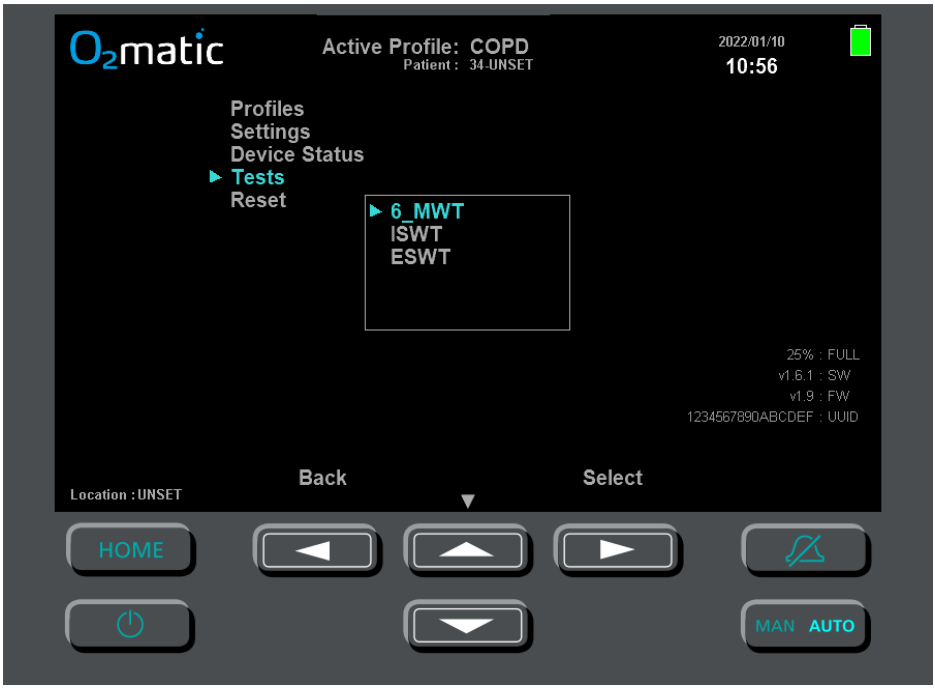


Figure 20 - Test Selection

When a test has been selected the Test Setup Screen appears and the test can be customized by the user.

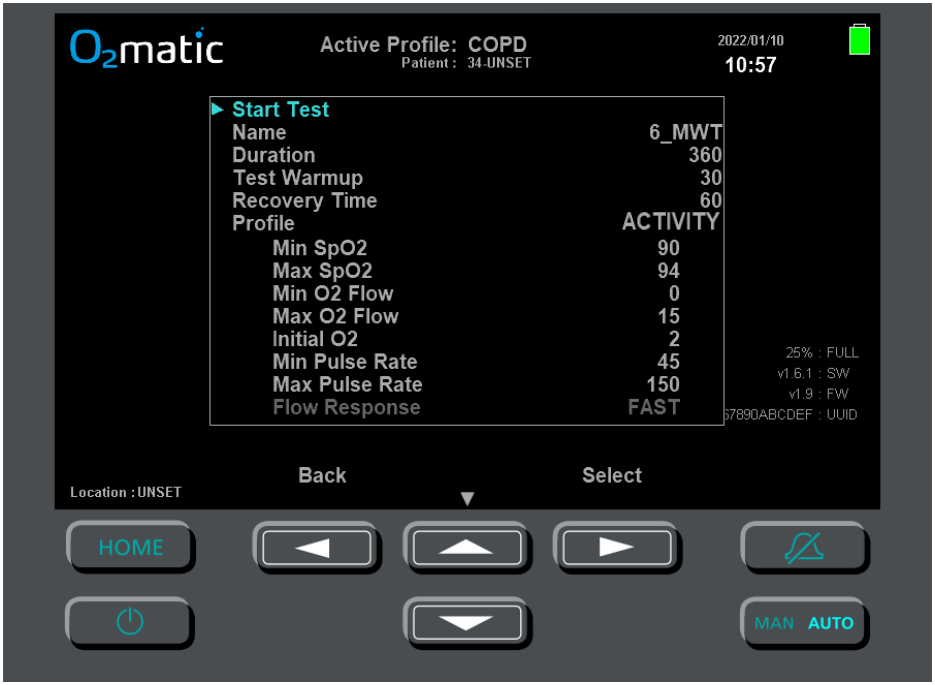


Figure 21 - Test Setup

The ACTIVITY profile has a 'FAST' Flow Response and Max Pulse Rate of 150 bpm, to support physical exertion. For a list of factory pre-set profiles, see table A5 in Appendix A.

To start the test, place the cursor on 'Start Test' in the top and press 'Select' with the right arrow button on the device.

Now the test will start with the first phase (warm-up), and the screen returns to the Home Screen, with a countdown in the left bottom corner displaying the remaining warm-up time.

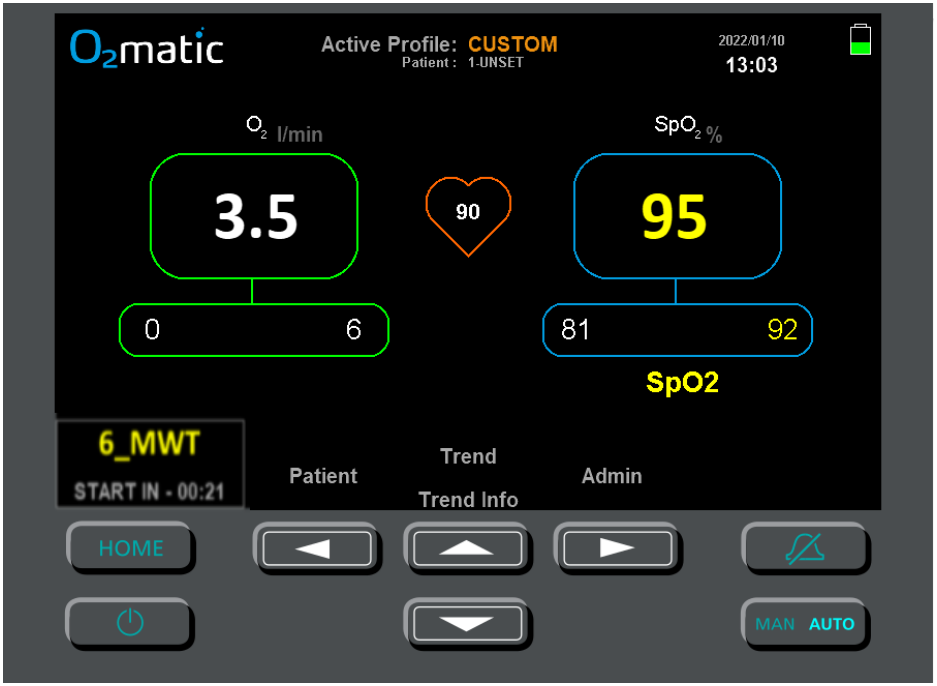


Figure 22 - Warm Up time

When the warmup is completed, the second phase of the test will commence, and the following will happen:

- 'START IN' countdown is replaced by 'TIME LEFT' countdown.
- The device beeps twice.
- The 12 minutes (12M) Trend Graph resets.
- Test log begins recording.
- The 'Active Profile' change to the one used in the test profile. The pre-defined test shows 'WALKING' in the top middle of the screen.

Note: If the User has changed a value from the pre-defined test profile which is actively used, the profile name will turn yellow while the test is running to indicate that the test is customized.

Figure 23 - Test in progress

When the test countdown is finished, the third and final phase, which is the recovery phase, will commence. During this phase, the patient should be made ready to resume normal treatment with the previous patient profile and the following will happen:

- The device beeps twice
- Test log finishes recording
- The TIME LEFT countdown is replaced with RECOVERY

When the RECOVERY countdown concludes, the device returns to the previously active profile.

	**Caution** Always stay with the patient during recovery to verify patient status upon resuming normal treatment.

Note: The standard ACTIVITY profile has 15 L/min Max O2 Flow, while other profiles may have a lower maximum O2 Flow. Therefore, if the patient has not recovered adequately in the recovery phase, the patient may experience a sudden drop in the O2 flow.

To stop a test already running, press “End test”. The user is then prompted to either Cancel (continue test) or Confirm to stop the test. The completed part of the test is still logged even if the test gets cancelled.

Note: When a running test is cancelled the RECOVERY period is also cancelled and the previous Active Profile resumes right away.

Appropriate setup

The following figures show an appropriate setup for performing tests involving walking as an example.

	**Caution** The test setup chosen by the medical staff must protect: • The patient from falling • The device from physical impacts

Figure 24 - Appropriate setup side view

Note: Check how oxygen bottle and hoses are placed to avoid the wheels or the patient's legs being entangled.

Figure 25 – Secure device attachment

⚠	**Caution** The device must be fixed securely using appropriate attachment equipment.

Note: PRO 100 use a standard T-slot bracket. For more information regarding attachment please contact us at info@o2matic.com.

The mobility requirement of the pre-defined tests dictates that they can and may be performed on battery power only.

If the battery reaches a 'Very Low Battery' charge state during the test, a high intensity audio alarm will begin, and 'Battery Fail' will blink in a red font on the screen.
If this state occurs, stop the test and re-connect the device to external power at once.

	**Caution** If a 'Low Charge' battery state occurs, stop the test immediately and attach device to external power.

4.5 Shutdown

To properly shut down PRO 100 press and hold  **(A)** for 3 seconds.

To cut off power completely after shutdown, toggle off the main power switch **(L)** on the back of the device.

NOTE: If the main power switch **(L)** is toggled off without performing a proper shut down, PRO 100 will treat this as power failure and turn on the battery failsafe mode and trigger an alarm.

NOTE: It is possible to shut down the device by holding  **(A)** down for 8 seconds. This is not the intended shutdown, but instead a forced shutdown mainly used for service situations. A forced shut down will trigger an alarm, that can only be disengaged by turning the device on and shutting it off in the proper manner.

5 Warnings and Alarms

PRO 100 has built in alarms and warnings that indicate the patient's health status. Alarms are issued when the patient's SpO_2 move slightly outside desired level without being critical alarms.

	**Warning** Alarms need immediate action and must never be ignored. Always verify normal alarm states before leaving patient. Make sure that the mute indicator is "off" before verifying alarm states.

PRO 100 is designed so that audible alarms can be detected by the operator, from up to 10 meters away.

NOTE: When navigating in menus, the device still operates however alarms are muted. Upon no operator activity for 60 seconds the home screen will reappear, and the alarm will sound if triggered.

5.1 Alarm level indicators

Type	Visual indications	Audible	Audio Alarm Signal Priority	Audible indications	Acoustic delay
Warning	Yellow font (constant)	No	**None**	None	None
Alarm	Blinking orange font	Yes	**Medium**	3 beeps every 10 sec	2 minutes
Critical alarm	Blinking red font	Yes	**High**	10 beeps repeated every 5 sec	None

Figure 26: Alarm level indicators

5.2 Alarm zones

There are 5 alarm zones (see figure 27) on the Home Screen. Oxygen flow-based alarms are located under the oxygen flow, pulse-based alarms under pulse and SpO_2 based alarms under SpO_2. In the top center of the screen there are two alarms zones. The top one is related to the signal of the sensor. This zone contains multiple alarms and prioritization of these are described in section 5.4. If the device is not connected to a power source the Battery Mode turns on, the top and bottom of the screen now show a red bar, and a warning pop-up appears on the screen. Below this zone there is a zone for the “check status” indication. See section 5.3 for further information on possible alarm events and a description of these.

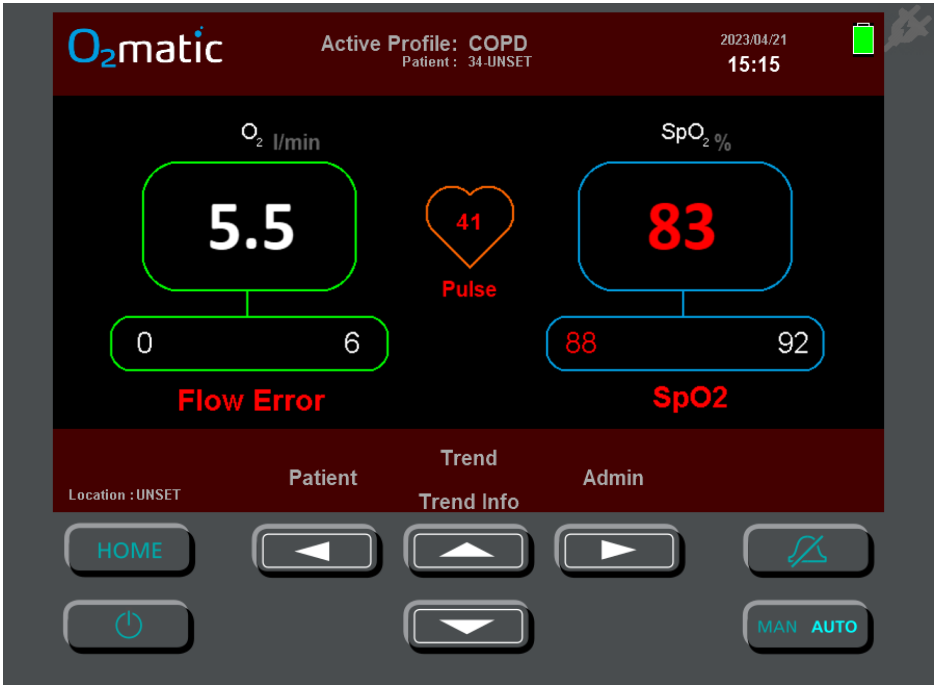


Figure 27: PRO 100 alarm zones

In figure 27 three alarms are present, Flow Error alarm, Pulse alarm, and SpO_2 alarm.

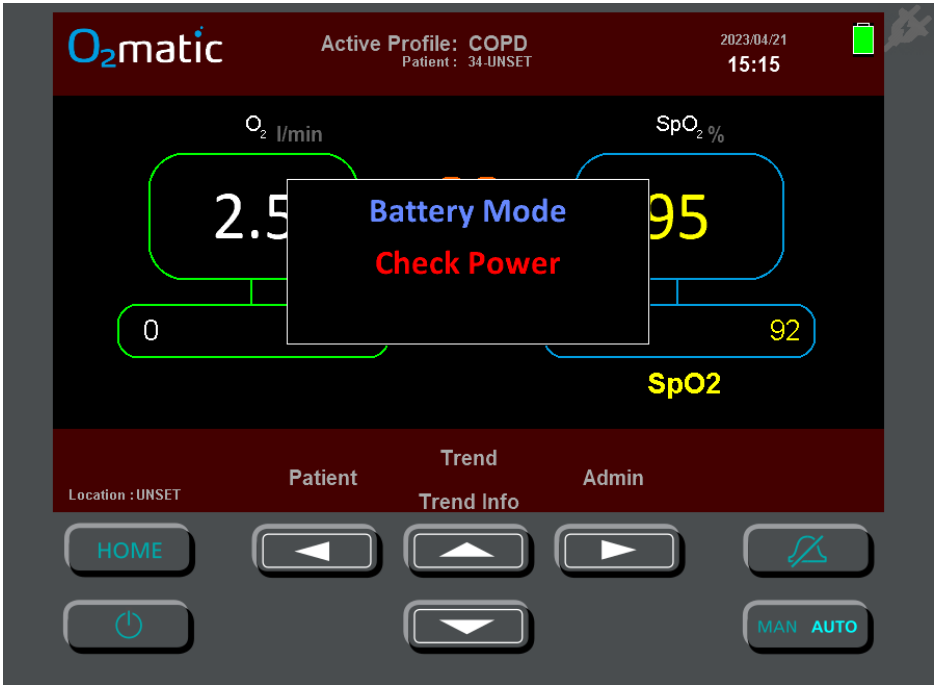


Figure 28: PRO 100 alarm zones 2

Figure 28 shows Battery Mode alarm pop-up and red top and bottom.

SpO2 Alarms

Visual indication	Alarm type	Alarm description	Solution
SpO_2	Warning	SpO_2 higher than defined	Verify patient condition
SpO_2	Warning	SpO_2 1-3 % below defined	Verify patient condition
SpO_2	Alarm	SpO_2 more than 3% below defined	Verify patient condition
SpO_2	Critical Alarm	SpO_2 lower than 80%	Verify patient condition

Pulse Alarms

Visual indication	Alarm type	Alarm description	Solution
Pulse	Alarm	Pulse higher/lower than defined	Verify patient condition
Pulse	Critical Alarm	Pulse higher than 200 BPM	Verify patient condition
Pulse	Critical Alarm	Pulse lower than 40 BPM	Verify patient condition

Signal Alarms

Visual indication	Alarm type	Alarm description	Solution
No Signal	Warning	No signal from oximeter for less than user set (adjustable)	Readjust the sensor on the patient's finger
No Signal	Critical Alarm	No signal from oximeter for more than user set or more than 5 mins*.	Readjust the sensor on the patient's finger
Not connected	Critical Alarm	Not connected to oximeter	Connect oximeter to PRO 100. If the problem persists, send device for service

***Adjustable between 0 and 30 minutes on devices with firmware version 1.26 or higher. Otherwise adjustable between 0 and 5 minutes.

Oxygen Alarms

Visual indication	Alarm type	Alarm description	Solution
Flow Error	Critical Alarm	Incorrect O2 flow into device	Check oxygen source. If problem isn't from source device needs service
O2	Alarm	Oxygen control error	Check oxygen source. If problem isn't from source device needs service

Power/Battery Alarms

Visual indication	Alarm type	Alarm description	Solution
Check Status	Critical Alarm	"Battery failed" under device status	Restart device, if alarm persist device needs service
Battery symbol alarm constant	Alarm	Low battery	If device has been without external power, recharge the battery. Else have the battery changed
Check status Battery symbol alarm blinking	Critical Alarm	Critically low battery	If device has been without external power, recharge the battery. Else have the battery changed. It is not recommended to use device in this alarm state
Power symbol alarm blinking	Alarm	No power	Connect power adapter to power source and to O2matic PRO

***Battery capacity warnings are outside general alarm indication terminology as they are indicated with red symbols but without audio.

Device Alarms

Visual indication	Alarm type	Alarm description	Solution
Check status	Alarm	Memory Fail	Restart device, if alarm persist device needs service
Sensor error	Critical Alarm	Oximeter Sensor	Device needs service
Check status	Alarm	Acoustic Alarm	Restart device, if alarm persist Device needs service
Check status	Alarm	Back Up Circuit	Restart device, if alarm persist Device needs service
Check status	Warning	Memory Full	Do full export of patient data, if alarm persist reset device to factory default, if alarm persist device needs service
Check status	Alarm	Valve	Restart device, if alarm persist device needs service
Check status	Alarm	Flowmeter	Restart device, if alarm persist device needs service

5.3 Possible alarm events

A failure in one of the most critical internal components triggers the same visual “Check status” indication (except sensor error). Further identification can be made in the Device Status screen in the admin menu.

5.4 Alarm priorities

All pulse oximeter sensor related alarms share the same zone in the following prioritized showing order:

Priority	Alarm / visual indication	Description
1	Sensor error	Internal functionality error
2	Not connected	Not connected to device
3	No signal	Not connected to patient

6 Electromagnetic Emissions and Immunities

6.1 Emissions compliance class and group

Phenomenon	Test method	Class	Group
Conducted RF emissions	EN 55011	Class A	Group 1
Radiated RF emissions	EN 55011	Class A	Group 1
Harmonic current emissions	EN 61000-3-2	Class A	-
Voltage changes, voltage fluctuations and flicker emissions	EN 61000-3-3	-	-

6.2 Immunity test levels

Phenomenon	Test method	Immunity test level
Electrostatic discharge immunity	EN 61000-4-2	+/- 8 kV contact +/- 2, 4, 8 kV air
Radiated RF electromagnetic field immunity	EN 61000-4-3	3 V/m 80 MHz to 2.7 GHz 80 % AM 1 kHz

Phenomenon	Test method	Immunity test level
Immunity to proximity fields from RF wireless communication equipment	EN 61000-4-3	385 MHz, 27 V/m, 18 Hz PM (50 % duty cycle square wave) 450 MHz, 28 V/m, FM +/- 5 kHz dev., 1 kHz sine 710 MHz, 9 V/m, 217 Hz PM (50 % duty cycle square wave) 745 MHz, 9 V/m, 217 Hz PM (50 % duty cycle square wave) 780 MHz, 9 V/m, 217 Hz PM (50 % duty cycle square wave) 810 MHz, 28 V/m, 18 Hz PM (50 % duty cycle square wave) 870 MHz, 28 V/m, 18 Hz PM (50 % duty cycle square wave) 930 MHz, 28 V/m, 18 Hz PM (50 % duty cycle square wave) 1720 MHz, 28/ V/m, 217 Hz PM (50 % duty cycle square wave) 1845 MHz, 28 V/m, 217 Hz PM (50 % duty cycle square wave) 1970 MHz, 28 V/m, 217 Hz PM (50 % duty cycle square wave) 2450 MHz, 28 V/m, 217 Hz PM (50 % duty cycle square wave) 5240 MHz, 9 V/m, 217 Hz PM (50 % duty cycle square wave) 5500 MHz, 9 V/m, 217 Hz PM (50 % duty cycle square wave) 5785 MHz, 9 V/m, 217 Hz PM (50 % duty cycle square wave)

Phenomenon	Test method	Immunity test level
Electrical fast transient/burst immunity	EN 61000-4-4	+/- 2 kV 100 kHz repetition frequency
Surge immunity – AC power ports	EN 61000-4-5	Line-to-line: +/- 0.5, 1 kV line to line Line-to-ground: Not applicable, PRO 100 is a Class II device
Immunity to conducted disturbances induced by RF fields – AC power ports	EN 61000-4-6	3 V (6 V in ISM bands*) 0.15-80 MHz 80 % AM 1 kHz
Power frequency magnetic field immunity	EN 61000-4-8	30 A/m 50 Hz
Voltage dips, short interruptions and voltage variations immunity	EN 61000-4-11	0 % U_T; 0.5 cycle at 0°, 90°, 135°, 180°, 225°, 270° and 315° 0 % U_T; 1 cycle at 0° 70 % U_T; 10 cycles at 0° 0 % U_T; 250 cycles at 0°

*) The ISM (industrial, scientific and medical) bands between 0.15 MHz and 80 MHz are 6.765 MHz to

6.795 MHz; 13.553 MHz to 13.567 MHz; 26.957 MHz to 27.283 MHz; and 40.66 MHz to 40.70 MHz.

7 Maintenance

Expected maintenance for PRO 100 consists of cleaning. For any other maintenance activity contact the distributor. This device does not need to be calibrated.

PRO 100 has two separate alarm systems. Upon failure on one of them, user is notified with a warning on display. Thus, there is no need to verify the functionality of the alarm system.

	**Warning** This device is not intended to be maintained during use.

7.1 Cleaning

PRO 100 should be cleaned after each use.

	**Warning** Do not clean the device while connected to a patient. Disconnect the AC power adaptor from the device before cleaning. Do not clean device in any other manner than described in this user manual

Use wet towel, disinfecting wipes or cloth with either water or alcohol. Dry off surfaces with a dry towel or cloth afterwards.

Important: Make sure that there are no dust or lint in the air input or air output.

In the context of disinfecting the device after treating patients with the COVID-19 virus, it is advised to cleanse all surfaces using one of the following disinfection solutions:

• 0.1% sodium hypochlorite (bleach)

• 62% to 72% ethanol

Each of the listed solutions serve to decontaminate surfaces and have been demonstrated to be effective for the human coronavirus[1].

7.2 Exporting data

It is possible to export profiles and patient logs from PRO 100. Profiles can also be imported to other devices to minimize risk of having different setups on different devices. Patient logs can be used to analyse data more thoroughly. For more information contact us at info@o2matic.com.

To export data:

Remove the screws from the USB hatch
Make sure that the device is turned on
Connect your device to a computer/laptop via a standard USB cable
Enter the USB password on the device to unlock the USB port
Check “device connections” on your computer. It should be showing up like any other USB device
Enter the USB drive

You will see the following files:

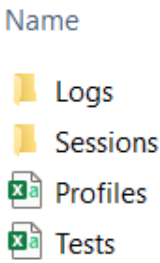


Figure 29 – Root files

[1] Infection Control Today (Best Approach to Disinfecting Surfaces Amid Novel Coronavirus Outbreak, Diamond, Frank, February 10, 2020)

Copy the desired files to your computer.

A list of patient sessions data can be found in the sessions folder.

A list of test logs can be found inside the Test Data folder. The files are named with the Timestamp of the test start.

In the figure below, a data log from a 6_MWT is shown

Test	Duration	Warmup	Cooldown					
6_MWT	360	30	60					
Patient	Profile	SpO2Acc	SpO2High	O2Low	O2High	O2Init	PulseHigh	FlowRate
4	ACTIVITY	90	94	0	15	5	150	100
Time	SpO2	Pulse	Flow					
0	93	80	02.00					
1	93	80	02.00					
2	93	80	02.00					
3	93	80	02.00					
4	93	80	02.00					
5	93	80	02.00					
6	93	80	02.00					
7	93	80	02.00					
8	93	80	02.00					

Figure 30 - 6_MWT data log

In the top 4 rows is shown the parameters for test setup. The next rows show the actual test data provided with one record per second (rows). It only records during the test Duration time and not the Warmup nor the Recovery time.

To create your own test:

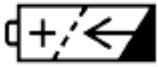
Go to the root of the drive and find the file named Tests.
Go to the next row (row 5) and provide it with a Name, Duration, Warmup Cooldown (Recovery) and a valid Profile name (for instance 'ACTIVITY', 'COPD' or a user defined one). To change an existing test, modify values for Duration, Warmup or Cooldown.

6_MWT	ACTIVITY	30	360	60
ISWT	ACTIVITY	30	600	60
ESWT	ACTIVITY	30	600	60

Figure 31 - TESTS File

7.3 Changing battery

PRO 100 must use specific rechargeable batteries.
It is recommended to change batteries at least every second year to ensure optimal functionality. To ensure safety the battery must be changed by authorized personnel.

	**Warning** Only use rechargeable and approved Battery 
	**Warning** Only Authorized Personnel allowed to change battery

8 Service and Support

This section describes service and support. For more information contact your distributor or visit www.O2matic.com

8.1 Warranty

Warranty period is one year from the date of delivery, for each PRO 100, exclusive of the pulse oximetry sensors and other accessories. Authorized personnel shall repair or replace any PRO 100 found to be defective in accordance with this warranty, free of charge. For this to be valid, O2matic must be notified by the purchaser of what serial number that belongs to the affected device. Furthermore, the provided notification shall occur within the applicable warranty period. This warranty excludes cost of delivery to and from O2matic ApS. O2matic ApS reserves the right to charge a fee for a warranty repair request on any PRO 100 found to be within specifications. PRO 100 must be repaired by authorized personnel only. Any sign or evidence of opening PRO 100, other than the USB hatch, except by authorized personnel, shall void the warranty as well as any tampering or kind of misuse of PRO 100.

8.2 Service

Terms and conditions regarding servicing PRO 100, outside the warranty period, depends on the chosen service agreement. Visit www.O2matic.com for more information.

8.3 Training

Training of personal is possible. Visit www.O2matic.com for more information.

8.4 Support and Contact

For support or more information please contact us:

Website: www.O2matic.com

Manufacturer and Technical Support:

O2matic ApS

Nørrelundvej 10
2730 Herlev
Denmark
+45 5052 9810

Local distributor

9 Specifications

Physical	
Weight	1850 g
Dimensions	205x265x95 mm
Display size	7”
Display resolution	800 x 480
Connection	DB9, USB
Alarm volume	56 dB
Electrical	
Main	100-240 VAC, 50/60 Hz
DC input	12 VDC
Power consumption	12 VA
Battery type	Lithium Polymer
Battery Capacity	1,5 hours
Classifications	
Type of protection	Class ll and internally powered
Degree of protection	Type BF – Applied part
Ingress protection	IPX0
Method of sterilization	None
Suitability of use	Oxygen rich environment
Mode of operation	Continuous
Environmental	
Operating temperature	5°C – 35°C
Storage temperature	-20°C – 60°C
Operating humidity	10% – 90%
Storage humidity	10% – 90%
Operating altitude	0 - 2000 meters
Input pressure	up to 100 PSI (6 bar)
Performance	
SpO_2 reading	70% - 100% ± 2
Heart rate	40 – 240 ± 5
Flow rate	0 – 15 l/min
Alarm delay	< 20 secs
Flow accuracy	0.1 l/min or 5% - Whichever is higher
General	
Expected service life	5 years
Language	English

Appendix A – Detailed Specifications

Table A1 - Input validation:

Validation Type	Validation Rate
Heart rate alarm upper limit input range	100 – 200 BPM
Heart rate alarm lower limit input range	40 – 80 BPM
SpO_2 alarm limit input range	80 – 100 %
Oxygen flow - Automatic mode	0 – 15 l/min
Oxygen flow – Manual mode	0 – 15+ l/min*
Oximeter Signal Alarm delay	0 – 5 min**

***** In manual mode flow it is possible to open up the valve at maximum. When doing this the O2matic device shows 15+ l/min and shows a warning of "inaccurate flow". The actual output is based on current oxygen source. At 4 bars pressure input the O2matic PRO delivers 30 l/min.

******Adjustable between 0 and 30 minutes on devices with firmware version 1.26 or higher. Otherwise adjustable between 0 and 5 minutes.

Table A2 - Alarm specifications:

Alarm Specification Type	Specification
Alarm signal generation delay	Less than 2 secs
Display update	30 ms
Decibel (dB)	56
Danger SpO_2 alarm	3 % under low
Critical SpO_2 alarm	Less than 80 %

Table A3 - Default settings table

Default Type	Default Value
Pause screen timer	30 mins
Mute button timer	120 secs
Oximeter Signal Alarm delay	300 secs
Mode	Automatic

Table A4 – Factory set profiles

Name	Min SpO2	Max SpO2	Min O2 Flow	Max O2 Flow	Initial O2 Flow	Max Pulse rate	Flow response
COPD	88	92	0	6	2	130	NORMAL
HYPOXEMIA	94	98	0	15	5	130	NORMAL
ACTIVITY	90	94	0	15	5	150	FAST

Table A5 – Flow response settings

Flow response	Rate
Normal	1x
Fast	5x

Appendix B – Accessories

Warning

Use of any other accessories than specified here, may inflict serious injuries to the patient and/or damage the device.

Power supply

Model: Mean Well GEM12I12

Input: 100-240VAC, 50/60 Hz, 0.4-0.2A

Output: 12V, 1A, 12W max.

Sensors

Pulse oximeter sensors are applied parts for PRO 100. Refer to their instructions for use for further information.
PRO 100 works with all Nonin Purelight® pulse oximetry sensors and should only be used with these.

Caution

The accuracy of the SpO_2 measurement may be affected if the total sensor length (including extension cables) is greater than 3 meters.

Accessory	UDI-DI/GTIN-14
UNI-EX-1 - Universal Extension Cable (1m)	0 833166 001044
UNI-EX-3 - Universal Extension Cable (3m)	0 0833166 001051
6000CA – Cloth adult box	0 0833166 009965
6500SA - Disposable Durafoam Pulse Oximetry Sensors	0 0833166 001846
7000A – Flexi-Form III adult disposable box	0 0833166 001976

8000AA - Adult articulated internal spring finger clip	0 0833166 000153
8000AA-3 - Adult articulated internal spring finger clip	0 0833166 000191
8000J - Adult flexsensor w/25 FlexiWrap	0 0833166 003536
8000J-3- Adult flexsensor w/25 FlexiWrap	0 0833166 004717
8000Q2 – Ear clip sensor	0 0833166 000757
8000SL – Large Reusable Pulse Oximetry Soft Sensor	0 0833166 002287
8000SM – Medium Reusable Pulse Oximetry Soft Sensor	0 0833166 002232
8000SS – Small Reusable Pulse Oximetry Soft Sensor	0 0833166 002249

Masks and catheters

PRO 100 can be used in combination with any standard oxygen mask or nasal catheter.

Masks and catheters are applied parts for PRO 100. Refer to their instructions for use for further information.

Oxygen input hoses

PRO 100 can be used in combination with standard hoses designed for pure oxygen for hospital use. The inlet is a standard NIST connector and is designed in accordance to ISO 18082:2014 (EN).

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This user manual booklet is current as of February 2024. For information of device updates and news please visit

www.O2matic.com