O2matic

User Manual

OMC PC-100 / PRO 100

Instructions for use

2021.02.15

O2matic

Table of contents

1 Introduction, General Warnings and Cautions.

The O_2matic 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. The O_2matic device 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.

The O_2Matic device 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 Contraindications

a. ***Do not use in an explosive atmosphere or in the presence of flammable anesthetics or gases.***
b. ***Do not use on multiple patients simultaneously***
c. ***O_2matic must not be used with devices which delivers a fixed fraction of oxygen (FiO_2) regardless of oxygen flow, such as the Venturi masks, as O_2matic 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:

d. ***Less than 18 years old***
e. ***In the O_2matic mode with suspected CO poisoning***
f. ***That is not spontaneously breathing***

g. ***Who is incapable to keep airways free of secretions***
h. ***For whom the SpO_2-signal is not stable***

1.2 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.

a. ***Use only Nonin Purelight pulse oxymetri sensors, as other sensors might not meet the same accuracy criteria required by the O_2matic.***
b. ***Refer to the applicable sensor instructions for use for additional warnings and cautions.***
c. ***Regularly check the battery indicator. If lit, See section 7.3 for battery instructions.***
d. ***O_2matic is only to be used with pure oxygen.***
e. ***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.***
f. ***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.***
g. ***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 O_2Matic device, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.***
h. ***O_2matic shall never be used as a substitute for personal and qualified observations by medical and nursing staff, as O_2matic 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

1.3 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.

i. Do not place O_2matic in a corner, as it can be difficult to connect and disconnect accessories.

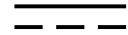
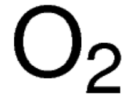
j. The accuracy of the SpO_2 measurement may be affected if the total sensor length (including extension cables) is greater than 3 meters.

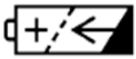
k. Pulse oximetry sensors may have reading troubles when used on patients with cold extremities due to reduced blood circulation. For more information please contact your local distributor.

l. Follow local or national recycling instructions regarding disposal of device and accessories.

m. 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 the O_2matic.

1.4 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		Standby

	"ON"		"OFF"
	Class II equipment	IPX0	Ingress protection from dust and water
	Equipment shall only be used with rechargeable battery.		WARNING

1.5 Essential performance

The essential performance of the O_2matic *device 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, the* O_2*matic device shall trigger the relevant alarms.*

1.6 Operators and safety

O_2matic 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.

The O_2matic has a failsafe rechargeable battery that keeps the device running upon short power breaks. The device has two power related buttons, **Main power** and **Standby,** 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 O_2matic 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.

1.7 Button functionality

When navigating through settings and information screens in the O_2matic, only the four navigation buttons on the front of the O_2matic 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.

2 Installation and Setup

Before starting any patient treatment, the O_2matic must be installed and setup accordingly as described in the following.

2.1 Overview

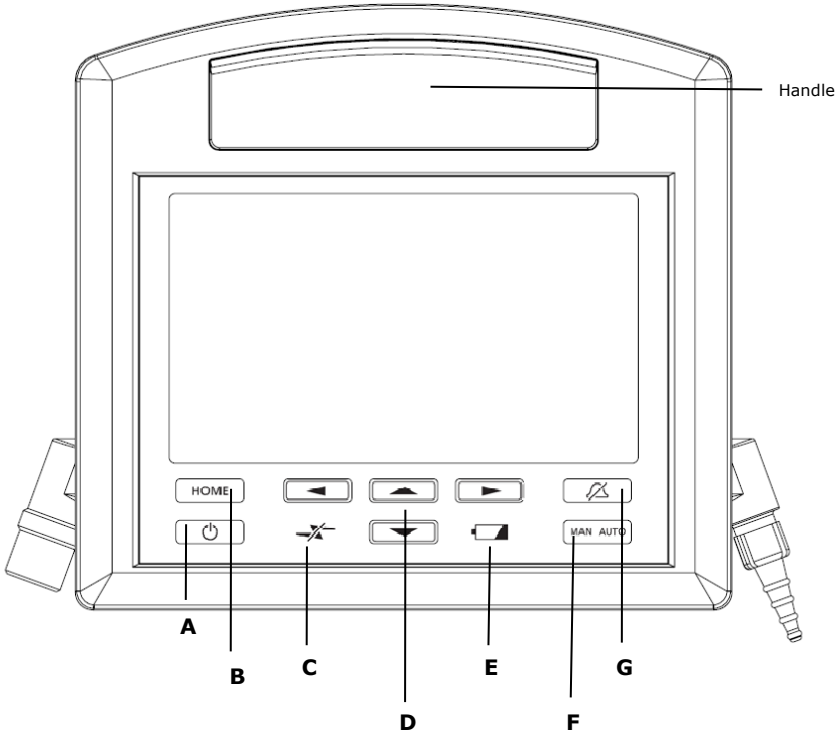


Figure 1: O_2matic from the front

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

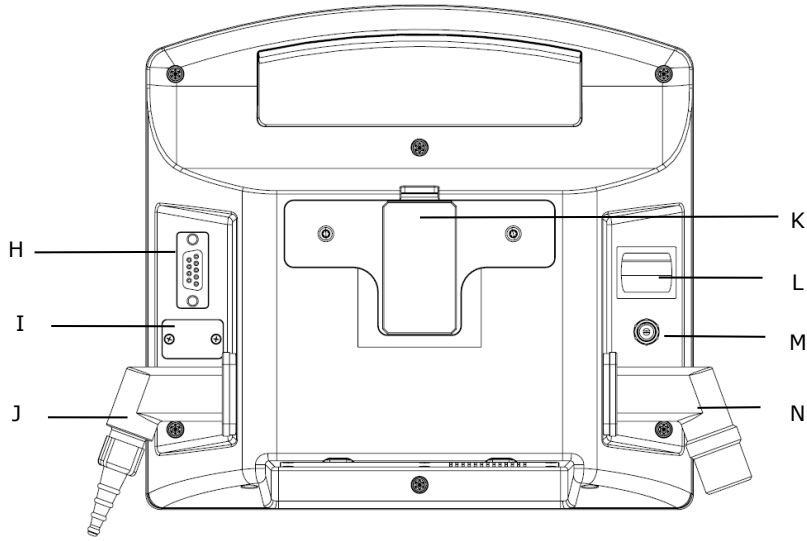


Figure 2: O_2matic from behind

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

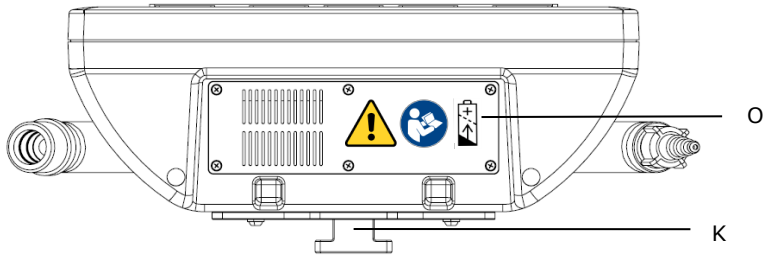


Figure 3: Bottom of O_2matic

2.2 Installation

O_2matic must be installed near the patient, either on a rail or other fittings matching the standard slide on the back of the O_2matic. To install O_2matic:

a. ***Slide your regions corresponding power plug into the AC adapter.***
b. ***Connect the AC power to the wall outlet and to the O_2matic device power supply. For safety reasons, the connector is a screw-lock mechanism.***

Warning

Only use the AC power adaptor provided by O_2matic. Any other power supply may interfere with the proper operation of the device.

c. ***Connect the oxygen hose to the source of oxygen in the wall or an oxygen cylinder. Then connect oxygen hose to the oxygen inlet of the O_2matic.***

Warning

O_2matic is only to be used with pure oxygen.

d. ***Flick power switch (L) to "I" on the back of The O_2matic.***
e. ***Turn on The O_2matic by pressing (A) for 2 seconds.***

The O_2matic device should now be on and the Home Screen appears.

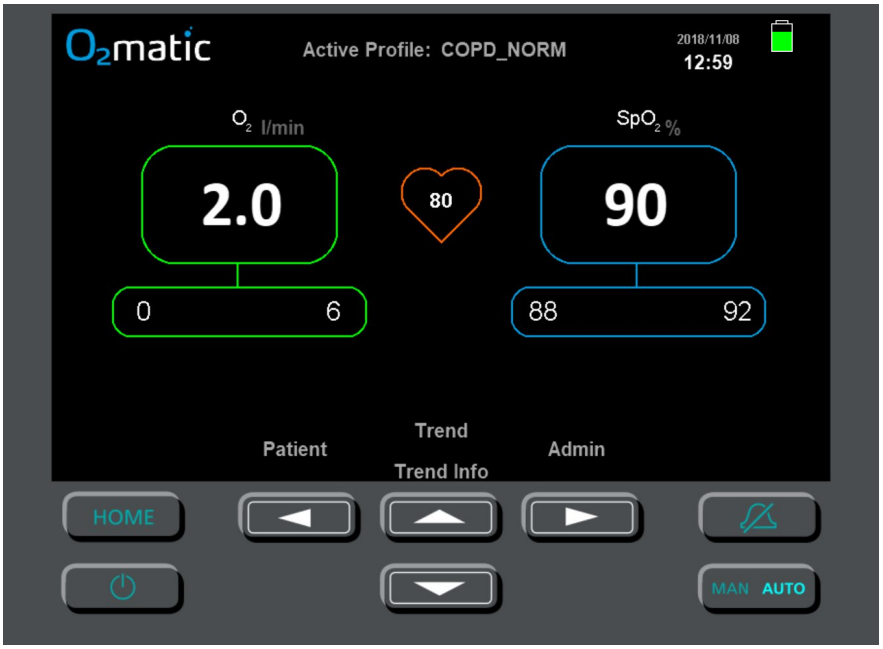


Figure 4: User interface O_2matic (Home Screen)

The O_2matic device does by default always provide treatment. Therefore, the device "expects" input signal from the pulse oximeter sensor, worn by the patient, and will start an alarm immediately if there is no signal. To mute the alarm, press the Mute button (G), and the alarm will be muted for 2 minutes. The button is lid to indicate that it is muted.

Note: Audible alarms are disabled in menus. O2matic returns back 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: O_2matic goes in to pause screen mode after 30 mins. Press any button to get back to the home screen.

2.3 Setting up the device

All setup functionality in The O2matic are gathered in the **Admin Menu**. From the **Home Screen** press ► to enter the **Admin Menu** shown below.

Figure 5: O2matic 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.***
4. ***Navigate to the desired parameters and adjust them as needed.***
5. ***Return to home screen by pressing HOME (B).***

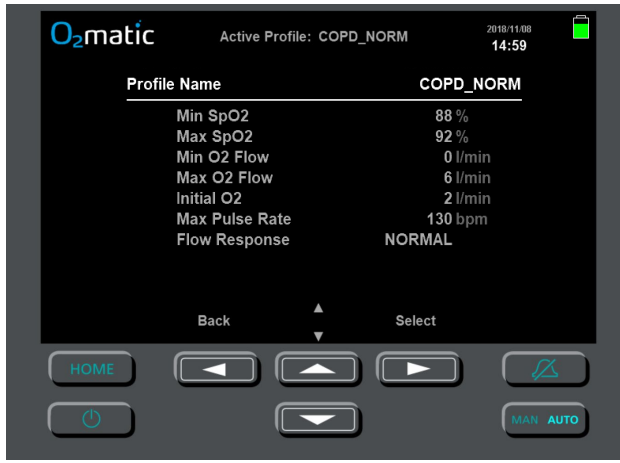
Figure 6: O2matic Profile settings

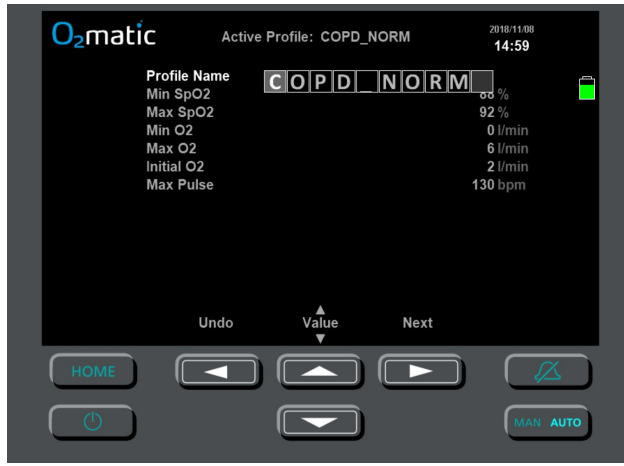
	**Warning** Setting up profile limits to extreme values can render warnings and alarms meaningless.

NOTE: The O2matic 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 Edit.***
3. ***Navigate to the desired parameters and adjust them as needed.***
4. ***Return to home screen by pressing*** HOME ***(B).***





Figures 7 and 8: O_2matic Edit Profile menu (COPD_NORM)

NOTE: A profile have a parameter named flow response, which can be used to 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 be adjusted to increase comfort for the patient. See **appendix A** for further info.

The O_2matic has built in alarms and warnings that indicate the patient's health status. Warnings are issued when the patient's SpO_2 moves slightly outside desired level without being critical.

2.4 Importing settings

If you have multiple O2matic devices and you want a specific set of settings on all the devices this can be done easily by importing the same settings file to all the devices. This minimizes the risk of inconsistency between devices.

NOTE: The O2matic device 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 administrator pin code. For more information about the physical tool, visit www.o2matic.com

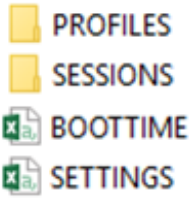
Warning

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

To import settings or profiles:

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

You will see the following files:



*f. **Insert your previously exported settings file and replace it with the existing settings file.***

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:

*a. **Enter the admin menu***
*b. **Select security***
*c. **Select Set USB pin (default is 1111)***
*d. **Input the new USB pin***

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 security.***
c. ***Select Reset USB pin.***
d. ***Input the master pin code.***

To reset to factory changes:

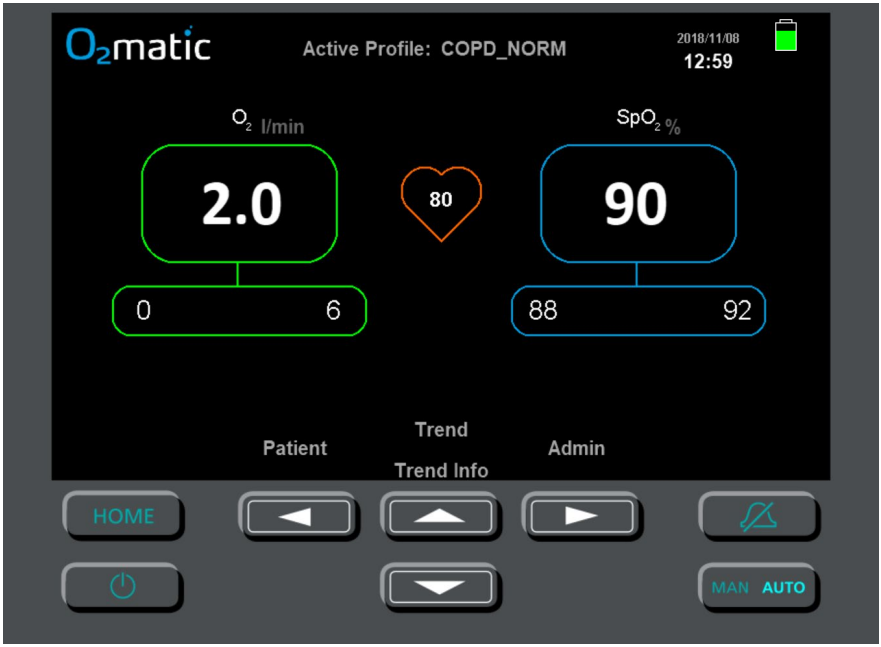
a. ***Enter the admin menu.***
b. ***Select reset.***
c. ***Input USB pin code.***

3 Starting Treatment

d. Turn on The O2matic by pressing HOME ***(A). The Home Screen appears.***

The O2matic is designed to be as simple as possible and for maximum safety, the device always starts up in the "O2matic 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 lid to indicate that it is muted. Entering any menu will also mute the alarms.

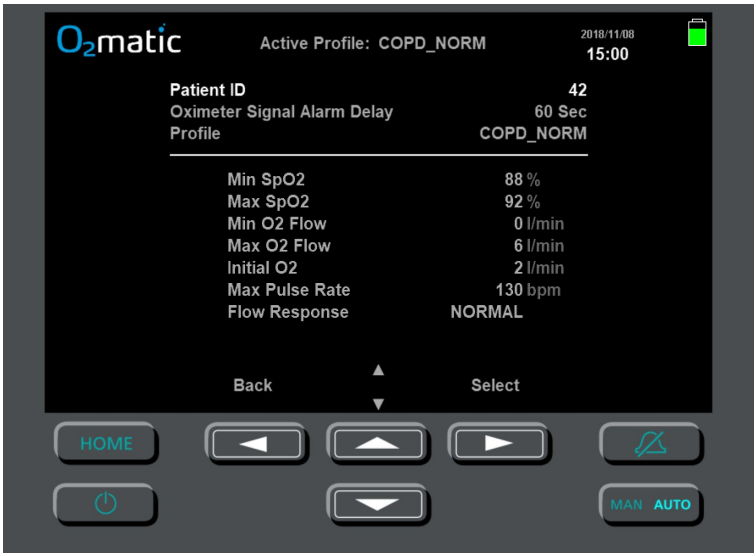
Upon startup the device resumes in the latest selected profile. If the device was switched off while in manual mode, it will regardless, for safety reasons, start up in O2matic mode.



Figures 9: O2matic Home Screen

3.1 Assign a new patient to device

e. To assign a new patient to the device enter the Patient menu. From the HOME ***(B) screen select*** ◄ ***Patient.***



Figures 10: Patient Menu

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

a. 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 hospitals 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.

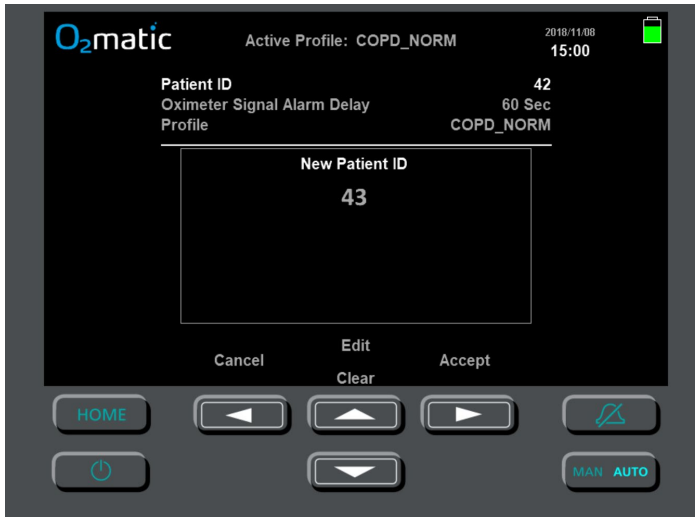


Figure 11: Patient ID change

b. 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.

c. Select a profile.

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.

d. Place the sensor on the patient's finger

	**Warning** Only use Nonin PureLight pulse oximetry sensors. Any other sensor may interfere with the proper operation of the device.

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

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.

e. Apply a nasal catheter or an oxygen mask on the patient.

4 Treatment and Operation

This section describes the normal operational modes for O_2matic.

4.1 Treatment modes

The O_2matic has two distinct modes for treatment. An automatic "O_2matic Mode" and a "Manual Mode". To switch between modes, press the MAN AUTO (F). The text under MAN AUTO **(F)** is lid to indicate which mode is active.

O_2matic mode

The "O_2matic Mode" is a controlled mode where The O_2matic adjust the oxygen dosage based on the monitored patient parameters, such as SpO_2 and current oxygen flow. O_2matic acts within the specified interval of oxygen set in the active profile, as well as the SpO_2 threshold.

NOTE: In the "O_2matic mode" the O_2matic is automatically weaning the patient from oxygen, by giving the optimal oxygen flow necessary to the patient, within the defined SpO_2 interval.

Upon slight exceedance of the interval, O_2matic triggers a warning by changing the font to yellow, and adjusting accordingly. Upon a longer or steeper exceedance of the lower interval, O_2matic 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 patient is lost, O_2matic 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.

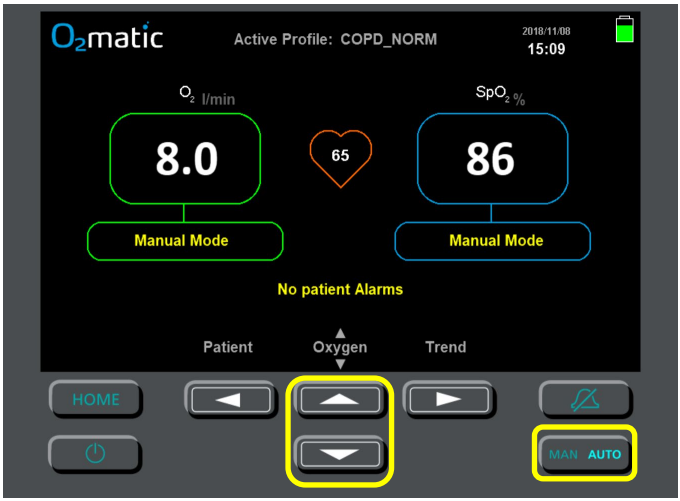


Figure 12: O2matic manual mode

Important INFO: When the oxygen flow exceeds 15 liters/min the flows inaccuracy can be around ±2 liters/min.

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

Flow range	**Increments**
0 – 10 l/min	0,5 l/min
10 – 15 l/min	1 l/min
15 – 20 l/min	5 l/min

Important INFO: No patient related alarms are active in the Manual Mode.

4.2 Patient assessment

d. The O2matic has two distinct information screens to support better patient assessment. From the HOME (B) screen use ▲ and ▼ to cycle through them.

Trend screen

The trend (Info) Screen shows charts related to the pulse, SpO_2, and oxygen dosage. It is possible to "zoom" in and out on the chart to view trends from the last 5 minutes – last 24 hours, with ◄ and ►.

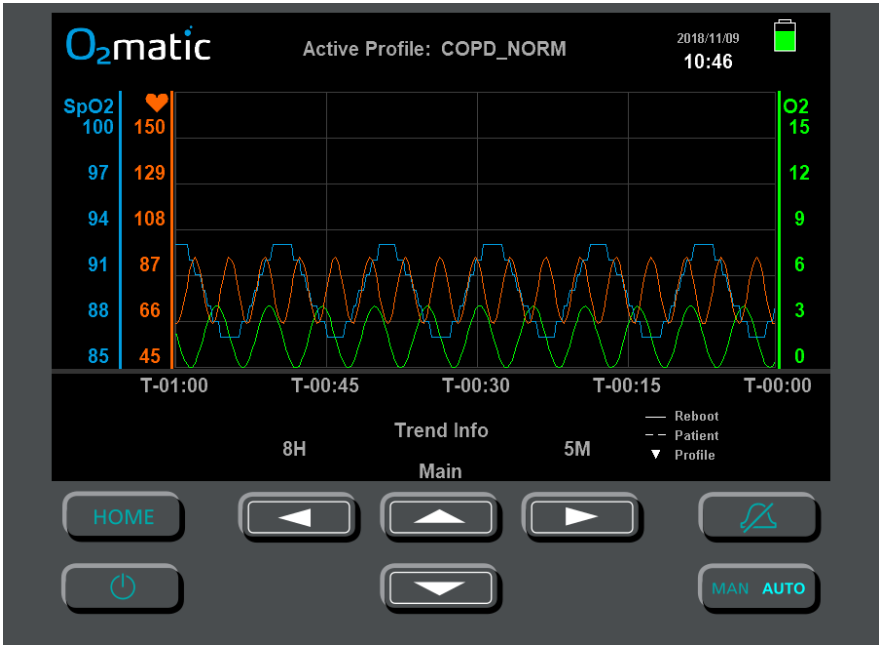


Figure 13: O2matic trend screen – last hour

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.

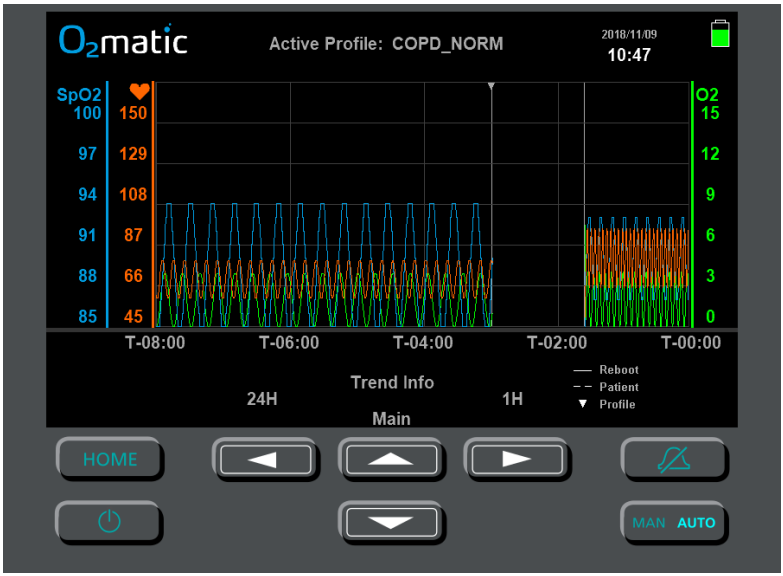
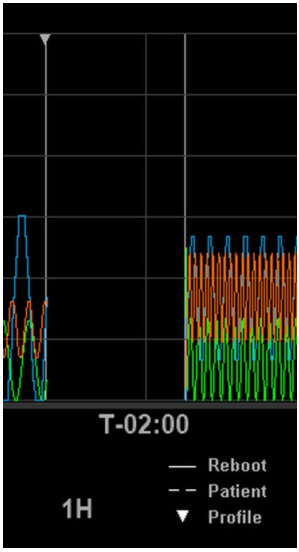


Figure 14: O_2matic trend screen – last 8 hours



In figure 15, an extract of figure 14, showing the three legends, and the two that are present on the trend. In the top left corner, a triangle is visible indicating the patient profile has been changed or customized. The line underneath the triangle indicate the device has been rebooted (turned off) or on.
At the second reboot (turned on) the profile is unchanged and therefore no triangle is present. It has been the same patient throughout the off time period. If another patient had been paired with the machine, it would be shown by a dotted line vertical line.

Figure 15: Extract from figure 14 focusing on the legends

Info screen

The Info screen shows average SpO_2, O_2 and pulse rate numbers for the last 24 hours, as well as minimum (MIN) and maximum (MAX) for each treatment parameter. The T-HH:MM at MIN and MAX show how long ago the MIN or MAX occurred. For example, in below info screen, the lowest O_2 supply of 1 liter a minute occurred at T-00:18 that is 18 minutes ago.

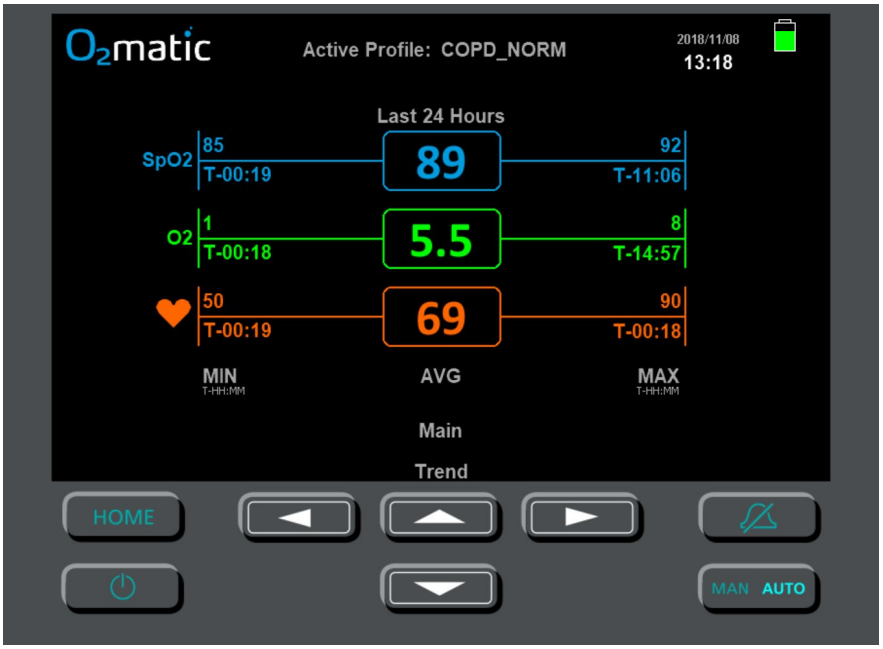


Figure 16: O_2matic info screen

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% 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 go below 85%. If cancelled, the value stays at 85%.

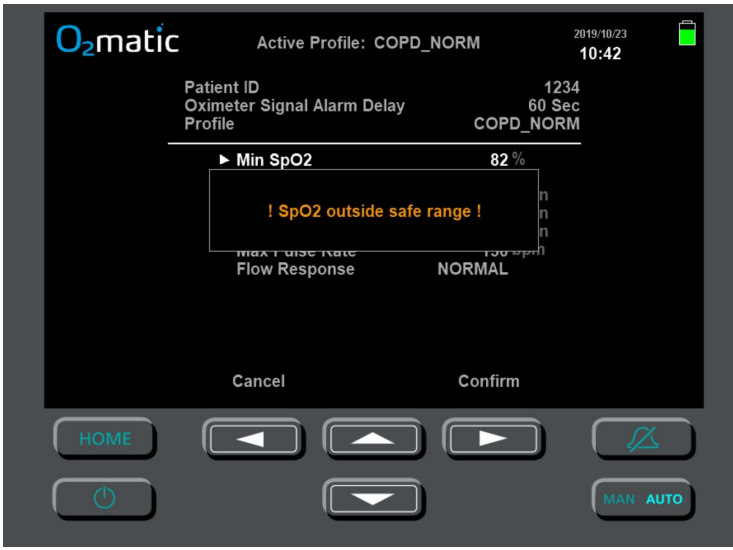


Figure 17 - SpO2 outside safe range prompt

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

Figure 8 - 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.

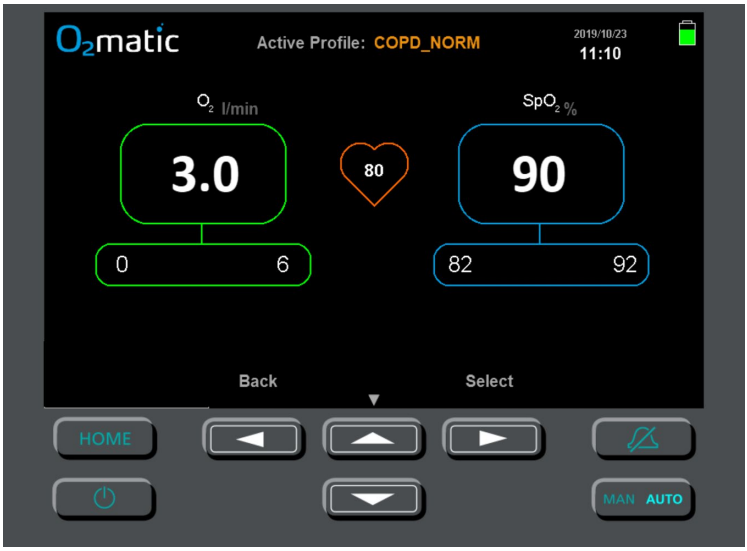


Figure 19 - Critical Profile active

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

The O2matic device 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** Test should only be done with normal battery state. Ignoring this and doing tests in low battery state may result in power down before test conclusion.

	**Caution** Tests should only be performed under supervision

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

- ***The Six Minute Walking Test (6_MWT)***
- ***The Incremental Shuttle Walk Test (ISWT)***
- ***The 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 REMAINING***
- ***Recovery – shown as RECOVERY***

To start a '6-minute walking test':

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

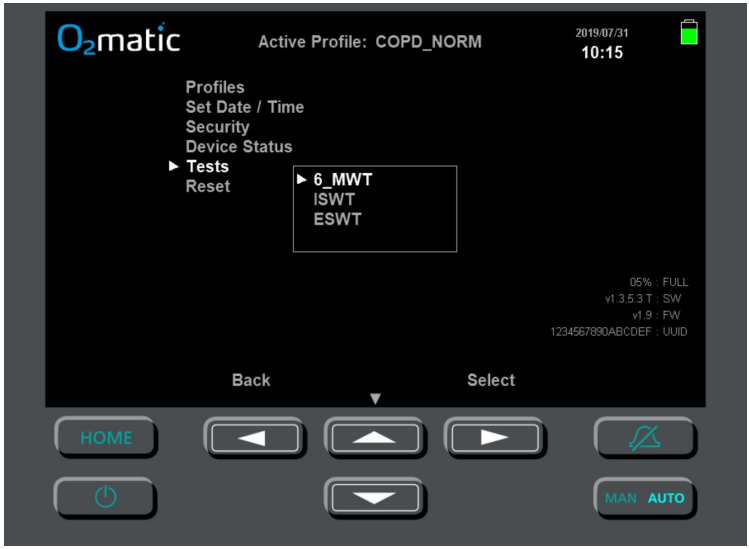


Figure 20 - Test Selection

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

Figure 91 - Test Setup

The WALKING 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.

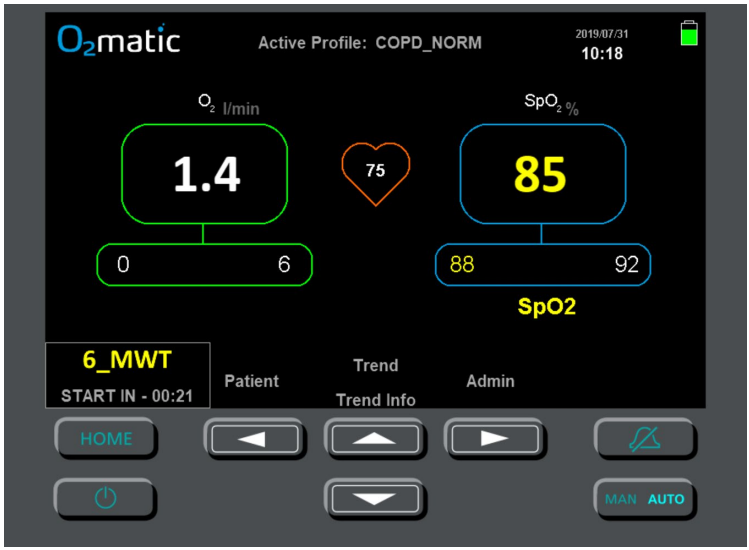


Figure 22 - Warm Up time

When the warmup is completed, the second phase will commence (the actual test) 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 begin 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.

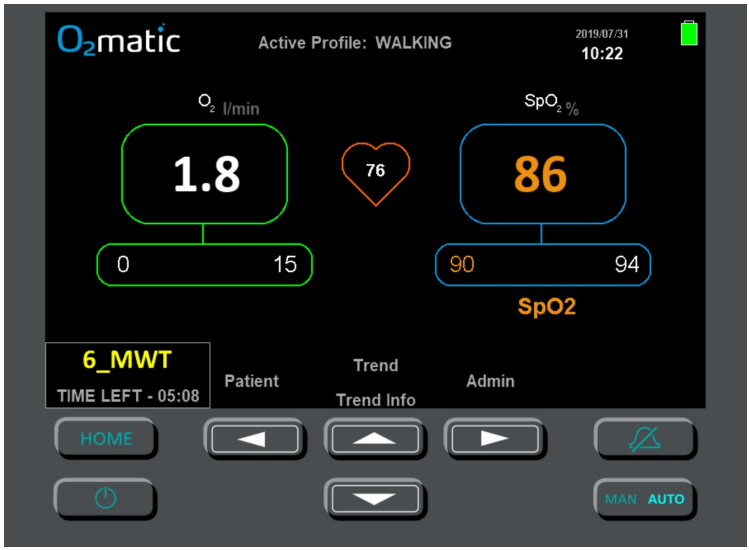


Figure 23 - Test in progress

When the test countdown is finished, the third and final phase (RECOVERY) 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 previous active profile.

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

Note: The standard WALKING profile has 15 L/min Max O2 Flow, while other profiles may have a much lover 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 stopping the test. The actual part of the test is still logged even if it 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 figures in this section show an appropriate setup for performing tests involving walking as an example.

Caution

The test setup chosen by the user *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: The O2matic device use a standard T-slot bracket. For more information regarding attachment please visit www.o2matic.com

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

If the battery reaches a 'Low Battery' charge state during the test, a high intensity audio alarm will initiate and 'Battery Fail' will blink in a red font on the screen.
If this state occurs, stop the test and re-attach 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 the O_2matic press and hold  **(A)** for 3 seconds.

To cut off power completely after shut down, 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, the O_2matic 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

The O_2matic has built in alarms and warnings that indicate the patient's health status. Warnings are issued when the patient's SpO_2 move slightly outside desired level without being critical.

Warning

Alarms needs 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.

O_2matic 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
warning	Yellow font (constant)	Yes	**None**	None
Alarm	Blinking orange font	Yes	**Medium**	3 beeps every 10 sec
Critical alarm	Blinking red font	Yes	**High**	10 beeps repeated every 5 sec

5.2 Alarm zones

There are 5 alarm zones on the O_2matic 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 on external provided power 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 the section 5.3 for further information on possible alarm events and a description of these.

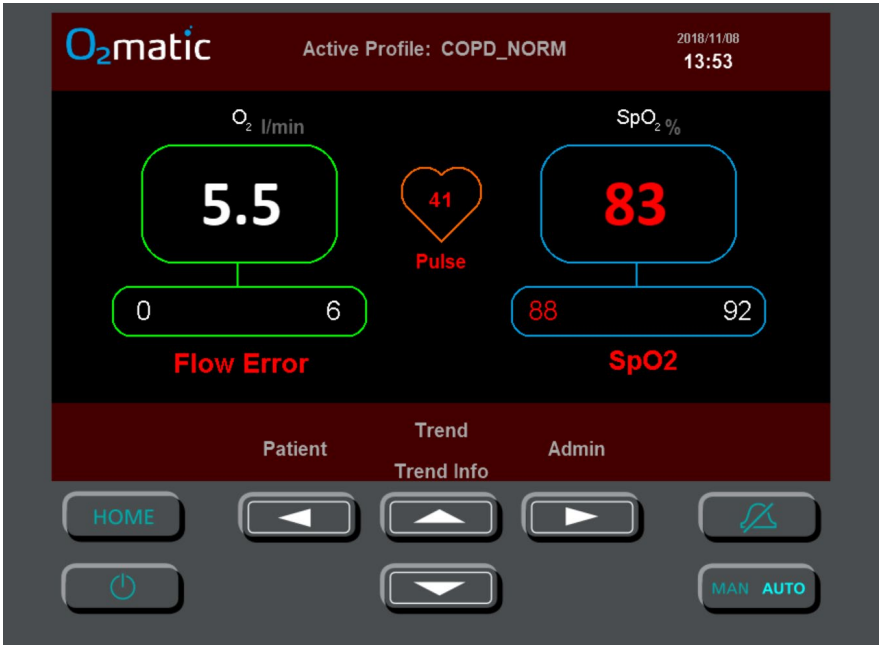


Figure 26: O_2matic alarm zones

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

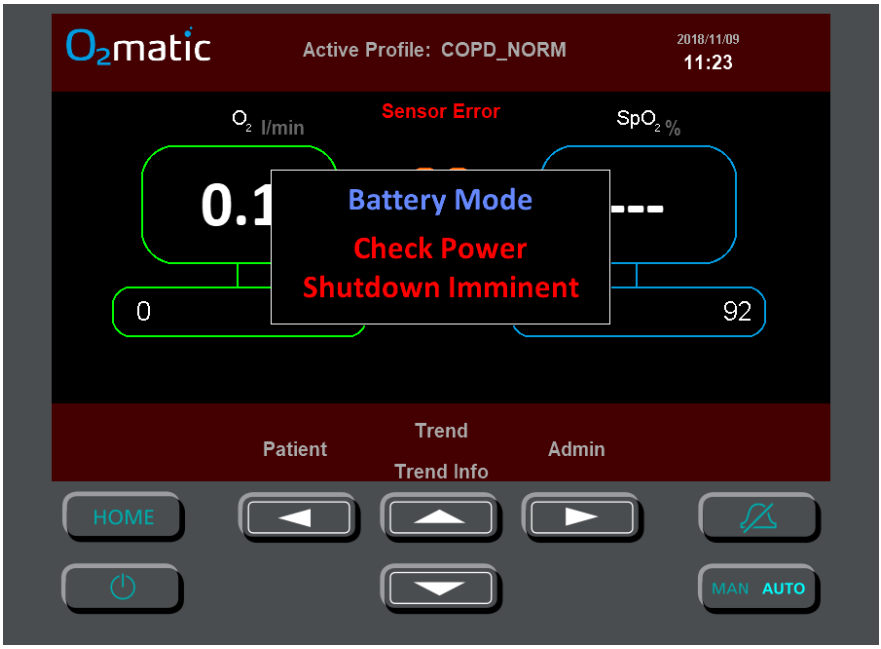


Figure 27: O2matic alarm zones 2

This figure show Battery Mode alarm pop-up and red top and bottom. And a Sensor Error (No Pulse Oximeter input signal).

Area	Visual indication	Alarm type	Alarm description	Solution
SpO_2	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	Pulse	Alarm	Pulse higher than defined	Verify patient condition
	Pulse	Critical Alarm	Pulse higher than 150 HR/min	
	Pulse		Pulse lower than 45 HR/min	
Signal	No signal	Alarm	No signal from oximeter for fewer than 300 secs (adjustable)	Readjust the sensor on the patient's finger
	No signal	Critical Alarm	No signal from oximeter for more than 300 secs (adjustable)	
	No signal		Oximeter power failure	Restart device, if alarm persist O_2matic needs service
	Not connected		Not connected to oximeter	Connect the oximeter to O_2matic. If the problem persists, send O_2matic for service
Oxygen	Flow Error	Critical Alarm	Incorrect O_2 flow into device	Check oxygen source. If problem isn't from source O_2matic needs repair
	O_2	Alarm	Oxygen control error	Check oxygen source. If problem isn't from source

				O_2matic needs repair
Power /Battery	Check status	Critical alarm	"Battery failed" under device status	Restart device, if alarm persist O_2matic 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 O_2matic
Device	Check status	Alarm	Memory fail	Restart device, if alarm persist O_2matic needs service
	Sensor error	Critical alarm	Oximeter sensor	O_2matic needs service
	Check status	Alarm	Acoustic alarm	Restart device, if alarm persist O_2matic needs service
	Check status	Alarm	Back up circuit	

	Check status	Alarm	Memory full	Do full export of patient data, if alarm persist reset device to factory default, if alarm persist O2matic needs service
	Check status	Alarm	Valve	Restart device, if alarm persist O2matic needs service
	Check status	Alarm	Flowmeter	

5.3 Possible alarm events

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

The grey device alarms in the table are related to the most critical internal components. A failure in one of these components triggers the same visual "Check status" indication (except sensor error). Further identification can be made in the device status screen under 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

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,

Phenomenon	Test method	Immunity test level
		217 Hz PM (50 % duty cycle square wave) 5785 MHz, 9 V/m, 217 Hz PM (50 % duty cycle square wave)
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, O_2matic 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[a]) 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°

a) 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

Warning

This device is not intended to be maintained during use.

Expected maintenance for O2matic consists of cleaning. For any other maintenance activity contact the distributor. This device does not need to be calibrated.

O2matic 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.

7.1 Cleaning

O2matic should be cleaned after each use.

Warning

Do not clean 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, have been demonstrated to be effective for the human coronavirus[1].

7.2 Exporting data

It is possible to export settings, profiles, and patient logs from the O_2matic device. Settings and profiles can be used to import 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 see www.o2matic.com

To export data:

1. ***Remove the screws of the USB hatch.***
2. ***Connect your device to a computer/laptop via a standard USB cable***
3. ***Enter the USB password on the device to unlock the USB port.***
4. ***Check "device connections" on your computer. It should be showing up like any other USB device***
5. ***Enter the USB drive***

You will see the following files:

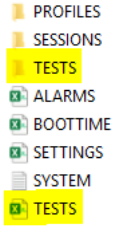


Figure 28 – Root files

6. ***Copy the desired files to your computer.***

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

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

A list of test logs can be found inside the TESTS 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	120	30	30					
Patient	Profile	SpO2Acc	SpO2High	O2Low	O2High	O2Init	PulseHigh	FlowRate
1	WALKING	90	94	0	15	2	150	150
Time	SpO2	Pulse	Flow					
0	93	80	0					
1	93	80	2					
2	93	80	1					
3	93	80	1					
4	93	80	1					
5	93	80	1					
6	93	80	1					
7	93	80	1					
8	93	80	1					
9	93	80	1					
10	93	80	1					
11	93	80	1					
12	93	80	1					

Figure 29 - 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 next row (row 5) and provide it with a Name, Duration, Warmup Cooldown (Recovery) and a valid Profile name (for instance 'Walking', 'COPD_NORM' or a User created one). To change an existing test, modify values for Duration, Warmup or Cooldown.

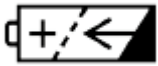
	A	B	C	D	E
1	Name	Profile	Duration	Warmup	Cooldown
2	6_MWT	WALKING	360	30	60
3	ISWT	WALKING	600	30	60
4	ESWT	WALKING	600	30	60

Figure 30 - TESTS File

Note: To see a description of the content in the Settings file, see appendix B.

7.3 Changing battery

The O2matic must use specific rechargeable batteries.
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 O2matic device, exclusive of the pulse oximetry sensors and other accessories. Authorized personnel shall repair or replace any O2matic found to be defective in accordance with this warranty, free of charge, for which O2matic has been notified by the purchaser by serial number that there is a defect, provided notification occurs 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 O2matic found to be within specifications. O2matic must be repaired by authorized personnel only. Any sign or evidence of opening the O2matic, other than the USB hatch, except by authorized personnel, shall void the warranty as well as any tampering or kind of misuse of the O2matic.

8.2 Service

Terms and conditions regarding servicing the O2matic, 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:***

O_2matic 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
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	85 – 150 HR/min
SpO_2 alarm limit input range	80 – 100 %
Oxygen flow - O_2matic mode	0 – 15 l/min
Oxygen flow – Manual mode	0 – 20 l/min
Oximeter Signal Alarm delay	0 – 300 secs

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

Defaul Type	Default Value
Pause screen timer	30 mins
Mute button timer	120 secs
Oximeter Signal Alarm delay	60 secs
Mode	O_2matic

Table A4 – Factory set profiles

Flow response	Rate
Slow	25 %
Normal	100 %
Fast	150 %

Table A5 – Factory set profiles

Name	Min SpO2	Max SpO2	Min O2 Flow	Max O2 Flow	Initial O2 Flow	Max Pulse rate	Flow response
COVID_LFLOW	92	96	0	8	2	130	SLOW
COVID_HFLOW	92	96	0	15	5	130	NORMAL
COPD_NORM	88	92	0	6	2	130	SLOW
ASTHM_PNEUM	94	98	0	10	3	130	SLOW
WALKING	90	94	0	15	2	150	FAST

Appendix B – Exported File Contents

Settings file

Parameter	Description	Input range
LowIntensityAlarmTimer	Delay for Low Itensity Alarm in minutes	Between 60 and 300 secs
MuteButtonTimer	Mute button duration	Between 60 and 300 secs
HomeTimer	Time before return to home from inactivity	Between 60 and 300 secs
SampleDuration	Seconds between each session log	Between 1 and 30 secs
NoSignalAlarmDelay	Seconds before a no signal alarm is sent	Between 0 and 300 secs
LowIntensityAlarmDelay	Seconds before low intensity alarm	Between 0 and 300 secs
TimeSpentUnder AcceptableSpO2	Seconds before long period low intensity alarm	Between 60 and 300 secs
ki	Flow Response rate	Between 0,25 and 1
Debug	Debug	**Only for service use**

Appendix C – 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 the O_2matic. Refer to their instructions for use for further information.
Use only Nonin Purelight pulse oximetry sensors.

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

6000CA – Cloth adult box

6000CI – Cloth infant box

6000CN – Cloth neonatal box

6000CA – Cloth pediatric box

7000A – FlexiFrom III adult disposable box

7000D – FlexiFrom III assortment (4-A,2-I,2-N, 2-P)

7000I – FlexiFrom III infant disposable box

7000N – FlexiFrom III neonatal disposable box

7000P – FlexiFrom III pediatric disposable box

8000AA-Adult articulated internal spring finger clip

8000AA-2M-Adult articulated internal spring finger clip

8000AA-3M-Adult articulated internal spring finger clip

8000AP-Pediatric articulated internal spring finger clip

8000AP-3M-Pediatric articulated internal spring finger clip

8000J - Adult flexsensor w/25 FlexiWrap

8000J-3M- Adult flexsensor w/25 FlexiWrap

8000Q – Ear clip sensor

8000SL – Soft sensor large

8000SM – Soft sensor medium

8000SS – Soft sensor small

8001J - Neonatal flex sensor w/25 FlexiWrap

8001JFW – Neonatal FlexiWrap sensor w/25 FlexiWrap

8008J - Infant flex sensor w/25 FlexiWrap

8008JFW – Infant FlexiWrap sensor w/25 FlexiWrap

Masks and catheters

O_2matic can be used in combination with any standard oxygen mask or nasal catheter.

Masks and catheters are applied parts for the O_2matic. Refer to their instructions for use for further information.

Oxygen input hoses

O_2matic 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)

Notes

Notes

Notes

O₂matic ApS
Nørrelundvej 10
2730 Herlev

Contact
Mail: Info@o2matic.com
Web: www.o2matic.com
Tel: +45 5052 9810

This user manual booklet is current as of February 2021. For information of device updates and news please visit

www.o2matic.com