

O₂matic



HOME OXYGEN THERAPY

End User Manual
Instructions for use

Model: HOT 100

2023.02.23

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Intended Purpose

O2matic HOT is an electro/mechanical medical device, intended for oxygen therapy optimization for non-critical patients at hospitals, outpatients and patients in home care. The regulation of oxygen is managed by a software algorithm which is monitored by dual control systems.

HOT 100 is an intelligent oxygen regulator capable of measuring and controlling the oxygen supply to the patient based on predefined threshold ranges prescribed by the medical staff. It regulates and adjusts the oxygen flow based on trends in the data, and the selected profile. The characteristics of this equipment make it suitable for use at home and hospitals (CISPR 11 class B) where patients are defined as being non-critical, not in critical care and can take care of themselves. If the patient feels ill or uncomfortable, the patient must always contact a physician.

Medical Indication

The O2matic HOT device is intended for non-critical patients with no need for intended critical care oxygen therapy. The use is for hospitals or patients in home care with the need of oxygen therapy and short-term increased oxygen demand due to pulmonary or cardiac conditions.

The O2matic device is intended for:

- Chronic hypoxemic respiratory failure

On a stable patient HOT 100 automatically attempts to reduce the oxygen flow, also defined as "*weaning*". This ensures the treatment will be phased out appropriately and helps the patient recover. It aims to provide the highest standard of oxygen delivery and can do so in the comforts of the patient's home.

The characteristics of this equipment make it suitable for use at home and hospitals (CISPR 11 class B) where patients are defined as being non-critical, not in critical care and can take care of themselves.


If the patient feels ill or uncomfortable, the patient must always contact a physician.

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1 Warnings, Cautions and Symbols

This section contains information regarding how to safely use this device, which should be read by the user in any case. Only oximeter(s) approved by O₂matic can be used. For more information regarding approved pulse oximeters please contact your service provider.

1.1 Warnings

	<p>Warning</p> <p>Indicates that you must be extremely careful when executing these instructions. Not complying with these warnings can cause serious injuries and even death.</p>
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- Use only pulse oximetry sensors that are delivered by O₂matic. Contact your service provider for more information on approved pulse oximetry for use with the HOT 100. Use of any other pulse oximeters increases the risk for compromising patient safety and will void the warranty.
- Do not use in an explosive atmosphere or in the presence of flammable anesthetics or gases.
- Refer to the applicable sensor instructions for use for additional warnings and cautions.
- Regularly check the battery indicator. If lit, see section 5.3 for battery instructions.
- HOT 100 is only to be used with medical oxygen.
- Only use accessories such as masks, catheters and hoses approved by you service provider.
- Do not open the device under any circumstances. Do not use any tools on the device.
- Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating as intended.
- 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 (Radio frequency) 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 HOT 100 device, including cables specified by the manufacturer. Otherwise, this could result in degradation of the performance of this equipment.
- Use of any other oximeters than the one provided will void the warranty.
- If the minimum values of the treatment allow the oxygen flow to go below 0.5 l/min the device should not be connected to a concentrator, but instead an oxygen source capable of going below 0.5 l/min.

For additional information refer to IEC 60601-1.

1.2 Cautions

	<p>Caution</p> <p>Indicates that you must be careful when executing these instructions. Not complying with these caution directives can cause minor injuries or equipment damage.</p>
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- If HOT 100 is stored or transported outside operating temperature limits (5-40°C) it needs to cooldown/warm up for 1 hour. Keep the device away from direct sunlight and hot surfaces.
- Pulse oximetry sensors may have difficulty reading when used on patients with low perfusions due to reduced blood circulation. In the case of poor perfusion or low-quality signal then the saturation measurement icon appears lit, and the sensor should be moved to an alternative site to obtain the best possible signal.
- The HOT 100 and the pulse oximetry sensor should only be used by the patient with the ordination. Nobody else than the intended person shall use the pulse oximeter.

- Avoid using nail polish nails when using pulse oximetry sensor. Nail polish can cause impaired reading functionality of the pulse oximetry sensor.
- 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 service provider regarding take-back or recycling of the O₂matic.
- Extended exposure to the device(s) may cause irritation to the skin, pyrogenicity or trigger allergies.
- During treatment the device should always be turned on.
- To avoid disconnecting please keep the device away from pets, pests and children.
- If the device has not been used for 2 weeks leave the device on and charging for at least an hour before using/configuring it.
- The device does not have automatic barometric compensation and the quantitative effect of using devices in high altitudes can effect the accuracy up to 20%. This accuracy does not effect the treatment of the patient is the device will reacts to patient SpO₂.

1.3 Disclaimer

O₂matic cannot assume responsibility for patient safety, upon:











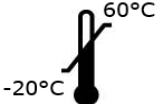

- Any sign or evidence of opening the HOT 100, except by authorized personnel.
- Use of any unapproved pulse oximeters.
- This IFU has been issued in compliance with requirements set out in Council Directive 93/42 EC concerning Medical Devices.
- All liability is discontinued if the product is not used as intended and as described in this IFU.
- Use of a HOT device which has not been set up specifically for that patient.


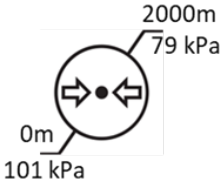
1.4 Label and Symbols




Figure 2: HOT 100 label found beneath

The labelling on the device is the manufacturers label situated on the bottom and back of the device. The optimal reading condition of the labelling is at the same reading distance and angle, as a person would hold and read the cover of a book. In 'office lighting' illumination predominant in hospitals.

	<p>Refer to instruction manual/booklet. Follow instructions for use</p>		<p>Direct current: 5 VDC</p>
	<p>Manufacturer</p>		<p>CE mark: Made in compliance with all relevant directives</p>
	<p>Do not use if the package is damaged</p>		<p>Serial number</p>
	<p>Not for general waste</p>		<p>For use in oxygen rich environment</p>
	<p>Alternating current</p>		<p>Type BF Applied part</p>
	<p>Temperature limits</p>		<p>On/Off</p>

	<p>Class II equipment</p>	<p>IP22</p>	<p>Protection against Fingers or similar objects and vertically Dripping water when tilted at 15°.</p>
	<p>For use in altitudes 0 - 2000 m</p>		

1.5 Safety

The HOT 100 has a failsafe rechargeable battery that keeps the device running upon disconnection from main power for up to 4 hours. To shut down the HOT 100 press and hold  for 4 seconds. Upon intended shutdown, or unintended shutdown, such as total loss of power, the device maintains its last settings.

In case of malfunction, it reverts to the defined safe-mode, where the user is informed by turning on the warning icon and an audible alarm.

In safe-mode the flow of oxygen is reduced to zero. The patient shall change to an alternative oxygen supply and contact the service provider.

As part of the treatment the patient can be assigned a dedicated tablet which will have the O₂matic app installed. The app will inform the patient of any relevant notifications and display information from the HOT device. During treatment it is advised not to turn off the dedicated tablet.

2 Installation and Setup

Before using the device, it must be installed as described in the following section. It is important to read the instructions thoroughly and familiarize oneself with the information given. It is the service provider's responsibility to correctly set up the device and comply with the warranty of any pulse oximetry.

2.1 Overview

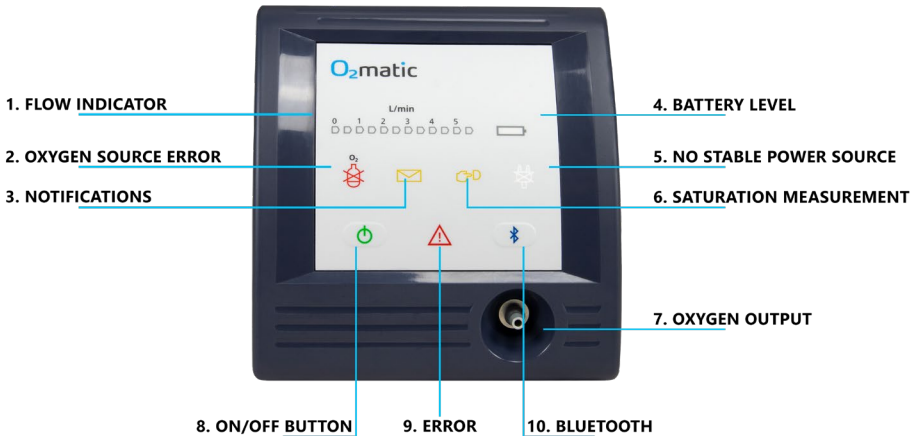
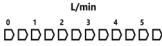











Figure 3: Front of HOT 100

	<p>1. FLOW INDICATOR Shows the amount of oxygen currently being delivered.</p> <p>Upon start-up of the device, the values of the flow range are lit for 3 seconds, indicating the flow limitations for current device configuration.</p> <p>The flow indicator displays 0 – 5.5 l/min on the foil. If the device is delivering more than 5.5 l/min the 5,5 mark will be blinking.</p>
	<p>2. OXYGEN SOURCE ERROR The device is not receiving the correct amount of oxygen if this icon is blinking. Check oxygen source.</p>
	<p>3. NOTIFICATIONS Contact health care provider.</p>
	<p>4. BATTERY LEVEL Green blinking: Charging. Green: Battery status is good. Yellow: Battery status is low. Red: Battery status is critical. Red blinking: Shutdown imminent</p> <p>If battery level is red, an audio alarm is initiated until the device is connected to a power source.</p>
	<p>5. NO STABLE POWER SOURCE Connect to stable power source when possible.</p>
	<p>6. SATURATION MEASUREMENT Blinking: Put pulse oximeter or readjust if already on.</p> <p>Constant lid: The session has begun. Keep the pulse oximeter on until the icon has turned off.</p>

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	Off: Session completed. Take pulse oximeter off.
	7. OXYGEN OUTPUT Connect your oxygen mask or nasal catheter here.
	8. ON/OFF BUTTON Green: device is on.
	9. ERROR Stop using the device. Follow trouble shooting section.
	10. BLUETOOTH® On: Device is connected to tablet. Blinking: Not connected Off: Bluetooth turned off.

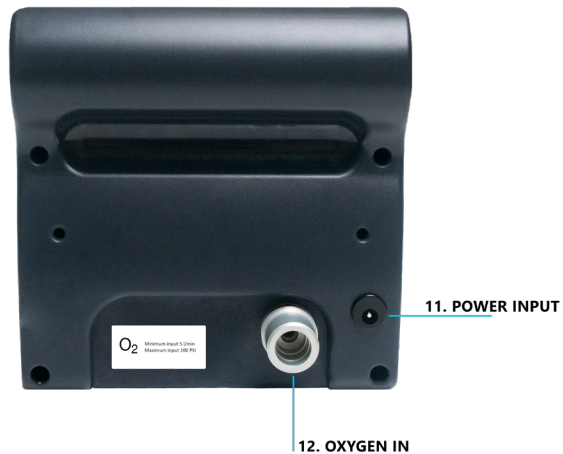





Figure 4: Back of HOT 100


	<p>11. POWER SUPPLY Power supply connection. When connected and device is turned on, it will recharge its batteries and avoid running out of power.</p>
	<p>12. OXYGEN IN Connect your oxygen source to this socket to ensure the device can receive and regulate the oxygen flow.</p>

2.2 Installation

To install HOT 100:

- Place the HOT 100 in a distance so you can hear the notifications at a flat surface, such as a table.
- Connect the AC power adaptor to the wall outlet and to the HOT 100 power plug.

	<p>Warning Only use the AC power adaptor provided by O₂matic. Any other power supply may interfere with the proper operation of the device.</p>
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- Connect the oxygen hose to your source of oxygen like a concentrator or an oxygen cylinder. Then connect oxygen hose to the oxygen inlet of the HOT 100. High pressure hoses shall be used with oxygen sources over 1 bar.
- Connect the oxygen output to your oxygen mask or nasal cannula and put on the mask.
- Turn on the HOT 100 by pressing and holding down  for 4 seconds.

The HOT 100 should now be turned on.



Warning

The nasal catheter needs to be placed in the correct position during treatment. Contact your service provider if you are in doubt.



Warning

All cables connected to the HOT device should be positioned safely to best prevent tripping and/or strangulation. Keep any unnecessary cables away from the device.





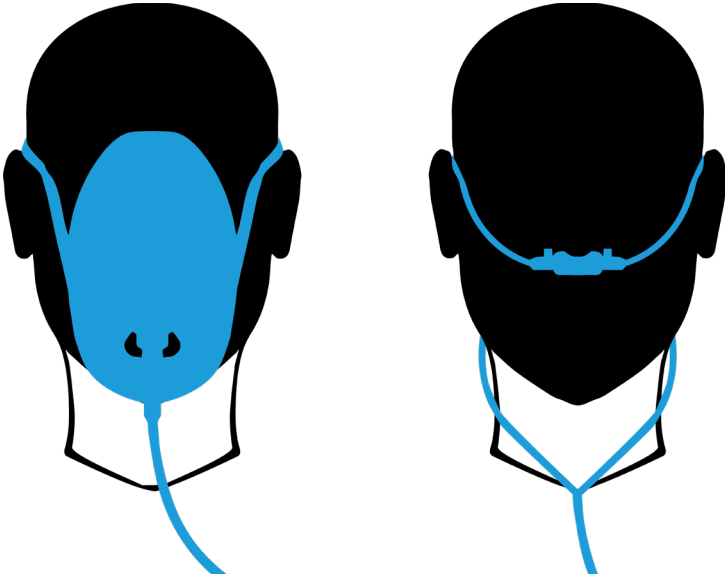





Figure 5: Oxygen mask and nasal catheter appliance

	<p>Warning HOT 100 is only to be used with medical oxygen.</p>
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Afterwards the device should be ready to start the treatment within 5 seconds. If you are having trouble installing or using the device, please contact your service provider for further assistance.

3 Starting Treatment


This section explains how to get started with using the HOT 100 device and explains the flow of the treatment.


- Turn on the HOT 100 by pressing  (A) The device will emit a short beep to indicate the alarm speaker is on and the green light on the on/off button indicates that the HOT 100_device is turned on. NOTE: It may take up to 10 seconds before there is a clear signal from the pulse oximetry sensor.
- Put on oxygen mask or nasal catheter
- Put on the paired pulse oximeter and leave it on until the icon  on the device turns off.
- Thereafter, the patient should keep their nasal catheter or mask on and take the pulse oximeter off until the next treatment session.

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

The HOT 100 will already have been customized to you by the responsible medical service providers.

It is not always possible or needed to have continuous measurement of oxygen saturation. HOT 100 has an intelligent algorithm that only needs a few daily measurements of oxygen saturation, as long as the patient is stable, but it is recommended to do a new measurement when changing activity. Depending on the stability of the patient, the intelligent algorithm determines how often measurements has to be done. The number and the length of measurements can vary from time to time.

	<p>Caution</p> <p>Depending on configuration the HOT can spend up to five minutes after turning on measuring exclusively and does NOT adjust the oxygen flow. If the signal during this period is interrupted for more than one minute, the process must be repeated from the beginning.</p>
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	<p>Warning</p> <p>Only the patient should be connected to the pulse oximeter. By not complying with this the patient could risk receiving the wrong treatment.</p> <p>The patient should only use one pulse oximeter at a time.</p>
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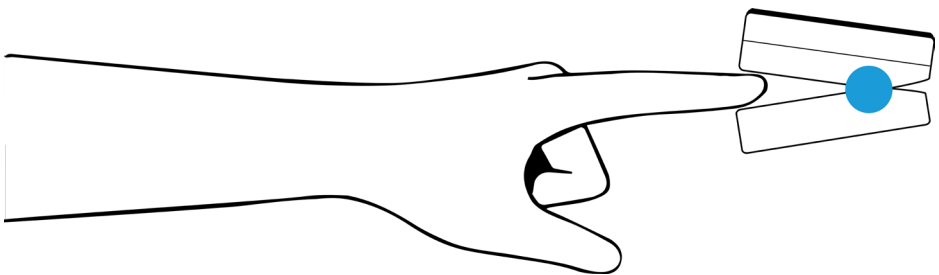



Figure 6: Pulse oximetry demonstration

When a new measurement is required, the oxygen measurement icon  lights up on the display. Once it lights up, if the user does not start the measurement within one hour, then an acoustic notification will be played. However, it is always possible to do a new measurement even if the oxygen measurement icon has not been turned on. To begin the measurement session, simply put the pulse oximeter on a finger and follow the instructions on the tablet or until the measurement icon is no longer lid.

It is recommended to do a new measurement before sleeping and when the activity level changes.

If HOT 100 has been turned off, then a new measurement is required.

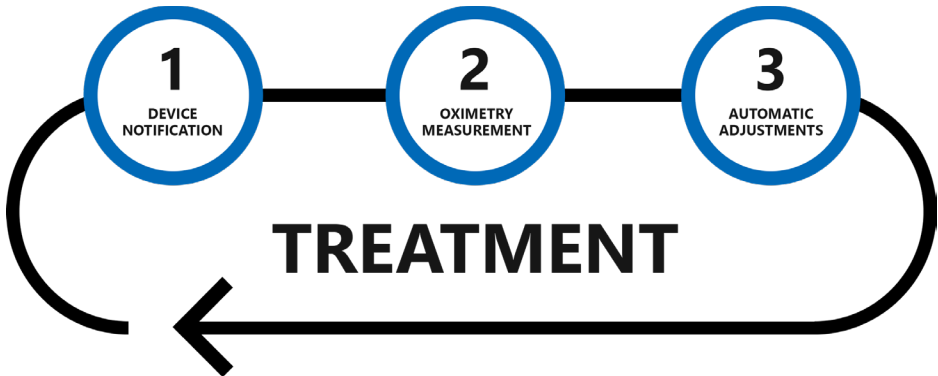



Figure 7: O₂matic treatment cycle

No one else but the patient shall use the pulse oximetry sensor that is paired with HOT 100.

Pulse oximetry sensors may have reading troubles when used on patients with low perfusions due to reduced blood circulation. In the case of low perfusion or low-quality signal the sensor should be moved to an alternative site to obtain the best possible signal or you may be asked to do a new measurement within one hour.

Avoid using nail polish and of acrylic nails when using pulse oximetry sensor. For more information regarding the pulse oximetry contact service provider.

	<p>Warning</p> <p>If the HOT 100 is dropped down from above 30 cm, then the device shall be checked by installer, before it can be safely used.</p>
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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.

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


Warning

Never smoke during treatment. This can inflict serious injuries.

If the patient feels ill or uncomfortable, the patient shall always contact their service provider.



To properly shut down HOT 100 press  for more than 5 sec. The light in the on/off button turns off, when the device is turned down.



Warning

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



Warning

HOT 100 device shall be functional in altitude range 0 to 2.000 meter.

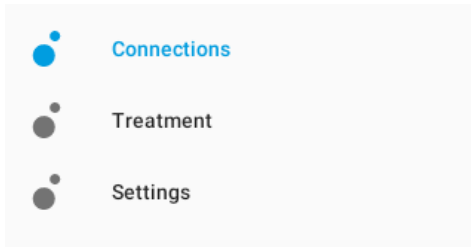
3.1 Application

Both the device and app installation will be performed by a designated installer. Should the patient experience any issues with the device or tablet they should contact their service provider. HOT 100 can be used without the app, however for more information on the treatment, it is recommended that the patient also uses the app.

The designated app will be paired with your device and be set up for you by an installer. Once the tablet is ready for use open the application "O2matic HOT".

Important note: Make sure the device is always connected to a Wi-Fi network and Bluetooth is turned on during use.

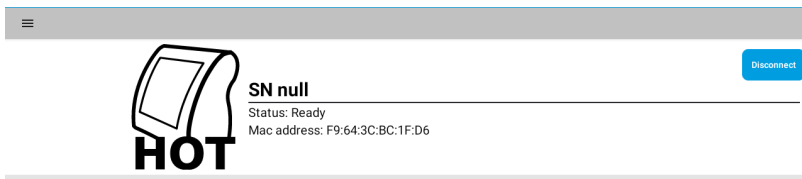
Once you open the app the “Connections” screen will be displayed for you. By pressing the menu icon, the following menu points are displayed:



Connections

The Connections page lists all connected devices, sensors, and patient/treatment information. From this page the user can connect and disconnect the tablet from their device.

If disconnected the screen instead shows a list of available HOT 100 devices to connect to.



Patient

Patient settings

O2Maticid: 20

First name: Ejvette

Language: da

Country: dk

Contact information

Healthcare service provider: null

Technical support: null

Treatment

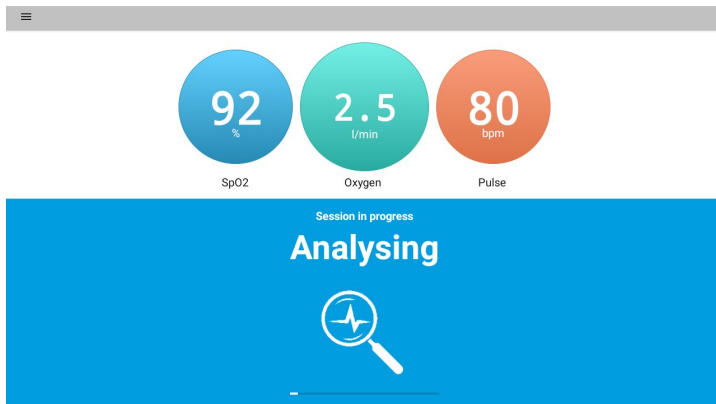
Profile name: WithLod 1

Treatment

On the Treatment page, you can inspect the current amount of oxygen being delivered. When in a treatment or using the pulse oximeter, the user interface will

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display the measured pulse, oxygen saturation (SpO2) as well as give you feedback on the current treatment you are taking. After finishing a treatment, the application will let you know when to take off the pulse oximeter and then calculate the time of the patient's next measurement.



If the Error or Notification symbol is lighting up on the device, a message will be displayed on this page, which will include an explanation of notification and instruct you going forward.

Further down below you can see the measured data from previous measurements. This page will be empty if no measurements have been performed. By pressing on marked points shown on the graph, the patient can learn more about their previous treatments. The patient is also able to filter out certain information and control the extend of time the graph is currently displaying information from.


Settings


From this page the user is able to change the language used in the application and changing the license of the application, if necessary.

4 Maintenance and Support

This section contains important information regarding safely maintaining the device. This device does not need to be calibrated.

4.1 Cleaning

	<p>Warning</p> <p>Disconnect the AC power adaptor from the device before cleaning it. Do not clean device in any other manner than described in this user manual.</p>
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	<p>Warning</p> <p>If the HOT 100 is malfunctioning or does not provide the correct treatment, please contact your service provider.</p>
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Expected maintenance for HOT 100 consists of cleaning. For any other maintenance activity contact the distributor. This device does not need to be calibrated.

Use wet towel or cloth with either water or alcohol. Dry off surfaces with a dry towel or cloth afterwards. The device should be thoroughly cleaned once a week.

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

4.2 Trademark

The Bluetooth® word mark and logos are registered trademarks owned by Bluetooth SIG, Inc.

4.3 Support and Contact

For support or more information please contact:

Website:

www.o2matic.com

Manufacturer and technical Support:

O₂matic

Nørrelundvej 10

DK-2730 Herlev

Denmark

Tel: +45 5052 9810

info@o2matic.com

Your local distributor

5 Specifications

Physical

Weight	800g
Dimensions	205x265x95 mm
Connection	Bluetooth
Alarm volume	56 DB – Always on

Electrical

Main	120-240 VAC, 50/60 Hz
DC input	12 VDC
Power consumption	10 VA
Battery type	Lithium Ion
Battery Capacity	4 hours
Input pressure	Up to 100 PSI (6 bar)

Classifications

Type of protection	Class II and internally powered
Degree of protection	Type BF – Applied part
Ingress protection	IP22
Method of sterilization	None
Suitability of use	Oxygen rich environment
Mode of operation	Continuous

Environmental

Operating temperature	5°C – 40°C
Storage temperature	-20°C – 60°C
Operating humidity	10% – 90%
Storage humidity	10% – 90%
Operating altitude	0 - 2000 meters

Performance

SpO ₂ reading	70% - 100% ± 2
Heart rate	40 – 240 ± 5
Flow rate	0 – 15 l/min (Total flow output tolerance is 5%)
System response rate	1 sec
Data sample rate	1 sec

General

Expected service life	5 years
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6 Troubleshooting

The acoustic sounds that are initiated by the HOT 100 all follow a basic system, which makes it easy to distinguish between actions needed to be taken. There is one type of notification and one type of alarm.

Notification: can be recognized by five fast repeated beeps over 2 seconds which is then repeated once every minute.

Action: Put on pulse oximeter.

Alarm: Has two phases of alarming make a beeping sound up until 1 hour. If ignored for more than an hour, the sound of the alarm will change. Instead it will now repeatedly run the alarm for 3 seconds followed by 7 seconds of silence.

Action: Check troubleshooting section and follow the described actions.

1. When oxygen symbol lights up

- a. Check oxygen source and make sure it is connected properly. If the patient is using a concentrator, make sure it is set to max output.
- b. If the patient is using an oxygen tank, make sure there is still enough oxygen in it.
- c. See if any hoses are bend/pinched or otherwise obstructed/damaged.
- d. Restart the device.
- e. If you are still experiencing issues, contact the service provider and consider switching to an alternative oxygen source.

2. Alarm symbol lights up and a loud alarm is heard

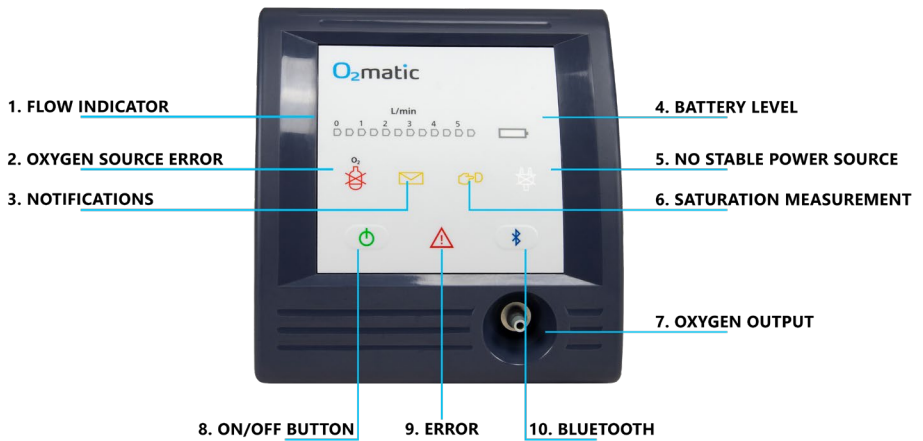
- a. If the no oxygen symbol is blinking you should perform the step 1., described above.
- b. Turn the device on and off. If the issues persist, contact the service provider.

3. Unable to connect with smart device

- a. Restart device and smart device.
- b. If the problem persists, contact your service provider.

4. Oxygen concentrator alarming

- a. If you are using an oxygen concentrator and it is alarming check if the HOT 100 device is running. If it is not; turn it on.
- b. When you have confirmed that the device is running, check if the device is alarming. If it is alarming the device should be restarted.
- c. If the concentrator continues to alarm while the device is running (and not alarming as well) then turn off the oxygen concentrator, disconnect the oxygen hose for 20 seconds. Then reconnect the oxygen hose and turn the oxygen concentrator back on.
- d. Should the problem persist after the above steps, please contact your service provider.



This user manual booklet is current as of February 2023. For more information of device updates and news please visit www.o2matic.com