

O₂matic



Model: HOT 100

2024.08.16


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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 before use. 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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- The HOT 100 device and corresponding pulse oximeter should only be used by the intended patient. Use by any other person can result in improper treatment and can lead to serious damage to the patient.
- Use only pulse oximetry sensors that are delivered by O2matic or O2matic approved partners. 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 of compromising patient safety and will void the warranty.
- Do not use in an explosive atmosphere or in the presence of flammable anaesthetics or gases.
- Never smoke during treatment. This can inflict serious injuries.
- Refer to the applicable sensor instructions for use for additional warnings and cautions.
- Regularly check the battery indicator. If power is low, connect to a power source to avoid unintended shutdown. For more information see Table 2 for battery instructions.
- HOT 100 is only to be used with medical oxygen.

- Only use accessories such as masks, catheters and hoses approved by your service provider.
- Do not open the device under any circumstances. Do not use any tools on the device.
- If the HOT 100 is dropped down from above 30 cm, then the device shall be checked by the service provider, before it can be safely used.
- Do not use device when in alarm state. If troubleshooting doesn't solve the issue, please contact service provider.
- 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.
- All cables connected to the HOT 100 device should be positioned safely to best prevent tripping and/or strangulation. Keep any unnecessary cables away from the device.
- Only use the AC power adaptor provided by O2matic. Any other power supply may interfere with the proper operation of the device.
- 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.
- Make sure that the oxygen source can provide the minimum and maximum O₂ flow defined in the patient's treatment profile. Be aware that some oxygen sources have minimum flow requirements and can trigger an alarm from the oxygen source.

1.2 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.

- 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 saturation when used on patients with poor perfusion due to reduced blood circulation. In the case of poor 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 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 HOT 100 device.
- Extended exposure to the HOT 100 device may cause irritation to the skin, pyrogenicity or trigger allergies.
- Depending on configuration the HOT 100 can spend up to five minutes after turning on only to measure 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.
- To avoid disconnection, please keep the device away from pets, pests and children.
- Placing the HOT 100 device outside hearing distance can result in user not reacting to alarms e.g. indicating improper flow.

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.
- Any unintended use of the product as described in this IFU in which case all liability is discontinued.
- Use of a HOT 100 device which has not been set up specifically for that patient.

1.4 Label and Symbols



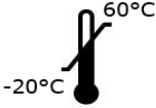


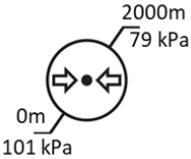


Figure 1: HOT 100 label found on the bottom

Manufacturers label is situated on the bottom 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 a well-lit room.

	<p>Refer to instruction manual/booklet. Follow instructions for use</p>	<p>IP22</p>	<p>Protection against fingers or similar objects and vertically dripping water when tilted at 15°.</p>
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	Manufacturer
	Do not use if the package is damaged
O_2	For use in oxygen rich environment
	Temperature limits
	Class II equipment
	Alternating current
	For use in altitudes 0 - 2000 m




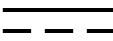

SN	Serial number
CE 0123	CE mark: Made in compliance with all relevant directives
 Pure SAT	Type BF Applied part
	On/Off
	Not for general waste
	Direct current: 5 VDC

Table 1: Symbols on labels and packaging


1.5 Safety and low power mode

The HOT 100 has a rechargeable battery that keeps the device running when not connected to power for up to 6 hours. If disconnected from main power and upon battery depletion, the device has a failsafe battery that notifies the user for a short amount of time. 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 HOT 100 device maintains its last settings.

If the HOT 100 device has not been used for two weeks leave the HOT 100 device on and charging for at least an hour before using/configuring it.

If the HOT 100 device is on low power (less than 15% battery capacity) the HOT 100 device will not start up if not connected to power.

If connected to power and the battery capacity is below 15%, the HOT 100 device will start up in a charging state and automatically turn on when 15% capacity is reached. Pressing the  again in this mode, will start-up the device normally.

Important note: In charging state, the “On/off button” icon is blinking, and the HOT 100 device will not provide oxygen treatment.

2 Setup

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

2.1 Overview of icons and buttons

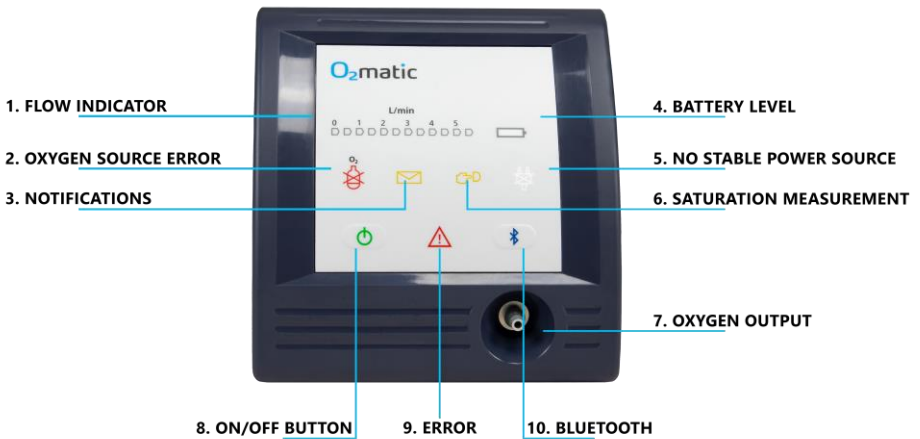







Figure 2: Front of HOT 100

	<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 without pulse oximeter 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 (far right) mark will be blinking.</p>
	<p>2. OXYGEN SOURCE ERROR Device is not receiving the correct amount of oxygen. Check oxygen source and follow troubleshooting section.</p>
	<p>3. NOTIFICATIONS Contact healthcare 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 On: Device is not connected to a stable power source, connect when possible. Blinking: Device is below 15% charged and currently in charging state. See troubleshooting section.</p>






	<p>6. SATURATION MEASUREMENT</p> <p>On: The session has begun. Keep the pulse oximeter on until the icon has turned off.</p> <p>Blinking: Put on pulse oximeter or readjust if already on.</p> <p>Off: Session completed. Pulse oximeter can be taken off.</p>
	<p>7. OXYGEN OUTPUT</p> <p>Connect your oxygen mask or nasal catheter here.</p>
	<p>8. ON/OFF BUTTON</p> <p>On: Device is on.</p> <p>Blinking: Device is below 15% charged and in charging state. See troubleshooting section.</p>
	<p>9. ERROR</p> <p>See troubleshooting section.</p>
	<p>10. BLUETOOTH®</p> <p>On: Device is connected to smart device.</p> <p>Blinking: Not connected.</p> <p>Off: Bluetooth is turned off.</p>

Table 2: Device icons

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

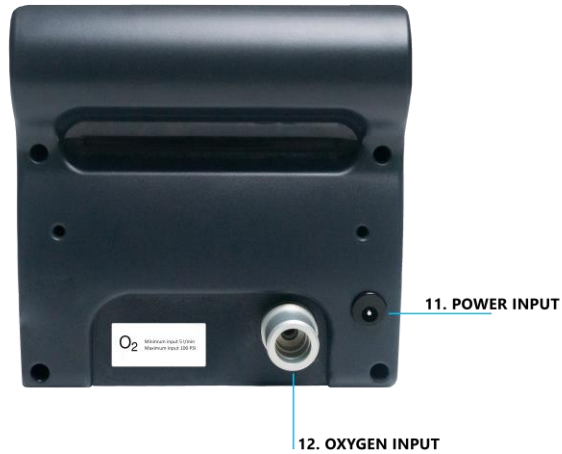


Figure 3: Back of HOT 100




	<p>11. POWER INPUT 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 INPUT Connect your oxygen source to this socket to ensure the device can receive and regulate the oxygen flow.</p>


Table 3: Power & oxygen inputs

2.2 Setup of HOT 100 device


To setup HOT 100:

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

	<p>Warnings</p> <ul style="list-style-type: none">• Only use the AC power adaptor provided by O2matic. Any other power supply may interfere with the proper operation of the device.• All cables connected to the HOT 100 device should be positioned safely to best prevent tripping and/or strangulation. Keep any unnecessary cables away from the device.
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	<p>Cautions</p> <ul style="list-style-type: none">• 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.• To avoid disconnection, please keep the device away from pets, pests and children.• Placing the HOT 100 device outside hearing distance can result in user not reacting to improper flow.
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- 3 Connect the oxygen hose to your source of oxygen such as a concentrator or an oxygen cylinder.

	<p>Warnings</p> <ul style="list-style-type: none">• HOT 100 is only to be used with medical oxygen.• Make sure that the oxygen source can provide the minimum and maximum O₂ flow defined in the patient's treatment profile. Be aware that some oxygen sources have minimum flow requirements and can trigger an alarm from the oxygen source.
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- 4 Connect the oxygen hose to the oxygen input of the HOT 100.



Figure 4: Connection of oxygen hose to the oxygen input on the HOT 100 device and connection of oxygen mask or nasal catheter to oxygen output on the HOT 100 device. Note that connecting tubes provided to you might differ in appearance from the ones depicted.



Figure 5: Close-up of connection of oxygen hose to the oxygen input on the HOT 100 device and connection of oxygen mask or nasal catheter to oxygen output on the HOT 100 device. Note that connecting tubes provided to you might differ in appearance from the ones depicted.

- 5 Connect the oxygen output to your oxygen mask or nasal cannula and put it on yourself.

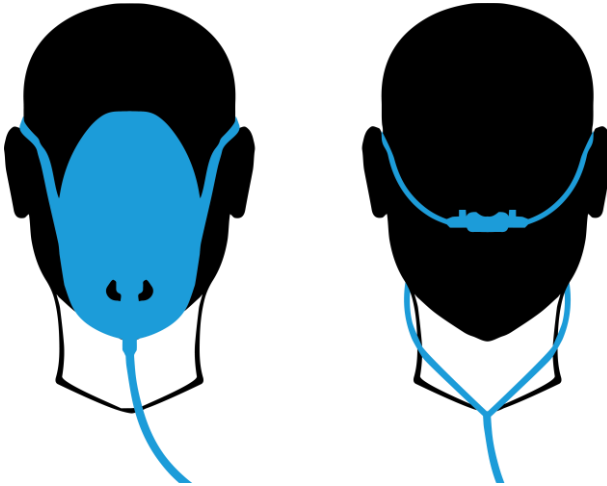



Figure 6: Oxygen mask and nasal catheter application

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

	<p>Warnings</p> <ul style="list-style-type: none">• Only use accessories such as masks, catheters and hoses approved by your service provider.• 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.
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If you are having trouble setting up or using the device, please contact your service provider for further assistance.

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3 Using the device

This section explains how to receive automated oxygen dosage using the HOT 100. Before using the HOT 100 device follow section 2 to set it up to your needs.

3.1 Session

For the HOT 100 device to calculate the suitable level of oxygen flow for the user, it will require the user to do a session at certain time intervals. From the time the pulse oximeter is placed on the finger, until it is taken off, the HOT 100 device receives measurements of SpO2 and pulse. This period of time where the pulse oximeter is sending measurements is referred to as a session. If the pulse oximeter is taken off for more than 60 consecutive seconds during a session, the session must be restarted.

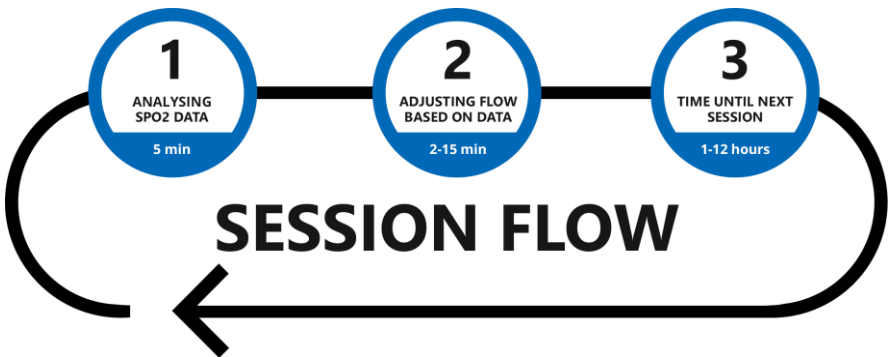


Figure 7: O2matic HOT 100 session flow

A session consists of two phases, being the Analysing phase and Adjusting phase.

- **Analysing phase**
In the analysing phase, the pulse oximeter measures oxygen saturation (SpO2) for a duration of 5 minutes, without adjusting the oxygen flow.
- **Adjusting phase**
The pulse oximeter measures oxygen saturation (SpO2) and adjusts the oxygen flow based on these measurements. The duration of this phase depends on the stability of saturation among other things.

Note: The analysing phase can by the healthcare professionals have been disabled as part of setting up the treatment profile. If the analysing phase is disabled, the session will upon startup skip the analysing phase and go directly to the adjusting phase.

The time until next session is calculated by the HOT 100 device. The lower or more varying the measurements of a session, the more frequently the HOT 100 device will ask the user to perform a session. Based on the measurements of a session, the HOT 100 device calculates the appropriate fixed oxygen flow to be supplied to the user until the next session is started.

When the user is not wearing the pulse oximeter, a fixed oxygen flow is provided. The amount of fixed oxygen provided is determined by the HOT 100 device based on the measured data from the last session.



Caution

Depending on configuration the HOT 100 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.

3.2 Performing a session

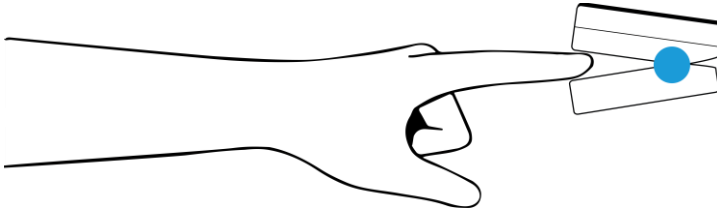




Figure 8: Pulse oximetry demonstration



- 1 If HOT 100 device is not already turned on, press and hold down  for 4 seconds to turn the device on. 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. The HOT 100 will once turned on provide flow of oxygen within 5 seconds.

Note: If battery charge is below 15%, the HOT 100 device will start up in charging state, see section 1.5.

- 2 To start a session put on the paired pulse oximeter.


	<p>Warnings</p> <ul style="list-style-type: none">• 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.• The HOT 100 device and corresponding pulse oximeter should only be used by the intended patient. Use by any other person can result in improper treatment and can lead to serious damage to the patient.• Refer to the applicable sensor instructions for use for additional warnings and cautions.
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Note: It may take up to 10 seconds before there is a clear signal from the pulse oximetry sensor.

- 3 Leave the pulse oximeter on until the saturation measurement icon  on the HOT 100 device turns off.
- 4 After the saturation measurement icon  has turned off, you can keep the pulse oximeter on to keep getting oxygen flow matching your current oxygen saturation or you can take the pulse oximeter off at any time.
- 5 After taking the pulse oximeter off, the HOT 100 device will calculate the time until next session and determine the appropriate fixed oxygen flow to be delivered until next session.


Important Note: It is not required to have the pulse oximeter on all the time. It is however recommended to do a new measurement before sleeping and when the activity level changes.

Important Note: Depending on the level of oxygen in the blood, the intelligent algorithm determines how often measurements have to be done. The number of and length of measurements may vary from time to time.


- 6 When a new session is required, the saturation measurement icon  on the HOT 100 device starts to blink. If the session is not started within one hour, then an acoustic notification will be played.


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

It is always possible to do a new measurement even if the oxygen measurement icon has not yet started to blink. To begin the session, simply follow step 2-4.

- 7 To turn the HOT 100 device off press  for more than 5 sec. The light in the on/off button turns off, when the device is turned down. No oxygen flow is provided when the HOT 100 device is turned off.

Important Note: If feeling ill or uncomfortable, you shall always contact your healthcare provider.

	<p>Warnings</p> <ul style="list-style-type: none">• Never smoke during treatment. This can inflict serious injuries.• Do not use in an explosive atmosphere or in the presence of flammable anesthetics or gases.• If the HOT 100 is dropped down from above 30 cm, then the device shall be checked by the installer, before it can be safely used.• Regularly check the battery indicator. If power is low, connect to a power source to avoid unintended shutdown. For more information see Table 2 for battery instructions.• Do not use device when in alarm state. If troubleshooting doesn't solve the issue, please contact service provider.
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	<p>Caution</p> <p>Avoid using nail polish when using pulse oximetry sensor. Nail polish can cause impaired reading functionality of the pulse oximetry sensor.</p>
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3.3 Smart device connection

The HOT 100 can be used without connection to a smart device. However, for more information on the treatment, it is possible to connect to the HOT 100 device to a tablet or smartphone with the “O2matic – HOT” app found in the Google Play Store.

Note: If a smart device is provided to you by your service provider, with the purpose of collecting treatment data, it is important to make sure the smart device:

- Is always connected to a Wi-Fi network
- Has Bluetooth turned on during use
- Is located within Bluetooth range of the HOT 100 device
- Is charged and connected to power when possible

Once you open the “O2matic – HOT” app, you have the following menu points available in the menu found in the top left corner of the screen:

Connections

Connect to a HOT 100 device on the “Connections” page. By clicking on the HOT 100 device matching the serial number (SN) found on the label at the bottom of the HOT 100 device. This page lists all information regarding the connected device. This includes patient/treatment information and paired sensors.

Treatment

On the “Treatment” page, you can inspect the current amount of oxygen being delivered. When wearing the pulse oximeter, the measured oxygen saturation (SpO₂) and pulse are displayed. When a session is done, this page will let you know when to take off the pulse oximeter and display the time next session has to be made.

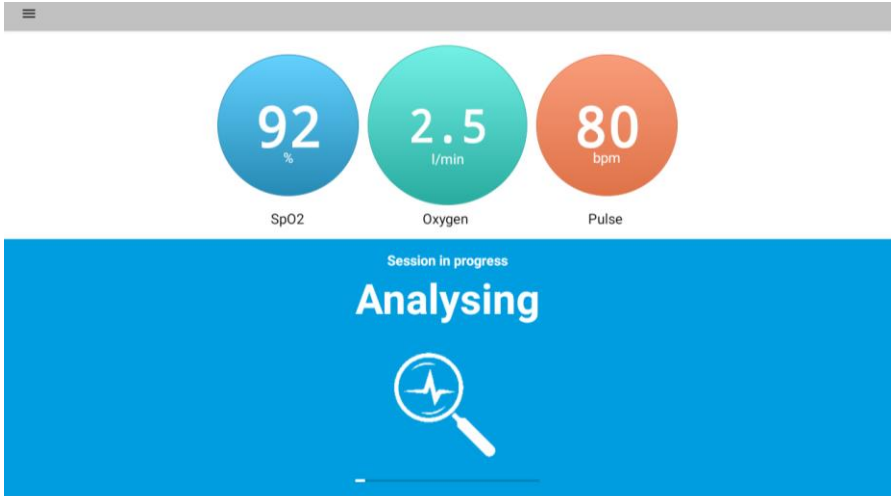


Figure 9: "O2matic - HOT" app - treatment screen

If the Error or Notification icon on the device is lit, a message will be displayed on this page, which will include an explanation of the notification and instruct you going forward. You can also refer to troubleshooting section.

Further down below you can see the measured data from previous measurements.


Settings


In the "Settings" menu it is possible to change the language and app license used in the application.

Important Note: Removing the license cannot be undone. Do not remove the license without a service provider present, as this will require a new setup from the service provider.

4 Cleaning and Support

This section contains important information regarding safely maintaining the device. This device does not need to be calibrated. Expected maintenance for HOT 100 consists of cleaning. For any other maintenance activity contact your service provider.

	<p>Warning</p> <p>Do not open the device under any circumstances. Do not use any tools on the device.</p>
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	<p>Caution</p> <p>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 HOT 100 device.</p>
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4.1 Cleaning

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.

For general purposes use a damp cloth, disinfecting wipes or cloth with either water or alcohol. Dry off surfaces with a dry towel or cloth afterwards.

For cleaning of pulse oximeter please refer to the IFU for that device.

Important: Make sure that there are no dust or lint in the air input or air output. Refer to instructions for use of the paired pulse oximeter for cleaning and maintenance requirements.

4.2 Support and Contact

For general support and questions contact your local service provider.

Manufacturer

O2matic

Address

Nørrelundvej 10

DK-2730 Herlev

Denmark

Contact information

Tel: +45 5052 9810

info@o2matic.com

www.o2matic.com

5 Specifications

Physical

Weight	700 g
Dimensions	150x150x100 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

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% (Non-condensing. Does not require water vapor partial pressure greater than 50 hPa. and atmospheric pressure range of 700 – 1060 hPa.)
Storage humidity	10% – 90%
Operating altitude	0 - 2000 meters

Performance

SpO ₂ reading	70% - 100% ± 2
Heart rate	40 – 240 bpm ± 5
System response rate	1 sec
Data sample rate	1 sec
Flow rate	0 – 15 l/min (Total flow output tolerance is 5%)
Input pressure	Up to 100 PSI (6 bar)

Expected service life

HOT 100 device	5 years
Battery	2 years
Power supply	5 years
Pulse oximeter	Refer to sensor IFU

6 Troubleshooting

The acoustic sounds from 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 sound and one type of alarm sound (with two phases).

Notification sound



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

Action: Put on pulse oximeter.

Alarm sound



Has two phases of alarming. If device detects an anomaly and goes into alarm state it will start beeping once every second for 1 hour. If ignored for more than 1 hour, the sound of the alarm will change. 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.



'Oxygen source error' icon lights up

- 1 Check oxygen source and make sure it is connected properly. If using a concentrator, make sure the output is set to max oxygen flow of the prescribed treatment.
- 2 If using an oxygen tank or liquid oxygen, make sure there is still enough oxygen in it.
- 3 See if any hoses are bent/pinched or otherwise obstructed/damaged. If damaged, please contact your service provider.
- 4 Turn the HOT device off and on again to restart.
- 5 If you are still experiencing issues, contact the service provider and consider switching to an alternative oxygen source until the issue has been resolved.





'Error' icon lights up and a loud alarm is heard (Safe mode)


- 1 Turn HOT 100 device off to stop alarm sound from being played.
- 2 Check oxygen source and make sure it is connected properly. If using a concentrator, make sure it is set to max oxygen output.
- 3 If using an oxygen tank or liquid oxygen make sure there is still enough oxygen in it.
- 4 See if any hoses are bent/pinched or otherwise obstructed/damaged. If damaged, please contact your service provider.
- 5 Turn the HOT 100 device on again.
- 6 If you are still experiencing issues, contact the service provider and consider switching to an alternative oxygen source until the issue has been resolved.



'No stable power source' icon is blinking (Charging state)

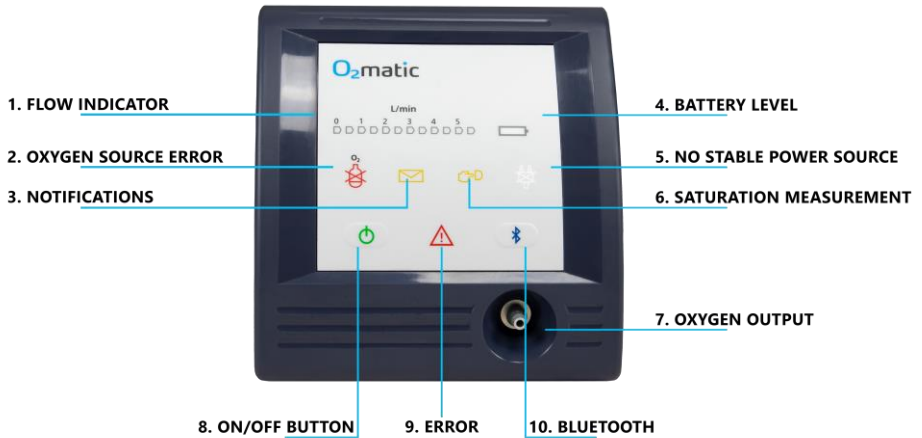
- 1 HOT 100 device has less than 15% charge and is currently in charging state. In this charging state the HOT 100 device is not providing oxygen treatment.
- 2 If oxygen treatment is desired, press the "On/Off button" . The HOT 100 device should now start up and begin providing oxygen treatment, and the  icon should be constantly lit.
- 3 Keep HOT 100 device charging until at least 15% charged before removing AC power adapter.

Unable to connect with Smart device

- 1 Check that HOT 100 device isn't already connected to another smart device, by confirming that the Bluetooth icon on the HOT 100 device is not constantly lit,
- 2 If HOT 100 device is connected to another smart device, disconnect on that smart device to allow the other smart device to connect with HOT 100 device.
- 3 Restart HOT 100 device and smart device and check if the problem is resolved.
- 4 If not, reset/forget Bluetooth connection on smart device and long press Bluetooth button  on HOT 100 device for 8 seconds.
- 5 Should the problem persist after the above steps, please contact your service provider.

Oxygen concentrator is alarming

- 1 If you are using an oxygen concentrator and the concentrator is alarming check if the HOT 100 device is running. If not; turn HOT 100 device on.
- 2 If HOT 100 device is already on and alarming, turn HOT 100 device off and on.
- 3 If the HOT 100 device is running normally, turn off the oxygen concentrator, disconnect the oxygen hose for 20 seconds. Then reconnect the oxygen hose and turn the oxygen concentrator back on.
- 4 Should the problem persist after the above steps, please contact your service provider.



This user manual booklet is current as of August 2024. For more information on device updates and news please visit www.o2matic.com