

O₂matic



HEALTHY OXYGEN THERAPY

End User Manual
Instructions for use

2020.10.29

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O₂matic HOT (Healthy Oxygen Therapy) 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 O₂matic HOT device will adjust the flow of oxygen to the patient based on the saturation in the blood, making this treatment precise in getting the correct oxygen flow.

On a stable patient O₂matic HOT 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. 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 your home.

The characteristics of this equipment make it suitable for use at home and hospitals, where patients are not in critical care and can take care of themselves.

1 Warnings, Cautions and Symbols

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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- a) Use only pulse oximetry sensors that are approved by O₂matic. Contact your service provider for more information on approved pulse oximetry for use with the O₂matic HOT. Use of any other pulse oximeters increases the risk for compromising patient safety and will void the warranty.
- b) Do not use in an explosive atmosphere or in the presence of flammable anesthetics or gases.
- c) Refer to the applicable sensor instructions for use for additional warnings and cautions.
- d) Regularly check the battery indicator. If lit, see section 5.3 for battery instructions.
- e) O₂matic HOT is only to be used with pure oxygen.
- f) Only use accessories such as masks, catheters and hoses approved by you service provider.
- g) Do not open the device under any circumstances. Do not use any tools on the device.
- h) 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 normally.
- i) 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.
- j) 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 O₂Matic HOT device, including


O₂matic HOT end user manual

cables specified by the manufacturer. Otherwise, this could result in degradation of the performance of this equipment.

- k) Use of any other oximeters than the one provided will void the warranty.


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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- a) If O₂matic 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.
- b) 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.
- c) The O₂matic HOT and the pulse oximetry sensor should only be used by the patient with the ordination.
- d) Avoid using nail polish nails when using pulse oximetry sensor. Nail polish can cause impaired reading functionality of the pulse oximetry sensor.
- e) 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.
- f) Extended exposure to the device(s) may cause irritation to the skin, pyrogenicity or trigger allergies.
- g) During treatment the device should always be turned on.
- h) To avoid disconnecting please keep the device away from pets, pests and children.
- i) If the device has not been used in a while leave the device on for 30 seconds before using it.

1.3 Safety

The O₂matic HOT has a failsafe rechargeable battery that keeps the device running upon short power breaks. To shut down the O₂matic HOT 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 will be assigned a dedicated tablet which will have the O₂matic HOT 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.

1.4 Disclaimer

O₂matic cannot assume responsibility for patient safety, upon:


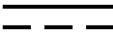





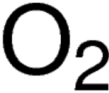


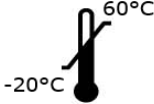



- Any sign or evidence of opening the O₂matic HOT, except by authorized personnel.
- Use of any unapproved pulse oximeters.
- This IFU has been issued in compliance with requirements set out in Council Directive 93/42 EC concerning Medical Devices.
- All liability is discontinued if the product is not used as intended and as described in this IFU.

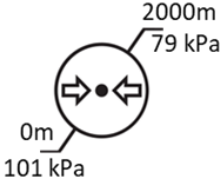
1.5 Label and Symbols



Figure 2: O₂matic label found beneath

The labelling on the device are 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.

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

 <p>2000m 79 kPa</p> <p>0m 101 kPa</p>	<p>For use in altitudes 0 - 2000 m</p>

	<p>objects and vertically Dripping water when tilted at 15°.</p>
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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

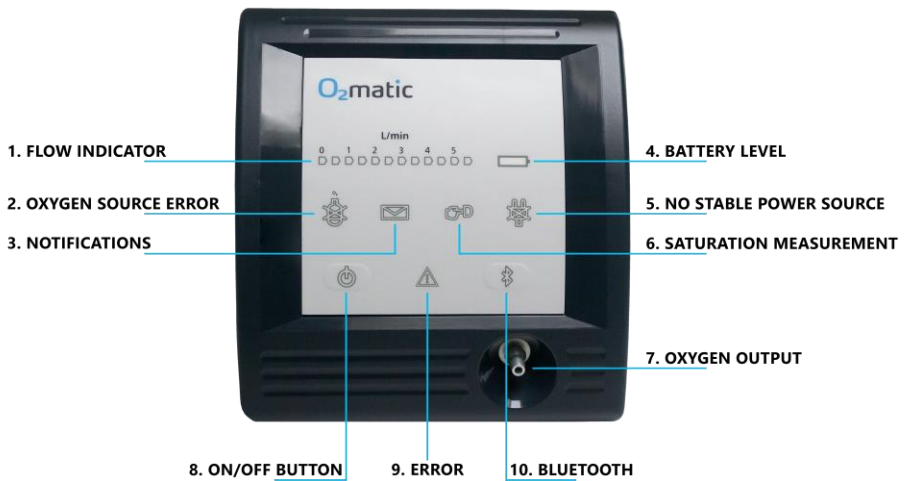




Figure 3: Front of O2matic

	<p>1. FLOW INDICATOR</p> <p>Shows the amount of oxygen currently being delivered. If the amount of oxygen the device is delivering is different from the expected amount, the device will light up two values. One value is blinking which refers to the expected amount of oxygen. The other will light up statically, which indicates how much oxygen is currently being delivered.</p> <p>Upon start up, two values are lit for 3 seconds, indicating the flow limitations for current device configuration.</p>
	<p>2. OXYGEN SOURCE ERROR</p> <p>Check oxygen source.</p>
	<p>3. NOTIFICATIONS</p> <p>Check your App for more information.</p>
	<p>4. BATTERY LEVEL</p> <p>Green blinking: Charging Green: Battery status good Yellow: Battery status low. Connect to power source when possible Red: Battery status critical. Connect to power source immediately Red blinking: Battery fail. Contact service provider</p> <p>Function of the device is not affected by the device being connected to power or not.</p>
	<p>5. NO STABLE POWER SOURCE</p> <p>Connect to stable power source when possible.</p>
	<p>6. SATURATION MEASUREMENT</p> <p>Constant lid: Put pulse oximeter on finger. Treatment will start. Blinking: Signal is lost, reconnect by adjusting your finger. Off: Session finished. Take pulse oximeter off finger.</p>
	<p>7. OXYGEN OUTPUT</p> <p>Connect your oxygen mask here.</p>
	<p>8. ON/OFF BUTTON</p> <p>The button will light up when the device is turned on.</p>

	<p>9. ERROR Stop using the device and contact your service provider.</p>
	<p>10. BLUETOOTH When connected to the app this symbol will light up.</p>

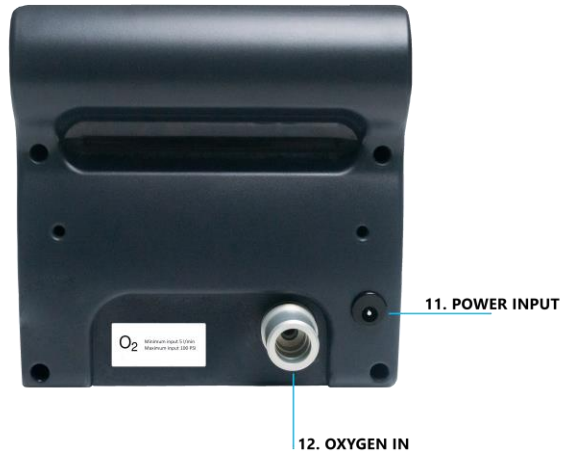



Figure 4: Back of O₂matic

	<p>11. POWER SUPPLY Here is where the power supply should be connected. By connecting the other end to a power source, the device will recharge its batteries and avoid running out of power. Connect the device to a power source and do not turn off the device while it is charging.</p>
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**12. OXYGEN IN**

Connect your oxygen source to this socket to ensure the device can receive and regulate the oxygen flow.


2.2 Installation

To install O₂matic HOT:

- a) Place the O₂matic HOT near yourself at a flat surface, such as a table.
- b) Connect the AC power adapter to the wall outlet and to the O₂matic HOT device power plug.

**Warning**

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

- c) 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 O₂matic HOT.
- d) Connect the oxygen output to your oxygen mask or nasal cannula and put on the mask.
- e) Turn on the O₂matic HOT by pressing and holding down  for 4 seconds.

The O₂matic HOT device 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.





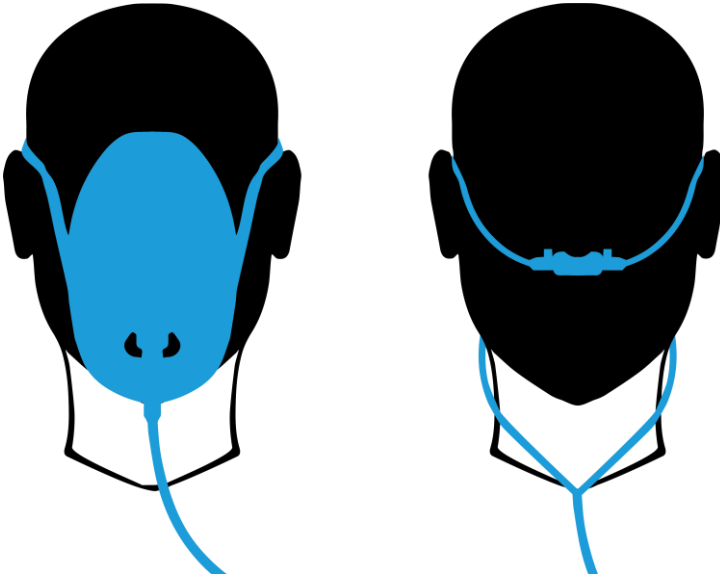



Figure 5: Oxygen mask and nasal catheter appliance

	<p>Warning O₂matic HOT is only to be used with pure 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 device and connecting it to your smartphone or tablet.

Turn on the O₂matic HOT by pressing  **for more than 4 seconds**. The green light on the on/off button indicates that the O₂matic HOT device is turned on.

The O₂matic HOT 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. O₂matic HOT has an intelligent algorithm that only needs a few daily measurements of oxygen saturation. The number and the length of measurements can vary from time to time. If oxygen source is a concentrator make sure its set to the maximum flow.



Warning

Only the patient should be connected to the pulse oximeter. By not complying with this the patient could risk receiving the wrong treatment.



Warning

The patient should only use one pulse oximeter at a time.



Caution

The HOT spends the first five minutes after turning on measuring exclusively. If the signal during this period is interrupted for more than one minute, the process must be repeated from the beginning.

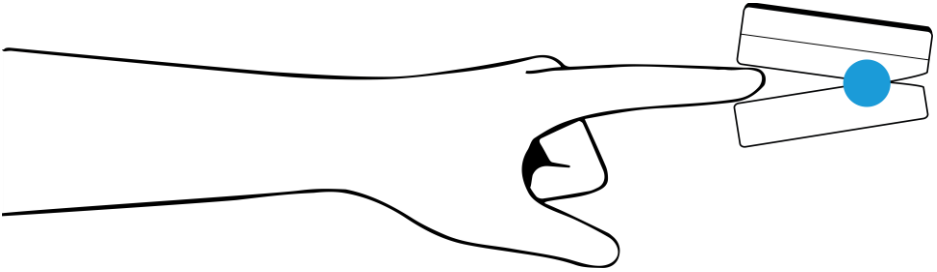



Figure 6: Pulse oximetry demonstration

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 the O₂matic HOT device has been turned off, then a new measurement is required.

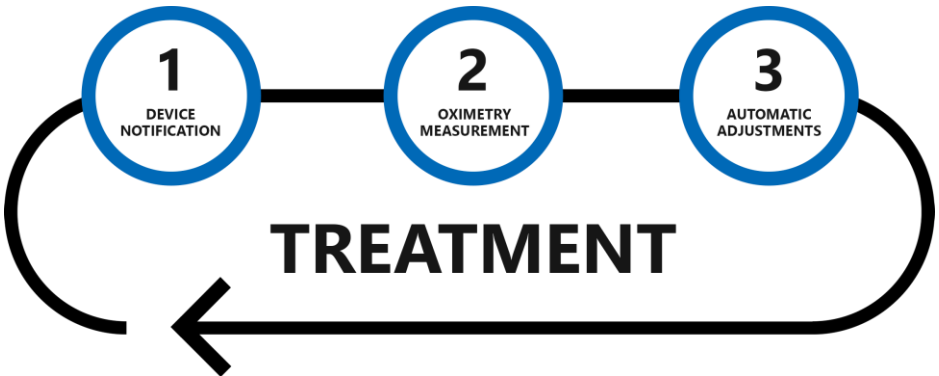



Figure 7: O₂matic treatment cycle

No one else but the patient shall use the pulse oximetry sensor that is paired with O₂matic HOT.


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 O₂matic device is dropped down from above 30 cm, then the device shall be checked by installer.</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.

	<p>Warning</p> <p>Never smoke during treatment. This can inflict serious injuries.</p>
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	<p>Warning</p> <p>Never use any flammable products on the patient as this can cause serious injuries.</p>
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	<p>Warning</p> <p>O₂matic HOT device shall be functional in altitude range 0 to 2.000 meter</p>
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If the patient feels ill or uncomfortable, the patient shall always contact their service provider.

To properly shut down the O₂matic press  for more than 5 sec. The light in the on/off button turns off, when the device is turned down.

3.1 Connecting your tablet or smartphone to O₂matic

The O₂matic HOT is designed to be as simple as possible and for maximum safety. The device can be used stand-alone without any apps.

If you are interested in additional information and trends, you can always connect your Android smartphone or tablet to the O₂matic HOT. It requires that your device has as a minimum **Bluetooth**® 4.2 and is using Android O₂matic BYOD App.

Start by downloading the app from Google play:


<https://play.google.com/store/apps>


Search for "O₂matic BYOD" and install the app on your device. Then follow the instructions on the app.

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 device is malfunctioning or does not provide the correct treatment, please contact your service provider.</p>
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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	1850 g
Dimensions	205x265x95 mm
Connection	Bluetooth
Alarm volume	56 DB

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 – 5 l/min (measured down to 0,1L/min accuracy)

General

Expected service life	5 years
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6 Troubleshooting

The acoustic sounds that are initiated by the O2matic HOT all follow a basic system, which makes it easy to distinguish between actions needed to be taken.

There are 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.
- b. If the patient is using an oxygen tank, make sure there is still oxygen in it.
- c. See if any hoses are bend/pinched or otherwise 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

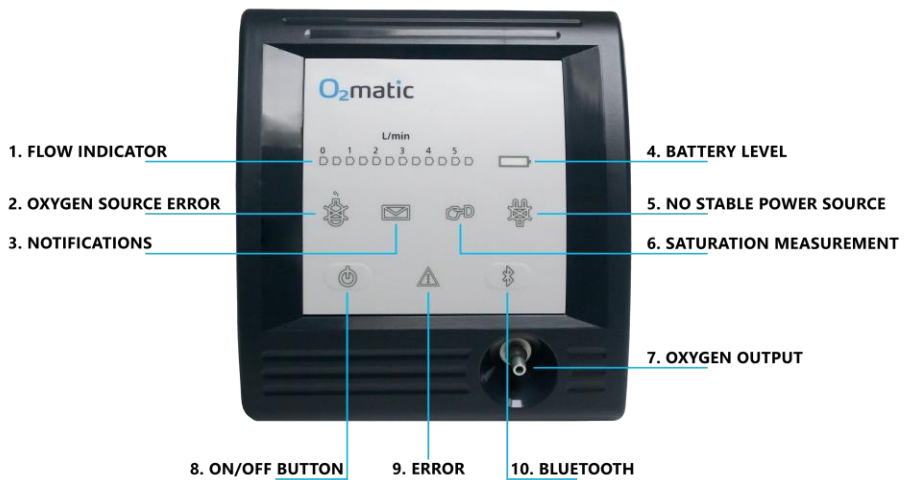
- a. Restart device and smart device.
- b. If the problem persists, contact your service provider.

4. Oxygen concentrator alarming

- a. If you are using an oxygen concentrator and it is alarming check if the 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.

Notes

Notes



This user manual booklet is current as of October 2020. For more information of device updates and news please visit www.o2matic.com

Change Log

Version	Date	Document Change Description
01	2020.01.23	<ul style="list-style-type: none"> • First version
02	2020.03.20	<ul style="list-style-type: none"> • Second version
03	2020.03.24	<ul style="list-style-type: none"> • Third version, generally stripped the document of all unnecessary information for the user (patient)
04	2020.03.24	<ul style="list-style-type: none"> • Marked unresolved sections with yellow
05	2020.04.01	<ul style="list-style-type: none"> • Figures and images have been updated
06	2020.05.15	<ul style="list-style-type: none"> • Added and corrected various requirements to the IFU.
07	2020.05.20	<ul style="list-style-type: none"> • Fonts and spacing have been adjust and new graphics have been added.
08	2020.09.01	<ul style="list-style-type: none"> • Added recommended reading distance regarding labels, to the "1.2 labels & symbols" sub-chapter. In the same chapter "IPX2" has been changed to "IP22" and a new description to the symbol has been added.
09	2020.09.10	<ul style="list-style-type: none"> • Fall back mode described in section 1.1 • Flow range indication described in section 2
10	2020.10.29	<ul style="list-style-type: none"> • Trademark and disclaimer sub-chapters added • General proofreading changes • Restructure the document

D 8.4.1.10

		<ul style="list-style-type: none">• Update images to current versions of device/software/label/other• Troubleshoot section added• Layout changed as preparation for print
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