User Manual

Oxitone 1000M

Spot check wrist worn pulse oximeter

CAT.NO.OM2002

25.01.2021

Rev. 1.2

Important

This user guide is subject to periodic review, update and revision. Customers are cautioned to verify that the manual's information applies to the software and hardware present in the equipment.

The product performs as described and in accompanying labels when assembled, operated, maintained and repaired in accordance with the instructions provided.

This product must be cleaned and checked periodically. Do not use a defective product. Parts that are broken, missing, plainly worn, distorted or contaminated should be replaced immediately. Do not repair this product or any of its parts other than in accordance with written instructions provided by Oxitone.

The user of this product shall have the sole responsibility of any malfunction that results from improper use, faulty maintenance, improper repair, unauthorized service, damage or alteration by anyone other than Oxitone.

Oxitone Medical Ltd. Is liable for the safety, reliability or the performance of this instrument only if:

- The instrument has been used according to the accompanying operating instructions.
- Any fittings, readjustments, changes or repairs have been carried out by Oxitone Medical Ltd. authorized representatives or agents.

Information provided by Oxitone is believed to be accurate and reliable. However, Oxitone assumes no responsibility for the use of such information nor for any infringement of patients or other rights for third parties, that may result from its use.

This user guide is intended to provide the necessary information for proper operation of the Oxitone 1000M 

Caution: Federal law (U.S.) restricts this device to sale by or on the order of a licensed physician.

For further information contact:
Oxitone Medical Ltd.
17 Atir Yeda Street - Kfar Saba, Israel 4464312
Office: +972-9-8346731 Fax: +972-9-7998172
Email: info@oxitone.com
E-mail: Oxitone@Oxitone-medical.com
Web Site: http://www.Oxitone-medical.com

CE Notice

Marking by the CE symbol indicates compliance of this device with the European Medical Device Directive 93/42/EEC concerning Medical Devices. This non-invasive pulse oximeter is designed according to the international standard ISO13485:2016, medical devices.

EC REP

EU authorized representative for Oxitone Medical Ltd.:
MedNet EC-REP GmbH
Borkstraße 10 | 48163 Münster | Germany
www.mednet-eurep.com

UDI: (01) 07290017350004

Rev.	Date	History Change
1.0	4 April 2020	Initial Document
1.1	16 Aug 2020	Correct and add that under normal conditions, the battery will lose less than 25% capacity after lasts for approximately 300 charge/discharge cycles instead of 250 charge/discharge cycles. Correct capacity to Approximately 24 hours after full charge. Update Logo
1.2	25 Jan 2021	Update EC REP name, Update Logo, Correct UDI, update charger label and monitor label.

Disclaimer

Information provided by Oxitone Medical Ltd. is believed to be accurate and reliable. However, Oxitone Medical Ltd. assumes no responsibility for the use of such information, nor for any infringements of patents or other rights of third parties, that may result from its use.

PLEASE READ THIS USER MANUAL BEFORE OPERATING THE SYSTEM.

Table of Contents

1. ABOUT THIS USER MANUAL

This User Manual provides the information necessary to operate and maintain the Oxitone 1000M wrist worn pulse oximeter device.

PLEASE READ THIS USER MANUAL BEFORE OPERATING THE SYSTEM. If any part of this User Manual is not clear, contact Customer Support for assistance.

PLEASE RETAIN THIS USER MANUAL FOR FUTURE REFERENCE.

1.1. TYPES OF WARNINGS, CAUTIONS AND NOTES

Three types of special message appear in this User Manual:

Warning: A warning indicates precautions to avoid the possibility of personal injury or death.

Caution: A caution indicates a condition that may lead to damage to equipment, or a lower quality of treatment.

Note: A note provides other important information.

2. OVERVIEW OF SYSTEM

2.1. DESCRIPTION OF DEVICE

The Oxitone 1000M wrist worn pulse oximeter is a small, lightweight, portable device that non-invasively monitors and displays numeric values of arterial blood functional oxygen saturation of arterial Hemoglobin (%SPO_2) and pulse rate (P.R.). It is intended for spot-checking on adult patients (18 years and above) in the hospital, clinics, long-term care and home use. It is not provided sterile nor can it be sterilized.

Auxilary measurement
The Oxitone 1000M direct mode skin temperature sensor is designed for use in routine continuous monitoring of skin temperature when the other sensors which might better reflect core body temperature are not available. The sensor is designed for placement on the surface of the wrist hand skin.

Principles of operation
The Oxitone 1000M pulse oximeter uses a two-wavelength pulsatile system-red and infrared light-to distinguish between oxygenated (O_2Hb) and reduce (HHb) hemoglobin, each of which absorbs different amounts of light emitted from the oximeter sensor. The system then calculates the relative percentage of these two constituents and displays functional SpO_2. The skin temperature sensor is placed on the surface of the skin and is a part of the plastic enclosure that provides thermal insulation (isolated from ambient temperature) for more accurate skin temperature measurement.

Important note:
Skin temperature:
Temperature of the skin of the PATIENT at a point on which the sensing device intended to measure the temperature is placed [SOURCE: IEC60601-2-19:2009]. The Oxitone 1000M can measure skin temperature as a relative indication of surface temperature. It is not intended to be used to indicate core body temperature or to measure a fever.

Features and benefits
- Simple, intuitive operation
- Automatic self-test at start-up. After start-up, the monitor continuously performs background self-tests.
- Compact, durable, lightweight, ergonomic hand wrist attached.
- Spot check tests results in up to 15 seconds.
- Recharge battery operation for approximately 24 hours.
- Easy-to-read **OLED** display in subdued lighting conditions.
- Battery status reporting.
- Vibration shaker (ERM) for On/Off, battery depletion and system error.
- The device requires no calibration or maintenance other than battery recharging.

Spot-on connectivity
- Easily integrates into most telemedical devices via BLE smart wireless technology (PC APP).

3. CONDITIONS FOR USE

3.1. INDICATIONS FOR USE

The Oxitone Model 1000M Pulse Oximeter is a small, wrist-worn device indicated for use in measuring and displaying functional oxygen saturation of arterial hemoglobin (% SpO2) and pulse rate. It is intended for spot-checking of adult patients with wrist between 13-22 cm circumferences in hospitals, clinics, long-term care, and home use.

3.2. CONTRAINDICATIONS

See Sec' 4.3 Safety Instructions

3.3. OXITONE 1000M BLE CONNECTIVITY

BLE Technology

BLE (Bluetooth Low Energy) technology allows wireless connections between electronic devices. The technology is based on a radio link that offer fast and reliable data transmissions. BLE uses a license-free, globally available frequency range in the ISM band-intended which ensures communication compatibility worldwide.

Oxitone's use of BLE technology allows all the device's measurements to be transmitted compatible BLE-enabled device. BLE connectivity gives patients increased ability to move freely.

Oxitone 1000M use of BLE wireless technology allows SpO_2 and pulse rate data to be transmitted through a Bluetooth radio to a compatible Bluetooth-enable device.

4. SAFETY

4.1. ELECTRICAL SAFETY

The device complies with requirements of IEC/EN 60601-1 for general requirements for safety of medical electrical equipment:

- Class II Equipment type BF applied part
- Mode of operation: Spot check
- Degree of mobility: Portable.

4.2. EMC COMPLIANCE

This device has been tested and found to comply with the IEC60601-1-2:2007 standard and with CISPR 11:2009+A1(10) Group 1 Class B limits

4.3. SAFETY INSTRUCTIONS

Warnings

Do not use with patients with significant deformity, swelling, irritation, degenerative changes or edema of the hand wrist.

Do not use with patients with localized infection, ulceration or skin lesions involving the wrist.

Do not use with patients that have restricted blood flow e.g. tourniquet, pressure cuff or IV line.

Do not use with patients with tremors or convulsions.

Do not use with patients with peripheral vascular disease affecting the hands.

Do not use with neonatal or pediatric patients.

This device is not defibrillation proof per IEC60601-1.

Do not use the device in an MR environment or in an explosive atmosphere.

In case of discomfort, inspect the device sensor application site to ensure correct sensor alignment and skin integrity.

Avoid excessive pressure to the sensor application site as this may cause damage to the skin beneath the sensor (device straps tighten).

The Oxitone 1000M is located on the patient wrist to activate the device properly. Check the application site every 4 hours for skin integrity. If there is any concern, remove the Oxitone 1000M and replace with another pulse oximeter with a different application site.

Patient sensitivity varies depending on medical status or skin condition.

This device is intended only as an adjunct in patient assessment it must be used in conjunction with other methods of assessing clinical signs and symptoms.

- The device must be able to measure the pulse properly to obtain an accurate SPO2 measurement. Verify that nothing is hindering the pulse measurement before relying on the SPO2 measurement.
- Operation of this device below the minimum amplitude of 0.3% modulation may cause inaccurate results.
- General operation of the device may be affected by the use of an electrosurgical unit (ESU). This device should not be used adjacent to other equipment. If adjacent use is necessary, the device should be observed carefully to verify normal operation.
- Keep the oximeter away from young children.
- Oxitone 1000M monitor is intended for indoor operation.
- The monitor should not be used as a substitute for laboratory blood analyzer.
- Do not use before reading and understanding this user guide.
- Not for use in shower, bath tub, sink or pool.
- Excessive device wearing pressure for prolonged periods can induce pressure injury.
- Only apply the device on clean, intact wrist skin.
- Do not use the Oxitone 1000M outside the declared environmental conditions (see Section *Error! Reference source not found.*). Operating the device outside the declared environmental conditions can lead to incorrect measurements.
- Do not use the device when alarms are required.

Cautions

- The device is designed to determine the percentage of arterial oxygen saturation of functional hemoglobin. Factors that may degrade pulse oximeter performance or affect the accuracy of the measurement include the following:
  - * Improperly applied device
  - * Jewelry or ornaments on the tested hand wrist
  - * Poor pulse quality
  - * Excessive motion
  - * Methemoglobin (Met Hb)
  - * Cardio green or indocyanine and other intravascular dyes
  - * Anemia or low hemoglobin concentrations
  - * Carboxyhemoglobin (COHB)
  - * Venus pulsation
  - * Dysfunctional hemoglobin
  - * Avoid Excessive light such as sunlight or direct home lighting and pulsating strobe lights
- The device has no audible alarms and is intended for spot-checking.
- The device may not work when circulation is reduced. Warm or rub the hand wrist area to increase perfusion.
- The device is designed to be attached to either hand wrist.

- To avoid the risk of confusing or misinterpreting patient data when transmitting data via Bluetooth, verify the device is paired with the correct display unit.
- Clean the device before applying it to a new patient (See section ***8. Cleaning and Disinfecting***)
- Do not sterilize, autoclave, or immerse this device in liquid. Do not pour or spray any liquids into the device.
- Do not use caustic or abrasive cleaning agents, or any cleaning products containing ammonium chloride or isopropyl alcohol.
- Do not use cleaning solutions other than those recommended here, as permanent damage could result (See Section ***8. Cleaning and Disinfecting***).
- The device should not be used as a replacement or substitute for ECG based arrhythmia.
- Pulse rate measurement is based on the optical signal detection of a peripheral blood flow pulse and therefore may not detect certain arrhythmias.
- Do not expose the Oxitone 1000M to excessive moisture such as direct exposure to rain. Excessive moisture can cause the monitor to perform inaccurately or fail.
- This device is a precision electronic instrument and must be repaired by Oxitone qualified technical professionals. Field repair of the device is not possible. Do not attempt to open the case or repair the electronics. Opening the case may damage the device and void the warranty.
- A functional tester on the market cannot be used to assess the accuracy of the pulse oximeter monitor.
- The equipment complies with IEC60601-1-2 Class B for electromagnetic compatibility for medical electrical equipment and / or systems. This standard is designed to provide reasonable protection against harmful interference in a typical medical installation. However, because of the proliferation of radio frequency transmitting equipment and other sources of electrical noise in health care and other environments, it is possible that high levels of interference due to close proximity or strength of a source might disrupt the performance of this device. Medical electrical equipment needs special precautions regarding EMC, and all equipment must be installed and put into service according to the EMC information specified in this manual – see Section ***11.1.1. Manufacturer's Declaration (EMC***).
- Radios and cellphones can affect the device and must be kept at least 10 meters (33 feet) away from the device.
- Portable and mobile RF communications equipment including CT, MRI, diathermy, RFID, and electronic article security systems can affect medical electrical equipment.
- Follow local, state, and national governing ordinances and recycling instructions regarding, disposal or recycling of the device and device components, including batteries.
- In compliance with the European Directive on Waste Electrical and Electronic equipment (WEEE) 2002/96/EC, do not dispose of this product as unsorted municipal waste. This device contains WEEE materials; please contact your distributor regarding return or recycling of the device. If you are unsure how to reach your distributor, please call Oxitone Medical Ltd. for your distributor's contact information.
- Do not disassemble any part from the device.
- Do not use if the device casing is damaged.
- This monitor is not user-serviceable.

- Not for use in the presence of a flammable anesthetic.
- Oxitone 1000M use of Bluetooth wireless technology allows SpO_2 and pulse rate data to be transmitted through a Bluetooth radio to a compatible Bluetooth device giving patience increased ability to move freely – without being hindered by cables. Oxitone 1000M module uses a Bluetooth radio with a range of about 10 meters (33 feet) (spherical radius). Moving outside this range may cause missing or lost data.
- Skin temperature values is not body core temperature (vital sign).

5. SETTING UP THE SYSTEM

5.1. SYSTEM COMPONENTS

The components of the Oxitone 1000M system are shown below:

Wrist device – front view 5.1.1

Wrist device – rear view 5.1.2

Battery charger

5.2. PREPARING FOR USE

To operate the Oxitone 1000M effectively, the operator must:

- Be familiar with its controls and operation.
- Understand its status and messages (see Section ***6.1. Monitoring Screen and Display Symbols*** and Section *Error! Reference source not found.*).

Caution: The Oxitone 1000M is designed to operate on adult patients with wrist between 13-22 cm circumferences.

5.2.1. INITIAL SETUP

- Inspect the Oxitone 1000M case for damage.
- Fully charge the device – see Section ***9.1. Charging the Battery***.

Note: The initial battery charge can take up to 2 hours. The battery should be recharged as needed, before the Oxitone 1000M can be used.

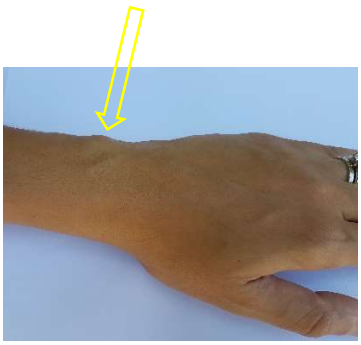
5.3. PUTTING ON THE WRIST WORN DEVICE

Note: Make sure the device is fully charged before wearing it. See Section ***9.1. Charging the Battery*** for charging instructions.

Place the device on your hand wrist with the **optical aperture elastic concave surface** (see below) on top of the *Ulna bone* (the knobby protrusion of the wrist). The ON/OFF switch and the company logo will face towards you.

Then secure the oximeter device by fastening the straps for stable and comfortable use. Avoid excessive pressure to the monitor application site as a result of fastening the straps too tightly.

Optical aperture elastic concave surface



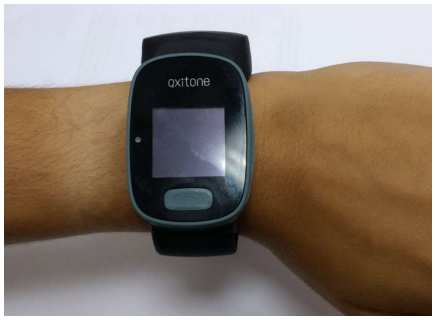
left-hand Ulna bone

Caution: Proper placement on your wrist is essential for SpO2 measurements.

Note: The device cannot be worn with the battery charger.

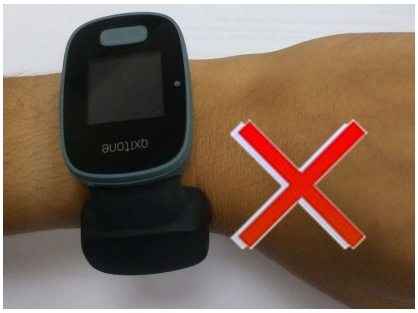
Note: If the device does not turn on, refer to “troubleshooting” for additional information.

CORRECT PLACEMENT



Correct placement of device, with the U-shaped part of device on top of the Ulna bone

INCORRECT PLACEMENT

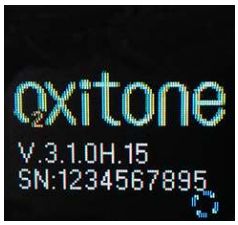


Incorrect – device upside down

5.4. POWER ON AND DISPLAY STARTUP SCREEN

To start the system, press the **Power On** button on the front of the device for ½ a second:

The OLED screen will be illuminated and after releasing the button, the Oxitone logo will briefly appear:



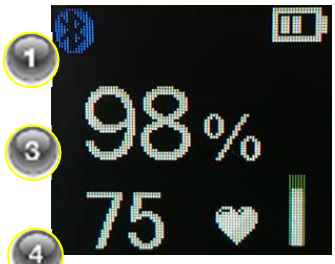
The Measurement in Progress screen will be displayed for a few seconds, during which the user must stay still in order to get a first measurement:

6. MONITORING

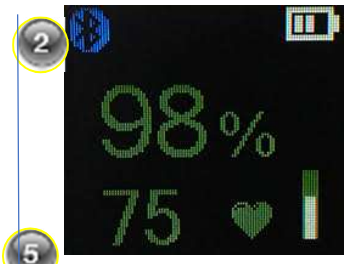
6.1. MONITORING SCREEN AND DISPLAY SYMBOLS

Note: After 30 seconds, the screen display will automatically turn off. To switch display on, press the button. Alternatively, you may turn your wrist in the natural motion of viewing a watch, and the display will become visible.

After a brief pause, while the system is collecting information, the monitoring screen displays:



Monitoring screen – active monitoring



Monitoring screen –oxygen monitoring inactive

Note: When the system is not monitoring a value, the value is grayed-out.

1	**Blue Tooth connection status**	
		Blue Bluetooth symbol, indicates the device is connected to another device.
		Red Bluetooth symbol, indicates there is a problem with the BLE component, if the indication persists after a power cycle, the device needs servicing at Oxitone's service center.
		White Bluetooth symbol, indicates the BLE is functioning but not connected.
2	**Battery charge level indicator**	
		Low battery. Recharge battery
		Critical battery depleted. After the device will issue a warning, it will turn off after 30 seconds
		Full charged battery

3	**Amount of oxygen in your blood (functional oxygen saturation of arterial hemoglobin)**	**98 %**	System is monitoring OK
		98 %	System is not monitoring (value is grayed-out)
4	**Your pulse rate. Pulse rate is the number of times your heart beats per minute.**	**65** ♥	System is monitoring OK
		65 ♥	System is not monitoring (value is grayed-out)
5	**Signal strength indicator**		Relative signal strength

6.1.1 **BLE Roles:**

BLE roles are split into pre-connection and post-connection.

Pre-connection

At startup the Oxitone 1000M is either a peripheral or a central.

- A peripheral advertises itself and waits for a central to connect to it.
- A central scans for other devices, a central is usually a smartphone PC.

After a peripheral makes a connection it's called a slave, after a central makes a connection it's called a master.

Post connection

After a BLE connection has been established, devices can be either a client or a server.

- A client accesses remote resources, a client is usually the master (host).
- A server has a local database of resources (profiles/services/characteristics), if provides resources to the remote client. A server is usually a slave.

A client sends read and write operations to the server, and the server responds with data.

A server can send data to the client without a read/write request using indicate and notify operations.

Oxitone 1000M has the role of a peripheral (server/slave).

6.1.2 **Spot Checking**

The oximeter device will start to measure and display values of % SpO_2 and pulse rate (bpm) at refreshing intervals of one second (SpO_2 averaging time is 12 seconds). In order to insure optimum accuracy, please note the following:

- Do not secure the device with tape.
- Ensure that the tested hand has unrestricted blood flow.
- Do not select a testing site near potential electrical interference.

FREQUENCY OF INSPECTION OF APPLICATION SITE FOR SKIN INTEGRITY

Inspect the application site, for intact skin, every four hours. If there is any change in the skin integrity, remove the Oxitone 1000M to alternate wrist site.

6.2. NUMERIC DISPLAY – SPO2

A SpO2 reading is associated with correct device placement, measuring small physiological changes during the measurement, and acceptable levels of arterial perfusion at the measurement site. Inaccurate measurements may be caused by:

- Elevated levels of carboxyhemoglobin (COHb)
- Elevated levels of methemoglobin (Met Hb)
- Intravascular dyes such as indocyanine green or methylene blue
- Elevated levels of Bilirubin
- Severe anemia
- Low arterial perfusion
- Motion artifact

6.3. NUMERIC DISPLAY – PULSE RATE

The pulse rate displayed on the Oxitone 1000M may differ slightly from the heart rate displayed on ECG monitors due to differences in averaging times.

Power off	NA	Strong click, aprox. 200msec

6.4. TIME SCREEN

A brief tap on the button will display the Time screen:

If you tap the button again, the Steps screen will display (see below). Otherwise, after 30 seconds the Measurement screen will automatically be displayed.

6.5. STEPS SCREEN

While viewing the Time screen, tap briefly on the button to display the Steps screen:

Note: Steps are calculated for the current day, from 12 am to 12 pm. At 12 am the Steps value is automatically reset to zero.

After 30 seconds, the Measurement screen will automatically be displayed.

Note: steps monitoring defines as general wellness product. Intended for only general wellness use.

6.5.1 Skin Temperature

SKIN TEMPERATURE SCREEN

While viewing the Steps screen, tap briefly on the button to display the Skin Temperature screen:

The skin temperature value is updated every one second.

In case of temperature sensor malfunction, dashes will be displayed.

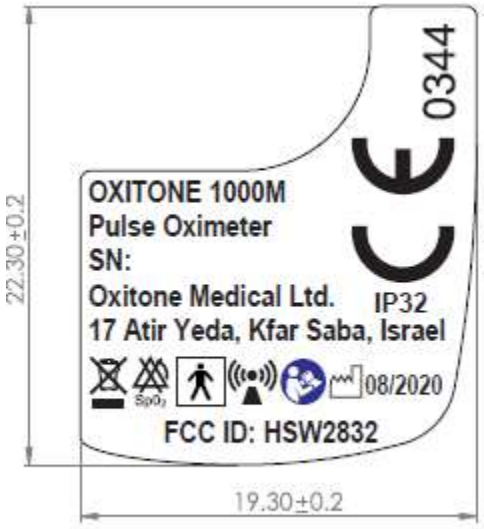
After 30 seconds, the Measurement screen will automatically be displayed.

6.6. ALARM AND MESSAGES

Event	Message type and duration	Vibration type and duration
Power on	Oxitone logo and version number is displayed for aprox. 5 seconds	Strong vibration for 1 second
Signal acquisition on power up	"Stay still measurement in progress" message displayed until first measurement is obtained	NA
Battery depleted	"Low battery level" Pop up message for 15 seconds (or button press). 	Strong buzz for aprox. 350msec
Battery Critical	"Please recharge battery" Pop up message, until auto power off after 30 seconds. 	Strong buzz for aprox. 350msec
BLE connection request	"Press button to connect to…" Pop up message for 15 seconds (or button press if user confirms). 	Strong buzz for 750msec
No power to charger	"Please connect charger to wall outlet" Pop up message until power applied	Strong buzz for aprox. 350msec
Charger fault	"Charger fault detected" Pop up message until charger disconnects	Strong buzz for aprox. 350msec
System Error	"#xxx Service required" Pop up message, requires reset to remove. 	1 Second

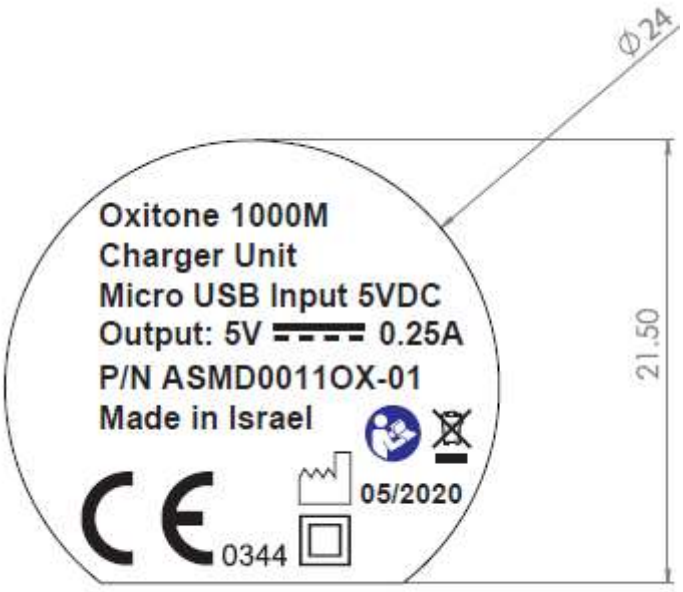
7. LABELS AND SYMBOLS

7.1. DEVICE LABEL



SCALE 4:1

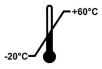
7.2. CHARGER LABEL



SCALE 4:1

7.3. SYMBOLS

A number of internationally recognized symbols are found on the labels. These relate to safety requirements and standards and are described below.

Symbol	Meaning
	Follow instructions for use
	Consult instructions for use
	Type BF Applied Part (Patient isolation from electrical shock)
	CE marking indicating conformance to EC Directive No. 93/42/EEC concerning medical devices
	Authorized representative in the European Community
	Indicates separate collection for electrical and electronic equipment (WEEE)
	Not for continuous monitoring (no alarm for SpO_2)
IP32	Protected against vertically falling water drops and ingress of solid foreign objects greater than or equal to 2.5mm (0.1in.) in diameter per IEC 60529
SN	Manufacturer Serial number
	Storage / Shipping temperature range of -20°C to 60°C
	Federal law restricts this device to sale by or on the order of a physician (USA audiences only)
	Date of manufacture
	Double isolation (charger unit)
	Bluetooth figure mark
	Non-ionizing electromagnetic radiation. Equipment includes RF transmitters. Interference may occur in the vicinity of equipment marked with the symbol.
	Symbol for manufacturer name and address

8. CLEANING AND DISINFECTING

This instrument requires routine cleaning, which includes removal of any soil or dirt from the external surfaces. A soft cloth dampened lightly with water may be used.

In-between patients the Oxitone 1000M should be cleaned and low-level disinfected.

To clean, wipe the device surfaces with a soft cloth swab moistened in ethyl alcohol. Note that ethyl alcohol is considered both a cleaning agent and a low level disinfecting agent

To low-level disinfect the device after each patient, follow these steps:

- Remove the device from the patient.
- After cleaning any visual debris from the surface of the device, again thoroughly wipe the surface with an ethyl alcohol (70-85%) swab and a long Q-tip.
- Allow the device to dry completely before returning it to operation.


Caution: The system is approved for IPX0. To avoid damage to device, be careful of liquid spillage while cleaning.


Caution: To avoid damage to the surface of the instrument, take care not to scratch the display while cleaning.


Caution: Turning off the device before cleaning.


Caution: Remove any substances or material that may interfere with the transmission of light.


Caution: Clean and low level disinfect the device before applying it to a new patient.


Caution: Do not sterilize, autoclave, or immerse this device in liquid. Do not pour or spray any liquid into the device.


Caution: Do not use caustic or abrasive cleaning agents, or any cleaning products containing ammonium chloride, isopropyl alcohol, petroleum-based or acetone solutions.


Caution: Do not use cleaning solution other than those recommended here, as permanent damage could result.


Caution: Alcohols are volatile and flammable and must not be used near open flames.

9. SERVICE AND MAINTENANCE

Note: The user or any technical personnel who are not formally authorized by Oxitone Medical Ltd. should not open the device under any circumstances. Opening the device could damage the unit and will void the warranty provided by Oxitone Medical Ltd.

The System does not require maintenance or service on a routine basis, except as suggested in this User Manual. It is expected that the internal Batttery will last for minimum 300 recharging cycles, or 3 years. Service should only be provided by an authorized Oxitone Medical Ltd. representative.

9.1. CHARGING THE BATTERY

The Oxitone 1000M device contains a rechargeable 3.7 volt lithium polymer battery. Before using the device, the battery must be fully charged.

To charge the battery, perform the following steps:

- Attach the monitor (wrist worn) unit to the charger (docking station) by sliding the monitor into the charger opening, until you hear the secure click to ensure good electrical contact.
- Plug in the DC power (5V) cord to the charger power entry connector (micro USB). Make sure it is securely plugged in.
- Plug the DC power module into an AC power source.
- Verify that the battery is charging.

Under normal conditions, the battery will lose less than 25% capacity after lasts for approximately 300 charge/discharge cycles

To obtain maximum battery life, charge the monitor battery whenever it is not used. The battery will not overcharge.

Cable Micro USB and adaptor

Charger and wall connector

9.2. ACTIVATE BLUETOOTH RADIO

Connecting to Oxitone 1000M

- Whenever the Oxitone 1000M (client/host) tries to connect for the first time to the watch, the Oxitone 1000M (watch) will vibrate and display a message to the user that a device (the device name will be displayed on the screen) tries to connect to it.

- If the user presses the button (accepts the connection) the devices will be connected, and the watch will start searching the measurement data to the host.
- If 15 seconds passed and the user did not accept the connection, the watch will reject the connection request. The device that tried connecting to the watch will not be able to connect for a whole minute (to prevent multiple connection requests).
- After the first time the user accepts a connection, the host ID is saved to the watch, and the next time the same host will try to connect, the user will not be asked to accept the connection (the connection will be approved automatically). The watch "Remembers" only one host at a given time.

9.2.1 BLE Connectivity Overview

BLE Technology
BLE (Bluetooth Low Energy) technology allows wireless connections between electronic devices. The technology is based on a radio link that offers fast and reliable data
transmissions. BLE uses a license-free, globally available frequency range in the ISM band, which ensures communication compatibility worldwide.
Oxitone's use of BLE technology allows all the device's measurements to be transmitted compatible BLE-enabled device. BLE connectivity gives patients increased ability to move freely.

BLE indications
There are 3 indication of the BLE state:
White BLE symbol - indicates the BLE is functioning but not connected.
Blue BLE symbol - indicates the device is connected to another device.
Red BLE symbol - indicates there is a problem with the BLE component, if the indication persists after a power cycle the device needs servicing in Oxitone service center.

BLE Roles
BLE roles are split into pre-connection and post-connection:

Pre-connection
At startup a device is either a peripheral or a central.
A peripheral advertises itself and waits for a central to connect to it.
A central scans for other devices, a central is usually a smartphone or PC.
After a peripheral makes a connection it’s called a slave, and after a central makes a connection it’s called a master.

Post-connection
After a BLE connection has been established, devices can be either a client or a server.
A client accesses remote resources, a client is usually the master (host).
A server has a local database of resources (profiles/services/characteristics), it provides resources to the remote client. a server is usually the slave.

A client sends read and write operations to the server, and the server responds with data.
A server can send data to the client without a read/write request using indicate and notify operations.

Oxitone 1000M has the role of a peripheral (server/slave)

Connecting to Oxitone 1000M

- Whenever a device (client/host) tries to connect for the first time to the watch, the watch will vibrate and display a message to the user that a device (the device name will be displayed on the screen) tries to connect to it.
- If the user presses the button (accepts the connection) the devices will be connected, and the watch will start sending the measurement data to the host.
- If 15 seconds passed and the user did not accept the connection, the watch will reject the connection request. The device that tried connecting to the watch will not be able to connect for a whole minute (to prevent multiple connection requests).
- After the first time the user accepts a connection, the host ID is saved to the watch, and the next time the same host will try to connect the user will not be asked to accept the connection (the connection will be apporved automatically). The watch 'remembers' only one host at a given time.

- Whenever a device (client/host) tries to connect, for the first time, to the watch, the watch will vibrate and display a message to the user that a device (the device name will be displayed on the screen) tries to connect to it.
- If the user presses the button (accepts the connection) the devices will be connected, and the watch will start sending the measurement data to the host. The watch will display a blue BLE symbol to indicate the watch is connected.
- If 15 seconds passed and the user did not accept the connection, the watch will reject the connection request. The device that tried connecting to the watch will not be able to connect for a whole minute (to prevent multiple connection requests).
- After the first time the user accepts a connection, the host ID is saved to the watch, and the next time the same host will try to connect the user will not be asked to accept the connection (the connection will be approved automatically). The watch 'remembers' only one host at a given time.

Note: It is the user's responsibility to accept or reject a connection request, in order to make sure his vital signs will not be transmitted to an unknown device.
In case the watch losses connection to the host device (disconnected), the BLE symbol will turn white.

9.3. SERVICE AND REPAIR POLICY

Warranty repair and service must be performed by Oxitone Ltd. When Oxitone warranty is not applicable, repairs are made by Oxitone or authorized representatives, using current list price for replacement part(s) plus a reasonable labor and handling charge.

10. TROUBLESHOOTING

The following table lists some typical conditions that may occur with the system.

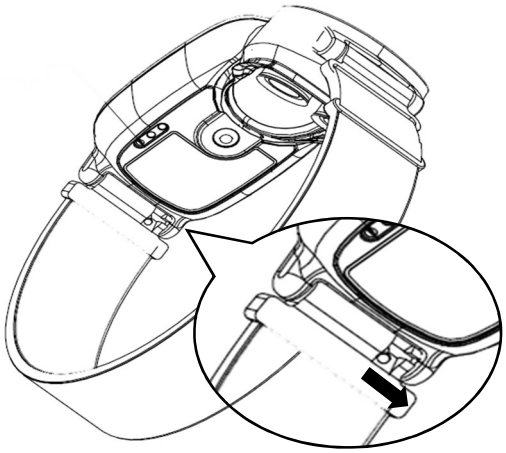
Condition	Possible Cause	Recommended Action
Incomplete or no reading	Sensor (device) placement	Ensure sensor is placed on a well perfused site. Ensure that the sensor is worn in the correct orientation and alignment (See Section ***5.3. Putting on the wrist worn Device***). Replace the device to alternat hand wrist.
	Excessive motion	Minimize or eliminate patient movement at the sensor site
	Signal quality	Make sure the measurement site is well perfused, free of debris and there is no dirt or pollution on the optics. Check the testing environment for interference (RF). Shield the sensor from excessive light sources (such as computer displays) or strobing lights.
Device does not power on	Low battery	Recharge the battery.
Unit does not momentarily vibrate when powered on	Resonant system failure (LRA)	Turn off the instrument and then power it on. If the problem reoccurs or persists return for service (see Section ***9. Service and Maintenance***).
OLED cracked or not working	System failure	Turn off the instrument and then power it on. If the problem reoccurs or persists return for service (see Section ***9. Service and Maintenance***).
Push button stuck (On or Off position)	Appears if something is pressing against the button on the monitor. Appears when the last button pressed was not released properly or could not make contact.	Make sure nothing is pressing against the button. Press the button again. If the condition persists, the device requires service or replacement.

Condition	Possible Cause	Recommended Action
Battery does not charge	Device charging contacts (see Sec' 5.1.2) contaminated	Clean contacts according to Sec' 8 cleaning instructions
The APP cannot find the pulse oximeter	The Bluetooth may not be working	Reestablish the Bluetooth connection, if still not successful, restart your PC.
Persistent system error displayed. Power ON.	Hi voltage ESD	Power OFF the device and back twice. If not working the device requires service or replacement.

10.1. REPLACING THE STRAPS ON THE OXITONE 1000M

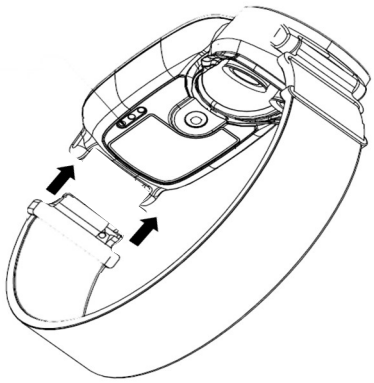
Follow the below steps to replace your Oxitone 1000M starps.

1. Slide the band's spring bar inwards.

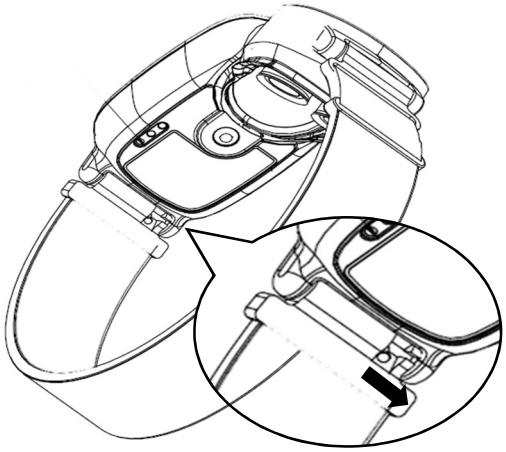


2. Pull the band away from the Oxitone 1000M body.

3. Insert one end of the spring bar into the Oxitone 1000M.



4. Slide the spring bar inwards and connect the band.



11. SPECIFICATIONS AND COMPLIANCE STANDARDS

Performance	
Measurement Range	
SpO_2	0%-100%
PR (pulse rate)	30-250 bpm
Accuracy	
Arterial Oxygen Saturation, 70% to 100%[1]	± 3%
Pulse Rate Accuracy[2]	± 3 bpm
Resolution	
Arterial Oxygen Saturation (SpO_2)	1%
Pulse Rate	1 bpm
Skin temperature range (direct mode)	29.0°C-43.0°C (84.2°F-109.5°F)
Accuracy	±0.1°C
Interfering Substances	
Refer to safety Information, Warnings and Cautions	
Product	
Test time	30 seconds
Electrical	
Battery Powered	Rechargeable lithium polymer 3.7VDC 370 mAh
Capacity (operation)	Approximately 24 hours after full charge
Number of spot checks on fully charged battery	Minimum 500
Battery charging time	Up to 2 hours. Power off (min. 300 recharging cycles)
Charger Isolation: class ll double isolation	5V AC/DC Adapter
AC Power for bench top charger	100-240V, 50-60 Hz, 10VA max
Measurement LED'S Wavelength and Output Power	
Red	660nm @ 1.05 mW max. average
Infrared	940nm @ 0.95 mW max. average
Environmental	
Operating temperature	32°F to 97°F (0°c to +36°C)
Operating humidity	5% to 95%, non-condensing
Pressure	700 to 1060 hPa
Operating altitude	-378m to 3050m (-1240 feet to 10000 feet)
Storage and transportation	
Storage temperature	(-20°C to +60°C) (-4°F to 140°F)
Humidity	5% to 95% non-condensing
Pressure	465hpa to 1060 hPa
Elevation altitude	-378m to 6000m
	(-1240 feet to 19685 feet)
Physical Characteristics	
Dimensions (monitor enclosure)	W36XL72XH24mm
Weight	40 gram
Visual alarm	Low battery, system failure

Display / Indicators	
Data display: SpO_2%, pulse rate (PR) beats per minute, battery level indicator, system status poor signal indicator and skin temperature.	
Type	OLED
Compliance	
Equipment Classification	IEC 60601-1
Type of Protection (battery power)	Internally powered
Accuracy Pulse Oximeter Equipment	ISO 80601-2-61
Degree of Protection – Sensor	Type BF-Applied Part
Mode of operation	Spot Check
Enclosure degree of ingress protection	IP 32
Biological evaluation	ISO10933-1:part 1-11
Usability IEC60601-1-6	IEC60601-1-2:2014 (EMC)
Homecare IEC60601-1-11	
Photobiological safety of lamps IEC 62471	
ISO80601-2-56 Thermometers	
Interfering Substances	
Refer to Section ***4.3. Safety Instructions***	

Note: This monitor complies with ISO 10993-1, Biological evaluation of medical devices-part1.

Note: This product complies with RoHS.

Bluetooth Wireless Technology Information: Contains FCC ID: HSW2832

Bluetooth Compliance: Version 5.0 single mode low energy

Operating Frequency: 2.4 to 2.4835 GHz

Output Power: TX: +3 dBM

Operating Range: 10meter radius (line of sight)

Network Topology: Star - bus

Operation: Slave

Model 1000M

Anntena Type: Integrated chip type antenna

Modulation Type: Frequency Hopping spread Spectrum

Data Rate: 1Mbit/second

Data Latency: 6ms

11.1 ACCURACY TESTING

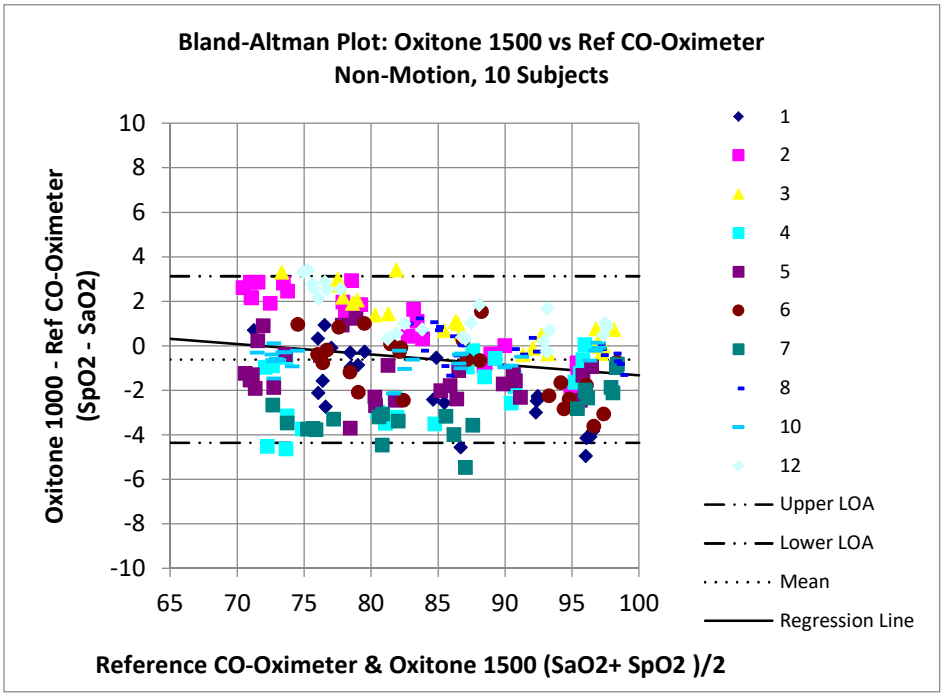
[1]The SpO_2 accuracy has been validated in human blood studies on healthy adult male and female volunteers with normal levels of carboxyhemoglobin (COHb) and methemoglobin (Met Hb) and with light to dark skin pigmentation, induced hypoxia studies in the range of 70-100% SpO_2 against a laboratory Co-Oximeter per ISO 80601-2-61. The variation equals plus or minus one standard deviation. Plus or minus one standard deviation encompasses 68% of the population.

Accuracy summary of Oxitone 1000M – comparison to reference CO-oximetry:

Oxitone1000M Pulse Oximeter	70—100	90--100	80--<90	67--<80	A_{RMS} Spec 3% for range of 70%-100%
Bias	-0.6	-1.1	-0.9	0.1	Pass
A_{RMS}	1.9	1.7	2.0	2.1	

Note: The range of 70% to 100% includes reference data down to 67%.

The following graph shows plots of error (SpO_2-SaO_2) using the Oxitone 1000M with a linear regression fit and upper 95% and lower 95% limits of agreement, as described by the Bland and Altman method. Each sample data point is identified by subject from a clinical study in non-motion conditions.



[2]Oxitone 1000M has been validated to pulse rate accuracy for the range of 30-250 bpm in bench top testing against a Fluke ProSim 8 simulator. This variation equals plus or minus one standard deviation which encompasses 68% of the population.

11.1.1 MANUFACTURER'S DECLARATION (EMC)

Caution: The Oxitone 1000M has been tested and found to comply with the limits per IEC 60601-1-2:2014 Standard and 93/42/EEC directive. These limits are designed to provide practical protection against harmful interference in a medical device installation.
Refer to the following tables (table 1 2 3 and 4 below) for specific information regarding this device compliance.

Federal Communication Commission (FCC) Notice (USA)

Warning: Changes or modifications to the device not expressly approved by Murata Electronics N.A. could void the user's authority to operate the equipment.

This device complies with Part 15 of the FCC rules. Operation is subject to the following two conditions: (1) this device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

The FCC requires the OEM to be notified that any changes or modifications not expressly approved by Murata may void the user's authority to operate the equipment. While an applicator of the MBN52832 module in a product is not required to obtain a new FCC authorization for the module, this does not preclude the possibility that some other form of authorization or testing may be required for that end product.

The device using the integrated antenna has been tested to comply with FCC CFR Part 15. The device meets the requirements for modular transmitter approval as detailed in the FCC public notice DA00.1407.

This requirement has been tested and found to comply with the limits for a Class B digital device, pursuant to Part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does not cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna.
- Increase the separation between the equipment and receiver.
- Connect the equipment into an outlet on a circuit different from that to which the receiver Is connected.
- Consult the dealer or an experienced radio/TV technician for help.

Federal Communication Commission (FCC) Notice (Canada)

The term "IC" before the certification/registration number only signifies that the industry Canada technical specifications were met.

Le terme "IC" devant le numéro de certification / d'enregistrement signifie seulement que les spécifications techniques Indsutrie Canada ont été respectées.

This device complies with Industry Canada license-exempt RSS standard(s). Operation is subject to the following two conditions: (1) this device may not cause interference, and (2) this device must accept any interference, including interference that may cause undesired operation of the device.

Cet appareil est conforme avec Industry Canada RSS standard exepmts de license(s). Son utilization est soumise á Les deux conditions suivantes: (1) cet appareil ne peut pas provoquer d'interférences et (2) cet appareil doit accepter Toute interference, y compris les interférences qui peuvent cause un mauvais fonctionnement du dispositif.

This device complies with Health Canada's Safety Code 6 / IC RSS-210. The installer of this device should ensure that RF radiation is not emitted in excess of the Health Canada's requirement. Information can be obtained at: http://www.hc-sc.gc.ca/ewh-semt/pubs/radiation/radio_guide-lignes_direct-eng.php

Cet appareil est conforme avec Santé Canada Code de sécurité 6 / IC RSS-210. Le programme d'installation de cet appareil do it s'assurer que les rayonnements RF n'est pas émis au-delá de lexigence Santé Canada. Les informations peuvent étre obtenues: http://www.hc-sc.gc.ca/ewh-semt/pubs/radiation/radio_guide-lignes_direct-eng.php

This radio transmitter MBN52832 has been approved by Industry Canada to operate with the antenna types listed below with the maximum permissible gain indicated. Antenna types not included in this list, having a gain greater than the maximum gain indicated for that type, are strictly prohibited for use with this device.

Le present émetteur radio (identifier le dispositif par son numéro de certification ou son numéro de modéle s'il fait partie du matériel de catégorie l) a été approuvé par Industrie Canada pour fonctionner vec les types d'antenne énumérés cidessous et ayant un gain admissible maximal et l'impédance requies pour chaque type d'antenne. Les types d'antenne non inclus dans cette liste, ou dont le gain est supérieur au gain maximal indiqué, sont strictement interdits pour l'exploitation de l'émetteur.

Table 1: Electromagnetic Emission

Emission Test	Compliance	Electromagnetic Environment - Guidance
This device is intended for use in the electromagnetic environment specified below: *The customer and / or user of this should ensure that it is used in such an environment*		
RF Emissions CISPR11	Group 1	This device uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF Emissions CISPR11	Group B	This device is suitable for use in all establishments, including domestic and those directly connected to the public low-voltage power supply network that supplies building s used for domestic purposes.
Harmonic Emissions IEC 61000-3-2	N / A	
Voltage Fluctuations / Flicker Emissions IEC 61000-3-3	N / A	

Table 2: Electromagnetic Immunity

Immunity Test	**IEC Test Level** **60601-1-2**	**Compliance** **Level**	**Electromagnetic Environment Guidance**
This device is intended for use in the electromagnetic environment specified below:The customer and / or user of this should ensure that it is used in such an environment			
Electrostatic Discharge (ESD) IEC 61000-4-2	8 kV contact ± 15 kV air discharge	± 8 kV contact ± 15 kV air discharge	Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, relative humidity should be at least 30%.
Electrical Fast Transient / Burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for power supply lines	N / A	N / A
Surge IEC 61000-4-5	± 1 kV different mode ± 2 kV common mode	N / A	N / A
Voltage dips, short interruption, and voltage variations on power supply input lines IEC 61000-4-11	± 5% U_T(> 95% dip in U_T) for 0.5 cycle ± 40% U_T(60% dip in U_T) for 5 cycles ± 70% U_T(30% dip in U_T) for 25 cycles < 5% U_T(> 95% dip in U_T) for 5 sec.	N / A	N / A
Power Frequency (50/60 Hz) Magnetic Field IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial, hospital or home environment.

NOTE: U_T is the AC mains voltage before application of the test level.

Table 3: Guidance and Manufacturer's Declaration-Electromagnetic Immunity

Immunity Test	**IEC 60601-1-2 Test Level**	**Compliance Level**	**Electromagnetic Environment Guidance**
This device is intended for use in the electromagnetic environment specified below: *The customer and / or user of this should ensure that it is used in such an environment*			
Portable RF communications equipment should be used no closer to any part of the device, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.			
			Recommended Separation Distance
Conducted RF IEC 61000-4-6	$3V_{rms}$ 150 kHz to 80 MHz	N / A	N / A
Radiated RF IEC 61000-4-3	10V/m 80 MHz to 2.5 GHz	10V/m	$80\ \text{MHz to } 800\ \text{MHz}\ d = 1.17\sqrt{P}$ $800\text{MHz to } 2.5\ \text{GHz d} = 2.33\sqrt{P}$ Where P is the maximum output power rating of the transmitter in wats (W) according to the transmitter manufacturer and *d* is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey[a], should be less than the compliance level in each frequency range.[b] Interference may occur in the vicinity of equipment marked with the following symbol: 

a. Field strengths from fixed transmitters, such as base stations for radio (cellular / cordless) telephones and land mobile radios, amateur radio, AM and FM radiobroadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the device is used exceeds the applicable RF compliance level above, the device should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the device.

b. Over the frequency range 150 kHz to 80MHz, field strength should be less than 3V/m.

NOTES:

NOTE 1: At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

The following table details the recommended separation distances between portable and mobile RF communications equipment and this device.

Table 4: Recommended Separation Distance

This device is intended for use in the electromagnetic environment in which radiated RF disturbances are controlled. Users of this device can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communication equipment (transmitters) and the device as recommended below, according to maximum output power of the communications equipment.			
	Separation Distance According to Frequency of Transmitter		
Rated Maximum Output Power of Transmitter W	150 kHz to 80 MHz $\mathrm{d} = 1.17\sqrt{P}$	80 MHz to 800 MHz $\mathrm{d} = 1.17\sqrt{P}$	800 MHz to 2.5 GHz $d = 2.33\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.37	0.37	0.74
1	1.2	1.2	2.3
10	3.7	3.7	7.4
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance *d* in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTES:

NOTE 1: At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

11.1.2 WARRANTY

Oxitone Ltd. warrants to the initial purchaser for a period of one (1) year from the date of purchase that: (1) each new product and the software media as delivered are free from defects in workmanship or materials, and (2) the product and software will perform substantially as labeled in the directions for use. Oxitone's sole obligation under this warranty is to repair or replace any product or software that is covered under warranty.

To request a replacement under warranty, purchaser must contact Oxitone for a returned goods authorization. If Oxitone determines that a product must be replaced under warranty, it will be replaced and the cost of shipment covered. All other shipping costs shall be the responsibility of purchaser.

11.2 LIMITED WARRANTY

Oxitone Ltd. warrants that Oxitone 1000M system meet their published specifications at the time of shipment from the factory. Oxitone further warrants that Oxitone 1000M product was calibrated at the factory prior to shipment.