



OXOS

# Wireless Charger

Instructions for Use

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# 1 - Introduction

This manual describes operation for the W1 Wireless Charger for the MC2 Portable X-ray System (also referred to as the MC2 System). The device is intended for qualified medical personnel who have been trained in the use of the MC2 System and who have read this Instructions for Use and Accompanying Documents.

## Intended Use

The W1 Wireless Charger is designed to provide locked holster and wireless power delivery to the Emitter in the use of the MC2 System. As such, this device is intended for use in environments, with patients, and alongside other devices as described in the MC2 System's Instructions for Use.

## Indications for Use

The Wireless Charger is intended for use with only the MC2 System. The MC2 Portable X-ray System is indicated for use by qualified/trained personnel, and its full indications can be found in its respective accompanying documents.

## Contraindications

The W1 Wireless Charger is NOT intended for contact with non-intact skin.

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## Owner's Responsibility

The owner has the responsibility to ensure that only properly trained, qualified personnel who have obtained credentials from the appropriate authorities operate the MC2 Portable X-ray System and all accessories. The owner has the responsibility to ensure system compatibility, operator qualifications, operator personal protective equipment, and the continued compliance of equipment and operating specifications. Unauthorized changes or modifications to any part of the system could have hazardous consequences. In addition to complying with federal guidelines, the owner is responsible for complying with applicable state and local guidelines, which may include:

- X-ray device registration and licensing

- Operator training program or a radiation worker safety program
- Ensuring only qualified personnel are authorized to operate the system

The MC2 Portable X-ray System and all accessories are sold with the understanding that the operator assumes sole responsibility for radiation safety (as well as any state, provincial, or local regulatory compliance) and that OXOS Medical, and its agents or representatives, do not accept responsibility for the following:

- Injury or danger to personnel from x-ray exposure
- Image over/under exposure due to poor operating techniques or procedures
- Equipment not properly serviced or maintained in accordance with instructions contained in this publication
- Equipment which has been damaged, modified, or tampered with in any way

## Manufacturer's Responsibility

OXOS Medical, Inc. certifies each W1 Wireless Charger in accordance with applicable standards (refer to *Regulatory Requirements* below). After-sale operating practices and safety are the responsibility of the operator/responsible organization.



Prescription Use Only: Federal law restricts this device to sale by or on the order of a physician or licensed practitioner.

## Regulatory Requirements



The owner is responsible for verifying continued compliance with all applicable regulations and standards. Consult local, state, federal and/or international agencies regarding specific requirements and regulations applicable to the use of this type of medical electronic equipment. This product complies with applicable standards, including, but not limited to, the following:


- IEC 60601-1: Medical electrical equipment – Part 1: General requirements for basic safety and essential performance;
- IEC 60601-1-2: Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral Standard: Electromagnetic disturbances – Requirements and tests;
- IEC 60601-1-6, Medical electrical equipment Part 1-6: Collateral standard: Usability


## 2 - General Safety


Potential hazards exist in the use of any medical electronic devices and x-ray systems. The following section describes hazardous and potentially hazardous conditions and how to adequately protect device operators and others from possible injury. There are three hazard classifications, denoted below:


Hazard Classification List		
Symbol	Label	Description


	<b>WARNING</b>	Indicates a potentially hazardous situation that, if not avoided, could result in death or serious injury.
	<b>CAUTION</b>	Indicates a potentially hazardous situation that, if not avoided, may result in moderate to minor injury, equipment damage or loss of data.
<b>NOTE</b>	<b>NOTE</b>	Highlights unusual points that require special attention.


 **WARNING: DO NOT USE IF DAMAGED** If any part of the device is known (or suspected) to be damaged or defective, do not use the system and contact OXOS for assistance. Operation of the equipment with defective components could lead to fatal or other serious personal injury, or to clinical misdiagnosis/mistreatment.


 **WARNING:** Only use OXOS-supplied components and approved accessories. Use of or connection to incompatible components or accessories may lead to major shock, burn, or injury or result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.


 **WARNING:** The MC2 System and accessories should always be used within the specified use environments, environmental conditions and useful life of the equipment, as specified in these Instructions for Use. Not doing so may result in serious injury or equipment damage.


 **WARNING:** Never modify or disassemble any of the system components. Only personnel authorized by OXOS may modify or repair the device(s).

 **WARNING:** A class C fire extinguisher, which meets applicable regulations and standards, must be available wherever the device is being used. Using the wrong type of fire extinguisher presents electrical shock and burn hazards.

 **WARNING:** The W1 Charger is not waterproof. If you suspect liquids entered the device, disconnect any power cords from the wall outlet, and contact OXOS for assistance.

 **WARNING:** If you suspect condensation presence within equipment housing, do not operate the device, disconnect any chargers from the wall outlet, and contact OXOS for assistance.

 **WARNING:** Do not touch the patient and any exposed metal components, including ports and connector pins, simultaneously as electrical discharge may occur.

 **WARNING:** Do not use this equipment in environments rich with oxygen, nitrous oxide, or flammable anesthetics. Use in potentially flammable environments may lead to fire.

## 3 - System Overview

### Components and Accessories List

W1 Components Supplied by OXOS	REF Number	Description
Wireless Charger	W1	The Wireless Charger
Instructions for Use	IFU-W1	The IFU provides operator instruction, risk information, and technical details for the W1 Wireless Charger.

<b>MC2 System Devices Available from OXOS</b>	<b>REF Number</b>	<b>Description</b>
Emitter	E1	The Emitter includes the operator control panel, x-ray tube, automatic collimator, and tracking, imaging, and viewfinder cameras.
Wired Charger	H1	The Wired Charger connects to power outlets to charge the Emitter or Cassette.
Cart	K1	The Cart may be used for system transport, hands-free operation, image display (via a touchscreen monitor), and charging the Emitter and Cassette.

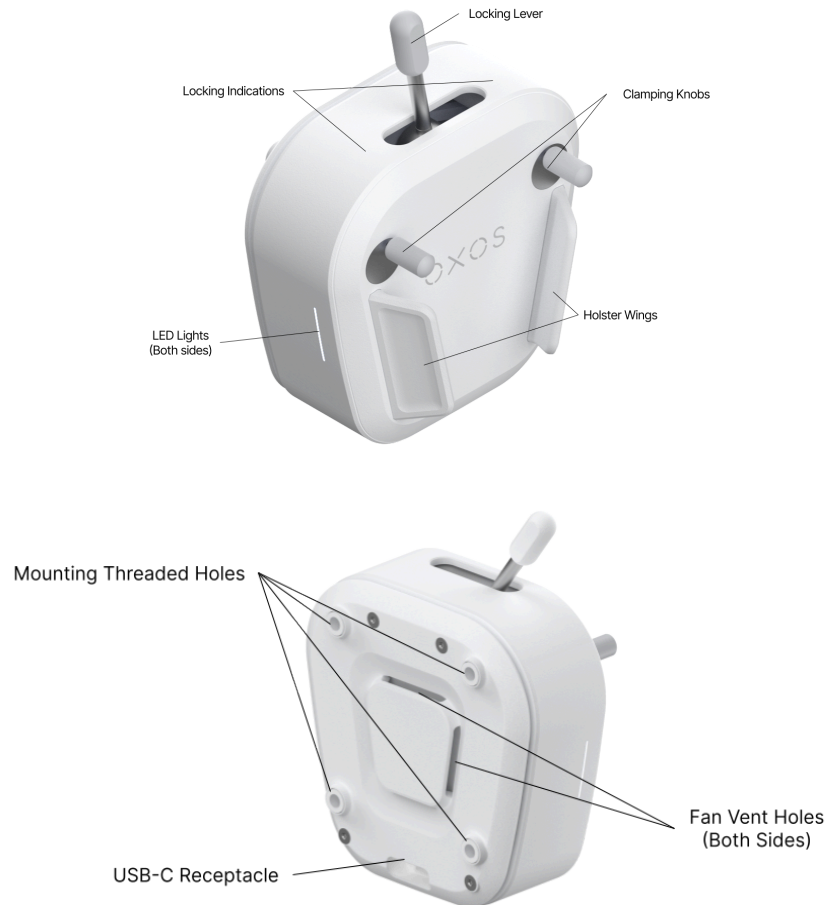
<b>Optional Accessories Supplied by User</b>	<b>REF Number</b>	<b>Description</b>
Sterile Drapes and Covers	N/A	Sterile drapes and covers may be used during exams to prevent contact with unprepared surfaces.

## Major Components

The Wireless Charger is intended to interface with the E1 Emitter for positioning and locking and connect to the H1 Wired Charger to receive power for wirelessly charging the E1 Emitter. The Wireless Charger may also be supplied as part of the K1 Cart. Information about the E1 Emitter, H1 Wired Charger, or K1 Cart can be found in their respective Instructions for Use.

## Wireless Charger

The Wireless Charger is intended to holster, lock, and provide wireless power delivery to the Emitter in the MC2 System. It includes primarily a USB-C connection port, Holstering Wings, Clamping Knobs, a Locking Lever, and Indicator LED Lights.



## 4 - Using the Wireless Charger

### Initial Inspection

Before use, inspect the Wireless Charger items for:

- Obvious signs of damage
- Cracked, chipped, or broken components
- Sounds of loose internal components
- Loose or faulty seals
- Missing covers, labels, or windows
- Broken or non-functioning buttons



**WARNING: DO NOT USE IF DAMAGED.** If any part of the device is known (or suspected) to be damaged or defective, do not use the device and contact OXOS for assistance.



**Do Not Disassemble:** Unauthorized modification or disassembly of the MC2 System will void the customer warranty, resulting in a non-serviceable unit by OXOS. Do not attempt to open the device, perform maintenance, or perform component replacement.

## Connecting to Wired Charger and Outlet



**WARNING:** Ensure fan ducts in the back of the Wireless Charger are not obstructed in use or storage. Obstructing airflow may cause overheated parts, fire, and equipment damage.



**WARNING:** Multi-socket outlets or power strips are strictly prohibited unless they are rated to IEC 60601-1 and are provided with all necessary markings and certificates of conformance. Connecting the device to multi-socket outlets that are not properly rated may result in fire.



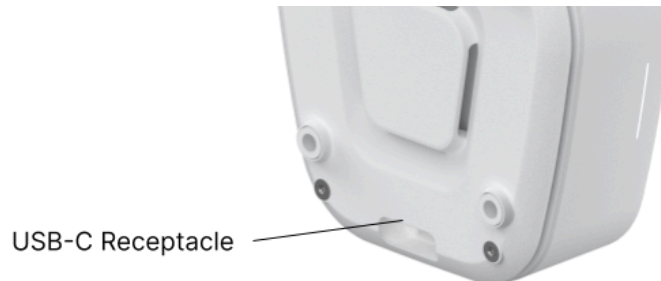
**WARNING:** Only use OXOS-supplied components and approved accessories. Use of or connection to incompatible components or accessories, such as off-the-shelf USB-C chargers, may lead to major shock, burn, or injury.

**NOTE**

The MC2 System is supplied with two H1 Wired Chargers which may be used with C7 power cords up to 3m in length.

**Follow these steps to Connect the H1 Charger to the W1 Wireless Charger:**

1. Connect the Wired Charger to a power outlet. The LED light on the Wired Charger will illuminate.
2. Connect the Wired Charger USB-C connector to the power on the lower back of the Wireless Charger.



3. Check the Wireless Charger's LED lights to make sure they power on. There is no switch or button associated with Wireless Charger power states.

**NOTE**

The W1 Wireless Charger may be supplied as part of other accessories such as the Cart; In which case, the power cord may already be connected.

## Holstering and Locking the Emitter

Holster and Lock the Emitter by following the below steps. To unlock and remove the Emitter, follow them in reverse:

1. Move the Locking Lever all the way to the right towards the Unlocked Lock indicator on the top of the Wireless Charger.





2. Holding the Emitter by its handle, slide the Emitter cleat downward into the Wireless Charger's matching holstering wings until it settles into position.



3. Ensure there are no fingers or materials above the Emitter Cleat in preparation for locking.
4. Move the Locking Lever all the way to the left towards the Locked Lock indicator on top of the Wireless Charger. The Clamping Knobs should rotate to hold the Emitter Cleat and the Locking Lever should settle in the Locked Position. Slightly lift the Emitter to confirm it is locked in place before letting go.



**WARNING:** Ensure the Wireless Charger is upright before unlocking to prevent the Emitter from unexpectedly falling out.

## Wirelessly Charging the Emitter

Holstering the Emitter into the Wireless Charger while the Wireless Charger is powered through USB-C should begin charging the Emitter. The LED lights on the Wireless Charger will begin pulsing white to indicate that charging is occurring.

The Emitter is NOT required to be powered to charge wirelessly, but if the Emitter's battery is full, you may see intermittent charging.



**WARNING:** Ensure the Wireless Charger is upright before unlocking to prevent the Emitter from unexpectedly falling out.



**WARNING:** Do not touch the Wireless Charger and the patient at the same time. Doing so may result in electrical shock or equipment damage.



**WARNING:** Do not connect another USB-C charging cord to the Emitter's USB-C Port while wirelessly charging. Doing so may result in electrical shock or equipment damage.



**WARNING:** Do not touch the wireless charger while emitting x-rays. Doing so may result in electrical shock or equipment damage.



**WARNING:** Do not place other metals or devices in close proximity to the wireless charger. Doing so may cause the charger to supply power to those metals or devices, potentially damaging them or heating them to harmful temperatures.

## LED Indicators

Visual and Audible Indicators for Wireless Charger		
Condition	LED Lights	Description
Powered Off	Off	The Wireless Charger is unplugged or not receiving power.
Waiting for Emitter	<b>Solid Cyan</b>	The Wireless Charger has power, but is waiting for an aligned Emitter before beginning power transmission.
Charging	<b>Pulsing Cyan</b>	The Wireless Charger is wirelessly transmitting power to the Emitter.
Error	<b>Pulsing Red</b>	The device is in an error state. If persistent, contact OXOS.



**WARNING:** LEDs may not be visible under bright lights or sunlight.

### NOTE

The Wireless Charger **only** charges the Emitter. To charge the Cassette, connect an H1 Wired Charger as described in the MC2 Instructions for Use.

## Sterile Covers

Sterile and non-sterile covers and sheets for the equipment may be used. OXOS recommends the PC-1072 TF Probe Cover from Preferred Medical Products, LLC, but a cover with sufficient area to avoid tearing and stretching is essential.

The Wireless Charger was designed and tested to be capable of operating in a sterile bag. Cover the component completely to prevent accidental contamination near the bag opening. Ensure the bag is flush against the front and side faces of the Wireless Charger to ensure it does not interfere with the device's functions. Drapes and bags are also recommended to mitigate equipment damage from liquid ingress and patient cross-contamination. Replace drapes or bags after each use.

Detailed procedures for sterility and fitting sterile covers are the responsibility of the facility.

## Troubleshooting

In the case of device errors, refer to the following troubleshooting instructions. If the system continues to show signs of malfunction or error, discontinue use immediately and contact OXOS for assistance.

Troubleshooting		
Device Behavior	Potential Problem Cause	Action to be Performed
Wireless Charger does not power on	Outlet is off or not functioning	Ensure the power outlet is functioning and the H1 Wired Charger, if available, has a lit green light.
	Power cord to charging brick is not connected	Ensure the AC Cord from the outlet to the H1 Wired Charger is connected and its green light is lit.
	Component is too cold or hot	Warm or cool the component to within operating temperature (See <i>Technical Specifications</i> ).
	Damaged MC2 wired charger cable	Inspect the MC2 wired charger cables, if any damage is observed, discontinue use and contact OXOS.
Emitter does not holster into place	Locking Lever is engaged	Disengage the Locking Lever and Clamping Knobs before holstering the Emitter.
	Wireless Charger is upside down	Ensure the Emitter and Wireless Charger are aligned as described in <i>Holstering and Locking the Emitter</i>
	Material or an obstruction is present in the Holster	Remove any material inside the Wireless Charger's holstering wings, including labels that may impact the holstering alignment
Clamping Knobs do not lock the Emitter	The Locking Lever is not engaged completely	Slide the Locking Lever until it reaches the end of travel, settling into the "locked" position.
	Material or an obstruction is present in the Holster	Remove any material inside the Wireless Charger's holstering wings, including labels that may impact the holstering alignment
The Emitter or Wireless Charger overheats often	The cooling means inside the component(s) is not functioning correctly	Discontinue use and contact OXOS.
Wireless Charger does not charge	Intermittent connection	Remove Emitter from Wireless Charger then re-holster Emitter locking in place. Wait 10 seconds, if charging does not start then repeat the troubleshooting step.

In the event that device behavior is observed which has no listing above, contact OXOS for assistance.

## 5 - System Upkeep

### Routine Cleaning



**CAUTION:** Only the cleaning and disinfecting agents listed in these Instructions for Use have been tested for compatibility and effectiveness by OXOS. Do not use other cleaning solutions, since certain chemical combinations may deteriorate the device plastics prematurely.



**Do Not Disassemble:** Unauthorized modification or disassembly of the MC2 System will void the customer warranty, resulting in a non-serviceable unit by OXOS. Do not attempt to open the device, perform maintenance, or perform component replacement.

The Wireless Charger should be cleaned periodically, between patients, and before storage per your facility's cleaning protocols. Follow the steps below to clean the Wireless Charger:

1. Remove the Emitter and clean separately, following the MC2 System's Instructions for Use.
2. Remove power to the Wireless Charger by unplugging the USB-C Cord and waiting a few seconds.
3. Spray 70% alcohol or Cavicide all-purpose cleaning solution onto a clean lint-free wipe and gently wipe down the exterior surfaces.
4. Allow the Wireless Charger to air dry before reconnecting the power.

## Periodic Maintenance Schedule

At least once monthly, inspect the external surfaces of all components for damage, loose or missing parts, and frayed or damaged cords. Do not use the device if it displays one or more of the above conditions until the problem is corrected and has been verified as operating correctly and safely. The user is not required to calibrate or maintain the Wireless Charger other than routine cleaning procedures as described above. OXOS will perform all servicing that may include disassembly or calibration.

## Storing the System After Use

The Wireless Charger should be cleaned periodically and before packing away, as per your facility cleaning protocols. At a minimum, clean and store in a cool, dry location, away from direct sunlight, following the environmental conditions in *Technical Specifications*.

## End of Life Procedure

The Wireless Charger has an expected service life of 5 years. At end of life, ship products to OXOS to minimize environmental risks associated with disposal. Disposal should always be performed in accordance with local, state, and federal regulations. Disposal of accessories and consumables associated with this equipment should also be performed in compliance with local, state, and federal regulations. All materials and components that could present risks to the environment must be removed from the end-of-life system before disposal.

Please contact OXOS before discarding these products and materials.

## 6 - Symbols and Labels

The section describes the symbols and labels on the Wireless Charger. Symbols and labels on the product and in this publication may indicate that the MC2 System meets the requirements of specific organizations, and/or describe potential hazards that, if ignored, may risk injury.

### Symbols

Symbol	Reference	Description
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	MR Unsafe	<b>MR Unsafe</b> To prohibit storage or use in an MRI room or similar
	ISO 7010 P069	<b>Not to be serviced by users</b> To prohibit carrying out servicing by users
	ISO 7000 1641	<b>Operator's manual</b> To indicate that the operating instructions should be considered when operating the device or control close to where the symbol is placed.
	GUDID Barcode	<b>Global Unique Device Identification Database (GUDID) Barcode</b> To encode product information in the GUDID, including GTIN, serial/lot number, and date of manufacture. It is always paired with human-readable information.
	ISO 7000 2493	<b>Catalogue number</b> To identify the manufacturer's catalogue number, for example on a medical device or the corresponding packaging.
	ISO 7000 2606	<b>Do not use if package is damaged</b> To indicate that the device must not be used if the package holding the device is damaged, for example on packaging of medical devices.
	ISO 7000 0632	<b>Temperature limit</b> To indicate the maximum and minimum temperature limits at which the item shall be stored, transported or used.
	ISO 7000 2620	<b>Humidity limitation</b> To indicate the acceptable upper and lower limits of relative humidity for transport and storage.
	ISO 7000 2621	<b>Atmospheric pressure limitation</b> To indicate the acceptable upper and lower limits of atmospheric pressure for transport and storage.
	ISO 7000 3082	<b>Manufacturer</b> To identify the manufacturer of a product. On the health app quality label: to identify the manufacturer of the health app.
	WEEE Symbol	<b>Waste Electrical and Electronic Equipment (WEEE) Directive Symbol</b> To indicate the equipment must be disposed properly, in accordance with the instructions for use.
	FCC Icon	<b>Federal Communications Commission (FCC) Symbol</b> To indicate information related to the FCC, such as FCC ID.
	—	<b>Locked Symbol</b> Indicates the Locking Lever's position when the wireless charger is Locked
	—	<b>Unlocked Indicator</b> Indicates the Locking Lever's position when the wireless charger is Unlocked

## Equipment Labels



1		<b>Regulatory Label</b> Includes warning and informational symbols
2		<b>Build Label</b> Includes UDI barcode, Serial/Lot Number, and Date of Manufacture
3		<b>Locked Symbol</b> Indicates the Locking Lever's position when the wireless charger is Locked
4		<b>Unlocked Indicator</b> Indicates the Locking Lever's position when the wireless charger is Unlocked
5	<b>ONLY USE OXOS H1 CHARGER</b>	<b>Only use OXOS H1 Charger</b> Indicates to the user to only connect and use an OXOS-supplied H1 Charger

## 7 - Technical Specifications

### General Specifications

- Rated for Continuous Operation
- Degree of protection against ingress of water: IP00
- Dimensions:

Specification	Weight
Weight	2 lb
Height	7.5 in
Width	4.9 in
Depth	3.1 in

### Environmental Conditions

Item	Limits
Humidity	Between 20 to 90% non-condensing
Altitude	Between 1000 ft below sea level and 8,000 ft above sea level
Operating Temperature	Between 0°C to +29.9°C
Storage Temperature	Between -10°C to +55°C

### Electrical and Electromagnetic Specifications

The W1 Wireless Charger must be powered with the OXOS H1 Wired Charging Brick complying with these specifications:

- **Manufacturer / Model:** Phasium MANGO100S-USB-PDB
- **Nominal Output Power:** 100W (typical efficiency 86%)
- **Input Rated Voltage / Frequency:** 120V / 60Hz

The W1 Wireless Charger port should not be connected to any other USB-C devices, including peripherals providing or consuming power. When connecting the H1 Wired Charging Brick, ensure it is connected to a power source that meets its requirements.

### Electromagnetic Disturbances

The system complies with relevant international and national laws and standards on EMC for this type of product when used as intended. Such laws and standards define both the permissible electromagnetic emission levels from the product and its required immunity to electromagnetic interference from external sources.



**WARNING:** Only use OXOS-supplied components and approved accessories. Use of or connection to incompatible components or accessories may lead to major shock, burn, or injury.



**WARNING:** Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30cm (12 inches) to any part of the MC2 System and accessories, including cables specified by the manufacturer. Otherwise, performance degradation of the equipment could result.



**CAUTION:** This equipment generates, uses, and can radiate radio frequency energy. The system may cause or be subject to radio frequency interference with other medical and non-medical devices and radio communications. There may be risks of reciprocal interference posed by ME EQUIPMENT.



**CAUTION:** W1 Wireless Charger has been tested in wireless environments consisting of different wireless technologies (Bluetooth, WiFi 802.11b and cellular communications) with multiple transmitters used simultaneously. If using in environments where other wireless technologies are being used, the user should evaluate the potential risk of interference. It may be necessary to take mitigation measures such as re-orienting or relocating the system or shielding the location.



**CAUTION:** Use of the MC2 System adjacent to or stacked with other equipment could result in device failure and should be avoided. If such use is necessary, observe and verify normal operation of the MC2 System in the configuration in which it will be used prior to use.

If not installed and used in accordance with the instruction manual, this equipment 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 cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, please contact OXOS for assistance.

If this equipment is found to cause interference (which may be determined by switching the equipment on and off), the operator should attempt to correct the problem by one or more of the following measure(s):

1. Reorienting the Wireless Charger or the affected device;
2. Increasing the distance between the Wireless Charger or the affected device; or
3. Changing the power supply for either device so they do not share the same power source.

## Environmental Statement

The W1 Wireless Charger is suitable for use in Professional Healthcare Facility environments. This system has not been evaluated to CISPR25 or ISO 7637-2. The operator or responsible organization should ensure that it is only used in the appropriate environments.

## Electromagnetic Emissions

Electromagnetic Emissions, Tests, Certifications, and Notes apply to the wireless charger alone. If the Wireless Charger is supplied as part of another accessory, please refer to the respective Instructions for Use or Accompanying Documents for information on Electromagnetic Information

**NOTE**

Emissions Test	Compliance	Electromagnetic Enforcement - Guidance
RF & Conducted Emissions CISPR 11	Class A, Group 2	The W1 Wireless Charger is suitable for use in Professional Healthcare Facilities, except for near high frequency surgical equipment.



Harmonics IEC 61000-3-2	N/A	The W1 Wireless Charger is rated for use at 120V. Do not use the W1 Wireless Charger in an environment that supplies more than 120V.
Flicker IEC 61000-3-3	N/A	

## General Electromagnetic Immunity

Immunity Test	IEC 60601-1-2 Test Level and Compliance Level	Electromagnetic Environment Guidance
Electrostatic Discharge (ESD) IEC 61000-4-2	$\pm 8$ kV contact $\pm 2$ kV, $\pm 4$ kV, $\pm 8$ kV, $\pm 15$ kV air	Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical Fast Transient/burst IEC 61000-4-4	$\pm 2$ kV for power supply lines $\pm 1$ kV for input/output lines 100kHz repetition frequency	Mains power quality should be that of a typical professional healthcare environment
Surge IEC 61000-4-5	$\pm 1$ kV Line-Line $\pm 2$ kV Line-Ground	Mains power quality should be that of a typical professional healthcare environment.
Conducted RF IEC 61000-4-6	3 V <sup>b)</sup> , 0,15 MHz – 80 MHz 6 V in ISM bands <sup>b)</sup> Amateur radio bands between 0,15 MHz and 80 MHz 80 % AM at 1 kHz	Portable and mobile RF communications equipment should be used no closer to any part of the W1 Wireless Charger, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.
Radiated RF IEC 61000-4-3	10 V/m (before modulation) 80 MHz – 2,7 GHz 80 % AM at 1 kHz	Equations and key recommended separation distances are shown in Section 12.5.2  Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey <sup>a)</sup> , should be less than the compliance level in each frequency range.
Power Frequency Magnetic Field IEC 61000-4-8	30 A/m 60 Hz	Power-frequency magnetic fields should be at levels characteristic of a typical location in a typical professional healthcare environment.
Voltage dips, short interruptions, and voltage variations on power supply input lines IEC 61000-4-11	0 % UT; 0,5 cycle: At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°  0 % UT; 1 cycle and 70 % UT; 25/30 cycles Single phase: at 0°	Mains power quality should be that of a typical professional healthcare environment.  If the user of the W1 Wireless Charger requires continued operation during power mains interruptions, it is recommended that the W1 Wireless Charger be powered from an uninterruptible power supply.
Proximity magnetic fields IEC 61000-4-39	30 kHz, 8 A/m, CW 134.2 kHz, 65 A/m <sup>b)</sup> , 2.1 kHz modulation <sup>c)</sup> 13.56 MHz, 7.5 A/m <sup>b)</sup> , 50 kHz modulation <sup>c)</sup>	Radiated fields should be at levels characteristic of a professional healthcare environment.

a) Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast, 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 MC2 System is used exceeds the applicable RF compliance level above, the W1 Wireless Charger should be observed to verify normal operation.

b) r.m.s., before modulation

c) The carrier shall be modulated using a 50% duty cycle square wave signal.

## Immunity to Proximity Fields from RF Wireless Communications Equipment

Test Frequency (MHz)	Band <sup>a)</sup> (MHz)	Service <sup>a)</sup>	Modulation <sup>b)</sup>	Maximum Power (W)	Distance (m)	IMMUNITY TEST LEVEL (V/M)
385	380-390	TETRA 400	Pulse modulation <sup>b)</sup> 18 Hz	1.8	0.3	27
450	430-470	GMRS 460 FRS 460	FM <sup>c)</sup> + 5 kHz deviation 1 kHz sine	2	0.3	28
710	704-787	LTE BAND 13, 17	Pulse modulation <sup>b)</sup> 217 Hz	0.2	0.3	9
745						
780						
810	800-960	GSM 800/900, TETRA 800, IDEN 820, CDMA 850, LTE Band 5	Pulse modulation <sup>b)</sup> 18Hz	2	0.3	28
870						
930						
1720	1700-1990	GSM 1800; CDMA 1900; DECT; LTE BAND 1, 3, 4,25; UMTS	Pulse modulation <sup>b)</sup> 18Hz	2	0.3	28
1845						
1970						
2450	2400-2570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation <sup>b)</sup> 18Hz	2	0.3	28
5240	5100-5800	WLAN 802.11 a/n	Pulse modulation <sup>b)</sup> 18Hz	0.2	0.3	9
5500						
5785						

a) For some services, only the uplink frequencies are included.

b) The carrier shall be modulated using a 50% duty cycle square wave signal.

c) as an alternative to FM modulation, 50% pulse modulation at 18 Hz can be used because while it does not represent actual modulation, it would be the worst case.

## Recommended Separation Distances

The W1 Wireless Charger is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the operator of the W1 Wireless Charger can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the W1 Wireless Charger as recommended below, according to the maximum output power of the communications equipment.

This product may cause interference to radio equipment and should not be installed near maritime safety communications equipment or other critical navigation or communication equipment operating between 0.45–30 MHz.

Rated maximum output power of transmitter W	Separation distance according to frequency of transmitter (d in meters)		
	150 kHz to 80 MHz $d=1.2/\sqrt{P}$	80 MHz to 800 MHz $d=1.2/\sqrt{P}$	800 MHz to 2.7 GHz $d=2.3/\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.72
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23
For transmitters rated at 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.			

## Wireless Compliance

This device complies with FCC rules in 47 CFR § 18.

The FCC certification of this device refers to RF exposure testing performed in typical operating conditions, where a person is no closer than 10 centimeters from the device surface at all times, except for non-repetitive patterns with transient time intervals in the order of a second. Only in the stated conditions, the device is shown to fully comply with the FCC RF Exposure requirements of KDB 447498.

Any changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.

## Wireless Specifications

Feature	Description
Transmission Profile	110 - 140 kHz, Amplitude Shift Key (ASK) load modulation
Standards	IEEE802.11ac/a/b/g/n
Quality of Service (QoS)	The W1 Wireless Charger is not reliant on an external or internal network for critical features related to essential performance or safety, therefore it does not require a specific level of network quality.
Effective Radiated Power (ERP)	110-140 kHz: 100W
Emissions	FCC, CE
Compliance	FIPS, FISMA

## EMC & Essential Performance

EMC events will not cause unacceptable risks due to degraded essential performance. Some strong EMC events may require the device to be restarted to exit safety mode and return the device to nominal functioning. The operator may notice minor flickering during strong electromagnetic events. If these issues persist, it is recommended that the Wireless Charger be repositioned away from potential sources of noise. It may also be necessary to move the system to a different A/C outlet that is on a different circuit.

If the system does not recover after a power reset or shows other signs of malfunction, discontinue use of the equipment immediately. Remove power to the system by unplugging the power cord from the AC receptacle. Notify a qualified technician at OXOS. Do not operate the system until the service technician advises that it is operating properly.

## MRI Safety Information



The MC2 System and all accessories, including the W1 Wireless Charger are MR Unsafe. Keep them outside the MRI scanner room.

## 8 - Limited Warranty

### Coverage

OXOS Medical, Inc. warrants its MC2 System to be free from any material defects in material or workmanship for a period of one (1) year (the "Warranty Period") from the date of purchase or rental from OXOS Medical, Inc. or OXOS authorized resellers. OXOS Medical, Inc. also warrants any accessories purchased from OXOS Medical, Inc. to be free from any material defects in material or workmanship for the period of one (1) year (also referred to as the "Warranty Period") from the date of purchase.

The sole liability of OXOS Medical, Inc. is limited to, at OXOS Medical, Inc.'s choice, repair or replacement of any parts that OXOS Medical, Inc. or OXOS authorized resellers determine to be defective. Contact OXOS Medical, Inc. for a Return Material Authorization (RMA) number and shipping instructions. Parts proving defective shall be repaired or replaced free of charge (labor and shipping included), if defective equipment is returned (shipment return service) to OXOS Medical, Inc. (Georgia, USA) or the location of an authorized service center during the Warranty Period. Equipment repaired or replaced under warranty shall continue to be warranted for the balance of the original Warranty Period. All warranty claims must be made no later than the expiration of the applicable Warranty Period. Unauthorized shipment or shipment contrary to OXOS Medical, Inc.'s instructions will void this warranty. OXOS Medical, Inc. will solely determine final disposition of any warranty claim.

### Limitations of Coverage

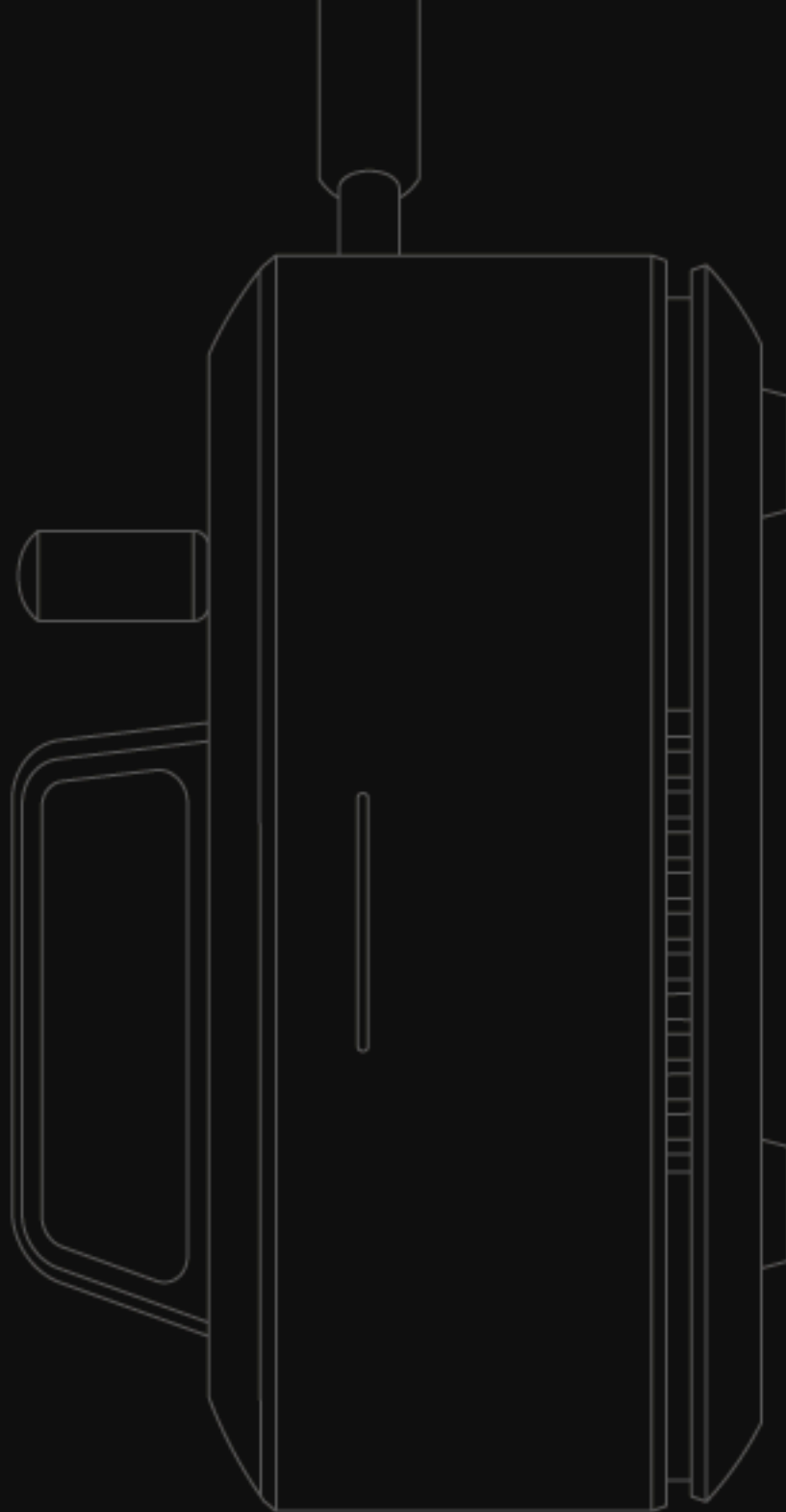
This warranty does not apply to equipment that is or has been abused, misused, modified or altered (including opening enclosure or tampering), improperly maintained, subjected to use beyond rated conditions, or damaged as a result of any carelessness or accidents. This warranty does not cover any problem that is caused by ordinary wear and tear, improper use, misuse or abuse, or improper storage or maintenance.

### Limitations of Liability

OXOS Medical, Inc. makes no other warranty, either expressed or implied, with respect to any equipment purchased from OXOS Medical, Inc. including, without limitation, any implied warranties of merchantability or fitness for a particular purpose, whether or not OXOS Medical, Inc. may have been informed of the actual uses to which any of such equipment may be put. OXOS Medical, Inc. shall not under any circumstance be liable for incidental, indirect, consequential, punitive or exemplary damages, including, without limitation, damages for delay or lost profits, business interruption, even if OXOS Medical, Inc. has been advised of the possibility of such damages. In no event shall liability of OXOS Medical, Inc. arising from the purchase, sale or use of the equipment, or breach of any warranty made above, exceed in the aggregate the

purchase or rental price paid therefore during the twelve (12) months immediately preceding the event giving rise to liability.

The owner and/or operator of this equipment acknowledges many states in the U.S. have regulations regarding the operation of radiation-emitting equipment, and it is the responsibility of the owner and/or operator of this equipment to understand and comply with all local regulations and rules. OXOS makes no warranty regarding fitness of the device for any particular use or purpose under any particular state law or regulation. There are no warranties which extend beyond the description on the face hereof.



**DOCUMENT REVISION HISTORY**

Rev	Description of Change	Approved By	Approval Date:	DCO #
A	Initial Release	Refer to <a href="#">ECR-287</a>		
B	Added Warning Statements, Cleaned Language	Refer to <a href="#">ECR-271</a>		
C	Update General Safety warnings to include wireless charger information. Specify power cord type and length. Update General Electromagnetic Immunity Table to add relevant W1 testing and clean up.	Refer to <a href="#">ECR-359</a>		
D	Updated minor notes Updated Electromagnetic Emissions and Immunity information and classification	Refer to <a href="#">ECR-404</a>		
E	Modified Wireless Transmission and Compliance section Removed references to drapes and use in surgery Updated storage temperature upper limit to 55°C from 40°C Added troubleshooting step for intermittent connection Marketing Updates	Refer to <a href="#">ECR-703</a>		
F	Update Section 4 Disassemble Device statement to include statement about changes voiding the user's authority to operate the equipment. Updated RA Label picture to Revision E	Refer to <a href="#">ECR-727</a>		

Digital Key: [https://docs.google.com/document/d/1EEsTlL5aKc2P9xPPW0rn\\_g3z0q0kEDHVDDMfYuzddv0/](https://docs.google.com/document/d/1EEsTlL5aKc2P9xPPW0rn_g3z0q0kEDHVDDMfYuzddv0/)