

IMROC-IR™

Infrared Interventional MR Communications System

User Guide

Version 2.4

UG-IMROC-2.4 0621

Optoacoustics Ltd.

SOUND SOLUTIONS FROM LIGHT TECHNOLOGY

www.optoacoustics.com

About This Manual

This manual provides guidance for routine use of the IMROC™ Interventional MR Communications System after it has been formally installed by Optoacoustics' field service engineers.

General Notices

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- Proprietary information supplied within this manual remains the sole property of Optoacoustics.
- This manual is intended solely and exclusively for the use of authorized operators of the IMROC-IR System. No part of this manual shall be disclosed to any third party, electronically, mechanically or by any other means, without the express prior permission of Optoacoustics.
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Notices

The following are important notices regarding use of this equipment:

Intended Use

The IMROC-IR System is intended for use by trained personnel in functional, interventional and clinical MRI environments to facilitate audio communications during a scanning session. System devices provide real-time Scanner noise reduction and/or noise cancellation, while enabling multiple concurrent dialogs.

Personal Safety Precautions

The IMROC-IR System is certified completely safe for use in advanced as well as standard MRI environments, when it has been installed and configured by field service engineers who are authorized by Optoacoustics.

No special precautions for operation of this system by end users are required.

Equipment Safety Precautions

WARNING: To avoid the risk of electric shock, this equipment must only be connected to a supply mains with protective earth.

Do not open any module or device of IMROC-IR. Only authorized Optoacoustics field service engineers are authorized to open the System.

Do not twist or bend the optical cables to within a radius of less than 1 inch (2.5 cm). Excessive twisting or bending of the optical cables can cause optical signal loss and/or fiber breakage.

Electromagnetic Compatibility (EMC) Compliance

The IMROC-IR System is certified as compliant with 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). Refer to document: OPTO-IEC60601-1-2 2021.

Sanitary Precautions

- **Microphones:** The hygienic pop screen should be replaced before each use.
- **Headphones:** Left and right hygienic earphone covers should be replaced before each use.

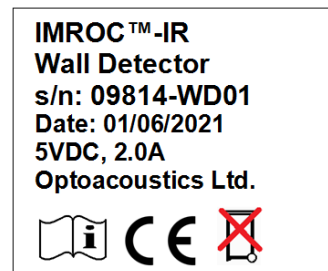
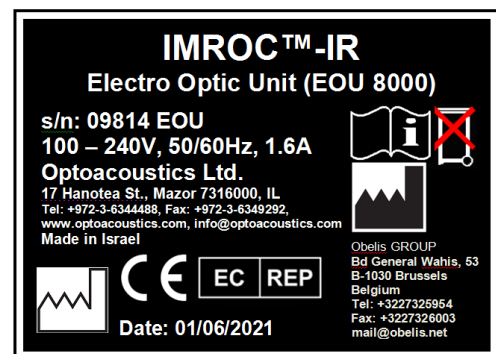
Headset Handling and Care

- Always return the IMROC-IR headsets to their velcro hooks at the end of each session.
- Always handle and carry the IMROC-IR headsets by the earphone cups or head band – do not carry it using the fiber optic cable.

Identification and Regulatory Labels

The following identification and regulatory labels are used with the IMROC-IR System:

Manufacturer's Identification Label:



Following shows the location of each label on its related System component:

Label on the EOU (includes Model Identification):



Labels on the Control Console:



Labels on the IR Wall Transceiver:



Labels on each Headset:



Labels on the Battery and Battery Charger:



Regulatory Label Symbol Explanations:



Consult instructions for use or consult electronic instructions for use.



This item is designated as Body Floating (BF) Applied Part. (IEC 60601-1).



Do not discard this item as unsorted waste. Send to separate collection facilities for recovery and recycling. (EU WEEE Directive)



This electrical item is MR safe. It can be placed and used in the MRI scan room.



This electrical item is MR conditional. It can be used in the MRI scan room when it has been installed at the required distance from the scanner bore by an Optoacoustics engineer.



This electrical item is MR unsafe. Do not use or place this item in the MRI scan room.



Conformité Européenne (CE) certification.

Example Packaging Label

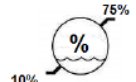
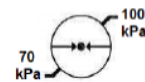
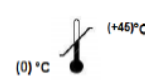
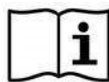
Model: **IMROC™-IR**



SN: **09705**

Dimensions: x x cm

Weight: Kg



03-2021

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1. Introduction to IMROC

The **Interventional MR Optical Communication Infrared System (IMROC-IR)** is an optical and IR-based communications system for the scanner room. With revolutionary digital wireless IR-Diffusion headphones and highly directional optical microphones, up to seven concurrent dialogs (between five doctors, a patient and technologists in the control room) are enabled, while at the same time ensuring a high level of human protection from the strong ambient noise produced by the scan.

IMROC-IR is not a part of any MRI-related diagnostic use.

1.1 How Does IMROC-IR Work?

The Staff and Patient wear full duplex Headsets through which they communicate with each other. The Staff Headsets use diffusion IR wireless protocol to communicate to multiple Wall Transceivers which are connected via fiber optic cables to the EOU 8000, which processes all incoming signals. The Patient Headset is connected directly via fiber optic cable to the EOU 8000. A technologist, sitting in the Control Room, uses the Control/Mixing Console connected to the EOU 8000 to adjust communications.

Headset control enables total flexibility over who can listen and who can talk, independently or simultaneously. The Patient may listen to music at the same time.

IMROC-IR consists of Sub-assemblies in 2 or 3 different rooms:

- 5 Staff Headsets with Personal Audio Control Units; 1 Patient Headset; Headset Storage Hangers (in the Scanner Room)
- EOU 8000, the 'heart' of the communications processing (in the Equipment Room or optionally close to the Control/Mixing Console in the Control Room)
- Control/Mixing Console with Headset, connected to the EOU via low voltage electrical cable inside a shielding conduit beneath the floor (in the Control Room)
- Recharging Station for Headsets (in the Control Room or other accessible place)

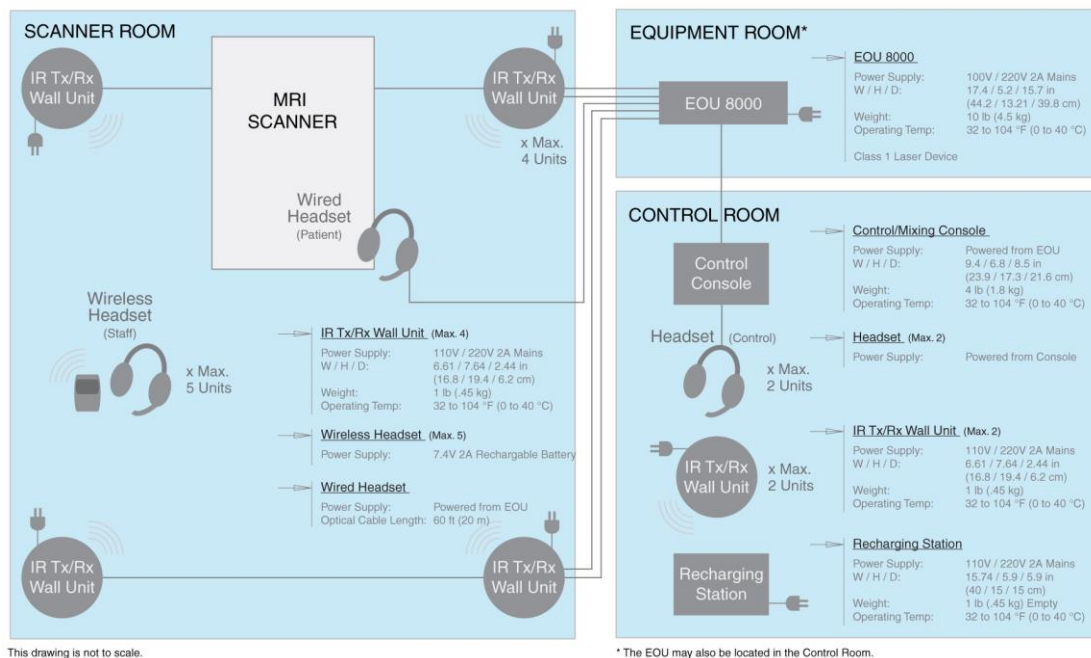


Figure 1: IMROC-IR System Block Diagram

1.2 Features and Benefits

- Lightweight, robust wireless communications system
- Passive system that is absolutely immune to and does not influence EMI/RFI fields – there is no interference with MR imaging
- Compact, easy to carry over-the-belt Personal Audio Control Unit with mode switch and volume control
- High fidelity audio (even during noisy scans)
- High level of ambient noise reduction – in the ear and in the microphone
- Simple switching system enables doctor to talk with Patient and/or another doctor

1.3 IMROC-IR Sub-Assemblies Overview

1.3.1 Staff Headset

The Staff Headset consists of the following components:

- Staff Optical Microphone
- Staff Optical Headphones
- Personal Audio Control Unit (containing Li-Ion Battery Pack)
- Disposable hygienic Pop Screen
- Disposable hygienic Earphone Covers

The Staff Headset is permanently connected to the Personal Audio Control Unit via a fiber optic cable. Communications to and from the System are achieved wirelessly via the Wall Transceivers.



Figure 2: Optical Headset and Disposable Earphone Covers

NOTE: The IMROC-IR Staff Headset is rated “**MR Safe**” in accordance with ASTM designation F2503, “Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment”.

1.3.1.1 Staff Optical Microphone

The IMROC-IR Optical Microphone is a highly directional, noise-canceling optical microphone system, based on Optoacoustics' FOMRI microphone.

NOTE: The IMROC-IR Optical Microphone is permanently connected to the Headset.



Figure 3: Optical Microphone

- Uses a dual-channel orthogonal microphone that is coupled with a tailor-made DSP unit to eliminate virtually all ambient MR acoustic noise
- Enables higher intelligibility - no need for 'push to talk'
- Accumulative effect of the attenuated noise received in dual-channel microphones is at maximum when multiple channels are used concurrently
- Low latency
- Uses disposable hygienic Pop Screens



Figure 4: Disposable Pop Screen

1.3.1.2 Personal Audio Control Unit

NOTE: The Personal Audio Control Unit cable is permanently connected to its Headset.

The Unit has the following features:

- Rotating volume knob for adjusting Headphone speaker volume
- Four position selector for control over channels
- Volume knob and channel selector are easily accessible above sterile clothing. The Unit is designed to be clipped to a belt on the user.

- Contains the rechargeable Li-Ion Battery Pack
- The Unit contains a diffuse IR transmitter for communications

The Personal Audio Control Unit is permanently connected to the Staff Headset via a fiber optic cable. Communications to and from the System are achieved wirelessly via the Wall Transceivers.



Figure 5: Personal Audio Control Unit

1.3.2 Patient Headset

The Patient Headset is connected directly to the EOU 8000 via optical fiber cable. Patient Headset headphone volume is controlled by the Technician.

NOTE: The IMROC-IR Patient Headset is rated “**MR Safe**” in accordance with ASTM designation F2503, “Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment”.

1.3.3 Wall Transceiver Unit

The IMROC-IR Wall Transceiver uses proprietary diffused IR technology to enable wireless communications among all Headsets. From 1 to 6 Wall Transceivers may be installed in the Scanner Room in order to provide robust communications.

Each Wall Transceiver receives its power from nearby low voltage electrical wall outlets. Power-up and digital-to-analog I/O activity of each Wall Transceiver is achieved via fiber optic communication cables connected directly to the EOU 8000 in the Equipment Room.

When the Wall Transceiver is operational, a **BLUE LED** is lit on its front cover. There is no Power On/Off switch on the Wall Transceiver.

NOTE: The IMROC-IR Wall Transceiver is rated “**MR Conditional**” in accordance with ASTM designation F2503, “Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment”.



Figure 6: Wall Transceiver Unit

1.3.4 EOU 8000

The Electro-Optical Unit (EOU) 8000 is the ‘heart’ of the IMROC-IR system. It is the size of a standard personal computer case and can be located either in the Equipment Room or the Control Room.

Inside the EOU 8000 case are multiple components that provide the optics, electronics, DSP, I/O interface and mixing functions, as well as the System power supply.

The EOU 8000 is physically connected to multiple Wall Transceivers located in the Scanner Room via fiber optic cables, and to the Control/Mixing Console in the Control Room via a low voltage electrical cable.

The EOU 8000 is powered-on directly from Control/Mixing Console in the Control Room. Although the EOU has an independent power switch located on its back panel, this switch should remain in the ‘on’ position during normal operation.

NOTE: There are no user serviceable parts inside the EOU 8000. It should be opened only by field service engineers who are authorized by Optoacoustics.

1.3.5 Control/Mixing Console

The IMROC-IR Control/Mixing Console is a sound mixer for all Headsets in the System and also controls the EOU 8000.

Using the Console, the Staff member sitting in the control room can:

- Talk to any or all of Staff members
- Talk to the Patient
- Mute the Console loudspeaker from sounds coming from the Headset of any Staff member or Patient
- Monitor in the Console loudspeaker music that the Patient is currently listening to
- Adjust the volume of Console loudspeaker
- Connect to an external music player or PC
- Connect up to two additional Headsets for listening and speaking to Staff and Patient
- Connect to external loudspeakers

2. System Installation

IMROC-IR installation is performed by Optoacoustics engineers or their formally approved designate(s). For complete information, please contact the company.

3. Using the IMROC-IR System

Before beginning operation of the System, ensure that all batteries have been fully charged for use in the Personal Audio Control Units.

In the event of unexpected power outage, IMROC-IR system components do not require any special manual restart procedures (such as warm boot or re-identification). The System returns to default operating functionality whenever power is reapplied.

Using the IMROC-IR is simple and comprises the following basic steps:

- 1 Install a fully-charged battery into each Personal Audio Control Unit that will be used.
- 2 Switch on each Personal Audio Control Unit.
- 3 Switch on the Control/Mixing Console (Power button on back panel).

The System is immediately ready to be used. Each of the following sections detail the use of an IMROC-IR System component.

3.1 Using the Mixing/Control Console

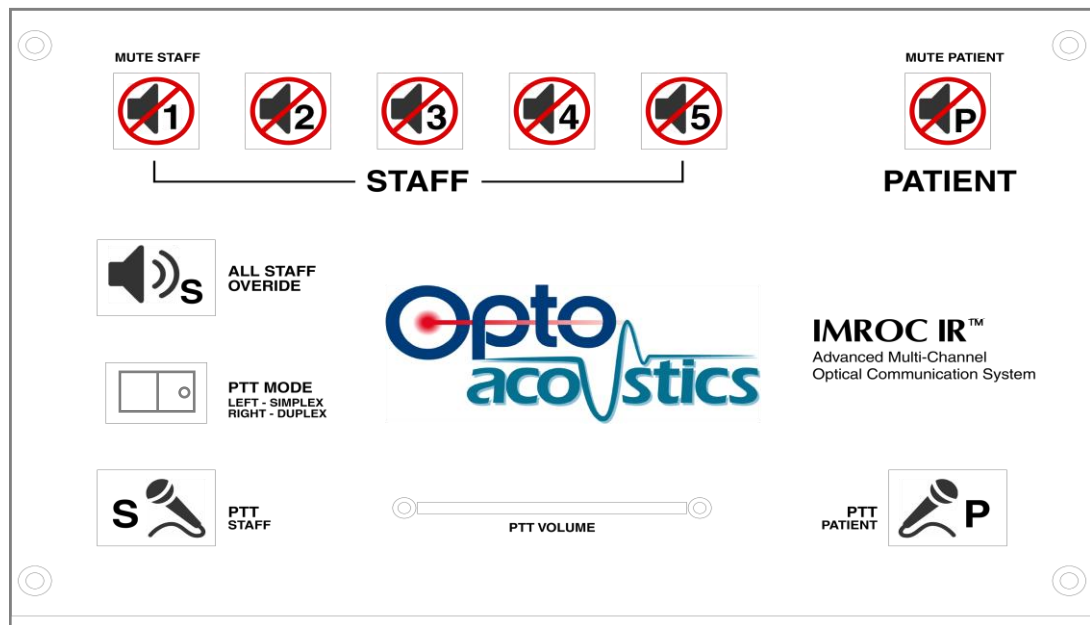


Figure 7: IMROC-IR Control/Mixing Console

- Switch **ON** the Power Button on the back side of the Control/Mixing Console. This also powers on the EOU 8000 and each of Wall Transceiver Units (the blue LED on each Wall Unit will be lit).
- See *Figure 7: IMROC-IR Control/Mixing Console*, on page 15 for console for the mapping of functional controls:
 - Press a **Mute Staff or Mute Patient** pushbutton toggle switch to activate muting for the selected individual Headset. The toggle is lit **RED** when muting is active.
 - Press the **All Staff Override** pushbutton toggle to instantly *cancel muting for all Headsets*. The toggle is lit **GREEN** when override is active.
 - Switch the push-to-talk **PTT Mode** rocker toggle to enable either one-way (simplex) or two-way (duplex) functionality.
 - Press the **PTT Staff** pushbutton switch to instantly communicate between the Control/Mixing Console and Headset users in the Scanner Room. The toggle is lit **GREEN** when active.
 - Press the **PTT Patient** pushbutton switch to instantly communicate between the Control/Mixing Console and the Patient in the Scanner Room. The toggle is lit **GREEN** when active.
 - Adjust the **PTT Volume** slider to control the Console PTT volume (it has no affect on the volume in the Headsets).
- The Console back panel provides connectors for two external headsets, as well as external line-in microphone and speaker.
- We recommend switching **OFF** the Console Power Button at the end of each session.

NOTE: The Console panel is not spill protected.

3.2 Using the Headset

When the Staff and Patient are wearing their headsets, all functions are automatic. Communications occur continuously in both directions (duplex mode) without the need for any manual switching.

To ensure the highest quality voice transmission and a minimum of noise, the microphone should be placed close to each Staff member's mouth.

Replace the Pop Screen and Headphone covers before each scanning session.

NOTE: The Headset is not spill protected.

3.2.2 Handling

- Special headset hooks are supplied with the system for securely mounting headsets in the Scanning Room when they are not in use. **Always return the headsets to their hooks at the end of each session.**
- Avoid excess stress or strain to Headset connections.
- Do not carry the Headset using the fiber optic cable. Always carry and handle the Headset by its earphone cups or its headband.

3.2.3 Hygiene

Hygienic microphone pop screens and earphone covers should be replaced before each session.

NOTE: The pop screen is not only hygienic (separating the Patient's mouth from the surface of the microphone head) but also improves speech quality, by removing 'popping' noise often caused by normal speech when close to the microphone.

Sealed packs of 100 pop screen units are ordered directly from Optoacoustics.

Hygienic earphone covers are available generically.

3.3 Using the Personal Audio Control Unit

The IMROC-IR Personal Audio Control Unit is permanently connected to every Staff Headset. It enables audio channel switching and volume control for the user.

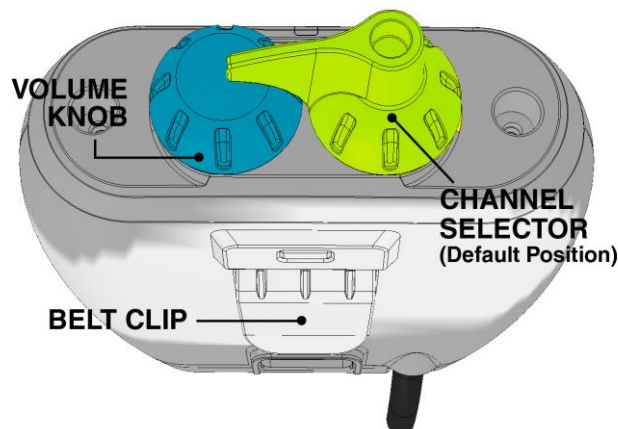






Figure 8: Personal Audio Control Unit Knobs

Each Personal Audio Control Unit has the following features:

- **Power Status LED** on the front of the Unit provides the following indications: GREEN indicates Battery is sufficiently charged, RED indicates Battery is not sufficiently charged, NOT LIT indicates the Unit is not operable.
- **Rotating Volume Knob** for adjusting speaker volume level. It has 4 positions: (1) medium, (2) high, (3) high - when ear plugs are used, and (4) very high - when ear plugs are used.
- **Channel Selector Knob** to switch the channel mixing mode. Each IMROC-IR system is manufactured to provide the customer's own unique specification for channel mixing modes. The Optoacoustics' field service engineer will provide you with the mode mapping installed for your specific System.

Figure 9: Personal Audio Control Unit - Modes of Operation on page 17 provides a matrix for all operating modes of Unit.

Channel Selector Position	Listen to Staff	Talk to Staff	Listen to Patient	Talk to Patient (Patient can hear User)
1 	+	+	—	—
2 	+	+	+	+
3 	—	—	+	+
4 	+	+	+	—

Default Mode (most commonly used) is Selector Position 4. The User can listen and talk to Staff and hear the Patient, but the Patient cannot hear User.

Figure 9: Personal Audio Control Unit - Modes of Operation

Only a fully charged Li-Ion Battery Pack should be used for each scanner session. After the session, each Unit's Battery Pack should be removed and recharged using the dedicated battery charger that is supplied with System.

3.4 Using the IMROC-IR Li-Ion Battery Charger

The IMROC-IR is delivered with a dedicated AC charger cradle that can recharge up to six Personal Audio Unit Li-Ion batteries simultaneously. The charger uses a standard electrical connector and electrical supply.

NOTE: Use of any other battery charging equipment for this purpose is unsafe and is strictly prohibited.

After each scanner session, all Li-Ion Battery Packs should be carefully removed from the Personal Audio Units and placed in the IMROC-IR charger cradle (shown below) for full recharging.



Gently insert a used Battery into any of the charger cradles for recharging. During the charging process:

- A **Red LED** will light next to a Battery to indicate that it is currently charging.
- A **Green LED** will light next to a Battery to indicate that it is fully charged.

A fully charged Battery may be left in the charger cradle until its next use without damage to the Battery or risk of overheating.

The length of time required for a single Battery to recharge completely will vary, depending on the power remaining after its last use. It may require about 3 hours for a fully discharged Battery to recharge completely.

Only a fully charged Li-Ion Battery Pack should be used for each scanner session.

3.5 Using the EOU 8000

IMPORTANT: The EOU 8000 rear power switch should always be in the **ON** position when the System is operating. The EOU power switch should be toggled **OFF only** when transporting the System.

Do not open the EOU 8000 case. Do not try to repair the System yourself. Always contact Optoacoustics Technical Support in the event of any System malfunction.

4. Troubleshooting

I don't hear anything in one of the Headsets.

It is possible that the fiber optical connection for that Headset has been detached or damaged.

If the problem persists, contact Optoacoustics Technical Support.

I don't hear anything in the Headsets. What should I do?

Shut down the System using the power switch on the Control/Mixing Console. Wait at least 30 seconds and then restart the System.

If the problem persists, contact Optoacoustics Technical Support.

5. Cleaning

COVID-19 NOTICE: Find specific cleaning instructions in the *COVID-19 Cleaning Notice* (Optoacoustics Document NOTICE-COVID19-01 2020).

With the exception of the EOU 8000, all components of the IMROC-IR System should be cleaned after each scanning session with standard sanitizing solutions that are approved for use in medical environments. Use a soft tissue or cloth on all surfaces. Wiping should be performed only – do not scrub or apply pressure to any IMROC-IR component surfaces, or submerge any component in liquid. Following cleaning, all components should be completely dry before using the System again.

NOTE: Clean the Headphones and fiber optic connecting cables with extra caution to avoid causing stress to any of the fiber optic cables or their connections.

6. Service and Maintenance

The IMROC-IR System should be serviced at least once every 24 months by Optoacoustics' Technical Support personnel.

7. System Specifications

The following environmental and equipment specifications are required for safe and effective operation of the IMROC-IR System:

SPECIFICATION	DETAIL
Operating Temperature	15-25°C (59-77°F)
Relative Humidity	Up to 75%
Atmospheric Pressure	100 kPa
Electrical (EOU): Rated Input: Classification: Fuse Type, Rating:	100-240 Vac, 50–60 Hz, Max. 1.6A Class I Equipment (Type BF) One (1) Glass Type, 10A 250A VC

The following environmental and equipment specifications are required for shipping and storage of the IMROC-IR System:

SPECIFICATION	DETAIL
Temperature	0-45°C (59-77°F)
Relative Humidity	Up to 75%
Atmospheric Pressure	70-100 kPa

8. EMC Declarations and Recommendations

This section provides electromagnetic compatibility declarations and recommendations for safe and effective operation of the IMROC-IR System, in accordance with regulatory requirements.

Declaration – Electromagnetic Emissions		
Emissions test	Compliance	Electromagnetic environment – guidance
RF emissions CISPR 11	Group1 Class A	The IMROC-IR 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.
Harmonic emissions IEC61000-3-2	Class A	The IMROC-IR is suitable for use in all establishments other than domestic, and may be used in domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes, provided the following warning is heeded: Warning: This equipment/system is intended for use by healthcare professionals only. This equipment/system may cause radio interference or may disrupt the operation of nearby equipment. It may be necessary to take mitigation measures, such as re-orienting or relocating the IMROC-IR or shielding the location.
Voltage Fluctuations And Flicker IEC 61000-3-3:2013	Complies	

Declaration – Electromagnetic Immunity			
IMMUNITY test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
Electrostatic discharge (ESD) IEC 61000-4-2	8 kV contact 2, 4, 8, 15kV air	8 kV contact 2, 4, 8, 15kV 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	2 kV for power supply lines 1 kV for input/output lines	2 kV for power supply lines N/A	Mains power quality should be that of atypical commercial or hospital environment.
Surge IEC 61000-4-5	1 kV line(s) to line(s) 2 kV line(s) to earth 2 kV Signal input/output) to earth	1 kV line(s) to line(s) 2 kV line(s) to earth N/A	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	0% UT; 0.5cycle at 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0% UT; 1cycle and 70% UT; 25/30 cycles Single phase at 0° 0% UT; 250/300 cycle	0% UT; 0.5cycle at 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0% UT; 1cycle and 70% UT; 25/30 cycles Single phase at 0° 0% UT; 250/300 cycle	Mains power quality should be that of atypical commercial or hospital environment. If the user of the IMROC-IR requires continued operation during power mains interruptions, it is recommended that the IMROC-IR be powered from an uninterruptible power supply or a battery.
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 atypical location in a typical commercial or hospital environment.
NOTE: UT is the a.c. mains voltage prior to application of the test level.			

[illegible]

Recommended separation distances between portable and mobile RF communications equipment and the IMROC-IR				
Rated maximum output power of transmitter W	Separation distance according to frequency of transmitter m			
	150 kHz to 80 MHz outside ISM bands $d = [\frac{3,5}{V_1}] \sqrt{P}$	150 kHz to 80 MHz in ISM bands $d = [\frac{12}{V_2}] \sqrt{P}$	80 MHz to 800 MHz $d = [\frac{12}{E_1}] \sqrt{P}$	800 MHz to 2,5 GHz $d = [\frac{23}{E_1}] \sqrt{P}$
0.01	0.12	0.2	0.4	1
0.1	0.37	0.64	1.3	2.6
1	1.17	2	4	8
10	3.7	6.4	13	26
100	11.7	20	40	80

Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communications equipment							
Test frequency (MHz)	Band ^{a)} (MHz)	Service ^{a)}	Modulation ^{b)}	Maximum power (W)	Distance (m)	Immunity Test level (V/m)	Compliance level (V/m)
385	380 – 390	TETRA 400	Pulse modulation ^{b)} 18 Hz	1.8	0.3	27	27
450	430 – 470	GMRS 460, FRS 460	FM ^{c)} ± 5 kHz deviation 1 kHz sine	2	0.3	28	28
710	704 – 787	LTE Band 13, 17	Pulse modulation ^{b)} 217 Hz	0.2	0.3	9	9
745							
780							
810	800 – 960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation ^{b)} 18 Hz	2	0.3	28	28
870							
930							
1720	1 700 – 1 990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse modulation ^{b)} 217 Hz	2	0.3	28	28
1845							
1970							
2450	2 400 – 2 570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation ^{b)} 217 Hz	2	0.3	28	28
5240	5 100 – 5 800	WLAN 802.11 a/n	Pulse modulation ^{b)} 217 Hz	0.2	0.3	9	9
5500							
5785							