mindmaze

Izar™

EN	User Manual	P1	FR	Manuel de l'utilisateur	P33
DE	Benutzerhandbuch	P59	ES	Manual del usuario	P83
IT	Manuale d'uso	P108	RO	Manual de utilizare	P133

D-2013-LBL-0131-AAD

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1. Safety Information

1.1 Warnings and precautions

Symbol	Meaning
	A WARNING statement provides important information about a potentially hazardous situation that, if not avoided, could result in serious injury or death
	A CAUTION statement provides important information about a potentially hazardous situation that, if not avoided, may result in minor or moderate injury to the user or patient or damage to any equipment connected
	Manufacturer name and address
	Manufacturing date
CE	CE Mark
EC REP	Authorised Representative in the European Community
swiss made software	Swiss Made Software
	Consulting instruction for use
	Follow the Instructions for Use
	Wash hands: advise the operator to wash his hands before the use of the system
UDI	Unique Device Identification

REF	Device article number
SN	Serial number
	WEEE Compliance Logo: the electronic device will not be disposed of through common waste means, and follow local regulations regarding electronic devices recycling
	Protect from water: advise the operator to protect the device from water and keep it away from rain
	Keep away from direct sunlight: advise the operator to protect the device from direct sunlight
	Indoor use only
	Pressure: accepted pressure transport range within which the transport package shall be stored and handled
	Temperature: accepted transport temperature range within which the transport package shall be stored and handled
	Humidity: accepted humidity transport range within which the transport package shall be stored and handled
	Lithium battery handling label
IP22	IP classification: the device is protected from ingress by particles greater than 12 millimeters and protected from water spray less than 15 degrees from vertical
	SGS North America Listed Mark: NRTL Mark for USA and Canada
	Non-ionizing radiation / RF

	Electrical safety Class I
	Izar™ is a Type BF (Body Floating) applied part
	Not made with natural latex rubber
	Alternating current input on AC power supply
	Direct current output from power supply
	Protection class II equipment: The AC Power Supply device has double insulation.
FC	Certification mark: Certifies that the radio equipment device is compliant with the Federal Communications Commission's (FCC) standards and regulations
IC	Industry Canada Certification mark: certifies that the radio equipment device is compliant with Innovation, Science, and Economic Development (ISED) Canada technical regulations and standards
Rx only	Caution: Federal law restricts this device to sale by or on the order of a licensed health care practitioner

Warnings	
⚠	THE DEVICE SHOULD ONLY BE USED WITH THE AUTHORISATION OF YOUR HEALTHCARE PROFESSIONAL
⚠	KEEP OUT OF REACH OF CHILDREN WHEN NOT UNDER DIRECT SUPERVISION
⚠	USAGE WITH CHILDREN Children over 5 years old can use Izar™ only in Europe, not in the USA. Children can use Izar™ under the DIRECT supervision of rehabilitation professionals.Children cannot use Izar™ in remote mode or at home
⚠	RISK OF INJURY Patients have to make only movements that have been instructed by the clinician in order to minimize the risk of injury due to new and incorrectly executed movements. Patients have to follow the therapy session plan prescribed by the rehabilitation specialist
⚠	KEEP OUT OF REACH OF PETS Keep Izar™, out of the reach of pets and most particularly dogs. A dog crushing Izar™ can generate battery fire or explosion
⚠	ENVIRONMENTAL WARNINGS • Izar™ is not designed for use in areas where an explosion hazard may occur. An explosion hazard may result from the use of flammable anesthetics, oxygen-rich environments, skin cleansing agents and disinfectants • Do not overheat Izar™. Do not place it close to a fireplace or a radiant heater • Do not expose Izar™ to moisture coming for example from nebuliser or steam kettle • Portable Radio Frequency communications equipment (including peripherals such as antenna cable and external antennas) should be used no closer than 30cm to any part of Izar™ including cables specified by MindMaze. Otherwise, degradation of the performance of this equipment could result

⚠	• Use of this equipment adjacent to or stacked with other equipment than MindMotion™ Go should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally • Do not immerse the device in water or other liquid. Izar™ is IP22. Izar™ docking station is IPX0 • Before use, allow Izar™ and its docking station to reach room temperature. If the unit has been transported or stored at temperatures below 0°C (32°F), leave it to reach at room temperature for about 2 hours, until any condensation has disappeared. If the unit has been transported or stored at temperatures above 40°C (104°F), leave it to reach at room temperature for about 2 hours • The plug socket must be close to the power adapter and be easily accessible • Before cleaning Izar™and its docking station, unplug the power adapter • Liquids and foreign material (such as dust, metal, etc.) must not be allowed to enter Izar™. If such material has entered into the unit, it must be immediately checked by a service technician, before it can be reused • Do not cover the docking station and do not place the docking station vents against a wall, as this could impact the docking station cooling • Make sure to keep the power input of the docking station accessible • Do not place any metallic object (coin, paper clip, etc.) between Izar™ and the docking station as it can trigger an error of the docking station or power down and avoid the recharge of Izar™ • Do not try to connect Izar™ to another host than the MindMotion™ Go device as this could result in a non-functioning device
⚠	PROPER USE • Do not modify the device. Modifications can destroy the device and generate electrical hazards or fire • Do not open Izar™ or any of its accessories • Use only accessories provided and recommended by MindMaze. Use of inappropriate accessories can negatively affect EMC performance, generate electrical hazards or fire • Disconnect the AC adapter immediately if there is abnormal heating or smell, or if smoke comes from the AC adapter or the device • Strangulation: do not wrap the adapter cable around your neck • Do not apply a force of more than 80 kg on Izar™, as this could damage the device and generate fire or explosion of the battery • Inspect Izar™ and its accessories before using it. Never use Izar™ or any of its accessories if it is damaged, as there is a risk of electrical shock

⚠	• In case of a change of performance of Izar™ or its accessories, outside of battery life reduction, stop using the device and contact MindMaze customer support
⚠	END-OF-LIFE DISPOSAL Follow instructions to dispose the device

Precautions

⚠	FOLLOW THESE PRECAUTIONS WHENEVER USING IZAR™ • Care should be used to avoid tripping on adapter cable • Wash your hands before and after using Izar™ to avoid any contamination. Wash and disinfect Izar™ between the usage with different patients • Do not use Izar™ if a patient has a skin infection or skin injury at the hands • Parts of Izar™ that come into contact with the patient when used as intended, are designed to fulfil the biocompatibility requirements of the applicable standards. Do not use Izar™ if you are allergic to Silicone or Polycarbonate plastic. If you experience an allergic reaction, stop using Izar™ and consult your healthcare provider
⚠	ENVIRONMENTAL PRECAUTIONS • Respect the environmental conditions specified in the ***Hardware component description*** section regarding use, storage and transport. Not respecting these limits can deteriorate the equipment or create an electrical dysfunction • Under extreme use conditions and especially during the charge, Izar™ and its docking station can reach a maximum temperature of 42 °C (107.5 °F). If you feel that Izar™ or the docking station is too hot, release the device and stop touching the docking station • Do not expose Izar™ to direct sunlight, because some of the components may reach unacceptably high temperatures • Respect the cleaning instructions specified in the ***Cleaning Instructions*** section. Inappropriate cleaning can damage the device or generate patient or operator contamination. Do not use incompatible cleaning agents

1.2 Serious Incident

Any serious incident occurring in relation to Izar™ should be reported to the manufacturer and the competent authority of the member state in which the user and/or the patient is established. Any unexpected operation shall be reported to the manufacturer.

2. Before use

Please refer to ***Safety information***.

2.1 Intended use

Izar™ is intended to rehabilitate and assess hand functions such as dexterous grasp, pinch and grip, as well as wrist movements in children (supervised, only in Europe, not in the USA) and adult patients with hand motor function impairment. This therapy device can be used as a controller for various activities allowing the patient to train within a therapy session and also alone to increase total therapy dose. The device can be used in all the environments the patient navigates; hospital, clinic, private practice and at home.

2.2 Intended user population

Patient:

Prevalent age: Children +5 years old (Europe only, not for USA) and adults (+18 years old in Europe, +22 years old in the USA).
Prevalent physical condition: any hand motor impairment.
Minimum knowledge required: understand instructions provided by the therapist.

Rehabilitation professional:

Minimum education level: physiotherapists, occupational therapists, neuropsychologists, various rehabilitation experts.
Minimum knowledge required: therapist degree.

Minimum experience: the rehabilitation professional should be able to supervise the patient during the rehabilitation and to define/adopt a rehabilitation adapted to the patient.

Relative:

Prevalent age: adult (+18 years old for Europe, +22 years old in the USA),
Prevalent physical condition: healthy people, no specific physical conditions are needed.
Minimum knowledge required: understand instructions and be able to supervise/accompany the patient during this rehabilitation session.

2.3 Contraindications

Please refer to ***Safety information***.

3. Product description

Izar™ is a medical device to support hand and wrist rehabilitation.

4. Setup

If you encounter any difficulties during installation, contact MindMaze customer support at ***customersupport@mindmaze.com***

4.1 Unpacking

H1. Izar™ with wrist strap

H2. Izar™ Docking Station

H3. Bluetooth Dongle

H4. Izar™ Power adapter with UK, US and EU plugs

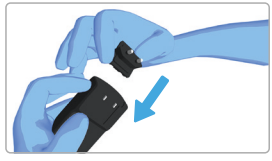
H5. Izar™ wrist strap installation tool

4.2 Device setup

Power Adapter

1. Insert the plug corresponding to your country

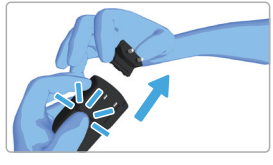
a. E-2013-PWR2-ACDC



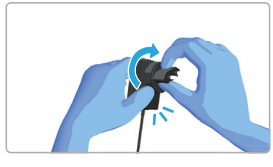
b. E-2013-PWR1-ACDC

2. In case you need to change the connector type

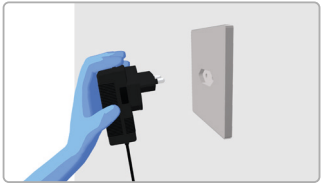
a. E-2013-PWR2-ACDC



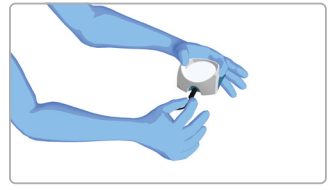
b. E-2013-PWR1-ACDC



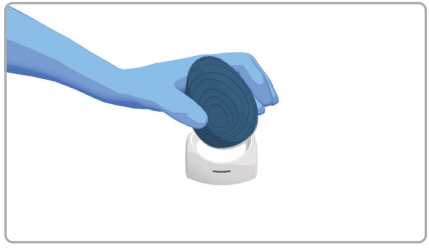
3. Connect the power adapter to the main



4. Connect the power adapter to the docking station



5. Place Izar™ on the docking station. Never place any foreign object, especially metallic, on the docking station as this will prevent Izar™ from being properly charged

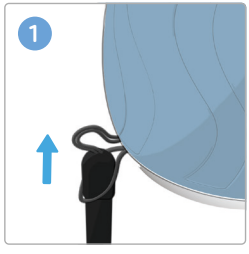


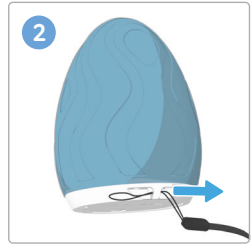
6. Insert the Bluetooth dongle into a USB port of the computer. Ensure to have the dongle as much as possible in front or on the side of the computer and not obstructed by a wall, a TV screen or a piece of furniture

Use only the power adapter included in the box.
Use the power adapter plug corresponding to your country.
Place the docking station on a table or a stable flat surface.
For Izar™ to stay connected to a given MindMotion™ GO, it must not be further than 3 m from it.

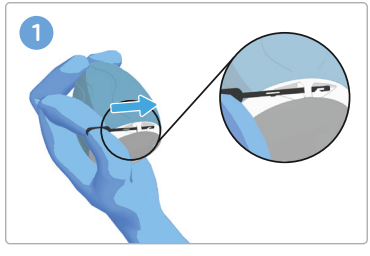
Wrist strap

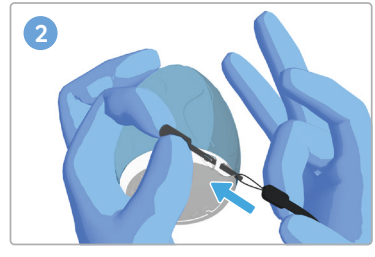
There is a wrist strap attached to Izar™. This is to attach Izar™ to the patient's wrist and to prevent Izar™ from falling accidentally during the therapy. In case you don't want to use the wrist strap you can remove with the following steps:

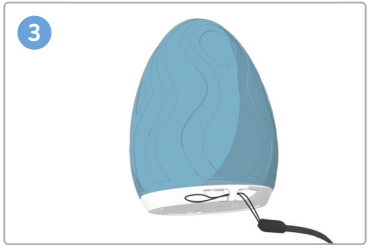


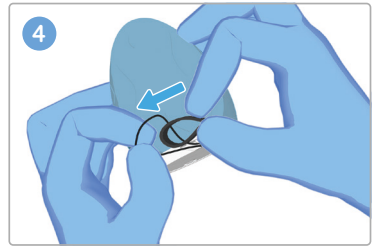


If the wrist strap is removed and you want to attach it again, follow these steps, using the wrist strap insertion tool:

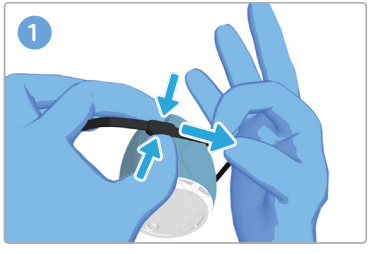


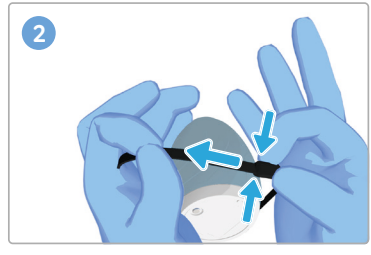






The length of the wrist strap can be adjusted using the length adjuster:





Insert the patient's hand in the wrist part located between the end of the wrist strap and the length adjuster.

4.3 Connection with MindMotion™ Go

To connect a new Izar™ to a MindMotion™ GO, click on icon in the top right corner and then on "Izar" in the left menu. Place Izar™ on the docking station and click on the Prepare button.

4.4 Troubleshooting

Izar™ is not working

Reset Izar™ by placing it on the docking station for at least a few seconds.
If the controller continues not to work:

- Check that the battery is sufficiently charged using Izar™ LED (***see LED indications***). If not, charge it by placing Izar™ on the docking station. Ensure that no foreign object is present on the docking station
- If the temperature of Izar™ or the docking station is very high, remove Izar™ and let the docking station cool down before recharging Izar™
- Verify that the pressure into Izar™ is sufficient. If not, use the button to correct this

Izar™ is not charging

If Izar™ does not charge or is not charged after more than 3 hours of charge, there is the possibility that the temperature is too high. If the docking station is in a warm environment, try to put it in a cooler environment. Alternatively, charge the device during the coolest time of the day (e.g during the night or early morning).
If the green LED on docking station is not on when you put Izar™ on the docking station:

- Check that the power adapter is correctly connected to the docking station and to the main
- Make sure no foreign object is present on the docking station

Bluetooth is off

If Izar™ cannot connect and a message appears saying Bluetooth is off, start by exiting MindMotion GO software and from the desktop select Start > Settings > Bluetooth & devices, then turn Bluetooth on.

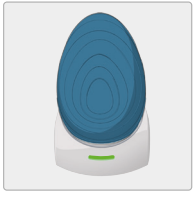
I don't find my device serial number (ID)

To find your device ID, simply turn around the device and see the number that is next to the symbol **SN**

5. How to use

Izar™ doesn't have a power switch, it automatically switches on when it is moved by the user. If not moved for one minute, it automatically goes into standby. During a session or while on the docking station, Izar™ is constantly on.

5.1 LED indications

	**On the docking station**	
	Blinking	While the ball is being charged
	Solid	When the ball is fully charged
	No LED	When Izar™ is not on the docking station, if the docking station is not properly connected to the main or in case of errors
	At the bottom of the IZAR	
	Slow Blinking	When in advertising/pairing mode
	Solid	When Connected

	Rapid Blinking	When streaming data
	Blinking	In case of error (refer to troubleshooting section)
Battery level indications at the bottom of Izar™ (when Izar™ is removed from the docking station)		
	Solid for 3 sec	If battery is full or almost full
	Solid for 3 sec	If battery should be recharged but can still do at least one treatment
	Blinking for 3 sec	If the ball has to be charged before being used

The docking station is equipped with an LED that will be:

- Blinking green while the ball is being charged
- Solid green when the ball is fully charged
- Off when Izar™ is not on the docking station, if the docking station is not properly connected to the main or in case of errors

Izar™ is equipped with an LED that will be:

- Slowly flashing blue when in advertising mode
- Solid blue when connected
- Rapidly flashing blue when streaming data
- Blinking magenta in case of error (refer to troubleshooting section)

When Izar™ is removed from the docking station or shook from standby mode, the LED will indicate level of charge:

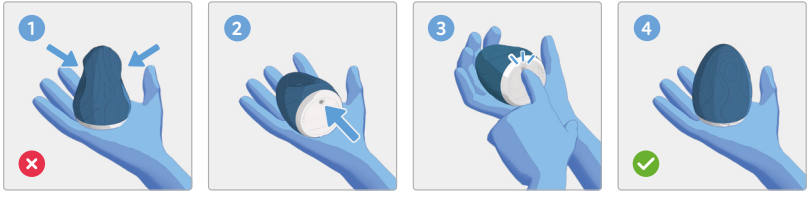
- Green for 3 seconds if battery is full or almost full
- Orange for 3 seconds if battery should be recharged but can still do at least one treatment
- Blinking orange for 3 seconds if the ball has to be charged before being used

5.2 Charge

Izar™ is charged by placing the device on the docking station. The charge is wireless, so it is important that Izar™ is correctly placed on the station, **without any object in between them**. The docking station LED will indicate the status of the charge.

5.3 Reset internal pressure

Izar™ is filled with air and measures the change of pressure inside itself. With time and usage, some air might go outside Izar™ which might make Izar™ softer than usual. In this case, the button can be used to let air into Izar™, so that Izar™ regains its initial rigidity. Press the button and hold for a few seconds until Izar™ is fully reinflated.



5.4 Cleaning

Izar™ and the wrist strap shall be cleaned after each training session if the next user is not the same. To clean Izar™, use a wipe and a disinfecting cleaning solution containing **70% isopropyl alcohol**. Do not use a solvent. Do not use an abrasive material. Do not immerse Izar™ or any of its accessories as this could damage the device. If the device or an accessory was accidentally exposed to liquid, make sure it is completely dry and inspect it before using it.
If you want to clean the docking station, first disconnect the power adapter connector from the docking station. Use a wipe and a disinfecting cleaning solution containing 70% isopropyl alcohol. Do not use a solvent. Do not use an abrasive material.

5.5 Maintenance

There is no other maintenance besides Firmware Updates (see MindMotion GO Software) that is required.

5.6 Technical specifications

- Model: Izar™ system
- Part number: MMIZ-01
- MDR Classification: Class I
- IP Classification of Izar™: IP22
- Battery: Lithium Polymer (Li-Po) rechargeable battery (3.7V 240 mAh). Minimal usage time before having to recharge the battery is 8 hours. Duration can vary depending on usage and environmental conditions
- Applied part: Type BF (Izar™)
- Power adapter: only power adapter provided by MindMaze and with P/N E-2013-PWRx-ACDC-xxx (MMIZ-Px with the box) can be used to recharge the battery of Izar™ with the docking station
- Power adapter electrical ratings:
  - Input: 100 - 240 V AC ~ 50-60 Hz 0.5 A (MMIZ-P2) / 0.6A (MMIZ-P1)
  - Output: 5 V DC 2 A (MMIZ-P2) / 1 A (MMIZ-P1)
  - Efficiency: VI
- Communications
  - Data communication: Bluetooth Low Energy (BLE)
  - Frequency band: 2,400 – 2,480 GHz (TX & RX)
  - Effective radiated power: 10 dBm
  - Wireless power transfer (WPT): Frequency band: 110- 205 kHz
  - Power Class: P < 5W
- Materials:
  - Docking station: ABS-Polycarbonate
  - Izar™ bottom part: ABS-Polycarbonate
  - Izar™ soft part: Silicone Rubber
  - Wrist strap: Silicone Rubber
  - Pressure relief button: Aluminium

- Weight: 75 g (ball)
- Dimensions (Izar™): 61 mm, height 81.5 mm

5.7 Storage and transport conditions

- Storage temperature:
  - -20°C to 45°C (-4°F to 113°F) for a duration ≤ 3 months
  - 0°C to 30°C (32°F to 86°F) for a duration > 3 months
- Storage humidity: 5% to 90%, non condensing
- Storage and transport pressure: 500 hPa to 1060 hPa
- Transport temperature: -20°C to 60°C (-4°F to 140 °F)
- Transport humidity: 5% to 90%

5.8 Operating conditions

- Operating temperature (except charging): 5°C to 40°C (41°F to 104°F)
- Charging temperature: 5°C to 30°C (41°F to 86°F)
- Operating humidity: 15% to 90%, non condensing but not requiring a water vapour partial pressure greater than 50 hPa
- Operating pressure: 700 hPa to 1060 hPa

5.9 Lifetime of the product

Lifetime of Izar™ will depend on the usage of the product, under which environmental conditions it is used and the care of the product. Under normal conditions of use, the expected lifetime of Izar™ and its accessories is 3 years. Passed this duration, you can continue using Izar™ as long as it is working correctly and it does not present a default. Do not store Izar™ for an extended period of time (over 6 months) without recharging it regularly (every 3 months), as this could damage the battery. Ideal charge level for storage is around 30%.

5.10 Spare parts / Repairs

The following parts can be ordered separately to replace defective, worn out or lost parts of the Izar™ system:

Part Number	Description
MMIZ-P1	AC/DC Power Adapter 1A
MMIZ-P2	AC/DC Power Adapter 2A
MMIZ-D1-R	Docking Station
MMIZ-W1-R	Wrist Strap

Do not try to repair or to replace any part of the device as this could result in a risk of fire or explosion. Contact MindMaze customer support for more information.

5.11 EMI Emissions

System characteristic	Description
Frequency (MHz)	2,400 – 2,480 MHz
Maximum declared output power (dBm)	6.14 dB
Maximum declared antenna gain (dBi)	3.5 dBi
Max EIRP (dBm)	9.8 dBm
Max EIRP (mW)	9.55 mW

5.12 Guidance and manufacturer's declaration – electromagnetic compatibility

Izar is intended for use in the electromagnetic environments specified in this document. Izar has been tested and found to be in compliance as shown. You should take care to use the device as described.

5.12.1 Electromagnetic Emissions

Emissions test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	Izar 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 CISPR 11	Class B	Izar system is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations IEC 61000-3-3	Complies	

5.12.2 Electromagnetic Immunity

Immunity test	IEC 60601 test level	Compliance level	Guidance
Electrostatic discharge (ESD)	± 8kV contact ± 2, ±4, ±8, ±15kV air	± 8kV 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	± 2kV for power supply lines ± 1kV for input/ output lines	± 2kV for power supply lines ± 1kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment
Surge IEC 61000-4-5	± 1kV power supply line to line ± 2kV power supply line to ground ± 2kV input/ output lines to ground	± 1kV power supply line to line ± 2kV power supply line to ground ± 2kV input/ output lines to ground	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 (100 % dip in UT) for 0,5 cycle 0 % UT (100 % dip in UT) for 1 cycle	0 % UT (100 % dip in UT) for 0,5 cycle 0 % UT (100 % dip in UT) for 1 cycle	Mains power quality should be that of a typical commercial or hospital environment

(Cont.) Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	70 % U_T (30 % dip in UT) for 25/30 cycles 0 % U_T (100 % dip in U_T) for 250/300 cycles	70 % U_T (30 % dip in U_T) for 25 cycles 0 % U_T (100 % dip in U_T) for 250 cycles	Mains power quality should be that of a typical commercial or hospital environment
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 or hospital environment
Conducted RF IEC 61000-4-6 Radiated RF IEC 61000-4-3	3 Vrms 150 kHz to 80 MHz 6 Vrms ISM Bands	3 Vrms 150 kHz to 80 MHz 6 Vrms ISM Bands	If the measured field strength in the location in which the Izar system is used exceeds the applicable RF compliance level, the Izar system should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the Izar system

Radiated RF immunity IEC 61000-4-3	10 V/m 80 MHz to 2,7 GHz	10 V/m 80 MHz to 2,7 GHz	Portable and mobile RF communications equipment should be used no closer to any part of the Izar system, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.Recommended separation distai $d = \frac{6}{E}\sqrt{P}$ E is the immunity test level in [V/m] d is the minimum separation in [m] P is the maximum power in [W]
Proximity fields emitted by RF wireless communication devices IEC 61000-4-3	385 MHz 27 V/m 50% PM 18 Hz 450 MHz 28 V/m 50% PM 18 Hz 710 MHz 9 V/m 50% PM 217 Hz 745 MHz 9 V/m 50% PM 217 Hz 780 MHz 9 V/m 50% PM 217 Hz 810 MHz 28 V/m 50% PM 18 Hz	385 MHz 27 V/m 50% PM 18 Hz 450 MHz 28 V/m 50% PM 18 Hz 710 MHz 9 V/m 50% PM 217 Hz 745 MHz 9 V/m 50% PM 217 Hz 780 MHz 9 V/m 50% PM 217 Hz 810 MHz 28 V/m 50% PM 18 Hz	RF wireless equipment maximum output power and separation distance tested (at 30 cm): TETRA 400: max 1.8 W GMRS 460, FRS 460: max 2 W LTE Band 13 and 17: max 0.2 W

(Cont.) Proximity fields emitted by RF wireless communication devices IEC 61000-4-3	870 MHz 28 V/m 50% PM 18 Hz 930 MHz 28 V/m 50% PM 18 Hz 1720 MHz 28 V/m 50% PM 217 Hz 1845 MHz 28 V/m 50% PM 217 Hz 1970 MHz 28 V/m 50% PM 217 Hz 2450 MHz 28 V/m 50% PM 217 Hz 5240 MHz 9 V/m 50% PM 217 Hz 5500 MHz 9 V/m 50% PM 217 Hz 5785 MHz 9 V/m 50% PM 217 Hz	870 MHz 28 V/m 50% PM 18 Hz 930 MHz 28 V/m 50% PM 18 Hz 1720 MHz 28 V/m 50% PM 217 Hz 1845 MHz 28 V/m 50% PM 217 Hz 1970 MHz 28 V/m 50% PM 217 Hz 2450 MHz 28 V/m 50% PM 217 Hz 5240 MHz 9 V/m 50% PM 217 Hz 5500 MHz 9 V/m 50% PM 217 Hz 5785 MHz 9 V/m 50% PM 217 Hz	RF wireless equipment maximum output power and separation distance tested (at 30 cm): TETRA 400: max 1.8 W GMRS 460, FRS 460: max 2 W LTE Band 13 and 17: max 0.2 W GSM 800/900: max 2 W TETRA 800: max 2 W iDEN 820: max 2 W CDMA 850: max 2 W LTE Band 5: max 2 W GSM 1800/1900: max 2 W CDMA 1900: max 2 W DECT: max 2 W LTE Band 1, 3, 4 and 25: max 2 W UMTS: max 2 W Bluetooth: max 2 W WLAN 802.11 b/g/n: max 2 W RFID 2450: max 2 W LTE Band 7: max 2 W WLAN 802.11 a/n: max 0.2 W

Note (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 access 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 Izar device should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocation of the Izar device.

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

5.12.3 Guidance

Portable and mobile RF communications equipment should be used no closer to any part of the devices, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.

Recommended separation distance (d):

$$d = \frac{6}{E}\sqrt{P}$$

where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey.

Note (a) should be less than the compliance level in each frequency range.

Note (b) To prevent electromagnetic interference, maintain a minimum distance between the portable and mobile RF communications equipment (transmitters) and the device as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter	80 KHz to 1000 MHz outside ISM bands	1GHz to 2.7GHz outside ISM bands	2.7GHz to 6GHz outside ISM bands
	$d = 0.6\sqrt{P}$	$d = 0.6\sqrt{P}$	$d = 0.6\sqrt{P}$
0.0	0.06	0.06	0.06
0.1W	0.19	0.19	0.19
1W	0.6	0.6	0.6
10W	1.9	1.9	1.9
100W	6.0	6.0	6.0
For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters [m] can be determined 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	$E = \frac{6}{d}\sqrt{P}$
The ISM (industrial, scientific and medical) bands between 150 kHz and 80 MHz are 6.765-6.795 MHz, 13.553-13.567 MHz, 26.957-27.283 MHz and 40.66-40.7 MHz	
Formulas coming from the IEC 60601-1-2	

Interference may occur in the vicinity of equipment marked with the following symbol:

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

6. FCC compliance information

6.1 Information to the user

This document, which describes the instructions for use for an intentional radiator, cautions the user that changes or modifications not expressly approved by the Manufacturer could void the user's authority to operate the equipment.

[54 FR 17714, Apr. 25, 1989, as amended at 68 FR 68545, Dec. 9, 2003]

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.

Note: This equipment 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 instruction, 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, the user is encouraged to try to correct 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

6.2 FCC human exposure limits

This device complies with FCC radiation exposure limits set forth for general population. This device must not be co-located or operating in conjunction with any other antenna or transmitter.
Caution: the user that changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.

Note: The separation distance between the user and/or bystander and the antenna and/or radiating element of the device is of at least 14mm.

7. IC compliance information

7.1 IC statement

Under Industry Canada regulations, this radio transmitter may only operate using an antenna of a type and maximum (or lesser) gain approved for the transmitter by Industry Canada. To reduce potential radio interference to other users, the antenna type and its gain should be so chosen that the equivalent isotropically radiated power (e.i.r.p.) is not more than that necessary for successful communication. This device complies with Industry Canada licence-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. This device complies with Industry Canada radiation exposure limits set forth for general population. This device must not be co-located or operating in conjunction with any other antenna or transmitter.

This device contains licence-exempt transmitter(s)/receiver(s) that comply with Innovation, Science and Economic Development Canada's licence-exempt RSS(s). Operation is subject to the following two conditions:

- This device may not cause interference
- This device must accept any interference, including interference that may cause undesired operation of the device

7.2 IC human exposure limits

This device complies with ISED radiation exposure limits set forth for the general population. This device must not be co-located or operating in conjunction with any other antenna or transmitter.

Note: The separation distance between the user and/or bystander and the antenna and/or radiating element of the device is of at least 14mm.

8. RF exposure compliance – Europe

Maximum RF Output power (9.55 mW peak EIRP) of the equipment is under 20mW, and thus, the test result is compliant without additional measurement. Therefore, EN 62311 (2008) "low power / inherent compliance decision" is applied.

9. Warranty

Please refer to section Safety information.
Warranty for defects. The Seller warrants to the Customer that the Products manufactured by the Seller that are sold to the Customer will be free from defects in material and workmanship as may be required for normal use for a warranty period of two (2) years following delivery of a Product. Notice of a defective Product under warranty must be given to the Seller in writing within ten (10) days following the discovery of such defect. Any oral or written statement concerning the Products inconsistent with the limited warranty set forth herein will be of no force or effect. The Seller's sole liability under the warranty will be, at the Seller's option, to either replace or repair the defective Product(s) or refund or credit the

purchase price to the Customer. This will be the Customer's exclusive remedy for a covered defect.
Limited warranty. The warranty, provided under the section above, does not cover and the Seller will have no warranty obligation whatsoever with respect to any damage to a Product caused by or associated with: (i) usage not in accordance with Product instructions or usage for a purpose not indicated on the labelling; (ii) abuse, misuse, neglect, improper maintenance or storage, accident, vandalism, or the negligence of any party other than the Seller; (iii) external causes, including natural disasters, acts of God, power failure, cosmetic damage or melting; (iv) use of unauthorised third party consumables and accessories with the Product; or (v) modifications or alterations to a Product not expressly authorised in writing by the Seller (e.g., any modifications to any software programs that are embedded in a Product). The Seller's obligations under its limited warranty are also contingent on the Customer's payment in pull of the Product purchase price. THE SELLER EXPRESSLY DISCLAIMS ALL OTHER WARRANTIES AND CONDITIONS, EXPRESS OR IMPLIED, STATUTORY OR OTHERWISE, INCLUDING, WITHOUT LIMITATION, WARRANTIES OR CONDITIONS OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE, AS WELL AS WARRANTIES ARISING FROM COURSE OF DEALING AND USAGE OF TRADE, AND THE SELLER DOES NOT REPRESENT OR WARRANT THAT ANY PRODUCT WILL MEET THE CUSTOMER'S REQUIREMENTS.

10. Disposal

At the end of their lifetime, Izar™ and its accessories shall be disposed of in conformity with the regulation of your country regarding electronic equipment. Particular attention shall be paid to Izar™ as it contains a lithium battery. Do not dispose of Izar™ and its accessories with regular waste.

For assistance, please contact your customer service team

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UK: +44 118 230 2021

Romania: +40726 723 082

Other: +800 4415 4415

customersupport@mindmaze.com

Or visit our website for additional contact information:

https://www.mindmaze.com/contact/

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Device Model: MMIZ-S1 FCC ID: 2AYHHMMIZ-S1 IC ID: 26802-MMIZS1

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