USER GUIDE

Model No.: 200

DATE: 02-AUG-2023

The UNIO device is intended for non-invasive use only, and should only be used as prescribed by a Physician or other Medical Professional for its intended use, in accordance with this User Guide.

The User Guide must be followed accurately. The UNIO device is to be used only with UNIO specified and supplied equipment and not in combination with other devices.

For external use only.

The UNIO device is to be operated and stored under dry conditions.

For any enquiries, customer service and technical support please contact your local UNIO Distributor.

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1. Introduction

1.1. UNIO and LIPUS Technology

The UNIO medical device is a Low Intensity Pulsed Ultrasound device (LIPUS).

LIPUS is a non-invasive ultrasound technology that is administered directly against the skin, sending a painless mechanical force through the tissue to stimulate the bone to heal. This process activates cell-reproduction and protein expression and enhances cellular behavior at the fracture site.

LIPUS devices have been found to support and accelerate the healing process of fresh fractures and non-unions. Specifically, the healing rate of non-union fractures after LIPUS treatment is on average 87% (65.6% - 100%) in multiple studies[5]. Studies have also shown that, on average, fresh fractures will heal 38% faster with ultrasound treatment and a cast[1,3].

UNIO is intended for non-invasive use only and must be used as prescribed by a physician or other medical professional for its intended use.

Treatment with UNIO is carried out for 20 minutes, once a day.

1.2. Information for the User

1.2.1 Indication and Intended Use

UNIO is indicated for the treatment of fresh bone fractures and established non-unions excluding treatment of the skull and vertebral column. The location and type of fracture will influence results.

1.2.2 Intended User

UNIO is intended to be used by the patient, as prescribed by a physician or other medical professional.

1.2.3 Intended Use Conditions

UNIO can be used in the presence of metal screws and plates.

When choosing a treatment site ensure that the site selected allows for full contact of the transducer face with the skin. Failure to do so may result in the transducer being only partially coupled to the skin. This may reduce the effectiveness of UNIO in treating the fracture.

Placement of the transducer directly over the internal fixation may result in the treatment signal being partially or fully blocked and may reduce the effectiveness of UNIO in treating the fracture.

The UNIO device is intended for at-home use under the following conditions:

- Operating Temperature Range: 5°C to 32°C (41°F to 89°F)
- Operating Relative Humidity Range: 15% to 75%
- Barometric Pressure Range: 700-1060hPA

Patients should treat themselves once per day.

Warning: The UNIO device must be operated under dry conditions. The UNIO device control unit and power supply must never be exposed to liquid. Do not place the UNIO device in water or operate in wet conditions.

The transducer, strap and gel are not sterile and placement on an open wound is not advised.

- Never use a damaged or broken device or component. In case of damage, please contact your local UNIO distributor
- Do not open and do not try to repair or modify the UNIO device
- Keep the UNIO device away from radiators and any heat source

- Do not drop any objects on the UNIO Device
- Never allow unsupervised use of the UNIO device by minors
- Use only the charger and the accessories supplied by your local UNIO distributor
- Handle the transducer with care as rough handling may adversely affect its output.
- The cords pose a risk for strangulation. Keep out of reach of children.

Please contact your local UNIO distributor in case of any questions or concerns.

WARNING: Use of the UNIO device adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.

1.2.4 Contraindications

There are no known contraindications with the use of the UNIO device.

1.2.5 Warnings

Whilst use of the UNIO device may be of clinical benefit, evidence of safety and effectiveness of UNIO has not been established in the following conditions:

(a) Non-union

- For the treatment of fractures of the vertebrae or skull
- In the skeletally immature
- Patients under 17 and over 86 years old

(b) Fresh Fracture

- For the treatment of fractures of the vertebrae or skull
- All fracture types
- In the skeletally immature
- Reduced fractures which remain substantially displaced
- For pregnant and breast feeding women
- For use in pathological fractures due to bone pathology or malignancy
- For complex fractures requiring surgical intervention to reduce and stabilize
- For use in patients with vascular disease or somatosensory dysfunction
- For use in patients with any neurological disorders which may affect the general wellbeing of the person, including and condition leading to nutritional deficiency
- For use in patients taking various medications including phosphonate therapy, steroids and cardiac medication
- If using for greater than the recommended 20 minutes per day
- For use outside the recommended clinical parameters, including prolonged use beyond prescribed guidelines
- Patients under 17 and over 67 years old.

1.2.6 Precautions

Whilst use of the UNIO device may be of clinical benefit, evidence of safety effectiveness has not been established in the following conditions. Use of the UNIO device under these conditions should only be undertaken under the direction of a medical professional.

- Reduced fractures which remain substantially displaced. The UNIO device will not correct and displacement
- For pregnant and women who are breast feeding
- For complex fractures requiring surgical intervention to reduce and stabilize

- If using for greater than the recommended 20 minutes per day
- For use outside the recommended clinical parameters, including prolonged use beyond prescribed guidelines

- Patients with cardiac pacemakers should get clearance from their medical professional prior to use.

1.2.7 Adverse Reactions

The following adverse reactions have been reported in patients using LIPUS devices[3,4] and may occur while using the UNIO device:

- Mild swelling
- Muscle Cramping
- Erythema

A potential allergic reaction to the coupling gel may also occur.

WARNING: If any of these occur immediately cease use of the UNIO device and seek immediate medical attention.

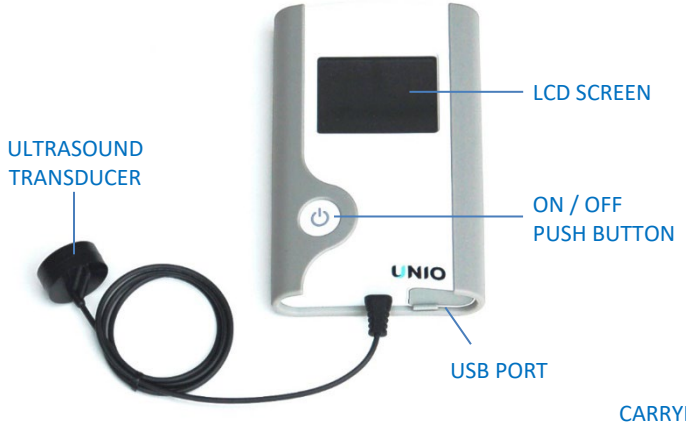
2. UNIO Device Kit

2.1. Components

The following components are part of your UNIO device kit, Model no. 200.

(a) Control Unit and Transducer

The UNIO device consists of a control unit and a transducer, housed in a carrying case also containing accessories. The transducer transmits a low intensity, high frequency pulsed ultrasound signal through the patient's skin to the fracture site to be treated. Note: The ultrasound transducer is an applied part. An applied part comes into physical contact with the patient to perform its function.



CARRYING CASE

(b) Accessories

ULTRASOUND GEL

250-gram (8.45 oz) bottle
Gel must be applied to the Transducer head prior to all treatment to enable ultrasound signal to pass from Transducer through skin to the fracture site. Only use Gel supplied by your local UNIO distributor.

ASSEMBLED TRANSDUCER HOLDER & STRAP

Used to position ultrasound Transducer over fracture site.
(Applied Part)

BATTERY CHARGER

USB Cable is used for charging the internal non-replaceable battery of the UNIO device. Length 1.5m.

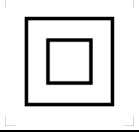
INSTRUCTION MANUAL

Operation instructions

WARNING: Using other than UNIO specified cables and accessories could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation. Failure to use the proper power supply and cord could lead to electrical shock or death. The UNIO device must only be used with UNIO supplied and specified equipment. The UNIO device must not be used in conjunction with other devices.

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

2.2 Symbols and Markings

Symbol / Marking	Description
	Class II Equipment
	Date of manufacture
	Non-sterile
	Non-ionizing electromagnetic radiation
	Not for General Waste
	Pulsed Waveform

	Type BF Applied Part
	Manufacturer
	Refer to instruction manual/ booklet
	Serial number
	Batch code
	Model number

3. UNIO Operating Guide

3.1. Before a Treatment

UNIO is a battery-operated device and will need to be charged for 12 hours prior to first use, using a country specific adapter. Your country specific battery charger is included in the UNIO device kit.

3.1.1 Rechargeable Battery and USB connection

The UNIO Control Unit is powered by a non-replaceable, rechargeable Lithium-Ion (Li-On) battery pack. A medical grade battery charger with a built-in USB connector is used to charge the internal battery. Note: Please ensure the battery is charged prior to use.

IMPORTANT: A country specific adapter must be used.

The USB mini connector on the bottom right of the UNIO device is used for charging.

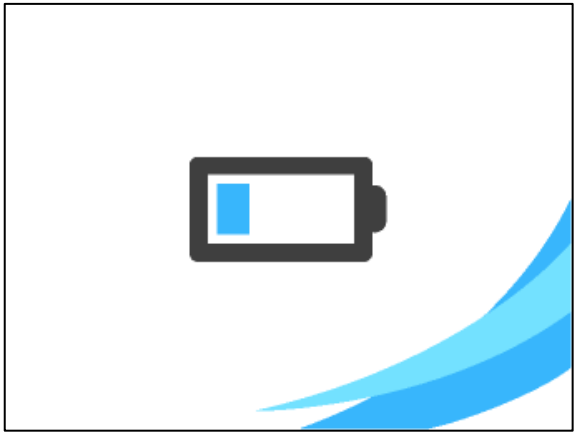
Please do not connect any unspecific device to the USB.

All functions of the UNIO device will be disabled if the device is not charged.

If the UNIO device enters Charging mode during a treatment a repeating beep is generated to alert the user that the treatment is disabled and to disconnect the USB cable. If the charger is disconnected within 30 seconds the treatment will continue where it left off. If the charger remains connected for 30 seconds or more the treatment will end when the charger is then removed.

If the device enters Charging mode from any other mode it will remain in charging mode until the USB connection is removed.

During the charging process, the LCD will show this battery symbol:



During the charging process, the UNIO device cannot be operated.

3.1.2 Audio Feedback

A high frequency audible sound is generated to give feedback when:

- Pressing the ON / OFF Push Button
- If gel is required
- At the completion of the treatment
- Low battery
- Hardware Fault
- Treatment limit reached

3.1.3 Error Symbols and Messages Displayed on LCD Screen

The Control Unit monitors the Transducer status, ultrasound output, and gel level continuously during the treatment cycle. The treatment will be interrupted if an error mode occurs. In this case the error message will be displayed as follows:

(a) Treatments Completed

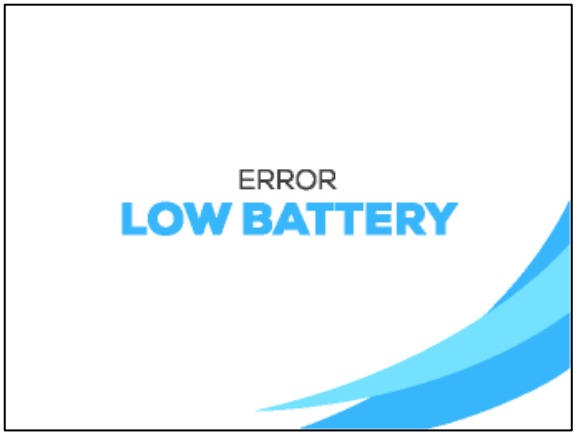
Indicates the number of treatments that have been completed by the user, up to a maximum of 200 treatments

(b) Insufficient Gel

If insufficient gel is detected before or during the treatment cycle, the Control Unit will suspend the treatment cycle until sufficient gel is applied. The Control Unit will generate an audible beep and the LCD screen will show as:

(c) Low Battery

If UNIO device detects that it has insufficient charge to complete a treatment the UNIO device generate an audible beep and the LCD screen will show as:

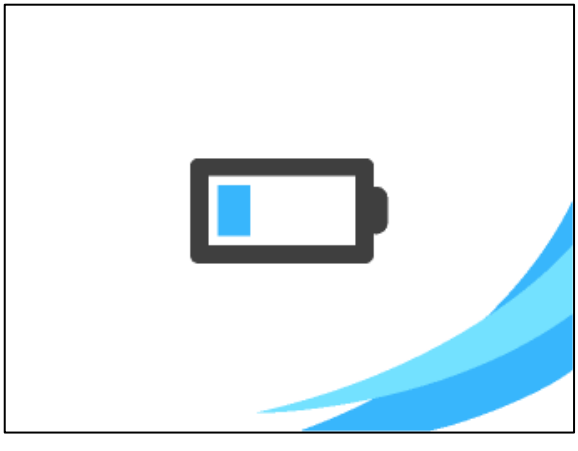


(d) Hardware Fault

If the UNIO device detects that it has a problem and cannot properly complete a treatment the UNIO device will generate an audible beep and the LCD screen will show as:

(e) Battery Charging

During the charging process, the UNIO device cannot operate. If the UNIO is plugged into a power source, the LCD screen will show as:



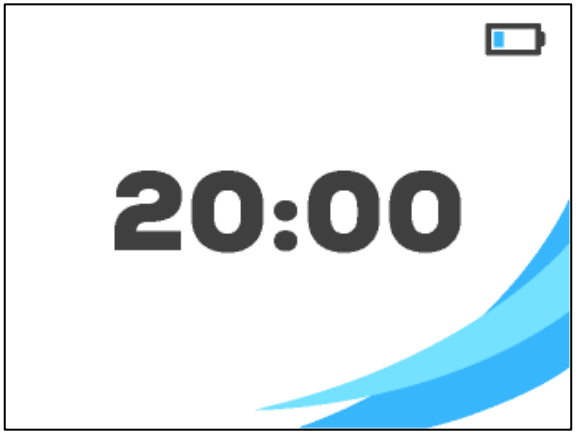
3.1.4 ON / OFF Push Button

The ON / OFF Push Button on the Control Unit allows the patient to start and terminate a treatment cycle.

(a) Starting a Treatment Session

IMPORTANT: Gel must be placed on the transducer head to enable transmission of the ultrasound signal from the transducer across the skin, to the fracture site

- Pressing and releasing the ON / OFF Push Button will start a 20-minute treatment session. The Control Unit will generate a short beep. The 20-minute countdown timer will commence counting down.



(b) Stopping a Treatment Session

To Stop a treatment session, press and hold the ON / OFF Button.

3.2. After a Treatment

Undo the strap and remove the Transducer head from the treatment site. Clean gel from the Transducer head, strap and skin with a soft cloth (not provided). Pack the UNIO device into the carry case for storage until next use. For further care instructions, reference section 5

4. Treatment Instruction

4.1. Non-Cast Use

Before starting, the Physician will mark an “X” over the fracture site, to ensure accurate placement of the Transducer holder for every treatment. You will need to ensure this point is reproducible for each treatment. An indelible marker may assist.

1. Place the strap with Transducer holder over fracture site and stabilize securely using the Velcro strap.

IMPORTANT: Do not over tighten the strap. Avoid reduction of blood circulation. It is also important that the Transducer holder be held securely over the site to be treated and ensure that the Transducer is accurately positioned.

2. Open the Transducer holder by squeezing the two-finger tab on either side of the Transducer holder towards the center.

3. Hold the Transducer and place a small amount of ultrasound gel on the face of the Transducer head, approximately 2.0 cm in diameter. Ensure enough gel is used to cover the entire surface of the Transducer.

4. Place transducer on your skin, through the transducer holder. Push the transducer down against the skin, ensuring the gel is spread evenly across the surface of the transducer. Note: The transducer must have skin contact to perform the treatment.

5. Ensure the cable is routed through the cut out in the cap and secure by closing the cap.

6. The foam mechanism on the cap provides light pressure on the Transducer. It ensures good contact to the gel and skin over the treatment area for proper ultrasound transmission.

7. Press the ON / OFF button to start the treatment. Timer will begin to count down from 20 minutes and turn off automatically

AFTER TREATMENT HAS COMPLETED

8. Undo the strap and remove the Transducer head from the treatment site. Clean gel from the Transducer head, strap and skin with a soft cloth (not provided). Pack the UNIO device into the carry case for storage until next use.

4.2 Using Strap Attachment Over Cast

IMPORTANT: A window must be cut into the patient's cast by a medical professional to deliver the treatment. UNIO requires direct skin contact to transmit the ultrasound signal to the fracture.

1. Secure the strap with Transducer Holder over your fracture site and stabilize it using the Velcro strap and holder.

2. Open the Transducer holder by pinching the two-finger tab on either side of the Transducer holder towards the center.

3. Hold the Transducer and place a small amount of ultrasound gel on the Transducer head, approximately 2 cm in diameter. Ensure gel covers the entire face of the transducer head.

4. Position the Transducer in the holder directly over the fracture site. Place transducer on your skin, through the transducer holder. Push the transducer down against the skin, ensuring the gel is spread evenly across the surface of the transducer. Note: The transducer must have skin contact to perform the treatment. Close cap to secure.

5. Press the ON / OFF button on the UNIO Control Unit to start the treatment. Timer will begin to count down from 20 minutes and turn off automatically when treatment is complete.

AFTER TREATMENT HAS COMPLETED

9. Undo the strap and remove the Transducer head from the treatment site. Clean gel from the Transducer head, strap and skin with a soft cloth. Pack the UNIO device into the carry case for storage until next use.

5. Care, Cleaning and Storage

5.1. Care and Cleaning

A single patient is the intended user of the UNIO device and may perform all care and cleaning procedures

- Please check the UNIO device and its components after each treatment for any visible damage including the transducer head, cables and associated connectors. Do not use if damaged.
- For charging only use the power supply provided with your UNIO device
- Never use cleaning agents and solvents to clean the UNIO device, its components or accessories. For cleaning, use only a soft cloth or tissue.
- The UNIO Device is not intended to be sterile or sterilized.
- The use of single patient use medical devices or components with multiple users may result in failure of the device to perform as intended, and patient illness or injury due to infection, inflammation, and/ or illness due to product contamination, and transmission of infection. Contact your local UNIO Distributor for reprocessing.

5.2. Storage

The UNIO device and its accessories should be stored and transported as follows:

- Temperature range: -25°C to 45°C
- Relative humidity range: 15% to 75%

If it is stored or transported in temperatures outside this range, allow UNIO time to come to room temperature for at least 30 minutes before operating.

The UNIO device and its accessories must be transported in its carrying case.

5.3. Disposal

The UNIO device should not be treated like normal household waste. Hence it is recommended that users follow local regulations for disposal of device. Many retailers and local governments have battery recycling programs that allow you to drop off old batteries. There are various drop-off centers for users to drop off the electronic waste like lithium-ion batteries in case of UNIO Model 200.

The Government of Canada has an inventory of recycling programs with respect to the type of waste that can be found here:

https://www.canada.ca/en/environment-climate-change/services/managing-reducing-waste/overview-extended-producer-responsibility/inventory-recycling-programs.html

The enclosure of the device is made of biocompatible polycarbonate material that can be disposed of into recyclables. Local provincial regulations around the same must be followed to allow for proper disposal at drop off locations set up by the government.

Empty gel bottles can be disposed of into recyclables.

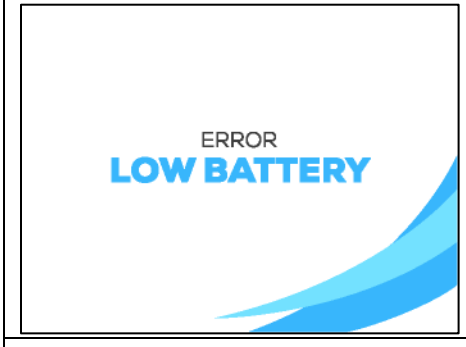
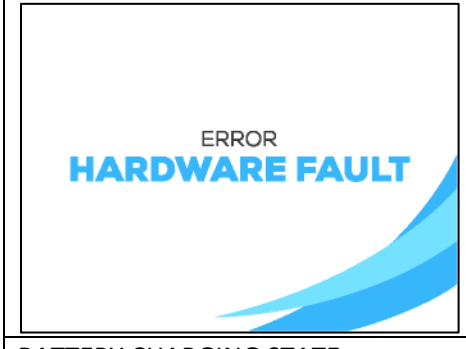
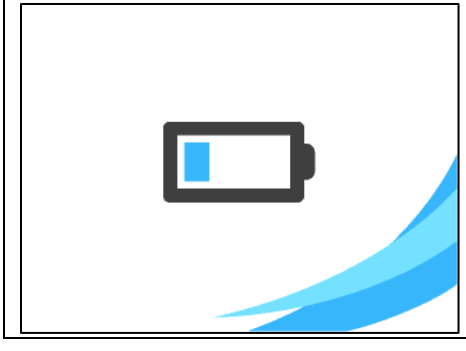
Please contact your local UNIO distributor for more information on correct disposal of your device.

6. Troubleshooting

6.1. General Device Operation

Issue	Possible Cause	Solutions
TREATMENTS COMPLETED 200 	Total Maximum treatments have been reached. The device will not operate.	Contact your local UNIO distributor.
ERROR LOW GEL 	If insufficient gel is detected before or during the treatment cycle, the Control Unit will suspend the treatment cycle until sufficient gel is applied. The Control Unit will generate an audible beep and show this screen.	Add Gel to ensure the entire transducer head is covered with gel.

6.2 During Treatment

Issue	Possible Cause	Solutions
ERROR LOW BATTERY 	If UNIO device detects that it has insufficient charge to complete a treatment, the UNIO device will generate an audible beep and the LCD screen will show this message.	Charge the battery with the supplied USB Power adaptor. Note: the UNIO device will not operate if it is connected to the power supply.
ERROR HARDWARE FAULT 	If the UNIO device detects that it has a problem and cannot properly complete a treatment, the UNIO device will generate an audible beep and the LCD screen will show this message.	Contact your local UNIO distributor. Note: Do not attempt to open the device. This will void your warranty.
BATTERY CHARGING STATE 	If the UNIO device detects that power is connected to the USB port, it will not provide a treatment and the LCD screen will show this picture. UNIO will not deliver a treatment if plugged into power.	Unplug the supplied USB power adaptor once it is sufficiently charged.

7. Warranty and Statutory Rights

The UNIO product is covered by a 2-year limited warranty. Please contact your local UNIO distributor for full warranty terms.

IMPORTANT: Do not try to repair or modify your UNIO device. This will void your warranty.

7.1. Enquiries

For any questions, concerns or assistance please contact your local UNIO distributor.

8. Technical Information

8.1. Control Unit Specification

- Effective Intensity (**I_e**)**:** 30 ± 30% mW/cm^2
- Temporal Average Power **P**: 117 ± 20% mW
- Beam Non-Uniformity Ratio (R_{BN}): 4.0
- Effective Radiating Area **A_{er}:** 3.88 ± 5% cm^2
- Ultrasound Frequency **f_{awf}:** 1.5 ± 5% MHz
- Waveform: Pulsed
- Pulse Duration (**PW):** 200 ± 5% µs
- Pulse Repetition Frequency (**PRF):** 1.0 ± 5% kHz
- Duty Cycle (**DF)**: 20%
- Beam Type (Q): Collimated

8.2. Battery Charger Specification

- Input Voltage: 100 - 240 Vac
- Input Current: 0.6 - 0.3 A
- Input Frequency: 50 - 60 Hz
- Output Voltage: 5.0 V
- Output Current: 1.2 A
- Output Power (Rated): 5 W Max

8.3. Electromagnetic Interference and Compatibility

Table 1 – Emission Class and Group Compliance

The UNIO device is intended for use in the electromagnetic environment specified below. The customer or the user of the UNIO device should assure that it is used in such an environment.		
Emissions Test	**Compliance**	**Electromagnetic Environment – Guidance**
RF Emissions CISPR 11	Group 1	The UNIO device uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF Emissions CISPR 11	Class B	The UNIO device 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/ Flicker Emissions IEC 61000-3-3	Complies	

Table 2 – Immunity Test Level Compliance

The UNIO device is intended for use in the electromagnetic environment specified below. The customer or the user of the UNIO 200 should assure that it is used in such an environment.			
Immunity Test	**IEC 60601 Test Level**	**Compliance Level**	**Electromagnetic Environment – Guidance**
Electrostatic Discharge (ESD) IEC 61000-4-2	±8 kV Contact ±15 kV Air	±8 kV Contact ±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	±2 kV for power supply lines	±2 kV for power supply lines	Mains power quality should be that of a typical residential or hospital environment.
Surge IEC 61000-4-5	±0.5 kV, ±1 kV line to line	±0.5 kV, ±1 kV line to line	Mains power quality should be that of a typical residential or hospital environment.
Voltage Dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	0% U_T (100% dip in U_T) for 0,5 cycle 0% U_T (100% dip in U_T) for 1 cycles 70% U_T (30% dip in U_T) for 25 cycles 0% U_T (100% dip in U_T) for 5 sec	0% U_T (100% dip in U_T) for 0,5 cycle 0% U_T (100% dip in U_T) for 1 cycles 70% U_T (30% dip in U_T) for 25 cycles 0% U_T (100% dip in U_T) for 5 sec	Mains power quality should be that of a typical residential or hospital environment. If the user of the UNIO device requires continued operation during power mains interruptions, it is recommended that the UNIO device be powered from an uninterruptible power supply or a battery.
Power Frequency Magnetic Field (50/60 Hz) 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 residential or hospital environment.
NOTE U_T is the a.c. mains voltage prior to application of the test level.			

Table 3 – Immunity Test Level Compliance

<table>
<tr><td colspan="4">The UNIO device is intended for use in the electromagnetic environment specified below. The customer or the user of the UNIO device should assure that it is used in such an environment.</td></tr>
<tr><th>Immunity Test</th><th>IEC 60601
Test Level</th><th>Compliance Level</th><th>Electromagnetic Environment – Guidance</th></tr>
<tr><td>Conducted RF IEC 61000-4-6

Radiated RF IEC 61000-4-3</td><td>3 Vrms
150 kHz to 80 MHz

6 Vrms
ISM/Amateur Radio bands inside
150 kHz to 80 MHz

3 V/m
80 MHz to 2,7 GHz

RF communication equipment inside
80 MHz to 6 GHz</td><td>3 Vrms
150 kHz to 80 MHz

6 Vrms
ISM/Amateur Radio bands inside
150 kHz to 80 MHz

3 V/m
80 MHz to 2,7 GHz

RF communication equipment inside
80 MHz to 6 GHz</td><td>Portable and mobile RF communications equipment should be used no closer to any part of the UNIO device including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.

Recommended separation distance

$d = 1.2\sqrt{P}$

$d = 1.2\sqrt{P}$ 80 MHz to 800 MHz

$d = 2.3\sqrt{P}$ 800 MHz to 2.7 GHz

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 meters (m).

Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey[a] should be less than the compliance level in each frequency range[b]</td></tr>
<tr><td colspan="4">NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.</td></tr>
<tr><td colspan="4">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 UNIO 200 is used exceeds the applicable RF compliance level above, the UNIO 200 should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the UNIO 200

b) Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.</td></tr>
</table>

Table 4 – Recommended Separation Distances

Recommended separation distances between portable and mobile RF communications equipment and the UNIO device			
The UNIO device is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the UNIO device can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the UNIO device as recommended below, according to the maximum output power of the communications equipment.			
Rated maximum output power of transmitter W	**Separation distance according to frequency of transmitter** m		
	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	0.24
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23
For transmitters rated at a maximum output power not listed above, the recommended separation distance *d* in metres (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. NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies. NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			

References:

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