REHABTRONICS
TECHNOLOGY FOR RECOVERY

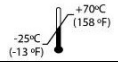
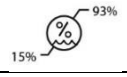
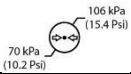
Prelivia

OPERATOR'S MANUAL

PR-IFU-EN
Revision 5.0
2024-01-04
Rx Only
(US Only)

Table of Contents

List of Symbols

Symbol	Definition	Application to the Prelivia System
	Warning	Important information or instructions that should be observed to avoid potential injury or damage to the device.
	Operating Instructions	Instructions for use can be referenced detailing operating instructions.
IP22	Ingress Protection Rating	The Prelivia enclosure is protected against dripping water (e.g. light rain)and ingress of finger-sized objects.
	Model Reference (Catalogue/Re-order Number)	Reference the accompanying model number next to this symbol when re-ordering components.
	Serial Number	Reference the accompanying device serial number next to this symbol if contacting support.
	Type BF Applied Part	Components that make patient contact have a degree of protection against electric shock.
	Manufacturer Information	Information next to this symbol gives the mailing address of the device manufacturer.
	Waste Electrical and Electronic Equipment(WEEE)	Do not dispose electronics with regular household waste. Consult localwaste management authorities to determine the acceptable means to dispose of electronic equipment.
	Transportation and storage temperature limits	Do not transport or store the Prelivia outside the temperature range indicated.
	Transportation and storage humidity limits	Do not transport or store the Prelivia outside the humidity rangeindicated.
	Transportation and storage pressure limits	Do not transport or store the Prelivia outside the pressure range indicated.
	Read Instructions	Read these instructions for important safety information.
	Do Not Reuse	Prelivia electrodes should not be reused.
	Medical Device	Prelivia is a Medical Device

Device Overview

The Prelivia is a 2-channel stimulator with each channel delivering stimulation to hydrogel electrodes. Intensities for each side, or pair of electrodes, are set independently. Once configured, each channel will deliver timed, periodic stimulation.

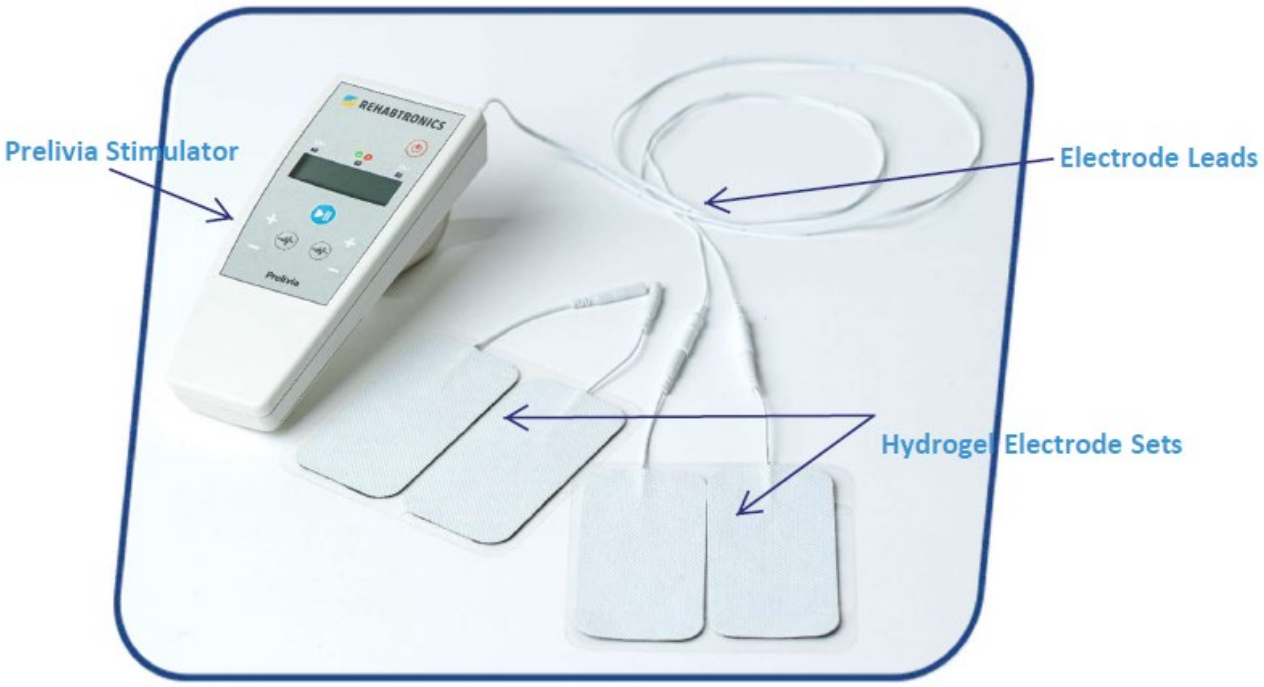
Operation is straightforward: simply apply the electrodes to the target region on the body, set the stimulation intensity, confirm that the patient's stimulation response is appropriate, and then start the stimulation program.

Indications for Use

- Increasing local blood circulation
- Prevention or retardation of disuse atrophy
- Relaxation of muscle spasms
- Muscle re-education
- Immediate post-surgical stimulation of calf muscles to prevent venous thrombosis
- Prevention of venous insufficiency and ischemia
- Maintaining or increasing range of motions

Prelivia is intended to by used by a Health Care Practitioner

System Components



Safety Information

Contraindications

The Prelivia stimulator should not be used on patients with any of the following conditions:

- Pacemaker
- Any implantable electrostimulation device
- myasthenia gravis
- Rhabdomyolysispace
- gluteal skin breakdown
- unstable fractures at risk of displacement by stimulation
- consumption of neuromuscular blocking drugs
- Skin breakdown over treatment areas that would preclude the use of surface electrodes

Warnings

- The long-term effects of chronic electrical stimulation are unknown.
- Stimulation should not be applied over the carotid sinus nerves, particularly in patients with a known sensitivity to thecarotid sinus reflex.
- Stimulation should not be applied over the neck, head, mouth or across the chest. Severe spasm of the laryngeal and pharyngeal musclesmay occur and the contractions may be strong enough to close the airway or cause difficulty in breathing.
- Stimulation should not be applied over the eyes or temple.
- Stimulation should not be applied over areas of suspected or confirmed bone fracture.
- Stimulation should not be applied transthoracically. Introduction of electrical current into the heart may cause cardiac arrhythmias.
- Application of electrodes near the thorax may increase the risk of cardiac fibrillation.
- Simultaneous connection of a patient to a high frequency surgical equipment may result in burns at the site of the stimulator electrodes and possible damage to the stimulator.
- Operation in close proximity (e.g. 1 meter) to a shortwave or microwave therapy equipment may produce instabilityin the stimulator output.
- Stimulation should not be applied transcerebrally.
- Stimulation should not be applied over swollen, infected, or inflamed areas or skin eruptions, e.g., phlebitis, thrombophlebitis, varicose veins, etc.
- Stimulation should not be applied over, or in proximity to, cancerous lesions.
- Do not apply electrodes over wounds or to areas with known skin conditions that may be aggravated by the electrodes, gel or stimulation therapy.
- Do not connect the stimulator outputs or the electrode leads to any other device or power source. Damage to the stimulator and potentially serious injury or death may result.
- Electrodes are for single patient use only.
- Routinely inspect the electrode contact areas to monitor for excessive or unusual irritation, swelling, blistering or other adverse reactions that may indicate an intolerance to the electrode or stimulation therapy. Discontinue use of the stimulation system and consult a physician immediately if any of these effects are observed.
- Monitor the level of patient discomfort, adjusting the electrodes and/or the stimulation settings if required.
- Discontinue the use of the stimulation system if excessive discomfort occurs or if the level of discomfort increases significantly.
- Use only the recommended electrodes.
- Do not use this product on patients with pacemakers.
- Do not attempt to disassemble, modify or repair any components
- Do not apply leads around neck, there is a risk of strangulations or entanglement in leads
- Do not use this product on patients with suspected or diagnosed conditions of rhabdomyolysis or myasthenia gravis.

Precautions

- Safety of powered muscle stimulators for use during pregnancy has not been established.
- Caution should be used for patients with suspected or diagnosed heart problems or epilepsy.

- Daily assessment of stimulation should be carried out, including assessing the set intensity, electrode placement,evoked responses and skin tolerance to the electrodes and stimulation.
- Some patients may experience skin irritation or hypersensitivity due to the electrical stimulation or electrical conductive medium (electrode gel). The irritation can usually be reduced by using an alternate conductive medium, or alternate electrode placement.
- Caution should be used in the presence of the following:
    - When there is a tendency to hemorrhage following acute trauma or fracture;
    - Following recent surgical procedures when muscle contraction may disrupt healing;
    - Over the menstruating or pregnant uterus; and
    - Over areas of the skin which lack normal sensation.
    - Over areas where the skin is hypersensitive.
- Electrode positions and stimulation settings must be determined by the prescribing practitioner.
- Powered muscle stimulators should be kept out of the reach of children.
- Powered muscle stimulators should be used only with the recommended leads and electrodes.
- Be sure the Prelivia electrodes are applied to patient before plugging into leads.
- Portable powered muscle stimulators should not be used while driving, operating machinery, or during activitieswhere involuntary muscle contractions may put the user at undue injury risk.
- Caution should be exercised when moving or manipulating a patient who is using the stimulator. If therapy is enabled, stimulation will occur without warning which may result in unexpected patient movement.
- Disable stimulation if the patient is going to stand. If stimulation occurs while a patient is standing, loss of balance ormuscle control may occur, leading to a fall and possible injury.
- Use caution when touching the electrodes or adjacent areas. If stimulation occurs while the electrodes are being touched, part or all of the stimulation current may be redirected.
- Do not use the stimulator in the presence of combustible or flammable atmospheres.
- Do not use the stimulator in enriched oxygen environments.
- The system shall not be used in the presence of high magnetic fields.
- Keep areas of skin where electrodes are applied clean and free of oily lotions, ointments or other contaminates thatmay impair the adhesion of the electrodes or the delivery of stimulation.
- Do not store or operate the Prelivia in conditions outside those listed. Doing so can damage components

CAUTION: In the United States, Federal law restricts this device to sale by or on the order of a physician.

Physical Reactions

Pain or Discomfort

If used as directed, the Prelivia should not cause any pain, however mild discomfort is possible. In most cases, however, such discomfort is easily remedied by simply decreasing the stimulation intensity. Ifdiscomfort persists, discontinue use.

Skin Irritation

Some reddening and indentation of the skin under electrodes is normal following a period of use, and further mild skin irritation may be experienced depending on factors such as the environment, durationof use, and patient skin-sensitivity.

If any sort of skin irritation develops, remove electrodes and discontinue use until the symptoms havecleared.

Allergic Reactions

Prelivia electrodes are designed to be biocompatible, hypoallergenic, and free of any toxic substances. Nevertheless, if allergic reaction to materials is suspected remove electrodes and discontinue use immediately.

Stimulator Overview

The Prelivia stimulator has a display, eight buttons, and three indicator lights as shown in Figure 1.

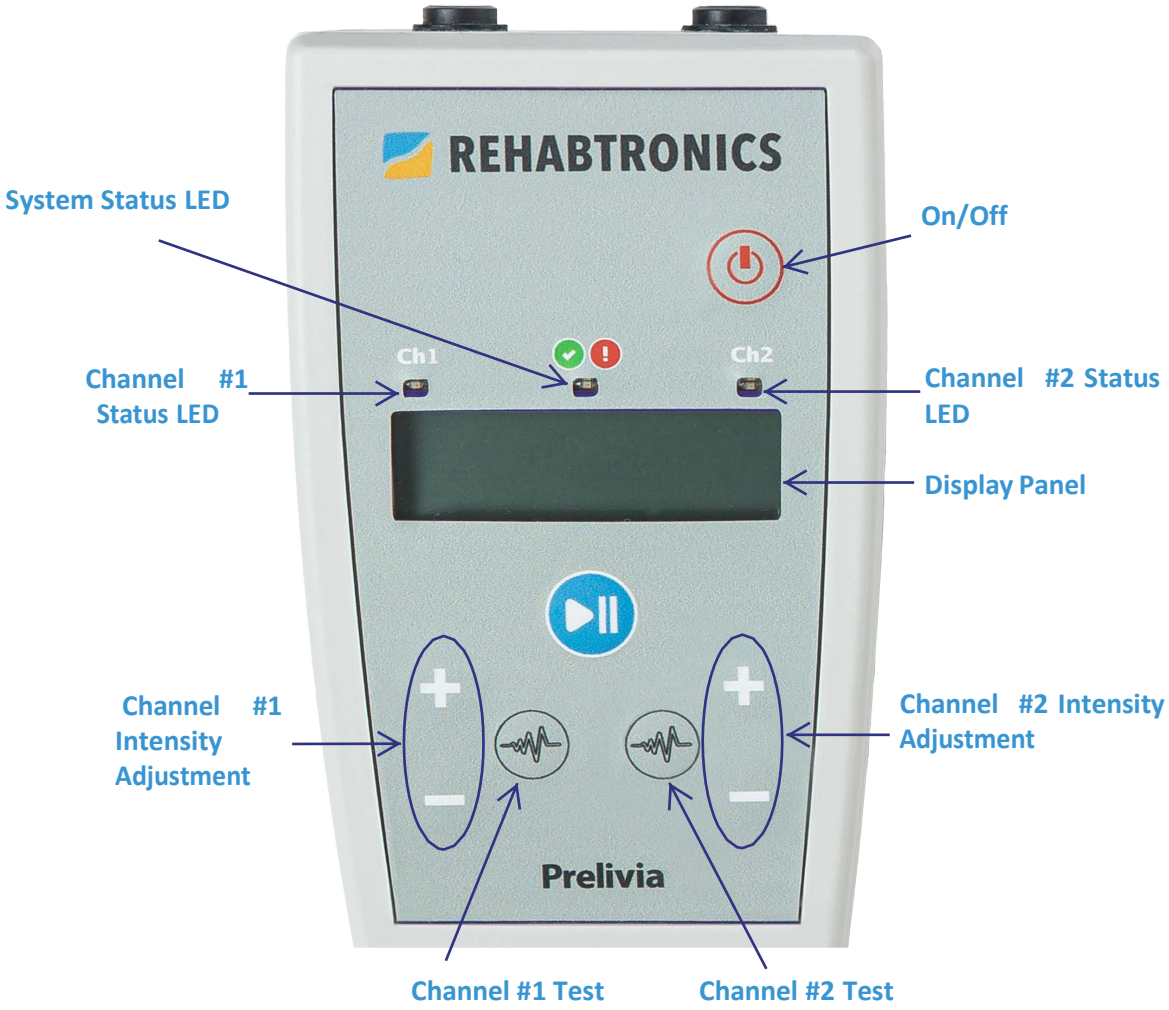


Figure 1: Prelivia Stimulator Front Panel

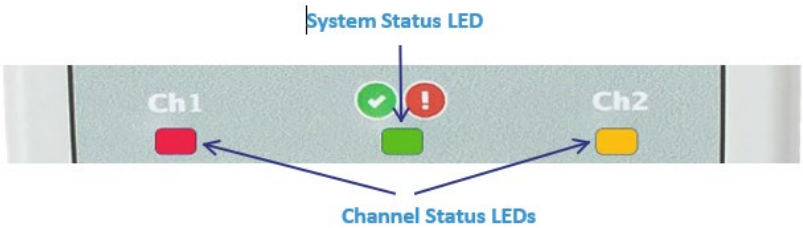
On/Off Button

The Prelivia stimulator has an On/Off button on the front panel to power the unit on and off:

- To Turn On: Press the On/Off button until the display is active. The unit will start in SetupMode.
- To Turn Off: Press the On/Off button until the PWR DOWN message is displayed.

Status LEDs

The Prelivia stimulator has three front panel indicator lights as shown in *Figure 2: LED Indicator Lights*



The following table describes the meanings of the System Status LED:

IES-1 Status LED functions		
IES-1 State	LED Behaviour	Status Indication
Setup Mode	Solid Green	Normal Setup Mode
	Solid Yellow	Low Battery
	Solid Red	System Error or Dead Battery
Run Mode	Brief Green Flash	System Normal
	Brief Yellow Flash	Low Battery
	Brief Red Flash	System Error or Dead Battery

The following table describes the meanings of the Channel Status LEDs:

IES-1 Channel 1 & Channel 2 LED functions		
IES-1 State	LED Behaviour	Status Indication
Setup Mode	Off	Setup Mode with stimulation off
	Green Strobe	Manual stimulation is active on the corresponding channel
Run Mode	Green Strobing	Channel stimulation is active (10 Seconds)
	Brief Green Flash	Channel operating normally
	Brief Red Flash	Previously active channel has been disabled due to error

Display Panel

The status of the display varies depending on whether the stimulator is in Setup Mode, or Run Mode:

	Setup Mode	**Run Mode**
Display Panel Status	Display backlight is on, and shows intensity settings of the two channels	Display backlight is normally off, Momentarily on upon button press

Run/Pause Button

The Run/Pause button is used to switch between Setup Mode and Run Mode:

- If the unit is in Setup Mode, press the Run/Pause button to enter Run Mode. The stimulator program will now be actively running, as indicated by a blinking green system-status LED.
- If the unit is in Run Mode, press and hold the Run/Pause button until the display turns on. The stimulation program will stop, and the unit will now be in Setup mode where the channel adjustment buttons can be used to adjust channel intensities.

Channel Adjustment Buttons

Stimulation intensity to each of the channel electrodes is adjusted using the channel adjustment buttonson the front panel, for each respective channel.

NOTE: these buttons are disabled when the stimulator is in Run Mode to avoid unintentional changeswhen the stimulation program is running.

To access the adjustment buttons, ensure the stimulator is in Setup Mode, and leads are connected tothe channel. While in Setup Mode:

- Stimulation intensity can be varied between 0 mA and 100 mA using the up/down arrow buttons for each channel.
    - If only one set of electrodes will be used, set the unused channel to 0 mA. Eitherchannel may be used for single channel operation.
- Channel Test buttons can be pressed to temporarily stimulate to the respective channels at the current intensity setting. Stimulation to the channel will continue for a maximum of 10 seconds as long as the Channel Test button is depressed. After 10 seconds of continuous stimulation, the button will need to be released and pressed again to continue test stimulating. Both buttonscan be pressed individually or simultaneously. The intensity settings should be periodically reassessed, including any time they are modified or reset so that appropriate muscle response isensured.

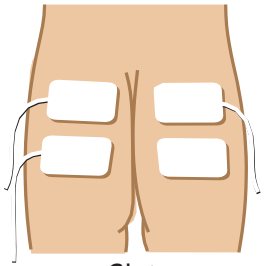
Electrode Lead Set Connections

The stimulator connects to the electrodes through wire leads. Plug in the electrode leads to the Preliva stimulator, and ensure they are fully inserted.

WARNING: Always use the strain relief section of the connector as a grip point to disengage or insertthe connectors on either end of the electrode lead sets. DO NOT attempt to pull out connectors usingthe wires since the fine conductors inside the cable may stretch or break. Broken leads may result in erratic or lost stimulation.

Instructions for Use

1. Confirm that the Prelivia Stimulator has AA alkaline batteries properly installed and is poweredoff.
2. Peel adhesive backing from electrodes, and affix the electrodes to the target area on the patient's body (typically the gluteus maximusmuscles) as shown. For more electrode placement suggestions see the following section.
3. Connect the hydrogel electrodes to the electrode leads, and connect the leads to the Prelivia Stimulator. Ensure that the leads are completely inserted into their connectors.
4. Turn on the Prelivia Stimulator by pressing the On/Off button until the display turns on.



Glutes

5. Use the left +/- controls and test button to adjust the stimulation intensity to the set ofelectrodes connected to channel #1. Intensity should be set to the point of causing visible muscle contractions.
6. Repeat the previous step for the electrodes connected to channel #2, using the right +/-controls and test button.
7. Initiate the stimulation program by pressing the Run/Pause button. The display illumination willturn off, and intensity adjustment buttons disabled. The system will begin to stimulate automatically after 5 seconds, and then continue simulating in 10 second bursts once every 10 minutes.

If at any point the "System Status" indicator LED on the Prelivia Stimulator is red, observe the message displayed by the unit and refer to the troubleshooting instruction.

Replace electrodes if they are not completely adhering to the surface of the skin, become dirty, or after12 hours of continuous use.

When removing electrodes, first disconnect from the Prelivia stimulator, and always lift electrodes fromthe edge, not the socket lead.

Device Maintenance

General Maintenance

The following general maintenance guidelines should be followed to ensure safe and effective use ofthe Prelivia system:

- Inspect all components prior to use. Do not use any components showing signs of damage.
- Do not store or operate any of the system components outside their specified operating and storage conditions.

WARNING: Do not perform any cleaning or maintenance while the equipment is in use. Ensure components are powered off prior to following any of the cleaning instructions in this section.

Battery Replacement

The Prelivia is powered by two 1.5 V AA size alkaline batteries. To replace the batteries:

1. Ensure the power is off.
2. Flip the unit over and locate the rear battery compartment door and slide the locking tab towards the bottom of the enclosure to remove the door.
3. Remove and replace the expended batteries, making sure to correctly orient the new batteries.
4. Gently align and replace the battery compartment door ensuring that the locking tab is moved toward the top of the enclosure locking the door in place.

CAUTION: The stimulator unit was designed to operate from two good quality 1.5 volt AA alkaline batteries. Use of low-quality batteries or other voltages can damage the unit or render it inoperative.

Cleaning

The Prelivia stimulator and leads can be cleaned, as needed, by simply wiping with a soft clothdampened with clean, warm water. Dry immediately with a soft cloth.

Some clinical or hospital protocols may require low-level disinfection of the Stimulator or Leads, between use. In such cases, the outer surface of these components can be wiped with a cloth soaked with low-level disinfectant. Continue to wipe as necessary to ensure all surfaces are kept wet with thesolution for at least three (3) minutes.

WARNING: Do not immerse any components in water or any other liquid. Doing so can permanently damage the electronics.

Electrode Replacement

The hydrogel electrodes are intended to be replaced regularly. Electrodes should be replaced in any ofthe following cases:

- If they show signs of not adhering properly to the skin.
- If there is any noticeable damage, tears, or separation of materials.
- If they become wet or soiled.
- Between patient treatments. Electrodes are for single-patient use only, and should never be reused.
- After 12 hours of continuous use.

Storage

The stimulator may be prepared for short-term storage simply by turning it Off.

For long-term storage or shipment, remove the batteries. Do not leave batteries in the unit if it will bestored for long periods as the batteries may gradually discharge and eventually leak.

Disposal

Rehabtronics Inc. considers the environment in all aspects of the product lifecycle, from design and engineering to packaging and recycling. We recommend that customers dispose of their used Preliviacomponents in an environmentally sound manner.

It is your responsibility to dispose of your waste equipment by handing it over to a designated collectionpoint for the recycling of waste electrical and electronic equipment. For more information about properdisposal of electronics, please contact your local city office or waste disposal service.

CAUTION: Do not dispose of electronic components with normal household waste. Contact your local waste-management services for information on how to best dispose of electronic equipment.

Troubleshooting

Stimulator Troubleshooting

Display shows "`Check #1`" or "`Check #2`"

- The electrode lead set may not be inserted properly.
    - Check the electrode lead connections to ensure they are fully inserted.
- The electrodes may have peeled, or otherwise not making good contact with the skin

- Check to ensure that electrodes are making good contact. If necessary, replace theelectrodes.

Display shows "`Batt Low`"

- The batteries are getting low and should be replaced soon. When first indicated, the stimulator should have approximately 12 hours of run-time battery remaining.

Display shows "`Bat Dead`"

- The batteries are depleted to the point where automatic stimulation has been terminated. Turnthe unit off, replace the batteries, reset the stimulation current, and restart stimulation.

Display shows "`Unit Hot`"

- Remove the Prelivia unit from the hot environment. If the environment is not actually hot, theunit may be defective and should be removed from clinical use.

Technical Specifications

General Specifications

Model	IES-1
Mode of Operation	Continuous
Applied Part Type	BF Applied Part
Power Supply / Type	2 x 1.5V AA Alkaline Batteries Internally Powered ME Equipment
Electrodes	Hydrogel Adhesive
Stimulation Output	Pulse Shape: Rectangular Pulse Width: 300 µs Pulse Frequency: 30 Hz Maximum Intensity: 100 mA Maximum Output Voltage: 155 V Maximum Charge per Pulse: 30 µC Maximum Average Current: 1.82mA RMS (@500 Ω, 100mA) Impedance Range*: 300 - 3000 Ω
Operating Conditions	Temperature: +5 °C to +40 °C (41 °F to 104 °F) Relative Humidity: 15% to 93% (non-condensing) Pressure: 70 kPa to 106 kPa (10.2 psi to 15.4 psi)
Transport and Storage Conditions	Temperature: -25 °C to +70 °C (-13 °F to 158 °F) Relative Humidity: 5% to 100% (non-condensing) Pressure: 70 kPa to 106 kPa (10.2 psi to 15.4 psi)

**The device will not stimulate if impedance is not within specified range. Maximum current can be affected by impedance level according to Ohm's Law with a static maximum voltage. All other pulse parameters are unaffected by impedance.*

Electromagnetic Compatibility

WARNING: If adjacent or stacked use with other equipment is necessary, the Prelivia should be observed to verify normal operation in the configuration in which it will be used.

WARNING: Use of any system components other than those specified or supplied by Rehabtronics Inc. may result in increased emissions or decreased immunity of the equipment, and may cause the system to be non-compliant with the electromagnetic compatibility requirements of IEC 60601-1-2:2014.

Guidance and Manufacturer's Declaration – Electromagnetic Emissions

The Prelivia and all its system components are intended for use in the electromagnetic environment specified below. The customer or the user of the Prelivia System should assure that it is used in such an environment.		
Emissions Test	**Compliance**	**Electromagnetic Environment - Guidance**
RF Emissions CISPR 11	Group 1	The equipment 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 equipment 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	

Recommended separation distances between portable and mobile RF communications equipment and the Prelivia System			
The Prelivia System and all its system components are intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Prelivia System can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the components of the Prelivia System 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 $d = [\frac{3,5}{V_1}]\sqrt{P}$	**80 MHz to 800 MHz** $d = [\frac{3,5}{E_1}]\sqrt{P}$	**800 MHz to 2.5 GHz** $d = [\frac{7}{E_1}]\sqrt{P}$
0.01	0.12	0.12	0.24
0.1	0.37	0.37	0.74
1	1.17	1.17	2.34
10	3.69	3.69	7.38

Guidance and Manufacturer's Declaration – Electromagnetic Immunity			
The Prelivia System and all its system components are intended for use in the electromagnetic environment specified below. The customer or the user of the Prelivia System 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 ±1 kV for input/output lines	±2 kV for power supply lines Test N/A for input/output lines	Mains power quality should be that of a typical commercial/residential or hospital environment.
Surge IEC 61000-4-5	±1 kV line(s) to line(s) ±2 kV line(s) to earth	±1 kV line(s) to line(s) ±2 kV line(s) to earth	Mains power quality should be that of a typical commercial/residential or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11 UT = 240 Vac, 120Vac	<5 % UT (>95 % dip in UT) for 0.5 cycle 40 % UT (60 % dip in UT) for 5 cycles 70 % UT (30 % dip in UT) for 25 cycles <5 % UT (>95 % dip in UT) for 5 sec	<5 % UT (>95 % dip in UT) for 0.5 cycle 40 % UT (60 % dip in UT) for 5 cycles 70 % UT (30 % dip in UT) for 25 cycles <5 % UT (>95 % dip in UT) for 5 sec	Mains power quality should be that of a typical commercial/residential or hospital environment. If the user of the equipment requires continued operation during power mains interruptions, it is recommended that the equipment be powered from an uninterruptible power supply or a battery.

Power frequency magnetic field (50 Hz/60Hz) 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/residential or hospital environment.

Guidance and Manufacturer's Declaration – Electromagnetic Immunity

The Prelivia System and all its system components are intended for use in the electromagnetic environment specified below. The customer or the user of the Prelivia System should assure that it is used in such an environment.

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment - Guidance
Conducted RF IEC 61000-4-6	6 Vrms 150 kHz to 80 MHz	6 Vrms 150 kHz to 80 MHz	Portable and mobile RF communications equipment should be used no closer to any part of the equipment including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = [\frac{3,5}{V_1}]\sqrt{P}$ $d = [\frac{3,5}{E_1}]\sqrt{P}$ 80 MHz to 800 MHz $d = [\frac{7}{E_1}]\sqrt{P}$ 800 MHz to 2,5 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] Interference may occur in the vicinity of known RF transmitting devices and equipment marked with thefollowing symbol:
Radiated RF IEC 61000-4-3	10 V/m 80 MHz to 2.7 GHz	10 V/m 80 MHz to 2.7 GHz	

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.

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 equipment is used exceeds the applicable RF compliance level above, the equipment should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the equipment

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

Manufacturer Contact Information

The manufacturer, Rehabtronics Inc., can be reached though any of the following channels:

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