iReliev™

Pain Management System

Model: iReliev™
Model #: ET-1313

Operating & Instruction Manual

Read Before Using

CE 0120

iReliev™
Pain Management System

Intended Use

The iReliev™ Pain Management System (Model # ET-1313) is intended for temporary relief of pain associated with sore and aching muscles in the upper and lower extremities (arm and/or leg) due to strain from exercise or normal household and work activities.

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Safety Instructions

Read operating and instruction manual before operation. Be sure to comply with all "CAUTIONS" and "WARNINGS" in this manual. Failure to follow instructions can cause harm to user or device.

Please read the following information carefully before using the **iReliev™ Pain Management System.**

Contraindications: Do not use this System if any of the following conditions are present.

- Do not use this System if you have a cardiac pacemaker, implanted defibrillators or any other implanted metallic or electronic device.
- Do not use this System if you have undiagnosed chronic pain.

Warnings for proper use and safety

If you have numbness, tingling or loss of feeling and/or sensation in your arms, hands, legs or feet this may represent a more serous problem like diabetic neuropathy. Consult your physician before using the iReliev™ device or pain management system.

If you have swelling of the arm or leg, it may be more serious than simple muscle pain from overuse. Consult your physician before using the device.

- If you are under the care of a Physician, consult with your Physician before using this system.
- The long-term effects of the iReliev™ system are not known.
- Do not place the electrode pads on or close to your heart.
- Do not place the electrode pads around or close to your neck. Do not apply stimulation over the neck. Severe spasm of the muscles may occur and the contractions may be strong enough to close the airway or cause difficulty in breathing.
  Stimulation over the neck could also have adverse effects on hearing or blood pressure.
- Do not apply stimulation across the chest because the introduction of electrical current into the chest may cause rhythm disturbances to the heart.
- Do not place the electrode pads on or around your head. The effects of stimulation on the brain are unknown.
- Do not use the electrode pads over or close to sores.
- Do not use the iReliev™ system while sleeping.
- Do not use if you feel numbness.
- Do not use the iReliev™ system in or close to water.
- Use the electrode pads only on normal, healthy, clean and dry skin. Do not use the electrode pads on open wounds or rashes, or over swollen, red, infected or inflamed skin.
- If you have ever had back surgery, consult your Physician before using the iReliev™ system.

Precautions for the safe use of the iReliev™ Pain Management System

- Read this operating and instruction manual before using the iReliev™ system for the first time.
- Keep this manual available whenever you use the iReliev™ system.
- The iReliev™ system is intended for individual personal use.
- The iReliev™ system is not effective for pain associated with central pain syndromes, such as headaches.
- The iReliev™ system is for pain caused by muscle soreness, and should be placed only around muscles where pain originates.
- The pain may indicate that you have some other health problem. You should know the reason and source of your pain before using the iReliev™ system. Do not rely solely on the treatment of the iReliev™ system for pain.
- The safety of using the iReliev™ system during pregnancy or birth has not been established.
- The effectiveness of the iReliev™ system depends greatly on a person's individual physical condition. It may not always be effective for every user.
- If you have had medical or physical treatment for muscle pain, consult with your treatment provider before using the iReliev™ system. You should contact your Physician prior to using the System following recent surgical procedures. Stimulation may disrupt the healing process.

⚠ Use Caution and consult your Physician before using the iReliev™ system if any of the following conditions apply to you:

- If you have suspected or diagnosed heart problem.
- If you have suspected or diagnosed epilepsy.
- If you have a tendency to bleed internally following an injury.
- If you recently had surgery, or have ever had surgery on your back.
- If areas of skin lack normal sensations, such as skin that tingles or is numb.
- During menstruation or during pregnancy.
- Some people may feel skin irritation or experience a very sensitive feeling in the skin due to electrical stimulation. If this occurs, stop using your iReliev™ system and consult your Physician.
- If skin under one or more pads feels irritated after using the stimulator for a long period of time, use the stimulator for a shorter period of time.
- Minor redness at stimulation placement is a normal skin reaction. It is not considered as skin irritation, and it will normally disappear within 30 minutes after the electrodes are removed. If the redness does not disappear 30 minutes after the removal of the electrode pads, do not use the iReliev™ stimulator again until after the excessive redness has disappeared.
- Turn off the iReliev™ stimulator if the stimulation feels unpleasant or does not provide pain relief.
- Keep your iReliev™ system out of the reach of children.
- Use your stimulator only with the electrode pads, lead wire cables and accessories recommended by the manufacture.
- Do not use the iReliev™ system when driving, operating machinery or when swimming.
- Before removing the electrode pads, be sure to turn OFF both power knobs to avoid unpleasant stimulation.
- **If your pain does not improve, becomes more than mild or if it continues for four to six days, stop using the iReliev™ system and consult your Physician.**

Adverse Reactions

- Skin irritation and burns under the pads have been reported by some people who have applied electronic stimulators to their skin.

Important:

- Do not use your iReliev™ system at the same time with any other device that transfers an electrical current into the body (e.g. another muscle stimulator).
- Stop using your iReliev™ system if you are feeling light headed or faint. Consult your Physician if this happens.
- Do not touch the electrode pads, lead connector pins and/or metal studs while the iReliev™ system is in the ON position.
- Do not use iReliev™ system if you are wearing a belly button ring. Remove ring before each session.

Note: If you are in any doubt about using the iReliev™ system for any reason, please consult your Physician before use.

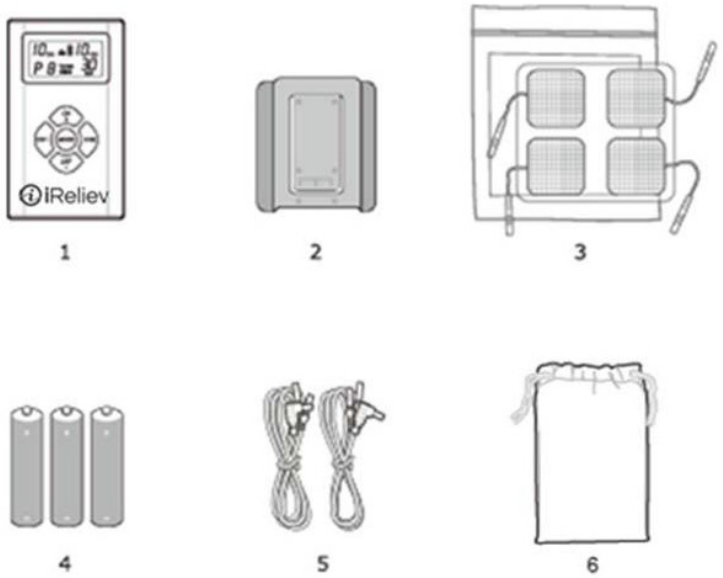
Electrode Pad Precautions

- To reposition the electrode pads during a session, always pause the program currently running, reposition the pads as directed on page 8 and then restart the program again.
- Only use iReliev™ compatible electrode pads with your iReliev™ device. Other electrode pads may not be compatible. Using non-compatible electrode pads with your device may compromise or degrade minimum safety standards
- The electrode pads are for single person use only.
- Do not submerge or immerse the electrode pads into water.
- Do not apply solvents of any kind to the electrode pads.
- Always ensure the iReliev™ unit is OFF before removing the electrode pads.
- Apply the whole surface of the electrode pads firmly to the skin. Do not use electrode pads which do not adhere properly to the skin.
- If your skin is red under the electrode pad after a session, do not start another session in the same area until the redness has completely disappeared.

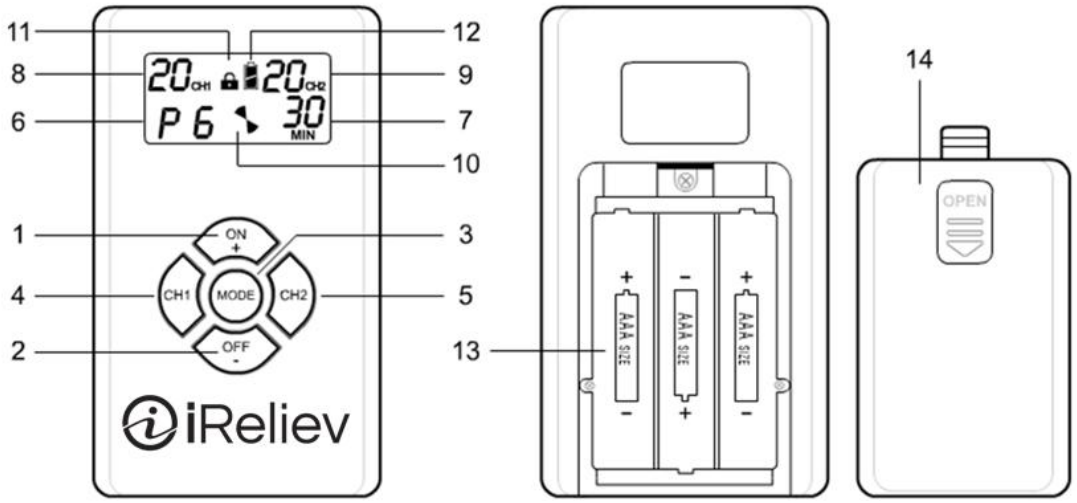
Introduction to your iReliev™ Pain Management System

PACKAGE CONTENTS

1. iReliev™ Device
2. 1 clip holder
3. 4 electrode pads
4. 3 AAA batteries
5. 2 lead wire cables
6. Storage bag



ABOUT THE iReliev™ DEVICE



FRONT VIEW REAR VIEW

1. Power on / adjust / increase setting key
2. Power off / adjust / decrease setting key
3. Program / therapy time selection
4. CH1 key
5. CH2 key
6. Program number
7. Therapy time remaining
8. CH1 intensity level
9. CH2 intensity level
10. Therapy duration status
11. Lock status indicator
12. Battery status indicator
13. Batteries compartment
14. Battery cover

How Your iReliev™ System Works

The iReliev™ stimulator generates continuous stimulation pulse, which can create pain relief. We cannot ensure that pain relief is 100% effective for everyone. However, when used according to information within this instruction manual, it can be a safe, non-addictive and a non-invasive pain reliever.

Conditions that may affect your iReliev™ System

Since the stimulator is a battery-operated electronic system, its output performance and safety may be affected greatly in extreme humidity. Therefore, it is very important to keep the iReliev™ stimulator and system dry to ensure the safety and performance.

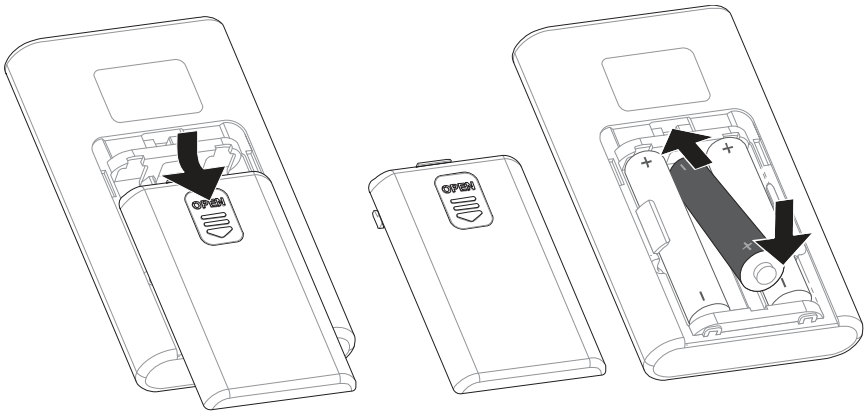
Operating Instructions

Preparing the Skin Prior to Stimulation Session

Proper preparation of the skin to be covered by the electrode pads allows more stimulation to reach targeted tissues, prolongs electrode pad life, and reduces the risk of skin irritation. After connecting the lead wire(s) to the iReliev™ stimulator, use the following steps to prepare your skin at the electrode pad placement sites:

1. Determine the placement sites for the electrode pads.
2. Wash the area with mild soap and water (do not use alcohol). Rinse and dry thoroughly.
3. Trim excess body hair from the area with scissors (do not shave).
4. As an option, you may apply skin prep to the area to form a protective barrier on your skin. Apply, let dry, and apply electrode pads as directed. This will both reduce the chance of skin irritation and extend the life of your electrode pads.
5. When removing electrode pads, always remove by pulling in the direction of hair growth.
6. It may be helpful to apply skin lotion on electrode pad placement area when not wearing the electrode pads.

Inserting/Changing the Batteries



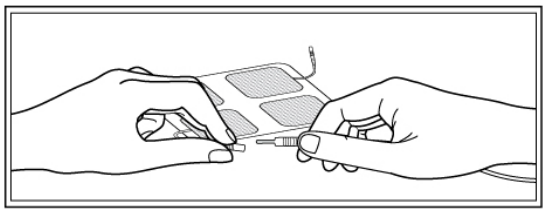
1. Open the battery compartment at the back of the device by pushing the battery cover labelled “Open” downward (this area features raised marks for easy identification).
2. Insert 3 AAA (1.5 V) batteries in the battery compartment; make sure to match up the\ symbols (+/–).
3. Close the battery cover by carefully placing the stud into the slot in the rear area and sliding it upward, applying slight pressure.
4. Follow the same procedure when replacing the batteries at a later date.

▲**Note :** for important precautions regarding the batteries ,please be informed:

- Always use only 3x1.5V(AAA) batteries.
- Keep away from children.
- Do not recharge.
- Do not short-circuit.
- Do not throw into a fire.
- Please recycle. Do not dispose of old batteries with your household waste; dispose of them safely at a recycling center or business where the batteries were purchased.

Connecting the Cable to the Device

Connect the lead wire to the electrode pads before applying to the skin.



Turning On the Device

1. Press and hold the ON+ button for one (1) second to turn on the device.
2. The most recently selected treatment time and program will flash when the unit is turned on.

▲**Note :** Do not turn the unit on until all electrodes and lead wires are properly attached.

▲**Note :** When stimulating the muscles of the arms or legs bear in mind that the muscle contraction may cause involuntary limb movement which could cause injury to you or others. Always ensure the limb is secured to prevent movement.

Turning Off the Device

1. The device turns off automatically after the therapy session time has elapsed.
2. To turn the unit off manually, press the OFF- button for three (3) seconds. The display will blank and the device will turn off.
3. In an emergency you may also pull the connector(s) from the device and then remove the belt.

▲**Note :** To prevent unpleasant electric shocks, never remove the device while it is still turned on.

Selecting the Treatment Program Mode

The iReliev™ stimulator (Model # ET-1313) offers eight different preset treatment program modes. The programs differ with respect to varying pulse widths and frequencies. The user may choose suitable stimulation mode depending on their personal condition, as indicated in the following steps:

1. Start from P1; only change each mode after a couple of seconds after sensing the stimulation of that mode.
2. Choose the suitable mode in which you feel most comfortable. Set the device on that mode.
3. In the case you don't feel certain about the most appropriate program mode, repeat steps 1 & 2.

Selecting the Therapy Intensity Level

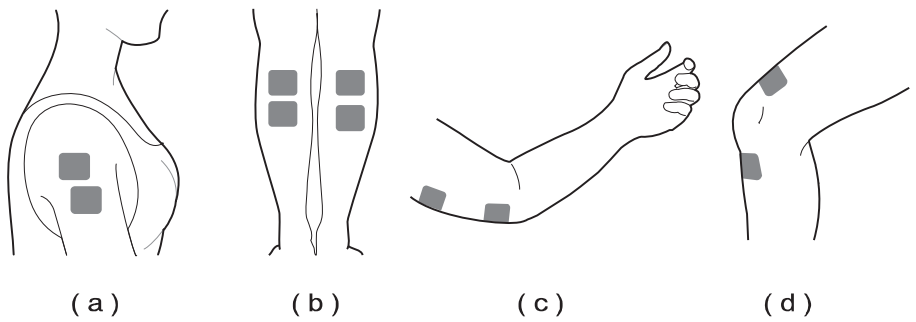
1. Intensity is adjustable according to the channel selected. Select the channel you wish to adjust by pressing CH1 or CH2. “CH1” or “CH2” will flash on the display.
2. To increase or decrease the intensity, press ON + (to increase) or OFF – (to decrease) repeatedly until the desired intensity level flashes on the display.

Note: You will feel the intensity increase or decrease as you select the intensity level. You can use this as a guide to select a level that is comfortable for you.

3. Press MODE to save your selection.

Placement of the Pads

1. Connect the lead wires to the electrode pad before applying them to the skin.
2. The electrode pad placement chart below illustrates the correct placement of the electrode pads for a selection of targeted muscles.



Place the electrodes *(a) shoulder (b) leg (c) elbow (d) Knee*

Remove the protective plastic shields from the electrode pads before placing the pads onto your skin. Replace the plastic shields after each session. This prevents the pads from drying out prematurely.

Care and Maintenance

Stimulator

The iReliev™ stimulator may be wiped clean with a small amount of soapy water on a clean cloth. Do not submerge the iReliev™ stimulator in liquids or expose it to large amounts of water.

• Never use aggressive cleaning products or stiff brushes to clean the device.
• Remove the batteries before cleaning the iReliev™ device.
• Do not use the iReliev™ device again until it is completely dry.
• Do not expose the device to direct sunlight and protect it from dirt and moisture.

Cables

• Disconnect the cables from the iReliev™ stimulator and electrodes.
• Do not pull on the lead wire cables but on the connectors attached to the ends of the cables.
• Store the stimulator with the lead wire cables in a clean, dry place.

Electrode Pads

The electrode pads are disposable and are assembled with adhesive that will dry after prolonged usage or storage. Electrode pads should be replaced when they lose their adhesive quality, or you sense a change in stimulation sensation.

If you’re in doubt about the integrity of the electrode pads, buy new electrode pads from your authorized iReliev™ distributor(s).

How to Store Your iReliev™ System

1. Store your iReliev™ system at room temperature in a dry place, out of the reach of children.
2. If the iReliev™ stimulator will not be used for more than a week, remove the batteries from the stimulator.

Replacement Parts

Be sure to use only iReliev™ Arm & Leg Pain Management System parts originally supplied.

The following replacement parts can be ordered:

Self -adhesive Pads (set of 4) iReliev™ Part no. measured by length and width of electrode size	CM5050 , size 50x50 mm , wired

Troubleshooting Guide

Always check the iReliev™ device and accessories before use to prevent damage and defects. Check the following:

1. Make sure the batteries have sufficient charge and are not corroded.
2. Make sure the lead wire cables fit tightly into the connection sockets of the device. The table below shows some common defects. If you cannot remedy the defects as described, contact your authorized iReliev™ distributor if it is not possible to remedy in the manner described:

Defect	Cause	Remedy
The device does not turn on	No batteries or bad batteries	Replace batteries
The device turns on and then off again	Batteries not inserted properly	Remove batteries & re-Insert again
	Batteries life expired	Replace batteries
The device turns on, but does not generate electric pulses	Lead wire cable(s) not connected properly, treatment time has expired	Connect lead wire cable(s) properly. Switch unit to the OFF position and turn it back on
	Therapy intensity level has not been set	See section “Selecting the Therapy Intensity Level” on page 8
The unit does not turn on even though new batteries have been inserted		Contact customer service

iReliev™ (Model # ET-1313) Stimulator Technical Specifications

Channel: Dual, isolated between channels.

Pulse amplitude: Adjustable 0 – 80mA peak into 500Ω load each channel.

Pulse Rate: As pre-programming operation mode.

Pulse Width: As pre-programming operation mode.

Software ramp up feature: Pulse width ramp up when change mode.

Timer: 5~60 min. selectable.

LCD: Show modes, pulse rate, pulse width, timer, CH1/CH2, intensity level.

Program modes:

Program	Max.	Phase duration	Rate	Function mode	Wave form Type
P1	80mA	260uS	15Hz	Constant	A
P2	80mA	260uS	60Hz	Modulated	A
P3	80mA	260uS	60Hz	Constant	A
P4	80mA	260~150uS	2 ~ 60Hz	Modulated	B
P5	80mA	260~150uS	60Hz	Modulated	A
P6	80mA	260uS	7 <->60Hz	Modulated	C
P7	80mA	260~156uS	60Hz	Modulated	A
P8	80mA	P1 ~P7		Cycle	A/B/C

Wave Form: Symmetrical Bi-Phasic square pulse.

Max Charge per Pulse: 20.8 micro-coulombs maximum.

Power Source : 3 x AAA / 4.5 Volt batteries

All electrical specifications are ±20% at 500Ω load.

Description of symbols:

(i) There are a number of technical symbols on your iReliev™ unit explained as follows:

SN This symbols means “Serial number“

This symbols means “Attention” consult the accompanying documents

This symbols means “Manufacturer“

This symbol means type BF equipment; this device offers protection against electrical shock by standard compliance to leakage currents of electrode pad.

(ii) Package of electrode pads are labeled as follows:

This symbol means “used before”, represent as “YYYY-MM” (for year and month).

Electromagnetic Compatibility

- The device complies with current specifications with regard to electromagnetic compatibility and is suitable for use in all premises, including those designated for private residential purposes. The radio frequency emissions of the device are extremely low and in all probability do not cause any interference with other devices in the proximity.
- It is recommended that you do not place the device on top of or close to other electronic devices. Should you notice any interference with other electrical devices, move the device or connect it to a different socket.
- Radio equipment may affect the operation of this device.

Electromagnetic Compatibility Information

<table>
<tr><th colspan="3">Guidance and manufacturer’s declaration – electromagnetic emissions</th></tr>
<tr><td colspan="3">The ET-1313 is intended for use in the electromagnetic environment specified below. The customer or the user of the ET-1313 should assure that it is used in such an environment.</td></tr>
<tr><th>Emissions</th><th>Compliance</th><th>Electromagnetic environment - guidance</th></tr>
<tr><td>RF emissions
CISPR 11</td><td>Group 1</td><td>The ET-1313 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.</td></tr>
<tr><td>RF emissions
CISPR 11</td><td>Class B</td><td rowspan="3">The ET-1313 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.</td></tr>
<tr><td>Harmonic emissions
IEC 61000-3-2</td><td>Class C</td></tr>
<tr><td>Voltage fluctuations/ flicker emissions IEC 61000-3-3</td><td>Complies</td></tr>
</table>

Guidance and manufacturer's declaration – electromagnetic immunity			
The ET-1313 is intended for use in the electromagnetic environment specified below. The customer or the user of the ET-1313 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	± 6 kV contact ± 8 kV air	± 6 kV contact ± 8 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 commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV line(s) and neutral	± 1 kV line(s) and neutral	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	<5 % U_T (>95 % dip in U_T) for 0,5 cycle 40 % U_T (60 % dip in U_T) for 5 cycles 70 % U_T (30 % dip in U_T) for 25 cycles <5 % U_T (>95 % dip in U_T) for 5s	<5 % U_T (>95 % dip in U_T) for 0,5 cycle 40 % U_T (60 % dip in U_T) for 5 cycles 70 % U_T (30 % dip in U_T) for 25 cycles <5 % U_T (>95 % dip in U_T) for 5s	Mains power quality should be that of a typical commercial or hospital environment. If the user of the ET-1313 requires continued operation during power mains interruptions, it is recommended that the ET-1313 be powered from an uninterruptible power supply or a battery
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	Not applicable	Not applicable
NOTE: U_T is the a.c. mains voltage prior to application of the test level			

Guidance and manufacturer's declaration – electromagnetic immunity			
The ET-1313 is intended for use in the electromagnetic environment specified below. The customer or the user of the ET-1313 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	3 Vrms 150 kHz to 80 MHz	3 Vrms	Portable and mobile RF communications equipment should be used no closer to any part of the ET-1313 , 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 2,5 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 metres (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. Interference may occur in the vicinity of equipment marked with the following symbol:
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms	
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 ET-1313 is used exceeds the applicable RFcompliance level above, the ET-1313 should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the ET-1313.

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

Recommended separation distances between portable and mobile RF communications equipment and the ET-1313

The ET-1313 is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the ET-1313 help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the ET-1313 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 2.5 GHz $d = 2{,}3\sqrt{P}$
0.01	0.12	0.12	0.23
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 meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

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.

Warranty

This iReliev™ Arm & Leg Pain Management System carries a one-year warranty from the date of purchase.

The warranty applies to the iReliev™ Arm & Leg Pain Management System and necessary parts and labor relating thereto. The distributor reserves the right to replace or repair the unit at their discretion.

The warranty does not apply to damage resulting from failure to follow the operating instructions, accidents, abuse, alterations or disassembly by unauthorized individuals.

iReliev™
Pain Management System

ExcelHealth Inc.
www.ExcelHealthInc.com

102 Trewin School Road
Park City, Montana 59063
www.iReliev.com

Made in Taiwan
IM-24-046RevB14
FDA-2407

EC REP SANICO Srl
Via F. Turati 7, I-20121 Milano, Italy
CE 0120