EMISSIONS - ALL EQUIPMENT AND SYSTEMS

The RecoveryRx device is intended for use in the electromagnetic environment specified below. The user of RecoveryRx should ensure that it is operated in such an environment.

Table 2. Guidance and manufacturer's declaration– electromagnetic emissions – for all medical electrical equipment and medical electrical systems.

EMISSION TEST	COMPLIANCE	ELECTROMAGNET ENVIRONMENT - GUIDELINE
RF Emissions CISPR 11	Group 2, Class B Frequencies (f): 30≤ f ≤80.8 MHz Limits (quasi-peak): 30 dB (µV/m) Distance: 10m	RecoveryRx emits electromagnetic energy to provide therapeutic treatment for tissue. At 33.8 MHz, reading is 23.7 dB (µV/m) with a margin on -6.3 dB (µV/m). RecoveryRx is suitable for use in all establishments, including domestic, and those directly connected to the public low-voltage power supply network that supplies buildings for domestic purposes
Harmonics EN 61000-3-2	N/A	The RecoveryRx is internally powered, so not applicable.
Flicker EN 61000-3-3	N/A	The RecoveryRx is internally powered, so not applicable.

Table 3. Guidance and manufacturer's declaration – electromagnetic immunity – for all medical electrical equipment and medical electrical systems.

IMMUNITY TEST	IEC/EN 60601 TEST LEVEL	COMPLIANCE LEVEL	ELECTROMAGNET ENVIRONMENT- GUIDANCE
ESD – Electrostatic discharge IEC/EN 61000-4-2	± 15kV air discharge, ± 8kV contact discharge	No conductive surfaces ± 8kV air ± 6kV contact	Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, relative humidity should be at least 30%
EFT – Electrical fast transient/burst EN 61000-4-4	± 2kV Mains ± 1kV I/Os	N/A as Recovery-Rx is internally powered	N/A as RecoveryRx is internally powered
Surge EN 61000-4-5	± 1kV Differential ± 2kV Common	N/A as Recovery-Rx is internally powered	N/A as RecoveryRx is internally powered
Voltage Dips/ Dropouts EN 61000-4-11	>95% Dip in U_T for 0.5 Cycle 60% Dip in U_T for 5 Cycles 30% Dip in U_T for 25 cycles >95% dip in U_T for 5s	N/A as Recovery-Rx is internally powered	N/A as RecoveryRx is internally powered
PFMF - Power frequency (50/60 Hz) magnetic field IEC/EN 61000-4-8	3 A/m	N/A as Recovery-Rx is internally powered	Power frequency magnetic fields should be that of a typical commercial or hospital environment

NOTE: U_T is the A.C. mains voltage prior to application of test level

Table 4. Guidance and manufacturer's declaration – electromagnetic immunity – for all medical electrical equipment and medical electrical systems.

IMMUNITY TEST	IEC/EN 60601 TEST LEVEL	COMPLIANCE LEVEL	ELECTROMAGNET ENVIRONMENT- GUIDANCE
Conducted RF IEC 61000-4-6	3 V_{rms} 150 kHz to 80 MHz	(V1) N/A as RecoveryRx is internally powered	Portable and mobile communications equipment should be separated from RecoveryRx by no less than the distances calculated/listed below:
Radiated RF IEC 61000-4-3	80 MHz – 2.6 GHz, 80% Amp. Mod. (1kHz)	(E1) 10 V/m	Recommended Separation Distance (m) $d=(3.5/V_1)\sqrt{P}$ (150 kHz– 80 MHz) $d=(3.5/E_1)\sqrt{P}$ (80 – 800 MHz) $d=(7/E_1)\sqrt{P}$ (800 MHz – 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 transmitters, as determined by an electromagnetic site survey, should be less than the compliance levels (V1 and E1) in each frequency range. Interference may occur in the vicinity of equipment containing a transmitter, marked with the following symbol

Table 5. Recommended separation distances between portable and mobile RF communications equipment and the medical electrical equipment and medical electrical systems – for medical electrical equipment and medical electrical systems that are not life-supporting.

MAX OUTPUT POWER (WATTS)	SEPARATION (m) 150 KHZ TO 80 MHz $d=(3.5/V_1)\sqrt{P}$	SEPARATION (m) 80 TO 800 MHz $d=(3.5/E_1)\sqrt{P}$	SEPARATION (m) 800 MHZ TO 2.5 GHz $d=(7/E_1)\sqrt{P}$
0.01	0.11	0.11	0.23
0.1	0.36	0.36	0.73
1	1.16	1.16	2.33
10	3.68	3.68	7.37
100	11.66	11.66	23.33

DEVICE SPECIFICATIONS

Table 1. RecoveryRx Device Specifications (Model 088)	
Carrier Frequency	27.12MHz
Peak Spatial Power Density	73 microwatts/ cm^2
Pulse Rate	1,000 pulses per second
Pulsed on Duration	100 micro seconds
Power Source	Lithium Battery - CR2032
Antenna Size	12cm
Treatment Area	110cm^2
Weight	9.5 grams
Operation Time	Up to 720 hours (on/off capability)
Expected Service Life	Up to 720 hours (on/off capability)

The following are the APPLIED parts:
1) Loop antenna; and 2) Module.

PATIENT is the intended OPERATOR

Visit www.RecoveryRx.co for more information!

CLINICAL TESTING SUMMARY

The clinical data for the RecoveryRX includes two randomized, double-blinded, placebo-controlled studies:

• A randomized, controlled, double-blinded study that investigated the effectiveness of RecoveryRx in treating postoperative pain in 18 women who underwent breast augmentation surgery. These women presented with the following average baseline demographics: 31.6 years of age, weight of 134 lbs and height of 5.52 ft. The primary outcome was a difference in daily pain, measured on a 0-10 visual analog pain scale. The results indicate that the effect of active treatment with RecoveryRx provides a statistically significant treatment effect (reduction in postoperative pain), when compared to placebo ($p<0.05$).

• A randomized, controlled, double -blinded study that investigated the effectiveness of RecoveryRx in treating postoperative pain in 72 women who underwent cesarean section surgery. These women presented with the following average baseline demographics: 26.1 years of age, gestation period of 39.5 weeks and <1 prior cesarean section surgeries. The primary outcome measure was differences in postoperative pain as assessed on a 0-10 visual analog scale. The results indicate that the effect of active treatment with RecoveryRx provides a statistically significant treatment effect (reduction in postoperative pain), when compared to placebo ($p<0.05$).

Conclusion:
The clinical data demonstrates that the RecoveryRx is at least as safe and effective as the predicate devices and can be used as a prescription device for the adjunctive treatment of postoperative pain.

References:

Khooshideh M, Latifi Rostami SS, Sheikh M, Ghorbani Yekta B, Shahriari A. Pulsed Electromagnetic Fields for Postsurgical Pain Management in Women Undergoing Cesarean Section: A Randomized, Double-Blind, Placebo-controlled Trial. Clin J Pain. 2017 Feb;33(2):142-147. doi: 10.1097/AJP.0000000000000376. PMID: 28060214.

Rawe IM, Lowenstein A, Barcelo CR, Genecov DG. Control of postoperative pain with a wearable continuously operating pulsed radiofrequency energy device: a preliminary study. Aesthetic Plast Surg. 2012 Apr;36(2):458-63. doi: 10.1007/s00266-011-9828-3. Epub 2011 Oct 25. PMID: 22037572.

POSTOPERATIVE PAIN CARE

Electromagnetic Pulse Therapy

DIRECTIONS FOR USE

Device Model 088

BioElectronics
Manufactured by: BioElectronics Corporation
4539 Metropolitan Court | Frederick, MD 21704 USA
www.bielcorp.com | 1-866-757-2284 | Stock Symbol: BIEL

U.S. PATENT #7551957B2, U.S PATENT #8412328, CANADA PATENT #2518210, AUSTRALIA PATENT #2014201303, EUROPEAN PATENT #1606010, CHINA PATENT #ZL201120086354, & U.S. AND FOREIGN PATENTS PENDING

Rx Only

CE 2460 EC REP
MDSS GMBH
SCHIFFGRABEN 41
30175 HANNOVER GERMANY

Read instructions before using

DFU-POSTOP-112
11-09-2022

FAQs

What is RecoveryRx Pulsed Shortwave Therapy (PSWT)?
PSWT pulses radio-frequency electromagnetic energy into the body. There is no sensation from these pulses. The RecoveryRx device is placed on or very close to the gauze/bandaging over the site of pain, such that the site of pain is centered within the loop. The device is safe to use during regular physical activity and during sweating. RecoveryRx is a PSWT device used to adjunctively treat postoperative pain.

How does the device work?
The device safely interrupts abnormal pain signaling in the nerves. This advanced therapy reaches into the painful area to provide real relief at the source. The device can be used 24/7.

Is the device safe?
The device is drug free and has no harmful side effects. The device can be worn by diabetics, arthritics, the elderly and bedridden.
Note: The device is nonsterile and should not be applied directly over open wounds, however it can be applied over bandaged wounds.

Is the device clinically proven?
Yes. The device has been clinically tested in multiple randomized, double-blinded, placebo-controlled studies (the gold standard for clinical trials). The device has also been cleared by the US FDA to treat postoperative pain. The technology has been used for decades in hospitals, clinics and home environments. There it has received an overwhelming amount of positive testimonials from both doctors and patients.

What will I feel?
ONLY BETTER! You will not feel heat nor will you feel the low level energy that is gently pulsed into the nerves.

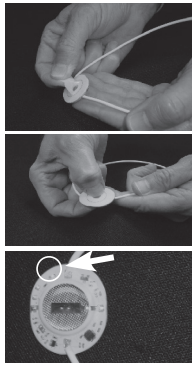
How long until I feel pain relief?
Depending on the severity of the injury, patient pain levels can begin to subside after only 2-3 hours of wearing the device and will continue to decrease as long as the device is being used continuously for at least 12 hours per day. However, in some instances it could take up to 3-4 days for the therapy to take effect.

RECOMMENDATIONS

Indications for Use:
Adjunctive treatment of postoperative pain. The device is to be used only on the instruction of a licensed medical practitioner.

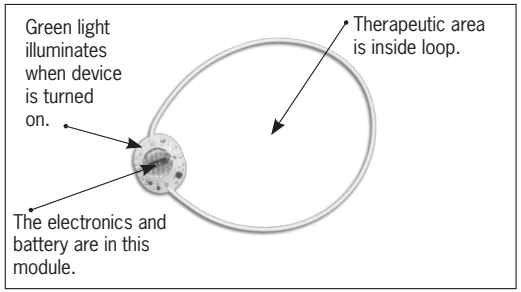
Recommended Treatment Duration (Use Time):
Use the device for a minimum of 12 hours per day, up to 24 hours per day.

HOW TO TURN DEVICE ON & OFF



How to turn the Device On:
Step 1: To activate the device, remove the white tab from the back of the device and push the silver on/off button for 1-2 seconds. Release the button.
Step 2: Once the device is activated, the green LED light on the front of the device will turn on. If the green LED light does not turn on, please repeat Step 1.
Step 3: Cover the incision with sterile gauze before applying the activated device.
Step 4: Position the loop over the injured area and secure in place with medical tape.

How to turn the Device Off:
To deactivate the device, press the silver button and hold it down for 1-2 seconds. Once the device is deactivated, the green LED light will turn off.



For Best Results:
Optimum results are achieved by extended duration treatment, ideally 24-Hours per day until healed or a minimum of 12-Hours per day. Individual results may vary.
You can use any type of wraps, adhesives, bandages or clothing to help hold the device in place.

MAINTENANCE AND STORAGE

- Use a damp cloth and mild soap to gently wipe clean after each use, when the device is soiled, or to remove any buildup of residue from medical adhesives.
- Device Operation: a temperature range of +5°C to +40°C;a relative humidity range of 15% to 90%, non-condensing, but not requiring a water vapor partial pressure greater than 50hPa
- Device Transport/Storage: a temperature range of -25°C to + 5°C, and +5°C to +35°C at a relative humidity up to 90%, non-condensing; >35°C to 70°C at a water vapor pressure up to 50hPa
- The device should be operated, stored and transported at an atmospheric pressure between 50 kPa and 106 kPa (0.5 atm and 1.04 atm) , up to an altitude of 5,575 m above sea level

Note: Consult your local electronics store or waste management company for guidance on proper disposal of the device.

APPLICATION

Adhesive Tape is intended to affix device over bandaged skin. Do not apply directly over incision.

Adhesive Tape
For best results and maximum hold, clean and thoroughly dry the skin around the area of application to remove dirt, oils, and lotions.

Bend the tape in the center with the paper backer facing you. (Figure 1).

Peel back the raised backer tabs exposing the middle section of tape without removing the backer from the ends. Do not touch tape adhesive. (Figure 2).

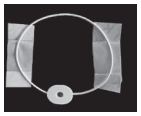
Place the tape on a flat surface with the exposed adhesive facing you, and place the activated RecoveryRx device so the wire is positioned in the center of the tape (Figure 3).

Position the loop directly over the area of pain. Using the ends with the backer, pick the tape up and apply it to the skin securing the loop to the skin. (Figure 4).

Once the center of the tape is holding on the device, remove the backer from the ends of the tape and finish securing the tape in place using gentle pressure. (Figure 5).

1

2

3

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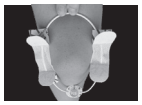

5


Note: Adhesive tape should be changed every 3 days or when the stickiness wears off, whichever may occur first.

Adverse Reactions:
- If pain persists within 7 days of use or worsens with use, discontinue use and seek medical attention.

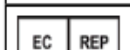
Warnings[3]:
- This medical device is to be sold only to or on the prescription of a suitably qualified medical practitioner. Please consult your doctor/physician before use.
- If your pain does not improve after using the device for 7days, stop using the device and consult your doctor.
- RecoveryRx is not a sterile device, so it should not come in direct contact with open wounds or irritable spots.
- Choking hazard: do not swallow the unit.
- Before using, check for damage to the module and cable insulation and do not use if there is damage.

Precautions[1]:
- There are no user-serviceable parts inside the unit. Do not attempt to modify or break open the device.
- Do not wear the device in the shower or bath; the device is not waterproof.
- Keep this unit out of the reach of children.
- If the LED light does not come on, it indicates that the device is no longer operational and can be disposed of according to local regulations.
- The device should not be used by/on children under the age of 17.
- The device is not intended for use on multiple patients.
- The IP (Ingress Protection) rating for the device is IP22 and therefore offers protection from touch by fingers and objects greater than 12 millimeters. Additionally, the device is protected from water spray less than 15 degrees from vertical.
- The device is non-sterile. Avoid exposing the device to lint, dust and light (including sunlight) to prevent discoloration and build up of residue.
- The time required for the ME EQUIPMENT to warm from the minimum storage temperature, or cool from the maximum storage temperature, is 1 hour.

Contraindications[2]:
- Do not use this device over a cardiac pacemaker, implanted defibrillator, deep brain stimulator and nerve stimulators or other active implantable device.
- Do not use this device if you are experiencing sudden, unexplained pain. Sudden, unexplained pain can be an indicator of a serious medical condition and may require immediate medical attention.
- Do not use the device if you do not know the cause of your postoperative pain. Contact your doctor to know more about the source of your pain.
- RecoveryRx is a therapy for the adjunct treatment of postoperative pain. Do not use for pain which is located deeper in the body, for example in the chest or stomach. This device is not intended to treat pain deep in the body.
- Do not use this device if you are pregnant or think you are pregnant.
- Do not use this device to treat cancer related pain. This device is not intended to treat cancer related pain.

[1] A precaution is used to identify a hazard that may result in minor or moderate injury to the user or patient or damage to the equipment or other property.
[2] Contraindications are known and reasonably foreseeable conditions under which the device should not be used because the risk of use clearly outweighs any possible benefit.
[3] A warning is used to identify a hazard that may lead to death or serious injury.

EXPLANATION OF SYMBOLS

Symbol	Description	Location	Other Information Location
	Manufacturer: This Symbol is accompanied by the name and address of the manufacturer.	Box	On Box: Barcode, Part#, Rev#, Warnings, Contents, Patent#
	Symbol for Authorized Representative In The European Community	Box	
	Upper and Lower limit of temperature	Box	On Label: Quantity, Description, Model number
	Attention, see warning statement	Box	
	Symbol for Not Sterile Product	Box	
	Upper and Lower limit of humidity	Box	
	Symbol for Follow instructions for use"	Box	
	Type BF Applied Part	Box	
	Conformity marking for medical devices sold in the EU	Box	
	Non-ionizing radiation	Box	
	Upper and Lower limit for operation, storage and transport for atmospheric pressure	Box	
	Not made with natural rubber latex	Box	
	**Prescription Only**	DFU Only	