EMISSIONS - ALL EQUIPMENT AND SYSTEMS

The ActiPatch device is intended for use in the electromagnetic environment specified below. The user of ActiPatch 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	ActiPatch 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). ActiPatch 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 ActiPatch is internally powered, so not applicable.
Flicker EN 61000-3-3	N/A	The ActiPatch 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	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 ActiPatch is internally powered	N/A as ActiPatch is internally powered
Surge EN 61000-4-5	± 1kV Differential ± 2kV Common	N/A as ActiPatch is internally powered	N/A as ActiPatch is internally powered
Voltage Dips/ Dropouts EN 61000-4-11	0% Dip in for 0.5 cycles, 70% Dip in for 25 cycles	N/A as ActiPatch is internally powered	N/A as ActiPatch is internally powered
PFMF - Power frequency (50/60 Hz) magnetic field IEC/EN 61000-4-8	30 A/m	N/A as ActiPatch 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 ActiPatch is internally powered	Portable and mobile communications equipment should be separated from ActiPatch by no less than the distances calculated/listed below:
Radiated RF IEC 61000-4-3	80 MHz – 2700 MHz, 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. ActiPatch Device Specifications (Model 088)	
Carrier Frequency	27.12MHz
Peak Spatial Power Density	73 microwatts/ cm²
Pulse Rate	1,000 pulses per second
Pulsed on Duration	100 micro seconds
Power Source	Lithium Battery - CR2032
Antenna Size	12cm
Treatment Area	110cm²
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

REFERENCES FOR CLINICAL SUMMARY

Bagnato GL, Miceli G, Marino N, Sciortino D, Bagnato GF. Pulsed electromagnetic fields in knee osteoarthritis: a double blind, placebo-controlled, randomized clinical trial. Rheumatology (Oxford). 2016 Apr;55(4):755-62. doi: 10.1093/rheumatology/kev426. Epub 2015 Dec 24. PMID: 26705327; PMCID: PMC4795538.

Brook J, Dauphinee DM, Korpinen J, Rawe IM. Pulsed radiofrequency electromagnetic field therapy: a potential novel treatment of plantar fasciitis. J Foot Ankle Surg. 2012 May-Jun;51(3):312-6. doi: 10.1053/j.fas.2012.01.005. Epub 2012 Jan 31. PMID:22297104.

El Mohammad AR, Koneru S, Staelin R, McLeod K, Tabbouche O, Rawe IM. Pulsed shortwave therapy in cervical osteoarthritis: An NSAID- controlled, randomized clinical trial. SN Comprehensive Clinical Medicine. 2021;3(1): 166–175. doi: 10.21203/rs.3.rs-34236/v1.

Visit www.ActiPatch.com for more information!

CLINICAL TESTING SUMMARY

Note: Treatment effects of device use were clinically assessed for up to 4 weeks.

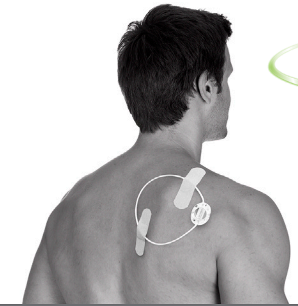
•A randomized, controlled trial on chronic cervical osteoarthritis (neck pain): This was a randomized, active-treatment controlled study to evaluate the safety and effectiveness of the ActiPatch medical device to reduce the pain level of patients diagnosed with cervical osteoarthritis. The active-treatment control was an NSAID of the Cox-2inhibitor family. There were 200 intent-to-treat patients, out of which 197 completed the four-week study. The primary endpoint for efficacy was reduction in pain (VAS score) while at rest and being active, over four weeks, when compared to the beginning of the study. The primary safety endpoint was all treatment-related adverse events during the study. 94% of the medical device treatment group reported a clinically significant decrease (30% reduction) in VAS pain (at rest) compared to 89% in the NSAID-treatment group. 94% of the medical device treatment group reported a clinically significant decrease (30% reduction) in VAS pain (active) compared to 87% in the NSAID-treatment group. For the secondary outcome of functionality (Neck Disability Index, or NDI), the medical device treatment group reported a 64% improvement compared to 52% in the NSAID-treatment control group. No adverse events were recorded with use of the medical device. In the NSAID-treatment group 2 subjects reported an adverse event, these being peripheral edema and hypertension, following which NSAID-treatment was ceased. Two other minor adverse events were recorded dysuria and increased blood pressure that didn't result in the subjects ceasing NSAID treatment.

•A randomized controlled trial on osteoarthritis of the knee: The osteoarthritis of the knee study was a double-blinded, randomized, placebo-controlled study to evaluate the safety and effectiveness of the ActiPatch medical device to reduce the pain level of patients diagnosed with knee osteoarthritis. The placebo treatment was a device that was identical to ActiPatch but did not produce an electromagnetic field when turned on. There were 66 intent-to-treat patients, out of which 60 patients completed the four-week study. The primary effectiveness endpoints were improvements in pain level over the four weeks as measured by the before and after VAS score and WOMAC scores, and the primary safety endpoint was all treatment-related adverse events during the study. 36% of the treatment group reported a clinically significant decrease in VAS pain compared to 9% for the placebo group, and 18% of the treatment group reported a clinically significant decrease in total WOMAC pain compared to 3% for the placebo group. In the medical device treatment group, 26% stopped pharmacological therapy whereas in the placebo group 33% started a new pharmacological therapy during the study. No adverse events were recorded.

•A randomized controlled trial on plantar fasciitis (heel pain): This was a randomized, double-blinded, placebo-controlled study to evaluate the safety and effectiveness of the ActiPatch medical device to reduce the pain level of patients diagnosed with plantar fasciitis. The placebo treatment was a device that was identical to ActiPatch but did not produce an electromagnetic field when turned on. A total of 70 patients were recruited into the study, and all 70 completed the study. The primary effectiveness endpoint was the daily morning (AM) VAS score, and the primary safety endpoint was all treatment-related adverse events during the 7-day study. The results showed that the average reported pain reduction between the first day's AM pain score and the 7th day's AM pain score for the treatment group was 40% compared to 7% for the control group.

MUSCULOSKELETAL PAIN RELIEF

Pulsed Shortwave Therapy



ActiPatch.

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 #ZL2011200863544, & U.S. AND FOREIGN PATENTS PENDING

LATEX 15% 90% NON STERILE Product is Non-Sterile Attention, see warning statement -13°F 158°F 50 kPa 106 kPa Non-ionizing Radiation Type BF Applied Part

CE 2460 EC REP Read instructions before using

MDSS GMBH
SCHIFFGRABEN 41
30175 HANNOVER GERMANY

DFU-MULTI-ENG-302
08-18-2023

FAQ'S

What is ActiPatch Pulsed Shortwave Therapy (PSWT)?
PSWT pulses radio-frequency electromagnetic energy into the body. There is no sensation from these pulses. The ActiPatch device is placed on or very close to the skin over the site of pain, such that the site of pain is centered within the loop. To experience pain relief, the device may need to be used for 3-4 days. The device is safe to use during regular physical activity and during sweating. ActiPatch is a PSWT device used to adjunctively treat musculoskeletal 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 technology clinically proven?
Yes. The device has been clinically proven through a series of clinical studies, of which more are ongoing, at leading medical institutions. The technology has been used for decades in hospitals and clinics and has received an overwhelming amount of positive testimonials from consumers.

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 or atleast 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:
For the adjunctive treatment of musculoskeletal pain

Note: Treatment effects of device use were clinically assessed for up to 4 weeks. Pain relief results may vary for each user. Always read the directions.Use only as directed. If symptoms persist see your healthcare professional

Any serious incident that has occured in relation to the device should be reported to the manufacturer.

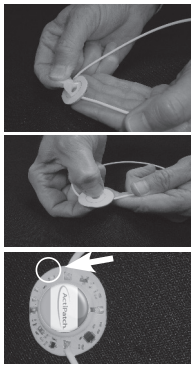
Recommended Treatment Duration (Use Time):
Use the device for a minimum of 12 hours per day, up to 24 hours per day.

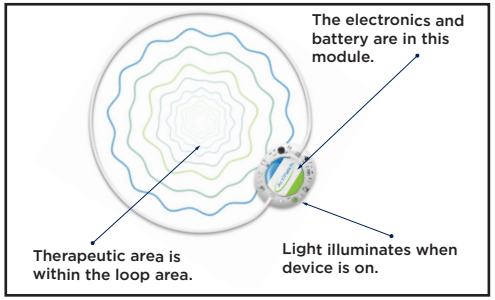
HOW TO TURN DEVICE ON & OFF

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.

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:
The device loop area should be placed directly over the source of the pain. For maximum pain relief, wear continuously in one area until pain diminishes. The device should be placed as close to the skin as possible. The therapy will also be effective through light clothing.

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

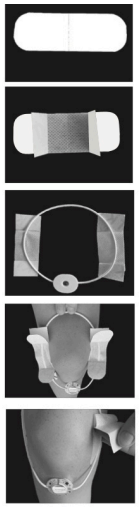
Note: Consult your local electronics store or waste management company for guidance on proper disposal of the device.

APPLICATION

One or more of the following ACCESSORY may be provided in your Therapy Kit: Adhesives

Note: Accessories are only intended to secure the ActiPatch device on the body. Accessory use is optional.

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

Position the loop of the ActiPatch 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 ActiPatch, remove the backer from the ends of the tape and finish securing the tape in place using gentle pressure. (Figure 5).

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

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Adverse Reactions:
- If pain persists within 3-4 days of use or worsens with use, discontinue use and seek medical attention.

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 to prevent 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.

Contradindications[2]:
- Do not use this device directly 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 musculoskeletal pain. Contact your doctor to know more about the source of your pain.
- ActiPatch is a therapy for the adjunct treatment of musculoskeletal 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.

Warnings[3]:
- If you are in the care of a doctor, consult your doctor before using this device.
- If your pain does not improve after using the device for 7 days, stop using the device and consult your doctor.
- ActiPatch 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.
- Keep out of the reach of children.
- Before using, check for damage to the module and cable insulation and use if there is no problem.

[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#
EC REP	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	
NON STERILE	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	
CE	Conformity marking for medical devices sold in the EU	Box	
	Non-ionizing radiation	Box	
	Upper and Lower limit for operation, storage and transport for atmo-spheric pressure	Box	
LATEX	Not made with natural rubber latex	Box	