

Specification

Medicur Pro is a Class IIa Medical Device conforming to the requirements of the Medical Device Directive (MDD93/42/EEC) and bears the CE mark - your assurance of product safety and efficacy.

Low frequency (LF coil)	2 kHz plus harmonics thereof up to 50 kHz modulated on a 3Hz, 7.8Hz or 20 Hz base frequency as selected.
UHF Coil	As per LF coil with a 250 MHz modulated frequency plus harmonics thereof.
Signal power	All electromagnetic radiation falls within the limits required by the EMC standard EN 60601-1-2
Battery types	Varta 3022/4022 GP batteries GP 1604G, Ever Ready PP3
Power source	Internally powered equipment
Battery life expectancy	3 months under normal use of 3 times per day.
Ingress rating	IPX0
Degree of protection against electric shock	Type B
Operating and storage	Temperature +10°C to +40°C, humidity 30% to 75% RH
Mode of operation	10 minute timed therapy periods on single depression of therapy. Continuous use possible by repeated subsequent depression of therapy key although continuous therapy is not recommended on any one patient.

Clinical Study

- 1) Ernst, E. A clinical trial of magnetic pulsed therapy for osteoarthritis. 2004
- 2) Pipitone, Nicolo, Scott, David L. Magnetic Pulse Treatment for Knee Osteoarthritis: A Double-Blind, Placebo-Controlled Study. Current Medical Research and Opinion 2001: Vol 17 No 3.
- 3) Fisher, E. The effectiveness of the Medicur pulsed electromagnetic field device for Osteoarthritis. 2004
- 4) Ludwig W, Umlauf R. Experiences of the analgesic results of magnetic field therapy. 1994 Exp.MedVol 5, pp279-283

Regulatory

CE: Medical Device Directive 93/42/EEC - Active Medical Device - Class IIa.

Symbols



Refer to instructions for use



TYPE B EQUIPMENT: the Medicur device is an Applied part in accordance with EN 60601-1



CE Marked to Medical Device Directive 93/42/EEC as amended by directive 2007/47/EC



This medical device applies an RF electromagnetic energy field in use



This device contains electrical and/or electronic equipment that must be recycled per EU Directive 2012/19/EU - Waste Electrical and Electronic Equipment (WEEE)

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MEDICUR[®] PRO

Instructions



Class IIa Medical Device



Introduction

Congratulations on purchasing Medicur Pro, it is a truly amazing device.

INTENDED USE

Medicur Pro is a portable Class IIa Medical device for drug-free pain relief designed to reduce the pain associated with conditions such as osteoarthritis, rheumatoid arthritis and back pain. It is primarily intended for unsupervised self-application by the patient in a home setting.

Medicur Pro is placed on or close to the site of the pain. The therapy lasts for 10 minutes at the end of which the device will automatically turn off. It is recommended that the treatment is given three times per day although it is not possible to over treat. Improvement may take up to 6 weeks.

Based on the long-established science of pulsed magnetic field therapy (not to be confused with passive static magnet products), Medicur Pro actively creates complex electromagnetic fields that act at a cellular level within the body to reduce pain.

Medicur is contraindicated for pregnant women, those fitted with a pacemaker or other active implantable device.

Your step by step guide to using Medicur...

1. Medicur Pro is effective through clothing so you do not need to remove clothing to experience it's benefits.

2. Remember that Medicur Pro's therapeutic waves radiate globally around the unit up to 30cm (12 inches). It therefore does not matter which way round the unit is facing.

3. Some customers find it best to hold the Medicur in place with their hands and other customers like to use the supplied strap to hold the device in place during treatment. A velcro patch is supplied with the strap and should be applied to the back of the Medicur Pro device. This will hold the Medicur securely on the strap.

4. The 3 different treatment settings (3 Hz 7.8 Hz & 20 Hz) offer subtle differences in the rate at which the complex electromagnetic fields are transmitted. Every treatment setting will provide effective pain relief, however we

recommend you use the treatment settings according to the following circumstances:

- Use the RED 7.8 Hz primary setting during the daytime.
- Use the BLUE 3 Hz button during evening/night.
- Use the GREEN 20 Hz during the day, where additional pain relief is required.

5. To start treatment, select the setting you require. The LED light will flash to show that the therapy has started.

6. Place the Medicur Pro device within 12 inches (30 cm) of the painful area for 10 minutes.

7. Do not expect to feel any sensation when using Medicur Pro, the electromagnetic field emitted from the device cannot be detected by the body's senses.

8. The device will switch off automatically after 10 minutes but can be stopped before then by pressing the OFF button.

A minimum of 3 treatments every day are recommended to a painful area (there is no limit to how many times you can use Medicur Pro every day). It is safe to treat more than one area if required. Medicur is also safe to use with any replacement joints or implants.

Those patients prescribed Medicur Pro by a hospital or pain clinic should follow the advice given by the doctor or other healthcare professional.

If you have any questions, please call FREEPHONE Careline on 0800 161 5670

Maintenance

An illuminated Low Battery light indicates that the battery is depleted. Replace the battery by removing the cover situated on the back of the device. Remove the depleted battery and insert a suitable replacement (see Specification overleaf).

Care should be taken to ensure that the battery is fitted the correct way around. The device will not function if the battery is fitted incorrectly, but it will not be damaged.

Warnings - *(these indicate a potentially hazardous situation which, if not avoided, could result in personal injury to the user or others).*

We recommend you do not use Medicur Pro with a pacemaker.

Only use on intact skin.

Do not use Medicur Pro during pregnancy.

Do not provide therapy on a continuous basis to any one patient - always have a break between therapy sessions.

Do not use Medicur Pro in the presence of a flammable anaesthetic mixture in air, oxygen or nitrous oxide.

Do not immerse Medicur Pro in any fluids as this may cause damage to the device.

Do not attempt to repair or service your Medicur Pro during use.

It is important to remember that pain is a symptom and diagnosis by a medical professional is advised.

Guarantee

Medicur Pro has a Product Lifetime Gurantee. This means if you experience any electrical or mechanical defect with the product, we will replace it.

Applied Standards

BS EN ISO 14971	Application of risk management to medical devices.
BS EN ISO 15223-1	Symbols to be used in medical device labeling.
BE EN 60601-1	Medical electrical equipment - Part 1: General requirements for basic safety and performance.
BE EN 60601-1-2	Medical electrical equipment - Part 1-2: Electromagnetic compatibility.

Guidance and manufacture's declaration - electromagnetic emissions

The Medicur is intended for the use in the electromagnetic environment specified below. The customer or the user of the Medicur should assure that it is used in such an environment.		
Emission Test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 2	The Medicur Pro must emit electromagnetic energy in order to perform its intended function. Nearby electronic equipment may be affected.
RF emissions CISPR 11	Class B	The Medicur Pro is suitable for use in all establishments, including domestic establishments and those directly connected to the delivery connected to the public supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2		
Voltage fluctuations/ flicker emissions IEC 61000-3-3		

Guidance and manufacture's declaration - electromagnetic immunity

The Medicur device has not been tested for immunity to electromagnetic disturbances.