

ManaFlex  **2**™

User Manual



1. Snap Controller onto Pad.

2. Apply ManaFlexx 2 to body as recommended by physician.



3. Turn on controller by pressing the "POWER" icon on controller for 1.5 - 2 seconds. After the device is on, you should see "1" displayed for a second, meaning Mode 1. After a second, the displays

"0", meaning the intensity is zero. (Note: 0 will display all the time until any button is pressed.

Press and release the Power button to change the mode from Mode 1 to Mode 2: After the mode is changed to Mode 2, you will see "2" displayed for a second, meaning Mode 2. After a second, the display returns to "0", meaning the intensity is zero. (Note: 0 will display all the time until any button is pressed.



4. Increase intensity up to 19 levels by pressing the "+" button.

Intensity level indicated by the LED number increasing.



5. Decrease intensity by pressing and releasing the "-" button.



6. The timer is 30 minutes. (Note: There is only one timer, which will change back to 30 minutes each time when the mode is changed). After the timer is up, the device will turn off. To turn the device off prior to timer duration, hold the Power button for 1.5 - 2 seconds.

ManaFlexx 2

ManaFlexx 2 Low Frequency UNIT Model NO. MF002-RX is the future in wellness, with electronic muscle stimulator (EMS) technology. With EMS technology, the device transmits bioelectrical pulse to activate muscle creating muscle contractions and muscle fatigue. You can use your ManaFlexx 2 almost anywhere. Use your ManaFlexx 2 per your doctor's instructions. It is suggested to be used one to two times a day for twenty minutes. For best results we recommend that you use your EMS unit in conjunction with a normal healthy diet and exercise.

Indications for Use

1. Relaxation of muscle spasms
2. Prevention or retardation of disuse atrophy
3. Increasing local blood circulation
4. Muscle re-education
5. Immediate post-surgical stimulation of calf muscles to prevent venous thrombosis
6. Maintaining or increasing range of motion

Powered muscle stimulators should only be used under medical supervision for adjunctive therapy for the treatment of medical diseases and conditions.

Portable powered muscle stimulators should not be used while driving, operating machinery, or during any activity in which involuntary muscle contractions may put the user at undue risk of injury.

Adverse Reactions

Stop using the device and consult with your physician if you experience adverse reactions from use of this device. Skin irritation and burns beneath the electrodes have been reported with the use of powered muscle stimulators.

Contents

- 1 EMS Control unit
- 1 User Manual
- 1 Gel pad
- 1 Charger
- 1 Quick Start Guide

Operation

Functions of the three buttons:

Operate button "POWER" turns device on, pressing/release the Power button again switches from Mode 1 to Mode 2. Pressing and holding "POWER" button will turn off device.

Intensity level: From 1-19 levels

"-" and "+" Buttons decrease (-) or increase (+) the intensity of the 1-19 increment levels.

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.

Caution should be used for patients with suspected or diagnosed epilepsy.

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 the healing process; Over the menstruating or pregnant uterus; and Over areas of the skin which lack normal sensation.

Some patients may experience skin irritation or hypersensitivity due to the electrical stimulation or electrical conductive medium. The irritation can usually be reduced by using an alternate conductive medium, or alternate electrode placement.

Electrode placement and stimulation settings should be based on the guidance of the prescribing practitioner.

Powered muscle stimulators should be kept out of the reach of children.

Powered muscle stimulators should be used only with the leads and electrodes recommended for use by the manufacturer.

Contraindication

Powered muscle stimulators should not be used on patients with cardiac demand pacemakers.

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 the carotid sinus reflex.

Stimulation should not be applied over the neck or mouth. Severe spasm of the laryngeal and pharyngeal muscles may occur and the contractions may be strong enough to close the airway or cause difficulty in breathing.

Stimulation should not be applied transthoracically in that the introduction of electrical current into the heart may cause cardiac arrhythmias.

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.

Indications For Use TENS

Transcutaneous Electrical Nerve Stimulation (TENS) devices are used for the symptomatic relief and the management of chronic (long-term) intractable pain and as an adjunctive treatment in the management of post-surgical and post-traumatic acute pain.

Contraindications TENS

Do not use within first 36 weeks of pregnancy except on the advice of your doctor or midwife.

Do not place electrodes on abdomen during pregnancy.

TENS devices can affect the operation of demand type cardiac pacemakers. In patients with known myocardial disease, epilepsy or arrhythmias, TENS should be used only with consultation and evaluation by a physician.

Do not use TENS on the eyelids.

Do not place electrodes directly over the carotid sinus nerves or arteries and laryngeal or pharyngeal muscles.

Do not apply TENS for undiagnosed pain syndromes until etiology (actual cause) is established.

Do not place electrodes in any position that allows current to flow transcranially (through the head). Do not use TENS on broken skin or on areas where normal sensation is absent.

Do not use TENS on children under the age of 12 unless under medical supervision.

Warnings TENS

This device should be used only by specifically following the instructions in this user's guide and under medical supervision and guidance.

TENS is ineffective for pain of central origin, for example, headaches. TENS is of no curative value. TENS is a symptomatic treatment that suppresses pain sensation that would otherwise serve as a protective mechanism on the outcome of the clinical process. The safety of TENS devices for use during pregnancy or delivery has not been established.

For external use only.

ELECTRONIC FETAL MONITORS and other electronic equipment such as ECG monitors can be affected when TENS is in use.

Do not attempt to use TENS or accessories in any other way than that described in this user's guide.

Precautions TENS

Turn the unit off before applying or removing the electrodes. Long-term stimulation at the same electrode site may cause skin irritation. If TENS therapy becomes ineffective or unpleasant, discontinue use until re-evaluated by a physician or therapist. Do not use TENS while driving or operating machinery.

Use only for the specific pain problem prescribed by a physician.

Do not place the TENS unit near excessive heat or in water.

To avoid cross contamination do not use another person's electrodes or allow your electrodes to be used by any other person.

Keep the TENS unit out of the reach of children.

Keep TENS unit away from sources of high magnetic fields for example TVs, microwave ovens and hi-fi speakers, as these may affect the LCD screen.

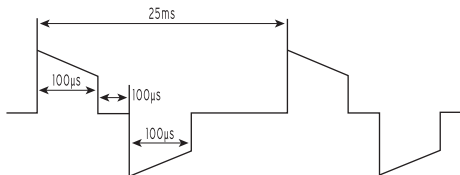
POWER OFF press the "OFF" button for 1.5 -2.0 seconds, the device will be turned off.

The device will automatically power off after working 30 minutes.

There is a LED intensity light. The higher number indicates the intensity level. (The LED light is off when the device is turned off.)

Output waveform

- 1) Output pulse width $100\mu\text{s}$;
- 2) output frequency: 100Hz ;



Maintenance

Make sure your skin is clean and free from any dirt, soil, oil or lotion. Before applying the pads, wet them with a few drops of water to help maintain adhesiveness. The pad should be covered with protective film after use. The pads may be washed by little water and air dried if dirty. The wash time cannot exceed thirty seconds.

Turn off unit after use and store it in a cool and dry place.

Product specifications

Name of product	ManaFlexx 2
Model No.	MF002-RX
Power Voltage	3.7V
Massage issuing frequency	0-100Hz
Consumed current	28mA
Strength level of adjustment	19 sections

Storage

Environmental condition for transport and storage Easily fragile product.

Keep the product in the dry place. Be away from water and rain. Product package should be recycled.

Stacked up 4 cartons at most.

Temperature range: 0°C to 48°C Humidity: 10% to 85%

Atmospheric pressure : 400hpa to 1060pha

Conformity to standards

1. The MF002-RX, electronic muscle stimulator is compliance with:

IEC60601-1 Medical electrical equipment -Part 1: General requirements for safety.

IEC60601-1-2 Medical electrical equipment -Part 1-2: General requirements for safety Collateral Standard" - Electromagnetic compatibility - Requirements and tests.

IEC 60601-2-10 Medical electrical equipment -Part 2: Particular requirements for the safety of nerve and muscle stimulators.

2.The electrode pad is compliance with:

EN ISO 10993-5 Biological Evaluation of Medical Devices - Part 5: Tests for In Vitro Cytotoxicity.

EN ISO 10993-10 Biological evaluation of medical devices - Part 10: Tests for irritation and delayed-type hypersensitivity.

Troubleshooting

If the device is not operating properly, please check it for the following problems or conditions. If the recommended action does not solve the problem, please return it to the authorized dealer for the replacement/repair of the device.

Consumer Warranty

ManaMed offers a 90-day standard warranty to the EMS products. Labor and parts are included during warranty period. Consumers are required to provide model number and dated proof of purchase (sales receipt) when contacting the company for the warranty service.

Non-warranty service is provided on a "per incident" basis. The consumer will verify that the product has failed and provide information for servicing the unit. All applicable repair, parts, shipping, handling, local tax and "per incident" fees will be charged for non-warranty repairs and support calls.



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