INSTRUCTION MANUAL

FOR THE

MT-330A Microcurrent

Distributed by:

V1.0

EVERYWAY

CE 0434

INDEX

Chapter 1 : INTRODUCTION

EXPLANATION OF PAIN

Pain is a warning system and the body's method of telling us that something is wrong. Pain is important; without it abnormal conditions may go undetected, causing damage or injury to vital parts of our bodies.

Even though pain is a necessary warning signal of trauma or malfunction in the body, nature may have gone too far in its design. Aside from its value in diagnosis, long-lasting persistent pain serves no useful purpose. Pain does not begin until coded message travels to the brain where it is decoded, analyzed, and then reacted to. The pain message travels from the injured area along the small nerves leading to the spinal cord. Here the message is switched to different nerves that travel up the spinal cord to the brain. The pain message is then interpreted, referred back and the pain is felt.

EXPLANATION OF MICROCURRENT

Microcurrent Therapy uses very small electrical currents (amounts of electricity measured in millionths of an ampere, or micro amps, symbolized as μA) to help relieve pain and heal soft tissues of the body. The "Microcurrent" designation distinguishes it from regular Microcurrent therapy, which uses currents measured in mA (or milliamps). Typical TENS devices deliver currents up to 80 mA, but the limit for Microcurrent is about 3 mA, equivalent to 3000 μA (or micro amps).

Microcurrent is used for the relief of pain, and because of its close proximity to our own body's current it is thought to work on a more cellular level.

INDICATIONS

Microcurrent is intended to be used to relieve chronic pain and post

surgical and post traumatic acute pain. The MT-330A unit sends comfortable impulses through the skin that stimulate the nerve (or nerves) in the treatment area. In many cases, this stimulation will greatly reduce or eliminate the pain sensation the patient feels. Pain relief varies by individual patient, mode selected for therapy, and the type of pain. In many patients, the reduction or elimination of pain lasts longer than the actual period of stimulation (sometimes as much as three to four times longer). In others, pain is only modified during stimulation. You should discuss this with your physician or therapist.

IMPORTANT SAFETY INFORMATION!

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

Chapter 2: CAUTIONS

1. Federal law (USA) restricts this device to sale by or on the order of a physician.
2. Do not use this device for undiagnosed pain symptoms until consulting a physician.
3. Patients with an implanted electronic device, such as a cardiac pacemaker, implanted defibrillator, or any other metallic or electronic device should not undergo Microcurrent treatment without first consulting a doctor.
4. Patients with heart disease, epilepsy, cancer or any other health condition should not undergo Microcurrent treatment without first consulting a physician.
5. Stimulation delivered by this device may be sufficient to cause electrocution. Electrical current of this magnitude must not flow through the thorax or across the chest because it may cause cardiac arrhythmia.
6. Do not place electrodes on the front of the throat as spasm of the laryngeal and pharyngeal muscle may occur. Stimulation

over the carotid sinus (neck region) may close the airways, make breathing difficult, and may have adverse effects on the heart rhythm or blood pressure.

7. Do not place electrodes on your head or at any sites that may cause the electrical current to flow transcerebrally (through the head).
8. This device should not be used while driving, operating machinery, close to water, or during any activity in which involuntary muscle contractions may put the user at undue risk of injury.
9. Turn the Microcurrent off before applying or removing electrodes.
10. Isolated cases of skin irritation may occur at the site of electrode placement following long term application. If this occurs, discontinue use and consult your physician.
11. If Microcurrent therapy becomes ineffective or unpleasant, stimulation should be discontinued until its use is re-evaluated by a physician
12. Keep this device out of the reach of children.
13. The MT-330A Microcurrent device has no AP/APG protection. Do not use it in the presence of explosive atmosphere and flammable mixture.

Chapter 3 : WARNINGS

1. Microcurrent devices should be used only under the continued supervision of a physician.
2. Microcurrent devices have no curative value.
3. Microcurrent is a symptomatic treatment and as such suppresses the sensation of pain, which would otherwise serve as a protective mechanism.
4. Microcurrent is not effective for pain of central origin. (This includes headache.)
5. Electronic monitoring equipment (such as ECG monitors and ECG alarms) may not operate properly when Microcurrent stimulation is in use.
6. Caution should be used in applying Microcurrent to patients suspected of having heart disease. Further clinical

data is needed to show there are no adverse results.

7. Electrodes should not be placed over the eyes, in the mouth, or internally.
8. Do not use while sleeping
9. Do not use during pregnancy unless directed by your physician.

Chapter 4: CONTRAINDICATIONS

1. Do not use Microcurrent over the carotid sinus (neck) region.
2. Microcurrent devices can affect the operation of demand type cardiac pacemakers.
3. Do not use the Microcurrent device if you have heart disease without consulting your physician.
4. Do not stimulate on the site that may cause current to flow transcerebrally – (through the head).
5. Do no apply Microcurrent for undiagnosed pain symptoms until etiology is established.

Chapter 5: ADVERSE REACTIONS

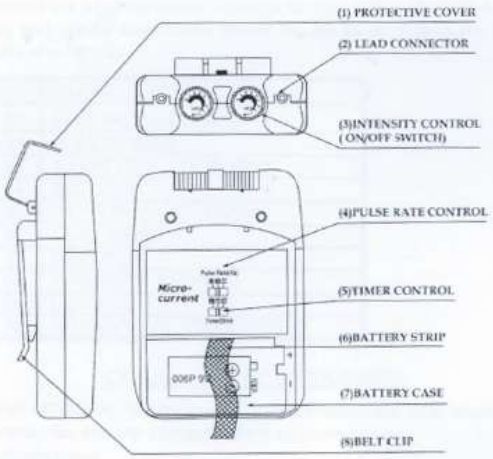
Skin irritation and electrode burns are potential adverse reactions. If irritation occurs, discontinue use and consult your physician.

Chapter 6: GENERAL DESCRIPTION

The MT-330A Microcurrent is a battery operated pulse generator that sends electrical impulses through electrodes to the body and reaches the nerves causing pain. The device is provided with two controllable output channels, each independent of each other. An electrode pair can be connected to each output channel.

The electronics of the MT-330A Microcurrent create electrical impulses whose intensity, duration, number per second and modulation may be altered with the controls/switches.

Chapter 7 : CONSTRUCTION



Chapter 8 : TECHNICAL SPECIFICATIONS

The technical specification details of MT-330A Microcurrent are as follows:

	MECHANISM	TECHNICAL DESCRIPTION
1	Channel	Dual, isolated between channels
2	Pulse Amplitude	Adjustable, 0-3mA peak into 4k ohm load each channel
3	Output Voltage	Adjustable, +12.0~-12.0 Volt (Open Current)
4	Pulse Rate	Selectable 0.3Hz, 8Hz and 80Hz (+/-10%)
5	Wave Form	Modified Square DC Biphasic Pulses changing polarity at intervals of 1 seconds.
6	Timer	20, 40 minutes and Continuous
7	Power Supply	One 9 Volt Battery
8	Battery Life	Approximately 100 hours at nominal settings.
9	Size	95(H) x 65(W) x 23.5(T) mm
10	Weight	115 grams(battery included)
11	Operating Condition	Temperature: 10°~40°C Relative Humidity: 30%~75% Atmosphere Pressure : 700hpa~1013hpa
12	Remark	+/-10% tolerance of all parameters

Chapter 9 : REPLACABLE PARTS

The replaceable parts and accessories of MT-330A Microcurrent devices are as given below – Except for lead wires, electrodes, battery and battery case cover, please do not try to replace the other parts of a device.

	PARTS
01	ELECTRODES LEADS
02	ELECTRODES
03	9V BATTERY ,TYPE 6F22
04	BELT CLIP
05	BATTERY CASE COVER
06	LEAD WIRES
07	MAIN PCB
08	INTENSITY KNOB
09	LID COVER
10	INTENSITY CONTROL COVER

Chapter 10 : ACCESSORIES

Each MT-330A Microcurrent comes complete with standard accessories and the standard labels as given below:

I. Accessories

REF. NO.	DESCRIPTION	Q'TY
1. KF4040	40 X 40 mm Adhesive Electrodes	4 pieces
2. KE-24	Electrodes Leads	2 pieces
3.	9 V Battery, type 6F22	1 piece
4.	Instruction Manual	1 piece
5.	Carrying Case	1 piece

II. LABEL

The label attached to the back of device contains important information about this device- model, supply voltage and caution. Please do not remove.

Chapter 11 : GRAPHIC SYMBOLS

1. Degree of Electrical Protection BF
2. Do not insert the plug into AC power supply socket.
3. Consult Operation Instructions
5. Manufacturer
6. SN Serial Number
7. DC Current(DC Power source)
8. IP22 Degrees of protection provided by enclosures (IP Code)

Chapter 12: OPERATING INSTRUCTIONS

1) Insert the 9V battery into the device's battery compartment. Make sure to remove the plastic seal on the 9V battery. Line up the positive and negative terminals on the battery with their corresponding terminals in the device. Make sure that both intensity control (ON/OFF Switch) knobs are in the off position.
2) Insert the lead wires into the lead wire sockets on top of the device.
3) Open the electrode package. Then insert each lead wire pin into the pig tail of the electrodes
4) Place the electrodes on your body as directed by your physician.
5) Select the pulse rate and timer settings as directed by your physician
6) Slowly turn on the device by rotating the Intensity control (ON/OFF Switch) knobs.
7) Slowly increase or decrease the intensity as directed by your physician by rotating the Intensity control (ON/OFF Switch) clockwise to increase, counter clockwise to decrease.
8) After Treatment, Turn the device off by rotating the Intensity control (ON/OFF Switch) counter clockwise to the zero setting.

Chapter 13 : PARAMETER CONTROLS

PULSE RATE

The Pulse Rate (hertz or pulses per second) chosen depends greatly upon the type of electrode placement given to the patient.

When using contiguous and dermatome electrode placements (i.e. stimulating directly through the area of pain or localized enervation), a quick pulse rate (setting greater than 80Hz on the Pulse Rate Control) is desired. The patient should not perceive individual pulses but rather have the sensation of steady continuous stimulation.

Despite above recommendations, each individual patient may require slight variations of the above settings, according to the nature of their condition and the direction of their physician.

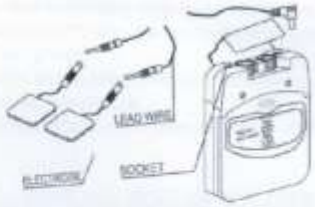
TIME DURATION

The onset of pain relief should occur shortly after the Intensity setting has been determined. However, in some cases, pain relief may take as long as 30 minutes to achieve. Microcurrent units are typically operated for long periods of time, with a minimum of 20 – 30 minutes and in some post-operation protocols, as long as 36 hours.

In general, pain relief will diminish within 30 minutes of the cessation of stimulation.

Chapter 14 : ATTACHMENT OF ELECTRODE LEAD WIRES

The wires provided with the system insert into the jack sockets located on top of the device. Holding the insulated portion of the connector, push the plug end of the wire into one of the jacks (see drawing); one or two sets of wires may be used.



After connecting the wires to the stimulator, attach each wire to an electrode. Use care when you plug and unplug the wires. Jerking the wire instead of holding the insulated connector body may cause wire breakage.

CAUTION

Do not insert the plug of the patient lead wire into any AC power supply socket.

Chapter 15: LEAD WIRE MAINTENANCE

Clean the wires by wiping with a damp cloth. Coating them lightly with talcum powder will reduce tangling and prolong life.

Chapter 16 : ELECTRODE OPTIONS

The electrodes are disposable and should be routinely replaced when they start to lose their adhesive nature. If you are unsure of your electrode adhesive properties, order replacement electrodes. Replacement electrodes should be re-ordered through or on the advice of your physician to ensure proper quality. Follow application procedures outlined in electrode packing, to maintain optimal stimulation and to prevent skin irritation.

Chapter 17 : ELECTRODE PLACEMENT

The placement of electrodes can be one of the most important parameters in achieving success with Microcurrent therapy. Of utmost importance is the willingness of the physician to try the various styles of electrode placement to find which method best fits the needs of the individual patient.

Every patient responds to electrical stimulation differently and their needs may vary from the conventional settings suggested here. If the initial results are not positive, speak to your physician about alternative stimulation settings and/or electrode placements. Once an acceptable placement has been achieved, mark down the electrodes sites and the settings, so the patient can easily continue treatment at home.

Chapter 18 : TIPS FOR SKIN CARE

To avoid skin irritation, especially if you have sensitive skin, follow these suggestions:

1. Wash the area of skin where you will be placing the electrodes, using mild soap and water before applying electrodes, and after taking them off. Be sure to rinse soap off thoroughly and dry skin well.
2. Excess hair may be clipped with scissors; do not shave stimulation area.
3. Wipe the area with the skin preparation your physician has recommended. Let this dry. Apply electrodes as directed.
4. Many skin problems arise from the "pulling stress" from adhesive patches that are excessively stretched across the skin during application. To prevent this, apply electrodes from center outward; avoid stretching over the skin.
5. To minimize "pulling stress", tape extra lengths of lead wires to the skin in a loop to prevent tugging on electrodes.
6. When removing electrodes, always remove by pulling in the direction of hair growth.
7. It may be helpful to rub skin lotion on electrode placement area when not wearing electrodes.
8. Never apply electrodes over irritated or broken skin.

Chapter 19 : APPLICATION OF RE-USABLE SELF ADHESIVE ELECTRODES

Application

1. Clean and dry the skin at the prescribed area thoroughly with soap and water prior to application of electrodes.
2. Insert the lead wire into the pin connector on the pre-wired electrodes.
3. Remove the electrodes from the protective liner and apply the electrodes firmly to the treatment site.

Removal

1. Lift at the edge of electrodes and peel; do not pull on the lead wires because it may damage the electrodes.
2. Place the electrodes on the liner and remove the lead wire by twisting and pulling at the same time.

Care and Storage

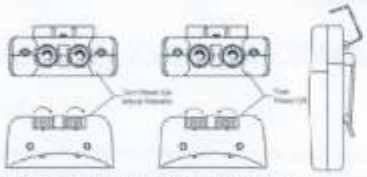
1. Between uses, store the electrodes in the resealed bag in a cool dry place.
2. It may be helpful to improve repeated application by spreading a few drops of cold water over the adhesive and turn the surface up to air dry. Over Saturation with water will reduce the adhesive properties.

Important

1. Do not apply to broken skin.
2. The electrodes should be discarded and replaced when they are no longer adhering.
3. The electrodes are intended for single patient use only.
4. If irritation occurs, discontinue use and consult your physician.
5. Read the instructions for use of self-adhesive electrodes before application.

Chapter 20 : ADJUSTING THE CONTROLS

1. Slide-on Cover:
   A slide-on panel cover covers the controls for selecting mode and adjusting settings. Your medical professional may wish to set these controls for you and request that you leave the cover in place.



2. Power On/Off Switch and Intensity Controls:
   If both controls are in the off-position, the device is switched off. By turning the controls clockwise, the appropriate channel is switched on.

The current strength of the impulses transmitted to the electrodes increases further when the control is turned clockwise.

To reduce the current strength or switch the device off, turn the control counter clockwise to the required setting or off-position, respectively.

The controls are protected by a cap to avoid unintentional change of Intensity.

4. Lead Connector :
   Connection of the electrodes is made with the two-lead connector (lead wires). The device must be switched off before connecting the cables. Both Intensity controls must be at the Off position. Electrodes must be pressed firmly on the skin.

5. Pulse Rate Control:
   Pulse rate is selectable at 0.3Hz, 8Hz or 80Hz. Usually 0.3 Hz provides the best pain relief. If Insufficient relief is obtained, try the 80 Hz or discuss with your physician.

6. Timer Control
   The treatment time can be selected by pressing the "Timer" control. There are 3 settings available, 20, 40 minutes and continue(C). Push the "Timer control" to select a setting needed.

9. Check/Replace the Battery:
   Over time, in order to ensure the functional safety of Microcurrent, changing the battery is necessary.

   1. Make sure that both Intensity controls are switched to off position.
   2. Slide the battery compartment cover and open.
   3. Remove the battery from the compartment.
   4. Insert the battery into the compartment. Note the polarity indicated on the battery and in the compartment.
   5. Replace the battery compartment cover and press to close.

CHAPTER 21 : BATTERY INFORMATION

PRECATIONS

1. Remove battery if equipment is not likely to be used for some time.
2. Please recycle the used battery in accordance with domestic regulation.
3. Do not throw the used battery into fire.

If you use rechargeable batteries, please follow the instructions.

RECHARGEABLE BATTERIES:

Prior to the use of a new unit, the rechargeable battery should be charged according to the battery manufacturer's instructions. Before using the battery charger, read all instructions and cautionary markings on the battery and in this instruction manual.

After being stored for 60 days or more, the batteries may lose their charge. After long periods of storage, batteries should be charged prior to use.

BATTERY CHARGING

(1) Plug the charger into any working 110 or 220/240v electrical outlet. The use of any attachment not supplied with the charger may result in the risk of fire, electric shock, or injury to persons.
(2) Follow the battery manufacturer's instructions for charging time.
(3) After the battery manufacturer's recommended charging time has been completed, unplug the charger and remove the battery.
(4) Batteries should always be stored in a fully charged state. To ensure optimum battery performance, follow these guidelines:
   (a) Although overcharging the batteries for up to 24 hours will not damage them, repeated overcharging may decrease useful battery life.
   (b) Always store batteries in their charged condition. After a battery has been discharged, recharge it as soon as possible. If the battery is stored more than 60 days, it may need to be recharged.
   (c) Do not short the terminals of the battery. This will cause the battery to get hot and can cause permanent damage. Avoid storing the batteries in your pocket or purse where the terminals may accidentally come into contact with coins, keys or any metal objects.
   (d) WARNINGS:
      1. Do not attempt to charge any other types of batteries in your charger, other than rechargeable batteries made for your charger. Other types of batteries may leak or burst.
      2. Do not incinerate the rechargeable battery as it may explode!

Chapter 22: MAINTENANCE, TRANSPORTATION AND STORAGE OF TENS DEVICE

1. Non-flammable cleaning solution is suitable for cleaning the device. Note: Do not smoke or work with open lights (for example, candles, etc.) when working with flammable liquids.
2. Stains and spots can be removed with a cleaning agent.
3. Do not submerge the device in liquids or expose it to large amounts of water.
4. Return the device to the carrying box with sponge foam to ensure that the unit is well-protected before transportation.
5. If the device is not to be used for a long period of time, remove the batteries from the battery compartment (acid may leak from used batteries and damage the device). Put the device and accessories in carrying box and keep it in cool dry place.
6. The packed Microcurrent device should be stored and transported under the temperature range of -20°C — + 60°C, relative humidity 20% — 95%, atmosphere pressure 700 hPa — 1013 hPa.

Chapter 23: SAFETY-TECHNICAL CONTROLS

For safety reasons, review the following checklist before using your MT-330A Microcurrent.

1. Check the device for external damage.
- deformation of the housing.
- damaged or defective output sockets.

2. Check the device for defective operating elements.
- legibility of inscriptions and labels.
- make sure the inscriptions and labels are not distorted.

3. Check the usability of accessories.
- patient cable undamaged.
- electrodes undamaged.
- battery is not corroded

Please consult your distributor if there are any problems with device and accessories.

Chapter 24: MALFUNCTIONS

Should any malfunctions occur while using the MT-330A Microcurrent, check

- whether the parameters are set to the appropriate form of therapy. Adjust the control correctly.
- whether the cable is correctly connected to the device. The cables should be inserted completely into the sockets.
- for possible damage to the cable. Change the cable if any damage is detected.
- If the electrodes have lost their adhesiveness. Replace if necessary.
- If the battery needs to be replaced or recharged. Replace or recharge if necessary.
* If there is any other problem, please return the device to your distributor. Do not try to repair a defective device.

Chapter 25: CONFORMITY TO SAFETY STANDARDS

The MT-330A Microcurrent devices are in compliance with the following standards:
EN 60601-1-2: 2007 Medical electrical equipment -
Part 1-2: General requirements for basic safety and essential performance
-Collateral standard: Electromagnetic compatibility -
Requirements and tests
EN 60601-1:2006 Medical electrical equipment -
Part 1: General requirements for basic safety and essential performance

Chapter 26 : WARRANTY

All MT-330A Microcurrent models carry a distributor warranty of three years from the date of delivery. The warranty applies to the stimulator only and covers both parts and labour relating thereto.

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

Manufacturer:

Everyway Medical Instruments Co., Ltd.
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Representative in the EU:

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INFORMATION FOR DISTRIBUTOR:

Please contact the above mentioned manufacturer for technical support and documentation when necessary.

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