Flex-MI™

Instruction Manual

Please read the Instruction Manual prior to use.

EMSI®

⚠ CAUTION Federal law requires a prescription from your physician before use of this product.

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1.0 | Intended Use

The Flex-MI™ is design for the following:

Interferential Stimulation

> Symptomatic relief of chronic intractable pain
> Adjunctive treatment for the management of post-traumatic or post-surgical pain

EMS- Electrical Muscle Stimulation

> Relaxation of muscle spasm
> Increasing local blood circulation
> Muscle re-education
> Prevention or retardation of disuse atrophy
> Prevention of venous thrombosis of the calf muscles immediately after surgery
> Maintaining or increase range of motion

2.0 | To The Patient

Please read this operating manual carefully before using the device. The instruction on the following page will show you how to use and care for your device in the general manner. You should be particularly familiar with the prescription information and precautions before proceeding.

You should consult with your clinician if you have specific questions or problems regarding the use of your device.

⚠ **CAUTION** ***Federal law restricts this device to sale by or on the order of a physician.***

3.0 | Contraindications

1. Any electrode placement that applies current to the carotid sinus (front of neck) region.
2. Any electrode placement that causes current to flow transcerebrally (through the head).
3. Any use of this device on patients who have a demand-type cardiac pacemaker.
4. The use of this device whenever pain syndromes are undiagnosed, until etiology is established.

4.0 | ⚠ WARNING

1. The long-term effects of chronic electrical stimulation are unknown.
2. Stimulation should not be applied over the carotid sinus nerves, particularly in patients with a known sensitivity to the carotid sinus reflex.
3. Stimulation should not be applied over the front of neck or mouth. Severe spasm of the laryngeal and pharyngeal muscles may occur and the contractions may occur and may be strong enough to close the airway or cause difficulty in breathing.
4. Stimulation should not be applied trans-thoracically in that the introduction of electrical current into the heart may cause cardiac arrhythmias.
5. Stimulation should not be applied over swollen, infected, or inflamed areas or skin eruptions, e.g., phlebitis, thrombophlebitis, varicose veins, etc.
6. Stimulation should not be applied over, or in proximity to, cancerous lesions.

7. For external use only.
8. Do not use device on the eye area.
9. This device should be used only under the continued supervision of a physician.
10. Safety for use during pregnancy or delivery has not been established.
11. Electronic equipment such as ECG monitors and ECG alarms may not operate properly when the device is in use.
12. Apply the electrodes to clean, dry and unbroken skin only.
13. This device 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.
14. This device should be kept out of the reach of children.
15. This device is not effective for pain of central origin, including headaches.
16. This device has no curative value.
17. This device is a symptomatic treatment, and as it suppresses the sensation of pain which would otherwise serve as a protective mechanism.

5.0 | Precautions

1. Caution should be used for patients with suspected or diagnosed heart problems.
2. Caution should be used for patients with suspected or diagnosed epilepsy.
3. Caution should be used in the presence of the following:
   (a) When there is a tendency to hemorrhage following acute trauma or fracture;
   (b) Following recent surgical procedures when muscle contraction may disrupt the healing process.
   (c) Over the menstruating or pregnant uterus; and
   (d) Over areas of the skin which lack normal sensation.
4. Some patients may experience skin irritation of 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.
5. Electrode placement and stimulation settings should be based on the guidance of the prescribing practitioner.
6. This device should be used only with the leads and electrodes recommended for use by the manufacturer.
7. Isolated cases of skin irritation may occur at the site of the electrode placement following long-term application.

8. Effectiveness is highly dependent upon patient selection by a person qualified in the management of pain patients.
9. If the stimulation levels are uncomfortable or become uncomfortable, reduce the stimulation amplitude to a comfortable level and contact your physician if problems persist.

6.0 | Adverse Reactions

1. Possible skin irritation or electrode burn under the electrodes may occur.
2. Possible allergic skin reaction to tape or gel may occur.
3. Electromagnetic Disturbances: There is a possibility that radio signals from high-frequency transmitters, e.g. mobile phones or similar mobile radio equipment, airport security systems, or metal detection devices (which themselves conform to the EMC regulations), may influence the proper functioning of the device if such equipment is operated in close proximity and with relatively high transmitting power.

The Flex-MI™ meets EMC requirements and is designed in such a way, that under normal conditions, there is no risk of malfunction caused by electromagnetic interference. However, in the case of signals from high frequency transmitters, the risk of electromagnetic incompatibility when operated in close proximity to electronic apparatus cannot be totally ruled out. In unusual circumstances, unintended functions of the Flex-MI™ could be initiated, possibly giving rise to undesirable risks for the patient or user such as a surge in energy level or ineffective treatment parameters.

7.0 | Unit Description

ON/OFF Button: Turns the unit ON and OFF.

Amplitude Controls: Controls the "INTENSITY" level of stimulating pulses.

MODE Button: Choose the IFC or EMS stimulation modes.

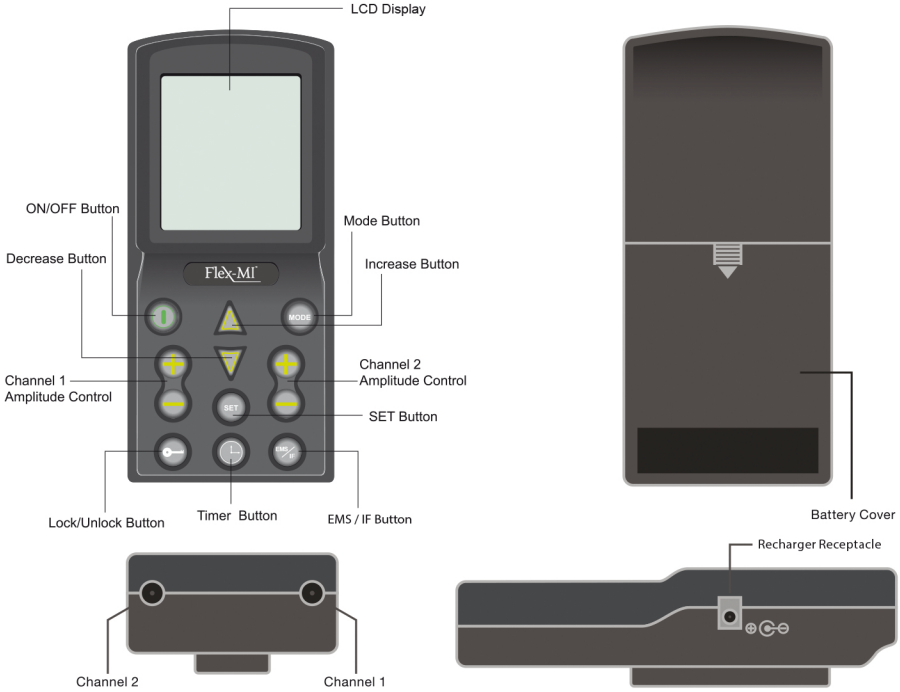
SET Button: Set the pulse width, pulse rate, ramp time, on time and off time.

TIMER Button: Sets the timer.

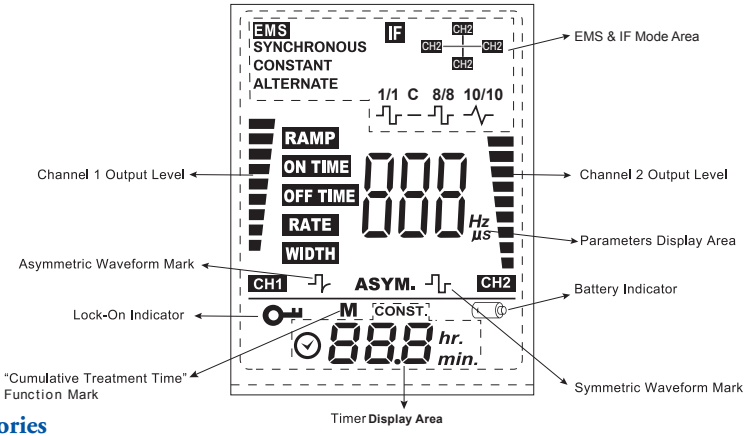
INCREASE & DECREASE Button: Increase and decrease pulse width, pulse rate, ramp time, on time, off time and choose the timer.

LOCK/UNLOCK Button: Locks or unlocks the unit.

EMS/IF Button: Choose EMS or IF waveform.


LCD Display
ON/OFF Button
Mode Button
Decrease Button
Increase Button
Flex-MI
MODE
Channel 1
Amplitude Control
Channel 2
Amplitude Control
SET
SET Button
Lock/Unlock Button
Timer Button
EMS / IF Button
Battery Cover
Recharger Receptacle
Channel 2
Channel 1

7.0 | Unit Description continued



Accessories

Electrode Leadwires: Two sets of electrode leadwires which are compatible with commercially available electrodes (standard 0.08 inch female connection) are provided with the Flex-MI™. Each output jack of the device is designed to accept a lead wire whose connector complies with FDA 21 CFR Part 898 requirements.

The Flex-MI™ is recommended for use with the EMSI self adhesive electrodes. (Re-order information on page 26)

Battery Charger:
Input: AC 110V, 50-60Hz, 0.2A
Output: DC 4.8V, 400mA

8.0 | Specifications

EMS Specifications

Channel:		Dual, isolated between channels
Power Source:		4.8V Ni-MH rechargeable battery pack
Output waveform:		Symmetric or Asymmetric waveform
Digital Output		20- Level adjustment LCD display, 10 sections of each section with 2 adjustments.
Symmetric	Output	0~±62V(Loading: 1000 Ω)
	Output Current	0~±62mA(Loading: 1000 Ω)
	Levels	1~20 levels: Each level increases ± 3.1V (Loading: 1000 Ω)
Asymmetric	Output	0~62V(Loading: 1000 Ω)
	Output Current	0~62mA(Loading: 1000 Ω)
	Levels	1~20 levels: Each level increases 3.1V (Loading: 1000 Ω)
Pulse Width		Variable, 50~400 µs
Pulse Rate		Variable, 2~150 Hz
On Time		1~99 seconds
Off Time		1~99 seconds
Ramp (Ramp Up & Ramp Down)		The time required to reach the pulse width value and amplitude setup value or from setup value to zero can be selected to be 1-8 seconds. (Ramp up value= Ramp down value).
Mode		Synchronous Constant Altertnate

IFC Specifications

Channel:	Dual, isolated between channels
Power Source:	4.8V Ni-MH rechargeable battery pack
Output waveform:	Symmetric waveform
Digital Output	20- Level adjustment

* All values + or - 10%

8.0 | Specifications continued

	LCD display, 10 sections of each section with 2 adjustments
Output	0~±23V(Loading: 1000 Ω)
Output Current	0~±23mA(Loading: 1000 Ω)
Levels	Level 1: ±2.1V Level 2: level 20 Each level increases ±1.1V (Loading: 1000 Ω)
Pulse Width	125μs for each phase, Fixed
Carrier Rate	4000Hz, Fixed
Different Rate	Variable, 1~250Hz
Treatment Functions	1/1 abrupt Continous 8/8 abrupt 10/10 ramped
Timer	5~90 minutes auto-shutoff or Constant
Patient Compliance Timer	Operation count: record of 60 sets (min.), max with 999 mins. Operation total time: max with 999 hrs.
Operation ambient:	Temperature range: 10°C ~ 35°C Humidity range: 20 ~ 90%RH
Storage & transportation:	Temperature Range: 0°C ~ 70°C Humidity Range: 20 ~ 90%RH
Timer:	5~90 minutes auto-shutoff or Constant
Size:	L (120mm) x W (54mm) x H (33mm)
Weight	156 grams (including battery)

9.0 | Stimulation Mode Descriptions

The stimulation mode offers a variety of stimulation modes. It is adjustable by pressing on the "MODE" button. Be sure that when adjusting these stimulation modes, the intensity output controls should be set to the minimum output first.

EMS Mode

MODE	Descriptions
Synchronous (S)	The pulses of CHANNEL 1 and CHANNEL 2 are synchronous. While Channel 1 is activated, Channel 2 will be activated simultaneously. The pulses active and inactive duration is. controlled by ON TIME and OFF TIME.
Constant (C)	Both CHANNEL 1 and CHANNEL 2 are continuous pulses under an adjustable pulse rate and pulse width. The functions of ON TIME, OFF TIME, and RAMP cannot be set.
Alternate (A)	The pulses of CHANNEL1 and CHANNEL2 are Alternative. When Channel 1 is activated, Channel 2 will be inactivated and vice versa.

9.0 | Stimulation Mode Descriptions continued

MODE	Descriptions
1/1 abrubt	When Set at “1/1” with the frequency control set a lOOHz, the interference 1/1 frequency would be at 75Hz for 1 second, then shift abruptlyt o l55Hz for 1 abrupt second, then back to 75Hz. The pattern will be repeated as long as the mode selector switch is set in the “1/1” mode.
(C) Constant	In the "C" (Continue) mode, then, is no change In the pulse rate, when set at the other modes. the interference frequency changes over time.
8/8 abrubt	The option “8/8” is identical to “1/1”, except that each interference frequency value (75Hz to l55Hz in the above example) is held for 8 seconds.
10/10 ramped	The option "10/10" work from the -25% volue to the +55% value graduallv instead of rapidly. For example, when the frequency control was set at lOOHz, the device will sweep gradual from 75Hz to 155Hz over a 10 second period, then from 155Hz to 75Hz during the next 10 seconds.

10.0 | Instructions For Use

NOTE: Always read this instruction manual before use.

PREPARATION FOR USE

1. **Check Battery:**

   The battery is packaged together in a pack. DO NOT UNWRAP BATTERY PACK. Proceed to insert battery pack into the battery compartment. BE SURE TO MATCH THE POSITIVE AND NEGATIVE ENDS OF THE BATTERY PACK TO THE MARKINGS IN THE BATTERY COMPARTMENT OF THE UNIT.

   NOTE: Before first and consequent uses, charge battery using the supplied proprietary EMSI battery charger (part no. CHAR0002).
   To charge: Plug male end of charger to the socket located on the right side of the LCD screen. Make sure the plug fits snugly into the socket. PERMANENT DAMAGE MAY OCCUR IF FORCE IS USED TO PLUG THE MALE END OF THE CHARGER INTO THE SOCKET. A green indicator light will illuminate and alternately flash as it is being charged. If red or flashing red, check battery for proper placement. If not solved, call customer service. When charging is done, a green steady light will illuminate. Frequency of use will determine life cycle of battery. Replace battery pack if/when battery becomes inefficient.

   NOTE: The device will NOT work if the charger is plugged into the device or an outlet. Use of unapproved charger (not issued by EMSI) may cause damage to device and will void any warranty.

   The Specifications of Charger:
   Input: AC 110V, 50~60Hz, 0.2A
   Output: DC 4.8V, 400mA

CONNECTING THE STIMULATOR

2. Connect electrodes to lead wires:

Insert the lead wire connector into electrodes connector (standard 0.08 inch female connection). MAKE SURE THAT NO BARE METAL OF THE PINS IS EXPOSED

⚠ CAUTION

The Flex-MI™ is compatible and recommended for use with EMSI electrodes. Always use electrodes and leadwires that came with the unit. Using other electrodes and leadwires may render the unit non-operable, ineffective, and void the warranty.

3. Connect lead wires to unit:

Before proceeding to this step, be sure the unit is turned OFF.

Holding the insulated portion of the lead wire connector, insert the angled-"L" plug into the receptacle on the top of the main unit. Please ensure the lead wires are inserted securely.

The unit has two output receptacles which are controlled by Channel 1 and Channel 2 Amplitude Control buttons on the front of the unit. You may choose to use one channel with one pair of lead wires or both channels with two pairs of lead wires.

⚠ CAUTION Always use leadwires that came with the unit. Using other leadwires may render the unit non-operable and void the warranty.

10.0 | Instructions For Use continued

4. **Place electrodes on skin:**

   Before applying electrodes, be sure that the skin surface over which electrodes are placed is thoroughly cleaned and dried. Apply electrodes to the exact site indicated by your physician following the instruction included with the electrodes labeling. Make sure that the electrodes are placed firmly to skin and make good contact between the skin and the electrodes. Place the electrodes over the skin; attach them properly, firmly and evenly.

5. **Treat as directed by prescribing clinician:**
   - Press the **ON/OFF** button to turn unit on. Activated Controls will be visible on LCD screen. Press Mode to select appropriate stimulation mode.
   - Press **Set** to select unit output for the following as directed by clinician:
     - pulse width, pulse rate, ramp time, on time and off time, if applicable.
     - adjust to the desired setting by pressing the triangular increase/decrease button.
   - Choose **Symmetric or Asymmetric** waveform by pressing waveform button in lower right corner of the unit.
   - Press the **Timer** button to set time. Adjust in increments of 5 minutes up to 90, or continuous by repeatedly pressing the triangular increase/decrease button.
   - Adjust the **Amplitude** (pulse intensity) of Channel 1 and/or Channel 2 as directed by your clinician.
   - To discontinue treatment for any timer setting, press the **ON/OFF** button.

NOTE: This device is capable of "locking" out either IFC or EMS features. To isolate device into a specific treatment (EMS or IFC) mode, ensure device is not providing any stimulation and is on the desired treatment mode. Press and hold Channel 1 and Channel 2 negative (-) amplitude button for 5–7 sec until audible beep is heard. This will allow only IFC or only EMS modes to function. To reverse, follow above steps.

6. Turn Unit Off:

Press the "ON/OFF" button to turn unit off. Then unplug the electrode lead wires, grasping them by the plug, not the cord. If treatment will be resumed shortly the electrodes may be left on the skin. When the electrodes are removed, clean the skin thoroughly with mild soap and water. If there is skin irritation, consult your medical professional.

NOTE: When the timer runs out, the unit will turn off automatically and you are not required to press the "ON/OFF" button. Unit will also turn off automatically after 5 minutes if no activity is made when the unit is initially turned on.

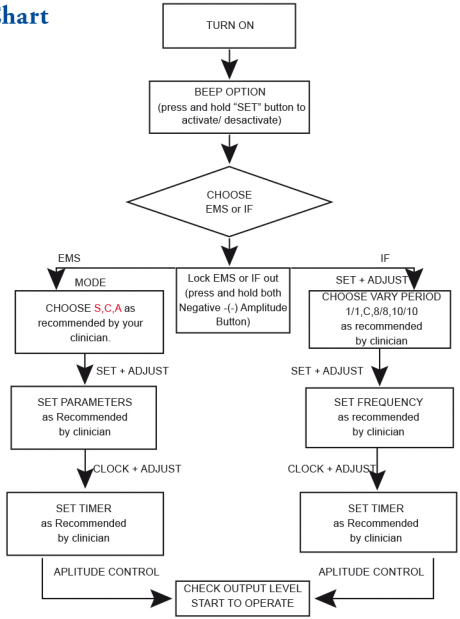
NOTE: This device is safeguarded with a Locking mechanism to avoid possible mishandling when treatment is in session. The user can manually "Lock" the settings for the duration of the treatment by pressing and holding the "key" button for 3 seconds (a beep (if enabled) will confirm device is locked). The device also automatically "locks"if no treatment button is pressed for 1 minute. Once locked, other than the power button, no buttons are active. To disable the "Lock" during treatment session for adjustment or stoppage, press and hold the "key" button for 3 seconds (a beep will confirm device is unlocked). The user can then adjust amplitude, settings, etc.

SPECIAL CARES IN OPERATING

- Clean and dry the skin surface of the body area to be treated.
- Inspect the electrode cords and electrode pads for wear. If they are not in good condition, they should be replaced. If they are acceptable, then insert the cord pins into each electrode pad. Electrodes are for single patient use, and are to be used in accordance with the labeling provided with the electrodes. Electrodes should not be used for multiple patients.
- Make sure the electrode pads are firmly fixed in place to obtain effective conduction.
- Use the electrode sites recommended by your prescribing physician.
- Increase the output level SLOWLY to that recommended by your clinician. Usually, that will mean increasing intensity until you can feel the tingling sensation (high pulse rates) or pulsing sensation (low pulse rates) of the stimulation. Your prescribing clinician will tell you how far they wish you to turn up the intensity.
- If at any time the electrical stimulation begins to feel uncomfortable, reduce the stimulation amplitude to a comfortable level and contact your physician if the problem persist.
- The possibility of electromagnetic disturbance from other equipment in or outside your home exist. Use caution in using electrical stimulation in situations which may have a potential high frequency transmitter such as in close proximity to mobile phones in use, airport security systems, or hand held detectors.

When you are finished using the unit (prior to timer finishing), turn the device off and the LCD display will disappear. This will conserve battery life. You may now remove the electrode pads from your body.

Operation Procedure Chart



11.0 | Patient Compliance Timer

The patient compliance timer can memorize 60 sets of operation records; the total record time is 999 hours. The patient compliance timer is accessible only when the unit is turned off.
Press and hold **"MODE"** button, then press the "ON/OFF" button simultaneously to initiate the patient compliance timer.

1. **Individual treatment time:**

   Press **"INCREASE"** button (triangle button) or **"DECREASE"** button (inverted triangle button) to scroll through the records of treatment times.

   Press and hold **"Set"** button for 3 seconds to delete the displayed record. After the displayed record is deleted, the unit will acknowledge with an audible response "Bi".

   NOTES:

   (a) If the treatment time is under one minute, it will not be recorded. For example, if your treatment time is 10 minutes and 30 seconds, the patient compliance timer will record 10 minutes, not 11 minutes.

   (b) The patient compliance timer will record up to 999 minutes for each treatment. Therefore, if you use the stimulator for over 999 minutes, it will record 999 minutes and the recorded time will flash to indicate the treatment time is over 999 minutes.

11.0 | Patient Compliance Timer continued

2. Cumulative treatment time:

When initiating patient compliance timer, press **"Mode"** to shift the record of individual treatment time with the number of sessions to the record of cumulative treatment time. When showing the record of cumulative treatment time, there will be an **"M"** mark flashing on the screen.

Press and hold **"Mode"** & **"Set"** button simultaneously for 3 seconds to delete all the records including individual treatment time record and cumulative treatment time record.

The patient compliance timer will keep the records even when the battery has no charge. Only when users press and hold "Set" or "Mode" & "Set", the records will be deleted.

12.0 | Care and Maintenance

1. Cleaning

Clean the housing by wiping with clean damp cloth only.
To avoid corrosion, do not immerse in water.
Do not store in direct sunlight or humid environments, i.e. Bathrooms.

2. Low Battery Indicator:

When the low battery indicator flashes, the battery should be recharged as soon as possible (see page 18).
If replacement is needed, use the following part numbers:

Battery: BATT0004
Battery charger: CHAR0002

3.Electrode Pad Use and Disposal

Electrodes are intended for single patient use only.
Electrodes should not be used if they no longer adhere firmly to the treatment area.

12.0 | Care and Maintenance continued

4. Device Storage and Disposal

If the device will be stored for an extended period of time, remove the battery from the device and store all components in a cool, dry location. When storing, ensure battery contacts do not touch any metallic materials. Electronic components should be disposed according to local statutes and regulations for electronic devices and NiMH batteries. If local disposal is not available, please contact EMSI for proper disposal options.

5. Accessory Replacement

To order replacement accessories, please contact EMSI Customer Service at:

Phone: 800-588-8383/(813) 931-2369
E-mail: customerservice@wecontrolpain.com

Specify the unit type is Flex-MI™ Stimulator and the electrode size recommended by your ordering clinician.

13.0 | Troubleshooting

If your unit does not seem to operate correctly, refer to the chart below to determine possible causes.

The LCD indicator illuminates but unit does not function properly.	**Low Battery indicator flash.**	**None of LCD indicators illuminate.**
1. Check all control settings. Are they set to values prescribed by your medical professional? 2. Are electrodes in proper position and adhering to the skin? See Section 11, Instructions for Use and the electrode manufactures instruction for applying the electrodes. 3. Check lead wires. Be sure all connectors are firmly sealed. See Section 11, Instructions for Use, Item 3. 4. Replace cord set with another to check for broken wires.	 Recharge battery pack	Recharge battery pack

If none of these measures correct the problem, please contact a Customer Service Representative.

EMSI
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Phone: 800-588-8383/(813) 931-2369 | **Fax**: 800-588-9282 | **E-mail**: customerservice@wecontrolpain.com

Descriptions

	Manufacturer		Keep Dry		Caution: Read Instruction Manual	IP 22	Protect the ingress of solid objects 1.55mm in diameter and greater and vertically falling water drops when enclosure tilted up to 15°
	Type BF applied part		Do not put in regular trash	Rx only	For Prescription use only		

14.0 | Declarations-EMC

Guidance and manufacturer's declaration-electromagnetic *emissions*

The **Flex-MI™** is intended for use in the electromagnetic environment specified below.
The customer or the user of the **Flex-MI™** should assure that it is used in such an environment.

Emission test	Compliance	Electromagnetic environment-guidance
RF emissions CISPR 11	Group 1	The **Flex-MI™** uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The **Flex-MI™** is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations /flicker emissions IEC 61000-3-3	Compliance	

Guidance and manufacturer's declaration-electromagnetic *immunity*

The device is intended for use in the electromagnetic environment specified below, and should be only used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment-guidance
Electrostatic discharge(ESD) IEC 61000-4-2	±8 kV contact discharge ±15 kV air discharge	±8 kV contact discharge ±15 kV air discharge	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%
Power frequency (50 or 60 Hz) magnetic field IEC 61000-4-8	30 A/m 50 or 60Hz	30 A/m 50 or 60Hz	Power frequency magnetic fields, should be at levels characteristic of a typical location in a typical commercial or hospital enviroment
Electrical fast transient/burst IEC 61000-4-4	±2kV for power supply lines ±1kV for input/output lines	±2kV for power supply lines ±1kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.

Guidance and manufacturer's declaration-electromagnetic immunity continued

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment-guidance
Surge IEC 61000-4-5	±2kV Power lines	±2kV Power lines	Mains power quality should be that of a typical commercial or hospital environment.
Interruptions and voltage variations on power supply input lines IEC 61000-4-11	0% UT; 0,5 cycle At 0, 45, 90,135, 180, 225, 270 and 315. 0% UT; 1 cycles 70% UT; 25/30 cycles 0% UT; 250/300 cycle	0% UT; 0,5 cycle At 0, 45, 90,135, 180, 225, 270 and 315. 0% UT; 1 cycles 70% UT; 25 cycles 0% UT; 250 cycle	Mains power quality should be that of a typical commercial or hospital environment. If the user of the device requires continued operation during power mains interruptions, it is recommended that the device be powered from an uninterruptible power supply or a battery

NOTE-UT is the a.c. mains voltage prior to application of the test level.

Guidance and manufacturer's declaration-electromagnetic *immunity*

The device is intended for use in the electromagnetic environment specified below, and should only be used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment-guidance
Conducted RF IEC 61000-4-6	3 Vrms At 0.15-80MH 6Vrms At ISM & Radio Amateur Freq.	3 Vrms At 0.15-80MHz 6 V/m At ISM & Radio Amateur Freq.	Portable and mobile RF communications equipment should be used no closer to any part of the **Flex-MI™** including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance:** $d = 1.2\sqrt{P}$ $d = 1.2\sqrt{P}$ 80MHz to 800 MHz $d = 2.3\sqrt{P}$ 800MHz to 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 metres (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, [a] should be less than the compliance level in each frequency range.[b] Interference may occur in the vicinity of equipment marked with the following symbol: 
Radiated RF IEC 61000-4-3	3 Vrms at 80-2700 MHz (10Vlm Home Healthcare) Am Modulation And 9-28Vlm at 385-8000MHz. Pulse Mode and other Modulation	3 Vrms at 80-2700 MHz (10Vlm Home Healthcare) Am Modulation And 9-28Vlm at 385-8000MHz. Pulse Mode and other Modulation	

Recommended separation distance between portable and mobile RF communications equipment and the device.

The device is intended for use in an electromagnetic environment in which radiated RF disturbances are under control. User can help prevent electromagnetic interference by keeping the device at a minimum distance from portable and mobile RF communications equipment (transmitters). Below table details output power of transmitter:

Rated maximum output power of transmitter W	**Separation distance according to frequency of transmitter m**		
	150 kHz to 80 MHz $d = 1.2\sqrt{P}$	**80 MHz to 800 MHz** $d = 1.2\sqrt{P}$	**800 MHz to 2.5 GHz** $d = 2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in metres (m) can be estimated using the equation applicable to the frequency of the transmitter, where p is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

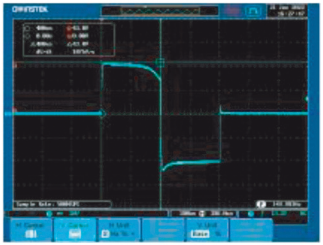
NOTE 1. At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2. These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

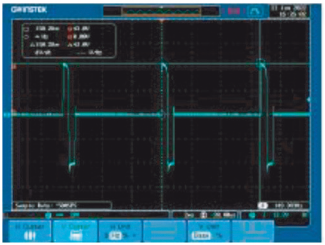
EMS (500Ω Loading)

Alternate

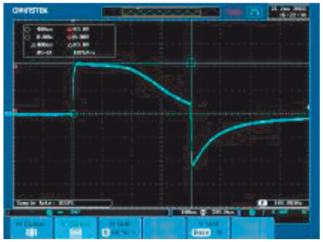
Symmetric, Single Pulse Waveform



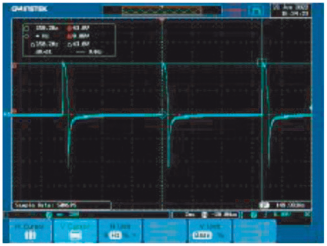
Symmetric, Multi Pulse Waveform



Asymmetric, Single Pulse Waveform

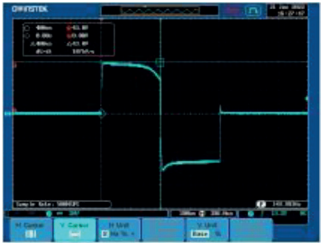


Asymmetric, Multi Pulse Waveform

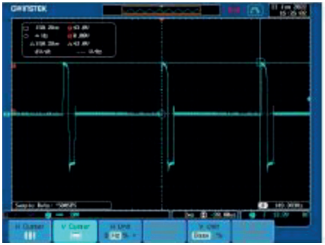


Synchronous

Symmetric, Single Pulse Waveform

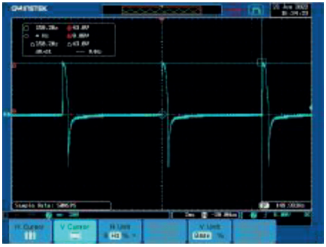


Symmetric, Multi Pulse Waveform



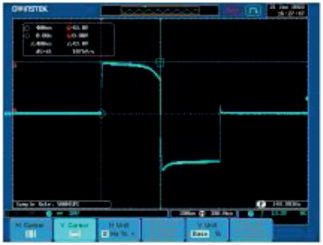
Asymmetric, Single Pulse Waveform

Asymmetric, Multi Pulse Waveform

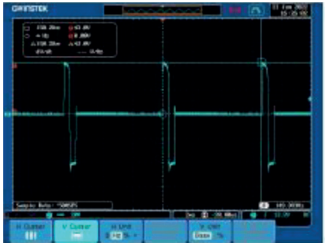


Constant

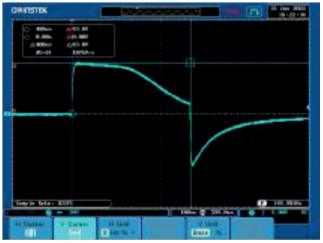
Symmetric, Single Pulse Waveform



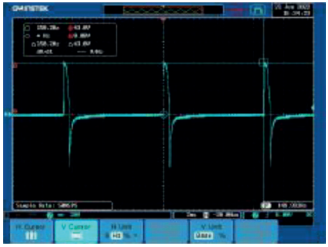
Symmetric, Multi Pulse Waveform



Asymmetric, Single Pulse Waveform



Asymmetric, Multi Pulse Waveform

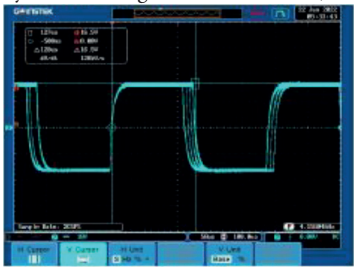


IFC (500Ω Loading)

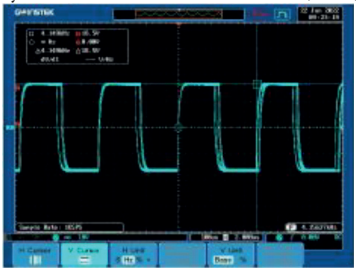
Symmetric, Single Pulse Waveform (CH1)

Symmetric,Multi Pulse Waveform (CH1)

Symmetric, Single Pulse Waveform (CH2)



Symmetric,Multi Pulse Waveform (CH2)



WARRANTY

This product is warranted to the original consumer for a period of one (1) year from the original acceptance of this device. This product warranty extends only to the original consumer of the product. This product is warranted against defect or workmanship for this period. This warranty is voided if this product has been damaged by misuse, abuse, neglect, or otherwise used in a manner not suited or prescribed for this product. This warranty is voided with use of unapproved electrodes, lead wires, chargers, or batteries. This warranty does not cover what is considered to be normal wear and tear, replacement of batteries, lead wires, electrodes, and other accessories. EMSI reserves the right to honor/dishonor product warranty as it sees fit.

⚠ CAUTION Federal law requires a prescription from your physician before use of this product.

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