Please read the Instruction Manual prior to use.

CAUTION: Federal law requires a prescription from your physician before use of this product.
CAUTION: Federal law requires a prescription from your physician before use of this product.
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1.0 | Intended Use

The EMSI Flex-MT® Plus is design for the following:

**TENS - Transcutaneous Nerve Stimulation**
- Symptomatic relief of chronic intractable pain
- Post traumatic and post surgical pain relief

**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 | Warnings

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 TENS 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. TENS 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-MT® Plus 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-MT® Plus 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 TENS 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.

Symmetric/Asymmetric Button: Choose symmetric or asymmetric waveform.
7.0 | Unit Description continued

Electrode Leadwires: Two sets of 1100mm (43 inch) electrode leadwires which are compatible with commercially available electrodes (standard 0.08 inch female connection) are provided with the Flex-MT® Plus. 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-MT® Plus is recommended for use with the previously cleared Everlife self adhesive electrodes. (Re-order information on page 26)

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

Accessories
### Specifications

**EMS/TENS Specifications**

<table>
<thead>
<tr>
<th>Channel:</th>
<th>Dual, isolated between channels</th>
</tr>
</thead>
<tbody>
<tr>
<td>Power Source:</td>
<td>700 mAh 4.8V Ni-MH rechargeable battery pack</td>
</tr>
<tr>
<td>Output waveform:</td>
<td>Symmetric or Asymmetric waveform</td>
</tr>
</tbody>
</table>

**Symmetric**

<table>
<thead>
<tr>
<th>Output</th>
<th>0~±65V (Loading: 1000Ω)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Peak Pulse Output</td>
<td>65mA (Loading: 1000Ω)</td>
</tr>
<tr>
<td>Level</td>
<td>Level 1~Level 20: Each level increases ±3.25V</td>
</tr>
</tbody>
</table>

**Asymmetric**

<table>
<thead>
<tr>
<th>Output</th>
<th>0~65V (Loading: 1000Ω)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Peak Pulse Output</td>
<td>65mA (Loading: 1000Ω)</td>
</tr>
<tr>
<td>Level</td>
<td>Level 1~20: Each level increases 3.25V</td>
</tr>
</tbody>
</table>

**Pulse Width:** Variable, 50~400 µs

**Pulse Frequency:** Variable, 2~150 Hz

**EMS only**

<table>
<thead>
<tr>
<th>On Time:</th>
<th>1~99 seconds</th>
</tr>
</thead>
<tbody>
<tr>
<td>Off Time:</td>
<td>1~99 seconds</td>
</tr>
</tbody>
</table>

* All values + or - 10%
8.0 | Specifications continued

<table>
<thead>
<tr>
<th>Ramp (Ramp Up &amp; Ramp Down)</th>
<th>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).</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patient Compliance Timer</td>
<td>Operation count: record of 60 sets (min.), max with 999 mins. Operation total time: max with 999 hrs.</td>
</tr>
<tr>
<td>Operation ambient:</td>
<td>Temperature range: 10°C ~ 35°C Humidity range: 20 ~ 90%RH</td>
</tr>
<tr>
<td>Storage &amp; transportation:</td>
<td>Temperature Range: 0°C ~ 70°C Humidity Range: 20 ~ 90%RH</td>
</tr>
<tr>
<td>Timer:</td>
<td>5~90 minutes auto-shutoff or Constant</td>
</tr>
<tr>
<td>Size:</td>
<td>L (120mm) x W (54mm) x H (33mm)</td>
</tr>
<tr>
<td>Weight</td>
<td>156 grams (including battery)</td>
</tr>
</tbody>
</table>

9.0 | TENS 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.
## TENS Mode

<table>
<thead>
<tr>
<th>MODE</th>
<th>Interpretations</th>
</tr>
</thead>
<tbody>
<tr>
<td>Burst (B)</td>
<td>The burst mode provides a “burst” of seven pulses. There are two bursts that are delivered per second. Positive pulse and negative pulse iterate continuously at fixed 100Hz. Pulse width are adjustable from 50-400µs</td>
</tr>
<tr>
<td>Normal (N)</td>
<td>The normal mode produces a continuous train of impulses. The stimulation parameters are not automatically interrupted nor varied in any way. In this mode, the pulse rate (from 2 to 150Hz) and pulse width (from 50 to 400µs) are fully adjustable. The normal mode is quite versatile because it may be applied with a variety of rate and width settings.</td>
</tr>
<tr>
<td>Modulated Rate &amp; Width (MRW)</td>
<td>The pulse rate and width are automatically varied in a cycle to produce a pleasant, massage-like sensation. It’s believed that nerves can become accustomed to, or “accommodated” to the same electrical stimulus after a period of time and thus would require increasing the intensity to further “block” the pain. The MRW mode was produced to offer a variety of different electrical stimulation, thus preventing nerve accommodation so that less intensity is required for long and effective treatment. In this mode, during the beginning of 0.5 second period, the WIDTH decreased to 50% of its original setting and then during the next 0.5 second period, the RATE is decreased to 50% of its original setting. Therefore, the total cycle time is 1 second.</td>
</tr>
</tbody>
</table>


<table>
<thead>
<tr>
<th>MODE</th>
<th>Interpretations</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Modulated Intensity and Pulse Width (SD)</strong></td>
<td>The SD modulation consists of alternating modulated intensity and pulse width, so that the intensity is always increasing while the pulse width is decreasing and vice-versa. The stimulation intensity is modulated to 62.5% maximum of setting (width equal to setting). The pulse width is modulated to 67% of setting (intensity equal to setting). Total cycle time is 6 seconds. Pulse rate (from 2 to 150Hz) and pulse width (from 50 to 400µs) are fully adjustable.</td>
</tr>
<tr>
<td><strong>Bi-Pulse (Bi-Pulse)</strong></td>
<td>The Bi-Pulse modulation delivers 4 pulses per second to Channel 1 (i.e. the pulse rate of Channel 1 is fixed at 4Hz) while delivering 100 pulses per second to Channel 2 (i.e. the pulse rate of Channel 2 is fixed at 100Hz). Stimulation is burst on for 1 second, then off for 1 second. There illustrates each pulse as a vertical line. Pulse width (from 50 to 400 µs) is fully adjustable.</td>
</tr>
</tbody>
</table>
## 10.0 | EMS Treatment Functions Descriptions

<table>
<thead>
<tr>
<th>MODE</th>
<th>Interpretations</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Alternative</strong> “A”</td>
<td>The pulses of CHANNEL 1 and CHANNEL 2 are Alternative. When Channel 1 is activated, Channel 2 will be inactivated and vice versa.</td>
</tr>
<tr>
<td><strong>Synchronous</strong> “S”</td>
<td>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.</td>
</tr>
</tbody>
</table>
11.0 | Instructions For Use

NOTE: Always read this instruction manual before use.

PREPARATION FOR USE

1. Check Battery:
   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 battery charger.
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 (usually 3-4 hours
on a fully discharged battery), a green steady light will illuminate. Typical charge may last several hours of
use depending on frequency and intensity of treatment.

NOTE: The device will NOT work if the charger is plugged into the device. Nor will the device work if
the charger plug is plugged into 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:**
   1. Always use 1.5” x 1.5” (16cm²) electrodes or larger.

   2. The Flex-MT® Plus is compatible and recommended for use with EMSI electrodes (or comparable). 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.
11.0 | 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 (5 TENS Options, 2 EMS options).
- Press **Set** to select unit output for the following as directed by clinician:
  - pulse width, pulse rate, ramp time, on time and off time
  - 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 TENS or EMS features. To isolate device into a specific treatment (EMS or TENS) 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 TENS 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.

Caution: 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.
### 11.0 | Instructions For Use continued

#### Operation Procedure Chart

<table>
<thead>
<tr>
<th>Step</th>
<th>Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Turn On</td>
</tr>
<tr>
<td>2</td>
<td>Press “MODE” Button</td>
</tr>
<tr>
<td>3</td>
<td>Choose MODE (TENS or EMS)</td>
</tr>
<tr>
<td>4</td>
<td>Press and hold both Negative (-) Amplitude Button</td>
</tr>
<tr>
<td>5</td>
<td>Lock out (TENS or EMS)</td>
</tr>
<tr>
<td>6</td>
<td>Set Parameter (Rate, Width...etc.)</td>
</tr>
<tr>
<td>7</td>
<td>Press “Symmetric/Asymmetric” Button</td>
</tr>
<tr>
<td>8</td>
<td>Choose Symmetric or Asymmetric waveform</td>
</tr>
<tr>
<td>9</td>
<td>CLOCK + ADJUST</td>
</tr>
<tr>
<td>10</td>
<td>Set Timer</td>
</tr>
<tr>
<td>11</td>
<td>Amplitude Control</td>
</tr>
<tr>
<td>12</td>
<td>Check Output Level</td>
</tr>
<tr>
<td>13</td>
<td>Start to Operate</td>
</tr>
</tbody>
</table>
12.0 | **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”.

   **NOTE:**
   
   (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.
12.0 | 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.

13.0 | Care and Maintenance

1. Low Battery Indicator:
   When the low battery indicator flashes, the battery should be recharged as soon as possible.

2. 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.

3. Electrode Pad Disposal
   Electrodes should not be used if they will no longer adhere firmly to the treatment area.
   Electrodes are single-use, and should not be used by more than one patient.
4. Electrode Replacement
To order replacement electrodes, please contact EMSI Customer Service at:

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

Specify the unit type is Flex-MT® Plus Stimulator and the electrode size recommended by your ordering clinician.
14.0 | Troubleshooting

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

<table>
<thead>
<tr>
<th>The LCD indicator illuminates but unit does not function properly.</th>
<th>Low Battery indicator flash.</th>
<th>None of LCD indicators illuminate.</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Check all control settings. Are they set to values prescribed by your medical professional?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>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.</td>
<td>Recharge battery pack</td>
<td></td>
</tr>
<tr>
<td>3. Check lead wires. Be sure all connectors are firmly sealed. See Section 11, Instructions for Use, Item 3.</td>
<td></td>
<td>Recharge battery pack</td>
</tr>
<tr>
<td>4. Replace cord set with another to check for broken wires.</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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

EMSI
3504 Cragmont Dr. Suite #100 | Tampa, FL 33619
Phone: 800-588-8383/(813) 931-2369 | Fax: 800-588-9282 | E-mail: customerservice@wecontrolpain.com
15.0 | Declarations-EMC

Guidance and manufacturer’s declaration-electromagnetic emissions

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

<table>
<thead>
<tr>
<th>Emission test</th>
<th>Compliance</th>
<th>Electromagnetic environment-guidance</th>
</tr>
</thead>
<tbody>
<tr>
<td>RF emissions</td>
<td>Group 1</td>
<td>The Flex-MT® Plus 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.</td>
</tr>
<tr>
<td>RF emissions</td>
<td>Class B</td>
<td>The Flex-MT® Plus 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.</td>
</tr>
<tr>
<td>Harmonic emissions</td>
<td>Class A</td>
<td></td>
</tr>
<tr>
<td>Voltage fluctuations</td>
<td>Compliance</td>
<td></td>
</tr>
</tbody>
</table>
**Guidance and manufacturer’s declaration-electromagnetic immunity**

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

<table>
<thead>
<tr>
<th>Immunity test</th>
<th>IEC 60601 test level</th>
<th>Compliance level</th>
<th>Electromagnetic environment-guidance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Electrostatic discharge (ESD)</td>
<td>±6 kV contact ±8 kV air</td>
<td>±6 kV contact ±8 kV air</td>
<td>Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%</td>
</tr>
<tr>
<td>IEC 61000-4-2</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Electrical fast transient/burst</td>
<td>±2kV for power supply lines ±1kV for input output lines</td>
<td>±2kV for power supply lines Not applicable</td>
<td>Mains power quality should be that of a typical commercial or hospital environment.</td>
</tr>
<tr>
<td>IEC 61000-4-4</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Surge IE</td>
<td>±1kV line(s) to line(s) ±2kV line(s) to earth</td>
<td>+ 1kV differential mode not applicable</td>
<td>Mains power quality should be that of a typical commercial or hospital environment.</td>
</tr>
<tr>
<td>61000-4-5</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
### Guidance and manufacturer’s declaration-electromagnetic immunity continued

<table>
<thead>
<tr>
<th>Immunity test</th>
<th>IEC 60601 test level</th>
<th>Compliance level</th>
<th>Electromagnetic environment-guidance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Voltage Dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11</td>
<td>&lt;5% UT (&gt;95% dip in UT) for 0.5 cycle &lt;br&gt;40% UT (60% dip in UT) for 5 cycles &lt;br&gt;70% UT (30% dip in UT) for 25 cycles &lt;br&gt;&lt;5% UT (&gt;95% dip in UT) for 5 s</td>
<td>&lt;5% UT (&gt;95% dip in UT) for 0.5 cycle &lt;br&gt;40% UT (60% dip in UT) for 5 cycles &lt;br&gt;70% UT (30% dip in UT) for 25 cycles &lt;br&gt;&lt;5% UT (&gt;95% dip in UT) for 5 s</td>
<td>Mains power quality should be that of a typical commercial or hospital environment. If the user of the Flex-MT® Plus requires continued operation during power mains interruptions, it is recommended that the Flex-MT® Plus be powered from an uninterruptible power supply or a battery.</td>
</tr>
<tr>
<td>Power frequency (50/60 Hz) magnetic field IEC 61000-4-8</td>
<td>3A/m</td>
<td>3A/m</td>
<td>The Flex-MT® Plus power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.</td>
</tr>
</tbody>
</table>

**NOTE** - UT is the a.c. mains voltage prior to application of the test level.
Guidance and manufacturer’s declaration-electromagnetic immunity

The **Flex-MT®** Plus is intended for use in the electromagnetic environment specified below. The user of the **Flex-MT®** Plus should assure that it is used in such an environment.

<table>
<thead>
<tr>
<th>Immunity test</th>
<th>IEC 60601 test level</th>
<th>Compliance level</th>
<th>Electromagnetic environment-guidance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Conducted RF</td>
<td>3 Vrms</td>
<td>3 Vrms</td>
<td>Portable and mobile RF communications equipment should be used no closer to any part of the <strong>Flex-MT®</strong> Plus including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.</td>
</tr>
<tr>
<td>IEC 61000-4-6</td>
<td>150 KHz to 80 MHz</td>
<td>3 V/m</td>
<td><strong>Recommended separation distance:</strong></td>
</tr>
<tr>
<td>Radiated RF</td>
<td>3 V/m</td>
<td>2.3 √P</td>
<td>d = 1.2 √P 80 MHz to 800 MHz</td>
</tr>
<tr>
<td></td>
<td>80 MHz to 2.5 GHz</td>
<td></td>
<td>d = 2.3 √P 800 MHz to 2.5 GHz</td>
</tr>
</tbody>
</table>

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 transmitters, as determined by an electromagnetic site survey, should be less than the compliance level in each frequency range.

Interference may occur in the vicinity of equipment marked with the following symbol: 📻

**NOTE 1** - At 80 MHz and 800 MHz, 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.

(a) Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the **Flex-MT®** Plus is used exceeds the applicable RF compliance level above, the **Flex-MT®** Plus should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the **Flex-MT®** Plus.

(b) Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.
Recommended separation distance between portable and mobile RF communications equipment and the Flex-MT® Plus

The Flex-MT® Plus is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The user of the Flex-MT® Plus can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Flex-MT® Plus as recommended below, according to the maximum output power of the communications equipment.

<table>
<thead>
<tr>
<th>Rated maximum output power of transmitter (W)</th>
<th>Separation distance according to frequency of transmitter (m)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>150 kHz to 80 MHz</td>
</tr>
<tr>
<td></td>
<td>( d = 1.2\sqrt{P} )</td>
</tr>
<tr>
<td>0.01</td>
<td>0.12</td>
</tr>
<tr>
<td>0.1</td>
<td>0.38</td>
</tr>
<tr>
<td>1</td>
<td>1.2</td>
</tr>
<tr>
<td>10</td>
<td>3.8</td>
</tr>
<tr>
<td>100</td>
<td>12</td>
</tr>
</tbody>
</table>

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.
16.0 | Waveform Reference

TENS (500Ω Loading)

(1) B (Burst)
Symmetric

Multi Pulse Waveform

Asymmetric
(2) **N (Normal)**
Symmetric, Single Pulse Waveform

Multi Pulse Waveform

Asymmetric
(3) MRW (Modulated Rate & Width)

Symmetric

Single Pulse Waveform (MAX Rate & min Width)

Multi Pulse Waveform (MAX Rate & min Width)

Asymmetric
(4) SD (Strength Duration)
Symmetric
Single Pulse Waveform (Max Width & min Intensity)

Multi Pulse Waveform (Max Width & min Intensity)

Asymmetric
(5) Bi (Bi-Pulse)
Symmetric
Single Pulse Waveform (Channel 1)  
Multi Pulse Waveform (Channel 1)

Asymmetric
Symmetric
Single Pulse Waveform (Channel 2)  Multi Pulse Waveform (Channel 2)

Asymmetric
EMS (500Ω Loading)

A (Alternate)
Symmetric, Single Pulse Waveform

Multi Pulse Waveform

Asymmetric
**S (Synchronous)**
Symmetric, Single Pulse Waveform

Multi Pulse Waveform

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