enCurve

Short-wave Therapy Equipment

Operator’s Manual

CAUTION: Users must read this manual carefully and thoroughly before using this product.
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No part of this manual may be re-manufactured or copied in any form without the written consent of Lutronic Corporation.

Use of this manual

This manual is designed so that users of enCurve system may easily understand the characteristics as a medical instrument, the safety device of the instrument and the method for use. In order to use this instrument properly and safely, users must be fully aware of all the details given in this user’s manual. Users should be trained and educated properly before using this instrument.

IMPORTANT

As the recommended treatment values for each symptom and/or effects are standards to be used for consultative purposes only, we recommend adjusting such values for patients depending on each patient's special circumstances and treatment history. Lutronic shall not be liable for any injuries, problems or issues that arise as a result of negligence or inexperience in using the product supplied by Lutronic Corporation rather than as a result of any actual defect on the product itself as supplied by Lutronic Corporation.
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</tbody>
</table>
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Chapter 1. Overview

1.1 Introduction to the system

The enCurve system is designed so that it has been manufactured in accordance with international standards for medical devices in order to guarantee user safety and durability of use. This device is convenient to use and a prolonged lifetime is guaranteed. The device is easy to maintain, requiring only basic maintenance/repair efforts from the user such as cleaning the device thoroughly on a periodic basis.

- The control panel is in the form of an LCD touch screen so that users may easily adjust parameters for optimal settings.

- The enCurve system is an electronic therapeutic device that uses a radiofrequency of 27.12MHz on the human body.

- It consists of the main equipment body, control panel, arm, handle for moving, patient stop switch, and an applicator that applies 27.12MHz.

- Aim the applicator at the relevant body part and press the Start button on the control panel to apply radiofrequency of 27.12MHz.

- This product is a device designed for pain relief in patients with knee osteoarthritis.

1.2 Indications

Pain relief in patients with knee osteoarthritis

---

**WARNING**

If adjustments or manipulation of the device do not comply with the instructions given in this manual in any way, then persons may be exposed to potentially hazardous light energy and/or electrical current.
### 1.3 Symbols used in this manual and the device

<table>
<thead>
<tr>
<th>Symbols</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td><img src="electric-lightning" alt="" /></td>
<td>This symbol indicates that the operational voltage of this product is in the danger limit set out in the Protective Regulations for Electrical Shocks (ISO 7010 / W012).</td>
</tr>
<tr>
<td>![WARNING]</td>
<td>This symbol indicates the warning status of possible dangerous circumstances and emergencies which might expose users, patients or staff members to severe electric shock or other injury, or under which severe damage may occur to the device itself.</td>
</tr>
<tr>
<td>![CAUTION]</td>
<td>This symbol indicates the caution status of possible dangerous circumstances and emergencies which might expose users, patients or staff members to severe electric shock or other injury, or under which severe damage may occur to the device itself.</td>
</tr>
<tr>
<td>![IMPORTANT]</td>
<td>This symbol indicates that prior to any procedure with the enCurve system, the operator should check each patient’s circumstances and treatment history to assure good clinical results.</td>
</tr>
<tr>
<td>![person]</td>
<td>This symbol indicates that the product specifications comply with Class BF of the Protective Regulations regarding electrical shocks (IEC 60417 / 5333).</td>
</tr>
<tr>
<td>![OFF]</td>
<td>This symbol indicates that the POWER is OFF, which complies with the Protective Regulations for electrical shocks (IEC 60417 / 5008).</td>
</tr>
<tr>
<td>![ON]</td>
<td>This symbol indicates that the POWER is ON and is in compliance with the Protective Regulations for electrical shocks (IEC 60417 / 5007).</td>
</tr>
<tr>
<td>![information]</td>
<td>This symbol indicates that the operating instructions should be considered when operating the device or control close to where the symbol is placed. (ISO 7000-1641)</td>
</tr>
<tr>
<td>Symbol</td>
<td>Description</td>
</tr>
<tr>
<td>--------</td>
<td>-------------</td>
</tr>
<tr>
<td><img src="image1.png" alt="Image" /></td>
<td>Consult accompanying documents. This symbol advises the reader to consult the accompanying documents.</td>
</tr>
<tr>
<td><img src="image2.png" alt="Image" /></td>
<td>This symbol indicates that the equipotentiality and is in compliance with the Protective Regulations for electrical shocks (IEC 60417 / 5007).</td>
</tr>
<tr>
<td><img src="image3.png" alt="Image" /></td>
<td>This symbol indicates the need for separate collection for electrical and electronic equipment in compliance with the Waste Electrical and Electronic Equipment (WEEE) Directive. This symbol indicates that electrical and electronic equipment wastes must not be disposed as unsorted municipal waste and must be collected separately. Please contact the manufacturer or an authorized disposal company to decommission your equipment according to local regulations.</td>
</tr>
<tr>
<td><img src="image4.png" alt="Image" /></td>
<td>This symbol indicates generally elevated, potentially hazardous, levels of non-ionizing radiation, or to indicate equipment or systems e.g. in the medical electrical area that include RF transmitters or that intentionally apply RF electromagnetic energy for diagnosis or treatment.</td>
</tr>
<tr>
<td><img src="image5.png" alt="Image" /></td>
<td>This symbol indicates important items to be noted during the use of this device.</td>
</tr>
<tr>
<td><img src="image6.png" alt="Image" /></td>
<td>This symbol indicates a reference clause that is relevant to the contents in this operator’s manual.</td>
</tr>
<tr>
<td><img src="image7.png" alt="Image" /></td>
<td>Authorized representative in the European Community</td>
</tr>
<tr>
<td><img src="image8.png" alt="Image" /></td>
<td>Manufacturer</td>
</tr>
<tr>
<td><img src="image9.png" alt="Image" /></td>
<td>Date of manufacture</td>
</tr>
<tr>
<td><img src="image10.png" alt="Image" /></td>
<td>Serial number</td>
</tr>
</tbody>
</table>
2.1 Overview

This chapter provides the basic safety and precautionary items regarding enCurve system. The items will also serve to inform users of the electrical safety and radiofrequency characteristics of the system.

All persons involved in the enCurve system operation (e.g. operator, patient, and staff) should be aware of all the potential dangers and the safety regulations of the system. The system should not be handled without proper knowledge and training. The operator or the staff should inform patients of precautions prior to treatment.

The enCurve system is designed to ensure optimal safety for operators, staff and patients and is equipped with the safety system described below:

1. This system utilizes a fast-acting fuse at 250V/15A which protects the system from possible current and voltage complications. The Safety Extra Low Voltage (SELV) method is employed in this system. The fuse installed in the inner area of the enCurve system successfully blocks unwanted power surges.

2. Protective device through software loaded onto the enCurve system

   • Once the system is turned on, the safety devices operate and allow users to use the system safely.

   • The device automatically runs a monitoring system that continuously scrutinizes the entire treatment procedure in order to keep the user notified of the system’s safety status.

   • The software installed in enCurve system will stop emission of the infrared or visible energy immediately when an error occurs. A message code will be promptly displayed on the touch screen LCD to notify the operator of the error and its status.
2.2 Treatment-related safety procedures

Before performing an operation, the operator and staff members must check the following safety items.

1. Access to the treatment room should be restricted to personnel essential to the procedure and who are well trained in the required safety precautions.

2. Everyone including the operator and the staff members should be fully aware of the technical details of the device. If necessary, all persons should able to halt the system immediately in case of an emergency.

3. Because electric sparks can ignite flammable liquids and gases from the system, please check for flammable gases before using the equipment.

4. Common power supply must be AC100~120V or AC220~230V in order to use and operate the enCurve system safely.
Chapter 2. Safety Precautions

2.3 General precautions for physicians, staff and patients

- The enCurve system weighs about 67.1kg. Mishandling of the system may cause damage to the system internally and externally both, possibly adversely affecting its performance. More care must be taken when moving the equipment if there is a door sill in the exit.

- The system is designed in such a way that its center of mass is optimized to facilitate convenient moving of the system. Handle it with extreme care.

- Do not attempt to move the instrument while holding the arm or applicator. Attempting to do so will disrupt the center of mass and may cause the instrument to fall over resulting in damages to system and surrounding persons.

- Check the ground state and do not touch the plug with wet hands.

- Must not be used simultaneously with other equipment

- Any metal on the patient’s body must be removed.
  (Ex: earring, ring, watch, glasses, coins, brassiere, USB drive, etc.)

- Using a mobile electronic device (ex: mobile phone, tablet, MP3 device, etc.) while the equipment is in use may cause the device to malfunction due to radiofrequency emitted by the equipment. Such devices must therefore not be used and placed far away from the equipment during a procedure.
2.4 Precautions against fire hazards

- Be especially careful when using the system around flammable gases or oxygen. Ignition of these materials could result in explosion or fire.

- Various types of covers and gowns commonly used in procedures should be made of material that is flame resistant. Avoid using materials saturated with oxygen.

- A fire extinguisher should be placed near the device at all times.

- As electric spark could lead to ignition of inflammable liquids or gases in the system, check whether there are any inflammable gases, before using the device and take precautions.

- The equipment must not be operated with anything, such as a piece of cloth, covering the ventilation grill of the equipment.
2.5 Safety system for the enCurve system

This system includes safety devices fully compliant with international standards to secure the safety of operator, staff and patients.

2.5.1 Emergency stop button

- In case of an emergency, operating can be stopped immediately by pressing the emergency stop button.

- To restore operation, rotate the button clockwise (in the direction of the arrows) until it pops out again and follow the normal startup sequence. See Chapter 5 for startup procedure.

- This emergency stop button should not be used as part of a normal operation procedure. Because it may lead to a electrical damage in the system.

2.5.2 Patient stop switch

- During an emergency, the patient can immediately stop the equipment by pulling on the stop switch located at the back.
2.6 Main international standards applied to enCurve system

This system complies with the following international standards for the safety of doctors and patients.

<table>
<thead>
<tr>
<th>Standard/Regulation</th>
<th>Title</th>
<th>Ratification</th>
</tr>
</thead>
<tbody>
<tr>
<td>IEC 62366</td>
<td>Application of usability engineering to medical devices</td>
<td>2014</td>
</tr>
<tr>
<td>IEC 60601-2-3</td>
<td>Medical electrical equipment - Part 2: Particular requirements for the safety of short-wave therapy equipment</td>
<td>2012</td>
</tr>
<tr>
<td>EN 62304</td>
<td>Medical device software-Software life cycle processes</td>
<td>2006</td>
</tr>
<tr>
<td>EN ISO 14971</td>
<td>Medical devices - Application of risk management to medical devices</td>
<td>2012</td>
</tr>
<tr>
<td>EN 980</td>
<td>Graphical symbols for use in the labeling of Medical devices</td>
<td>2008</td>
</tr>
<tr>
<td>EN1041</td>
<td>Information Supplied by the manufacturer of medical devices</td>
<td>2008</td>
</tr>
<tr>
<td>21 CFR part 820 (FDA)</td>
<td>Quality System Regulation</td>
<td>2009</td>
</tr>
<tr>
<td>MFDS</td>
<td>Electromagnetic waves safety test standard for medical device</td>
<td>-</td>
</tr>
<tr>
<td>MFDS</td>
<td>Electrical/mechanical safety test standard for medical device</td>
<td>-</td>
</tr>
</tbody>
</table>
2.7 Safety labels for enCurve system

Pursuant to domestic and international standards, various types of safety and system information labels are attached to the appropriate locations.

CAUTION
Physicians and staff should be fully aware of the locations and the meaning of all the safety labels attached to the system.

Figure 2.3 Locations of Labels on the Front
2.7.1 Caution label of emergency stop
The emergency stop button is used for immediate stop of the radiofrequency equipment in case of emergency. The label is located above the emergency stop button on the front of the system.

![STOP](image)

Figure 2.4 Caution label of emergency stop

2.7.2 Warning label for improper moving
This label is a warning sign for users not to grab any parts indicated when moving the device.

![WARNING](image)

Figure 2.5 Warning label for improper moving

2.7.3 Warning label for radiofrequency radiation exposure
This label warns radiofrequency radiation exposure. It means that users and patients do not see inside of applicator during radiofrequency radiation.

![CAUTION](image)

Figure 2.6 Warning label for radiofrequency radiation exposure
2.7.4 Warning label against electrical shock

The label warns of electrical shock and exposure to high voltage in the instance that the panel is opened or removed. Only authorized and trained persons may open or remove the cover.

![Warning label of electrical shock](image)

Figure 2.7 Warning label of electrical shock

2.7.5 Warning label for replacing the installed applicator

This warning label advises the operator of the correct position of the arm and applicator when changing one head for another, to prevent injury to personnel or damage to the system. Please check “Chapter 4 Installation”.

![Warning label for replacing installed applicator](image)

Figure 2.8 Warning label for replacing installed applicator
2.7.6 Grounding label

This symbol indicates that this product adopts equi-phase grounding which complies with the protective regulations for electrical shocks.

![Grounding label](image)

**Figure 2.9 Grounding label**

2.7.7 Power cable label

This label warns users of the precaution when connecting the main power cord to a wall outlet.

![Power cable label](image)

**Figure 2.10 Power cable label**

2.7.8 Nameplate Label

This label states the product name, the model name and other electrical specifications.

![Nameplate label](image)

**Figure 2.11 enCurve system nameplate label**
Chapter 3. System Description

3.1 Overview

This chapter provides a general description of the enCurve system, including its main components, system control, and technical specifications.

3.2 System specifications

<table>
<thead>
<tr>
<th>Performance</th>
<th>System specification</th>
</tr>
</thead>
<tbody>
<tr>
<td>Frequency</td>
<td>27.12 MHz</td>
</tr>
<tr>
<td>Output Power</td>
<td>Max 300W</td>
</tr>
<tr>
<td>Treatment duration</td>
<td>Max 30 minute (under 10 ~ 200 W)</td>
</tr>
<tr>
<td></td>
<td>Max 20 minute (under 205 ~ 300 W)</td>
</tr>
<tr>
<td>Impedance</td>
<td>25Ω</td>
</tr>
<tr>
<td>User interface</td>
<td>Touch LCD Display</td>
</tr>
<tr>
<td>Cooling system</td>
<td>Air Cooling</td>
</tr>
<tr>
<td>Body dimensions</td>
<td>475mm × 758mm × 1133mm (W × L × H)</td>
</tr>
<tr>
<td>MDD Class</td>
<td>Class  IIa</td>
</tr>
<tr>
<td>Electrical shock class</td>
<td>CLASS I, TYPE BF</td>
</tr>
<tr>
<td>Weight</td>
<td>67.1 kg</td>
</tr>
<tr>
<td>Electrical rating</td>
<td>Single phase AC100-120V or AC220-230V, 50/60Hz</td>
</tr>
<tr>
<td></td>
<td>Power consumption: 1300VA</td>
</tr>
<tr>
<td></td>
<td>(Fuse 125V/25A or 250V / 15A)</td>
</tr>
</tbody>
</table>
3.3 Components of the enCurve system

enCurve system is largely composed of three main components. USB port is located at the rear of main system body. The USB port is used to only update the system. It cannot be used with general USB.

- Main system body
  Dimensions (mm): 475(W) x 758(L) x 1133(H)
- Arm
- Applicator

Figure 3.1 Main components of the enCurve system
3.3.1 System main body

The system main body is an essential part for device operation. It is composed of components and modules necessary for controlling and operating the device. The system main body is organized as follows.

<table>
<thead>
<tr>
<th>Components</th>
<th>Functions</th>
</tr>
</thead>
<tbody>
<tr>
<td>System control module</td>
<td>This includes the emergency stop button which controls the overall operation of the entire system. The control module receives input signals from other modules and sends output signals to execute the proper operation of the system.</td>
</tr>
<tr>
<td>Power supply</td>
<td>Converts the commonly-used power supply (AC 100-120V or AC 220-230V) to the level of electric power that the device requires and provides it for each module.</td>
</tr>
<tr>
<td>Applicator</td>
<td>Receives a radiofrequency of 27.12MHz outputted by the system and applies it to the treatment area.</td>
</tr>
<tr>
<td>Control panel</td>
<td>Displays information of the current status and the value of each parameter. The function of each button is explained in detail in Chapter 5.</td>
</tr>
<tr>
<td>Handle and casters</td>
<td>The Two of the four casters may move in all four directions. The handle may be used to easily move and direct the casters. The casters additionally have locking devices to allow the operator to station the device firmly and safely in a fixed position.</td>
</tr>
</tbody>
</table>
3.3.2 Arm & Applicator

The function of the arm is to adjust the height of the applicator for treatment.

The side angle of the applicator can be adjusted to suit the physical characteristics of the patients.

CAUTION

- Do not use excessive force when adjusting the angle of the applicator.

- A gap must be maintained between the treatment area and the applicator to ensure they do not touch.

- For the safety of patients, the angle of the applicator must not be adjusted while the enCurve system is in operation. To adjust the angle, press the Stop button on the equipment’s control panel and adjust the angle of the applicator once the equipment has stopped before pressing the button once more to continue with the procedure in the remaining time.
3.4 System software

The software installed in enCurve system provides the optimal environment for clinical operations. It is programmed for the following purposes:

- Selection and application of optimal and individual surgical parameters for each patient.
- Prompt and accurate control of the driving device for the enCurve system.
- Ability to consistently monitor the device in order to secure the safety of the operator, staff and patients.
- Fires an accurate level of energy in accordance with the procedure parameters configured by the user.
Chapter 4. Installation

4.1 Overview
Chapter 4. describes the installation method for the enCurve system as well as the optimal environment for using this device. Only personnel authorized or trained by Lutronic Corporation may move or install the device.

4.2 Installation component list
Before installing the system, check that the following list of installation components is complete.

<table>
<thead>
<tr>
<th>No</th>
<th>Items</th>
<th>Qty</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>enCurve system body</td>
<td>1 unit</td>
</tr>
<tr>
<td>2</td>
<td>Applicator (AB applicator / Multi Applicator)</td>
<td>1 Set (Optional)</td>
</tr>
<tr>
<td>3</td>
<td>Arm</td>
<td>1 unit</td>
</tr>
<tr>
<td>4</td>
<td>Wire support</td>
<td>2 EA</td>
</tr>
<tr>
<td>5</td>
<td>Main power cable</td>
<td>1 unit</td>
</tr>
<tr>
<td>6</td>
<td>Operator’s Manual</td>
<td>1 vol.</td>
</tr>
</tbody>
</table>

NOTE
If desired, additional components may be purchased from Lutronic Corporation or your local distributor.
4.3 Conditions for installation

4.3.1 Space requirements

Optimum efficiency of the equipment will be maintained by meeting the following conditions for the installation space.

- Before installing the device, first consider the location and ensure that there is adequate space for installation. (Install the device in a place that is not humid and without any harmful effect or risk on the device.)

- The minimum distance between the device and any wall should be at least 30cm. (Install the device in a place that is stable and flat.)

- Install the device as far as possible from other medical devices or any device that generates heat.
4.3.2 Electrical requirements

Power supplied to the enCurve system should satisfy the following requirements in order to maintain optimal efficiency and electrical safety.

- The wall outlet should include at least two sockets with grounding terminals.

- First check whether the output power from the wall outlet is single phase, AC100~120V or AC220~230V and 50/60Hz before connecting the power plug.

- After checking that the wall outlet in the operating room complies with the voltage and power requirements of the device, the operator can prepare to operate the enCurve system.

- An 250V/15A circuit breaker-type fuse is used to protect the device from excessive voltage. If the fuse is open-circuited, contact the Lutronic Corporation customer service department for proper actions to be taken.

- For the safety of patients, operator, staff members, as well as electrical safety, connect the external ground terminal of the device to the dedicated ground terminal in the operating room. Please contact Lutronic Corporation customer service department to ensure safe grounding during installation.

- Never use instantaneous big current around the device and the place where the electromagnetic wave exposure is serious.

- If the Air mode was used during the procedure, the power plug must be disconnected from the power outlet after the final treatment of the day has been completed.

**WARNING**

Verify the electrical requirements and use the correct power supply or a power supply system. Failure to follow these instructions may lead to damage to the device, device malfunctions and/or fatal electrical shock to users. Improper installation and use of the device may void the warranty coverage.
4.3.3 Environmental requirements

The environment for using enCurve laser system should satisfy the following requirements:

- **Atmosphere**
  - Use of the device in a strong corrosive or acidic atmosphere may lead to corrosion of the electrical cord, the electrical components or the laser module.
  - Air-borne dust particles should be kept to a minimum. Such fine particles of dust may severely damage the device once it has entered into the electrical components or the laser modules.

- **Temperature/relative humidity**
  - The optimal temperature for storing the device is a range of 50°F(10°C) to 104°F(40°C). The optimal temperature for using the device is a range of 68°F(20°C) to 86°F(30°C). Atmosphere is a range of 80kPa ~ 106kPa.
  - Relative humidity should remain between 0% and 90%, and install the device in an airy place in order to keep proper humidity according to the temperature.

- **Maximum altitude : Standard commercial shipping altitude**
  - Temperature : 23 ~ 131°F (-5 ~ 55°C)
  - Relative Humidity : 90% at 95°F (35°C) non-condensing
    32% at 137°F (55°C) non-condensing

- **Place to avoid**
  - Watery area with high humidity
  - Area with direct rays of the sun
  - Dusty area with poor ventilation
  - Area with high salt content
  - Area with chemical substance or gas
  - Area free of danger from slope, vibration, or shock
4.4 Installation of the device

4.4.1 STEP 1: Connecting the head to the arm

1. Note the four arm connection guide grooves as shown in Figure 4.1.

2. With the arm extended, locate the four connecting lugs on the end of the arm, offer the head up to the arm and carefully mate the lugs with the grooves. Turn the head in a counter-clockwise direction to fix the head securely to the arm as shown in Figure 4.2.

Figure 4.1 Four arm connection guide grooves

Figure 4.2 Connecting the applicator and arm
Chapter 4. Installation

**WARNING**

- When you connect the head and arm, do not fold the arm in. If the arm were to pop outwards suddenly, it could cause serious injury to anyone standing near the enCurve system.

- When uninstalling the installed applicator for another, always turn the system off at the main power button located on the top of the system main body. Never change heads with the system powered on.

3. Locate the two knurled locking screws. Holding the head by one of the handles, insert and tighten the locking screws by hand to lock the head safely to the arm. Do not overtighten the screws.

Figure 4.3 Tightening the locking screws
4. Attach the applicator wire to the wire socket at the back of the equipment as shown in Figure 4.4.

![Figure 4.4 Connect the applicator wire at the back of the equipment](image)

5. Connect the applicator wire connected to the equipment to the applicator as shown in the Figure below.

![Figure 4.5 Applicator wire connection](image)
Chapter 4. Installation

CAUTION

- When connecting the applicator wire, mount it using the applicator cradle attached on the top of the Arm.
- Excessive force must not be used when connecting the applicator wire due to the possibility of damage.
- The wire must not get tangled when installing the equipment and the space between the wires must be at least 20 cm.

NOTE

In installation, refer to the Quick Guide provided by LUTRONIC.

4.4.2 STEP 2: Connecting the main power cable

4.4.3 STEP 3: Final check-up and locking the system in place

1. Position the device in a place that satisfies the requirements of 4.3 Conditions for Installation.

2. Depress the locking devices located on all four casters of the system to lock it in the position.
   (Before moving the system again, please be sure to release all the locking devices.)

CAUTION

Before moving the device, the arm, main power cord, and applicator must be safely positioned. Move the device slowly, by holding the handle for move and dragging it. After moving the device, the wheels must be locked.
4.4.4 STEP 4: Supplying the main power

Make sure that the status of main power switch on the main connections panel is in the position indicating that the main power is off and not running.

![Figure 4.6 the main power](image)

**CAUTION**

When the device is not to be used for any period, make sure that the status of the main power switch is in the (OFF) position. Also, make sure that the cable state and if the cable is broken or disconnected, do not use it.

Furthermore, if the device is to be left unused for a long period of time, please remove the main power cord from the wall outlet and the main power socket of the device. In particular, if Air Mode was used during treatment, the plug must be pulled off from the wall outlet once the treatment for the day is completed.
4.5 Moving the device

When moving the device in the treatment room or to a remote location, first carefully check the following items. Only personnel authorized and trained by Lutronic Corporation may move the device. All other persons must explicitly read and follow the instructions below.

4.5.1 Moving the device in the treatment room

- To move the device safely, repeat the steps shown in “4.4 Installation of the Device” but in the reverse order.
- Using the moving handle to transport the device, move the device to the new location that is compliance with the “4.3 Conditions for Installation” and reinstall the device according to “4.4 Installation of the Device.”

**CAUTION**

Only move the equipment by pushing it forward and backward using the handles. The handles must not be used to lift the equipment as this may result in it being damaged.

4.5.2 Moving the device to a remote location

- When moving the device to a remote location, contact your Lutronic Corporation distributor for safe and efficient transportation.

**CAUTION**

When moving the device to a remote location, contact your Lutronic Corporation distributor to do so safely and efficiently. This will prevent potential damage to or breakage of the device and potential physical injuries to the operator and staff.
Chapter 5. Operation

5.1 Overviews

This chapter contains detailed operating instructions, precautions to be taken and warning items for the enCurve system.

The touch-screen control panel allows users to set the desired parameters and displays useful system information during operation. The on-board microprocessor constantly monitors all system functions when the system is running.

Please see below for information on the controls.

Figure 5.1 Control panel of the enCurve system
1. **Power[W]**

The radiofrequency output power can be configured using the -/+ button. Pressing the +/- button once adjusts it in 5W increments, while holding it down for 3 seconds adjusts it in 10W increments.

[Range: 10 ~ 300W(Max)]

2. **Time[min]**

The radiofrequency firing time can be configured using the +/- button. Pressing the +/- button once adjusts it in 1-minute increments, while holding it down for 3 seconds adjusts it in 5-minute increments.

[Range: 1 ~ 30 minutes(Max)]

3. **Current power(W)**

Displays the actual power outputted from the radiofrequency power.

* Current Power(W) = Setting Power(W) – Reflective Power(W)

4. **Remaining time(min)**

Displays the remaining time of the firing of the radiofrequency power.

5. **FORTE**

This function saves and recalls the RF power and time that is used frequently by the user.

6. **Reflective power(W)**

Displays the error of the setting power and measured power.

7. **Start/Stop**

Displays the start( ) / stop( ) state of the radiofrequency discharge. It can be a button. Blinking denotes the pause state.

8. **Home**

Moves to the home screen.
9. Setup

In setup mode the user can adjust the volume of the control panel’s sound effects and move to service mode.

10. AIR

AIR Mode works when AB mode is set. Generates air with the mode method selected in the GUI through the applicator.
[Off / Mode1 / Mode2 / Mode3]

11. POWER button

Switches the equipment on/off.

12. START/STOP button

This switch starts and stops the radiofrequency discharge. Configuring the parameter and pressing the button will start the procedure and, if the user wishes to stop momentarily during a procedure, pressing the button will pause the equipment. Pressing the button again will restart it.

13. EMERGENCY button

Pressing this button during an emergency will immediately stop the equipment’s operation.

NOTE

When the set treatment time has elapsed, an audible warning will sound, the emission of light energy automatically stops and the system enters the Completed mode.
5.2 Checklist of precautionary and inspection items

Prior to performing a treatment procedure, please check the following items. Pay close attention to the precautionary items presented in Chapter 2. Safety Precautions

✓ Have you read the user manual carefully and understood it?
✓ Is the system main body clean?
✓ Is the selected head installed properly according to the instructions contained in Chapter 4. Installation?
✓ Are the casters for the device properly locked in order to prevent the device from moving?
✓ Is the power plug connected to an outlet in the treatment room that is of the appropriate energy, namely AC100-120V or AC220-230V with proper grounding?
✓ Have you checked that the emergency stop switch is working properly?
✓ Is the equipment being operated by a doctor?
✓ Have you removed all metal objects from the patient’s body?

---

WARNING

Before connecting the power plug of the device to the local power supply outlet, be sure that the local power supply is AC100~120V or AC220~230V with proper grounding. Never look directly into the radiofrequency when power is applied. Serious eye injury and/or blindness could result.

---

CAUTION

Periodically check applicator and cable to prevent the system to malfunction
5.3 Operation of the enCurve system

5.3.1 STEP 1: Turning on the system

1. Flick the main power switch, located at the back of the system, to the on (I) position.

![Figure 5.2 Main power on](image)

2. Pressing the Power switch at the front of the equipment will display the initial state in the control panel. The Power button lights up green while the START/STOP button lights up in white.

![Figure 5.3 Turning the power on with the power switch](image)
3. As the system is powering up, the initial screen will appear as in Figure 5.4.

![Initial screen](image)

**Figure 5.4 Initial screen**

### 5.3.2 STEP 2: Operating mode

1. Press the +/- button of ① and ② to configure the power and time needed in the procedure, as shown in Figure 5.5.

![Procedure power and time configuration](image)

**Figure 5.5 Procedure power and time configuration**

2. Pressing the ③ AIR button will launch a separate pop-up window, as shown in Figure 5.6, where mode1, mode2, or mode3 can be selected. Select the mode relevant to the procedure parameter and press off to cancel its use.
3. Press the START/STOP button once the procedure parameter configurations have been completed.

4. An automatic adjustment will be performed for about 10 seconds to consider the impedance of the patient, after which the radiofrequency discharge will begin as shown in Figure 5.8. will be displayed on the control panel when the radiofrequency discharge is being fired.
5. The radiofrequency discharge will automatically stop once the configured time has elapsed. Press the START/STOP button in the middle of a procedure, as shown in Figure 5.9, if you require the equipment to stop. Doing so will stop the radiofrequency discharge and the icons will blink alternately to indicate that the equipment is in a paused state.

![Figure 5.9 Power button](image)

6. Press the START/STOP button if you wish to resume firing the radiofrequency discharge.

**NOTE**

- Parameters cannot be modified using the control panel while the radiofrequency is being fired.
- The Parameters of mode1, mode2, and mode3, which can be selected in Air mode, cannot be changed by the user.

**WARNING**

There must be a gap of at least 20 cm between the wires during use and you must make sure to never touch the wires. Touching a wire while the equipment is in operation may result in malfunction or damage to the equipment.
5.4 Setup

1. Press the button on the top right of the control panel screen (4), as shown in Figure 5.10, to enter Setup mode, as shown in Figure 5.11.

![Figure 5.10 Pressing the setup button](image1)

![Figure 5.11 Setup mode](image2)
2. Pressing the left and right speaker buttons in volume, as shown in Figure 5.11, will adjust the sound effect volume of the control panel screen.

![Volume Control](image)

**Figure 5.12** Volume control
5.5 Turning off the system after treatment

5.5.1 Normal turn-off

1. When enCurve system stops the operation, please press the power button on the control panel. And press the main power button on the back of the device for shutting off the main power supply.

2. Keep the enCurve system in a secure place so that no-one other than qualified and trained personnel can have access to or use the device.

3. When the device is not to be used for a long time, disconnect the main power cord from the wall outlet.

5.5.2 Emergency turn-off

1. The operator should use the emergency stop button in case of an emergency only. Pressing the emergency stop button consequently stops the device immediately.

2. To restart the device, turn the emergency stop button clockwise until it stops, and then turn the device.

---

**WARNING**

When turning the equipment off by pressing the power button, the equipment will require approximately 2 minutes of preparation time before the power is turned off. Pressing a button or the power switch while the equipment is preparing to turn off may result in malfunction or damage to the equipment, and improper usage of the equipment is not covered by the product warranty.
5.6 Applicator position adjustment

5.6.1 General position adjustment

1. Position the applicator right above the area for treatment (knee and sides) evenly as shown in the photo.

2. Position the applicator, including the wings on both sides, closest possible to the area for treatment, while maintaining the most even space from the skin. Make sure that the knee skin of the patient does not touch the applicator.

![Figure 5.13 Adjustment of applicator and patient](image)

3. If the skin part of the knee comes in contact with the applicator, adjust the position of the applicator by widening the space between the knee and the applicator.

4. If it is difficult to maintain the space between the applicator and the knee because the patient has a small body, put the rolled towel under the back of the patient so that the space between the skin and the applicator does not stay too distant.

5. After the start of the treatment, it is possible to adjust the position and the space slightly, to strengthen deep heat by maintaining stable and low reflective power.
Figure 5.14 Adjusting applicator and position
5.7 What should be checked with patient on treatment

- From the time when 5 minutes passed from the start to the end of the treatment, it is recommended to check the patient’s reaction and reflective power values every 5 to 10 minutes, check whether the treatment is maintained stably, and check the status of change in the sense of deep heat felt by the patient.

- Once the treatment starts, the patient immediately feels thermal sensation on the area of treatment. As time passes by, the thermal sensation expands to the entire body. As there could be cases whether the patient feels strong thermal sensation or uncomfortable feel at a particular point of one flank, the patient should be informed of such possibility in advance.

- If a patient feels something uncomfortable during the treatment, increase the space between the applicator wings and the skin surface a little. Here, make sure the space is shorter than 3cm, as the energy delivered to the area of treatment drops by a big margin, if the space from the skin surface is too big. If the patient feels less uncomfortable after the space adjustment, adjust the space again by narrowing the space in about 3 minutes. If the patient does not feel uncomfortable, maintain the space after checking.

- Check on the perspiration of the patient regularly. As the heat could be delivered much faster due to perspiration, apply towel between the patient and the applicator for absorption of perspiration.
6.1 Overview

This chapter describes procedures for periodic checks and troubleshooting any problems with the enCurve including information on any messages generated by the self-testing and diagnostic system.

**CAUTION**

When inspecting the device first turn off the power and then disconnect the power cord. Attempting to inspect the device while the electrical power is on may result in severe damage to the device or the user.

enCurve is designed to minimize maintenance and management. Also the device does not affect essential performance by cleaning. In order to guarantee the most effective result of the operation, the exterior of the device should be kept thoroughly clean at all times.

In addition, the device should be calibrated output by responsible organization or manufacturer per once a year.

6.2 Cleaning the system console

- Soak a soft pad in non-corrosive cleansing liquid such as Isopropyl alcohol or ethanol (90% or more) and gently wipe the surface area of the device.

- Wipe down the device once again with a clean, dry pad or let it naturally air dry.

**CAUTION**

Do not apply cleansing liquid directly to the system main body as it may damage, harm or cause the system to malfunction.
6.3 Troubleshooting

6.3.1 When the system fails to power up after pressing the main power button, please check the following items.

- Check that the power cord is correctly inserted into the main power outlet.
- Check that the main power button has been pressed.
- Check the condition of the fuse inside the device.

6.3.2 When the device is powered up but radiofrequency is not emitted.

- Check that the applicator Wire is properly connected between the main body and the applicator. Use the wire anchors to maintain a gap of at least 20 cm between the wires.

---

**CAUTION**

If emission of the radiofrequency fails to occur after a reasonable period of time, turn off the device and wait 5 minutes before turning it on again. If the problem persists, do not disassemble the device or take any inappropriate or unauthorized actions by yourself. Always contact an authorized Lutronic distributor or Lutronic Corporation for assistance.
6.4 Error messages

- The system is monitored constantly and informs the user of any problems by message codes.
- When an error occurs, the corresponding message code will be displayed on the control panel as shown in the example in Figure 6.1. In case of any error message, the radiofrequency emission will stop immediately.
- The following is the list of error messages and the actions to take.

<table>
<thead>
<tr>
<th>Item</th>
<th>Status of device</th>
<th>Message</th>
</tr>
</thead>
<tbody>
<tr>
<td>Emergency</td>
<td>Notification when the user pressed the emergency stop switch in an emergent situation. To operate the device again, make the emergency button pops out by turning the emergency stop switch clockwise (arrow).</td>
<td><img src="image" alt="Emergency message" /></td>
</tr>
<tr>
<td>Interlock</td>
<td>Notification when RF Power output is not stable</td>
<td><img src="image" alt="RF Interlock message" /></td>
</tr>
<tr>
<td></td>
<td>Turn off the power of the device. Then, start the device again.</td>
<td></td>
</tr>
<tr>
<td>Door Open</td>
<td>Notification when the external case opens due to shock to the device. Turn off the power of the device. Then, start the device again. If the same symptom is repeated, contact your authorized Lutronic distributor or Lutronic Corporation for assistance.</td>
<td><img src="image" alt="Door Open message" /></td>
</tr>
</tbody>
</table>
### CAUTION

The operator is advised to take proper actions for the nature of each message code. If the error persists after taking proper action, contact your authorized Lutronic distributor or Lutronic Corporation for assistance. If a person not formally authorized by Lutronic Corporation opens the cover of the device or takes any improper actions, the warranty will be voided. Fatal damage to the device severe physical injury may occur.

#### 6.5 Requests for periodic A/S

For more detailed information on periodic service for this device, contact your authorized Lutronic distributor or contact Lutronic Corporation for assistance.

In addition, local distributors have authority of disposal. So the local distributors can choose the disposal method.

| **RF Alarm** | Notification when the reflective power is high, during RF power output. 
Turn the device off. Check the position and state of the patient. Start the device again. |
| **Safety Switch on (Stop switch for patient)** | This switch allows the patient to directly stop RF output. Notification when it is pulled. 
Check the position and state of the patient. Start the device again. |
| **Energy Setup Error** | Notification when error occurred in RF output setting. 
Turn off the power of the device. Then, start the device again. If the same symptom is repeated, contact your authorized Lutronic distributor or Lutronic Corporation for assistance. |
Chapter 7. Clinical Information

7.1 Overview
The following clinical information comes from materials excerpted from literature in the relevant fields of study. Lutronic Corporation shall not be held liable in any way for potential problems that may occur due to inadequate or wrongful use of such materials or excerpts.

7.2 General cautions

- The operator of the system must read the user manual thoroughly. Before using the product, the system operator should familiarize himself/herself with all safety requirements and operation procedures.
- Make sure all operators are familiar with the enCurve system’s controls.
- Improper installation, operation or maintenance of the enCurve system may result in malfunctions of this unit or other devices.
- The enCurve system console has a touch screen. Do not use sharp objects or ballpoint pens to operate the touch screen. A special, soft tip stylus is provided for this purpose.
- Malfunction of the system could result in an unintended increase of power output and unintended injury to the patient. If the system shows any deviation from a normal operating situation, discontinue use and report the fault to Lutronic Corporation authorized service personnel.
- Accessories that are not manufactured by Lutronic Corporation for use with the enCurve system must not be attached to the system to prevent potential harm to the patient and/or damage to the unit.
- Avoid the use of liquids in the immediate vicinity of the system.
- Do not cover the cooling vents to avoid the equipment overheating.
- Do not let the cable touch the applicator during the treatment.
- During treatment, do not touch the applicator or applicator wire.
- During treatment, the applicator and applicator wire should maintain
separate state. The applicator or applicator wire that come in contact during treatment may cause inappropriate sensation, skin burn, or damage to the applicator or wire. The applicator wire should not be crossed or touched.

- Inappropriate handling of the accessories may adversely affect characteristics.
- Use of controls or adjustments or performance of procedures other than those specified in this manual may result in hazardous exposure to electromagnetic energy.
- You should never, under any circumstances, attempt to hold the applicator in your hands during therapy.
- Always position the unit and the applicator in such a way that there is no danger to the patient, the operator or other persons. Therefore, you must read and observe the safety instructions and the list of contraindications before putting the system into operation.
- Keep all unnecessary persons out of the treatment location. No other person should be located within 36 feet of the unit.
- The patient should not be allowed to come into contact with conductive parts which are earthed or which have an appreciable capacitance to earth and which may provide unwanted pathways for the radio-frequency current. In particular, beds or chairs having metal frames should not be used.
7.3 Caution regarding contraindications

Do not treat(or expose) patients if the following conditions are present:

- Implanted electronic devices such as a cardiac pacemaker, bladder stimulator, spinal cord stimulator or electrodes for a myoelectric prosthesis, or implanted metallic leads. Do not treat patients who have had an implant in the past unless you are absolutely certain that the implant and all leads in their entirety have been removed. Note that fads are often left implanted after the implant is removed, the effects of the applied radiofrequency on the pacemaker could cause ventricular fibrillation. Any persons with pacemakers must also remain outside of the treatment area. No one wearing a cardiac pacemaker should be within 45 feet of an operating unit.

- Wearing Hearing aids

- Negatively affected by heat

- Hemorrhages or risk of hemorrhage.

- Septic conditions and empyemas.

- Malignant tumors and undiagnosed tumors

- Implants, areas where implants have been removed, damaged implants, and metal inclusions

- Implants that could be impaired by electromagnetic field.

- Swellings that still feel warm

- Thermohyposthesia

  (diminished perception of temperature differences).

- Thermohyperesthesia

  (very acute thermoesthesia or temperature sense exaggerated perception of hot and cold).

- Acute inflammations

- Severe arterial obstructions(stage III and IV)

- Gynecological disorders involving acute inflammation.

- Wetness, perspiration, or damp bandages.

- Permeating irradiation of the thorax in cases of severe heart diseases(heart valve diseases, myocardial insufficiency, myocardiac infarct, severe coronary sclerosis).
- Pregnancy, since irradiation could cause teratogenous damage due to alterations of blood circulation and diffusion.
- Menstruation
- Pregnant woman
- Nursing
- Sudeck's syndrome, stage I and II
- Basedow's disease (irradiation on could cause serious states of agitation).
- Varicose veins (irradiation could cause congestive pain)
- Cardiac condition
- Deep vein thrombosis, phlebitis, varices
- Arterial disease, Circulatory insufficiency
- Occlusive vascular disease, such as arteriosclerosis obliterans and thromboangitis obliterans, in which organic occlusion and ischemia are evident.
- Ischemic tissues in individuals with vascular disease where the blood supply would be unable to follow the increase in metabolic demand and tissue necrosis might result.
enCurve must not be applied:

- Over eyes
- Over the testes
- Over the pelvic or low back area when an IUD is present.
- Over cardiac pacemakers and defibrillators, cochlear implants, bone growth stimulators, deep brain stimulators, spinal cord stimulators, and other nerve stimulators.
- Over open lamina (after laminectomy spina bifida)
- Over superficial endoprosthesis or metal implants.
- Directly over the carotid sinuses, cervical stellate ganglion, or vagus nerve located in the anterior neck triangle.
- Directly over cancerous tumors or lesions due to its potential to increase blood flow to the area of malignancy.
- Over neoplastic tissues or space occupying lesions.
- Directly over the epiphysis of growing bones.
- In the presence of systemic or local infection (sepsis, osteomyelitis, tuberculosis) or if the patient has an elevated temperature.
- If there is a scar in or near the treatment area, check with the patient and/or the patient's chart to determine if there is metal under the scar.
- enCurve should not be applied over the uterus unless specific assurance can be attained from the patient that she is not pregnant.
- Person aged 18 or younger, or weak or old person

### 7.4 Side effects

- Mild pain
- Mild swelling
- Feeling of vasodilatation
- Deterioration of pain
7.5 Temperature and effect of heating part

Therapeutic changes only occur when the temperature of the tissue rises to 40~45°C and shortwave diathermy heats the deep tissue to 40~45°C.\(^1\)

Heating by shortwave diathermy induce vasodilation, elevation of pain threshold, reduction in muscle spasm, acceleration of cellular activity, and increased soft tissue extensibility.\(^2-4\)

Reference


IMPORTANT

With the exception of defects in the equipment itself supplied by Lutronic Corporation, Lutronic Corporation will not bear any responsibility for problems that arise due to the negligence or poor understanding by the user in the process of using the product.
8.1 Overview

- Chapter 8 describes unpaid services available for those who use the device properly and exclusions from such unpaid services are provided by the warranty of this product.

- Based on the standards for resolving consumer dispute, Lutronic provides warranty on product as provided below:

8.2 Unpaid services

If the operator has used the device in a proper way and would like the device to get after-sales, the operator is eligible for unpaid service up to one year from the date of purchase, as guaranteed by Lutronic Corporation.

8.2.1 Unpaid service items

- Free complimentary service includes maintenance of the main body of the system, applicator, and arm.

- If Lutronic Corporation receives a request for parts/labor during the warranty period, such requests will be handled in a prompt manner. Depending on the condition of the system to be repaired, Lutronic Corporation may decide to repair or replace the system either on the premises of Lutronic’s headquarters or the location where the system is installed.

- If it is necessary to recall the system for the purpose of adjustment or inspection, Lutronic will provide the information that our customer requests or allow them to rent a temporary device.


**WARNING**

In order to maintain the coverage of unpaid services, only service persons formally authorized by Lutronic should be allowed to configure, modify or inspect the system. If the system is used for purposes other than originally intended or not in compliance with the instructions given in this manual, then the user shall be ineligible for any type of unpaid services. Lutronic Corporation customers are strongly advised to be fully aware of all the details of this manual. In any case, Lutronic Corporation reserves all rights and responsibilities for judging the nature of damages to the product and the possible causes for such damages. Such judgment made by Lutronic Corporation shall be deemed to be finalized and cannot be overridden.

**8.2.2 Exclusion to unpaid service within the period of the warranty**

If the operational procedures and cautionary items specified in this manual were not properly followed, altered, or neglected in any manner, the purchaser will not be eligible for unpaid service. Please pay close attention to the items below while using the device.

- Damages that result from moving the equipment by pulling the applicator and Arm with excessive force are not covered by the warranty

- If the device is modified or disassembled for purposes other than those initially intended, then user and device will be excluded from the coverage of this warranty.
8.3 Paid services

If 1 year has passed from the date of the device installation, paid services are provided. For any damage to the device caused by the fault of the consumer or by act of god (fire, salt damage, flood, lightening, etc.) as provided below, paid services are provided.

8.3.1 Paid service items

- Damage to the device caused by arbitrary disassembly or alteration of the device or damage to the device caused by negligence in usage (water logging, breakage, etc.)

- Damage to the device caused by repair by a service agent not fully authorized by Lutronic or service agent of a supplier of Lutronic not designated

- Damage to the device caused by use of supplies not designated by Lutronic or lack of compliance with disinfection method.

- Damage to the device caused by lack of compliance with the device operation procedures or safety precautions specified in this manual or lack of compliance with precautionary advice

- Damage to the device caused by act of god (Fire, salt damage, flood, lightening, etc.)

CAUTION

For any service requests not caused by damage to the device, paid service could apply, regardless of the warranty period. So, the content this manual must be familiarized.
This letter of warranty can replace any form of implicit or explicit warranty agreed by interested parties. However, the sales agent shall not provide any kind of warranty for the condition of the laser or its marketability for any purpose.

Practice name: __________________________
Doctor: ____________________________
Address: _____________________________________________________________
Tel: __________________________ Fax: ____________________________
E-mail: __________________________
Model: __________________________
Serial No.: __________________________
Date of purchase: __________________________
Expiration date of warranty: __________________________
Sales Agent: __________________________ Tel: __________________________
Date of installation: __________________________

Important! To validate this warranty, please completely fill out the above items and email it to the address or number below within fifteen days of the installation.

Lutronic Corporation.
Lutronic Center, 219, Sowon-ro, Deogyang-gu, Goyang-si, Gyeonggi-do, Korea
E-mail: office@lutronic.com
Appendix A. EMC compatibility

A.1 Electromagnetic emissions

The enCurve is intended for use in the electromagnetic environment specified below. It is the responsibility of the customer or user to assure that the enCurve 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 – CISPR 11</td>
<td>Group 2</td>
<td>The enCurve must emit electromagnetic energy in order to perform its intended function. Nearby electronic equipment may be affected.</td>
</tr>
<tr>
<td>Harmonic emissions EN 61000-3-2</td>
<td>Class A</td>
<td>The device is suitable for use in all establishments, other than domestic, and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.</td>
</tr>
<tr>
<td>Voltage fluctuations/flicker emissions EN 61000-3-3</td>
<td>Complies</td>
<td></td>
</tr>
</tbody>
</table>

A.2 Electromagnetic immunity

The enCurve is intended for use in the electromagnetic environment specified below. It is the responsibility of the customer or user to assure that the enCurve is used in such an environment.

<table>
<thead>
<tr>
<th>Immunity test</th>
<th>EN 60601 test level</th>
<th>Compliance level</th>
<th>Electromagnetic environment – guidance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Electrostatic discharge (ESD) EN 61000-4-2</td>
<td>± 6 kV contact</td>
<td>± 6 kV contact</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></td>
<td>± 8 kV air</td>
<td>± 8 kV air</td>
<td></td>
</tr>
<tr>
<td>Electrical fast transient/burst EN 61000-4-4</td>
<td>± 2 kV for power supply lines</td>
<td>± 2 kV for power supply lines</td>
<td>Mains power quality should be that of a typical commercial or hospital environment.</td>
</tr>
<tr>
<td></td>
<td>± 1 kV for input/output lines</td>
<td>N/A – no input/output lines</td>
<td></td>
</tr>
<tr>
<td>Surge EN 61000-4-5</td>
<td>± 1 kV line(s) to line(s)</td>
<td>± 1 kV line(s) to line(s)</td>
<td>Mains power quality should be that of a typical commercial or hospital environment.</td>
</tr>
<tr>
<td></td>
<td>± 2 kV line(s) to earth</td>
<td>± 2 kV line(s) to earth</td>
<td></td>
</tr>
</tbody>
</table>
Voltage dips, short interruptions and voltage variations on power supply input lines EN 61000-4-11

<table>
<thead>
<tr>
<th>Voltage Level</th>
<th>Test Condition</th>
<th>Compliance Level</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt; 5 % UT</td>
<td>(&gt;95% dip in UT for 0.5 cycles)</td>
<td></td>
</tr>
<tr>
<td>40 % UT</td>
<td>(60% dip in UT for 5 cycles)</td>
<td></td>
</tr>
<tr>
<td>70 % UT</td>
<td>(30% dip in UT for 25 cycles)</td>
<td></td>
</tr>
<tr>
<td>&lt; 5 % UT</td>
<td>(&gt;95% dip in UT for 5 s)</td>
<td></td>
</tr>
</tbody>
</table>

Mains power quality should be that of a typical commercial or hospital environment. If the user of the enCurve requires continuous operation during power mains interruption, it is recommended that the enCurve be powered from an uninterruptible power supply or a battery.

Power frequency magnetic field EN 61000-4-8

<table>
<thead>
<tr>
<th>Frequency</th>
<th>Test Level</th>
<th>Compliance Level</th>
</tr>
</thead>
<tbody>
<tr>
<td>50/60 Hz</td>
<td>3 A/m</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

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

<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 150 kHz to 80 MHz</td>
<td>3 V</td>
<td>Portable and mobile RF communications equipment should be used no closer to any part of the enCurve including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.</td>
</tr>
</tbody>
</table>

**Recommended separation distance**

\[
d = \left[ \frac{3.5}{E_1} \right] \sqrt{P}
\]

- For 80 MHz to 800 MHz:
  \[
d = \left[ \frac{3.5}{E_1} \right] \sqrt{P}
\]
- For 800 MHz to 2.5 GHz:
  \[
d = \left[ \frac{7}{V_1} \right] \sqrt{P}
\]

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).
### Radiated RF

<table>
<thead>
<tr>
<th>IEC 61000-4-3</th>
<th>3 V/m 80 MHz to 2.5 GHz</th>
<th>3 V/m</th>
</tr>
</thead>
</table>

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:

![Symbol](image)

### A.3 Recommended separation distances

The enCurve is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the enCurve can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the enCurve 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>150 kHz to 80 MHz</td>
<td>80 MHz to 800 MHz</td>
</tr>
<tr>
<td>d = [3,5] ( \sqrt{\frac{P}{V_i}} )</td>
<td>d = [3,5] ( \sqrt{\frac{P}{E_i}} )</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>
<tr>
<td>200</td>
<td>17</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.
The use of accessories and cable other than those specified may result in increased emissions or decreased immunity performance of the equipment.

The equipment or system should not be used adjacent to or stacked with, other equipment. If adjacent or stacked use is necessary, the equipment or system should be tested to verify normal operation in the configuration in which it is being used.
Appendix B. Parameter Guideline

B.1 Overview

Appendix B provides treatment parameter for effective and safe treatment with enCurve. It is certain that parameter guideline is based on published literature and clinical evaluation. It is just recommendation and optimal treatment parameter might be different according to physician’s technique and patient skin condition. Before treatment, physician should examine patients’ skin condition and history.

B.2 Treatment parameter

<table>
<thead>
<tr>
<th>Indications</th>
<th>Input power</th>
<th>Treatment Time (min)</th>
<th>No. of Treatment</th>
<th>Tx. Interval</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pain relief in patients with knee osteoarthritis</td>
<td>300</td>
<td>15</td>
<td>12~24 sessions</td>
<td>3 days</td>
</tr>
</tbody>
</table>

- Notes for treatment
  - Each patient sat on a chair and placed her legs on a table with both knees fully extended during treatment, while receiving enCurve with an applicator operating at a frequency of 27.12MHz, an input of 300W.

B.3 Reference

- Akyol Y, Durmus D, Alayli G, Tander B, Bek Y, Canturk F, et al. Does short-wave diathermy increase the effectiveness of isokinetic exercise on pain, function, knee muscle strength, quality...

IMPORTANT

The above treatment parameters are general settings for guidance only. We recommend adjusting treatment values depending on each patient's individual needs, special circumstances and treatment history. LUTRONIC® shall not be liable for injuries, problems or issues that arise as a result of negligence or inexperience using products supplied by Lutronic.