Select™
PAIN CONTROL

User's Manual

CAUTION: Federal Law (USA) restricts this device to sale by or on the order of a physician (or licensed practitioner).

The following symbols may be located on the back of the Select stimulator:

Type BF Applied Part

Attention, consult accompanying documents

Lead wires comply with the Performance Standard for electrode lead wires (21 CFR part 898)

9900900

Electronic Testing Lab, indicates product meets US and Canadian product safety standards. This device complies with UL 60601-1 and CSA C22.2 No. 601-1-M90.

Council Directive 2002/96/EC concerning Waste Electrical and Electronic Equipment (WEEE). Indicates a requirement not to dispose of WEEE as municipal waste. Contact your local distributor for information regarding disposal of the unit and accessories.

Empi

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Introduction

Congratulations! Your physician has prescribed Empi's Select Pain Control system to help you with pain management. Empi is dedicated to helping you regain your active lifestyle – from our field sales representatives training you on how to use the system, to our patient coordinators following up with you. We make your success our goal.

How Select Works

What is Pain?

Pain is an unpleasant sensation that can serve a useful purpose by alerting us to a possible or actual injury or disease. When the body is functioning normally, pain serves as a warning system that something is not right. Without pain a person would not know when to get away from danger or seek medical help. But pain becomes a problem when it continues after treatment has started or long after an injury is healed.

There are two types of pain: acute and chronic. Acute pain is limited in duration. Typical examples are sprains, incisional pain or muscle strain. This type of pain is typically associated with workplace or recreational injuries. Chronic pain, however, is a long-lasting, persistent pain that ceases to serve as a warning system and becomes a problem. The Select was developed to help relieve some types of both chronic and acute pain.

What is TENS?

TENS stands for Transcutaneous Electrical Nerve Stimulation. Pain, whether chronic (long-term) or acute (short-term), can be relieved through a variety of methods, including drugs, topical ointments, surgery, and electrical stimulation. TENS devices deliver electrical pulses through the skin to the cutaneous (surface) and afferent (deep) nerves to control pain. Unlike drugs and topical ointments, TENS does not have any systemic side effects.

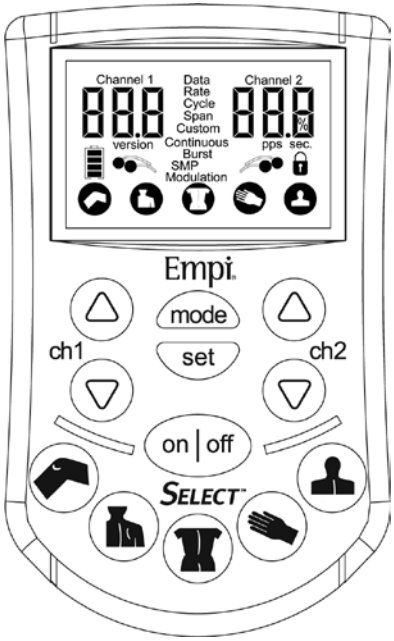
How Does TENS Control Pain?

The Select provides pain relief in two ways. The first is the gate control method. When the body is injured, both pain and non-pain impulses are sent to the brain from the nervous system. These pulses travel through the cutaneous nerves to the deeper, afferent nerves, and then to the spinal cord and brain. Along the path are many areas referred to as "gates," which determine which impulses are allowed to continue on to the brain. The gates prevent the brain from receiving too much information too quickly. Since the same nerve cannot carry a pain and a non-pain impulse at the same time, the stronger, non-pain impulse from the Select device "controls the gate."

The second method of pain control is the endorphin release method. The Select device can be set to trigger the body's natural pain killers, called endoprhins. These chemicals interact with recpetors, blocking the perception of pain. This is similar to the way the pharmaceutical drug morphine works, but without the side effect associated with morphine.

No matter which pain control method is employed, the Select has been proven useful in pain management. By reading this manual and carefully following the treatment instructions provided by your clinician, you can attain maximum benefit from your Select device.

Introduction



Main Operating Components

Consult a health care professional (clinician) if you have specific questions or problems regarding the use of the device. They are most familiar with your situation and are the best source of additional guidance. This system should be used only under proper medical supervision and only as described by this manual.

Before using your Select Pain Control system, please read all of the indications, contraindications, warnings, and precautions in the Prescribing Information section (on page 8).

Prescribing Information

In general, stimulation should be used under medical supervision in the management of specific conditions.

Read, understand, and practice the precautionary and operating instructions found in this manual. Know the limitations and hazards associated with the Select Pain Control system. Observe any and all precautionary and operational decals placed on the unit.

Indications

TENS devices are indicated for:

- Symptomatic relief and management of chronic, intractable pain
- Adjunctive treatment for post-surgical and post-trauma acute pain
- For the relief of pain associated with arthritis

Contraindications

TENS treatments should not be used if you have any of the following:

Cardiac pacemakers – Do not use this device if the patient has a demand-type cardiac pacemaker or any implanted defibrillator.

Transcerebral stimulation – Do not apply electrical stimulation transcerebrally (through the head).

Carotid sinus – Do not use electrical stimulation over the carotid sinus nerves (throat).

Unknown etiology – Do not use this device when pain syndromes are undiagnosed. Use only after origin of pain has been diagnosed.

Prescribing Information

Warnings

Supervised use – This device should only be operated under the prescription and supervision of a physician (or licensed practitioner) that is familiar with the precautionary measures and operational functions associated with the unit being used.

Long-term effects – The long-term effects of chronic use of electrical stimulation are unknown. Electrical stimulation devices do not have any curative value.

Symptomatic treatment – This device is a symptomatic treatment and, as such, suppresses the sensation of pain, which would otherwise serve as a protective mechanism.

Central origin pain – Electrical stimulation is not effective for central origin pain such as headache.

Pregnancy – The safety of using electrical stimulation during pregnancy or birth has not been established.

Throat stimulation – Severe spasm of the laryngeal and pharyngeal muscles may occur when the electrodes are placed across the throat or mouth. This may be strong enough to close off the airway or cause breathing difficulty.

Transthoracic stimulation – Do not apply electrical stimulation transthoracically (through the chest area) in that the introduction of electrical current into the heart may cause cardiac arrhythmias.

Skin and vascular problems – Do not use this device over infected areas, skin eruptions, or areas of decreased sensation.

Heart disease – Precaution should be taken prior to using electrical stimulation on patients suspected of having heart disease.

High frequency surgical devices – Simultaneous connection of a patient to a high frequency surgical device may result in burns at the site of the electrodes and possible damage to the device.

Damage from liquids – Do not immerse the device in water or other liquids. Water or liquids could cause malfunction of internal components of the system, causing a risk of injury to the patient.

Electrical shock – To prevent electrical shock, disconnect the unit from the power source before attempting any maintenance procedures.

Uncomfortable stimulation – If the stimulation levels are uncomfortable or become uncomfortable, reduce the intensity to a comfortable level. Contact your clinician if this does not resolve the problem or if the problem persists.

Prescribing Information

Skin reactions – On rare occasions, therapy can result in transient skin reactions such as rash, inflammation, irritation, or burns. These skin reactions may be the result of individual sensitivity to the condition of the skin at the onset of treatment, reaction to the materials in the electrodes, or a poor connection between the electrode and your skin. If a visible skin reaction does occur, discontinue the treatment and consult the prescribing physician or licensed practitioner.

Lead connection – Do not connect the lead wires to an AC power source or other equipment not specified as safe for the lead wires. Doing so could result in severe shock or burns whether or not the lead wires are attached to the stimulator.

Electromagnetic compatibility – Care must be taken when operating this device adjacent to or stacked with other equipment. Potential electromagnetic or other interference could occur to this or other equipment. Try to minimize this interference by not using other equipment in conjunction with it. (i.e. cell phones, etc.)

Accessories – Use only accessories that are specially designed for this device. Do not use accessories manufactured by other companies on this device. Empi is not responsible for any consequence resulting from using products manufactured by other companies. The use of other accessories or cables may result in increased emissions or decreased immunity of this device.

Defibrillation signals – Remove the TENS electrodes before defibrillation signals are applied. Defibrillation of a person wearing a TENS device can damage the device whether it is turned on or off. Under some circumstances there can be risk of burns under the electrode sites during the defibrillation.

Safety – The safety and efficacy of the Select system depends on the proper use and handling of the device and accessories. If used improperly, the Select system has a potentially hazardous electrical output. It must be used only as prescribed. Electrode or lead wire burns may result from misuse. Electrodes and lead wires should be securely fastened to prevent inadvertent disconnection. The length of lead wires could result in injury. Electrodes and lead wires will eventually wear out. Check accessories regularly for signs of wear, and replace if needed.

Proper electrode size – Output current density is related to electrode size. Improper application may result in patient injury. If any question arises as to the proper electrode size, consult a licensed practitioner prior to therapy session.

Prescribing Information

Precautions

Epilepsy – Use caution for patients with suspected or diagnosed epilepsy when using this device.

Hemorrhages – Use caution when there is a tendency to hemorrhage, such as following acute trauma or fracture.

Post-surgical use – Use caution following recent surgical procedures when muscle contraction may disrupt the healing process.

Uterus – Do not use electrical stimulation over a menstruating or pregnant uterus.

Sensory loss – Do not use electrical stimulation where sensory nerve damage is present, causing a loss of normal skin sensation.

Unequal electrode size – Using different size electrodes together can cause skin irritation or increased stimulation intensity under the smaller electrode. Some programs may require the use of different sized electrodes for treatment.

Prescription – Use electrical stimulation only in the prescribed manner and for the prescribed diagnosis. If there are any changes in an existing condition, or if a new condition develops, the patient should consult a physician.

Effectiveness – Effectiveness is highly dependent upon patient selection by a clinician qualified in the management of pain or rehabilitation.

Keep out of reach of children – Keep this device out of the reach of children. If the patient is a child, make sure he/she is properly supervised during electrical stimulation.

Leads and electrodes – Use the device with only the leads and electrodes provided for use by the manufacturer. The safety of other products has not been established, and their use could result in injury to the patient. Use only the electrode placements and stimulation settings prescribed by your practitioner.

NOTE: An electrode active area of no less than 1.227 in^2 (7.917 cm^2) is recommended for the Select system.

NOTE: The Select system requires the use of Empi lead wires with the custom safety connection as pictured.

Prescribing Information

Electronic equipment – Electronic monitoring equipment (such as ECG and ECG alarms) may not operate properly when electrical stimulation is in use.

Microwave or radio frequency sources – Operation in close proximity, such as 3 feet (1 meter), to shortwave or microwave therapy equipment may produce instability in the device output and may shut the device off.

Machinery operation – Patient should never operate potentially dangerous machinery such as power saws, automobiles, etc. during electrical stimulation.

Flammable – Do not use the device in an environment where flammable or explosive fumes may exist.

External use – This device is for external use only.

Electromagnetic energy – Do not operate this unit in an environment where other devices are being used that intentionally radiate electromagnetic energy in an unshielded manner. Portable and mobile RF communications equipment can affect medical electrical equipment.

Sharp objects – Do not use sharp objects such as a pencil point or ballpoint pen to operate the buttons on the control panel.

Cables and connectors – Inspect cables and connectors before each use.

Treatment outcome – Treatment outcome will be influenced by the patient's psychological state and use of drugs.

Negative reaction to stimulation – Patients who react negatively to the stimulation sensation after an adequate trial period or who find stimulation intolerable should not undergo further treatment.

Operation conditions – This unit should be operated in temperatures between 50° F and 104° F (10° C and 40° C), atmospheric pressures between 50 and 106 kPa, and relative humidity between 30% and 75%.

Transportation and storage conditions – This unit should be transported and stored in temperatures between -40° F and 158° F (-40° C and 70° C), atmospheric pressures between 50 and 106 kPa, and relative humidity between 10% - 90%.

Batteries – Remove the Select system batteries if the unit is to be unused for an extended period of time, i.e. 2 weeks or more.

Transportation of batteries – Do not carry batteries in a pocket, purse or any other place where the terminals could become short-circuited, e.g. by way of a coin or paper clip. Intense heat could be generated and injury may result.

Using device while sleeping – Do not use while sleeping because the lead wires or the electrodes may become disconnected.

Prescribing Information

Heat and cold products – The use of heat or cold producing devices, such as electric heating blankets, heating pads or ice packs, may impair the performance of the electrode or alter the patient's circulation/sensitivity and increase the risk of injury to the patient.

Battery charger – Only the Empi battery charger should be used with Empi rechargeable batteries. Do not attempt to recharge any battery other than the rechargeable battery supplied by Empi for this device. Attempts to charge alkaline or other non-rechargeable batteries could cause the battery to overheat, burst, or be permanently damaged.

Radio frequency generation – This equipment generates, uses, and can radiate radio frequency energy and if not installed and used in accordance with the instructions, may cause harmful interference to other devices in the vicinity. However, there is no guarantee that interference will not occur in a particular installation.Harmful interference to other devices can be determined by turning the unit on and off. Try to correct the interference using one or more of the following: reorient orrelocate the receiving device, increase the separation between the equipment and consult the Empi Service Department for help.

Dangers

Dangerous voltage – Stimulus delivered by the TENS waveforms of this device, in certain configurations, will deliver a charge of up to 20 microcoulombs (µC) or greater per pulse and may be sufficient to cause electrocution. Electrical current of this magnitude must not flow through the thorax because it may cause a cardiac arrhythmia.

Biohazardous materials – Handle, clean, and dispose of components and accessories that have come in contact with bodily fluids according to national, local, and facility rules, regulations, and procedures.

Adverse Effects

Skin irritation, inflammation, and electrode burns beneath the electrodes are potential adverse reactions.

Quick Reference

When you are very familiar with the operation of the Select system, use the following steps as a quick reference to operate the device. For more information, refer to the Operation section in this manual.

Starting a Therapy Session

1. Connect the lead wire(s) to the electrodes and the device.

   NOTE: Make sure the device is turned off before connecting the lead wires to the device.

CORRECT

NOT CORRECT

2. Wash and dry the skin areas where you will be applying the electrodes. Use skin prep if necessary.
3. Apply the electrodes to your skin.
4. On the device, press the on|off button to display the Program screen. The software version will flash, then the entire LCD display will be displayed for 1/2 second. The last program used will display.
5. Use the Ch1 and Ch2 buttons (fig. ch) to set the intensity for each channel,as directed by your clinician. The program will begin to operate.
6. On the device, press the on|off button to shut the device off.

fig. ch

Changing a Therapy Session

1. Follow steps 1 through 4 in Starting a Therapy Session, above.
2. Select offers nine (9) program options. Selecting a specific program option is done by pressing the mode button or one of the five Quick Select Program buttons.

3. Use the Ch1 and Ch 2 buttons (fig. ch) to set the intensity for each channel, as directed by your clinician.
4. On the device, press the on|off button to shut the device off.

fig. ch

Quick Reference

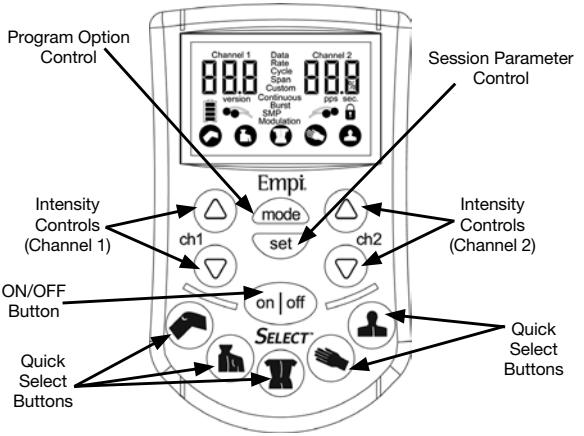
Ending a Therapy Session

1. On the device, press the on|off button to shut the device off.
2. Unclip the belt clip from your clothing.
3. Disconnect the lead wire(s) from the device.
4. Disconnect the lead wire(s) from the electrodes.
5. Remove the electrodes from your skin. Follow the instructions on the electrode package for storing electrodes. If necessary, use adhesive remover to remove any remaining adhesive (or gel) from your skin.
6. Use skin cream or lotion to moisturize your skin after removing the electrodes.
7. Remove the batteries from the device prior to storing.
8. Store the components in the carrying case.

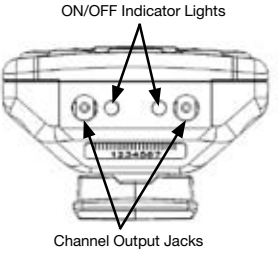
System Components

Device

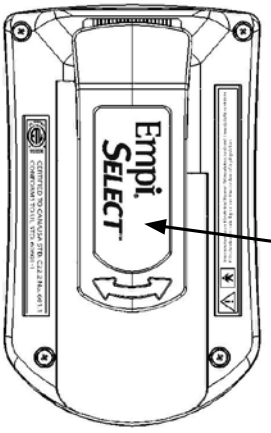
The Select system is a battery-operated electrical stimulator. The device has five Quick Select programs and four program options that can be customized by a clinician.



Device Front View



Device Side View

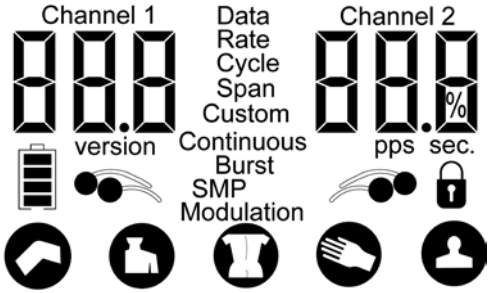


Device Back View

System Components

LCD Screen

This is the area that displays the therapy settings as you program and use the stimulator.



- **Channel icons** – denotes the channel being used – Channel 1 and/or Channel 2.
- **Intensity** – displayed under the Channel icons and ranges from 0.0 to 60.0 in 0.5 increments.
- **Software version** – displays for a few seconds when the Select is turned on.
- **Data** – denotes that the unit is in Data Retrieval Mode or in Quick Select Button Reset Mode.
- **Rate** – when adjusting the pulses per second, “Rate” will be displayed next to the value, along with “pps”.
- **Cycle** – when adjusting the cycle time, “Cycle” will be displayed next to the cycle time value along with “sec”.
- **Span** – when adjusting the span percentage, “Span” will be displayed next to the span percentage value along with “%”.
- **Custom text** – for each of the Quick Select Program options, when the default parameters have been changed and saved, the Custom text will denote that the buttons have been customized.
- **Program options** – four program options (Continuous, Burst, SMP and Modulation) can be selected with the Mode button.

- **Lock icon** – when treatment intensity is set at greater than zero and no activity has occurred within 15 seconds, the Lock icon appears to tell the user that the unit is locked and intensity/program cannot be changed until it is unlocked.

- **Pad contact icons** – two icons – one for each channel; icons will display and flash, indicating bad contact.

- **Battery icon** – displays the battery life.
- **Quick Select programs** – five pre-set programs for particular body areas (Knee, Shoulder, Low Back/Hip, Hand/Wrist, and Back).

System Components

Operating Buttons

These are the buttons you use to program your therapy settings, such as selecting the treatment program and intensity.

- **On/Off** – used to turn the stimulator on and off.
- **Quick Select programs** – used to select the most commonly used programs for a particular body area (Knee, Shoulder, Low Back/Hip, Hand/Wrist, and Back).
- **Mode** – used to select one of four program options (Continuous, Burst, SMP and Modulation).
- **Set** – used to change the therapy session parameters (Rate, Cycle Time, and/or Span Percentage) based on which program option is selected. Also used to access the Timer function.
- **Ch 1** Increase – used to increase the intensity of the electrical current sent through the channel 1 output jack.
- **Ch 1** Decrease – used to decrease the intensity of the electrical current sent through the channel 1 output jack.
- **Ch 2** Increase – used to increase the intensity of the electrical current sent through the channel 2 output jack.
- **Ch 2** Decrease – used to decrease the intensity of the electrical current sent through the channel 2 output jack.

NOTE: Pressing the Up or Down intensity controls increases or decreases the intensity in 0.5 increments. Intensity range is 0.0 to 60.0. The Up or Down intensity controls can be held down to increase or decrease the intensity faster.

Intensity Lockout Feature

Once the intensity is raised above zero, with no activity for greater than 15 seconds, the unit will initiate lockout of the increase intensity buttons. A lock symbol will appear on the display to signify that this has occurred. This feature prevents any unintended key presses to increase intensity or change the program option.

*** To unlock, press the Ch 1 or Ch 2 decrease button.**

Output Jacks

The output jacks are where you connect the lead wires to the device. The output jacks are labeled on the LCD display. Channels 1 and 2 operate independently. There are two (2) LED indicator lights, one for each channel.

NOTE: At a high rate, the LED indicator light will flash, looking like it is constantly on. At a low rate, the LED indicator light will flash slowly.

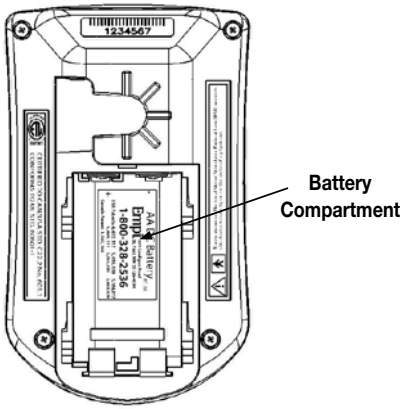
System Components

On/Off Indicator Lights

The On/Off Indicator Lights indicate that the device is operational. The brightness of flash changes with the output intensity. As the intensity of the stimulation increases, the brightness of the light also increases. (Above 40 pps, the light will appear to be on continuously.)

Battery Compartment

The device is supplied with “AA” alkaline batteries. The battery compartment is located on the back of the device. Refer to pages 22-23 for battery installation.



Belt Clip

The belt clip is flexible so you can clip the device to your clothing, allowing you to receive your treatment while going about your daily activities.

Carrying Case

A carrying case is included to help protect the Select system and keep it clean. Store your device and its components in the case when they are not in use.

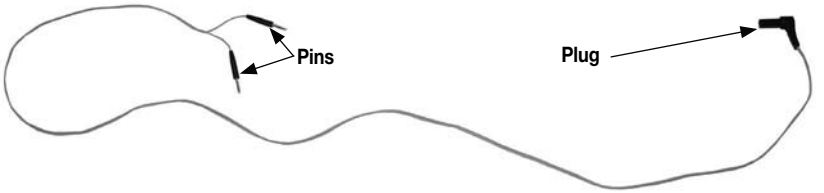
Documentation

Read and understand this user’s manual carefully before operating the Select device. The user manual is provided in English and Spanish. If you have questions or cannot read these languages, contact your clinician.

System Components

Lead Wires

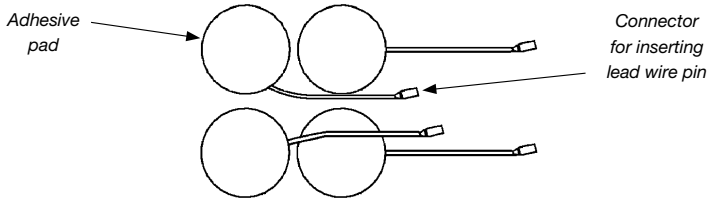
Lead wires connect the device to the electrodes. They carry the electrical pulses from the device to the electrodes on your skin. You must have an electrode on both the pins for the device to work properly.



Electrodes

There are several types and sizes of electrodes, and each type has different characteristics. The Select usually includes two (2) packs of four (4) 2-inch round or 2-inch square, reusable, self-adhering electrodes, as shown below. Each electrode has a connector for inserting a lead wire pin and an electrical-conductive adhesive pad that attaches to your skin. These electrodes are flexible and conform to the skin very well. They can be reused 10 to 15 times, depending on skin type and electrode care.

Inspect your electrodes before every use. Replace electrodes as needed. If you need additional electrodes, contact Customer Service at 800-328-2536.
To use these electrodes:



1. Attach the lead wire to the electrode.
2. Remove the liner from the electrode and store in plastic bag.
3. Apply the electrode to the prescribed skin area.
4. Replace electrodes that do not adhere properly to the skin or that fail to deliver proper stimulation.

CAUTION: Do not pull on the electrode wire. Doing so may damage the wire and electrode.

Operation

Overview

CAUTION: United States Federal Law restricts this device to sale by or on the order of a physician or licensed practitioner.

This section includes the following instructions for performing a therapy session. Perform these instructions in the order they are presented:

- Installing the Batteries
- Connecting the Lead Wires to the Electrodes
- Connecting the Lead Wires to the Device
- Preparing the Skin for a Therapy Session
- Applying the Electrodes to the Skin
- Turn on the Device
- Timer Function
- Select the Treatment Settings
- Intensity Lockout Feature
- Quick Select Feature
- Program Option Control
- Begin Treatment
- Record Treatment
- End Treatment
- Data Retrieval

This section also includes the following instructions:

- Changing the Batteries
- Charging the Batteries
- Maintenance
- Cleaning
- Storage
- Disposal

Before operating the Select system, read the previous sections of this manual that describe the system and its features. To gain the maximum benefit from your Select system, carefully follow your clinician's instructions and use the system for only the specific symptoms detailed by your clinician. If you have any questions or problems, or experience any new symptoms or painful areas, contact your physician, therapist, or clinician for appropriate diagnosis and treatment. They are most familiar with your specific situation and are the best source of additional guidance.

Operation

Installing the Batteries

The Select operates with two “AA” alkaline (or rechargeable) batteries. Install the batteries before using the Select. In addition, install new batteries whenever the “Low Battery” icon flashes in the LCD display. For information about charging the batteries, refer to **Charging the Batteries** in this **Operation** section.

CAUTIONS:

- Do not connect the stimulator to any electrical outlet.
- Do not mix battery types. Use either two alkaline or two nickel metal hydride (NiMH) rechargeable batteries.
- Remove the batteries from the stimulator during storage to prevent battery leakage. Failure to do so may damage the stimulator.
- Replace batteries immersed in water or liquid. Failure to do so may damage the stimulator.
- Never recharge alkaline batteries. An explosion may result.
- If using rechargeable batteries, carefully read and follow all instructions provided with the batteries and the battery charger.
- Dispose of batteries according to current federal, state, and local regulations.

Failure to observe these precautions can result in injury, damage to the device and batteries, or the environment.

To install the batteries into the device:

1. Turn off Select device.
2. Twist belt clip 90 degrees to either the right or left (two clicks). **Fig. 1**
3. Gently press down and slide the battery compartment toward you. **Fig. 2**
4. At this point, you have the option to remove the belt clip by sliding it to the left. If you want to keep the belt clip on the device, simply leave it turned at a 90-degree angle. **Fig. 3**
5. Insert batteries, making sure positive and negative ends match the label inside the battery compartment.
6. Line up all four tabs on the side of the battery cover so they slide into slots in body of device. Cover should be flush with back of device. Slide up until cover clicks. (Return belt clip to original position if using.) **Fig. 4**

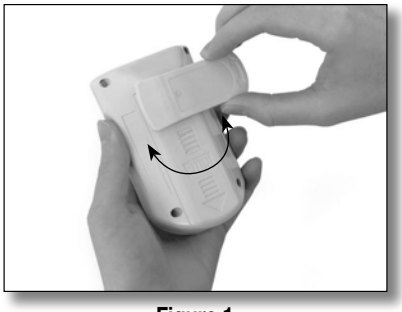


Figure 1

Figure 2

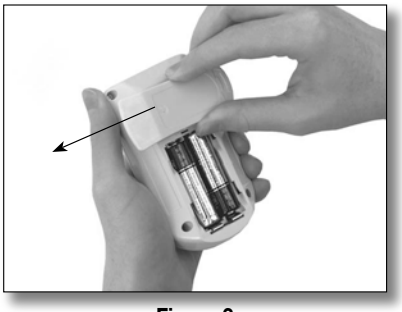


Figure 3

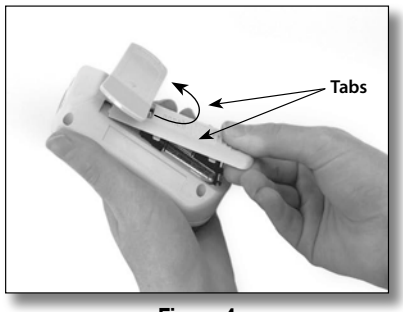


Figure 4

Connecting the Lead Wires to the Electrodes

To connect the lead wire(s) to the electrodes:

1. Decide if you are using one lead wire (two electrodes) or two lead wires (four electrodes). Follow clinician's instructions.
2. Locate the pins at the ends of the lead wire(s). If necessary, refer to the image in the **System Components** section.
3. Locate the pin insertion points on two or four electrodes as necessary.

NOTE: Refer to the electrode package for complete instructions.

4. With the electrodes still attached to the protective backing, insert one lead wire pin into each electrode's insertion point. Insert the pins entirely so that no metal shows.

NOTE: Connect only one lead wire to each electrode.

5. Connect the lead wires to the electrodes before applying the electrodes to the skin. This will reduce the possibility of dislodging the electrodes.

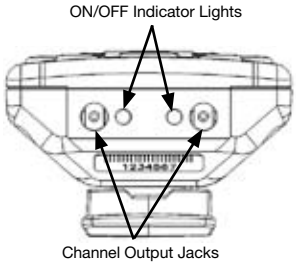
Operation

Connecting the Lead Wires to the Device

CAUTION: The device must be off before connecting the lead wires to the device.

1. Locate the plug(s) at the end of the lead wire(s). If necessary, refer to the illustration in the System Components section (page 20).
2. Locate the output jacks at the top of the device. They are labeled Channel 1 and Channel 2 on the LCD display.
3. Insert one lead wire plug into each output jack. If using only one lead wire, you can use either of the output jacks.

NOTE: Use care when you connect and disconnect the lead wires from the electrodes and the device. Pulling on the lead wire instead of its insulated connector may cause lead wire breakage.



Preparing the Skin for a Therapy Session

Proper preparation of the skin covered by the electrodes allows more stimulation to reach targeted tissues, prolongs electrode life, and reduces the risk of skin irritation.

To prepare your skin at the electrode placement sites:

1. Identify those areas where your clinician has recommended electrode placement.
2. Wash the area gently with mild soap and water, then rinse and dry the area thoroughly. (The use of rubbing alcohol is discouraged except where necessary to decrease excessive oils on the skin.)
3. It may be necessary to trim excess body hair with scissors prior to applying the electrodes. Do not shave the area immediately before beginning treatment. Wait 24 hours after shaving an area before initiating treatment at that site. Failure to adequately prepare the skin may cause improper adhesion or skin irritation and provide less than ideal stimulation.

Operation

NOTE: Skin is not accustomed to exposure to the electrode gel and adhesives used with the Select. While Empi takes great care and tests all electrode materials to avoid problems, irritation may appear as redness, small pimple-like lesions, or blisters. If your skin develops any persistent redness or irritation, do not continue to apply the electrodes to the same area. Discuss this with your clinician or call an Empi representative.

Applying the Electrodes to the Skin

To apply the electrodes to the skin:

1. Make sure the device is off.
2. Remove the protective backing from the electrode and save the backing for reuse.
3. Place the adhesive (gel) surface of the electrode on the skin placement site prescribed by your clinician.
4. Press the entire surface of the electrode into place, making sure it is secure.
5. Repeat steps 2 through 4 for all electrodes.

NOTES:

- Inspect the electrodes before each use.
- Place the electrodes on the skin as recommended by your clinician. Position the electrodes with a minimum of two (2) inches apart between them. Do not let them touch each other. Do not reposition the electrodes while the device is turned on. The electrodes should be comfortable to wear and should be placed exactly where you have been shown. The most common problems with TENS therapy are caused by failure to wear the electrodes as directed.
- The pad contact icon will display and flash if there is bad contact between the electrode and the skin.
- After three (3) seconds of bad contact, the intensity will drop to 6.0. If good contact has been reestablished within 30 seconds, the intensity will ramp back up to the original setting. If there has been more than 30 seconds of bad contact, the intensity will drop to zero. Intensity can be increased once good contact has been established.
- Do not place electrodes on cut, broken, or irritated skin. If skin irritation develops, immediately discontinue device use, remove the electrodes, and contact your clinician.
- For long-term stimulation, change electrode sites whenever possible. Contact your clinician for new placement sites.
- Replace self-adhesive electrodes that do not adhere well or fail to deliver proper stimulation.
- Do not refrigerate electrodes. Keep them from heat sources. Refer to the electrode packaging for information about electrode use and care.

Operation

Turning On the Device

Turn on the Select by pressing the On/Off button. Turning the unit on will default to the last treatment used. The intensity of both channels will be 0.0 when the unit is turned on.

Choosing the Treatment Settings

Your clinician has recommended one of the program options explained in the Quick Select Feature or Program Option Controls sections in the Operation section of this manual. Set the device to the recommended setting if different from the one shown on the display.

NOTE: Follow your clinician's instructions about changing the recommended settings to achieve optimum comfort level.

Intensity Lockout Feature

To unlock the unit, simply press the intensity decrease ▽ button for the channel you wish to change and the unit will unlock. This allows the intensity to be adjusted either up or down. The program can also be changed when the intensity is above zero. As soon as the program is selected, the unit will automatically decrease the intensity of the current program to zero on both channels and change to the new program selected. Intensity can then be increased on that program.

Quick Select Feature

The Select has five buttons that allow you to quickly choose the most commonly used programs for a particular body part. Choices include Low Back/Hip, Knee, Hand/Wrist, Shoulder, and Back. By pressing one of the Quick Select buttons, the unit is automatically set up for a particular program option. Intensity is still adjusted by pressing the intensity control buttons and will start at zero.

NOTE: Holding a Quick Select body part button for five (5) seconds after adjusting the parameters will save the parameters and the "Custom" text icon appears. The "Custom" text icon will flash if any parameters are adjusted and saved.

NOTE: See the Intensity Lockout Feature section above to change the program parameters.

Knee Program Option 1

Shoulder Program Option 2

Low Back/ HipProgram Option 3

Hand/Wrist Program Option 4

Back Program Option 5

Quick Select Button Reset Mode

With the unit off, pressing the On/Off button while holding down the Set button will take you to the Quick Select Button Reset Screen. The “Data” text icon will appear.

The body part icons will be displayed along with the “Custom” text icon associated with the body part icon. “CP” appears on the screen to clear all five programs saved on the unit.

Pressing both Down arrow buttons on each intensity channel and then releasing the buttons will confirm the clearing of programs and reset the Quick Select buttons to the default parameters. See the default parameters for each program in the **Specifications** section. The “Custom” text icon will no longer be displayed. Pressing the On/Off button will cancel the clearing of the programs and will reset the programs to default parameters.

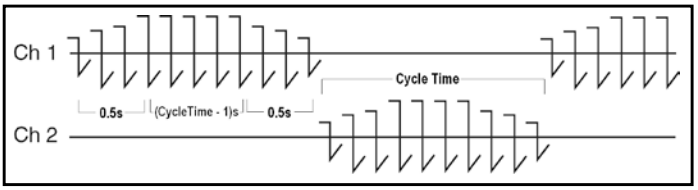
Pressing the On/Off button will exit the Quick Select button reset screen, or after one (1) minute has passed and no buttons have been pressed, the unit will automatically exit the Quick Select button screen and turn off.

Program Option Controls

Select offers nine (9) program options. To select a specific program option, depress the Mode button or one of the Quick Select buttons.

1 Quick Select Knee Program - Alternating Ramped Burst (ARB)
2 Quick Select Shoulder Program - Simple Modulated Pulse (SMP)
3 Quick Select Low Back/Hip Program - Modulated Amplitude (MA)
4 Quick Select Hand/Wrist Program - Simple Modulated Pulse (SMP)
5 Quick Select Back Program - Modulated Amplitude (MA)
6 Continuous (C)
7 Burst
8 Simple Modulated Pulse (SMP)
9 Modulation

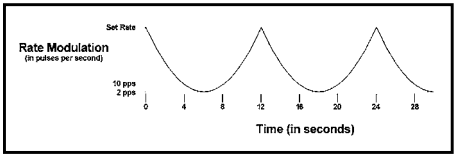
Quick Select Knee Program – Alternating Ramped Burst (ARB)

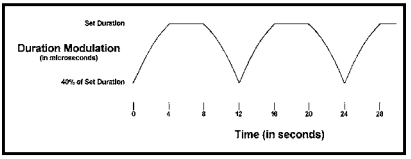


The Alternating Ramped Burst program is the same as the Burst, but Channel 2 starts after Channel 1 has completed a cycle. Channel 1 gradually increases intensity from 0 to the set level over 0.5 seconds, holds at the set intensity for 5.0 seconds, and then decreases intensity over 0.5 seconds. After decreasing intensity to zero, Channel 1 stays off while Channel 2 increases, holds, and decreases via the same pattern as Channel 1.

Operation

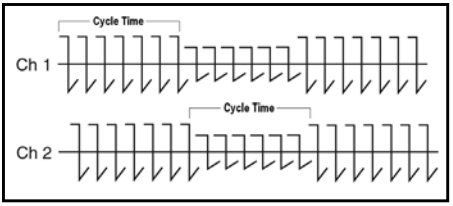
Quick Select Shoulder, Hand/Wrist Programs – Simple Modulated Pulse (SMP)





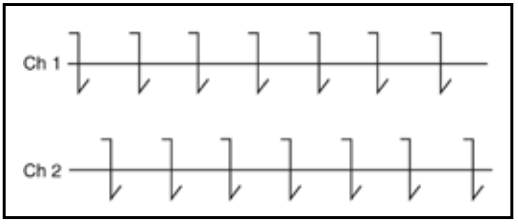
The Simple Modulated Pulse (SMP) program delivers a group of pulses as a repeating 12-second cycle. Within each cycle, the rate and duration of the pulses vary while the intensity remains constant. This mode is unique because the rate stays in the 2 to 10 pps range for 1/3 of the cycle time (4 seconds) as the rate modulates down to 2 pulses per second (pps) and then back up again.

Quick Select Back, Low Back/Hip Programs – Modulation Amplitude (MA)



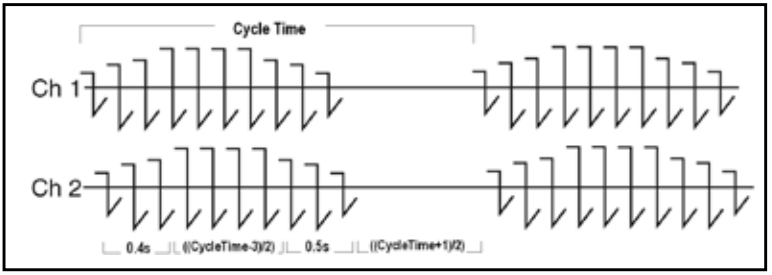
In the Modulation Amplitude program, for 0.5 seconds the intensity is at 100% of the set level and for the next 0.5 seconds, the intensity is at the set span percentage (60%) of the preset level. The cycle is then repeated. There is no off time.

Continuous (C)



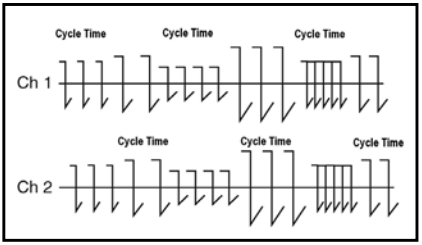
This setting produces a continuous stimulation at the set intensity. Channel 1 pulses alternate with Channel 2 pulses.

Burst



The Burst program gradually increases the intensity from 0 to the set level over 0.4 seconds, maintains it at the set level for 1.0 seconds, and then gradually decreases the intensity over 0.5 seconds. The device then sends no stimulation for 3.0 seconds. Channel 1 pulses alternate with pulses of Channel 2.

Modulation



Rate is selected pseudo-randomly from 8 rates: 2, 10, 20, 40, 60, 80, 100, or 150 pps. Span percentage for pulse duration is selected pseudo-randomly from 7 values between 50% of set pulse duration and the set pulse duration. Each combination is on for the selected cycle time.

Operation

Beginning Treatment

After inserting the batteries, connecting the electrodes, connecting the lead wires, preparing the skin, and applying the electrodes, you are ready to begin your therapy session. For button identification information, refer to **Device Physical Features** in the **System Components** section of this manual.

NOTE: Most therapy sessions are for 30 to 120 minutes with 30 to 60 minutes between sessions. Follow your clinician's instructions.

1. Press the Channel 1 and Channel 2 intensity controls until the stimulation is strong but comfortable. It is important that you can feel the stimulation.
2. The On/Off indicator lights should be on. The LCD display will show a low battery icon to indicate low battery status.

⚠ **CAUTION:** Always turn the Select device off when changing the battery.

3. The output of the device may decrease slightly during stimulation as the batteries wear down. If this happens, you may need to increase the intensity slightly to maintain adequate stimulation.

Recording Treatment

Before turning off the TENS device, you may want to record the location of the electrodes, the settings of all controls and any progress achieved. Good record keeping will help when resuming treatment or reviewing progress with your clinician. If after several treatments you do not achieve pain relief, consult your clinician for new electrode placement or stimulation program alternatives.

Ending Treatment

1. Turn the device off. Disconnect the lead wires, grasping them by the insulated connector, not the lead wire.

NOTE: Turning the unit off will end the treatment and save the following information for data retrieval: number of sessions, total time of all sessions, average session length, and the average intensity used for each channel.

2. Remove the electrodes carefully from your skin, peeling them off gently in the direction that body hair lies. The electrodes may be left in place if treatment will be resumed shortly.
3. After the electrodes are removed, clean the skin thoroughly with mild soap and water. For electrode storage and care, refer to electrode packaging for instructions.

NOTE: The Select will automatically shut off when both channels are at a zero intensity for one (1) minute or if the batteries are low.

Operation

Using the Timer

Your Select device has a timer that can be set from one to 60 minutes.

1. With the device turned on, press the Set button until the screen displays “dur” to the left and “Off” to the right. (The number of times Set button needs to be pressed to reach this screen will vary depending on the mode selected.)
2. When this screen is displayed, press the Channel 2 up button to set the number of minutes you want the Select to run. The timer can be set in one-minute increments, up to 60 minutes. To decrease the number of minutes, press the Channel 2 down button until the desired timing for your treatment is reached.
3. Once the desired time is set or (the timer is turned Off), press the Mode button to return the device to the normal treatment screen. After the treatment session has started, the keypad will lock in 15 seconds. Pressing either the Channel 1 or Channel 2 up button after the keypad locks will toggle the screen between the treatment screen and the timer screen.
4. To unlock the keypad, press either Channel 1 or Channel 2 down button. To return to the timer screen, press the Set button as in step 1. To cancel the treatment program at any time, simply turn the device Off.
5. When timed treatment is complete, the device will automatically turn Off; remove and store electrodes.

Data Retrieval

When the unit is in Data Retrieval mode, the user can cycle through several codes that contain information saved from treatments.

With the unit off, pressing the On/Off button while holding down the Mode button will take you to the Data Retrieval screen. The “Data” text icon will appear. Pressing the Mode button will cycle through the data saved on the unit.

- **SES** – The number of sessions (maximum 255). Sessions are counted only when intensity is ≥ 3.0. “SES” will be displayed on the left side of the screen while the number of sessions will be displayed to the right of it.
- **HrS** – The total time of all sessions (hours – maximum 999). “HrS” will be displayed on the left side of the screen while the time will be displayed to the right of it in the format “hours.”
- **ASL** – The average session length (hours and tenths of hours). “ASL” will be displayed on the left side of the screen while the session length will be displayed to the right of it in the format “hours . tenth of hours”.
- **Channel 1** – The Channel 1 text icon will be displayed along with the average intensity for Channel 1.

- **Channel 2** – The Channel 2 text icon will be displayed along with the average intensity for Channel 2.

Pressing the On/Off button will exit the Data Retrieval screen or after one (1) minute has passed and no buttons have been pressed, the unit will automatically exit the Data Retrieval screen and turn off.

Resetting to Default Parameters

While in Data Retrieval mode, press the Set button. “CL” appears on the screen to clear the memory saved on the unit. Pressing both Down arrows on each channel will confirm that memory is cleared and reset all options to factory defaults. See the default parameters for each program in the **Specifications** section (pages 35-43). Pressing the On/Off button will cancel clearing the memory and resetting all options to factory defaults.

Changing the Batteries

The Select device is powered by two (2) “AA” batteries. For best results, use Empi alkaline or rechargeable batteries. The Select device can assess battery condition at start up. When the ON button is held down for two seconds, the battery icon will appear on the screen by itself. If no bar, or only one bar appears, the device will not turn on until the batteries are replaced. Change or replace the batteries when the low battery icon flashes on the LCD display, or if the device will not turn on.

Full Battery Icon

Low Battery Icon

CAUTION: Turn device off and disconnect the electrode lead wires before inserting fresh batteries.

1. Pull the belt clip and battery compartment off the unit to access the batteries.
2. Remove the discharged batteries. Dispose of the batteries in accordance with national, state or local regulations.
3. Place the new battery into the space provided. Be sure the terminals are correctly aligned. The “+” of the battery should be lined with the “+” terminal of the device and the “-” of the battery should be lined with the “-” terminal. Do not force the battery. If force is required, you may be putting the battery in backwards. Check the “+” and “-” markers.

CAUTION: Inserting the batteries incorrectly may cause the batteries to rupture or generate intense heat if allowed to remain in the incorrect position. This may cause irreversible damage to the batteries. If there are signs of this type of damage, discard or recycle the batteries and order replacements.

Charging the Batteries

If you purchased the optional rechargeable battery system, you will typically charge one set of batteries while using the other. If the low battery icon flashes, recharge the batteries as soon as possible.

CAUTION: Do not attempt to charge alkaline batteries or any battery other than an Empi rechargeable battery.

1. Place the batteries in the charger. The batteries should slide in easily. If force is required, you may be putting the batteries in backwards. Check the "+" and "-" markers.
2. Plug the charger into any standard 110V/60Hz outlet.
3. If the batteries are new or have been stored for a long period of time, full capacity will not be reached until the batteries have been through 3-5 charge/use cycles.
4. Rechargeable batteries have a natural life of approximately 500 charge/use cycles. Once this is reached, it is not possible to achieve full capacity. At this point, batteries should be disposed of and replacement ones can be ordered through Empi at 1.800.328.2536.

NOTE: Batteries have a natural property to release the stored energy in small amounts (this phenomenon is called 'self-discharge'). This property is particularly noticeable in rechargeable batteries such as Nickel Metal Hydride batteries etc. as compared to dry cell (alkaline) batteries. For this reason, rechargeable batteries cannot be used unless charged after purchase.

Regardless of the type of battery, this natural 'self-discharge' phenomenon occurs. In order to get the NiMH batteries to 'activate' back to its full capacity, you must charge/use or discharge from 3 to 5 times. All NiMH batteries must be 'activated' when they are brand new or if they have been stored unused. Once NiMH batteries reach their end of life (approx. 500 cycles), they should be disposed of, as continuing to 're-charge' them will not do any good.

Operation

Maintenance

Check the unit before each use for signs of wear and/or damage. Replace wear items as required. Send damaged units back to factory for repair.

Wear items are:

1. Electrodes
2. Lead wires
3. Batteries

Cleaning

Cleaning the device: Use a damp cloth moistened with mild soap and water to clean the exterior of the device. Use of other cleaning solutions may damage the case. Never immerse the device in water or other liquids. Do not use cleaning fluids or solvents to remove stains or dirt. These liquids may damage the plastic case and lead wires.

Cleaning the battery contacts: Gently clean the battery contacts using a cotton-tipped swab soaked in rubbing alcohol. Do not use sandpaper or other abrasive material.

Cleaning the lead wires: Periodically wipe the lead wires clean with a cloth dampened in a mild soap solution, then gently wipe them dry. Use of rubbing alcohol on the lead wires will damage the insulation and dramatically shorten their life.

Storage

To properly store the device for an extended period of time, i.e. two weeks or more, remove the batteries and store the device in a dry location. Store all the operating components in the carrying case. Batteries should be stored in the carrying case, in a dry location at 50° F to 86° F (10° C to 30° C) and away from direct sunlight.
Rechargeable batteries slowly lose their charge in storage so they should be recharged every six months. The batteries can lose their capacity to hold a charge when they are stored for long periods of time. You can renew their capacity by charging and discharging them several times. If your batteries do not retain a charge during standard operation, contact Empi Customer Service at 1.800.328.2536.

Disposal

Dispose the unit in accordance with national, state or local regulations. If needed, ship the used device, postage prepaid, to the Empi Service Center for proper disposal or recycling. Please enclose a note indicating that the item is being returned for disposal or recycling. Outside of North America, contact your Authorized Empi Distributor, or contact Empi directly at 1.651.415.9000.

Specifications

Physical Characteristics

Standard Measurement Conditions 23°C, 1Ω Resistive load, 4.2V d.c. supply voltage

Waveform Balanced asymmetrical biphasic; nominally constant voltage positive phase and constant current negative phase over the AAMI load range of 200 to 1kΩ. 20% tolerance unless stated otherwise. See Figures B and C.

Standard Measurement

	Output	*See Figure*
Both Phases (Vpp)*	0 to 60V	A
1kW resistive (Ipp)*	0 to 60mA	A

*Vpp = Volts peak to peak *Ipp = mA peak to peak

Pulse duration Adjustable; 0 to 400 µs at 50% peak amplitude. See Figure A on Page 38. Determined by the intensity setting.

Maximum Current

Absolute Average Value: 10 mA into 500Ω

Root Mean Square: 10 mA into 1kΩ

Electrode Surface Area 1.227 in^2 (7.917 cm^2) minimum area recommended.


Type BF Applied Part.

Internally powered only. Ordinary protection against entry of liquids. Continuous operation.

Physical Dimensions

Size (H x W x D) 4.31 in x 2.38 in x 1.38 in
(10.95 cm x 6.03 cm x 3.49 cm)

Approx. Weight (with batteries) 4.9 oz. (138.9 grams)
(without batteries) 3.7 oz. (104.9 grams)

Environmental Conditions

Operating Temperature 50° F to 104° F (10°C to 40°C), RH 30% to 75%, 50kPa to 106kPa

Transport and Storage Temperature -40° F to 158° F (-40°C to +70°C), RH 10% to 90%, 50kPa to 106kPa

Specifications

Program Options	Default Parameters
1 Alternate Ramped Burst (ARB) Quick Select Knee Program	Rate = 100 pps; Ramp Up Time = 0.5s; On Time = 5s; Off Time = 6s; Channel 2 follows Channel 1; Channel 2 Ramp Up starts at the end of Channel 1 Ramp Down. Ramp Up starts from 0.
2 Simple Modulated Pulse (SMP) Quick Select Shoulder Program	Rate = 125 pps; Cycle Time = 12s; Span Percentage = 40%; Rate stays in the 2-10 pps range for 1/3 of the cycle time (4 seconds) as the rate modulates down to 2 pulses per second (pps) and then back up again.
3 Modulated Amplitude (MA) Quick Select Low Back/Hip Program	Rate = 125 pps; Cycle Time = 1s;Span Percentage = 60%; amplitude modulation is done through pulse duration modulation; 0.5s intensity is at 100% of set level and next 0.5s intensity is at 60% (set span percentage of preset level).
4 Simple Modulated Pulse (SMP) Quick Select Hand/Wrist Program	Rate = 125 pps; Cycle Time = 12s; Span Percentage = 40%; Rate stays in the 2-10 pps range for 1/3 of the cycle time (4 seconds) as the rate modulates down to 2 pulses per second (pps) and then back up again.
5 Modulated Amplitude (MA) Quick Select Back Program	Rate = 125 pps; Cycle Time = 1s; Span Percentage = 60%; amplitude modulation is done through pulse duration modulation; 0.5s intensity is at 100% of set level and next 0.5s intensity is at 60% (set span percentage of preset level).
6 Continuous (C)	Rate = 125 pps; Adjustable 2-150 pps in 5 pps intervals; continuous at set intensity.
7 Burst	Rate = 15 pps; Ramp Up Time = 0.4s; On Time = 1s; Ramp Down Time = 0.5s; 3s of no stimulation.
8 Simple Modulated Pulse (SMP)	Rate = 125 pps; Cycle Time = 12s; Span Percentage = 40%; Rate stays in the 2-10 pps range for 1/3 of the cycle time (4 seconds) as the rate modulates down to 2 pulses per second (pps) and then back up again.
9 Modulation	Rate is pseudo-random between 2, 10, 20, 40, 60, 80, 100, and 150 pps; Cycle Time = 1s; Span percentage = 50, 58, 66, 75, 83, 91, and 100%; duration is modulated between 7 values between 50% of set pulse duration and the set pulse duration.

Specifications

Program Options	Adjustable Parameters
1 Alternate Ramped Burst (ARB) Quick Select Knee Program	Intensity (Ch1 and Ch2) = 0-60 in 0.5 intervals Duration = 0-400 µs Rate = 2-150 pps in 5 pps intervals Cycle Time = 2-20s in 1s intervals
2 Simple Modulated Pulse (SMP) Quick Select Shoulder Program	Intensity = 0-60 in 0.5 intervals Duration = 0-400 µs Rate = 20-150 pps in 5 pps intervals Cycle Time = 1-20s in 1s intervals Span = 20%-95% in 5% intervals
3 Modulated Amplitude (MA) Quick Select Low Back/Hip Program	Intensity = 0-60 in 0.5 intervals Duration = 0-400 µs Rate = 2-150 pps in 5 pps intervals Cycle Time = 1-20s in 1s intervals Span = 20%-95% in 5% intervals
4 Simple Modulated Pulse (SMP) Quick Select Hand/Wrist Program	Intensity = 0-60 in 0.5 intervals Duration = 0-400 µs Rate = 20-150 pps in 5 pps intervals Cycle Time = 1-20s in 1s intervals Span = 20%-95% in 5% intervals
5 Modulated Amplitude (MA) Quick Select Back Program	Intensity = 0-60 in 0.5 intervals Duration = 0-400 µs Rate = 2-150 pps in 5 pps intervals Cycle Time = 1-20s in 1s intervals Span = 20%-95% in 5% intervals
6 Continuous (C)	Intensity (Ch1 and Ch2) = 0-60 in 0.5 intervals Duration = 0-400 µs Rate = 2-150 pps in 5 pps intervals
7 Burst	Intensity (Ch1 and Ch2) = 0-60 in 0.5 intervals Duration = 0-400 µs Rate = 2-150 pps in 5 pps intervals Cycle Time = 5-20s in 1s intervals
8 Simple Modulated Pulse (SMP)	Intensity = 0-60 in 0.5 intervals Duration = 0-400 µs Rate = 20-150 pps in 5 pps intervals Cycle Time = 1-20s in 1s intervals Span = 20%-95% in 5% intervals
9 Modulation	Intensity (Ch1 and Ch2) = 0-60 in 0.5 intervals Duration = 0-400 µs Cycle Time = 1-20s in 1s intervals

Specifications

To Select Parameters for Programs

To Initiate	Press Set button while device is on in the appropriate program option. Display will show what Program is currently selected.
To Toggle	Press the Set button again to toggle through the parameters.
To change	Use the Channel 1 or Channel 2 Intensity buttons to change the parameters.
To Exit	Press Mode button. Automatic exit will happen after 10 seconds and display the Treatment Screen.

Data Retrieval Codes

SES	# of sessions (maximum 255)
ASL	Average session length (hours and tenths of hours)
HrS	Total hours in use
Channel 1	Actual average intensity
Channel 2	Actual average intensity

Battery Information

Supply Voltage Range	2.26V d.c minimum to 3.3V d.c. maximum
Low Voltage Indicator Threshold	2.26V d.c.

Waveforms shown are typical:

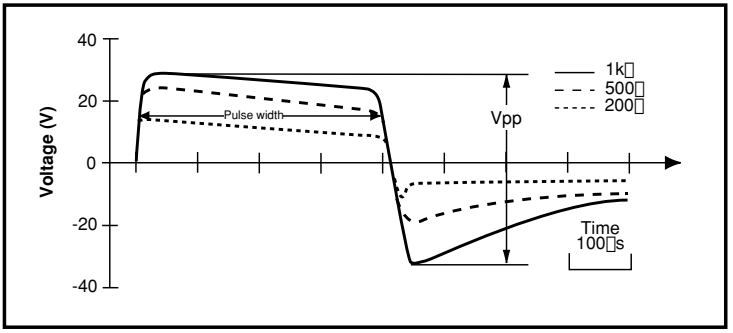


Figure A. Standard measurement output voltage across purely resistive loads at maximum High Output Intensity setting. Pulse duration and Vpp measured as shown across a 1 KΩ load.

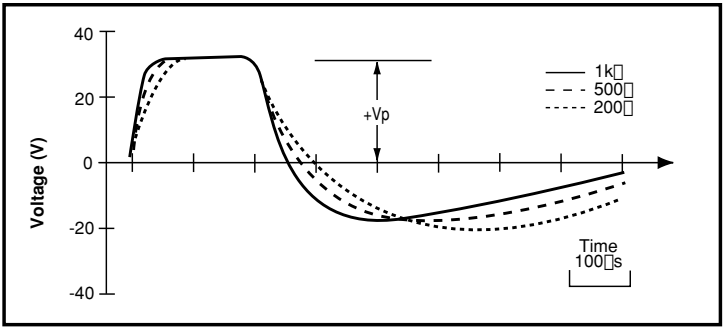


Figure B. Output voltage across AAMI loads at 50% of maximum High Output Intensity setting. Output is nominally constant voltage for intensity settings of 20 (80μs) or greater.

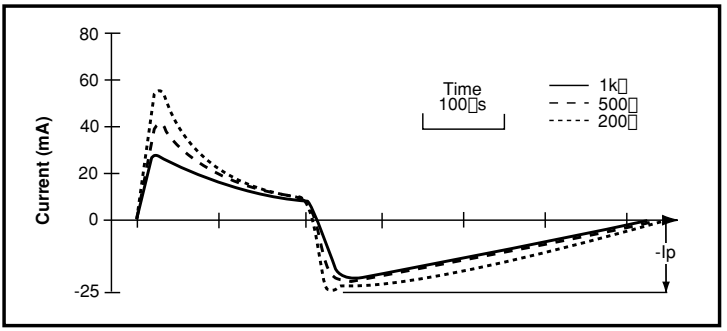


Figure C. Output current into AAMI loads at 50% of maximum High Output Intensity setting. Negative phase (undershoot) is nominally constant current.

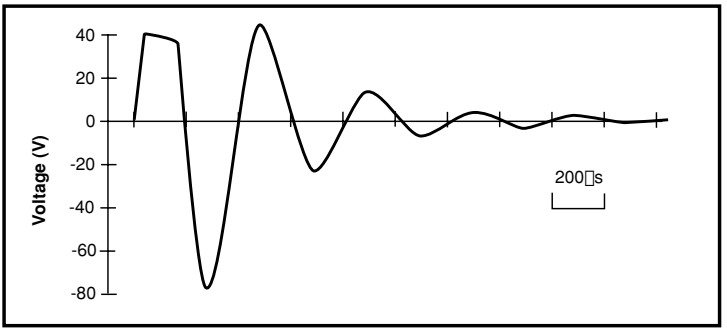


Figure D. Output voltage across a 1MΩ resistive load at 50% of maximum High Output Intensity setting.

Specifications

Guidance and manufacturer's declaration – electromagnetic emissions		
The Empi Select is intended for use in the electromagnetic environment specified below. The customer or the user of the Empi Select should assure that it is used in such an environment.		
Emission tests	**Compliance**	**Electromagnetic environment - guidance**
RF emissions CISPR 11	Group 1	The Empi Select uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The Empi Select is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Not Applicable- Battery Operated Device	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Not Applicable- Battery Operated Device	

Guidance and manufacturer's declaration – electromagnetic immunity			
The Empi Select is intended for use in the electromagnetic environment specified below. The customer or the user of the Empi Select should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	±6kV contact ±8kV air	±6kV contact ±8kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	±2kV for power supply lines ±1kV for input/output lines	Not Applicable- Battery Operated Device	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1kV differential mode ±2kV common mode	Not Applicable- Battery Operated Device	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5% U_T (>95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5 sec	Not Applicable- Battery Operated Device	Mains power quality should be that of a typical commercial or hospital environment.
Power frequency (50/60Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE U_T is the a.c mains voltage prior to application of the test level.			

Specifications

Guidance and manufacturer's declaration – electromagnetic immunity			
The Empi Select is intended for use in the electromagnetic environment specified below. The customer or the user of the Empi Select should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
			Portable and mobile RF communications equipment should be used no closer to any part of the Empi Select, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance**
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3V	$d = \frac{[3.5]}{V1}\sqrt{P}$
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	$d = \frac{[3.5]}{E_1}\sqrt{P}$ 80 MHz to 800 MHz $d = \frac{[7]}{E_1}\sqrt{P}$ 800 MHz to 2.5 GHz
			where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey[a], should be less than the compliance level in each frequency range[b]. Interference may occur in the vicinity of equipment marked with the following symbol: 
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 Empi Select is used exceeds the applicable RF compliance level above, the Empi Select should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the Empi Select.

[b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Specifications

Recommended separation distances between portable and mobile RF communications equipment and the Empi Select			
The Empi Select is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Empi Select can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Empi Select as recommended below			
Rated maximum output power of transmitter **W**	**Separation distance according to frequency of transmitter** **m**		
	150 kHz to 80 MHz $d = [\underline{3.5}]\sqrt{P}$ $V1$	**80 MHz to 800 MHz** $d = [\underline{3.5}]\sqrt{P}$ $E1$	**800 MHz to 2.5 GHz** $d = [7]\sqrt{P}$ $E1$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23
For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (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 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.			

Troubleshooting

For repair of device, call 1.800.862.2343 (Mon-Fri)
For supplies, call 1.800.328.2536 (Mon-Fri)

For optimal use:

1. Replace lead wires annually.
2. Please follow the directions on the electrode packaging for the care of electrodes. The life of the electrodes varies, depending on skin conditions, skin preparation, storage and climate. Replace electrodes that no longer stick.
3. Ensure batteries are charged before each use. Unplug the battery charger from the wall once charge is complete.

NOTE: If the following measures fail to alleviate the problem, please call the repair department at 1-800-862-2343.

Problem	Possible Cause	Solution
Display does not come on.	Battery/ Battery contact failure	1. Try fresh batteries. 2. Ensure batteries are inserted correctly. Check the following on the battery contacts: • All contacts are in place. • All contacts are not broken. • All contacts are not pushed in. They should make contact with the battery when it is inserted.
Stimulation weak with fresh batteries.	Electrodes 1. Dried out or contaminated 2. Placement Lead wires 1. Old/worn/damaged	 1. Replace. 2. Electrodes must be a minimum of 2 inches apart. 1. Replace.
Stimulation stops with fresh batteries.	Poor electrode contact Damaged or worn electrodes or lead wires	Reapply electrodes, secure firmly. Electrodes must be a minimum of 2 inches apart. Replace.
Stimulation weakens within minutes of starting treatment with fresh batteries.	This is a normal body adaptive process	Increase the intensity.
Stimulation is uncomfortable.	Intensity is too high Electrodes are too close together Damaged or worn electrodes or lead wires Electrode active area size is too small.	Decrease intensity. Reposition the electrodes. Electrodes must be a minimum of 2 inches apart. Replace. Replace electrodes with ones that have an active area no less than 1.227 in^2 (7.917 cm^2).

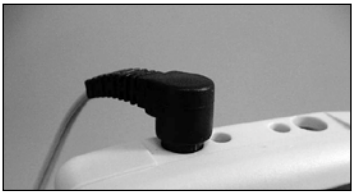
Troubleshooting

Problem	Possible Cause	Solution
Stimulation is ineffective.	Improper electrode placement	Reposition electrodes. Electrodes must be a minimum of 2 inches apart.
	Unknown	Contact clinician.
Stimulation only felt on one electrode.	Improper electrode placement	1. Reposition electrodes. Electrodes must be a minimum of 2 inches apart.
	Electrode life exceeded	2. Replace electrodes.
Stimulation on one channel (side) only.	Electrodes 1. Worn or damaged 2. Improper placement 3. Electrode life exceeded	 1. Replace. 2. Reposition electrode. Electrodes must be a minimum of 2 inches apart.
	Lead wires 1. Worn or damaged Component failure	 1. Replace. Try each lead wire independently in each channel. If there is no output on either channel, the lead wire is defective and should be replaced. If there is output on one channel only, a component may have failed. Call the repair department.
Intermittent output	Lead wires	1. Verify connection is secure. 2. Turn down the intensity. Rotate lead wires in socket 90°. If still intermittent, replace lead wire. 3. If still intermittent after replacing lead wire, a component may have failed. Call the repair department.
	Program option in use	Some programs will seem intermittent. This is expected. Refer to the Program Option Controls in the Operation section for a description of the program option.
	Electrode life exceeded	Replace electrodes.
Rechargeable batteries don't last or life is short.	Brand new or stored batteries	1. This is normal operation. Please charge and use in device. You must do this 3-5 times before full capacity is reached.
	Used NiMH batteries have reached end of life	2. Try step 1. If this does not work, replace batteries.
Electrode icon error *This is a safety feature. See pages 23-25 for operation.	Lead wires	1. Make sure the lead wires are completely pushed into the lead wire socket.
	Electrodes	2. Check lead wire and electrodes to make sure that they are still good.

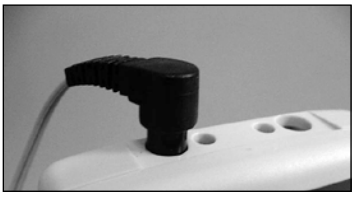
Troubleshooting

To self-test for any of the mentioned problems, perform the following steps:

1. Place new batteries in the device.
2. Verify the device is off.
3. Insert the lead wire into Channel 1 of the unit.

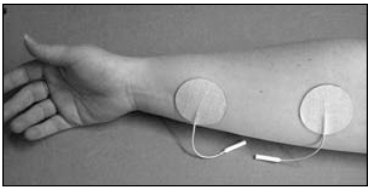


CORRECT



NOT CORRECT

4. Insert one new lead wire into two new electrodes.
5. Place the new electrodes on your forearm as shown in the figure below.



6. Turn your device on.
7. Select Continuous Mode. This is a continuous treatment program. The lights on the device should be steady.
8. Slowly increase the intensity until you can feel it. If you do not feel any sensation, lower the intensity to zero and rotate the lead wire 90 degrees. Slowly increase the intensity.

No sensation: Call the repair department

Sensation is felt - even if weak: Device is working properly. You may need to reposition the electrodes or contact your clinician.

9. Repeat steps 1 through 8 for Channel 2.

Replacement Parts

The following replacement parts can be ordered from Empi at 1-800-328-2536.

Part	Part Number
Select Kit	199584-001
Select Device	199580-001
Carrying Case	199495-001
Premium Electrodes - 2” Round	198622-001*
Lead Wire, Safety Socket, TENS Black 40 in (100 cm) in cable length, unshielded	193068-100
Lead Wire, Safety Socket, TENS Black 60 in (150 cm) in cable length, unshielded	193057-150
Battery Charger, AA NiMH	
Battery, Rechargeable, AA NiMH – 4-pack	
User Manual	360357

* There are several types and sizes of electrodes that can be used with the Select.

Warranty

I. Warning

While, in the opinion of Empi ("Empi"), the use of the Select Transcutaneous Electrical Nerve Stimulator (TENS) (the "Product") has met with some success in the treatment of pain, Empi makes no warranties to the purchaser as to the effectiveness of the product.

II. Warranty

Empi warrants all of their manufactured product to be free from defects in workmanship and materials for life.
Battery charger/rechargeable batteries, carrying cases, lead wires, electrodes, and other accessories are warranted to be free from defects in workmanship and materials at the time of delivery.
Empi will repair or replace, at its facility, any product found to be defective. This warranty does not apply to any product damaged by misuse, or repaired or altered by anyone other than Empi in St. Paul, Minnesota.
This warranty is in lieu of any or all other warranties, expressed or implied. No person is authorized to bind Empi to any representation of warranty other than those specifically set forth herein.
NOTE: Warranty period begins with the date of purchase from manufacturer.

III. Limitation of Liabilities and Disclaimer of Warranties

A. Empi's sole obligation in the case of any breach of its warranties set forth in Paragraph IIA above, shall be, at Empi's option, to repair or replace the Product with a new or factory reconditioned product without charge to Purchaser or to refund the purchase price of the Product. In order to recover under this Warranty, Purchaser must send Empi written notice of the defect (setting forth the problem in reasonable detail) prior to expiration of the Warranty Period, and within 30 days of discovery of the defect. Upon Empi's written request and authorization, Purchaser shall return the Product to Empi, freight and insurance prepaid, for inspection. Notice and return shipment shall be sent to Empi at Clear Lake Industrial Park, Clear Lake, South Dakota 57226. Purchaser may request shipment approval by calling Empi Warranty Repair Department on its toll free number 1-800-862-2343. In the case of repairs or returns outside of North America, notification and return shipment shall be sent to an Empi Authorized Service Center. To locate the appropriate service center outside of North America, contact your Authorized Empi Distributor, or contact Empi directly at 1-800-328-2536. Empi will not be responsible for damage due to improper packaging or shipment. If Empi determines in its sole reasonable discretion that the Product contains defective workmanship or materials, Empi will refund to the Purchaser the purchase price for the defective product, or return the repaired Product or a replacement thereof to Purchaser, freight and insurance billed to the Purchaser, as soon as reasonably possible following receipt of the Product by Empi. If Empi determines in its sole reasonable discretion that the Product does not contain

defective workmanship or materials, Empi will return the Product to the Purchaser, freight and insurance billed to the Purchaser.

B. This Warranty is voided immediately as to any Product which has been repaired or modified by any person other than authorized employees or agents of Empi or which has been subjected to misuse, abuse, neglect, damage in transit, accident or negligence.

C. EXCEPT AS PROVIDED IN PARAGRAPH IIA, THE PRODUCT IS BEING SOLD ON AN "AS IS" BASIS, ALL ACCESSORIES ARE SOLD "AS IS", AND THE ENTIRE RISK AS TO THE QUALITY AND PERFORMANCE OF THE PRODUCT IS WITH PURCHASER. THE WARRANTY PROVIDED IN PARAGRAPH IIA IS INTENDED SOLELY FOR THE BENEFIT OF THE INITIAL PURCHASER AND EMPI DISCLAIMS ALL OTHER WARRANTIES, EXPRESS OR IMPLIED INCLUDING, BUT NOT LIMITED TO, ANY IMPLIED WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE; PROVIDED, HOWEVER, THAT NOTWITHSTANDING THE FOREGOING SENTENCE, IN THE EVENT AN IMPLIED WARRANTY IS DETERMINED TO EXIST, THE PERIOD FOR PERFORMANCE BY EMPI THEREUNDER SHALL BE LIMITED TO THE LIFETIME OF THE INITIAL PURCHASER. NO EMPLOYEE, REPRESENTATIVE OR AGENT OF EMPI HAS ANY AUTHORITY TO BIND EMPI TO ANY AFFIRMATION, REPRESENTATION OR WARRANTY EXCEPT AS STATED IN THIS WRITTEN WARRANTY POLICY.
(This Warranty gives Purchaser specific legal rights and Purchaser may also have other rights which vary from state to state. Some states do not allow limitations of how long an implied warranty lasts, so the above limitation may not apply to the Purchaser.)

D. EMPI SHALL NOT BE LIABLE TO ANY PERSON FOR ANY DIRECT, INDIRECT, SPECIAL, INCIDENTAL, OR CONSEQUENTIAL DAMAGES, LOST PROFITS OR MEDICAL EXPENSES CAUSED BY ANY DEFECT, FAILURE, MALFUNCTION OR OTHERWISE OF THE PRODUCT, REGARDLESS OF THE FORM IN WHICH ANY LEGAL OR EQUITABLE ACTION MAY BE BROUGHT AGAINST EMPI (E.G. CONTRACT, NEGLIGENCE OR OTHERWISE) THE REMEDY PROVIDED IN PARAGRAPH IIIA ABOVE SHALL CONSTITUTE PURCHASER'S SOLE REMEDY. IN NO EVENT SHALL EMPI'S LIABILITY UNDER ANY CAUSE OF ACTION RELATING TO THE PRODUCT EXCEED THE PURCHASE PRICE OF THE PRODUCT.
(This Warranty gives Purchaser specific legal rights and Purchaser may also have other rights which vary from state to state. Some states do not allow the exclusion or limitation of incidental or consequential damages, so the above limitation may not apply to
the Purchaser.)

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