EP-4™

Cardiac Stimulator

Instructions for Use

Part # 100040874 Ver. D
Software Version 2.0(Touch Screen) / 1.2(EP-4)

ST. JUDE MEDICAL™
MORE CONTROL. LESS RISK.

IMPORTANT ADVICE

(Device Incident / Return Policy)

Any alleged malfunction, deficiency, or deterioration in the characteristics and/or performance of this device, along with any alleged inadequacy in the labeling or "Instructions for Use" which might lead or have led to a serious injury or death, must be brought to the attention of the manufacturer listed below. Product Warranty can be found in Appendix D.

NOTE (European Union Only)
In the event the manufacturer cannot be notified, the EU Authorized Representative listed below should be contacted for any alleged adverse events in the European Economic Area or European Union.

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℞ ONLY

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About this Instructions for Use

This Instructions for Use (IFU) is intended to describe full functionality of the EP–4™ Cardiac Stimulator. It is strongly recommend that you read the Introduction and complete the Tutorial before you start to use the EP-4™ Cardiac Stimulator.

Indications for Use

The EP-4™ Cardiac Stimulator is indicated for use during clinical cardiac electrophysiology procedures.

Intended Use

The EP-4™ Cardiac Stimulator is intended to be used for diagnostic electrical stimulation of the heart for the purpose of refractory measurements, initiation and termination of tachyarrhythmias, and measurements of electrical conduction.

Vital Information

Throughout this IFU critical information will be set off from the rest of the text in the following ways:

IMPORTANT

Text set off in this manner and with a tag in the margin presents important information. Information that is vital to the proficient use of the stimulator is labeled as Important.

WARNING

A warning indicates information that is related to patient or operator safety, possible damage to the stimulator or other equipment.

PRECAUTION

A precaution indicates information to be considered prior to use related to patient or operator safety, possible damage to the stimulator or other equipment.

CAUTION

A caution indicates information that is not related to patient or operator safety.

In this IFU, references to particular keys on the computer keyboard are shown in **BOLD** type.

References to a particular stimulation parameter are shown underlined. For example, Cycle Len for the cycle length parameter.

1

Introduction

The EP-4™ Cardiac Stimulator is a tool for performing electrophysiological studies either in the clinic or the research lab. The EP-4™ Cardiac Stimulator has many features that simplify the execution and documentation of stimulation protocols.

Stimulation Module

The EP-4™ Cardiac Stimulator consists of an AC line powered stimulation module, a touch screen computer, and a keyboard. The stimulation module contains the microprocessor circuitry that controls the intensity and duration of two or four isolated stimulation outputs.

The output stimuli can be synchronized to the intracardiac signals or external signals. This signal is also used to report spontaneous heart rates and to provide suggested pacing cycle lengths for the overdrive and other protocols.

WARNING

The EP-4™ Cardiac Stimulator function is not guaranteed to be uninterrupted or error free.

St. Jude Medical offers several programs that warrant the EP-4™ Cardiac Stimulator to operate according to specification however there is no guarantee that the device will do so in all circumstances, over an indefinite period of time. Should the EP-4™ Cardiac Stimulator begin to operate outside of its specifications it could potentially fail to stimulate or unintentionally stimulate the patient; to avoid injury to the patient the EP-4™ Cardiac Stimulator and the patient must be observed for abnormal function of the device at all times while connected to the patient.
In case of recurrent or persistent unexplained life-threatening ventricular tachycardia or ventricular fibrillation occurring despite cardioversion/defibrillation during the use of the EP-4™ Cardiac Stimulator, disconnect the patient from the device and all other equipment. If micro-electrocution or recurrent DC current stimulation are detected, immediately disconnect patient at the intra-cardiac electrode catheter connectors on the front panel of the device.

WARNING

Do not stimulate any output channel connected directly to another device delivering energy to the patient.

To avoid possibility of unintended arrhythmia induction, do not stimulate the heart via a catheter during direct application of RF energy, internal cardioversion, electrocautery, or any other energy source on the stimulating output channel. Efficacy and potential for adverse effects during stimulation while connected to other energy radiating devices have not been established.

PRECAUTION

The EP-4™ Cardiac Stimulator is not a life support device – Operator must have available backup temporary external pacemaker.

The EP-4™ Cardiac Stimulator is intended for provocative stimulation of the human heart during diagnostic electrophysiological procedures. The EP-4™ Cardiac Stimulator is not intended or designed for use as a life support device. The EP-4™ Cardiac Stimulator has built-in emergency stimulation functionality for the purpose of immediate interim pacing in the event the device ceases to operate as specified or, in the presence of life-threatening bradycardia or asystole, until temporary external pacing can be established.

The EP-4™ Cardiac Stimulator is used in procedures, during which intentional or unintentional induction of potentially dangerous cardiac arrhythmias is likely to occur. The EP-4™ Cardiac Stimulator must only be used by appropriately qualified and experienced personnel in appropriate facilities and in conjunction with adequate safety equipment.

WARNING

Do not use this system on a PATIENT with an implanted electronic device (for example a cardiac pacemaker) unless specialist medical opinion has first been obtained.

WARNING

Simultaneous connection of a PATIENT to a high frequency surgical equipment may result in burns at the site of the catheter electrodes and possible damage to the stimulator.

WARNING

Operation in close proximity (i.e. 1m) to a shortwave or microwave therapy equipment may produce instability in the stimulator output.

WARNING

Application of catheter electrodes near the thorax may increase the risk of cardiac fibrillation.

WARNING

Current densities for any catheter electrodes exceeding 2 mA r.m.s./cm^2 may require the special attention of the user.

WARNING

The system may serve for clinical use only after it has been fully tested and approved according to standard St. Jude Medical procedures.

WARNING

The EP-4™ Cardiac Stimulator and its peripherals/accessories comply with IEC 60601-1-2 for EMI/EMC. However, since it produces and detects low level patient signals, other radiating devices may interfere.

WARNING

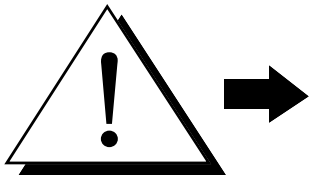
When connecting the EP-4™ Cardiac Stimulator or its components to any other device or system, verify proper operation before clinical use. Accessory equipment connected to the EP-4™ Cardiac Stimulator interface(s) must be certified according to the respective IEC standards, i.e. IEC 60950 for data processing equipment or IEC 60601-1 for electro medical equipment. All combinations of equipment must be in compliance with IEC 60601-1-1 2nd edition or 60601-1 3rd edition clause 16 systems requirements. Anyone connecting additional equipment to the signal input or output connectors configures a medical system, and therefore, is responsible that the system complies with the requirements of the system standard IEC 60601-1-1 2nd edition or 60601-1 3rd edition clause 16.

WARNING

Use only St. Jude Medical approved accessories, cables and peripherals. Use of non-approved accessories can degrade the system performance and compliance to safety, emissions and immunity standards.

WARNING

Interconnecting cables are subject to abuse if laid on the floor. Precautions must be taken to dress cabling to prevent damage.



CAUTION

This device and accessories should be recycled according to local and nationally laws after useful life.

WARNING

To avoid electrical safety hazard, check grounding reliability periodically.

WARNING

The EP-4™ Cardiac Stimulator system must be installed and setup by authorized St. Jude Medical personnel only.

WARNING

Service must be provided by qualified St. Jude Medical Personnel only. SJM shall be released from all obligations under its warranty if repairs or modifications are made to the Product by persons other than St. Jude Medical's service personnel.

PRECAUTION

The power cord is the main disconnect to the EP-4™ Cardiac Stimulator and the touch screen display. To disconnect the mains power, unplug the power cord. The device should be positioned such that access to the power cord connection is unobstructed.

Operating the EP-4™ Cardiac Stimulator

The EP-4™ Cardiac Stimulator is operated by pressing command keys on the keyboard or buttons on the touch screen computer. The operator is in close proximity to the touch screen and keyboard. Stimulation parameters (such as the stimulus duration) are displayed on the touch screen computer. These stimulation parameters are easily modified using the touch screen or keyboard and are stored on the computer hard drive. After an initial setup, most protocols will require very little changing of their parameters.

The EP-4™ Cardiac Stimulator offers all the power of a computerized stimulator yet its unique interface avoids complex commands. Stimulus patterns are controlled simply by changing parameters on the touch screen computer.

Symbols and Indicators Used on the System

The following sections list the symbols and indicators used on the EP-4™ Cardiac Stimulator and their meanings.

Read Instruction Manual

This is a general indication to notify the user to read and understand the instruction related to this component before operating this device.

Operator Training

The operator must be knowledgeable of the techniques of cardiac bradycardia and tachycardia stimulation. The operator must read and understand this manual before

operating the device. The operator should also be proficient at operating the emergency stimulation function on the front panel.

Front panel

The stimulus outputs, power switch and the associated indicators are conveniently located on the front panel of the stimulation module shown in Figure 1-1.

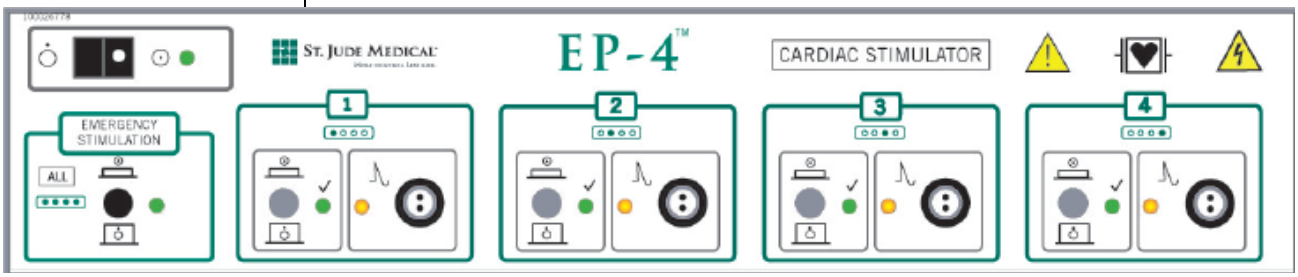


Figure 1-1 – EP-4™ Front Panel (4 channel version)

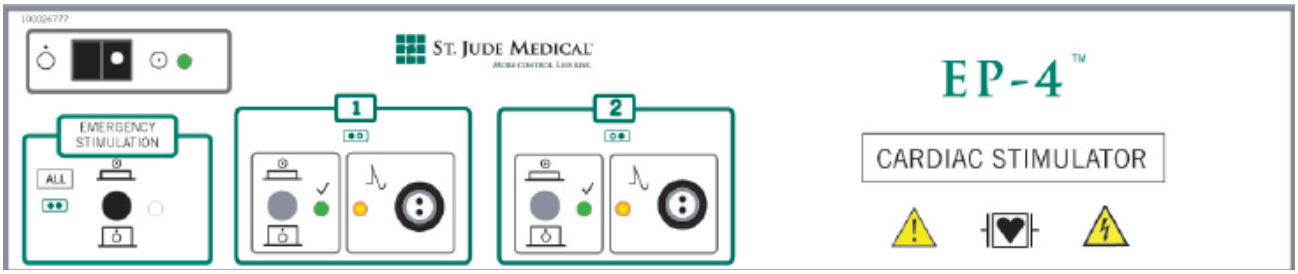


Figure 1-2 – EP-4™ Front Panel (2 channel version)

Power switch and Indicators

The left of the front panel contains the power switch and power ON green LED indicator. In the **ON** position the LED is illuminated. The power switch connects the stimulation module to AC power. In the **OFF** position the main power is disconnected and the LED is dark. Note that there is a power switch on the back panel.

IMPORTANT

The power switch turns the unit OFF if rapid termination of all pacing from all channels is required.

WARNING

Do not stimulate any output channel connected directly to another device delivering energy to the patient.

WARNING

The output of the EP-4™ Cardiac Stimulator delivers potentially harmful voltage and current that will, if programmed to, exceed 10 milli-Amperes and 10 Volts DC output on each channel.

Output switches and indicators

Along the front panel, the stimulation module outputs are turned ON and OFF using an output switch. There are two or four gray output switches and one black EMERGENCY STIMULATION button. There are two or four green LEDs associated with each channel which indicate when each output has been enabled. There are two or four amber LEDs on the front panel to indicate that pacing has been initiated and voltage may be present at the output connector. The output switches, which are normally left ON during clinical use, provide a means to physically disconnect the patient from the stimulator. The output is enabled when the gray output button is pressed in.

When the amber LED is flashing it indicates that output is present when the output switch is turned ON and the Green LED is turned ON.

EMERGENCY STIMULATION **BUTTON**

The EMERGENCY STIMULATION button is used to provide constant pacing to the patient through the output of all channels. This output is a 1000 msec cycle length, 10 mA pacing signal that is activated when the black button is pressed. This pacing function is described in detail in later sections in this IFU.

When the EMERGENCY STIMULATION function is activated, there is a green LED to indicate that the black EMERGENCY STIMULATION button has been depressed.

WARNING

The EMERGENCY STIMULATION button enables potentially hazardous voltage to be presented to all output channels without the use of controlled setup. When the EMERGENCY STIMULATION button and any of the channel output buttons are pressed in, output is delivered through the channel connectors as soon as the device is AC powered.

Potentially Dangerous Output Voltage: This indication notifies the user about potentially dangerous output voltage on the output connectors. The user is to read and understand the instruction related to this component before operating this device.

Defibrillation Protected: All patient connections are electrically isolated and equipped with a defibrillation-protected circuit.

CAUTION: This cautionary note informs the user of this device to allow only qualified personnel to service this unit.

The EP-4™ Cardiac Stimulator has no field serviceable internal parts. If service is required contact St. Jude Medical Technical Support in the United States at 1-800-374-8038.

Cardiac Stimulator

ON: Standby Power

ON: Stimulus Output Channel

OFF: Stand By Power

OFF: Stimulus Output Channel

Emergency Stimulation: Provides fixed stimulus pulse train output to all channels that is a 1000 msec cycle length, 10 mA pacing signal that is activated when the black button is pressed.

Channel One: Device output Channel (1)

Channel One: Device output Channel (1)
(On a two channel unit)

Channel One: Device output Channel (1)
(On a four channel unit)

Channel Two: Device output Channel (2)

Channel Two: Device output Channel (2)
(On a two channel unit)

Channel Two: Device output Channel (2)
(On a four channel unit)

Channel Three: Device output Channel (3)

Channel Three: Device output Channel (3)

Channel Four: Device output Channel (4)

Channel Four: Device output Channel (4)

All Channels: Applies to all output channels of the device.

All Channels: Applies to all output channels of the device. (On a two channel unit.)

All Channels: Applies to all output channels of the device. (On a four channel unit.)

Stimulus output pulse: Indicates the purpose of the channel output connector

Ready: Defines associated green LED indicating the output is ready

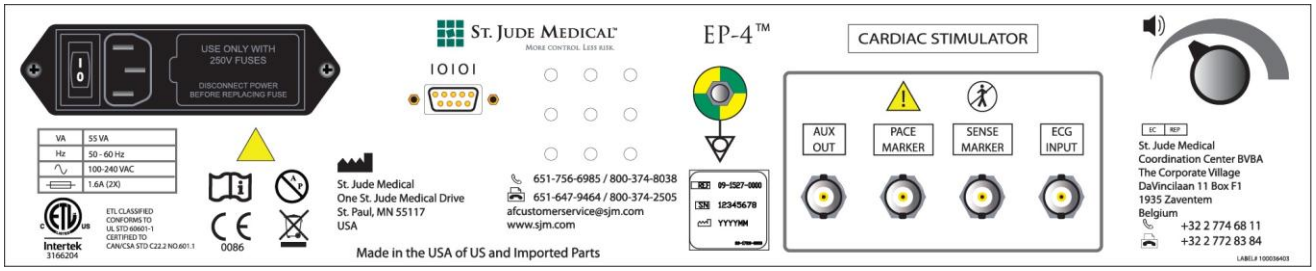


Figure 1-3 – EP-4™ Rear Panel

Rear panel

The rear panel of the stimulation module contains the connectors for the touch screen computer, the power cord, the ECG input, and three marker outputs. All these electrical connections are non-isolated.

WARNING

The ECG input, the auxiliary and marker outputs are NOT isolated. Never connect them directly to a patient.

MAINS, AC Line Power

The AC line power (100 VAC to 240 VAC) connects to the EP-4™ Cardiac Stimulator by the power input module located on the upper left side of the rear panel. A mains power switch is located next to the power input. A 10 Amp rated hospital grade power cord is provided and should be used to plug into the wall to provide power. The stimulator does not need to be un-plugged.

WARNING

The AC power cord must remain plugged in while the stimulator is in use. There is no battery backup for operation of the stimulator.

Computer Terminal Connector

The 9 pin DSUB connector in the left-center of the stimulation module back panel accepts the communication cable that connects the stimulation module to the computer terminal.

ECG Input

The ECG input accepts a signal which is used to synchronize the EP-4™ Cardiac Stimulator to an external event such as a surface ECG lead. This input is not isolated and should never be connected directly to a patient.

Sense and Auxiliary Marker Outputs

The back panel contains 3 outputs, which is used as event markers on a chart recorder. The PACE MARKER produces a pulse synchronized to the stimulus on any channel. The SENSE MARKER produces a pulse each time the ECG input detects a trigger.

The auxiliary output (AUX OUT) is used to remotely control the paper advance of a strip-chart recorder. This output can be turned ON and OFF from the keyboard.

Chassis Grounding Terminal

This terminal attaches internally to the stimulation module's case and is provided as a convenient equipotential point connection for grounding the case. This terminal can either be connected to other grounded equipment or a suitable grounding point.

Speaker Volume

This rotary knob is provided to adjust the volume of the beep tones that are emitted during various functions of the stimulator. The volume is increased by turning the knob clockwise.

WARNING

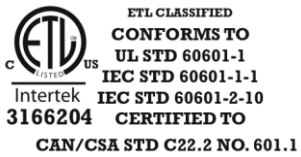
Do not connect Multiple Portable Socket Outlets (MPSO's) or extension cords to the system.

WARNING

Ground reliability can only be achieved when the power cord is connected to an equivalent receptacle marked "Hospital Grade".

Read Instruction Manual: This is a general indication to notify the user to read and understand the instruction related to this component before operating this device, particularly relative to safety.

Warning! The EP4 components are not suitable for use within Oxygen Rich Environments or in the presence of flammable gases, including flammable anesthetic mixtures with air or with oxygen or with nitrous oxide.



NRTL Certification Mark: Declaration of Conformity to the given Medical Device Standards backed by Nationally Recognized Test Laboratory.

Notified Body CE Mark

Separate collection of waste at end of life. Dispose of in accordance with the applicable country regulation.

Manufacturer

Phone

Fax

Serial Communications Port: Symbol indicates function of the adjacent connector.

REF

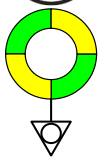
Part Number

SN

Serial Number

Date of Manufacture

Not for direct patient contact



Equipotential Post: This device is specified to operate only with a medical grade grounded power cord.

Should the user elect to utilize additional grounding to the device, this post provides a central equipotential connection post.

CARDIAC STIMULATOR

Cardiac Stimulator

AUX OUT

Auxiliary Output Connector: 20ms, 9V digital output to drive paper tape device.

PACE MARKER

Pace Marker Output Connector: 1ms, 5V digital output to indicate pulse output from the device.

SENSE MARKER

Sense Marker Output Connector: 20ms, 5V digital output to indicate sensed input to the device.

ECG INPUT

ECG Input Connector: 0 - 0.500V digital external sense input.

Speaker Control: Indicates purpose of the adjacent knob.

Volume Control: Indicates effective function orientation of the adjacent knob.

European Union Representative: Authorized representative in the European Community

Symbols and Indicators Used on the Product Packaging

The following section lists the symbols appearing on the product packaging to indicate handling and environmental considerations:

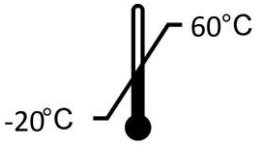
This End Up

Fragile

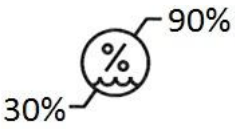
Keep Dry

Package Contains 1 Item

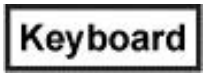
Do Not Use if Package is Damaged



Temperature Limitation



Humidity Limitation



Keyboard

Touch Screen Computer	**Touch Screen Computer**
Touch Screen Stand	**Touch Screen Stand**
	**Caution**
	**Consult Instructions for Use**
Rx ONLY	**US Federal law restricts this device to sale by or on the order of a physician.**

EP-4™ Cardiac Stimulator Components

The touch screen computer is connected to the stimulation module by a USB to serial converter (for an Advantech touch screen) or by a serial communication cable (for an ELO touch screen). For information about the power button, see the next section, "Touch Screen Power Button and Other Connections."

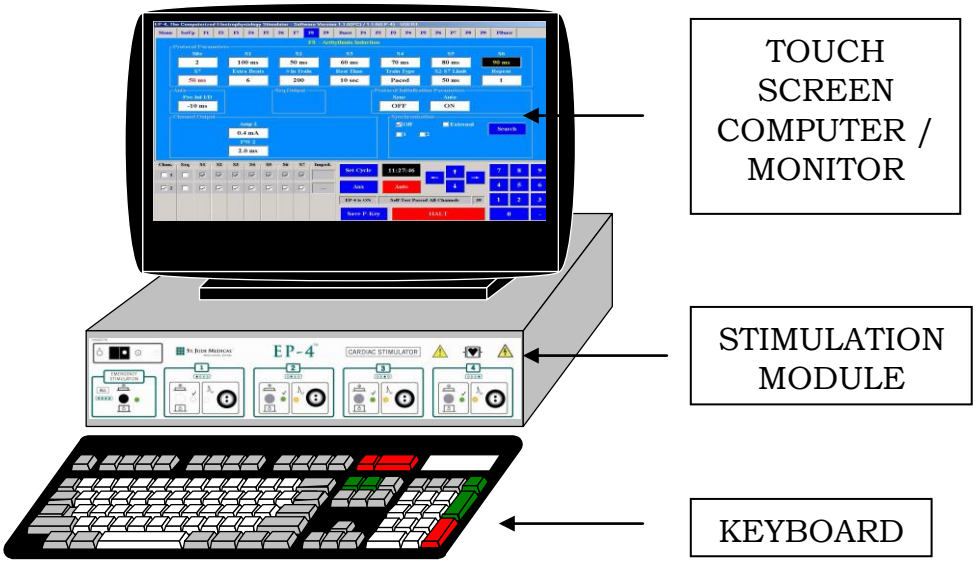


Figure 1-4 – EP-4™ Cardiac Stimulator Components

The touch screen computer should always remain attached to the stimulation module. The power cords of the monitor and the stimulator should be connected to the wall outlet using the power cords provided with the unit.

The keyboard has color coded keys that activate various functions on the stimulator. The keyboard has an adjustable pivoting base. A cable connects the keyboard to the touch screen computer.

WARNING

Care should be taken to avoid spillage of liquid onto the keyboard. This could cause the keyboard to become inoperable during use. Use a plastic shield if there is a chance of this happening in your environment.

Touch Screen Power Button and Other Connections

This section describes the touch screen power button and connections for the Advantech touch screen. If you have an ELO touch screen, see the next section, "ELO Touch Screen."

The touch screen power button (see E on Figure 1-6) and other connections are located at the back of the touch screen monitor (see Figure 1-5). When the touch screen is in an upright position, these connections are hidden from view.

Figure 1-5 – Advantech Touch Screen (back view)

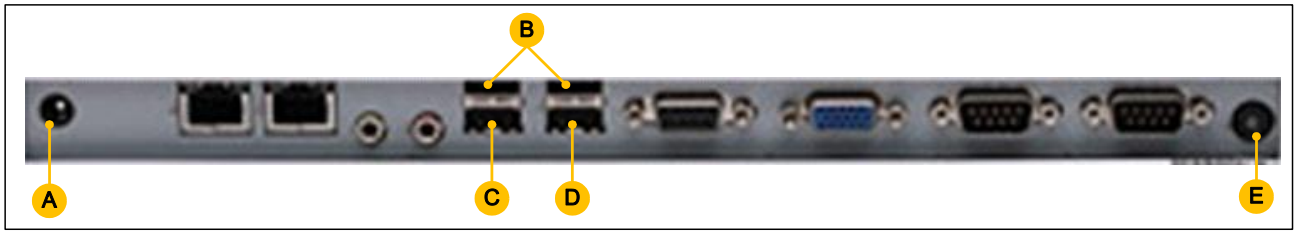


Figure 1-6 – Advantech Touch Screen connections

Advantech Touch Screen Connections (Figure 1-6)

A = Power input
B = Keyboard cable connection (either one can be used)
C = COM1
D = COM2
E = Power button

ELO Touch Screen

If you are using an ELO touch screen, the power button is located at the right side of the touch screen (A on Figure 1-7).

Figure 1-7 – ELO Touch Screen Power Button

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2

Installation

This chapter explains how to set up and connect the EP-4™ Cardiac Stimulator. A typical laboratory configuration of stimulation and recording equipment is shown in the second part of the chapter.

WARNING

Special attention must be given to proper grounding and electrical safety. Even small chassis leakage currents passing through the heart can induce fibrillation. A functioning defibrillator should always be available.

Do not connect any of the EP-4™ Cardiac Stimulator isolated connectors to non-isolated or grounded items. Do not connect any non-isolated EP-4™ Cardiac Stimulator connectors to patient isolated items or the patient.

Initial Setup

Before you install and apply power to the stimulator, visually inspect all the stimulator's components for possible damage to connectors, display screen, surfaces, etc. If you discover any damage, immediately notify the shipping carrier. Save the shipping containers and packing material for reshipment (if required).

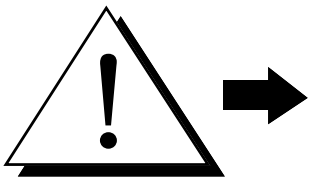
Set up of the EP-4™ Cardiac Stimulator only takes a few minutes. See instructions in this IFU for immediate use. More detailed information on interfacing the EP-4™ Cardiac Stimulator to other instruments is provided in the appendices in the back of this IFU.

Component Placement

- Place the stimulation module on top of a table.
- Place the computer / monitor base on top of the stimulator, ensuring the cable inputs in the rear can be reached.
- Place the keyboard in front of the stimulator on the table.

WARNING

Special attention must be given to component placement to ensure the EP-4™ Cardiac Stimulator cannot fall or be knocked over during a patient procedure.



PRECAUTION

The power cord is the main disconnect to the EP-4™ Cardiac Stimulator and the touch screen display. To disconnect the mains power, unplug the power cord. The device should be positioned such that access to the power cord connection is unobstructed.

"Chassis Grounding" and "Front Panel Components" terminals

The chassis of the stimulation module is grounded through the power cord. It is important that the power cord remain connected at all times.

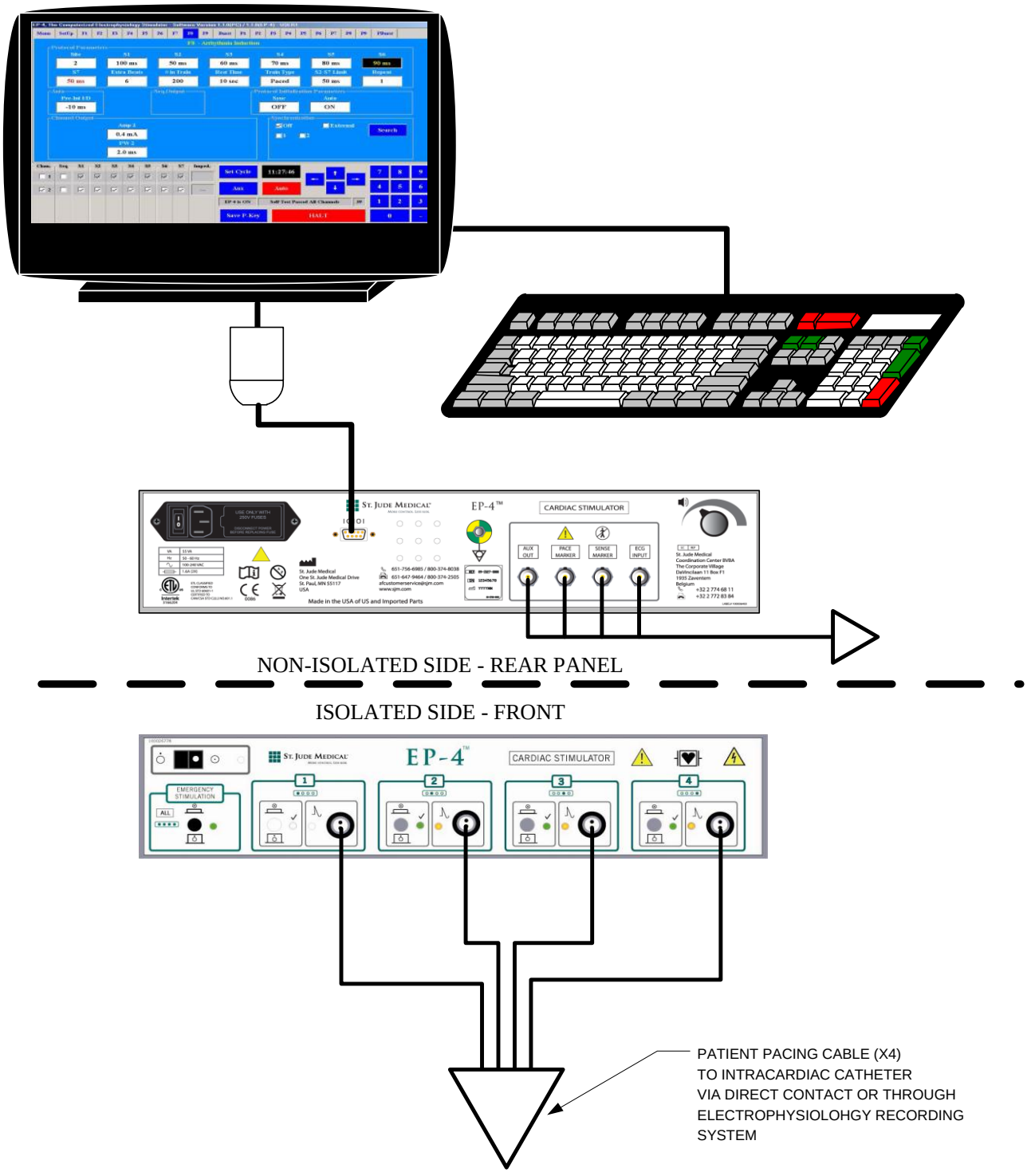


Figure 2-1 – EP-4™ Connection Diagram

Computer communication cable	• Attach the communication cable to the socket labeled "10101" on the rear of the stimulation unit and to the touch screen, via a USB to serial converter or cable. Tighten the thumb or jack screws on both sides of the serial cable.
The keyboard	• Attach the keyboard cable to the "Keyboard" connector at the back of the touch screen.
Power	• Plug the computer and stimulator into a wall outlet.

Preliminary test

- Turn ON the touch screen; the power button is at the back of the touch screen. See "Touch Screen Power Button and Other Connections" in Chapter 1.
- Turn ON the stimulation module using the power switches on the front and back panels.
- Wait until the self-test passes.
- Press the **F1** key on the top row of the keyboard followed by the **Menu** key.

The stimulator will display the F1 protocol and then the main menu.

- Turn OFF the stimulation module, the computer, and printer.

Connecting to other equipment

Connect the stimulator to a patient or recording system. A block diagram of a typical installation is shown in Figure 2-2. The maximum distance from the EP-4™ Cardiac Stimulator stimulation module to the recording system is limited by the patient cable length. See the Replaceable Parts section of the Service and Maintenance chapter for cable options.

Patient cables

The patient cable consists of a variable length flexible two conductor cable. The stimulator end is terminated by a keyed, 2-prong plug; the patient end is terminated by recessed 2mm pins.

- Insert the stimulator end of the patient cables with the white dot facing up into the stimulation channel sockets (1-4).
- Attach the patient end to the recording system or to the catheter directly.
- Use with electrophysiological diagnostic and ablation catheters.

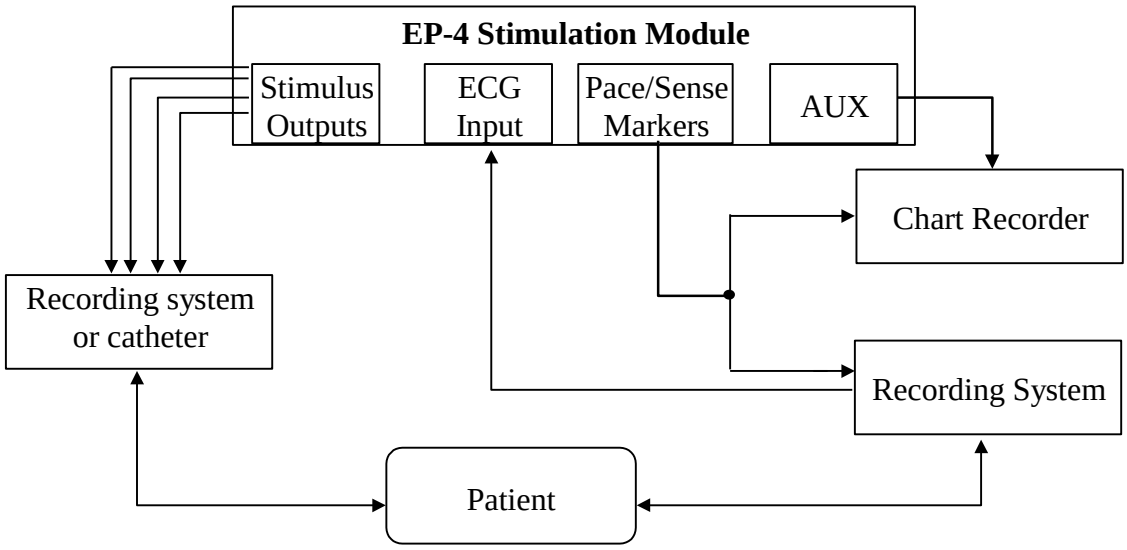


Figure 2-2 – Laboratory Setup

Sync signal

One of the features of the stimulator is its ability to synchronize a stimulus train to an external event, usually obtained from a surface ECG lead. Any signal with a peak amplitude in the 0.1 to 500 mV range will produce consistent triggers.

See Chapter 4 (Synchronizing Stimulus to the ECG) for more information about setting the trigger level.

- Connect the socket labeled “ECG input” on the rear of the stimulation module to the non-isolated output of appropriate ECG amplifier with a coaxial (BNC) cable**.**

WARNING

The ECG input is NOT isolated, never connect this input directly to the patient.

Auxiliary and marker outputs

To remotely turn ON and OFF the strip chart recorder, connect the Auxiliary output to the recorder’s dedicated ON/OFF control input.

- Attach one end of a BNC cable to the circular BNC socket labeled “AUX OUT” on the rear of the stimulation module, connect the other end to the ON/OFF control of the strip chart recorder. (For example, on a Gould ES1000 use the “Partial Remote Control” socket on the back panel).

See Appendix B for more information on recorder connection.

WARNING

The Auxiliary and marker outputs are NOT isolated, never connect these outputs directly to the patient.

Frequently, it is desirable to display an artifact of the stimulus on a strip chart recorder or oscilloscope. This can be accomplished by using the marker outputs of the EP-4™ Cardiac Stimulator or by using a shunted stimulus artifact from a lead switching recording system.

- If using the first method, connect a BNC cable to the chosen marker output on the back of the stimulation module to either an isolated output ECG amplifier or dedicated marker input channel of the recording system or strip chart recorder.

To view the trigger point in reference to the input signal, connect the ECG SENSE marker output.

- Run a BNC cable from the socket labeled “SENSE MARKER” on the rear of the stimulation module to an ECG amplifier.

Appendix B describes the electrical characteristics of the marker outputs in more detail.

Component Cleaning Maintenance

All electronic hardware case components can be surface cleaned with a soft cloth dampened with a mild detergent and water. The case is not environmentally sealed and none of the components should be immersed in water.

All cable assemblies can be surface cleaned with a mild detergent and water. Do not attempt to sterilize the cable assemblies.

Excessive dust can be removed using a pressurized, oil free, air supply to blow away dust. This should be done out of the clinical environment and away from other equipment so that freed dust is not reintroduced to other devices.

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3

Tutorial

This tutorial covers the most important features of the EP-4™ Cardiac Stimulator. It will take you through the protocols and give you some experience in changing and storing values within a function. It supplements the information in the reference section of this IFU and should take less than an hour to complete. Before you start the tutorial, set up the EP-4™ Cardiac Stimulator as described in Chapter 2: *Installation.*

To start this tutorial:

- Turn ON the power button at the back of the touch screen computer (if not already ON). See "Touch Screen Power Button and Other Connections," in Chapter 1.
- Turn the power switch of the stimulation module to the "On" position using the power switches on the front and back panels. Wait for the self test to complete.
- Push the stimulus output switches to ON.

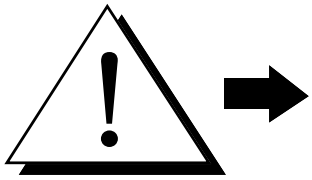
The stimulus output switches are provided as a convenient way to physically disconnect the stimulator from the patient. They are often left in the ON position during a study.

System Initialization

Each time the EP-4™ Cardiac Stimulator system is turned ON, the touch screen computer and the stimulation module perform a self-test. Turning the EP-4™ Cardiac Stimulator

OFF and ON will not initiate another self test unless it has been more than 12 hours since the last one.

The EP-4™ Cardiac Stimulator displays important messages in a message window. If at any time the stimulator is not performing, look for a message window on the screen.



PRECAUTION:

If the unit displays a self-test failure message, careful note should be taken of the channels identified. Any channel that fails self test will be inactive.

Normal operation of the EP-4™ Cardiac Stimulator is possible using any channel that has passed the self-test. St. Jude Medical recommends that users contact our technical services group at their earliest convenience to arrange for service for any stimulator unit with self-test failures.

At the end of EP-4™ Cardiac Stimulator self-test, the main menu displays.

- Turn OFF the power switch of the stimulation module.

Switching OFF the stimulation module causes a message to appear within 5 seconds.

- Turn ON the power switch of the stimulation module.

EP-4™ Cardiac Stimulator Keyboard

The EP-4™ Cardiac Stimulator keyboard contains the standard keys found on an ordinary typewriter as well as dedicated stimulation keys. The top row of keys selects either a stimulation protocol or a menu.

On the left side are the **Menu, Setup**, and **Save** keys. These are followed by 9 built-in protocol select keys (**F1-F9 and**

BURST) and 9 custom protocol select keys (**P1-P9**), a protocol select key reserved for future use (**F10/P10**), and two red emergency keys (**PGMD-BURST** and **BURST**).

Main Menu Display

Look at the main menu displayed on the computer screen. Each of the protocol select keys is listed next to the function it performs. For example, **F1** is shown next to "Threshold Determination". This indicates that the threshold protocol can be executed by pressing the **F1** key. The custom protocol keys (**P1-P9** or **Shift F1-F9**) either display the title of a modified protocol or "None" if nothing else has been stored in them.

You can return to the main menu at anytime by pressing the **Menu** key. Pressing this key will to stop stimulation and display the main menu.

Stimulus Protocols

The first selection listed on the main menu is F1, the "Threshold Determination" protocol. This protocol is designed to conveniently determine the current threshold at the selected site. The protocol is executed by pressing the **F1** key. Press F1 to execute this protocol.

- Select the Threshold Determination protocol by pressing the **F1** key.

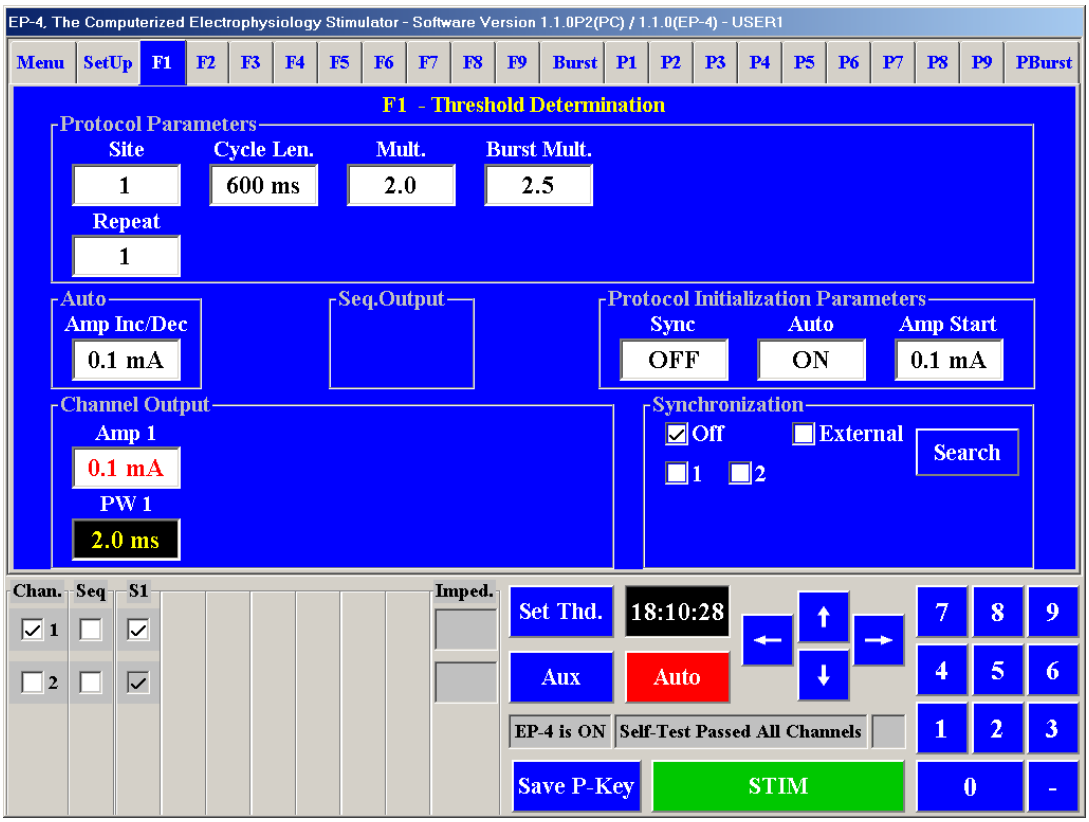


Figure 3-1 – Threshold Determination Screen

Press a protocol key to stop all stimulation and displays the selected protocol.

All the screens of the stimulus protocols have a similar layout. The title, together with the key used to invoke the protocol, is displayed on the top line of the protocol tab.

The central part of the display contains rows of boxes. These boxes are the parameters for the protocol. The parameter boxes can be considered the “dials” used to control the action of the stimulator.

The bottom left side of the screen contains check boxes that control which stimulus channels are active.

The bottom right side of the screen contains buttons for touch screen control.

Editing Parameters

Upon entering a protocol, the touch screen displays all parameters. All the protocol's parameters can be "edited" prior to and during stimulation.

The top most group of parameter boxes is the protocol parameters which are common to all the stimulation protocols. Each of the active parameter boxes has a label and a value. For example, the first parameter box has the label Site and the value "1". The 2 channel EP-4™ Cardiac Stimulator has two stimulus output channels labeled 1 and 2. The 4 channel EP-4™ Cardiac Stimulator has two stimulus output channels labeled 1 through 4.

Notice that the value "1" in the Site box is highlighted. The highlighted area is called the Edit cursor. The Edit cursor is moved from one parameter box to another by using the **Right** and **Left Arrow** keys, by pressing the left or right arrow buttons on the touch screen, or by touching a box on the touch screen.

- Press the **Right Arrow** key once.

The right arrow causes the Edit cursor to move one box to the right. You will notice that the Cycle Len. parameter box has now been selected.

- Press the **Left Arrow** key once.

Pressing the left arrow moves the cursor back to the Site box.

- Press either the **Right** or **Left Arrow** key repeatedly until you have moved the cursor through all the active parameter boxes.

Notice that there are blank areas of the screen, such as the Seq. Output field, that can contain parameter boxes. These boxes contain parameters that are irrelevant to the stimulus pattern determined by the other parameters. They will be enabled when they are active. Also notice that the parameter boxes are in a loop. Moving past the last box returns you to the first.

- Press and hold either the **Left** or **Right Arrow** key down.

The cursor moves rapidly through all the active boxes. In general, holding down a key will repeat the action of that key.

- Stop the edit cursor at the Cycle Len. box.

Changing Values

The **Up** and **Down Arrows** are used to modify the values of parameter values.

- Press the Down Arrow to alter the Cycle Len. parameter value.

The cycle length, which is the time between stimuli in this protocol, decrements by 10 msec with each press of the key. Holding down the key, repeats the decrement.

- Press and hold the **Down Arrow** key.

When the Cycle length reaches its lower limit, the parameter stops decrementing. In this case, you should see the value "100 msec".

The **Up** and **Down Arrow** keys change all the stimulus interval values by 10 msec per keystroke. Holding down the key rapidly repeats this change. For making large changes in a parameter you can use the "Shifted Arrow" keys. A *Shifted key* is typed by simultaneously holding down the **Shift** key and another key.

- Increase Cycle Len. to its upper limit by simultaneously holding down the **Shift** and **Up Arrow** key.

As you continue to hold down the **Shift-Arrow-Up**, the rate of change of the cycle length accelerates. Use the shifted arrow keys to move quickly to the vicinity of the desired value. Then use the un-shifted arrow keys to achieve the exact value.

Digit Entry

Numerical values can also be changed using the digit keys (**0–9**). This can be faster than using the arrow keys and allows interval values to be set to one millisecond resolution. To set the Cycle Len. to **539** msec, move the edit cursor to the Cycle Len. parameter.

- Press the **5** digit key.

You can use either the **5** on the numeric keypad or on the main part of the keyboard. The value of the box is rewritten with the digit "5" if you press the **5** key. The parameter flashes in different colors. This indicates that you are in digit entry mode. This also underlines a difference between arrow keys and using digit key entry. When using the arrow keys, the change of a value becomes effective immediately. In the *digit entry mode*, the value is undefined until the entry is completed by pressing the **Enter** key or the **Enter** button on the touch screen or by selecting a different parameter.

- Press **Enter**.

Press **Enter** to terminate the digit entry mode and the value is constrained to be within its programmed limits. Press **Enter** to terminate digit entry and examine the resulting value to ensure it is correct.

- Type **5**, **3**, and **9**, and press **Enter**.

(i.e. Type **5** then Type **3** then Type **9** and then **Enter**.)

The numbers are added at the least significant position and scroll to the left up to the maximum width of the value. Excess characters are dropped on the left. Press **Enter** and start again or add leading zeros to make corrections.

Now, move the edit cursor to the Amp 1 parameter box.

- Type **7** and **5** and press **Enter**.

The digits are added at the least significant position. Do not type a decimal point. To get 7.5 mA, for example, type **7** and **5** and press **Enter**.

There are some values (e.g., the current intensity increment/decrement) that can take negative values. The minus sign key **"-"** toggles the sign of a value. Also make a value negative by using the cursor arrows to move it through zero to the negative value.

- Move to the Amp Inc/Dec box and type **1**, **5**,and **-**, and press **Enter**.

This will set the value of Amp Inc/Dec to -1.5 mA. Typing additional **"-"** keys will toggle the value between "-1.5" and "1.5" mA.

Local Parameters

- Move the cursor to Cycle Len. and change the value to 550 msec using either the Arrow keys or digit entry.

- Press the **Menu** key

- Select **F1** again to get the Threshold protocol.

The Cycle Len. remained 550 msec upon reentry into the protocol. The last setting of the Threshold Cycle Len. is stored, even after the stimulator has been turned OFF. Cycle Len. is an example of a *local parameter*. Local parameters are stored in memory from one stimulator use to the next use.

Local parameters are only effective in their own protocol. For example, many protocols have their own independent Cycle Len. parameter. A change to this parameter in one protocol will NOT affect the cycle lengths of other protocols.

Most parameters are local to their respective protocols. However, a few parameters such as Amp 1 and PW 1 are *global*. Changes in these parameters are effective across most protocols. A description of each parameter and its type is given in the reference section.

- Change the PW 1 to 5.0 msec.

- Press the **F2** key.

Press the **F2** protocol select key to terminate the Threshold protocol and sets up the stimulator for the *F2 Refractory Determination* protocol. The screen for this protocol looks slightly different. The Protocol Parameters group has additional parameters. Notice that the change you made to the global PW 1 in *Threshold* show up in this protocol whereas changes in others do not. Return to Threshold.

- Press the **F1** protocol select key.

Automatic Parameters

Amp 1 has reverted to its previous value. The amplitudes in Threshold are examples of automatic parameters. Automatic parameters are initialized each time the protocol is selected. Many of the protocols have an automatic parameter. These parameters can be changed under program control and are the main variable of interest in a given protocol. For instance, in Threshold the variable is the current at a particular site, thus the Amp 1 through Amp 4 parameters are automatic.

The automatic changing of a value can be toggled ON and OFF at any time by the **Auto** key. When the automatic function is active the button color turns red.

- Press the **Auto** key several times.

The Amp 1 value turns red when the automatic mode is active. The Amp Inc/Dec parameter appears only when the automatic mode is enabled. Irrelevant information is hidden to simplify the display. The "Inc/Dec" in Amp Inc/Dec stands for Increment/Decrement. The Inc/Dec or I/D parameter in each protocol sets the magnitude of the change in the automatic value on each update.

- Select the CHAN 1 check box to turn it ON.

- Turn ON the automatic mode by pressing the Auto key on the keyboard.

- Change Amp Inc/Dec to 2.0 mA.

With this setting of the Amp Inc/Dec, Amp 1 will be incremented by 2.0 mA during each automatic update.

- Move the cursor to Amp 1.
- Press the **Up Arrow** once.
- Press **Shift**-**Arrow Up** once.

The **Up-arrow** increments the current by 0.1 mA. The **Shift–Up-arrow** increments the current by 2.0 mA. The shifted arrow up and down keys do not accelerate the change of automatic parameters as they do others, rather they change the parameter by its corresponding automatic I/D value. This feature allows the user to quickly reverse an automatic change or to skip ahead of the automatic change.

- Press the **Recall** key.

The **Recall** key reverts all the parameters of the protocols to the values entered when the protocol was first entered. Use this for repeating a particular study or undoing changes made.

- Press **Shift**-**Recall**.

Shift-Recall changes all the current protocol's parameters back to the original default values. The Cycle Len. reverts to 600 msec.

The Site Parameter

Each protocol has a Site parameter. It is possible by making an appropriate selection from the possibilities of the Site parameter, for a protocol that includes a conditioning train (Refractory Determination, Arrhythmia Induction, and Refractory Threshold) to pace on a different site during the conditioning train than from the site with the extra beats.

The possibilities for Site are:

1 Train and extras on 1 only
2 Train and extras on 2 only

3	Train and extras on 3 only (optional)
4	Train and extras on 4 only (optional)
1+2	Train and extras on 1 and 2 together
1->2	Train and extras on 1, then after Seq. Delay, 2
1 | 2	Train on 1 extras on 2
1+2 |2	Train on 1+2, extras on 2 (In F2 and F8)
1->2|1	Train Sequential, extras on 1 (In F2 and F8)
1->2|2	Train Sequential, extras on 2 (In F2 and F8)
Custom	Any other combination of channels selected with the site checkboxes in the lower left corner

Note: The sites with extra beats can only be selected in protocols with extra beats (protocols F2 and F8).

Stimulation

The green **STIM** key starts stimulation.

- Turn OFF the auto function by pressing the **Auto** key (the Auto button is not red).
- Press the green **STIM** key.

The **STIM** key starts stimulation. The protocol tab background turns a brighter color. In addition, the **STIM** button at the bottom of the screen turns RED and reads **HALT**.

- Press the Spacebar**.**

The **Spacebar** is another convenient way to stop stimulation.

Note: **Spacebar** will not stop stimulation when the EP-4™ Cardiac Stimulator is configured with an EP-WorkMate™ Recording System and touch screen controller.

The **Spacebar** has the same function as the **HALT** key. Try placing a finger of the left hand on the **Spacebar** and a finger of the right hand on the **STIM** key. Toggle back and forth between the two modes noting the differences in the display. The **Menu** key or any protocol key (**F1–F8** and **P1–P9**) will also stop stimulation.

- Start the stimulation again by pressing the **STIM** key.

- Turn ON the automatic function by pressing the **Auto** key.

Amp 1 is incremented with each stimulus and that the computer beeps with each update of the automatic value. Allow Amp 1 to increment to its maximum value. The computer will continue to beep at each update time even though the parameter limit has been reached.

- Stop stimulation by pressing the **Spacebar** or HALT keys.

Protocol Initialization Parameters

Protocol Initialization Parameters (used to initialize a protocol):

- the starting value of the automatic value,

- the starting value of the SYNC and AUTO variables, and

- other settings that modify the behavior of the protocol.

These setup values are saved in non-volatile memory. Once set, they remain in effect until changed.

The Threshold Determination Protocol consists of a series of pulses of successively higher (or lower) current strength. The pulses can be optionally synchronized to the spontaneous heartbeat.

Threshold can be determined either by starting at a high current value and decreasing it until conduction fails or beginning at a low current strength and increasing the strength. The default settings provide for increasing stimulus strength. To set the protocol for a decreasing current requires that we change the starting value for Amp 1 through Amp 4. The starting value for the current is set by the Amp Start parameter.

- Change Amp Start to 10 mA.

Changing the starting value of a parameter in a protocol initialization parameter does not affect the parameter until the protocol is selected again. Note the value of the Amp 1 parameter.

- Select Threshold by pressing **F1** again.

The Amp 1 value (and Amp 2) have now been initialized to 10 mA.

- Change the Amp Inc/Dec to -0.4 mA.

The protocol is now set to determine the threshold by starting at a high current and stepping down its value until loss of capture is seen to occur. This new setup is stored in memory when you select other protocols and when you turn OFF the device.

Sync Function

- Find and press the **Sync** key.

The Synchronization group parameters are displayed on the middle right side of the screen indicating that the SYNC function is ON. The SYNC *variable* has been set to ON. The Cycle Len. is removed from the screen and the cycle length is changed using the Synchronization parameter Delay. With the SYNC function ON, each stimulus will be produced after a trigger is detected. The delay is determined by the "Delay" setting in milliseconds. The SYNC setting is only meaningful when an ECG signal is applied to the ECG input and a trigger has been established. In the Threshold protocol when the SYNC variable is ON, every other beat will be paced. When SYNC is OFF, every beat will be paced, asynchronously. In other protocols, the SYNC setting effects only the first beat in a train.

The Sync *Protocol Initialization parameter* sets the starting value for the Synchronization of the protocol. If this parameter is set to OFF, each time threshold is selected the SYNC function will be turned OFF. This initial setting can be overridden by the **Sync** key at any time. Likewise, the Auto parameter sets the initial value for the AUTO function

by setting the AUTO variable. When the AUTO variable is set to on the **Auto** button turns red in color.

The Repeat parameter selects the number of times to repeat a stimulus pattern before executing an automatic update. To increment the current every fifth stimulus in Threshold protocol, set the Threshold Repeat parameter to 5.

- Set the Repeat parameter to 5.
- Press the **STIM** key.

The **STIM** key starts the stimulation. There are now five stimuli before the current is incremented.

- Stop stimulation by pressing Halt.

Multiplier Parameter

Most users set the stimulus strength at a multiple of the determined current threshold to assure consistent stimulation. The Mult. parameter sets a value, which will be multiplied by the determined threshold to produce a default current setting for the rest of the protocols. The multiplication and the setting of the current occurs when the **Set** key is pressed. The **Set** key takes the local active threshold Amp 1 through Amp 4, performs the multiplication and transfers the result to the global Amp 1 through Amp 4 parameters.

- Turn channel 1 ON.
- Set the Amp 1 parameter to 3.0 mA.
- Set the Multiplier to 2.2.
- Press the **Set** key.

The value of 6.6 mA displays in Amp 1. Select any other protocol and the global Amp 1 sets to this value. The Threshold protocol should not be used to manually set the current strengths. Do this in any other protocol since their current parameters are truly global.

Press the **Set** key in the **F1** Threshold when the threshold is reached after pressing **HALT**.

Custom Protocol Keys

The EP-4™ Cardiac Stimulator saves its parameters in memory for later use. Some users want several versions of a protocol. For instance, users may want a version of threshold that starts at a high current and goes lower as well as one that does the opposite. The Custom protocol keys **P1-P9** saves alternate versions of a protocol.

- Take a moment and change several of the parameters in the F1 protocol.

- When you are satisfied, press the **Save** key.

A dialog box displays asking for the protocol to save to. This window prompts the selection of one of these keys to store the modified protocol to.

- Press the **P1** key.

The dialog box is removed from the screen.

- Press **Shift**-**Recall** to return the parameters to their defaults.

There are two versions of the Threshold Determination protocol that are available by pressing a single key.

- Press **P1** to see the stored Threshold Determination protocol.

"P1" displays next to the title "Threshold Determination". You can determine if you are using the parent protocol or a saved protocol.

- Press **F1** to get the original protocol.

"F1" displays next to the title and the default parameter values.

All the parameters of stored protocols are *local*. Each stored

protocol has a completely independent set of parameters. Editing values in a stored protocol does not affect any other protocol. Use the Custom Protocol keys while a study is in progress. For instance, a set of stimulator settings that induces VT can quickly be stored in one of these keys. Conversely, a pacing rate that terminates this same tachycardia can be stored in another key. With the stimulator set in this way, inducing and terminating an arrhythmia can be a matter of pressing a few keys.

These custom protocols, like all the parameters, are stored in memory. They are stored in the system when the machine is turned OFF.

To remove a stored protocol, press **Save** while in the menu display and press the key you wish to erase. "None" is assigned to that key and the prior content is erased.

A more complete description of the action of all the keys is given in Chapter 4.

4

Reference

The keyboard and the touch screen computer control the EP-4™ Cardiac Stimulator.

The keyboard has a standard typewriter layout for text entry, as well as specialized keys that control the action of the stimulator.

Protocol Select Keys

The Protocol Select Keys are located on the top row of keyboard keys. Press any of these keys to stop the execution of the current protocol and redraw the screen with the parameters of the selected protocol.

Menu Key

The **Menu** key displays the list of stimulus protocols. The protocols are selected by pressing any of the Standard Protocol Keys (**F1**–**F8** and **BURST**) or the *Custom Protocol keys* (**P1-P9**).

SetUp Key

The **SetUp** key displays the setup menu.

STIM Key

The green **STIM** key starts stimulation.

Halt Keys

The red **HALT** key, or the **Spacebar** key, immediately stops the execution of any stimulus pattern. Press **STIM** while in **HALT** mode to resume execution of the pattern.

Arrow Keys

The **Right** and **Left Arrow** keys are used to move the editing cursor from one parameter box to another. The **Up** and **Down Arrow** keys are used to change the value of the parameter at the edit cursor location.

The arrow keys automatically repeat when held down. Shifted arrow keys accelerate the action of the un-shifted key.

Auto, Aux, Sync and Search Keys

The **Auto**, **Aux**, **Sync** and **Search** keys are used to toggle the respective state of these functions. The current state of these functions is always indicated by their button colors (red is turned ON), or their field parameters.

Auto Key

The **Auto** key toggles the automatic increment/decrement function ON or OFF.

Aux Key

The **Aux** key controls the state of the Aux port located on the rear panel of the stimulation module. This port is usually used to control the paper advance on a polygraph.

Sync Key

The **Sync** key toggles the ECG synchronization feature ON or OFF.

Search Key

The **Search** key allows a search for trigger level to be made. Press this key to force the stimulator to analyze the signal connected to the ECG input and set the gain and trigger level. The average search takes about 10 seconds.

Recall Key

The **Recall** key resets all the parameter values in the current protocol to the value they had when entering the protocol. This key makes it easy to repeat a sequence of changing stimulus trains or to return the protocol to its standard form after making a temporary change.

The **Shift-Recall** key sets all the parameters in the current protocol to their default values.

Save Key

The **Save** key is used to store modified protocols. Once pressed, you will be asked to press any of the programmable *custom protocol keys* (**P1**–**P9, PGMD-BURST**). This creates a new protocol with an independent set of parameters, which can be accessed by pressing that key. Anything previously stored in that key is overwritten and the main menu display is changed to reflect the source of the stored protocol. The user may edit the names of these saved protocols. Custom protocol key parameters are completely independent, and changes do not affect standard parameters and vice–versa.

Interval Adjustment Keys

Hot keys are available for incrementing and decrementing S1->S5.

Interval	Increment	Decrement
S1	H	N
S2	J	M
S3	K	,
S4	L	.
S5	;	/

Hot keys H, J, K, L, ';', increment the S1->S5 intervals and N, M, ',', '.', '/' should decrement them.

Main Menu

After the initial power ON test sequence is completed, the Main Menu is displayed on the computer terminal screen (Figure 4-1). Select one of the protocol keys.

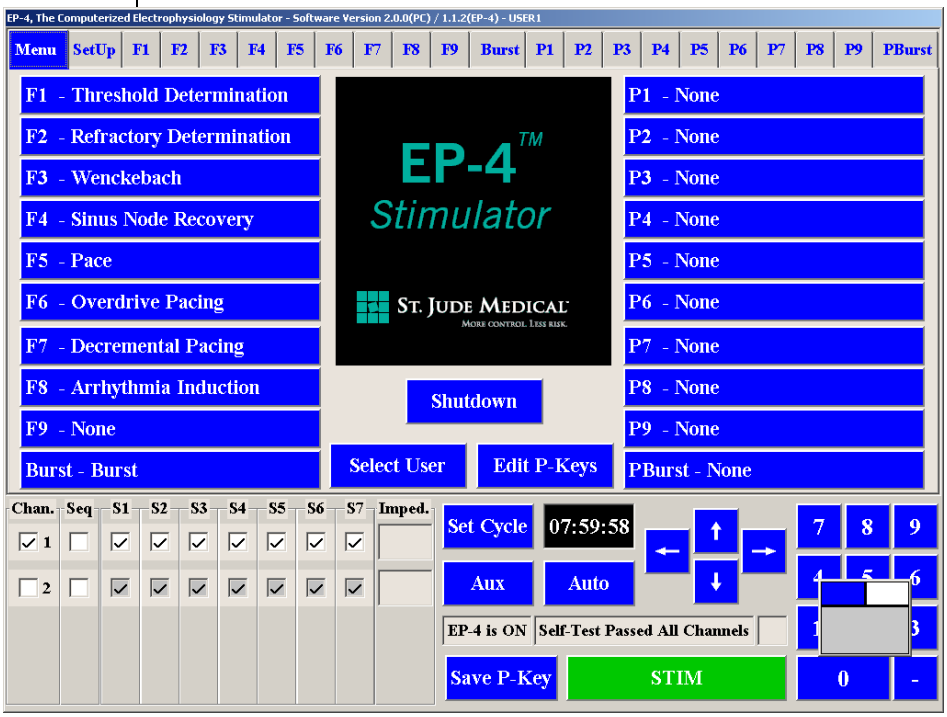


Figure 4-1 – Main Menu Display

Menu Key

The user can return to this display at any time by pressing the **Menu** key. If a stimulus protocol is executing at the time the **Menu** key is pressed, stimulation is halted and the menu displays. The left side of the menu lists the pre-programmed protocols by the key used to access them, F1-F9 and their names. The right side of the menu displays the contents of the nine custom protocol keys P1-P9.

Stimulus protocols are selected from the menu by pressing the key or button (F1–F9, P1–P9, PGMD-BURST, BURST) corresponding to the protocol desired.

Protocol Keys

The Protocol Select keys (**F1**–**F9**) have been preprogrammed for a particular stimulus protocol (e.g., F1; Threshold Determination). The initial parameter values of cycle length, current strength, etc. can be changed by the user. In general, parameter changes made by the user are stored in memory and remain in effect even while the machine is OFF. An alternate set of parameter values for a protocol may be saved in the Custom Protocol keys (**P1**–**P9**). A stimulus protocol stored in a Custom Protocol key behaves like the parent protocol but with different values of parameters.

Custom Protocol Names

The titles of the 9 custom protocols can be modified and saved. While in the Menu display, press the **Edit P-Keys** button to allow the keyboard to edit the title of any stored protocol. The text edit keys, arrow keys, and backspace are used to move to and to change the title. If nothing is stored in a particular custom protocol key, the name reverts to "None". The names given are displayed at the top of the protocol tab when the protocol is selected.

Using this feature can help avoid confusion when more than one version of the same protocol has been saved to the "**P-keys**".

Emergency Keys

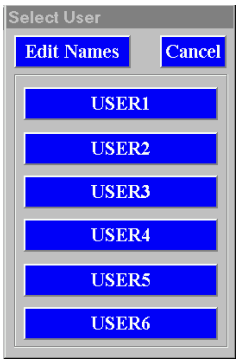
Two of the Protocol Select keys (**PGMD-BURST** and **BURST**) are called *Emergency keys* and are red.

SetUp Key

Press the **SetUp** key to display the SetUp menu. The SetUp menu contains selections, such as trigger level adjustment and beep tones. Press a digit key corresponding to the preferred function from the SetUp menu.

Select User Button

The touch screen computer saves up to 6 different users' programmed protocols and their settings. Press the **Select User** button to display the following window.



Select any of the user buttons to load the protocols and settings for that user.

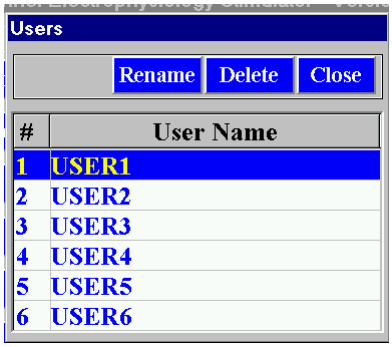
The default user names are USER1 through USER6. The user names are up to 19 characters consisting of any keyboard character.

User names are displayed in the title caption bar at the top right corner of the touch screen display.

NOTE: This is not a security feature. No passwords are required. User names are not hidden.

Edit Names

When selecting the **Edit Names** button, the following dialog box displays.



Rename Button

Select the **Rename** button to display an edit box to change the text. A new user name of up to 19 characters consisting of any character is allowed.

Delete Button

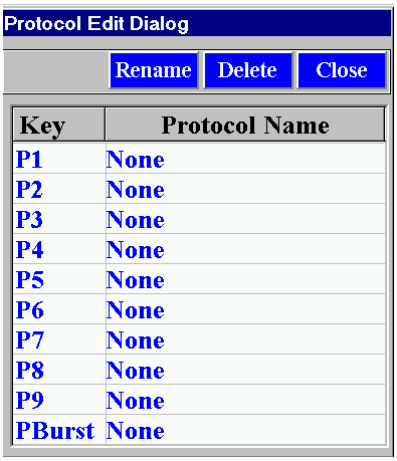
The **Delete** button changes the user name to USER1 through USER6 and removes the user's custom protocols.

Close Button

The **Close** button closes the dialog box.

Edit P-Keys Button

The touch screen computer saves programmed protocols and their settings on the hard drive. Press the **Edit P-Keys** button to display the following window.



The EP-4™ Cardiac Stimulator stores up to 10 P-Keys for **P1-P9, P-BURST** (Shift-F1 through Shift-F9) containing any programmed protocol and settings.

P-Key names are up to 39 characters consisting of any keyboard character.

	The default P-Key name when not stored is “None”.
Rename Button	Select the **Rename** button to display an edit box to change the text. A new user name of up to 39 characters consisting of any character is allowed.
Delete Button	The **Delete** button changes the user name to None.
Close Button	The **Close** button closes the dialog box.

Shutdown Button

The **Shutdown** button will halt the application and prompt you to turn OFF the touch screen PC computer.

If the EP-4™ Cardiac Stimulator is still turned ON, it will prompt you to turn it OFF first before continuing to shut down the computer.

Protocol Screen Format

A protocol screen is divided into areas containing parameter fields, controls, and information.

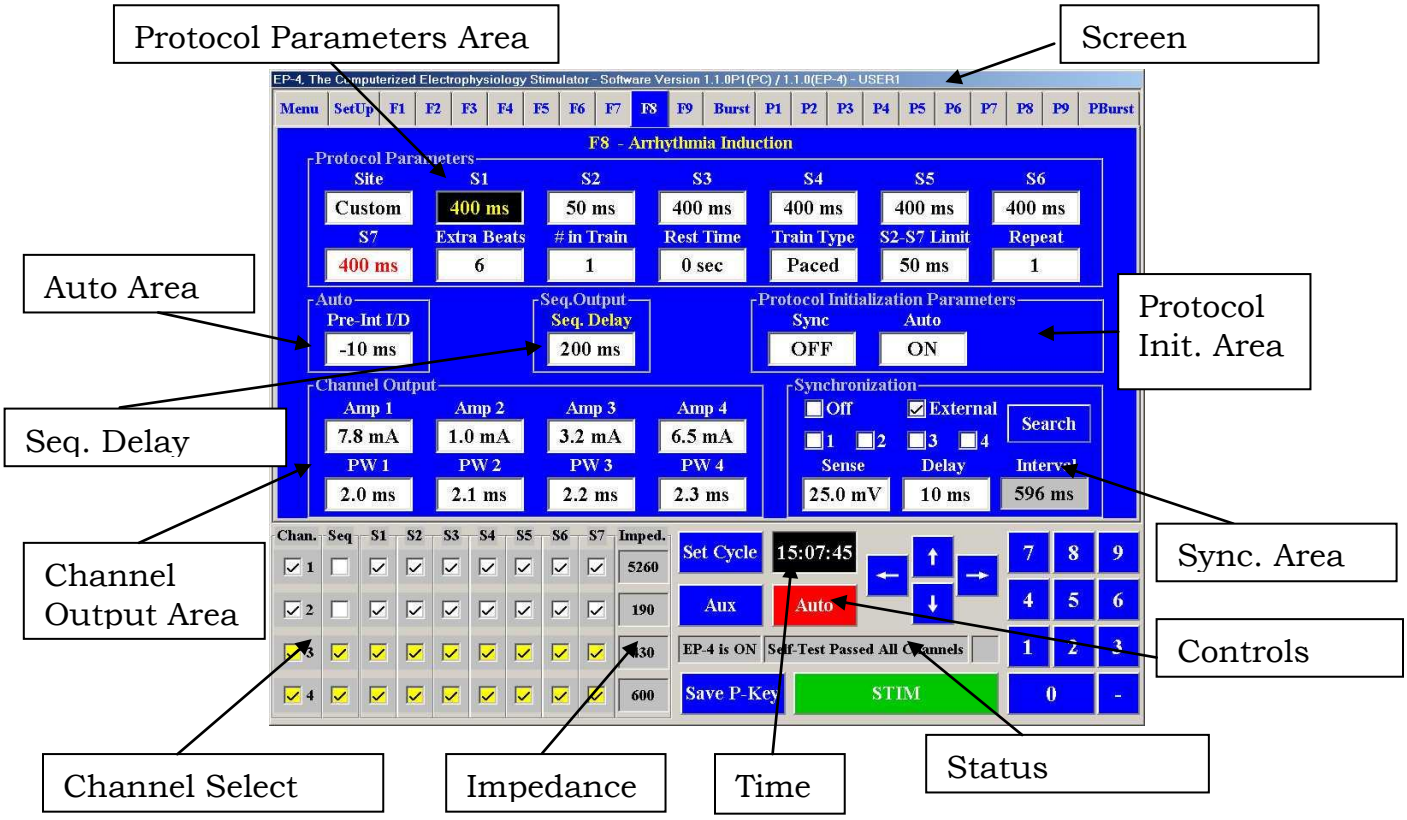


Figure 4-2 – EP-4™ Display Screen

Screen Header

A screen header is present (after the system initialization screen) during EP-4™ Cardiac Stimulator operation. The header will contain the software version and the user name.

Protocol Initialization Area

The Protocol initialization parameters area displays dialog boxes containing the parameters for the selected protocol. The active parameters for each protocol are displayed in the following chart. Changes to these parameters only take effect the next time the protocol is selected.

The protocol initialization area contains items formerly found in the EP-3™ Clinical Stimulator background edit screen that controls the initialization of Protocol Parameters. This area is protocol specific and the contents vary from protocol to protocol.

Protocol Name	**Active Parameters**
Threshold Determination	Sync., Auto, Cur. Start
Refractory Determination	Sync., Auto
Wencheback	Sync., Auto
Sinus Node Recovery	Sync., Auto, C.L. Start
Pace	Sync.
Overdrive Pacing	Sync., C.L. Start
Decremental Pacing	Sync., C.L. Start
Arrhythmia Induction	Sync., Auto
Burst	Sync

Synchronization Area

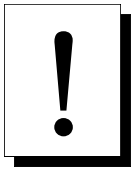
The synchronization area displays the channels in which synchronization with ECG can be chosen. When synchronization input channel is chosen, the sense, delay, and interval controls are activated. The sense control displays the variable for ECG sensitivity, the Delay control is the delay from the ECG before firing, and the interval is the interval the ECG is sensed.

Field Title	**Description**	**Dependencies**	**Default**	**Allowed Values**
Sense	Sensing Level in mV	Only when a SYNC channels is chosen.	2.5mV	0.1-10mV in steps of 0.1, 11-500mV in steps of 1
Delay	Between trigger and initiation of pacing train	Only when a SYNC channels is chosen.	500 msec	10-5000 msec in steps of 1

Controls Area

The Controls Area has buttons that mimic the functionality of the keys on the keyboard.

The Button area contains the keypad, the **Up**/**Down**/**Left**/**Right Arrow** keys, and control buttons. The arrow buttons control the increase/decrease of the active control. The keypad allows values to be entered in the active control. Select the **Set Beeps** button to display a dialog box, which displays the tone controls for the channels. The **Save P-key** button saves the changes made to the P-keys.



IMPORTANT

As the up/down/left/right arrow keys are pressed, the parameter fields are updated. This will reset some fields such as **Rest Time** and **# in Train** during a pacing train. When the fields are reset, the timing starts over. Thus constantly adjusting the **Rest Time** will extend it indefinitely until the arrow keys are left alone at which time the rest time will start.

Select the **Auto** button to activate the auto area control for the protocol. Select the main **Menu** button to display the protocol name dialog box where the names of the protocols can be changed. The **STIM** button starts the EP-4™ Cardiac Stimulator pacing in the active protocol. The error display indicator displays system errors.

Set Cycle Button	This is the same as the **Set** key on the keyboard.
Save P-Key Button	This is the same as the **Save** key on the keyboard.
Arrow Buttons	These are the same as the keyboard arrows (except holding them down does not scroll as the keyboard does).
Number Pad Buttons	This is the same as the number pad on the keyboard.
STIM/HALT Button	This is the same as the **STIM** and **HALT** keys on the keyboard.
Auto Button	This is the same as the **Auto** key on the keyboard.

Aux Button | This is the same as the **Aux** key on the keyboard.

Status Message

The status message displays the state of and any errors for the EP-4™ Cardiac Stimulator as they occur.

EP-4™ Cardiac Stimulator status messages include whether the EP-4™ Cardiac Stimulator is ON or OFF and any errors that may occur.

The stimulation train pulse and rest time counter also displays in the status area.

Time

The lower middle section of the screen contains the current time of day. An elapsed time clock can also be displayed. The elapsed time function is activated by pressing the **Timer** key located on the right side of the keyboard or by pressing the time window on the display.

The time parameter contains the current time of day in the format HH:MM:SS and is incremented every second.

Select the time or press the **Timer** key to display the stop watch timer dialog box below.

Start Button | The **Start** button starts the timer. The keyboard key **S** also starts the timer.

Stop Button | The **Stop** button stops the timer. The keyboard key **T** also stops the timer.

Reset Button | The **Reset** button resets the timer to 00:00:00. The keyboard key **R** also resets the timer.

Close Button

The **Close** button removes the timer dialog box from the screen. The keyboard key **C** also closes and hides the dialog box.

Set Time Button

The Set Time button allows you to enter a current time of day in the time window above it. Pressing the Set Time button again sets the system time to the numbers entered.

Impedances

All stimulation protocols measure impedance during each stimulation pulse. The impedance values are displayed next to each stimulation channel.

If the stimulus output switch is turned OFF, the impedance is displayed as **Switch**. If the switch is turned ON but the impedance value is abnormally high (>=10k Ohms), the impedance is displayed as **Cable**. The word cable in this context can mean any cable or catheter between the stimulator and the patient's heart.

Note: Impedance measurements do not occur at low stimulus amplitude (<1.0mA), pulse width output (0.5mS) or intermittent during rapid pacing trains (<100ms).

Channel Select Area

Check the box in the Channel Select Area for a site and its corresponding extra-stimuli. The Channel Select Area contains a control output for impedance measurements, which are measured from the patient cables.

Provide sequential pacing in this area. More information regarding these controls is provided in the following areas.

Channel Output Area

The channel output area displays the amplitude and pulse width variables for each channel. These variable boxes are AMP 1, AMP 2, AMP 3, and AMP 4 for current and PW 1, PW 2, PW 3, and PW 4 for pulse width (stim duration).

Selecting output channels

All stimulation screens produce stimulation outputs on all available channels. The **Sites** are labeled **1, 2, 3,** or **4** (1, 2 on the 2 channel version). These sites are chosen from the check boxes located in the Channel Train SetUp Area. Check the **S1** check box for each pacing site to set the pacing train to a pacing site. Check the remaining stimuli check boxes for extra beats.

Note: The stimuli check boxes vary depending on the protocol. Both the F2 and F8 protocols have an S2 check box. In the F8 protocol, the number of stimuli check boxes depends on the number of extra beats.

The output ranges are 0.1-20.0 mA at pulse duration of 0.1-10.0 msec.

Any or all of the channels can be turned ON for any of the protocols.

Sequential pacing

Check the **Seq** box (turning the entire row yellow) to perform sequential pacing between channels. This stimulates channel 1, delays the Seq. Output Delay and then stimulates channel 2.

Extra stimulus control

Check and uncheck the S1-S7 check boxes to control parts of the stimulus train. In this example, all S1 pulses are delivered on channel 1 and the S2 is delivered on channel 2.

Extra stimulus control with sequential delay

The following screenshot illustrates how to deliver all S1 train pulses on channel 1, then sequentially pace all S1 train pulses on channel 2, and then deliver the S2 pulse on channel 2.

Sequential Delay Area

The channel output area displays the channels, in the form of check boxes, which can be sequentially fired. When a channel is selected for sequential output, a **Seq. Delay** parameter is displayed for the sequential delay (in msec) for the selected channels.

Field Title	Description	Dependencies	Default	Allowed Values
Seq. Delay	Sequential delay between primary and sequential channels	Upper limit is **Prem. Int. or Cycle Len.** For sequential channels.	100 msec	10-1000 msec in steps of 10

Auto Area

The Auto Area displays the amplitude increment and decrement for the selected protocol. To activate the Auto Area, the **Auto** button should be pressed, turning the button's color to red.

Protocol Parameter Area

The Protocol Parameters Area contains all editable protocol specific parameters. Chapter 5 describes the title and function of each parameter.

Editing Parameters

Press one of the protocol select keys to select a stimulus protocol. The select protocol displays with the protocols parameters and their current values.

Each parameter has a labeled parameter box. The current value of the parameter is shown within this box.

An empty space (no label and no value) is an *inactive parameter*. Inactive parameters contain values, which are irrelevant to the currently selected stimulus pattern. Inactive boxes are turned OFF.

Edit Cursor

The *Edit cursor*, indicated by a reverse video display of a parameter value, designates which parameter is to be changed. The Edit cursor moves from box to box using the arrow keys. Hold an **Arrow** key down to move the edit cursor through the active boxes row by row until released. Inactive parameters are skipped.

Types of Parameter Values

Parameters are classified as either *Numeric* or *Non-Numeric*.

- Non-numeric parameter values are displayed as a string of text in the parameter box. Increment or decrement these parameters with the arrow keys to change the text of these parameters. Non-numeric values also wrap. Repeated incrementing of the value returns it to the starting value. Some non-numeric parameters (e.g., Train Type) determine which other parameters will become active.

- Numeric Parameters are displayed as a decimal value in the parameter box and are changed using the arrow keys or the digit keys. Numeric parameters have maximum and minimum limits. When one of these boundaries is reached, no further change is permitted. For some parameters the boundaries depend on the value of another parameter. For example, Cycle Len. cannot be less than the C.L. Limit.

Changing Parameter Values

Left and Right Arrows and TAB key

Parameter values are changed by first moving the Edit cursor to the value with the **Right** or **Left Arrow keys** and then modified with either the **Up** or **Down** key, or the digit keys (**0**–**9**).

Up and Down Arrows

Press the **Up** or **Down Arrow** key to increment or decrement the parameter under the edit cursor. The amount of the increment is usually equal to the resolution for the parameter. For example, stimulus duration (Stim. Dur.) has an increment and a resolution of 0.1 msec. Hold the **Arrow** keys down longer than a second to repeat the increment every 0.1 sec, as long as the key remains pressed.

Shift Up and Down Arrows

To increment at a faster speed, hold the **Shift** key down while also pressing the Up or Down Arrow keys.

In contrast, automatic parameters are incremented by the value of their automatic increment when using **Shift–Arrow** keys. This allows a particular automatic setting to be skipped or repeated easily.

Digit Keys

Numeric parameters are changed while editing by using the digit keys (**0–9** and **"-"**). Press any of the digit keys while the edit cursor is positioned on a numeric parameter to start digit input. The first digit pressed redraws the value and places the character chosen in the least significant position. Subsequent input causes the value to scroll left.

Do not type a decimal point "." to enter a decimal value because each digit is added to the least significant position. For example, "1.2" would be entered by typing a "1" followed by a "2".

Digit entry mode is indicated by the parameter flashing and is terminated by pressing the **Enter** key or any other non–digit key. If the entered value is out of range, the parameter value is constrained to the limit closest to the entered value.

Press the "-" key to change the sign of the entered value for those parameters that can assume negative values.

Stimulation

After the operator confirms that the selected protocol is selected and that all the parameters for the protocol are set to proper values, start stimulation by pressing the green **STIM** key. To terminate stimulation at any time

- Press the **HALT** or **Spacebar** key, or
- Press any Protocol key (**F1–F9, P1–P9, PGMD-BURST** or **BURST**). This displays the new protocol (F9 is currently reserved for future use).

Protocols are executed without regard to the state of the output switches. If a switch is OFF at an active site, a warning message displays.

Cycle Length and S1 Priming

All protocols except Threshold can set the drive train cycle length to a percentage of the spontaneous rate (as measured from the "ECG Input" port) by pressing the **Enter** key.

The percentage used in the calculation is either the protocol parameter % Cycle Len. (in Decremental Pacing and Overdrive), or the Pacing % parameter (in all other protocols) which is set in the SetUp function "Preferences". If no triggers are being received no change is made to Cycle Len.

Automatic Parameter Changes

The EP-4™ Cardiac Stimulator automatically changes parameters while stimulating. *Automatic parameters* are automatically changed values and are displayed with the parameter value and parameter title underlined. Protocols with automatic variables also have an associated Repeat parameter. This parameter determines the number of times

a stimulus pattern repeats before it is updated or the protocol is automatically terminated.

With the Repeat set to a positive number, the stimulus pattern will be repeated Repeat number of times before a change in the Automatic parameter is made.

Automatic Termination of Protocols

With Repeat set to a negative number stimulation progresses as before but stops after each automatic update. The **STIM** key must then be pressed to continue with the protocol.

For example, to execute a sequence twice and then stop, set Repeat to "-2". The sequence repeats twice, updates the automatic value, and then stops stimulating. To execute the next two sequences (with the new updated value) hit the **STIM** key again.

With Repeat set to "0", no change is made to the Automatic parameter and the protocol behaves as if AUTO was set to OFF.

Increments or decrements of an Automatic Parameter can be made either manually or automatically. Press the **Auto** key to toggle ON and OFF the automatic feature of the EP-4™ Cardiac Stimulator.

Each automatic parameter has an associated auto increment/decrement (Inc/Dec or I/D) parameter. This parameter is only active when the AUTO feature is ON. This is indicated by the **Auto** button turning red. The automatic increment parameter is the amount the variable is changed upon each update (e.g., in the F1 Threshold Determination protocol, the amount in mA the output current changes with each stimulus). Negative values for the Inc/Dec parameter decrement the automatic parameter.

Protocols with automatic variables also have an associated Repeat parameter. This parameter determines the number of times a stimulus pattern is repeated before an update.

Synchronizing Stimulus to the ECG

The trigger is used to start stimulus patterns as well as measure the spontaneous heart rate. The measured heart rate is displayed on the status line and simplifies the setting

of Overdrive Cycle Lengths. When in STIM mode, the stimulator waits two seconds for a trigger before writing a warning to the screen and beginning an automatic search for a new trigger level. In all stimulus protocols, initiation of the stimulus pattern is synchronized to an external signal applied to the "ECG Input" socket on the rear of the stimulator or to any of the 4 stimulation channels.

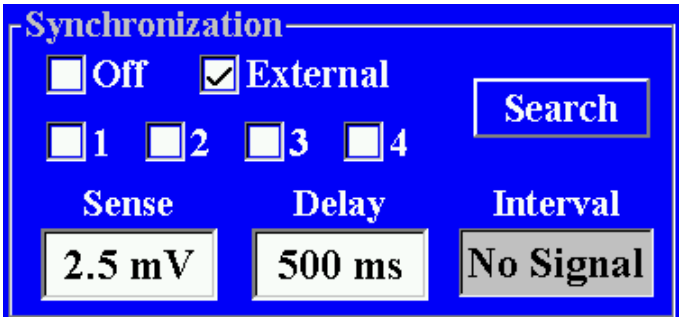
PRECAUTION

Synchronization performance can depend on the device connected to the external ECG Input on the rear of the stimulator (because of signal conditioning variability of the external device). The user should confirm synchronization performance during operation and adjust the Synchronization Sense level, Synchronization Delay, SetUp Level % parameter and the SetUp Blanking interval if necessary. Performance can be monitored by the Synchronization Interval and/or monitoring the SENSE MARKER output signal on the rear panel of the EP-4™ Cardiac Stimulator.

The Synchronization function can be toggled ON and OFF by the **SYNC** key.

Each stimulus protocol also has a Sync parameter in the Protocol Initialization Parameters, which sets the initial state of the Sync feature for each protocol upon entry to that protocol.

Synchronization is adjusted by the following controls.



Turning the synchronization function (Sync) ON means checking one of the input sources; External, 1, 2, 3 or 4. The External Synchronization option corresponds to the ECG Input connector on the back of the stimulator. Channels 1-4

are the pacing output and sensing input channels on the front of the stimulator.

When Sync is ON, a stimulus pattern starts only after the ECG input signal reaches the Sense *level* and after the Delay period. The **Search** key also automatically sets the sense level. Once the Sense level has been determined, decrease the level by 50% to ensure consistent triggering. This suggested scheme approximates what is done by the automatic search (with a Level % set to 50%).

Waiting for a sensed event is indicated on the status line by the words “No Signal” in the Synchronization Interval box. When not stimulating, this box is used to display the intrinsic cycle length of the heart once an adequate trigger signal is provided.

The Blanking time controls the minimum time between sensed events. It is used to eliminate triggering on large amplitude components of a cycle, which occurs after the peak amplitude.

When a trigger is received, the stimulus pattern starts after a delay set by the Synchronization parameter Delay.

The trigger waiting sequence is repeated for each stimulus cycle, that is, after each rest period.

The "ECG Marker" is used with the input trigger signal on an oscilloscope to see the location on the trigger signal the trigger is occurring. This is used for triggering on portions of the input signal other than the peak.

5

Protocols

This chapter describes each of the stimulus protocols in detail. Each section describes the stimulus pattern, use, and parameters for the protocol.

F1 Threshold Determination

The F1 Threshold Determination protocol is used to determine the minimum current intensity that elicits a response at a particular site of stimulation. Often a multiple of this value is used as the current intensity at that site for succeeding studies.

Selection and Setup

Press the **F1** protocol key to select the F1 Threshold protocol at any time. Pressing this key terminates any active protocol and re-draws the screen with the threshold protocol parameters (Figure 5-1).

In the Threshold protocol, any channel can be stimulated.

Note: It is recommended that only one threshold be determined at one time.

If the SYNC feature is ON (**Sync** button turns red and the Synchronization Delay parameter is active), a stimulus is applied every Delay milliseconds after a trigger is received. Every other beat is a stimulated beat once threshold has been reached. If SYNC is OFF, the Cycle Len. parameter is active and a stimulus is produced *every* Cycle Len. milliseconds.

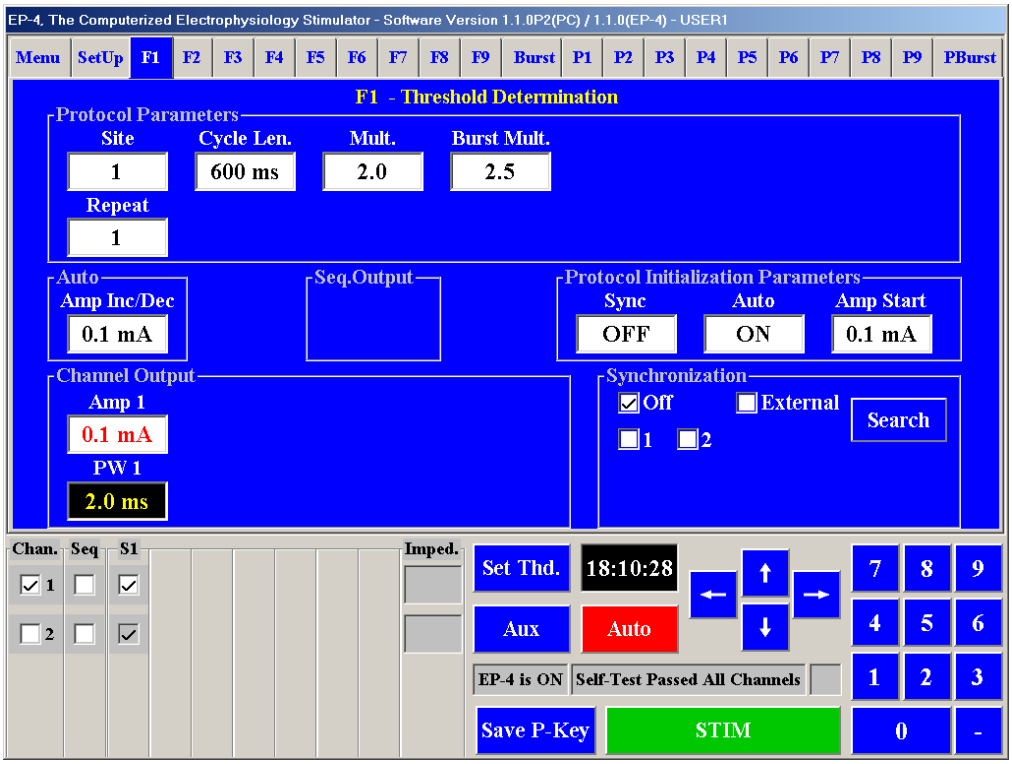


Figure 5-1 – Threshold Determination Protocol Screen

Automatic Parameter

The channel output amplitude (Amp 1 through Amp 4) is the Automatic Parameter for this protocol. If the AUTO feature is ON, indicated by the red **Auto** button, the current intensity automatically changes. The magnitude of the automatic change is set by the Increment/Decrement (I/D) Parameter, Amp Inc/Dec. A negative value for this parameter decrements the current intensity. The AUTO feature may be toggled ON or OFF at any time with the **Auto** key.

The value displayed in the automatic parameter box is the value used for the next stimulus; the display is updated before the value is used. To return to the previous value, use **Shift–Arrow** key (up or down) on the automatic parameter.

Determining a Threshold

Apply stimuli of progressively larger current intensity until a response is observed to determine threshold. Alternatively, the study may start with stimuli greater than threshold and decreasing the current. The F1 Threshold protocol can be set up for either increasing or decreasing current by adjusting the Amp Start parameter and the Amp Inc/Dec parameter. Once set, the values of these parameters remain in effect for each use of the protocol.

When all the parameters have been set to their desired value, the study is begun by pressing the **STIM** key, and ended by pressing **HALT** or the **Spacebar** key.

While stimulating, the current can be changed either manually or automatically. If AUTO is ON, (the **Auto** button color is red) the stimulus is applied Repeat times before the automatic increment.

The study progresses until the desired response is observed. Note that the EP-4™ Cardiac Stimulator *does not* determine when capture occurs. This must be done by the operator.

Press **Set** to multiply the value of the current of the active site by the parameter Mult. The resulting value becomes the starting value for the stimulus intensity for this site in subsequent studies.

As an aid to setting the currents for the Burst protocol, there is a separate Burst Mult. parameter. Press **Set** in this protocol to multiply the active current by Burst Mult. and sets the corresponding current in the Burst protocol.

NOTE: Variants of Burst saved to the "P-keys" will not be affected by pressing **Set** in the Threshold protocol.

IMPORTANT

The **Set** key must be pressed to set the default current strength for the active site. If you leave the protocol without pressing **Set**, the threshold value determined will be lost.

At this point, the threshold of any the other output channel is determined by turning the desired output channel ON, both at the front panel of the stimulator and the output

channel checkbox on the bottom left side of the display, and repeating the above procedure.

The Cycle Len. interval increments by pressing the **H** key and decrements by pressing the **N** key.

Threshold Determination Protocol Parameters

Parameter Title	Description
Site	The output channel site(s).
Cycle Len.	Conditioning Train Cycle Length
Mult.	Multiple of threshold to use in subsequent protocols
Burst Mult.	Multiple of threshold to use in Burst protocols
Repeat	# of Stimuli before changing intensity (AUTO = ON)

Threshold Determination Automatic Parameter

Parameter Title	Description
Amp Inc/Dec	Size of Current Change (AUTO = ON)

Threshold Determination Protocol Initialization Parameters

Parameter Title	Description
Sync	Start Value for SYNC variable
Auto	Start Value for AUTO variable
Amp Start	Start Value for Stimulus Intensity

F2 Refractory Determination

The F2 Refractory Determination protocol determines the shortest time after a train of conditioning beats that a response is evoked. This protocol also introduces a single extra beat at varying times after a spontaneous beat.

Selection and Setup

Press the **F2** protocol key at any time to enter the F2 Refractory Determination protocol.

Automatic Parameter

The premature interval (S2) is the Automatic Variable for this protocol. When AUTO is ON, this value is changed by Pre–Int I/D, the Automatic Increment-Decrement parameter each update.

The Refractory Stimulus Pattern

The stimulus pattern consists of a train of one or more beats followed by a single (S2) pulse. The parameter # in Train sets the number of beats in the conditioning train. The train is either paced or sensed as determined by the Train Type parameter. Premature Interval (S2) is the time between the last beat in the conditioning train and the extra (S2) beat. This is followed by an optional Rest Time and the sequence is repeated.

Determining a Refractory Period

Press the **STIM** key to start the protocol. If SYNC is ON, the stimulator waits for a trigger before starting each paced conditioning train. If the Train Type is SENSED the stimulator waits for # in Train triggers before introducing a single S2 pulse.

If AUTO is ON, the train and extra beat are repeated Repeat times before Pre–Int I/D is added to Premature Interval. The Pre-Interval can also be manually changed at any time.

The study progresses, altering the time of the S2 beat until capture or lack of capture is seen to occur.

Hot Keys

The S1 interval can be incremented by pressing the **H** key and decremented by pressing the **N** key.

The S2 interval can be incremented by pressing the **J** key and decremented by pressing the **M** key.

Refractory Determination Protocol Parameters

Parameter Title	Description
Site	The output channel site(s).
S1	Conditioning Train Cycle Length
S2	Premature Interval (S2)
# in Train	Number of pulses in conditioning Train
Rest Time	Rest period between stimulus patterns
Train Type	Sensed or Paced Train
S2 Limit	Lower limit of S2
Repeat	# of times to repeat train before auto update

Refractory Determination Automatic Parameter

Parameter Title	Description
Pre-Int. I/D	Size of Automatic Premature interval Change

Refractory Determination Protocol Initialization Parameters

Parameter Title	Description
Sync	Start setting for SYNC variable (ON or OFF)
Auto	Start setting for AUTO variable

F3 Wenckebach (Incremental pacing)

The F3 Wenckebach protocol (Incremental pacing) characterizes the conduction and refractory periods of the AV-node or for any study that requires rapid changes in pacing rates.

Selection and Setup

The Wenckebach protocol can be entered at any time by pressing the **F3** key.

Automatic Parameter

Cycle Len. is the automatic variable and C. L. Step is the Automatic increment/decrement parameter.

The Wenckebach Stimulus Pattern

The stimulus pattern consists of a train of # in Train pulses. If AUTO is ON, the train is repeated Repeat times before Cycle Len. is incremented (or decremented) by C. L. Step.

Decrementing the Cycle Length continues until Cycle Len. reaches its programmed minimum value or the **Auto** key is pressed.

The Variable Cycle Len. may also be manually changed at any time while the study is in progress.

Using the Wenckebach Protocol

Press the **STIM** key to start the protocol. If the SYNC variable is set to ON, stimulation is delayed until a trigger is received.

Progress of the study is displayed in the Cycle Len. parameter box.

The study is ended at any time by pressing the **HALT** or **Spacebar** key or any protocol key.

The parameter C.L. Limit allows a limit to be set for the Cycle Len. parameter that is higher than the built-in cycle length limitation. Setting this value prevents both manual and automatic decrements of the cycle length from going too low.

Hot Keys

The Cycle Len. interval can be incremented by pressing the **H** key and decremented by pressing the **N** key.

Wenckebach Protocol Parameters

Parameter Title	Description
Site	The output channel site(s).
Cycle Len.	Conditioning Train Cycle Length
# in Train	Number of pulses in conditioning Train
Rest Time	Rest period between stimulus patterns
C.L. Limit	Lower limit for Cycle Length
Repeat	# of times to repeat train before auto update

Wenckebach Automatic Parameter

Parameter Title	Description
C.L. Step	Size of Auto Cycle Length Change (AUTO = ON)

Wenckebach Protocol Initialization Parameters

Parameter Title	Description
Sync	Start setting for SYNC variable (ON or OFF)
Auto	Start setting for AUTO variable

F4 Sinus Node Recovery

The F4 Sinus Node Recovery protocol (SNRT) analyzes the response of the sinus node to overdrive suppression. The pulse pattern consists of a conditioning train followed by a recovery interval. The function provides for automatically decrementing the cycle length.

Selection and Setup

Press the **F4** key at any time to the Sinus Node Recovery function.

Automatic Parameter

Cycle Len. is the automatic variable and C.L. Step is the automatic increment/decrement parameter for this protocol.

Sinus Node Recovery Stimulus Pattern

The Pulse pattern consists of a train of pulses Train Dur. long, followed by a Rest Time recovery period. Changing the train Cycle Length changes the number of beats in the train.

If AUTO is ON, the cycle length is changed every Repeat trains by an amount set by the C. L. Step parameter. If SYNC is ON, each train starts Delay after a trigger.

Using Sinus Node Recovery

Press the **STIM** key to start the study. If SYNC is ON, the stimulator waits for a trigger. Automatic incrementing of the cycle length continues until it reaches its internally programmed limit or the **Auto** key is pressed.

The number of pulses in the train is computed by dividing the cycle length into the train duration. As the cycle length changes, the number of pulses in the conditioning train will change. While stimulating, the number of beats remaining in the current stimulus train displays in the status box.

The parameter Cycle Len. can also be manually changed at any time while the study is in progress.

Hot Keys

The Cycle Len. interval can be incremented by pressing the **H** key and decremented by pressing the **N** key.

Sinus Node Recovery Parameters

Parameter Title	Description
Site	The output channel site(s).
Cycle Len.	Conditioning Train Cycle Length
Train Dur.	Duration (secs.) of conditioning Train
Rest Time	Rest period between stimulus patterns
C.L. Limit	Lower limit for Cycle Length
Repeat	# of times to repeat train before auto update

Sinus Node Recovery Automatic Parameter

Parameter Title	Description
C.L. Step	Size of Auto Cycle Length Change (AUTO = ON)

Sinus Node Recovery Protocol Initialization Parameters

Parameter Title	Description
Sync	Start setting for SYNC variable (ON or OFF)
Auto	Start setting for AUTO variable
C.L. Start	Start value for Cycle Length

F5 Pace

The F5 Pace protocol drives the heart continuously at a fixed rate. The pulse pattern consists of an endless train of pulses.

Selection and Setup

Press the **F5** key at any time to enter the Pace Protocol.

There are no Automatic Variables used with this function.

Using the Pace Protocol

Press the **STIM** key to start pacing. If SYNC is ON, the Stimulator waits for a trigger. The pulse pattern consists of a train of pulses Cycle Len. Milliseconds apart.

While stimulating, the cycle length and stimulus intensity can be altered manually.

As with other protocols, press **HALT**, or **Spacebar** or any protocol key to stop the stimulus output.

Hot Keys

The Cycle Len. interval can be incremented by pressing the **H** key and decremented by pressing the **N** key.

Pace Protocol Parameters

Parameter Title	Description
Site	The output channel site(s).
Cycle Len.	Conditioning Train Cycle Length

Pace Protocol Initialization Parameters

Parameter Title	Description
Sync	Start setting for SYNC variable (ON or OFF)

F6 Overdrive Pacing

Overdrive pacing drives the heart at a rate of a fixed percentage faster (or slower) than the intrinsic heart rate. The Pulse Pattern consists of a continuous train of pulses.

Selection and Setup

Press the **F6** key to start the F6 Overdrive Protocol.

If adequate synchronization triggers are received, the Cycle Len. parameter is initialized to % Cycle Len. of the spontaneous cycle length. For example, if the measured spontaneous cycle length is 1000 msec and % Cycle Len. Value is 90%, the cycle length will be set to 900 msec.

If triggering is inadequate, Cycle Len. is initialized to C.L. Start. There are no Automatic Variables in F6 Overdrive.

Using the Protocol

Press the **STIM** key to start stimulus output. If Sync is ON, the Stimulator waits for a trigger.

Once begun, the pattern consists of a continuous train of pulses Cycle Len. milliseconds apart.

While stimulating, the Cycle Length and Stimulus Intensity can be manually altered. Press the **Enter** key to re-initialize the cycle length when changing the % Cycle Len. parameter.

Press the **HALT** key and **Spacebar** or any protocol key to stop the stimulus output.

Hot Keys

The Cycle Len. interval can be incremented by pressing the **H** key and decremented by pressing the **N** key.

Overdrive Pacing Protocol Parameters

Parameter Title	Description
Site	The output channel site(s).
Cycle Len.	Conditioning Train Cycle Length
% Cycle Len.	Set the Cycle Len. to a percent of the sensed rate

Overdrive Pacing Protocol Initialization Parameters

Parameter Title	Description
Sync	Start setting for SYNC variable (ON or OFF)
C.L. Start	If no sensed rate then use this value

F7 Decremental Pacing

In the F7 Decremental Pacing stimulus pattern, the cycle length can be automatically changed between each beat.

Selection and Setup

Press the **F7** key to select the Decremental Pacing protocol.

Automatic increment or decrement

Cycle Len. changes automatically and this is the only protocol where AUTO does not control the change;, its value is changed at each update by the parameter Unit I/D.

Decremental Pacing Stimulus Pattern

The stimulus pattern consists of a train of pulses where the inter-stimulus interval can change between each beat. The number of beats produced at each cycle length is set by the parameter. The number of times the cycle length is changed is set by the parameter Stim Units. The number of beats in a train is given by the formula:

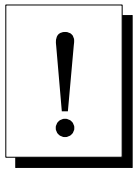
Number of beats in train = (# in Unit) X (Stim Units).

If #in Unit = 1 and SYNC is *OFF*, then there is one additional beat.

The parameter Stim Units defines the number of different Cycle Lengths produced in a train. It can be set from 2 - 99. The parameter # in Unit defines the number of pulses produced at each Cycle Length. It can be set from 1 - 100.

Using F7 Decremental Pacing

If the EP-4™ Cardiac Stimulator receives a satisfactory trigger, the Cycle Len. will be primed to a percentage of the spontaneous rate set by the parameter % Cycle Len. If no triggers are being received, the value of the parameter C.L.Start will be used. Subsequently press the **Enter** key to reset Cycle Len. If SYNC is ON, use the Cycle Len. as the delay between the trigger and the first pulse.



IMPORTANT

In F7 Decremental Pacing the delay between trigger and onset of the stimulus pattern is set by the Cycle Len. parameter. This is different than all other protocols where this delay is set by the synchronization Delay parameter.

Examples of the pulse patterns produced by F7 Decremental Pacing are shown in the figure 5-2. In these examples, Cycle Len. is set to 1000 msec, Unit I/D is set to -200 msec.

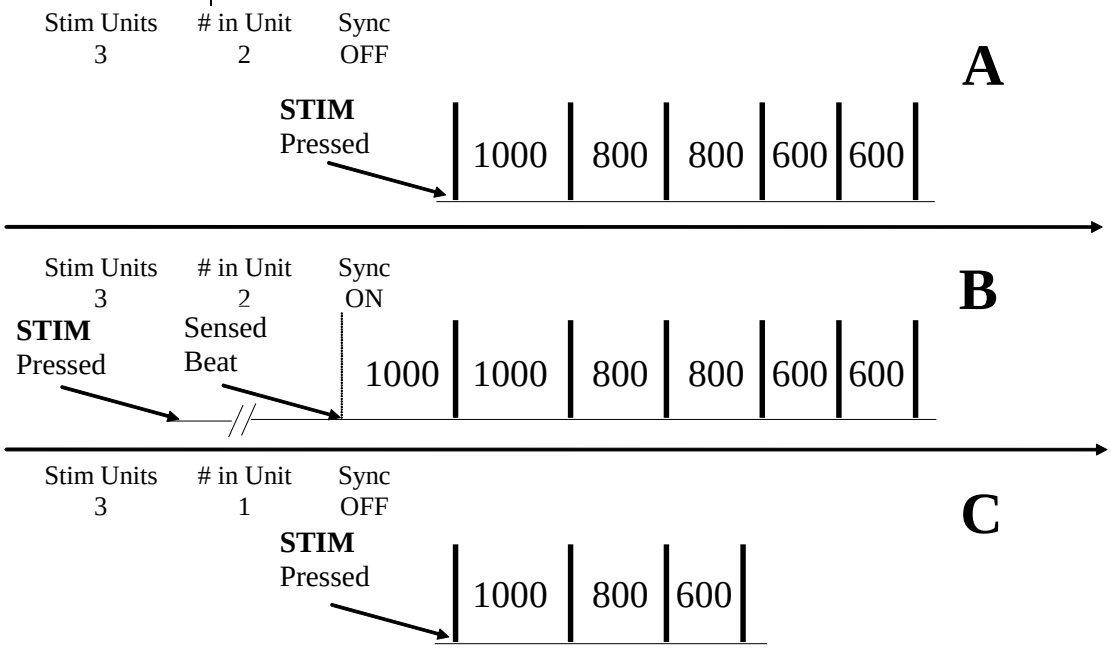


Figure 5-2 – Decremental Pacing Stimulus Patterns

In panel A, Stim Units is set to 3 and # in Unit to 2. Press the **STIM** key to start the train, a pulse is immediately produced and 1000 msec later another. The second stimulus unit with a cycle length decremented to 800 msec then starts. The last stimulus unit has a cycle length of 600 msec. The protocol automatically terminates, with the display left at 600 msec. To repeat the same train, press the **Recall** key or press the protocol key (**F7**) again.

WARNING

At the end of the protocol the cycle length is NOT reset. Pressing **STIM** again may result in very short cycle lengths. Always have the parameter C.L. Limit set. Press **Enter** or **Recall** to reset the cycle length.

In panel B, the parameters are set the same as in example A but the stimulator is in the SYNC mode (SYNC is ON). In this case, when the **STIM** key is pressed, the stimulator will wait for a trigger signal and then produce the first pulse of the train after a delay of Cycle Len. milliseconds, in this example, 1000 msec later. All other protocols use the value of Synchronization Delay rather than Cycle Len. as the time between trigger and first pulse.

Panel C shows the exceptional case of # in Unit being set to 1. After the stimulus pattern shown in the diagram is produced, the screen displays 600 msec as the cycle length.

Hot Keys

The Cycle Len. interval can be incremented by pressing the **H** key and decremented by pressing the **N** key.

Decremental Pacing Parameters

Parameter Title	Description
Site	The output channel site(s).
Cycle Len.	Conditioning Train Cycle Length
% Cycle Len.	Cycle Length Priming of spontaneous rate
Stim Units	Number of different Cycle Lengths produced in a Train
# in Unit	Number of pulses produced at each Cycle Length
Unit I/D	Size of automatic Cycle Length change
C.L. Limit	Lower limit for Cycle Length

Decremental Pacing Protocol Initialization Parameters

Parameter Title	Description
Sync	Start setting for SYNC variable (ON or OFF)
C.L. Start	Start value for Cycle Length

F8 Arrhythmia Induction

The F8 Arrhythmia Induction Protocol consists of a train of conditioning pulses followed by up to six extra beats (S2-S7). This protocol is most often used to induce atrial and ventricular arrhythmias.

Selection and Setup

Press the **F8** key to select the Arrhythmia Induction protocol.

The parameter Extra Beats determines how many (S2-S7) pulses are produced. The times for the extra beats are set independently of each other. These times are all measured relative to the previous beat.

Automatic Parameter

The last extra beat in the train is the automatic parameter for this protocol. For example, if the number of extra beats is set to 2, the second extra beat (S3) is the automatic parameter.

The Stimulus Pattern

The pattern consists of a train of # in Train beats separated by Cycle Len. milliseconds. This is followed by one to six extra beats (S2 - S7). After the last extra beat and the Rest Time interval, the pattern is repeated.

Using the Arrhythmia Induction Protocol

Press the **STIM** key to start stimulation. If SYNC is ON, the Stimulator waits for a trigger before beginning the conditioning train.

While stimulating, the number of extra beats can be changed by moving the cursor to the Extra Beats box and using the arrow keys. If the AUTO is ON, the last extra beat will be altered every Repeat number of trains.

HALT or **Spacebar** or any protocol select key stops the output.

Hot Keys

Interval	Increment	Decrement
S1	**H**	**N**
S2	**J**	**M**
S3	**K**	**,**
S4	**L**	**.**
S5	**;**	**/**

Arrhythmia Induction Protocol Parameters

Parameter Title	Description
Site	The output channel site(s).
S1	Conditioning Train Cycle Length
S2-S7	Inter-stimulus Interval of Extra Beats
Extra Beats	Number of Extra Beats
# in Train	Number of pulses in conditioning Train
Rest Time	Rest period between stimulus patterns
Train Type	Sensed or Paced Train
S2-S7 Limit	Lower limit value for S2-S7
Repeat	# of times to repeat train before auto update

Arrhythmia Induction Automatic Parameter

Parameter Title	Description
Pre-Int. I/D	Size of Automatic Interval change

Arrhythmia Induction Protocol Initialization Parameters

Parameter Title	Description
Sync	Start setting for SYNC variable (ON or OFF)
Auto	Start setting for AUTO variable

Burst

The Burst protocol consists of a single train. Burst administers a short rapid burst of pulses to terminate an arrhythmia.

Selection and Setup

Press the red **BURST** key at any time to select the burst protocol.

Burst Stimulus Pattern

The Burst stimulus pattern consists of a train of one or more beats. The value # in Train sets the number of beats in the burst train. Stimulation ends at the end of the last beat. This protocol terminates stimulation **automatically**.

The lower limit of the cycle length is less that other protocols permitting cycle lengths down to 10ms.

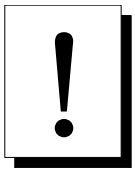
Sequential pacing is allowed in this protocol and there are no automatic parameters.

Using the Burst Protocol

The protocol can also be started by pressing the **STIM** key. If SYNC is ON, the stimulator waits for a trigger before starting each train. Press the **STIM** key to repeat the train.

Alternatively, press the **BURST** key twice to start stimulation if the setup field **Burst->Stim** is turned ON.

The **BURST** key is one of the two red emergency keys on the EP-4™ Cardiac Stimulator keyboard.



IMPORTANT

The user **should always check** to see that the parameters are set to reasonable values before pressing the **STIM** key.

The Burst channel output amplitude parameters are independent from all other protocols. Burst parameters Amp 1 through Amp 4 are different in Burst than in all other protocols. The user **must** set the Burst channel output amplitude parameters either by using the F1 Threshold protocol or by entering the Burst protocol and specifically setting them.

A separate Burst Mult. has been added to the F1 Threshold protocol for setting the Burst currents. Press **ENTER** in this

protocol to multiply the active current by Burst Mult. and set the corresponding current in the Burst protocol.

Note: Variants of Burst saved to the "P-keys" are be affected by pressing **ENTER** in the Threshold protocol.

Hot Keys

The Cycle Len. interval can be incremented by pressing the **H** key and decremented by pressing the **N** key.

Burst Protocol Parameters

Parameter Title	Description
Site	The output channel site(s).
Cycle Len.	Conditioning Train Cycle Length
# in Train	Number of pulses in Train

Burst Protocol Initialization Parameters

Parameter Title	Description
Sync	Start setting for SYNC variable (ON or OFF)

Emergency Pacing

The emergency pacing function offers the availability of non-computer controlled independent pacing of the patient. The touch screen computer does not have to be turned ON to turn ON emergency pacing.

Press at least two buttons on the front panel to initiate emergency pacing. The **Emergency Stim** and the Channel 1 (and/or 2, 3, 4) output must be in the **ON** position to activate emergency Stimulation out of Channel 1. When this sequence is initiated by turning ON these buttons, the Stimulator module delivers a constant current 10 milliAmp pulse at a cycle length of 1000 milliseconds and 2 millisecond pulse duration. Turning ON any other output channels delivers simultaneous output out of these channels as well.

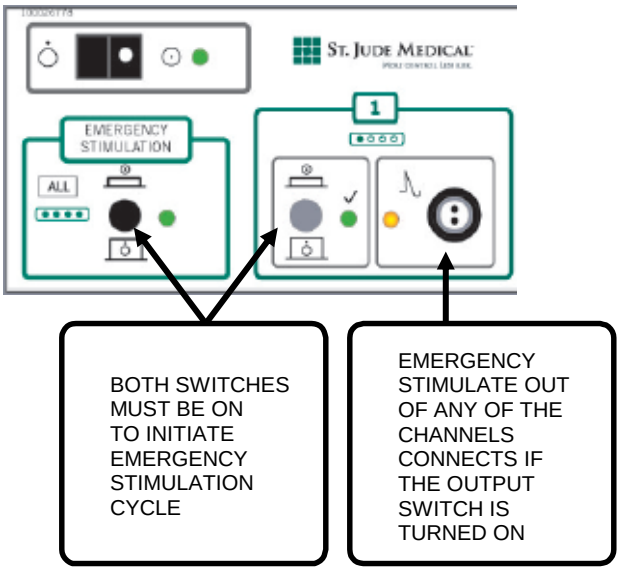


Figure 5-3 – Emergency stimulation buttons

This function of the EP-4™ Cardiac Stimulator operates independently of the EP-4™ Cardiac Stimulator computer and keyboard. The EP-4™ Cardiac Stimulator module must be functioning under power for this function to work correctly.

Note: There is no battery backup of the Emergency Stimulator

WARNING

The EMERGENCY STIMULATION button enables potentially hazardous voltage to be presented to the output without the use of software controlled setup. When the EMERGENCY STIMULATION button and any of the Channel Output buttons are pressed in, output is delivered through the output connectors as soon as the device is AC powered through the main power switch or plugging the device in when the main switch is already turned ON.

6

SetUp Functions

This chapter describes the setup functions available from the SetUp menu. The SetUp functions perform various maintenance duties not directly associated with individual protocols or producing stimuli. Press the **SetUp** key at any time to display the SetUp menu.

Blanking

Blanking period after a sensed event before sensing can occur again

Auto Bell

Auto Bell is ON or OFF. When ON, the terminal bell rings with each automatic update of a parameter. This does not affect other bells such as when an inactive key is pressed or when a limit of a parameter is reached.

Level %

Once an automatic search is performed, the Level is set to a percentage of its peak value (usually 50%).

Changing the Level % selects the percentage value to use.

% Cycle Len.

Pacing % sets the fraction of the measured spontaneous rate to use for the cycle length in protocols that don't have their own % Cycle Len parameter. Values are set from 20%-500%. See "Cycle Length and S1 Priming" in this document for details of this feature.

 # Channels

This sets the number of output channels to either 2 or 4 channels.

BURST->STIM	The EP-3™ Clinical Stimulator had the ability to start stimulation in the Burst protocol when the **BURST** key was pressed twice. The EP-4™ Cardiac Stimulator was originally designed to keep all protocols the same; pressing the protocol key and then the **STIM** key would start stimulation. This setup field allows the EP-4™ Cardiac Stimulator **BURST** key to be as it was with the EP-3™ Clinical Stimulator when turned ON.
WorkMate	This field outputs EP-4™ Cardiac Stimulator screen information to the EP-WorkMate™ Recording System when turned ON.
Language	This field changes the displayed language.
STIM Bell	This field enables the touch screen to beep whenever a stimulation pulse or synchronization event occurs. The Beep Frequencies defined below need to be set to non-zero values.
Beep Frequencies	This button changes the beep frequencies for pacing or sensing for sites 1, 2, 3 or 4 and the external sensing ECG Input. Setting any beep frequency to zero turns OFF the beep sound.

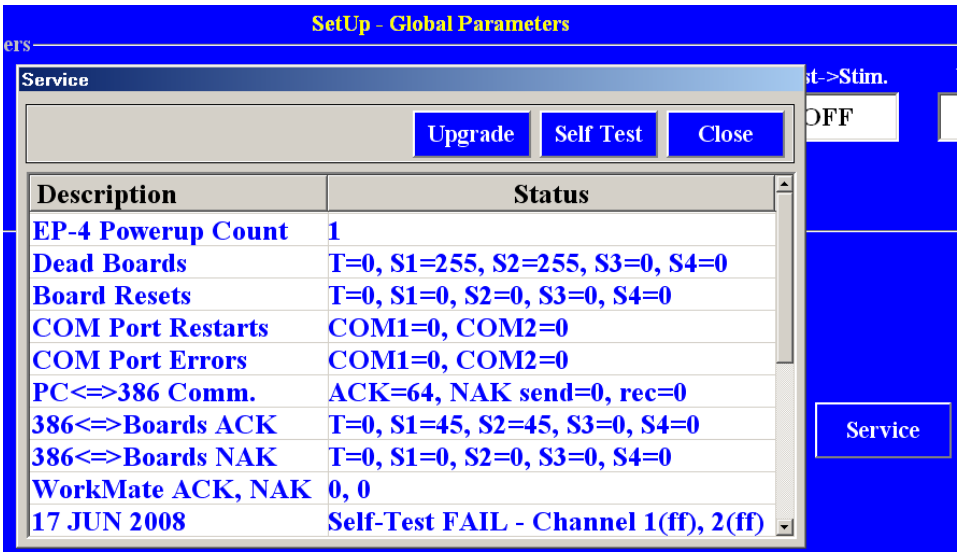
Service

The **Service** button displays a System Diagnostic Dialog box titled Service.

The interface has an **Upgrade** button and a **Self Test** button.

The last 10 self test failures and all communication and status information displays.

Protocols display and stimulation starts with this window active.



Upgrade Button

The **Upgrade** button starts a software upgrade process. Follow the directions delivered with the software upgrade for more information. During the upgrade process the touch screen restarts to ensure the stimulator is not in use at the time.

Self Test Button

The **Self Test** button performs a self test on the stimulation module. The EP-4™ Cardiac Stimulator displays important messages in a message window.

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7

Service and Maintenance

The EP-4™ Cardiac Stimulator can be maintained by the hospital on a regular basis.

The EP-4™ Cardiac Stimulator has no user replaceable internal service parts.

Service should be attempted by qualified personnel only.

Regular maintenance such as cleaning and performance checks can be performed by the user.

Maintenance

The EP-4™ Cardiac Stimulator has no recommended calibration schedule. The unit performs an internal self test that confirms the output. There are no adjustments to the output of the device, other than speaker volume, that can be performed by the user.

It is recommended that the unit be checked on a semi-annual basis at least for the following:

1. Physical Damage.

2. Functional Inspection.

3. Electrical Safety.

WARNING

Contact our technical services group to arrange for service for any stimulator Electrical Safety test failure. Do not use the system unless all Electrical Safety tests demonstrate a safe system.

General Cleaning

All electronic hardware case components can be surface cleaned with a soft cloth dampened with a mild detergent and water. The case is not environmentally sealed and none of the components should be immersed in water.

All cable assemblies can be surface cleaned with a mild detergent and water. Do not attempt to sterilize the cable assemblies.

Excessive dust can be removed using a pressurized, oil free, air supply to blow away dust. This should be done out of the clinical environment and away from other equipment so that freed dust is not reintroduced to other devices.

Monitor

The touch-screen display may need periodic cleaning to remove any dirt or oils that build up from handling. A common window cleaner or monitor cleaning solution should be used by applying to a lint free cloth and then to the monitor surface. Care should be taken not to allow cleaning fluid to drip down into the monitor case. Never spray the monitor surface with cleaner directly.

Cart

All surfaces should only be cleaned with mild soap and water when needed.

Service

WARNING

Service of the EP-4™ Cardiac Stimulator programmable Stimulator is limited to trained and qualified service personnel. Do not attempt repair without proper training.

Schematics and wiring diagrams are available to trained service personnel only.

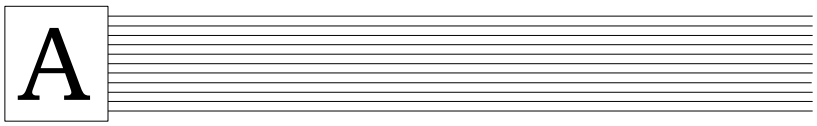
Replaceable Parts

43-0006-0001	Serial extension cable, 9F/9M 6 FT
43-0006-0002	Serial extension cable, 9F/9M 10 FT
43-0006-0003	Serial extension cable, 9F/9M 25 FT
43-0006-0004	Serial extension cable, 9F/9M 50 FT
43-0002-0001	BNC Cable, N/M, 8 FT
43-1698-0030	EP-4™ Stimulator Cable, 30 FT
43-1698-0015	EP-4™ Stimulator Cable, 15 FT
43-1698-0006	EP-4™ Stimulator Cable, 6 FT
43-1698-0003	EP-4™ Stimulator Cable, 3 FT
83-0001-0000	EP-4™ Keyboard (used with ELO Touch Screen)
100057886	EP-4™ Keyboard (used with Advantech Touch Screen)
51-1527-0000	BNC 30dB Attenuator Adapter
53-0006-0000	Power Cord, 6 FT
09-1694-1002	EP-4™ Touch Screen Computer (ELO)
100056164	EP-4™ Touch Screen Computer (Advantech)
09-1527-0000	EP-4™ Stimulator Module (4 channel)
09-1527-0002	EP-4™ Stimulator Module (2 channel)
35-1527-0002	1.6A 5 * 20 Fuse (Qty=2/unit)
100059043	EP-4™ Touch Screen Stand

System Messages

	A list and explanation of all system messages, error messages, and fault messages, are provided below except when messages are self-explanatory. These include important causes and possible action(s) that can be taken to resolve the problem indicated by the message are also contained below.
EP-4 HARDWARE IS NOT RESPONDING	There is a communication failure between the touch screen computer and the EP-4™ Cardiac Stimulator stimulation module. Check the RS-232 cable for defects and make sure it is plugged into the COM1 port of the touch screen computer.
Self Test Failed Channel X	The stimulation channels are independent of each other. Channel X has a self test failure. Call technical support for assistance.
An Internal EP-4 RESET Communication Error Has Occurred	The EP-4™ Cardiac Stimulator stimulation model reset itself due to an unknown cause. Call technical support for assistance.
CRC ERROR - Default Protocol	A protocol located on the hard drive is corrupted. Call technical support for assistance.
CRC ERROR - EP4 Save File	A protocol will not save to the hard drive. Call technical support for assistance.
TAG NOT FOUND TO DOWNLOAD	A protocol located on the hard drive is corrupted. Call technical support for assistance.

APPENDIX



Specifications

Isolated Stimulus Channels: 4

Stimulus Channel On Off Button:

4 Standard Output Channel Buttons

1 Emergency Pacing Button. Output out of channel 1-4 simultaneously

Pulse Amplitude (constant current source)**:**

Range:	0.1 – 20	mA	(2500 Ω load)
Increment:	0.1	mA	
Accuracy:	5% or 0.1	mA	(whichever is larger)

Impedance Measuring:

Range:	10 to 10,000 Ohm Load
Accuracy:	±5% above 1mA, ±10% above 5,000 Ohm

Pulse Duration

Range:	0.1 – 10.0	msec	
Increment:	0.1	msec.	
Accuracy:	0.05	msec.	(Pulse amplitude > 1 mA)

Interstimulus Interval (ISI)

Range:	S1	100–30000	msec
	S2-S7	50-10000	msec
	Burst	10–1000	msec
Accuracy:	±1 msec		
Increment:	1 msec		

Sequential (AV) Delay:

Range:	10-1000 msec
Accuracy:	±1 msec
Increment:	1 msec

Preprogrammed Protocols: 9

Threshold Determination, Sinus Node Recovery
Overdrive Pacing, Decremental Pacing, Refractory study
Arrhythmia Induction, Burst, Pace
Wenckebach block

Programmable Protocol Keys: 10

Number of Extrastimuli: 6 (S2-S7)

Emergency Pacing Function

1000 msec cycle length
10 mA constant current
2 ms pulse duration
Output out of Channel 1-4 simultaneously

External Non-Isolated Sensing (ECG Trigger from ECG Input):

Input range:	1mV - 0.5V	In 0.1mV steps to 10mV 1.0mV steps to 0.5V
Absolute max. input:	±5V	
Minimum refractory:	50 msec	After the start of the pacing pulse
Frequency range:	3.5-250Hz	

Internal Isolated Sensing (ECG Trigger from Stimulation Channels:

Input range:	0.1mV - 10mV in 0.1mV steps
Absolute max. input:	±500 mV
Minimum refractory:	50 msec after the start of the pacing pulse
Frequency range:	30-250Hz

Additional Outputs:

Four marker outputs:
- Pace Marker.
- Aux Out - Auxiliary/Paper advance.
- Sense Marker.

Pulse Type:
- Output voltage 0 to 5V

Audible Output:

Variable Volume control between 0dB-30dB output

Power Source:

Line Power:	100-240 VAC
Line Frequency:	50-60 Hz
Rated Power:	55W (100-240 VAC, 50-60 Hz)
AC Power Cord:	10A Rated
Fusing:	2 X 1.6A (5*20mm)

Stimulation Module:

Dimensions:	16 3/4" L x 14" W x 3 1/2" H
Weight:	15 lbs

Computer:

Type:	Color touch screen display
Dimensions:	Varies
Weight:	Varies
Processor:	Intel® Pentium Class

Computer Keyboard:

Dimensions:	18.8" x 7.8" x 1.7"
Weight:	3.3 lbs.

Environmental:

Operating Temperature:	+10 – +35° C
Storage Temperature:	-20 – +60° C
Relative Humidity:	30–75% non-condensing
Operating Altitude:	0–4572 m (7620 m storage)

Intended use:

The EP-4™ Cardiac Stimulator is intended to be used for diagnostic electrical stimulation of the heart for the purpose of refractory measurements, initiation and termination of tachyarrhythmias, and measurements of electrical conduction.

Electrical Safety:

Chassis Leakage:	<500 micro Amps
Patient Isolation Leakage:	< 50 micro Amps
Intra-lead Leakage:	< 10 micro Amps

Equipment Classification:

Type of Protection:	Class 1
Degree of Protection: (Against Electrical Shock)	Type CF defib protected

EP-4™ Cardiac Stimulator Electronic Emissions Declarations

Declaration – Electromagnetic Emissions		
The EP-4™ Cardiac Stimulator is intended for use in the electromagnetic environment specified below. The customer or the user of EP-4™ Cardiac Stimulator should assure that it is used in such an environment.		
Emissions Test	**Group 1 Compliance**	**Electromagnetic Environment – Guidance**
RF emissions CISPR 11	Group 1	The EP-4™ Cardiac Stimulator 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 A	The EP-4™ Cardiac Stimulator 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.
Harmonic emissions IEC 61000-3-2	Complies	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

Declaration – Electromagnetic Immunity			
The EP-4™ Cardiac Stimulator is intended for use in the electromagnetic environment specified below. The customer or the user of the EP-4™ Cardiac Stimulator 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 61000-4-2r	±6 kV contact ±8 kV air	±6 kV contact ±8 kV 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	±2 kV for power supply lines ±1 kV for input/output lines	±2 kV ±1 kV	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV differential Mode ±2 kV common mode	±1 kV differential Mode ±2 kV common mode	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	>95% dip in VNOM for 0.5 line cycle 60% dip in VNOM for 5 line cycles 30% dip in VNOM for 25 line cycles >95% of VNOM for 5 sec	Mains power quality should be that of a typical commercial or hospital environment. If the user of the EP-4™ Cardiac Stimulator requires continued operation during power mains interruptions, it is recommended that the EP-4™ Cardiac Stimulator be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) 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 the application of the test level			

Declaration – Electromagnetic Immunity

The EP-4™ Cardiac Stimulator is intended for use in the electromagnetic environment specified below. The customer or the user of the EP-4™ Cardiac Stimulator 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 EP-4™ Cardiac Stimulator, 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 150kHz to 80 MHz	3 Vrms	$d = 1.2\sqrt{P}$ $d = 1.2\sqrt{P}$ 80 MHz to 800 MHz $d = 2.3\sqrt{P}$ 800 MHz to 2.5 GHz
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	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 EP-4™ Cardiac Stimulator is used exceeds the applicable RF compliance level above, the EP-4™ Cardiac Stimulator should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the EP-4™ Cardiac Stimulator.

[b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than $[V_1]$V/m.

Recommended separation distances between portable and mobile RF communications equipment and the EP-4™ Cardiac Stimulator

The EP-4™ Cardiac Stimulator is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the EP-4™ Cardiac Stimulator can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the EP-4™ Cardiac Stimulator as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter W	**Separation distance according to frequency of transmitter m**		
	150 kHz to 80 MHz $d = 1.2\sqrt{P}$	**80 MHz to 800 MHz** $d = 1.2\sqrt{P}$	**800 MHz to 2.5 GHz** $d = 2.3\sqrt{P}$
0.01	.12	.12	.23
.10	.38	.38	.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 manufacture.

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.

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APPENDIX

B

Inputs and Outputs

Chassis Grounding Terminal

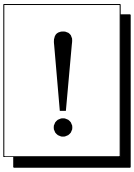
The green "Chassis Grounding Terminal" on the back panel of the stimulator module is connected to the chassis only. It is not connected to the non-isolated circuits of the stimulator, that is, the ECG input, Marker Outputs and EP-4™ Cardiac Stimulator terminal connector. The isolated stimulation outputs are fully isolated and are independent of the chassis and the grounding terminals. A separate grounding wire to the chassis is unnecessary as long as the power cord remains connected.

Stimulus outputs

The maximum current is 20 mA.

The stimulus outputs are polarized; the lower (positive) hole of the socket connects to the current source. The corresponding pin of the patient cable plug is marked by a red dot. The negative hole of the socket attaches to the current sink.

Two stimulus outputs can be connected in parallel; the total current then becomes the sum of the individual currents. Be sure to connect the two current sources and likewise the two current sinks.



IMPORTANT

The stimulus outputs cannot be placed in series. Do NOT connect a current source to a current sink.

Patient Cables

The EP-4™ Cardiac Stimulator is shipped with two to four patient cables. The standard cable, made from flexible medical grade PVC, is 30 feet long with a two pronged keyed connector on the stimulator end. The patient end is fitted with 2mm safety sockets. The 2mm safety sockets connect directly to most popular electrophysiological lead switching systems.

ECG Input

The ECG Input Trigger provides a way to synchronize stimulus patterns to external signals, most commonly from an ECG surface or intracardiac lead. An internal trigger signal is generated when the amplitude of the external signal reaches the sense level.

Connection of the "ECG input"

Connect the sensor ("ECG input" BNC jack at the rear of the stimulator) to the source of a conditioned triggering signal, for example the output of an ECG amplifier, with a BNC cable. To obtain optimum triggering, the external signal should be stable with a triggering peak, usually the QRS complex larger than the amplitude of any other peak. The amplitude of the input signal features a wide range of 1–500 mV. Any signal with peak amplitude within this range will produce consistent triggers.

WARNING

The ECG input is referenced to ground, this connection is NOT isolated and must never be directly connected to a patient.

The Synchronization Sense parameter in the Synchronization section described in Chapter 6 is the amplitude of the input signal after it is filtered by the EP-4™

Cardiac Stimulator. It may not be the same as measured on another system.

Automatic trigger setting algorithm

When you press the **Search** key, the stimulator automatically adjusts the sense level during a interval of up to 3 seconds. If a sensed event is found, the stimulator will set the sense level to 50% (or the Level % defined in the SetUp protocol) of the peak. A beep will occur each time a trigger occurs and the measured time between triggers (spontaneous cycle length), will be shown on the status line.

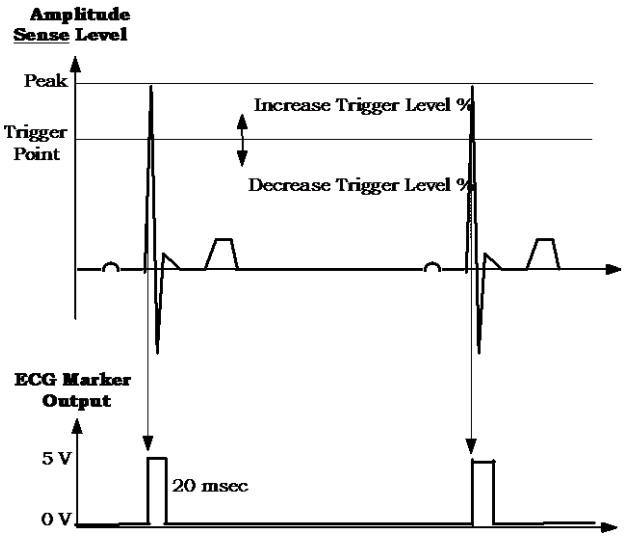


Figure B-1 – Sense Trigger Scheme and Marker output

You can determine which part of the input signal is producing the trigger by connecting the "ECG marker" to an oscilloscope. This marker output becomes 5 Volts when the trigger level is reached for a duration of 20 msec. The “Blanking” period (defined in the SetUp protocol) eliminates triggering on consecutive large amplitude components, such as the T-complex of an ECG signal.

If the automatic search is unable to find a peak, the “NO Sense” message is displayed in the Synchronization Interval display box. Check the cable connection. If the problem persists, increase the amplitude of the signal or try switching to a different lead.

Aux Output

WARNING

The Aux Output is referenced to ground, this output is not isolated and should never be connected directly to a patient.

You can use the auxiliary output to remotely turn ON and OFF a paper chart recorder. The **Aux** key sends a pulse to the Aux Output connector.

Marker Output Specification		
Pulse width	20	msec
Electrical characteristics:		
Source voltage (Off):	9	V
Source resistance:	100	KΩ
Sink voltage (On):	140	mV (I_{sink}= 0.5 mA)

Connecting a chart recorder

The ON/OFF input on a paper chart recorder often requires a low current contact closure to ground. The "Aux" output on the rear of the stimulation module can be connected directly to this type of input.

WARNING

The Aux ground (BNC shell) must always be attached to the ground terminal of the strip chart recorder. ALWAYS read the instructions of the recorder's manual before connecting the auxiliary output.

Sample Chart Recorder Connections		
Manuf./model	**Connector**	**Type**
GOULD ES 1000	Partial Remote Control, CHART (Back Panel)	Screw terminal, (use Spade Lugs)
E for M Model AR-6	Camera Remote	Phone Jack

To determine whether the connection is correct, turn ON the stimulator and strip chart recorder and press the **Aux** key. The strip chart should start. Press the **Aux** key again and the strip chart should stop accordingly.

Marker Outputs

The marker outputs provide a signal associated with an event. The ECG marker becomes 5 Volts for the onset of an ECG trigger and stays at 5 V for 20 msec. Likewise, the Pace Marker outputs 5V for the duration of the corresponding stimulus pulse. These outputs mark the respective events on a recorder or to synchronize external events.

WARNING

The Marker Outputs are referenced to ground, these outputs are NOT isolated. NEVER connect these outputs to a patient.

Connecting the marker outputs

The markers indicate the stimulator events on the oscilloscope or recorder. The Pace marker is generated, even if the stimulus output switches on the front panel of the stimulation module are in the OFF position.

Dedicated marker inputs are available on some strip chart recorders (Gould, ES 1000: M1, M2, M3 and M4 on the “Partial Remote Control panel”) requiring a contact closure, a direct connection can be made to these recorders.

You can also connect the marker outputs to an ECG amplifier. Two or more markers can be tied together to display all the information on one channel.

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APPENDIX

C

Difference Between the EP-4™ Cardiac Stimulator and EP-3™ Clinical Stimulator

The EP-3™ Clinical Stimulator had been in clinical usage from 1993 until its end of life announcement in 2008. The following are the functional differences between the EP-3™ Clinical Stimulator and the EP-4™ Cardiac Stimulator.

- The EP-4™ Cardiac Stimulator has either two or four stimulation output channels. The EP-3™ Clinical Stimulator had 2 stimulation output channels.
- The EP EP-4™ Cardiac Stimulator device is line powered instead of battery. The EP-3™ Clinical Stimulator had a battery to provide patient isolation.
- The EP-4™ Cardiac Stimulator has one high-level non-isolated marker channel for all stimulus channels. The EP-3™ Clinical Stimulator had separate marker channels for each stimulus channel.
- The EP-4™ Cardiac Stimulator device can sense from either an external non-isolated high level signal or one of the isolated low level pacing wires. The EP-3™ Clinical Stimulator could only sense from an external high level signal.

- The EP-4™ Cardiac Stimulator has an integrated speaker with a hardware volume control. The device will beep during stimulation and sensing as programmed. The EP-3™ Clinical Stimulator used the PC speaker for this function that had no volume control.

- The EP-4™ Cardiac Stimulator has an emergency stimulation hardware button which will start the stimulator pacing on all channels turned ON at 10mA(2mS) and 1000mS cycle length. The EP-3™ Clinical Stimulator relied on the user setting up these parameters into a protocol and running it from the PC.

- If there are no communications between the EP-4™ Cardiac Stimulator and the PC for 5 seconds, the stimulator will shut down. The EP-3™ Clinical Stimulator did not shut down if the PC discontinued responding.

- The EP-4™ Cardiac Stimulator protocols are stored on the PC hard drive. The EP-3™ Clinical Stimulator protocols were stored in memory, which could be erased.

- The connection to the EP-4™ Cardiac Stimulator is a 9 pin RS-232 cable instead of the EP-3™ Clinical Stimulator's 25 pin. This is for convenience.

- The EP-4™ Cardiac Stimulator has two or four push button relays controlling whether channels are OFF or ON. The EP-3™ Clinical Stimulator used toggle switches.

- The EP-4™ Cardiac Stimulator has the ability to measure stimulation impedance in real-time. This is important to understand whether there is a current path to the patient, to help diagnose broken cables, to indicate if switches are turned ON, etc.

- The EP-4™ Cardiac Stimulator AUX marker output port is not programmable. Pressing it sends a pulse of finite duration. The EP-3™ Clinical Stimulator used this port to program strip chart recorders.

- The patient database, notes and reporting functions have been removed in the EP-4™ Cardiac Stimulator. The

database in the EP-3™ Clinical Stimulator was not used by our customers.

- The EP-4™ Cardiac Stimulator upgraded the operating system from DOS to Windows 2000 to take advantage of new hardware and software that does not support DOS and to create a fresh new user interface. (Note: The current EP-4™ Cardiac Stimulator operating system is Windows XP.)

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APPENDIX

D

Warranty

For warranty information, contact your EP-4™ Cardiac Stimulator representative or distributor for a description of warranty coverage, service agreements, and replacement/upgrade component costs.

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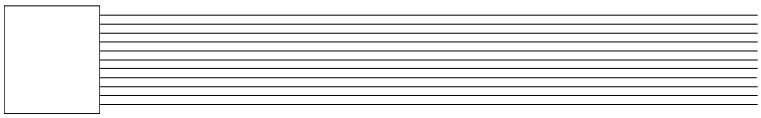

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