

SMART – E PROGRAMMER

USER MANUAL

Programming Interface

Model: SEP – 11

Programming Head

Model: SEH – 11








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Revision History

Revision	Date	Change Description
01	January 15 th , 2017	IFU
02	August 25 th , 2020	User Information

Explanation of Symbols

Serial Number	Symbol	Symbol Explanation
1.		Operating instructions
2.		Do not dispose of this product in the unsorted municipal waste stream. Dispose of this product according to local regulations
3.		Product documentation
4.		DEFIBRILLATION-PROOF TYPE BF APPLIED PART.
5.		General warning sign

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1. MANUAL CONTAINS

This manual explains the use of the SMART-E programmer for Pacemaker Model SEP-11 with SPL software. It is divided in the following sections:

Introduction

In this first section, the basic requirements, Connections, indications and the SPL software installation procedure are described. It is also indicated where to ask questions and find solutions to problems that cannot be solved through the manual.

NOTE: In this manual the SMART-E programmer for Pacemaker Model SEP-11 will be referred as SMART-E Programmer Model SEP-11 in rest of the document.

SPL software Screen

This section is directed mainly to those users who do not have previous experience in the use of a personal computer that runs Windows XP or Windows 98 operating system. It defines the terms used throughout the manual and explains the usual working procedures in Windows starting from a detailed description of the SPL software screen.

Actions

In this section the operations of interaction with the pacemaker that can be carried out with SPL software, as how to obtain information from the pacemaker and how to program it, are described.

Data

The handling of the stored information by SPL software database, the way of browsing in or modifying this information, and the transference to other applications, whenever necessary, are described here.

Tables

Tables with the values of the different programmable parameters according to the pacemaker model are annexed at the end of the manual.

SMART-E Programmer for Pacemaker



2. GENERAL

SMART-E Programmer includes Programming interface Model SEP-11, Programming head SEH-11, USB cable & ECG cable. Programmer is a device used for programming of the pacemaker with the help of PC/Laptop.

SMART-E Programmer Model SEP-11 is connected by means of an interface to a laptop/PC, which communicates by telemetry to the pacemaker implanted in the patient.

The SMART-E programming head Model SEH-11 must be placed over the implant zone, making sure that the light blinks following its frequency. The programming head strength is such that it can communicate with pacemaker when it is kept within air gap of 50 mm height. The button located in the programming head is usually used to "interrogate" the pacemaker, that is, the programmed values that determine its functioning.

Using SMART-E Programmer Model SEP-11 the Physician may interact with the pacemaker: modify the frequency and duration of the generated stimulus, measure pacing and sensitivity thresholds, study statistics and graphics of the assistance given by the heart stimulator, keep an electronic file of patients and their controls, print reports, calculate which is the battery consumption of each program, register standard programs for further use, reprogram the pacemaker in order to quickly control heart rhythm problems, etc.

Accessories

- Programming Interface Model SEP-11
- Programming Head Model SEH-11
- USB Cable
- ECG Cable

Characteristics

- **Weight -**
800 gms. (Including Programming Head Model SEH-11,USB & ECG cable)
- **Dimensions**
 - Programming Interface Model SEP-11 : 150 x 200 x 40 mm (L * W * H)
 - Programming Head Model SEH-11: 140 x 62.7 x 30.5mm (L * W * H)
- **Supply voltage, power –**
USB powered (5.0Volts DC)

IP Classification

- SMART-E Programmer Model SEP-11 ----- IP40
- SMART-E Programming Head Model SEH-11 ----- IP41

Conditions of Storage & Transportation

- Handle with care, storage temp 0 to 40°C.

Maintenance Conditions

- Not water proof, for any defects return back to the company.

Limited One Year Warranty

1. Limited Warranty and Replacement Agreement: SHREE PACETRONIX LTD. Provides assurance that if the SMART - E should fail to function within its specified tolerances within one year from date of purchase, due to faulty workmanship or a defective component excluding the battery, the Company will replace all components and provide service free of charge.

2. Limitation of Liability, Shree Pacetronix Ltd. shall not be liable for any medical expenses, adverse body reactions, or medical complications or other direct or consequential damages resulting from the use of SMART-E Programmer Model SEP-11 pursuant to this agreement or caused by any defect, failure or malfunction of the same, whether such claim for damages is based upon warranty negligence, contract strict liability tort or otherwise.

3. Disclaimer, this limited one year warranty is in lieu of all other warranties expressed or implied. Pacetronix specifically disclaims any implied warrantee of merchantability or fitness for a particular purpose. The remedies set forth herein shall be the exclusive remedies available arising out of the sale or use of the SMART - E. No person has any authority to bind Shree Pacetronix Ltd. to any representation or warranty except as set forth herein.

3. INTRODUCTION

Welcome to SMART-E programming system with SPL software, the application designed by Pacetronix to consult and modify the parameters that rule pacemaker activity belonging to their SSI / SSIR / DDD / DDDR / Bi-Ventricular pacemakers.

SPL software, created to be run in a personal computer with Windows XP or Windows 98 operating system, is connected by means of a programming interface to a small SMART-E Programming Head Model SEH-11, which communicates by telemetry to the pacemaker implanted in the patient.

The SMART-E Programming Head Model SEH-11 must be placed over the implant zone, making sure that the light blinks following its frequency. The SMART-E Programming Head Model SEH-11 strength is such that it can communicate with pacemaker when it is kept within air gap of 50 mm height. The button located in the SMART-E Programming Head Model SEH-11 is usually used to "interrogate" the pacemaker, that is, to show in the SPL software screen the programmed values that determine it's functioning.

Using SMART-E Programmer Model SEP-11 with SPL software the Physician may interact with the pacemaker: modify the frequency and duration of the generated stimulus, measure pacing and sensitivity thresholds, study statistics and graphics of the assistance given by the heart stimulator, keep an electronic file of patients and their controls, calculate which is the battery consumption of each program, register standard programs for further use, reprogram the pacemaker in order to quickly control heart rhythm problems, etc.

SPL software offers in a graphic interface of quick and easy handling, all these multiple options which improve the functioning of the pacemakers built by Pacetronix and achieve, in every case, accurate and personalized clinical follow-up.

4. TECHNICAL SERVICE

In case of additional help about SMART-E Programmer Model SEP-11, SPL software or about SSI / SSIR / DDD / DDDR / Bi-Ventricular pacemaker series you may consult Pacetronix through:

Mail: Plot No.15, Sector-II, Pithampur, Dist. Dhar (M.P.) 454775, INDIA

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Fax: 07292-2762728

E-mail: pacetronix@hotmail.com

Web: www.pacetronix.com

5. CONNECTORS AND INDICATORS DESCRIPTION

Rear View of SMART-E interface



5.1 Connections of Programming Interface

i. USB Cable Connection:

- **To PC**

Connect USB cable PC end to USB port of the PC to connect programming interface with the PC to powering up the SMART-E Programmer Model SEP-11 system.

- **To SMART-E Programmer Model SEP-11**

Connect USB cable Interface end to programming interface female connector USB I/O.

Make sure the connection of USB cable from both PC and Interface end.

ii. SMART-E Programming Head Model SEH-11 connection

Connect SMART-E Programming Head Model SEH-11 male connector to programming interface at Female connector SMART-E PROGRAMMING HEAD MODEL SEH-11.

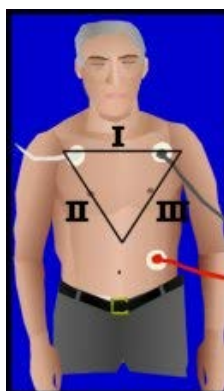
iii. ECG Cable connection

- **At SMART-E Programmer Model SEP-11 end**

Connect ECG cable male circular connector to the programming interface female ECG connector.

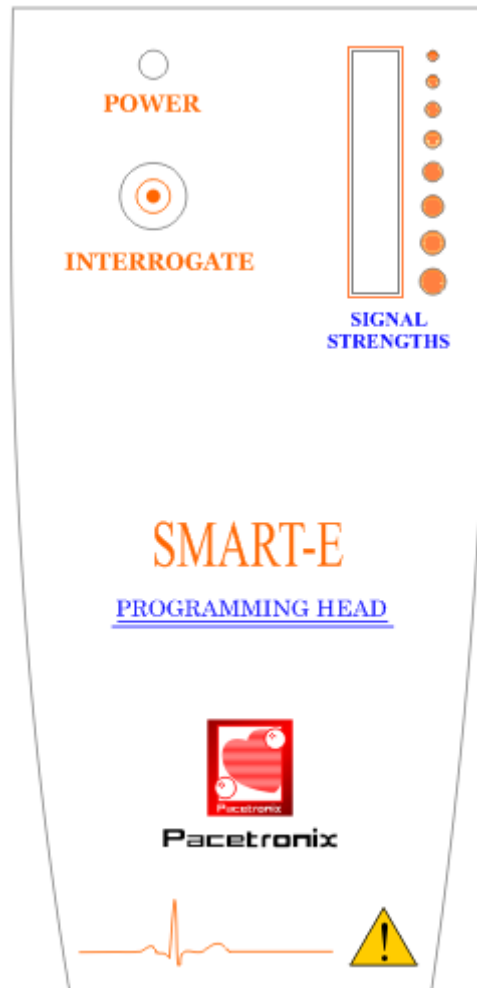
- **At patient end**

Connect ECG cable patient end electrode connectors to the patient by using disposable electrodes.



Note: - Make sure that patient's body should be cleaned first before placing disposable electrodes.

5.2 Indicators on SMART-E Programming Head Model SEH-11



I. Power-up indicator

Power-up indicator is placed on the SMART-E Programming Head Model SEH-11. When SMART-E Programmer Model SEP-11 powered-up by USB port of the PC, a green LED on LED bar glows, and indicating power-up of SMART-E Programmer Model SEP-11.

II. Signal Strength Indicator

LED bar placed on the SMART-E Programming Head Model SEH-11 indicates the telemetry signal strength when in contact with the programmable pacemaker.

Signal strength is divided in 3 parts.

1. Green LEDs- Good signal strength
2. Yellow LEDs- Mid range of signal strength
3. Red LEDs- Poor signal strength

6. SYSTEM REQUIREMENTS

To install SPL software in a personal computer/Laptop, it must run Windows XP or Windows 98 operating system. The basic characteristics of the required hardware are the following:

- 486 processor or more (Pentium recommended)
- RAM of 16 Mbytes
- 8.0 Mbytes of free space in the hard disk
- Programming Interface supplied by Pacetronix connected to the equipment.

Even if it is not strictly necessary to use a mouse to run the program, for all functions can be commanded from the keyboard, it is highly recommended to have one in order to handle it more comfortably.

6.1 Installation

To install SPL software verify that the computer fulfills the basic requirements indicated above and insert the CD labeled SPL software into your CD-ROM drive.

Double click the "setup" file in the folder. Once the Auto Run Installation program begins just follow the instructions.

The notebooks supplied by Pacetronix have SPL software preinstalled; in this case the installation is not necessary.



7. INSTRUCTION FOR USE

1. Please ensure before use that SMART-E Programmer Model SEP-11 should contain
 - I. Programming Interface
 - II. SMART-E Programming Head Model SEH-11
 - III. USB cable
 - IV. ECG cable (If required)
2. Connect USB cable's USB end to USB port of the PC/Laptop.
3. Connect USB cable's interface end to USB I/O of programming interface.
4. Connect SMART-E Programming Head Model SEH-11 to programming interface SMART-E Programming Head Model SEH-11 female connector.
5. Please ensure that a green LED glowing on the SMART-E Programming Head Model SEH-11 .

6. Now place SMART-E Programming Head Model SEH-11 on to implantable device (Pacemaker) site on the patient.
7. Please ensure that LED's are blinking on LED bar on the SMART-E Programming Head Model SEH-11.
8. For proper telemetry ensure that green LED's should blink. The SMART-E Programming Head Model SEH-11 must be placed over the implant zone, making sure that the light blinks following its frequency. The SMART-E Programming Head Model SEH-11 strength is such that it can communicate with pacemaker when it is kept within air gap of 50 mm height.
9. Positioning LED: It allows the easy detection of the right position of the SMART-E Programming Head Model SEH-11 over the pacemaker
10. Maximum programming time is 500ms.
11. Interrogation of pacemaker parameters can be done by using interrogate switch on the SMART-E Programming Head Model SEH-11 or by using mouse/keyboard with SPL programming software.
12. Programming of pacemaker parameters can be done by SPL software.
13. For detailed programming instruction please refer to Actions in this manual.

8. SPL SOFTWARE SCREEN

This section describes the general characteristics of the SPL software Screen and Windows XP / 98, the built in operating system, as well as some conventions applied throughout this manual. If the procedures for using Windows are already known, a jump over this section is advisable.

8.1 Use of the Mouse and Keyboard

Windows XP / 98 is a graphical user interface in which programs are executed in rectangular zones of the screen called *windows*. In all of them, the actions are carried out pressing *buttons* or choosing the commands grouped in lists called menus, so the user does not need to key in complicated instructions from the keyboard to be able to run them. Windows XP / 98 is operated, in general, through the movements produced by a mouse, translated into similar movements of a pointer in the screen. This manual indicates the following procedures to be carried out with the mouse:

Point Position the mouse pointer until the tip of the pointer rests on the indicated object.

Click Press and immediately release the left button without moving the mouse.

Double click Press and release the left button of the mouse twice in rapid succession.

Drag Press and hold down the left button while you move the mouse; then release the button.

Select Point and click.

In some cases, the actions executed using the mouse, can also be carried out using the keyboard by pressing different keys combinations called keyboard shortcuts. For example: when the computer is turned on, a screen called Windows XP / 98 Desktop, in which the **Start** button is seen in the left lower part, appears. In order to display the **Start Menu**, you can click on the button with the mouse, or press at the same time <Control> and <Esc> keys (as a keyboard shortcut).

8.2 Run SPL software

If the PROGRAMS option of the **Start Menu** is selected, the different available applications of the computer will be displayed. As it can be seen on the figure, once SPL software is installed an option with this name and icon appears.

If the option SPL software is not found it means that the application has been installed within a program group, then all the folders of the option PROGRAMS have to be searched using the mouse until SPL software is found in one of them.

The program is activated clicking on the SPL software icon.

8.3 SPL software Screen

SPL software occupies the entire screen with the exception of a Task Bar in which the **Start** button is found. This particular status of the window is known as *maximized*.

SPL software Screen shows the following parts:

Title bar

It appears in the upper part of the window. It shows the icon, the name of the program, and the pacemaker model being used.



◆ Title bar of SPL software

In the right side, three buttons that allow changing the window status appear:



Minimizes the size of the window reducing it to a button in the Task Bar. Clicking again on the button restores the previous size. The program is still open in the minimized window but it is not possible to work on it.



Reduces the maximized window to a minor size. In this status the window can be moved throughout the screen (dragging it from the title bar) and its size can be modified (moving the pointer up to the borders until it becomes a double arrow, and dragging it).

Notice that the button changes automatically



to allow the window to be maximized again. The change from maximized to normal or vice versa, can be also done by clicking twice on any of the empty parts of the title bar.



Closes the window and exits from SPL software.

Toolbar

It is located under the menu bar and has several buttons which allow a fast access to some commands:



Interrogate button: allows reading the information of the pacemaker. In order to make a successful interrogation, the interface must be on, correctly connected to the computer and must have enough battery. Besides, it should be verified that the light in the SMART-E Programming Head Model SEH-11 is blinking when it is located in the implant zone, indicating that the distance to the pacemaker is correct.



Program button: allows programming the pacemaker with the parameters displayed on the screen.



Temporary Programming this button allows a temporary programming mode in which the pacemaker paces with a high rate in Asynchronous mode. The temporary programming mode ends when the SMART-E Programming Head Model SEH-11 is moved away from the chest of the patient.



Marker button: This button puts the pacemaker in marker mode. Marks are obtained which indicates the activity of the heart (paced or sensed events).



Threshold button: displays a menu in which the pacing or sensing threshold to be determined are chosen. The pacing threshold corresponds to the minimum energy of a stimulus generated by the pacemaker able to provoke an effective heart contraction.

The sensing threshold is the minimum wave amplitude, generated by the heart, able to be detected by the pacemaker.



Statistics button: it allows reading the statistic values stored by the pacemaker, such as stimulus generated, sensed events, etc. The information is shown in absolute numbers, in percentages, or by means of bar graphics.



Impedance button: This button allows measuring the lead impedance.



Longevity calculation of pacemaker at different parameters setting.

Status Bar

It is located in the lower part of the SPL software Screen. It indicates the activity that the program is carrying on (interrogating, programming, etc.). The status bar also provides help, giving a clear and concise definition of any menu option or button pointed with the mouse or the arrows.

In the right part of the Status bar there are three boxes that indicate if the lock keys in the keyboard have been activated.

CAPS - The first box indicates if the key <Caps Lock> has been activated; any key from the keyboard appears as a capital letter on the screen.

NUM - In the second box, NUM appears if the key <Num Lock> that changes the functioning of the numeric keyboard, is pressed: if it is activated, numbers are written from there, otherwise those keys act as scroll arrows.

Dialog boxes

Many times, when commands from the menus or from the buttons of the toolbar are run, dialog boxes appear adding information and allowing to change the parameters of the current action. For example: when running the command PRINT from the menu, a dialog box appears, allowing the input of information about the pacemaker and the patient to be stored.

Printing Data ✖

Shree Pacetronix Ltd.

Patient Name **Implant Date**
Dr Name **Programming Date**
Hospital
Lead Sr. No. **A Impdance** **Threshold During Implant**
Pacer Sr. No. **V Impdance** **Threshold After Implant**

Charak-DR

Mode	DDD	BAT	2.83 Volts			
Rate	60 BPM	Pace Pol	A Uni	V Uni	SENS POL	S Uni
A Amp	5.0 Volts	V Amp	5.0 Volts		Pace AVI	140 ms
A PW	0.4 ms	V PW	0.4 ms		PVARP	350 ms
A Sens	.6 mV	V Sens	1.5 mV		Blanking	68ms
A Ref	250 ms	V Ref	325 ms		UR Behav	Wenkebach
AV Hysteresis	OFF	Upper Rate	120 BPM		Sens AVI	125 ms
ATena	Disabled	AT RT	--bpm		AT Ent Cnt	--
AT Ext Cnt	--	Auto Pol SW	OFF			

Fig: PRINT DIALOG BOX

Dialog boxes include buttons, some of them open other dialog boxes, while accept (**OK**) and **Cancel** buttons are generally used to run or ignore the command with all the marked options.

Finally the dialog boxes as the windows, have a title bar, from which they can be dragged throughout the screen. However they have, as a difference, a fixed size that cannot be changed.

8.4Actions

In this section the options of the Actions, Models and Standards menus are detailed. In these menus the commands related to the consulting and programming operations of pacemaker are grouped.



Interrogate

The first action to be carried out in order to access the information of the pacemaker is Interrogate. After interrogating, the model, serial number, battery condition, and the different programmable parameters are shown on the screen.

Once the SMART-E Programming Head Model SEH-11 is placed over the implant zone, the leds blink on the LED bar of head and the interrogation action can be performed in any of the following different ways.

1. Press the button in the SMART-E Programming Head Model SEH-11.
2. Click on the **Interrogate** button of the toolbar.
3. Activate the Tool menu and choose the INTERROGATE option.

If an error occurs, check the following: maybe the SMART-E Programming Head Model SEH-11 is more than 50 mm (air gap) far from the pacemaker (no blinking light); maybe the interface is off or it is not connected. Correct the situation and retry by clicking on the **Retry** button of the message box.

If the interrogation is successful, the different parameters of the pacemaker (which vary according to the model) appear on the screen (programming screen)

Some of the parameters are just informative and cannot be modified. They are:

Model:	The pacemaker model appears in the title bar
Serial :	The pacemaker serial number
Battery status:	Battery Status of Pacemaker



If it is necessary to immediately transmit a safe set of values to the pacemaker, the **Urgent programming** button on the toolbar, or the <F4> key on the keyboard can be used. Bear in mind that the <F4> key may be pressed anytime, even having dialog boxes opened in the SPL software Windows screen.

Each model has its own screen in which the programmable parameters appear. The detailed list of the parameters and their allowed values of each model, are included at the end of this Manual.

It is possible that the values of related parameters become inconsistent. In those cases, SPL software will show an error message explaining the conflict situation.



Pacing AV Delay cannot be less than the first Sensing AV Delay

◆ Error message

To replace previous values with the new ones, select value from corresponding dialog box. In order to roll back the changes, the **Cancel** button in the screen should be pressed. Parameter modification in SPL software does not imply pacemaker programming. To program the pacemaker, you should proceed according to what is detailed under **Programming** title.



Programming

The Programming action transmits the values that are in the screen to the pacemaker using telemetry. The SMART-E Programming Head Model SEH-11 should be correctly placed on the implant zone (the green LED must blink).

Programming can be performed in any of the following ways:

1. Click on the **Programming** button in the toolbar.
2. Click on the Actions menu and then choose the PROGRAMMING option.

If the programming action was performed successfully, the message "Programming OK" will appear, otherwise an error message box will be shown. In this case, in order to repeat the action, you can click the **Retry** Button or type <Enter> or press the SMART-E Programming Head Model SEH-11 button. On the other side, <Esc> key and the **Cancel** button will cancel the action.



Marker Mode

This button puts the pacemaker in marker mode. Marker mode shows the status of the pacemaker whether it is pacing or sensing the sinus rhythm. Pulse interval and count also visible on the screen. If an electrocardiograph cable is connected to the interface, ECG signals obtained which indicates the activity of heart (paced or sensed events)



Thresholds

One of the main functions that improve the pacemaker activity enlarging its life length and allowing that, at the same time, spontaneous heart signals are sensed, is the determination of pacing and sensing thresholds.

Pacing Threshold

Each generated stimulus is characterized by amplitude, expressed in volts (V), and a pulse width, expressed in milliseconds (ms). The minimum value combination, pulse width and amplitude, able to provoke an efficient stimulus, is known as the pacing threshold.

As the pacing threshold is known, low effective pulse width and amplitude values can be programmed. In this way, the pacemaker is not programmed with high values that cause unnecessary battery consumption.

Sensing Threshold

The lowest amplitude of the signal generated by a heart beat, able to be detected by the pacemaker, is defined as the sensing threshold. By programming the sensitivity of the pacemaker according to the threshold, all the spontaneous heart beats will be sensed obtaining a better behavior.

Threshold Measuring

To measure the thresholds it is necessary to monitor the patient using an electrocardiograph. After pressing the Threshold button or selecting the Threshold command from the Actions menu, the following options are displayed:

SENSING

In order to determine the sensing threshold, a rate that allows the patient to dominate the rhythm must be selected.

START button must be clicked to start the threshold detection, to increase the Sensitivity parameter NEXT button should be clicked. Once the electrocardiograph shows that the pacemaker senses the heart activity, the procedure should be stopped clicking the **End** button. In that moment, the pacing and sensing initial values will be automatically reprogrammed.

PACING

Pacing threshold can be determined using either pulse width or amplitude.

The first step is to change the rate until the pacemaker dominates the rhythm. Afterwards, by pressing the Start button threshold detection starts. This procedure must be repeated until the electrocardiograph shows that the energy of the stimulus is not enough, then click the End button.

The pacemaker will then be programmed with the initial values. Besides, a list with the different values used during the procedure will be shown. This list includes the pulse widths, the related energy values. This value indicates how many times is the pulse width / Amplitude greater than the detected threshold.

The physician will select a pulse width or amplitude from with a safety margin (approx 3 times). Higher the Safety Factor means a more reliable stimulus but also

more battery consumption. In order to program the selected value, you can press the **Program** button.

Naturally, in the cases of bicameral pacemakers, each chamber has its own pacing threshold. That is why in the command THRESHOLD, the options ATRIUM PACING and VENTRICULAR PACING are found. In the first case the procedure is the same as above, in the second it is necessary to vary the AV Delay until the pacemaker dominates the ventricle rhythm. Afterward the procedure is the same as the one described.



Longitivity (Estimated service life)

Parameters		
Mode	DDD	
Rate	60	BPM
Pacing	100%	
A PW	0.366	ms
V PW	0.366	
A AMP	2.5	Volts
V AMP	2.5	

Estimated Life		
10 Years 0 Months	at	2.80 V

Remaining Life		
0 Years 0 Months	at	

Battery Chemistry		
Model	WG 8950	
Voltage	2.8 V	
Capacity Ah	1.58 Ah	

◆ Dialog box for estimate the service life

Using the Longitivity dialog box, the user can vary the rate, mode, pulse width and amplitude of the stimulus to obtain the service life (in months and years) of the pacemakers of the corresponding model.(NOTE: Longitivity calculation is based on mathematical formulae to show approx longitivity, this should not be considered as final value)

The action Longitivity calculates and shows the results but does not program the pacemaker. The Select button loads the programming screen with the values selected in this dialog box.



Statistics

An important option of SPL software is found in the Actions menu under the name of STATISTICS. Using this function, accurate follow-ups of the pacemaker activity are achieved, because it is shown how many times the pacemaker had paced and how many times the activity of the patient was sensed.

The dialog box shows, in the first row, on a gray background, the names of the parameters that the pacemaker can register (see the table at the end of the manual) and, in the following rows, it shows the values obtained from the pacemaker. In order to interrogate the statistic values, press the **Read** button. SPL software saves the readings in its database for further use.

Some of the statistical data are specific of the model; other are always present, as the date and time of the reading, the times the pacemaker stimulated and sensed, and the percentage of this data in comparison with the total number of events (pacing and sensing).

The **Graphic** button shows the different values in a bar graphic format. The **Reset** button zeroes all the statistical values in the pacemaker, and the **Close** button ends the activity of the dialog box.

To carry on the reading and the deleting operations, it is necessary that the SMART-E Programming Head Model SEH-11 is properly placed.



Temporary Programming

The temporary programming action switches the pacemaker momentarily on to Asynchronous mode. The pacing rate can be selected through the rate dialog box of the temporary window.

After selecting the rate value, click in the Program button to start the temporary programming.

It is important to notice that, during temporary programming, the computer will be in constant communication with the pacemaker, not answering to commands from the mouse or keyboard. The Cancel button used to terminate this mode. Another way to finish the temporary programming and restoring the normal functioning of the pacemaker, is moving away the SMART-E Programming Head Model SEH-11 from the implant zone.



Impedance

It allows measuring the impedance of the lead connected to the pacemaker. This feature is useful because it allows confirming whether the pacing pulses are correctly transmitted to the heart. High impedance values may indicate that the effectiveness of the stimuli is low. An impedance value greater than 1500 Ohm means that the lead is broken and a value less than 250 Ohm means that there is a short circuit.



Urgent Programming

The urgent programming is an important safety feature of SPL software. The pacemaker is programmed immediately with safe values.

There are several ways to activate the Urgent Programming feature, naturally in all of them the SMART-E Programming Head Model SEH-11 must be correctly placed:

1. Click on the **Urgent Programming** button of the toolbar
2. Select the URGENT option of the Actions menu

The emergency programming is run immediately without intermediate steps.

9. DATA – LOG BROWSER

Besides the registers shown in the Statistics command, SPL software stores in a data base the values used to program the pacemaker in each control or visit, as well as personal and specific implant data of the patient. From the Log Browser menu, the physician will be able to access the data.

On the other hand, SPL software identifies automatically the pacemaker which is being interrogated and offers, on the List, all the registers stored in the database, related to that pacemaker. The latter is especially interesting for it enables to easily find the important information for the correct programming of the pacemaker, such as the values used for programming in other opportunities.

9.1 Implant

When the pacemaker is interrogated, SPL software automatically offers its serial number. In order to obtain other important data related to the implant process it is necessary that the physician defines an implant (using File's PRINT menu). This proceeding consists of associating the patient data (name, surname, address, etc.) with the pacemaker data (model, serial number) so as to have them available every time that the pulse generator is interrogated.

9.2 ECG

The description of the electrocardiogram of the patient is part of the information required to record an implant in the Data Base. It can be selected from log browser. Whenever marker starts , it automatically stores the marker and ECG data.

ECG Recording: ECG of a patient can record by clicking “ECG RECORDING”
Button

ECG Gain : 3 gains (0,1 ,2) can be set using the slider (Right Corner).

ECG Sensitivity : ECG sensitivity can be adjusted using slider (Right Corner) to show the Heart Rate.

9.3 Reports

The data base menu offers the possibility to create printed reports. This can be done from File’s Print menu. Saved reports can be visualize by File’s ‘OPEN’ menu

10. Tables

A). Parameter Values of SSI 8820 Pacemakers

Parameter	Valid values	Title on the screen
Mode	VVI, VVT, VOO, AAI, AAT, AOO, OVO, OAO	Mode
Basic Rate	From 30 to 120 ppm	Rate
Pulse Widths	0.07 ms and from 0.1 ms to 1.5 ms in steps of 0.1 ms	Pacing
Pulse Amplitudes	From 0.2 V to 7.5 V	Pacing
Electrical configuration for pacing	Unipolar / Bipolar	Pacing
Sensitivities	From 0.5 to 4.0mV in steps of 0.5mV	Sensing
Electrical configuration for sensing	Unipolar / Bipolar	Sensing
Hysteresis	0% to 20% in steps of 5%	Hysteresis
Refractory Periods	From 200 to 500 ms in steps of 15.625 ms	Refractory
Upper Rate	From 80 to 180 ppm	Trigger Rate

B). Parameter Values of SSIR 297 Pacemakers

Parameter	Valid values	Title on the screen
Mode	VVI, VVT, VOO, OVO, AAI, AAT, AOO, OAO, VVIR, VVTR, VOOR, AAIR, AATR, AOOR	Mode
Basic Rate	From 32 to 120 ppm	Rate
Pulse Widths	0.07, 0.10, 0.13, 0.16, 0.19 ... 1.5	Pacing
Pulse Amplitudes	32 values from 0.2 to 7.5 V	Pacing
Electrical configuration for pacing	Unipolar / Bipolar	Pacing
Sensitivities	From 0.5 to 4.0 mV in steps of 0.5mV	Sensing

Electrical configuration for sensing	Unipolar / Bipolar	Sensing
Hysteresis	2 ppm to 40 ppm	Hysteresis
Refractory Periods	From 200 to 500 ms in steps of 15.625 ms	Refractory
Upper Rate	From 80 to 180 ppm	Trigger Upper Rate
Rate response to acceleration		
Upper Rate	From 80 to 180 ppm in	Upper Rate
Coefficient of rate response to acceleration	From 1 to 16	Coef
Reaction time	From 10 to 60 s	Increase
Recovery time	From 1 to 10 m	Decrease
Automatic Refractory Change	When the rate is greater than 120 ppm, the refractory period decreases automatically to 250 ms	ARC

C). Parameter Values of DDDR 747R Pacemakers

Parameter	Valid values	Title on the screen
Mode	DDD, VDD, DDI, DVI, DOO, VVI, VVT, VOO, AAI, AAT, AOO, OAO, OVO, ODO, DDDR, VDDR, DDIR, DVIR, DOOR, VVIR, VOOR, VVTR, AAIR, AOOR, AATR, OFF	Mode
Basic Rate	From 30 to 120 ppm	Rate
Pulse Widths (A & V)	0.07, 0.1, 0.2, 0.3, 0.4 ... 1.5	Pacing
Pulse Amplitudes(A&V)	36 values from 0.2 to 7.5 V	Pacing
Electrical configuration for pacing	Unipolar / Bipolar	Pacing
Sensitivities	For Atrium- From 0.2 to 4.6 mV For Ventricle- From 0.5 to 7.5 mV	Sensing
Electrical configuration for sensing	Unipolar / Bipolar	Sensing

Hysteresis	4 BPM to 60 BPM	Hysteresis
Refractory Periods	From 200 to 500ms in steps of 25 ms	Refractory
Upper Rate	From 80 BPM to 180 BPM in steps of 2 BPM.(Behavior will be Wenckebach)	Trigger Upper Rate
PVARP		
RATE RESPONSE TO ACCELERATION		
Upper Rate	From 80 to 180 BPM in steps of 2 BPM.	Upper Rate
Coefficient of rate response to acceleration	From 1 to 15	Slope
Reaction time	From 10 to 60 Sec. in steps of 10 Sec	Up Time
Recovery time	From 1 to 10 Min. steps of 1 Min.	Dn Time
Automatic Refractory Change	On/Off. When programmed On, if the rate is greater than 120 BPM, the refractory switch to the minimum value between the programmed one and 250ms	ARC
A Tachy Therapy	Enable: On/Off A Trigger Rate: From 80 min-1 to 180 min-1 in steps of 2 min-1 Number of events for A-Tachy Entry: 4, 8, 16, 32 Number of events for A-Tachy exit: 4, 8, 16, 32	A Tachy. Therapy
Auto Polarity Switch	ON - OFF	Auto Pol. SW

D). Parameter Values of Trinity 3000 Pacemakers

Parameter	Valid values	Title on the screen
Mode	DDD, DDI, DOO, VDD, VVI, VVT, VOO, AAI, AAT, AOO, ODO. For Bi-Vent mode On-Off button	Mode
Basic Rate	From 30 to 132 ppm	Rate
Pulse Widths (A,RV& LV)	0.1, 0.2, 0.3, 0.4, 0.4 ... 1.5 ms	Pacing
Pulse Amplitudes (A,RV)	2.5V, 5.0V	Pacing
Pulse Amplitudes LV	5.0 V	
Electrical configuration for pacing	Unipolar / Bipolar	Pacing
Sensitivities	For Atrium- From 0.5mV to 4.0 mV For Right Ventricle- From 1.0 to 6.6 mV	Sensing
Electrical configuration for sensing	Unipolar / Bipolar	Sensing
Hysteresis	0%, 5%, 10%, 15%, 20% (single chamber modes)	Hysteresis
Refractory Periods (A & RV)	From 195 to 430 ms, in steps of 15.625 ms.	Refractory
Upper Rate (Trigger Mode)	From 60 to 147 ppm.	Trigger Rate

Blanking	From 21 to 68 ms, in steps of 15.625 ms.	Blanking
Post Sensing AV Delay	From 30 to 132 ppm.	

E). Summary of Parameters in Charak-DDDR 747R & Trinity 3000

Parameters	Charak-DR	Trinity 3000
Mode	Yes	Yes
Rate	Yes	Yes
Upper rate	Yes	No
Backup mode	No	No
Blanking	Yes	Yes
Pacing	Yes	Yes
Sensing	Yes	Yes
Refractory	Yes	Yes
PVARP	Yes	Yes
Coupled	No	No
AV Delay	Yes	Yes
AV Dynamic Delay	No	Yes
Hysteresis	Yes	Yes
Trigger rate	Yes	No
Trigger upper rate	Yes	Yes
Slope	Yes	No
Increment	Yes	No
Decrement	Yes	No
ARC	Yes	No
Minimized Ventricle	Yes	

Pacing		
A Tachy Response	Yes	
Rate Smoothing in AT	Yes	
Safety Polarity Switch	Yes	
Magnet Response	Yes	
Noise Detection	Yes	

F).SPL software statistical data for Pinnacle-R 297 & Pinnacle 8820

Screen Title:	
Date	Statistics reading date
Time	Statistics reading time
Histogram:	
E 0-80	Pacemaker pacing amount at a rate in the range 0 and 80 ppm
E 80-100	Pacemaker pacing amount at a rate in the range 80 and 100 ppm
E 100-120	Pacemaker pacing amount at a rate in the range 100 and 120 ppm
E 120-140	Pacemaker pacing amount at a rate in the range 120 and 140 ppm
E > 140	Pacemaker pacing amount at a rate higher than 140 ppm
S 0-80	Pacemaker sensed events amount at a rate in the range 0 and 80 ppm
S 80-100	Pacemaker sensed events amount at a rate in the range 80 and 100 ppm
S 100-120	Pacemaker sensed events amount at a rate in the range 100 and 120 ppm
S 120-140	Pacemaker sensed events amount at a rate in the range 120 and 140 ppm
S > 140	Pacemaker sensed events amount at a rate higher than 140
Percentages:	
% E 0-80	Generated pacing percentage related to the sum of paced and sensed events that occurred at a rate in the range 0 and 80 ppm
% E 80-100	Generated pacing percentage related to the sum of paced and sensed events that occurred at a rate in the range 80 and 100 ppm
% E 100-120	Generated pacing percentage related to the sum of paced and sensed events that occurred at a rate in the range 100 and 120 ppm

% E 120-140	Generated pacing percentage related to the sum of paced and sensed events that occurred at a rate in the range 120 and 140 ppm
% E > 140	Generated pacing percentage related to the sum of paced and sensed events that occurred at a rate higher than 140 ppm
% S 0-80	Sensed events percentage related to the sum of paced and sensed events that occurred at a rate in the range of 0 and 80 ppm
% S 80-100	Sensed events percentage related to the sum of paced and sensed events that occurred at a rate in the range of 80 and 100 ppm
% S 100-120	Sensed events percentage related to the sum of paced and sensed events that occurred at a rate in the range of 100 and 120 ppm
% S 120-140	Sensed events percentage related to the sum of paced and sensed events that occurred at a rate in the range of 120 and 140 ppm
% S > 140	Sensed events percentage related to the sum of paced and sensed events that occurred at a rate in the range higher than 140 ppm
Others:	
Times Noise	Number of times the pacemaker was interfered
Pacing Noise	Number of times the pacemaker generated pacing while interfered
Extrasystole	Number of extrasystoles detected by the pacemaker

11. CLEANING

SMART-E Programming Interface

The SMART-E Programmer Model SEP-11 Programming interface can be cleaned using a sponge or cloth moistened with water or 70% isopropyl alcohol.

Note: Do not expose the unit to ethers, acetone, or chlorinated solvents as these may damage the case or labels.

Caution: The SMART-E Programmer Model SEP-11 must not be immersed in water or cleaning agents. Severe damage to the device may occur.

SMART-E programming Head Model SEH-11

The SMART-E Programming Head Model SEH-11 can be cleaned using a sponge or cloth moistened with water or 70% isopropyl alcohol.

Note: Do not expose the unit to ethers, acetone, or chlorinated solvents as these may damage the case or labels.

Caution: The SMART-E Programming Head Model SEH-11 must not be immersed in water or cleaning agents. Severe damage to the device may occur.

Connecting Cables

The USB Cables, SMART-E Programming Head Model SEH-11 Cable, ECG cables supplied can be cleaned thoroughly with a mild detergent or 70% isopropyl alcohol to remove all visible dust marks. The cables may be immersed for cleaning. The cables must be thoroughly dried after cleaning. Inspection and testing by a qualified technician should be done after cleaning to verify proper cable function.

12. SAFETY & TECHNICAL CHECKS

Safety and technical checks should be carried out *on the* SMART-E Programmer Model SEP-11 and **SMART-E programming head model SEH-11** at least once every 6 months and after any malfunction or accident. Pacetronix does not recommend field repair of the device. For service or repair contact your local Pacetronix representative at the appropriate address.