GALIX
BIOMEDICAL INSTRUMENTATION, INC.

MULTIPROGRAMMABLE EXTERNAL PULSE GENERATOR WITH TACHYCARDIA TERMINATION, INTRACARDIAC ELECTROGRAPHY AND DATA LOGGING

GALIX MODEL ***PaceStar***

Operation Manual

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CAUTION:

The GALIX ***PaceStar-T/LT*** Pulse Generator can be used in the following pacing applications:

- Normal atrial pacing at rates from 30 to 200 ppm.
- Transitory atrial overdriving at rates from 120 to 600 ppm.
- Atrial tachycardia termination using extrastimulation.
- Normal ventricular pacing at rates from 30 to 200 ppm.
- Transitory ventricular overdriving at rates from 120 to 600 ppm.

WARNING:

Continuous high frequency operation (120 to 600 ppm) is contraindicated in ventricular applications. Tachycardia termination using the extrastimulation methods, especially the scanning algorithm, is also contraindicated in patients presenting acceleration or degeneration of cardiac rhythm in the presence of electrical stimuli.

NOTE:

The U. S. Federal Regulations restrict the sale of this device to or on order of a physician.

1. DESCRIPTION

1.1. CHARACTERISTICS OF THE GALIX PACESTAR

The GALIX ***PaceStar*** Multiprogrammable External Pulse Generator offers transitory pacing, high rate operation and monitoring of cardiac parameters. In addition to this, the models ***PaceStar-T*** and ***PaceStar-LT*** offers tachycardia termination using extrastimulation and cardiac electrography. The model ***PaceStar-LT*** also offers data logging for storing parameter changes, alarms, warnings, frequency trends, and intracavitary ECG signal. The ***PaceStar*** family can be used for cardiac surgery patients, emergency cardiac pacing, transitory management of arrhythmias and heart block, tachycardia termination and cardiac monitoring.

As a pulse generator for transitory pacing the GALIX ***PaceStar*** has the standard pacing modes of a single-chamber pacemaker, and delivers pulse rates from 30 to 200 ppm. These modes are:

- Asynchronous (AOO/VOO: SOO)
- Demand (AAI/VVI: SSI)

Pulse Rate, Pulse Amplitude, Pulse Width, Sensitivity, Refractory Period and Hysteresis can be programmed to achieve the highest pacing performance for any patient.

The GALIX ***PaceStar*** has a special function for high rate asynchronous pacing at rates from 120 to 600 ppm for tachycardia termination (overdriving method). The models ***PaceStar-T/LT*** *also* offer two additional methods using extrastimuli: pulse bursts and scanning.

In the Orthorhythmic Pulse Bursts method, the external stimuli are synchronized to the sensed spontaneous depolarizations at intervals that are 80% or 90% of the tachycardia cycle length. The stimuli are arranged in bursts and the user can program the number of pulses in the first and the last bursts to be generated. As long as the process progresses and the tachycardia does not terminate, the number of pulses per burst is increased by one from burst to burst until the last burst has been generated. The coupling interval between pulses is automatically calculated from the tachycardia cycle length (which is not user-programmable).

The other method is the Non-Orthorhythmic Scanning algorithm. In this case, the stimuli are arranged in bursts characterized by the Initial Delay between the sensed spontaneous depolarization and the first burst, the Coupled Delay between consecutive pulses in the burst and the Number of Pulses in the burst. All these parameters are programmable. If a particular burst does not terminate the tachycardia, the following one will be generated with an initial delay that is shorter than 5 msec. This process ends after generating a pulse burst with an initial delay 80 msec shorter than the one in the first burst.

In both tachycardia termination methods, the heart rate is measured over four consecutive cycles to check whether the tachycardia has been terminated. In such a case, pulse burst generation is stopped.

The GALIX ***PaceStar*** measures the remaining battery life and the stimulation time for a particular pacing mode. Likewise, it measures the intrinsic patient rate, the time interval between P-waves/R-waves, and the time interval between a pacing pulse and the following spontaneous depolarization. The GALIX ***PaceStar*** gives the physician the pacing percentage, the number of paced beats and the number of paced plus spontaneous beats on an hourly basis.

The ***PaceStar-T/LT*** models also offer Intracardiac Electrography. The Cardiac Electrography involves sampling of the intracardiac signal at a rate of 400 samples/sec. This information can be presented on the LCD display, providing the physician with a clear picture of the capturing-sensing process. The physician can select the amplitude and scanning scales of the ECG presentation to properly visualize the spontaneous depolarizations.

The ***PaceStar-LT*** is capable to log the following information:

- EVENTS (such as Tachycardia Termination Initiation, Parameter Value Change, and so on): up to 4000
- ECG STRIPS (resolution: 200 samples per second, 5 steps/mV, +/-20mV): up to 20 5-sec strips
- MINUTE HEART BEAT COUNT: up to 1500 values (1500 minutes of data)
- HOURLY HEART BEAT COUNT: up to 120 values (5 days= 120 hours of data)
- HOURLY PULSE COUNT: up to 120 values (5 days= 120 hours of data)

The collected information can be downloaded to the PC through the proprietary O-Box Optical USB Interface. This interface can be connected to any computer system (desktop, laptop, and so on) with a free USB port and running Windows. After downloading the data to the PC, the user can perform with the ***PaceStar Data Logger*** Software the typical database operations (file saving/opening, filtering, addition of comments, and so on).

The GALIX ***PaceStar*** has an exclusive design based on the latest-technology microcontroller as the heart of a low-power consumption architecture used for control, data handling and stimulation. This design permits excellent accuracy and flexible operation, therefore broadening the application scope to the user.

The interface with the physician is carried out by means of a graphic Liquid Crystal Display (LCD) and a membrane keyboard. The 64x128-pixel LCD allows fast and simultaneous reading of all important data, avoiding the possible errors made with the rough indication of the ‘knob cursor’ in conventional devices. The membrane keyboard makes the operation simpler. The implementation of keyboard locking by software avoids dramatic accidental changes in parameter values and makes the usual protective cover unnecessary.

The LCD shows the stimulation status through symbols indicating keyboard-locking condition, Electromagnetic Interference present, tachycardia detected, spontaneous depolarization detected and pulse generated. This information is supplemented with acoustic signals, thus providing the physician with a strong feeling of the stimulation process.

By pressing the special key EMERG, an emergency SSI pacing mode is accessed. Emergency parameters are:

Rate = 70ppm	**Amplitude** = 10V	**Sensitivity** = 2.4mV
Hysteresis = 0bpm	**Refractory Period** = 320 msec	**Width** = 1 msec

The power source of the GALIX ***PaceStar*** consists of two 1.5V AA alkaline batteries, providing more than 20 days of continuous operation with Emergency Pacing parameters. The equipment will temporarily work with only one battery. Thus, continuous operation is preserved if batteries are replaced sequentially. The GALIX ***PaceStar*** will not operate if both batteries are removed, but will keep both programmed and measurement data. The battery condition is indicated on the LCD. A persistent acoustic alarm is activated in case a battery replacement is needed.

The GALIX ***PaceStar*** has full electrical isolation and protection against software failure, electromagnetic interference (EMI), current leakage and defibrillator discharge.

1.2. PRESENTATION

The GALIX ***PaceStar-T/LT*** is supplied in a carrying handbag containing:

- One ***PaceStar-T/LT*** Pulse Generator
- One 5 FT (1.5 meter) extender cable
- One arm strap
- One waist strap
- Two 1.5V AA alkaline batteries
- One operation manual

In addition to this, the model ***PaceStar-LT*** is also supplied with the following parts:

- One USB ***O-Box*** (Optical Box) Interface
- One USB O-Box/PC cable
- One Optical PaceStar/O-Box cable
- One ***PaceStar Data Logger*** Software Diskette

1.3. APPLICATIONS

A list of some applications of the GALIX ***PaceStar-T/LT*** is shown below. The key functions of the equipment are indicated in round brackets:

PACING

- Transitory Ventricular Pacing of patients with conduction abnormalities.
- Transitory Atrial Pacing of patients with sinus arrhythmias and normal A-V conduction (Programmable Refractory Period).
- Transitory Pacing of patients with high stimulation thresholds (pulse amplitude up to 10V).
- Long term transitory pacing of patients with occasional loss of natural rhythm (programmable Hysteresis).
- Asynchronous pacing for sensing failure detection.
- Emergency SSI Pacing with reliable capture [RATE= 70ppm, AMPLITUDE= 10V, WIDTH= 1ms, SENSE= 2.4mV, REFR. PERIOD= 320ms, HYSTERESIS= 0bpm].

TACHYCARDIA TERMINATION

- Tachycardia termination with the Pulse Bursts Method, Orthorhythmic.
- Tachycardia termination with the Scanning Method; non-Orthorhythmic.
- Tachycardia termination with the Overdriving Method.
- Overdriving up to 600 ppm for some electrophysiological procedures (e.g.: Wenckebach-frequency).
- Tachycardia detection with optical and acoustic indicators.

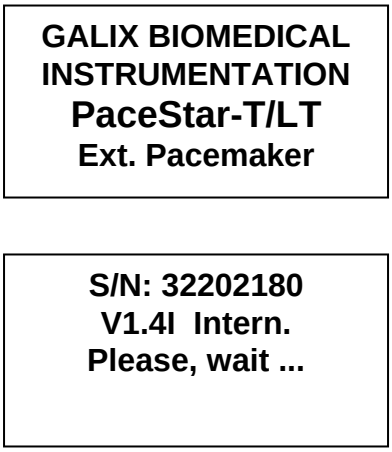
MEASUREMENTS

- Pacing Period.
- Pacing Percentage.
- Time Intervals between Pacing Pulses and P/R-Waves.
- Intracardiac Electrography.
- Monitoring of endocardial signals (Waveform, Frequency, Amplitude and Time Interval).
- Measurement and analysis of stimulation threshold, sensing threshold and rheobase line.

2. GETTING STARTED

Figure 2.1: ***PaceStar-T/LT***

- ***Note: Upon starting be sure the Catheter or Extension Cable is not connected. Get new 1.5V AA alkaline batteries and place them in the battery compartment observing the polarity. Press the ON/OFF key.*** The display will show the following succession of screens:



- ***After this introduction, press the EMERG key and the LOCK/UNLOCK key.*** The ***PaceStar-T/LT*** screen will look like:

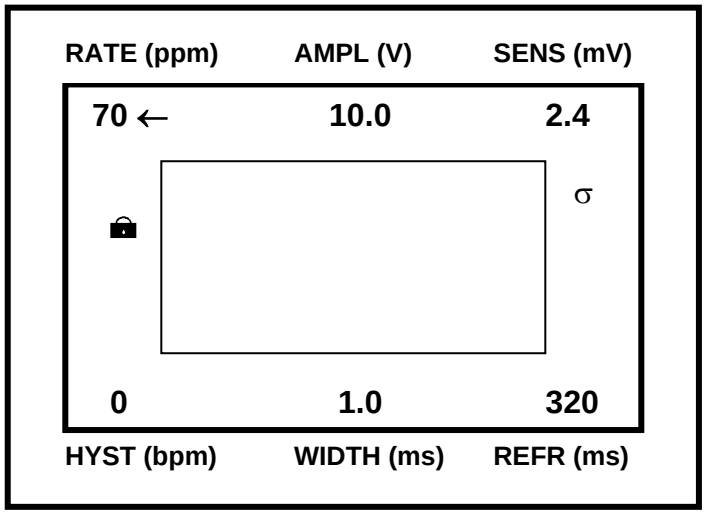


Figure 2.2 Normal Pacing Screen

indicating that the ***PaceStar*** is operating in SSI mode (AAI/VVI) with emergency parameters:

Rate:	70 ppm	Ampl:	10.0 V	Sens:	2.4 mV
Hyst:	0 bpm	Width:	1.0 ms	Refr:	320 ms

and that the keyboard is locked (symbol on the left side of the display).

The "σ" (on the upper right) flashes each time a pacing pulse is generated. Of course, because there is no sensed signal, the ***PaceStar-T/LT*** will generate pulses continuously at a rate of 70 ppm.

The central box is used to display measured Data, Configuration Options, ECG and messages. The information presented depends on the function selected. On the right and left sides of this central box status symbols may appear. These symbols will indicate Keyboard-locked, Pacing, Sensing, Noise, Tachycardia, Battery Replacement Need, Wrong Battery Polarity and Battery Removed. The positions of the symbols are the following:

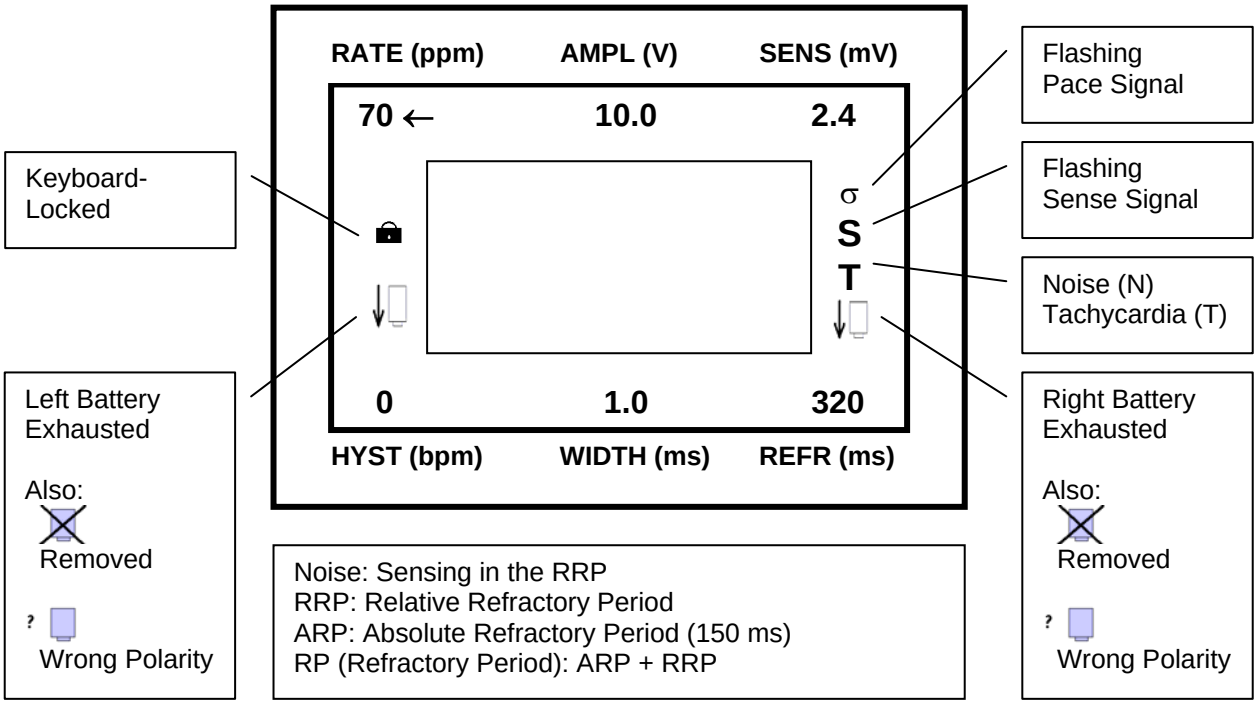


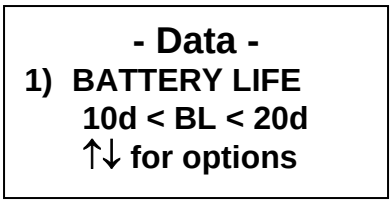
Figure 2.3: Status Indicators

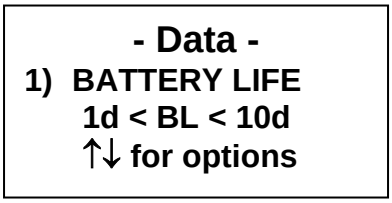
Whenever the keyboard is locked only the *EMERG*, *DATA*, *ECG*, *LOCK/UNLOCK* and *ON/OFF* keys are active. The keyboard locking avoids accidental change of stimulation or configuration parameters. The *EMERG* key is always active to give fast access to stimulation with a predefined set of parameters. The *ON/OFF* key is always active to allow unit turn-off at any time. The *DATA* and *ECG* keys present measurement results and intracardiac electrograms respectively, and therefore the stimulation parameters cannot be modified by accessing these functions.

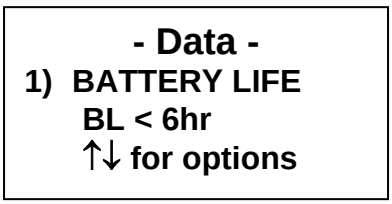
- ***Continue by pressing the DATA key.*** The battery life will appear. If you have inserted new ones, the message:

- Data -
1) BATTERY LIFE
BL > 20d
↑↓ for options

should appear (remaining battery life longer than 20days). Otherwise you may expect the messages:







In the latter case, a low-battery alarm sounds persistently every 5 seconds indicating that it is time for battery replacement. This alarm will also be activated if only one of the batteries become exhausted.

- The *UP* and *DOWN* keys allow the scrolling of the DATA menu. ***Press DOWN once.*** The stimulation time will appear. See the dynamic presentation changing every second.

- ***Press DOWN again.*** The patient rate and the P-P/R-R interval will appear full of asterisks. This means that there is no sensed signal.

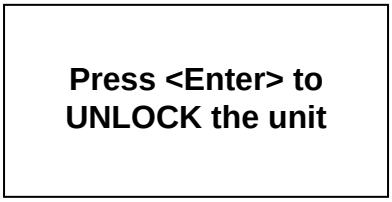
- ***Press DOWN once more***. Statistics concerning total number of pacing pulses (PU), total number of beats (BEA) and pacing percentage (%PM) will appear. Note that the presentation is dynamic. PU = BEA and %PM = 100 because there is no patient signal. The counters are cleared every hour.

- ***Press DOWN again.*** The unit version and serial number will appear.

- ***Play with the UP and DOWN keys to see how they work. Once finished, press the CANCEL key*** to resume the Normal Pacing Screen (Figure 2.2**)**

CHANGING PARAMETERS:

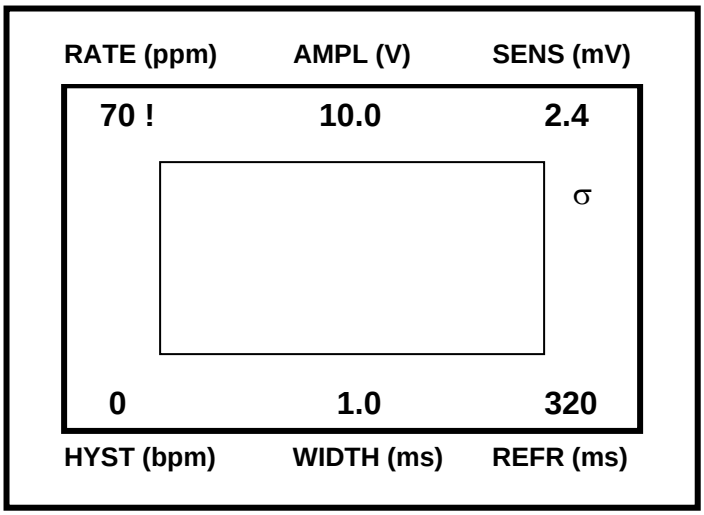
- Prior to modifying a pacing parameter it is necessary to unlock the keyboard. ***Press the LOCK key and then the ENTER key when the message***



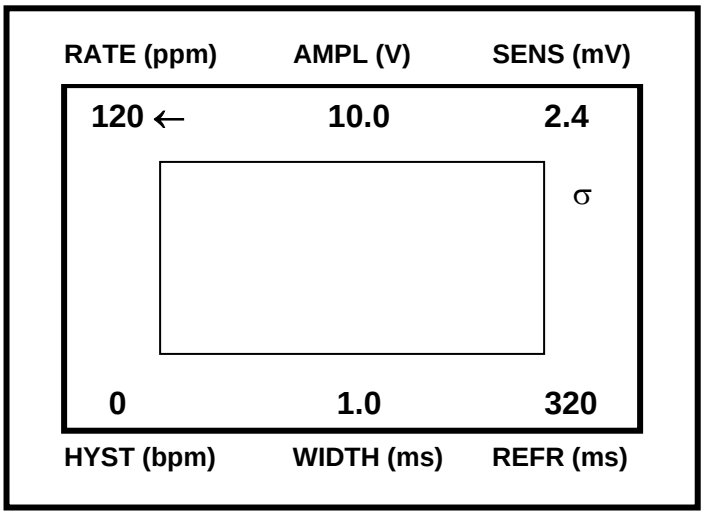
appears. The Keyboard-Locked symbol will disappear. Now, all the keys are active including the *TACHY* and *CONFIG* keys. ***Do not press them for the time being.***

- The *LEFT, RIGHT, UP* and *DOWN* keys are used to point to the parameter to modify. The pointing arrow will move accordingly. ***Try with these keys to get familiarized with the method. Finally point to the RATE parameter.***

- ***Press ENTER.*** The arrow will turn into an exclamation mark "**!**" indicating that rate modification has been enabled and that the value shown is the active one.

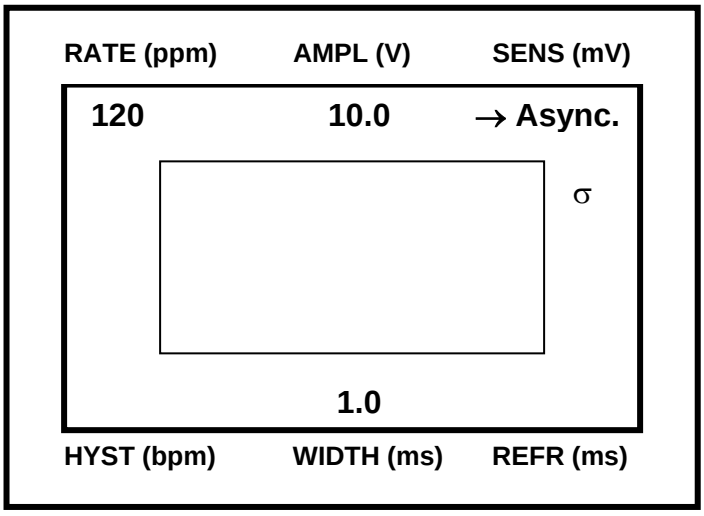


- ***Use UP and DOWN to change the value.*** Note that the "**!**" mark turns into "**?**" as long as the chosen value is different from 70. This means that the presented rate is different from the programmed one. ***Choose 120ppm and press ENTER.*** The ***PaceStar-T/LT*** will show the Normal Pacing Screen with the new rate value and the "σ" symbol will flash faster.



- ***Press ENTER again.*** The rate sector of the LCD will show **120 !** (120ppm is the latest selected rate). ***Play with UP and DOWN again. Choose 200ppm.*** You probably have noticed that the ***PaceStar-T/LT*** checks the rate limits and that there are two data change speeds. The faster data change speed is enabled by keeping the key pressed longer than two seconds.

- ***Quit the Rate Selection pressing the CANCEL key.*** The Normal Pacing Screen will appear. ***Select the Sensitivity level and press the ENTER key. Increase the Sensitivity level value presented by pressing the UP key.*** Upon exceeding 12mV, the label **Async.** will appear. ***Press the ENTER key to confirm this choice.*** The new Normal Pacing Screen will be:



indicating that the asynchronous SOO (AOO/VOO) Pacing Mode has been accessed. In this mode, sensing is fully disabled and the pacemaker stimulates at constant rate with the selected pulse amplitude and duration (120ppm, 10V and 1ms, respectively, in the example).

To release the SOO asynchronous pacing mode, it is necessary to access sensitivity selection and decrease the value by means of the *DOWN* key, and further confirm the selection by pressing the *ENTER* key.

- ***Following the procedures described try to modify AMPL, HYST, REFR and WIDTH to get a better feeling for the operation. After this, choose the following pacing parameters:***

Rate = 90ppm	Ampl = 4.0V	Sens = 3.2mV
Hyst = 5bpm	Width = 0.6ms	Refr = 250ms

- **Press the *ON/OFF* key. The message:**

Press <Enter> to TURN-OFF the unit

appears on screen asking the user to turn off the unit. If the *ENTER* key is not pressed in 3 seconds, the ***PaceStar-T/LT*** will return to the previous screen. ***Press no key to see this effect.*** The unit should return to the Normal Pacing Screen.

- **Press the ON/OFF key and then the ENTER key.** The following message will appear on the screen:

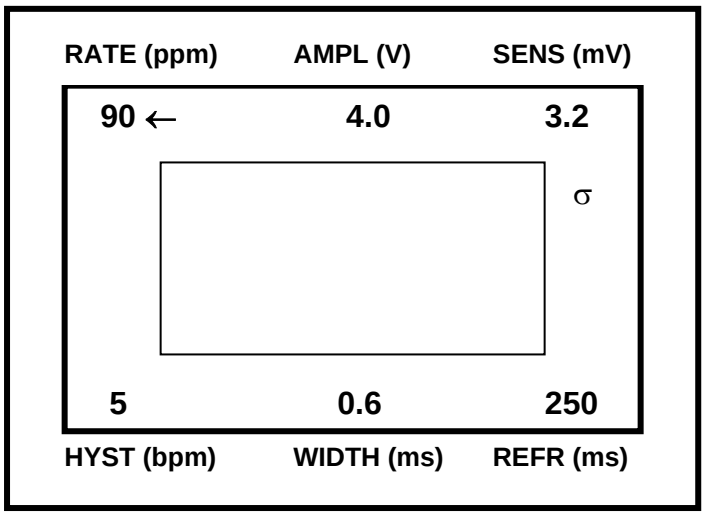
TURN-OFF in 2 seconds

After 2 seconds, the ***PaceStar-T/LT*** will go to power-down. The ***PaceStar-T/LT*** stores the programmed parameters for future use, even if the batteries are removed.

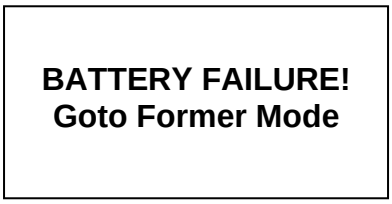
LET US TURN ON THE *PACESTAR* UNIT AGAIN:

- ***Press the ON/OFF key.*** After presenting the following introductory message:

the ***PaceStar-T/LT*** will resume the SSI mode with the parameters selected by the user before turning off. At any time you can turn off the ***PaceStar-T/LT*** using the procedure described above. The screen will present:



The ***PaceStar-T/LT*** recognizes a power-fail and saves the data in non-volatile memory before going automatically to power down. Let us check it. ***Remove both batteries by sliding the battery cover to the right/left to pull out the left/right battery cartridges.*** The display will become blank. ***Wait 30 seconds and place the batteries again. Press the ON/OFF key.*** A short "beep" will sound and the display will show:



The ***PaceStar-T/LT*** will now go to the SSI mode with the previously programmed parameters.

3. DISPLAY MESSAGES, KEYS AND ACOUSTIC SIGNALS

3.1. DISPLAY MESSAGES

The ***PaceStar-T/LT*** LCD has 64 lines of 128 pixels (see Figures 3.1 and 3.2). The upper and lower 12 horizontal lines of pixels are used to continuously display the value of the pacing parameters Rate, Amplitude, Sensitivity, Hysteresis, Pulse Width and Refractory Period. The central area comprising 40 horizontal lines of 128 pixels is used to show:

- Status Information,
- Messages,
- Data, or
- ECG.

Messages, Data or ECG are presented in a box depicted in the central area.

The Status Information comprises 4 characters placed vertically on the right and left sides of the Central Area of the display. This information consists of:

Right Side:

- Pacing: a flashing "σ" in the top position.
- Signal detected: a flashing "♥" in the second position from top to bottom.
- Noise or Tachycardia detection: an "**N**" or a "**T**" in the third position from top to bottom.
- Right Battery condition: different symbols on the fourth position from top to bottom for battery conditions:

  Exhausted  , Removed  , and Wrong Polarity  .
  If the battery is fresh, no battery symbol will appear.

Left Side:

- Data Logging Buffer Full Condition: a crossed-circle ⊗ picture in the first position from top to bottom means data the data logging buffer is full.
- Lock/Unlock condition of the keyboard: a lock picture  in the second position from top to bottom means keyboard-locked.
- Left Battery condition: different symbols on the fourth position from top to bottom for battery conditions:

  Exhausted  , Removed  , and Wrong Polarity  .
  If the battery is new, no battery symbol will appear.

- Noise is reported when the interval between signal detections in two consecutive cycles is shorter than 150ms.
- Tachycardia is detected when the interval between signal detections in two consecutive cycles is shorter than the one corresponding to the programmed Tachycardia Recognition Rate.

Figure 3.1: ***PaceStar-T/LT*** (Emergency parameters)

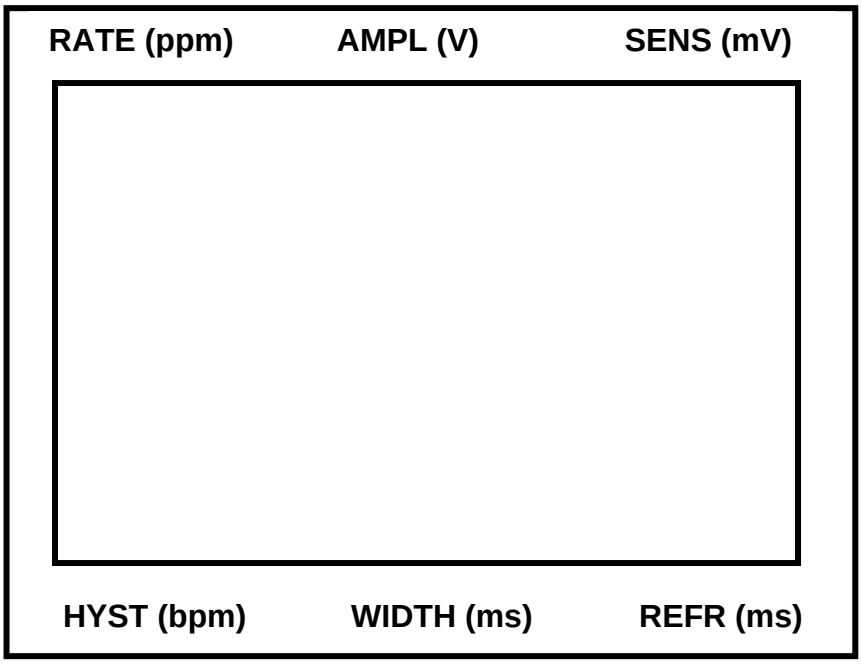


Figure 3.2: Display Layout

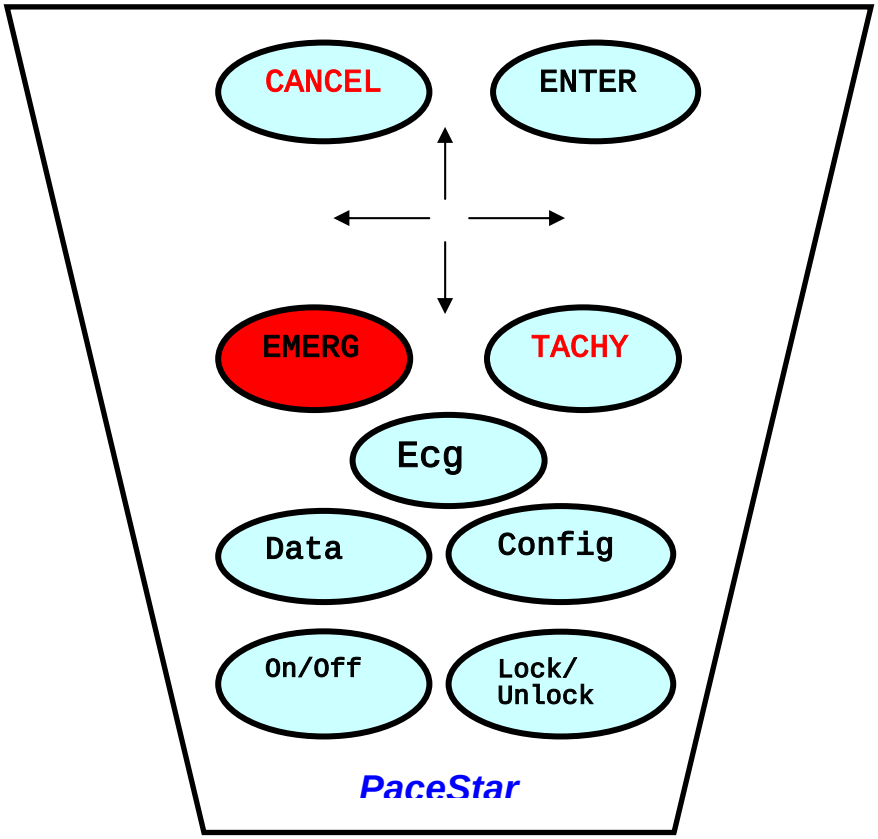


Figure 3.3: Membrane Keyboard Layout

The ***PaceStar-T/LT*** Messages are intended to guide the operator and depend on the function currently active. Examples of messages are:

Turn-off in 2 seconds

BATTERY FAILURE!

• **SET TACHY RECOGNIT. RATE?**

The Data provided in the central box refers to physiologic and administrative information. Examples of data provided are:

- Data -
1) BATTERY LIFE
1d< BL <10d
↑↓ for options

- Data -
3) FRE= 120 bpm
INT= 500 ms S--S
↑↓ for options

The Intracardiac ECG is depicted in the central box at different time and amplitude scales when this function is enabled.

The Normal Pacing Screen presents the Pacing Parameters (Rate, Amplitude, Sensitivity, Hysteresis, Width and Refractory Period) and the Status Information surrounding the central box. Alternatively, it may present the ECG in the central box.

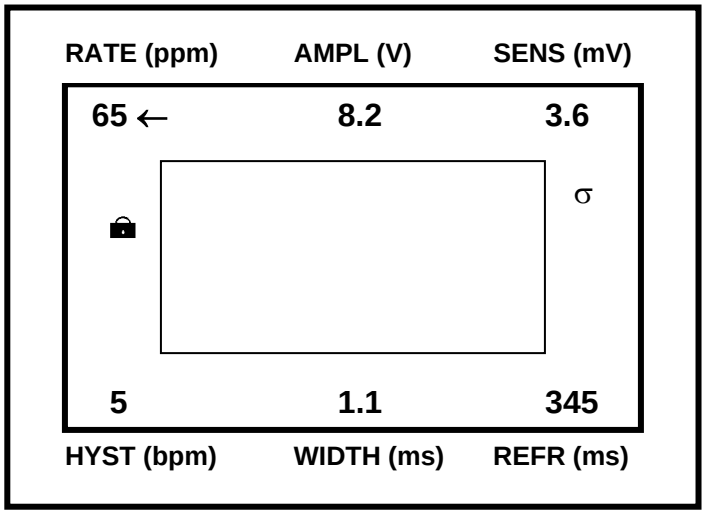


Figure 3.4: Normal Pacing Screen

3.2. COMMAND KEYS (*ON/OFF*, *LOCK/UNLOCK*, *DATA*, *CONFIG*, *ECG*)

There are two groups of control keys (see Figure 3.3):
- Command keys: ON/OFF, LOCK/UNLOCK, DATA, CONFIG and ECG.
- Data keys: LEFT, RIGHT, UP, DOWN, ENTER and CANCEL.

ON/OFF

When the ***PaceStar-T/LT*** is off, pressing the *ON/OFF* key turns on the unit.

When the ***PaceStar-T/LT*** is on, the user may turn off the unit by pressing the *ON/OFF* key and then pressing the *ENTER* key when the message:

Press <ENTER> **to TURN-OFF**

appears. The ***PaceStar-T/LT*** presents the message:

Turn-Off in **2 seconds**

before switching off. The switching off process may be aborted by keeping the *ON/OFF* key pressed during the presentation of this message. The ***PaceStar-T/LT*** will resume operation from the point previous to switching off.

During power-off the ***PaceStar-T/LT*** keeps all the programmed data and selections, even if the batteries become exhausted. The ***PaceStar-T/LT*** also switches to a power-off state if there is a power failure, but this is done automatically. The programmed data is kept unaltered in memory even if the batteries are removed.

What the ***PaceStar-T/LT*** does after switching on depends on the following cases:
- If there was an intentional switch off, it will present a short introductory message:

GALIX BIOMEDICAL **INSTRUMENTATION** **PaceStar-T/LT** **Ext. Pacemaker**

  and will then resume the former pacing mode.
- If there was a power failure, it will resume the former pacing mode without the introductory message.

LOCK/UNLOCK

When the ***PaceStar-T/LT*** keyboard is unlocked, pressing the ***LOCK/UNLOCK*** key locks it. The symbol  will appear on the left side of the display central box.

When the ***PaceStar-T/LT*** keyboard is locked, the user may unlock it by pressing the ***LOCK/UNLOCK*** key and then pressing the *ENTER* key when the message

Press <ENTER> to UNLOCK the unit

appears. The symbol  will disappear.

The *LOCK/UNLOCK* key is used to lock the keyboard to prevent accidental change of parameters. The lock inhibits all the keys excepting *LOCK/UNLOCK, EMERG*, *ON/OFF*, *DATA* and *ECG*. Locking/unlocking is only possible when the ***PaceStar-T/LT*** shows the Normal Pacing Screen.

The ***PaceStar-T/LT*** has timed autolocking; if no key is pressed, the keyboard will be locked automatically in 4 minutes.

DATA

When the display shows the Normal Pacing Screen (Figure 3.4), pressing the *DATA* key will present physiologic and administrative data in the central box. The user may scroll all the available information by means of the *UP* and *DOWN* keys.

The data provided are:
1) BATTERY LIFE
2) ACTIVE TIME ELAPSED
3) PATIENT HEART RATE and PATIENT CARDIAC CYCLE LENGTH
4) PACING PERCENTAGE, CUMULATIVE PACING PULSES and CUMULATIVE HEART BEATS
5) UNIT VERSION and SERIAL NUMBER
6) DATE AND TIME (only ***PaceStar-LT***)

CONFIG

When the display shows the Normal Pacing Screen and there is no lock condition, pressing the *CONFIG* key will open the Configuration Parameter menu in the central box. The user may scroll all the available configuration parameter for checking or modification by means of the *UP* and *DOWN* keys.

The configuration parameters and actions available are:

- ORTHORHYTHMIC TACHYCARDIA TERMINATION PARAMETERS SETTING
- SCANNING TACHYCARDIA TERMINATION PARAMETERS SETTING
- TACHYCARDIA RECOGNITION RATE SETTING
- STIMULATION CLOCK STARTING
- SENSE ACOUSTIC SIGNAL ENABLING/DISABLING
- STIMULUS ACOUSTIC SIGNAL ENABLING/DISABLING
- KEY-PRESSED ACOUSTIC SIGNAL ENABLING/DISABLING
- TACHYCARDIA ALARM ENABLING/DISABLING
- DISPLAY CONTRAST ADJUSTMENT
- LANGUAGE SELECTION
- TIME SET (only ***PaceStar-LT***)
- DATE SET (only ***PaceStar-LT***)
- DATA LOGGING ENABLING/DISABLING (only ***PaceStar-LT***)
- DATA LOGGING BUFFER CLEARING (only ***PaceStar-LT***)
- DATA-LOGGED DOWNLOADING (only ***PaceStar-LT***)

ECG

When the display shows the Normal Pacing Screen, pressing the *ECG* key will activate/deactivate the ECG presentation in the central box.

The user may scroll all the available time and amplitude scales by pressing the *ECG* key successively. The sequence of action elicited (period represented and amplitude range) is the following:

⇒ ECG ON (2s, +/-20mV)
⇒ ECG ON (2s, +/-4mV)
⇒ ECG ON (1s, +/-20mV) [+ LogECG in ***PaceStar-LT***]
⇒ ECG ON (1s, +/-4mV[+ LogECG in ***PaceStar-LT***]
⇒ ECG OFF

The user may Freeze/Unfreeze the ECG sweep by pressing the *CANCEL* key. This key is also used in the ***PaceStar-LT*** to record a 5-sec ECG strip when the 1-sec time scale presentation was activated.

3.3. DATA ENTRY KEYS (*LEFT, RIGHT, UP, DOWN, ENTER, CANCEL*)

The selection of the Pacing Parameter and modification of the Pacing Parameter Values are performed exclusively by the ***SCROLL (LEFT, RIGHT, UP, DOWN)***, ***ENTER*** and ***CANCEL*** keys. This is only possible under Keyboard-Unlocked condition. The following considerations are applicable:

- Pointed pacing parameter is identified with an arrow ("←"),
- Selected parameter is identified with a question mark ("?") or exclamation ("!") mark.
- Parameter pointing is performed by all LEFT, RIGHT, UP and DOWN scrolling keys.
- Parameter Value modification is performed by the UP and DOWN keys.
- ENTER key will select the pointed parameter for data changing, or confirm the value displayed.
- CANCEL key will cancel data change operation and confirm the former parameter value.

The procedure of the Pacing Parameter Data Entry is the following (assuming that the keyboard is unlocked):

SELECTION MODE (Normal Pacing Screen; Figure 3.4)

UP-DOWN:

Moves Cursor to point to other parameter

LEFT-RIGHT:

Moves Cursor to point to other parameter

ENTER:

Selects Parameter

Enters Data Modification Mode

CANCEL:

No Effect for Data Entry

Freezes/Unfreezes ECG trace if ECG presentation is active

DATA MODIFICATION

UP-DOWN

Changes Value of parameter

LEFT-RIGHT

No effect

ENTER

Confirms Value Displayed

Resumes Selection Mode (Normal Pacing Screen)

CANCEL

Discards Value Displayed

Keeps Former Value

Resumes Selection Mode (Normal Pacing Screen)

The *UP* and *DOWN* keys are also used to access the different items in the Data and Configuration Menus, and increase/decrease parameter values in the Configuration Menu. The *ENTER* key is used to confirm a particular selection and the *CANCEL* key to discard the entered value and keep the former value. The *CANCEL* key is also used to quit a submenu.

Some parameters, for instance the Tachycardia Recognition Rate, presents Auto Data Entry. In this particular case, every value modification is automatically confirmed without pressing the *ENTER* key.

3.4. THE EMERG KEY

EMERG is a special key for fast emergency SSI pacing access. The safety pacing parameter values are:

Rate: 70ppm, Ampl: 10V, Width: 1ms, Sens: 2.4mV,Hyst: 0bpm, Refr: 320ms

3.5. THE TACHY KEY

TACHY is a special key for accessing the Tachycardia Termination procedures. The ***PaceStar-T/LT*** has three methods: Overdriving, Orthorrhythmic Pulse Bursts and Scanning. There are two sets of parameters for the Pulse Burst and Scanning methods: programmed and customized. These extrastimulation methods are semiautomatic.

3.6. ACOUSTIC SIGNALS

There are two groups of acoustic signals:

- Indicators (pacing, sensing and key-pressed)
- Alarms (tachycardia, low battery)

The pacing or sensing signal consists of a short duration “beep”, generated simultaneously with the “**σ”** or “**♥”** status symbol, respectively. The acoustic signal of key-pressed consists of a short duration “beep” indicating that a key has been pressed. If the *UP* or *DOWN* keys are kept pressed when changing a parameter value, these “beeps” will provide an acoustic feedback of the value changing rate.

The tachycardia alarm consists of two “beeps” of different duration. These sounds will be repeated if the tachycardia is sustained. The battery alarm consists of 4 equally timed beeps every 5 seconds. If the remaining battery life is shorter than 6 hours, this alarm will continue sounding. It cannot be disabled.

The acoustic indicators and alarms may be disabled by software, with the sole exception of the battery alarm. In the default condition, the acoustic indicators and alarms are disabled.

4. OPERATION

CAUTION:
The GALIX ***PaceStar-T/LT*** Pulse Generator can be used in the following pacing applications:

- Normal atrial pacing at rates of 30 to 200 ppm.
- Transitory atrial overdriving at rates of 120 to 600 ppm.
- Atrial tachycardia termination using extrastimulation.
- Normal ventricular pacing at rates of 30 to 200 ppm.
- Transitory ventricular overdriving at rates of 120 to 600 ppm.

WARNING:

- Continuous high frequency operation (120 to 600 ppm) is contraindicated in ventricular applications. Tachycardia termination using the extrastimulation methods, especially the scanning algorithm, is also contraindicated in patients presenting acceleration or degeneration of cardiac rhythm in the presence of electrical stimuli.
- During the procedure for connecting the external pacemaker to the temporary lead implanted in a patient, an ECG MONITOR and a DEFIBRILLATION EQUIPMENT in standby SHOULD BE AVAILABLE.

4.1. PREPARATION FOR USE

Before connecting the ***PaceStar-T/LT*** unit to the patient lead, the user should check the battery condition and insert two fresh ones if necessary. Press the *ON/OFF* key to switching on the pulse generator and then press the *EMER* key to select the Emergency SSI pacing mode. Check that the flashing pacing signal "σ" appears on the LCD. The display will show the pacing parameters:

Rate: 70ppm Ampl: 10V Sens: 2.4mV
Hyst: 0bpm Width: 1ms Refr: 320ms

Press *DATA* and check the remaining battery life using the arrow keys to search for this option. If the remaining battery life is shorter than 6 hr or one of the batteries is exhausted, the visual signal will appear on the LCD and an acoustic alarm will sound. Under this condition or if the unit does not work properly, replace the batteries with fresh ones. Start from the beginning again.

Check that the keyboard is unlocked. If it is locked (symbol on the left side of the display) press the *LOCK/UNLOCK* key and then press *ENTER* to unlock the keyboard (the symbol disappears). Turn the unit off by pressing the *ON/OFF* key and then *ENTER*. The ***PaceStar-T/LT*** Pulse Generator is now ready to be connected to the patient lead.

The GALIX ***PaceStar-T/LT*** can work in two different positions: lying on the bedside table or attached to the patient by means of the arm strap or waist strap provided.

4.2. LEAD CONNECTION

Look at the connector on the upper right side of the unit. Take the extender cable and insert its cylindrical connector into the former one. To mate both connectors gently rotate the extender cable connector to align the guiding keys. A tactile click will indicate proper insertion.

The distal end of the extender cable has a two terminals catheter connector. The terminal with the "+" symbol has positive polarity and the one with the "-" symbol has negative polarity. The distance between contact holes is standard to allow the use of all kind of temporary catheters.

Insert the catheter pins to the extender cable connector pushing them into the holes respecting the polarity.

For unipolar applications the negative lead of the temporary catheter should be connected to the negative terminal. Bipolar lead systems may show different stimulation thresholds depending on the polarity of the connection. This difference is small for myocardial leads but may be important for endocardial leads. The stimulation thresholds will usually be lower if the distal tip is connected to the negative terminal of the unit.

To disconnect the extender cable from the ***PaceStar-T/LT*** unit pull the cylindrical connector grasping its body. Note that it is not possible to disconnect the extender cable pulling from the cable itself. The ***PaceStar-T/LT*** patient lead connector has a special feature that prevents accidental disconnection.

4.3. PACING

The ***PaceStar-T/LT*** has two pacing modes: SSI (AAI/VVI) and SOO (AOO/VOO).

The SSI mode is the default mode. The values of Rate, Amplitude, Sensitivity, Hysteresis, Width and Refractory Period parameters are displayed.

The SOO Mode is enabled by increasing the Sensitivity Value above 12mV. The label ***Async*** will replace the numeric sensitivity value on the LCD. In SOO mode, Sensitivity, Refractory Period and Hysteresis values are NOT displayed.

SSI mode can be resumed by pointing to the Sensitivity level (Async. label), pressing *ENTER* to allow data entry and pressing the *DOWN* key. The label Async will turn to 12mV. If the *DOWN* key is kept pressed, the sensitivity level will decrease. The selected sensitivity value must be confirmed by pressing *ENTER.*

4.4. STIMULATION THRESHOLD MEASUREMENT

- With the ***PaceStar-T/LT*** disconnected from the patient lead, follow the steps indicated in Section 4.1 with the only difference that pulse amplitude is set to a minimum (0.2V), and the rate is set 10ppm higher than the patient intrinsic rhythm. Before turning off the unit check that the pacing signal "σ" flashes at the selected rate.

- Connect the unit to the patient lead.

- Turn on the ***PaceStar-T/LT***. After the introductory messages, the unit will resume the operation mode previous to turning off.

- If the keyboard is locked, press the *LOCK* key and then the *ENTER* key to unlock it as explained in Section 3.2.

- Point to the Amplitude parameter and press *ENTER* to change the pulse amplitude. Increase the pulse amplitude slowly with the *UP* key and confirm with *ENTER*. The presence of the sense signal "♥" on the *LCD* will indicate that the ***PaceStar-T/LT*** has not captured the cardiac rhythm yet.

- Repeat the last procedure step until capture is established regularly. The indicated pulse amplitude is the Stimulation Threshold.

- If the ***PaceStar-T/LT*** unit will be used for continuous pacing, set the pulse amplitude to a value that provides a convenient safety margin (for instance: 40% larger than the stimulation threshold).

- If pacing will be mantained over several days the stimulation threshold may increase due to fibrotic tissue growth around the pacing electrode. In such a case, even larger values of pulse amplitude may be required for a safe capture.

NOTE: The stimulation threshold can also be determined starting with the largest pulse amplitude (10V) and decreasing it slowly until the capture is lost. The smallest pulse amplitude that produces consistent capture will be the stimulation threshold.

4.5. SENSITIVITY THRESHOLD MEASUREMENT

- With the ***PaceStar-T/LT*** disconnected from the patient lead, follow the steps indicated in Section 4.1 with the only difference that sensitivity level is set at 1mV and the rate is set at 10ppm less than the patient intrinsic rhythm. Before turning off the unit check that the pacing signal "σ" flashes at the selected rate.

- Connect the unit to the patient lead.

- Turn on the ***PaceStar-T/LT***. After some introductory messages the unit will resume the operation mode previous to turn off. The sensed signal "♥" on the LCD should flash at the patient intrinsic rate. Note that the lower the sensitivity level, the smaller the depolarization signal the ***PaceStar-T/LT*** can detect, and the more sensitive this device.

- If the keyboard is locked press the *LOCK* key and then the *ENTER* key to unlock it as explained in Section 3.2.

- Point to the Sensitivity parameter and press *ENTER* to allow sensitivity modification. Increase the sensitivity level slowly with the *UP* key and confirm with *ENTER*. The presence of the sensed signal "♥" on the LCD will indicate that the ***PaceStar-T/LT*** is still detecting the patient intrinsic signal.

- Repeat the last procedure step until the sensed signal "♥" disappears and the pacing signal "σ" flashes at the selected rate. The value of the sensitivity level represents approximately the size of the sensed cardiac signal.

- If the ***PaceStar-T/LT*** unit will be used for long term pacing, INCREASE the sensitivity by DECREASING the sensitivity level to allow changes in the cardiac signal. This is done by pressing the *DOWN* key and then the *ENTER* key.

- Safe cardiac signal detection is necessary to preserve the patient intrinsic rate while working in the SSI pacing mode. Low sensitivity levels increase the vulnerability to noise generated by artifacts. In principle, sensitivity levels smaller than 2mV should not be used for long term unattended pacing.

4.6. MEASUREMENTS AND STATISTICS (*DATA*)

The *DATA* key shows measurements and statistics data. These are:
1) Remaining Battery Life
2) Stimulation time
3) Patient Heart Rate and P-P/R-R interval
4) Pacing Percentage
5) Unit Version and Serial Number
6) Date and Time (only ***PaceStar-LT***)

The Remaining Battery Life (BL) estimate is presented in days or hours. In the case that the Battery Life is shorter than 6 hours, a Low-Battery alarm will persistently sound to signal that there is a battery replacement need. This alarm cannot be disabled. Simultaneously, the Display will indicate the condition, identifying the battery that has to be replaced. For safety reasons it is strongly recommended to replace both batteries in a sequential fashion. The ***PaceStar-T/LT*** temporarily operates with only one battery.

The Stimulation Active Time measures the time elapsed since the last turn-on or stimulation clock restart. Maximum count is 10 days. The presentation refreshes every second.

The ***PaceStar-T/LT*** updates the Patient Heart Rate every time the status sensing signal "♥" flashes. The label "S--S" follows the Time Interval between two consecutive P-waves or R-waves. If there is competition between the patient's heart and the pacemaker, the ***PaceStar-T/LT*** will also show the time interval between the pacing pulse and the P-wave or R-wave. In such a case, the labels "P-S" or "S-P" appear on the screen.

The Pacing Percentage is shown along with the number of generated pulses and the total number of beats (natural + paced). These counters are restarted every hour. The Pacing Percentage is the ratio between the number of paced beats and the total number of beats. The time period considered for the percentage calculation is also shown. Data is updated every second.

The Unit Version and Serial Number is provided for identification purposes.

In the ***PaceStar-LT*** model the Date and Time values are refreshed every second and provide the actual Date and Time used for logging processes. The Date Format is: Month/Day/Year. The Date and Time data should not be confused with the Stimulation Active Time that represents the time elicited from the latest turn on or the latest Stimulation Clock Starting Action. The Real Time Clock (RTC) continues running after the unit has been powered off or the batteries were removed.

4.7. CONFIGURATION PARAMETERS (*CONFIG*)

The tables below indicate the Configuration Parameters that can be accessed by pressing the *CONFIG* key under keyboard-unlocked condition (Default values are in parenthesis).

- TACHYCARDIA TERMINATION

CATEGORY	PARAMETER	RANGE/OPTIONS
PULSE BURST PARAMETERS	• Number of Pulses of First Burst • Number of Pulses of Last Burst	• 5 to 10 (8) • 10 to 20 (15)
SCANNING PARAMETERS	• Initial Delay • Coupled Delay • Number of Burst Pulses	• 200 to 400 ms (260) • 100 to 400 ms (260) • 1 to 10 (5)
TACHYCARDIA DETECTION	• Tachycardia Recognition Rate	• 100 to 200 bpm (150)

- TIME

CATEGORY	PARAMETER	RANGE/OPTIONS
STIMULATION TIMER	Not Applicable	# Restart / # No change
REAL TIME CLOCK (only ***PaceStar-LT***)	• Time • Date	• 00:00:00 to 23:59:59 • 00/00/2000 to 12/31/2099

- ACOUSTIC SIGNALS

CATEGORY	PARAMETER	RANGE/OPTIONS
BEEPS	• Pacing • Sensing • Key-pressed	# No / # Yes (No) # No / # Yes (No) # No / # Yes (No)
ALARMS	• Tachycardia	# No / # Yes (No)

- GENERAL

CATEGORY	PARAMETER	RANGE/OPTIONS
DISPLAY	• Display Contrast	1 to 12 (7)
LANGUAGE	• Language Option	# English (English) # Spanish # Portuguese

- LOGGING (only ***PaceStar-LT***)

CATEGORY	PARAMETER	RANGE/OPTIONS
DATA ACQUISITION	• Data Logging • Data Logging Buffer Clearing	# No / # Yes (No) # Execute / # No change
DATA TRANSMISSION	• Data-Logged Downloading	# Execute / # No change

Figure 4.1: Scanning Reversion Parameter Setting (English)

Figure 4.2: Scanning Reversion Parameter Setting (Spanish)

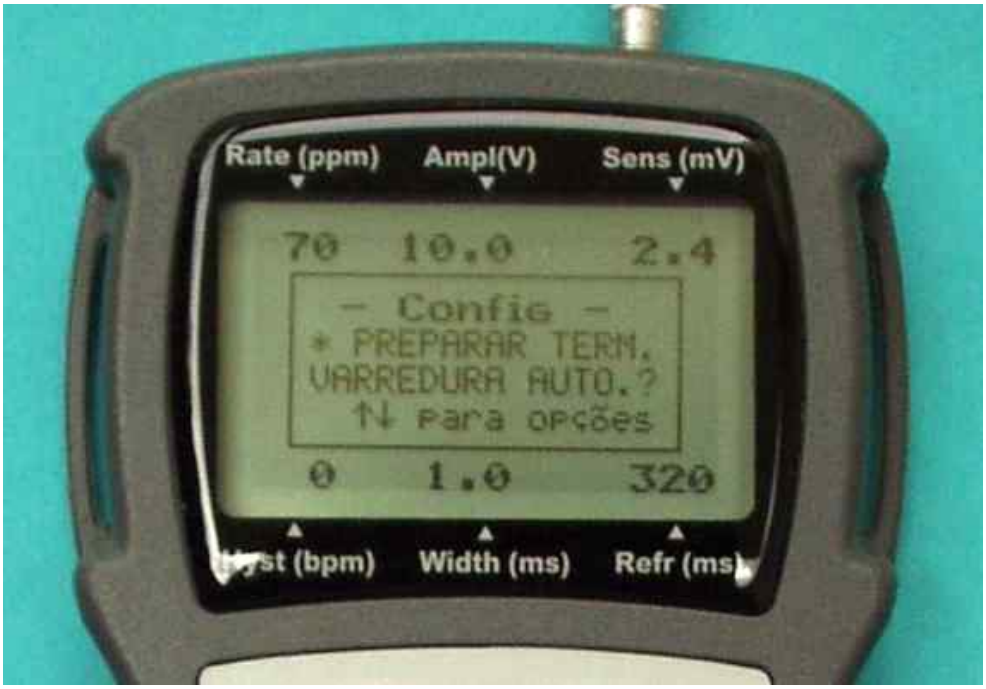


Figure 4.3: Scanning Reversion Parameter Setting (Portuguese)

4.8. INTRACARDIAC ELECTROGRAPHY (*ECG*)

The Intracardiac Electrography function is activated by pressing the *ECG* key. After a short presentation of the message:

ECG: +/-20mV, 2sec

The real time ECG trace will be presented on the central box of the LCD (see Figure 4.4)

The running ECG can be frozen at any time by pressing the CANCEL key. In the ***PaceStar-LT*** model this action also captures 5 seconds of ECG when the 40mm/sec scales are selected and data logging is enabled. Pressing the CANCEL key will unfreeze the screen.

The signal picked up by the patient leads can be depicted at 4 different amplitude and time scales:

- +/-20mV, 2 seconds (20mm/sec)
- +/- 4mV, 2 seconds (20mm/sec)
- +/-20mV, 1 second (40mm/sec)
  <CANCEL>: Logging (only in ***PaceStar-LT***)
- +/- 4mV, 1 second (40mm/sec)
  [<CANCEL>: Logging (only in ***PaceStar-LT***)

These alternatives are accessed by pressing the *ECG* key. A brief introductory message will indicate the display scales. Quitting the ECG function is performed by pressing the *ECG* key once more after accessing the last display scale.

The pacing pulses are marked with a rectangular trace (see Figure 4.5). During the Absolute Refractory Period following the pacing pulse (150ms duration), the ECG presentation is blanked and substituted by a horizontal line segment. The height of this pacing mark does not depend on the display scales.

Even though the pacing pulses are marked with a rectangular trace, the ECG recorded with the ***PaceStar-LT*** model is the actual signal present at the pacing electrodes. The intracardiac electrography logging provides an alternative means to evaluate pacemaker capture, catheter positioning, sensitivity level and arrhythmia. The ***PaceStar-LT*** can record up to twenty 5-sec ECG strips.

4.9. EMERGENCY PACING (*EMERG*)

By pressing the *EMERG* key, the pacing parameters are updated with the Emergency SSI Parameter Values. This key is always active even in the case of keyboard-locked condition.

After pressing the EMERG key, the PACE-STAR enters the SSI Pacing Mode with the following parameters:

Rate = 70ppm	Amplitude = 10.0V	Sensitivity = 2.4mV;
Hysteresis = 0bpm	Refractory Period = 320ms	Pulse Width = 1.0ms

The display will not show changes other than the new parameter values.

Figure 4.4: Sensing with ECG presentation

Figure 4.5: Pacing with pulse presentation

4.10. TACHYCARDIA TERMINATION (*TACHY*)

The ***PaceStar-T/LT*** identifies the presence of tachycardia whenever the instantaneous rate of two consecutive cardiac cycles is larger than the Tachycardia Recognition Rate. This condition is indicated by a flashing "**T**" symbol on the right side of the display, and an acoustic alarm, if enabled.

The tachycardia termination process is accessed by the pressing of the TACHY key under keyboard unlocked condition. The process consists of the two sequential steps:

- Method Selection
- Method Activation

The tachycardia termination process may be aborted anytime by pressing the CANCEL key once during the Method Selection, or twice during Method Activation.

Tachycardia Termination Method Selection:

- The screen will show the following three Tachycardia Termination Methods:
  # Overdriving
  # Orthorhythmic Pulse Bursts
  # Non-Orthorhythmic Scanning
  The user is prompted to select one of the displayed options (using *UP*, *DOWN*, and *ENTER* keys).

Tachycardia Termination Method Activation:

- The screen guides the operator (see Section 5 for a comprehensive explanation).

4.11. BATTERY REPLACEMENT

The battery compartment holds two 1.5V 'AA' alkaline batteries. With two new batteries the ***PaceStar-T/LT*** unit will work for more than 20 days if the ECG function is not enabled. The unit will not operate if both batteries are removed, but will retain all the programmed data.

If the 1.5V AA alkaline batteries are replaced sequentially, pacing will not be interrupted. The ***PaceStar-T/LT*** will operate temporarily with only one battery.

The replacement of the left/right battery is performed in the following way:

- Hold the ***PaceStar-T/LT*** unit
- Slide the rear locking button upward to release the lock mechanism. Hold it in that position.
- Slide the bottom compartment cover to the right/left.
- Pull the inner cartridge and remove the old battery (see Figure 4.6).
- Place a fresh battery in the cartridge observing the proper polarity.
- Push the cartridge into the battery compartment.
- Slide the cover to the left/right to get the cover plastic nail in the central position. A tactile "click" will indicate a proper mechanical locking.

Repeat the former steps with the remaining battery. Replacing both batteries is recommended.

The ***PaceStar-T/LT*** unit measures the remaining battery life. The physician can get this value by accessing the corresponding option in the Data Menu. An acoustic alarm consisting of four "beeps" will sound every 5 seconds whenever the remaining battery life is shorter than six hours or one of the batteries is exhausted. The ***PaceStar-T/LT*** unit also indicates the status of every battery on the LCD (see Section 3.1).

The Real Time Clock (RTC) continues running after the unit has been powered off or the batteries were removed.

Figure 4.6 Battery Compartment Open

4.12. DATA LOGGING PROCESS (PaceStar-LT model only)

When Data Logging is enabled, the ***PaceStar-T/LT*** records parameter value changes, events, ECG and counts in its RAM memory. The recorded information is passed to the internal Non Volatile Memory in the following cases:

- prior to transmit the information to the PC, after accessing the Download Option in the Configuration Menu
- after Data Logging was disabled, or
- during the turn off process

This information will be kept in the Non Volatile Memory until a Clearing Buffer command is issued. In this way, the logged information is protected against accidental deletion.

The Data Logging area of the RAM memory is split up in the following sectors:

- CONFIGURATION+EVENT+SYS-PACE
- ECG
- MINUTE HEART BEAT COUNT
- HOURLY HEART BEAT COUNT
- HOURLY PULSE COUNT

When one of this sectors is full (e.g.: ECG), a Buffer Full icon ⊗ will appear on the upper–left Area of the LCD, and the logging process for the particular message type will be suspended (e.g.: ECG Strip recording disabled). The logging of the remaining message types will continue. If the Non Volatile Memory becomes full, further logging is disabled regardless of the message type.
The icon ⊗ will disappear after a Buffer Clearing action is performed.

The beat and pulse counters are started in the following events:

- Turn-On Action under Enabled Data Logging Condition
- Data Logging Enabling Action
- Data Logging Buffer Clearing Action under Enabled Data Logging Condition

The beat and pulse counters are stopped in the following events:

- Turn-Off Action under Enabled Data Logging Condition
- Data Logging Disabling Action
- Data Transmission Action

After the counters are stopped the recorded information is passed to the non volatile memory.

When the date changes naturally (transition from 23:59:59 to 00:00:00) the ***PaceStar-T/LT*** issues a special message to guarantee data consistency. It is preferable not to set the Date or Time when logging function is enabled.

The status of the ***PaceStar-T/LT*** is automatically logged in the following events:

- Turn-On Action under Enabled Data Logging Condition
- Data Logging Enabling Action
- Data Logging Buffer Clearing Action under Enabled Data Logging Condition

The status description comprises the following messages:

VERSER (Version and Serial Number)
PACEPAR (Pacing Parameters)
CFGARR (Configuration Arrhythmia Parameters)
CFGGEN (Configuration General Parameters)
CFGLOG (Configuration Logging Parameters)
CFGSND (Configuration Sound Parameters)

The Data-Logged Downloading allows the transfer of the logged information to the PC for further analysis. Even in the case of a successful transmission, the protected data will not be deleted. The erasure of the recorded data is only performed by an intentional Buffer Clearing action.

To perform the data downloading it is necessary:

- to connect the provided optical cable to the ***PaceStar-T/LT*** and the ***O-Box*** interface, and the USB cable to the ***O-Box*** and the PC,
- to execute the ***PaceStar Data Logger*** program running in the PC under Windows
- to follow the instructions presented on the PC screen.

The system has been designed to provide a clear visual indication of the linking quality.

When the Non Volatile Data Logging Memory is full, the data downloading process may last 30 seconds. A progress bar on the PC screen provides a feedback of the transmission process status.

4.13. DATA LOGGING MESSAGES (PaceStar-LT model only)

The format of the messages sent through the optical fiber link is the following:

MeCode	**Century**	**Year**	**Month**	**Day**	**Hour**	**Minutes**	**Seconds**	**NH**	**NL**	**Info 1**	**. .**	**Info N**
1 Byte	**Date** (4 bytes, BCD)				**Time** (3 Bytes, BCD)			**N** (2 Bytes, int)		Information		

All ***PaceStar-T/LT*** Configuration, Event and Sys-Pace logging messages are sequential in nature. Data Tables and ECG messages are delivered at the end of the downloading procedure.

The messages are classified y 4 groups: Configuration (CFG), Data, Event and Sys-Pace. Every group is in term classified in up to 4 subgroups. Every message has a date, time and associated text, and can have one or more parameters.

CFG-ARR

Short	Description	Group	SubGroup	Message Text
TRR	Tachy Recognition Rate	CFG	ARR	New Tachycardia Recognition Rate:
BURUNI	Pulse Number of Initial Burst	CFG	ARR	New Number of Pulses of Initial Burst in Pulse Burst Method (user- programmed):
BURUNF	Pulse Number of Final Burst	CFG	ARR	New Number of Pulses of Final Burst in Pulse Burst Method (user programmed):
SCAUID	Initial Delay / Scan Burst	CFG	ARR	New Initial Delay in Scanning Method (user-programmed):
SCAUCD	Coupled Delay / Scan Burst	CFG	ARR	New Coupled Delay in Scanning Method (user-programmed):
SCAUNP	Pulse Number / Scan Burst	CFG	ARR	New Number of Pulses of Bursts in Scanning Method (user-programmed):
BURPAR	**User Burst Method Parameters**	**CFG**	**ARR**	**Parameter Values of Pulse Burst Tachycardia Termination Method**
SCAPAR	**User Scan Method Parameters**	**CFG**	**ARR**	**Parameter Values of Scanning Tachycardia Termination Method**
CFGARR	**Configuration Arrhythmia Parameters**	**CFG**	**ARR**	**Parameter Values of Extrastimulation Tachycardia Termination Methods**

CFG-GEN / CFG-LOG

Short	Description	Group	SubGroup	Message Text
KBLOCK	Keyboard Lock	CFG	GEN	**Keyboard** was **Locked**
KBULCK	Keyboard Unlock	CFG	GEN	**Keyboard** was **Unlocked**
DSPCON	Display Contrast	CFG	GEN	New Display Contrast:
LANG	Language	CFG	GEN	New Language:
SETDATE	Set Date	CFG	GEN	New Date:
SETTIME	Set Time	CFG	GEN	New Time:
CFGGEN	**Configuration General Parameters**	**CFG**	**GEN**	**Status of General Configuration Parameters:**
LGALLEN	Enable Logging of All Groups	CFG	LOG	**Logging Enabled**
LGALLDI	Disable Logging of All Groups	CFG	LOG	**Logging Disabled**
CFGLOG	**Configuration Log Parameters**	**CFG**	**LOG**	**Status of Logging Configuration Parameters:**

CFG-SOUND

Short	Description	Group	SubGroup	Message Text
BPPMEN	Enable PM Pulse Beep	CFG	SOUND	**Pacemaker Pulse "Beep"** was **Enabled**
BPPMDI	Disable PM Pulse Beep	CFG	SOUND	**Pacemaker Pulse "Beep"** was **Disabled**
BPSWEN	Enable S-Wave Beep	CFG	SOUND	**S-Wave "Beep"** was **Enabled**
BPSWDI	Disable S-Wave Beep	CFG	SOUND	**S-Wave "Beep"** was **Disabled**
BPKBEN	Enable Keyboard Beep	CFG	SOUND	**Keyboard "Beep"** was **Enabled**
BPKBDI	Disable Keyboard Beep	CFG	SOUND	**Keyboard "Beep"** was **Disabled**
ALTACEN	Enable Tachy Alarm	CFG	SOUND	**Tachycardia Acoustic Alarm** was **Enabled**
ALTACDI	Disable Tachy Alarm	CFG	SOUND	**Tachycardia Acoustic Alarm** was **Disabled**
CFGSND	**Configuration Sound Parameters**	**CFG**	**SOUND**	**Status of Acoustic Signals Configuration**

DATA-COUNT / DATA-GEN / DATA-ECG

Short	Description	Group	SubGroup	Message Text
BEAMCNT	Beats Minute Count	DATA	COUNT	**Table of Minute Heart Rate**
BEAHCNT	Beats Hourly Count	DATA	COUNT	**Table of Hourly Cumulated Beats**
PULHCNT	PM Pulses Hourly Count	DATA	COUNT	**Table of Hourly Cumulated Paced Beats**
VERSER	Version and Serial Number	DATA	GEN	**Pacemaker Identification:**
ECGSTRP	ECG Strip	DATA	ECG	**ECG Strip**

EVE-ARR / EVE-DEV / EVE-USR / EVE-PAT

Short	Description	Group	SubGroup	Message Text
LOGFULL	Logging Buffer Full	EVE	DEV	**Logging-Buffer-Full Condition** was **Detected**
DATECHG	Date Change	EVE	DEV	
PWRON	**Power On**	**EVE**	**USR**	**Turn-On Action**
PWROFF	Power Off	EVE	USR	**Turn-Off Action**
TTERHRA	High Rate Termination activated	EVE	USR	**Overdriving Tachycardia Termination** was **Activated.** Initial pacing rate was: .
TTERBUR	Burst Tachycardia Termination activated	EVE	USR	**Pulse Burst Tachycardia Termination** was **Activated.** Number of pulses in initial and final bursts were: and .
TTERSCA	Scan Tachycardia Termination activated	EVE	USR	**Scanning Tachycardia Termination** was **Activated.** Initial Delay was: . Coupled Delay was: . Number or Pulses was: .
TTERABO	Tachycardia Termination Aborted	EVE	USR	**Extrastimulation Tachycardia Termination Process** was **Aborted**
TTERSUC	Tachycardia Termination Successful	EVE	USR	**Extrastimulation Tachycardia Termination Process** was **Successful**. Emerging Patient Rate was:
TTERUNS	Tachycardia Termination Unsuccessful	EVE	USR	**Extrastimulation Tachycardia Termination Process Failed**

SYS-PACE

Short	Description	Group	SubGroup	Message Text
PRATE	Rate	SYS	PACE	New Pacing RATE:
PAMPL	Pulse Amplitude	SYS	PACE	New Pacing PULSE AMPLITUDE:
PSENS	Sensitivity	SYS	PACE	New Pacing SENSITIVITY LEVEL:
PHYST	Hysteresis	SYS	PACE	New Pacing HYSTERESIS:
PWIDTH	Pulse Width	SYS	PACE	New Pacing PULSE WIDTH:
PREFR	Refractory Period	SYS	PACE	New Pacing REFRACTORY PERIOD:
MSOO	SOO Pacing Mode	SYS	PACE	AOO/VOO Pacing Mode was Selected
MSSI	SSI Pacing Mode	SYS	PACE	AAI/VVI Pacing Mode was Selected
PACEPAR	**Pacing Parameters**	**SYS**	**PACE**	**Pacing Mode and Parameter Values**

5. TACHYCARDIA TERMINATION METHODS

5.1. OVERDRIVING

This method is often used to terminate atrial flutter and tachycardia. It consists of pacing the heart at high rates, in fact, rates higher than the rate of the present tachyarrhythmia in order to take over the cardiac rhythm. There are several procedures to terminate tachyarrhythmias using this overdriving technique, but they coincide in slowing down the pacing rate after the initial capture.

The GALIX ***PaceStar-T/LT*** provides a high rate operation range from 120 to 600 ppm, with sensitivity, pulse width and pulse amplitude fully programmable by the physician.

5.1.1 PROCEDURE

If the intrinsic rate of the patient is higher than the programmed Tachycardia Recognition Rate, the ***PaceStar-T/LT*** signals the presence of tachycardia with the symbol "T" in the status area of the LCD and an acoustic alarm, if enabled.

The steps to apply the overdriving method are the following:

- Press the *TACHY* key. The LCD displays the message:
  HIGH RATE:<<
  ORTHORH.:
  SCANNING:
  Select the option HIGH RATE moving the cursor with the arrow keys.

- Press *ENTER*. The message: OPERATE WITH CARE! will appear for a couple of seconds. The next screen will show the word HIGH RATE and the word INACTIVE along with a rate value. This rate value is 30% higher than the patient intrinsic rate, and is an automatic estimate of the pacing rate required for consistent capture. The physician can modify this value with the arrow keys.

- To start the high rate pacing, press *ENTER*. The ***PaceStar-T/LT*** will start pacing immediately, and the word ACTIVE will appear on the LCD. The physician may also modify the pacing rate with the arrow keys in accordance with a particular TACHY termination technique.

- To quit the High Rate Operation option press *CANCEL* the pacing mode that was active before starting the overdriving will be resumed. If the *EMERG* key is pressed the ***PaceStar-T/LT*** will enter the Emergency SSI Mode.

NOTE: if no key is pressed for 20 seconds the overdriving mode is automatically canceled.

5.2. PULSE BURST

Tachycardia termination using extra stimuli is based on the fact that a properly timed stimulus synchronized to the spontaneous heart depolarization, can block the reentrant conduction circuit, which is the cause of the sustained tachycardia. In other words, there is a termination region within the tachycardia cycle, during which an applied stimulus will end the tachycardia.

The different methods of tachycardia termination using extra stimuli differ in how the search for a coupling interval for termination is conducted. These have a criterion to determine whether the tachycardia has been terminated in order to stop the process. This criterion normally consists of taking four heart cycles after a termination attempt to measure the intrinsic heart rate. The ***PaceStar-T/LT*** criterion indicates that tachycardia is still present if all four cycle rates are higher than the Tachy Recognition Rate programmed.

The Pulse Burst Method consists of generating several bursts of pulses; the number of these pulses increases burst to burst. The coupling intervals between pulses and between the first pulse of the burst and the spontaneous heart depolarization are proportional to the tachy cycle length. This means that this method adapts automatically to different tachycardias.

5.2.1. OPERATING PARAMETERS

The operating parameters of this method are the following:

- Initial Delay: the interval between the last sensed depolarization and the first pulse of the burst. If the detected intrinsic rate is lower than 200 bpm the ***PaceStar-T/LT*** assigns an initial delay of 80% of the cycle length; if it is higher than 200 bpm the initial delay will be 90% of the cycle length.
- Coupled Delay: the time interval between two consecutive stimuli in the burst. The ***PaceStar-T/LT*** takes the value of the initial delay and assigns it to the coupled delay.
- Number of Pulses in the First Burst: it is user-programmable from 5 to 10. The default value is 8.
- Number of Pulses in the Last Burst: it is user-programmable from 10 to 20. The default value is 15. The number of pulses increases by one from burst to burst.

5.2.2. PROCEDURE

If the intrinsic rate of the patient is higher than the programmed Tachycardia Recognition Rate (see Section 4.7) the ***PaceStar-T/LT*** signals the presence of tachycardia with the symbol "**T**" in the status area of the LCD, and an acoustic alarm if enabled (see Section 3.6).

The steps to apply the pulse bursts method are the following:

- Press the *TACHY* key. The LCD displays the message:
  HIGH RATE:<<
  ORTHORH.:
  SCANNING:
  Select the option Orthorhythmic moving the cursor with the arrow keys.

- Press *ENTER*. The following message will appear:
  DEFAULT:<<
  PROGRAMMED:
  Select the Default Option if you want to use the factory-programmed set of parameter values (Ni= 8, Nf= 15). Select the Programmed option if you want to use the data previously programmed through the *CONFIG* key (see Section 3.2). Press *ENTER*.

- The number of pulses in the first burst (Ni), the number of pulses in the last burst (Nf) and the message “START REVERSION?” will appear on the LCD.

- To start the reversion process press *ENTER*. If the sensed intrinsic rate is out of the range for tachycardia termination, the message:
  TACHYCARDIA
  OUT OF RANGE!
  will appear on the LCD. On the other hand, if the ***PaceStar-T/LT*** unit accepts the tachycardia rate, the termination process will start. The coupled delay (INT) and the number of pulses of the burst currently generated are shown on the LCD.

- If the tachycardia is terminated during the process, the message SUCCESS! will be shown and the message START REVERSION? following. If after finishing the process the tachycardia remains, the message NO SUCCESS! will be shown before returning to the START REVERSION? prompt.

- The termination process may be aborted by pressing any key, particularly the *CANCEL* key. In such a case, the message REVERSION HALTED will be shown before resuming the START REVERSION? prompt.

- To quit the TACHY termination function, press the *CANCEL* key twice. If the *EMERG* key is pressed, the ***PaceStar-T/LT*** will enter the Emergency SSI Pacing Mode.

NOTE: The Pulse Bursts Method is Orthorhythmic. This means that the initial delay and the coupled delay are always related to the length of the tachycardia cycle, and do not have to be programmed in advance.

5.3. SCANNING

The Scanning Method consists of generating several bursts of pulses with fixed coupling interval between pulses, and a fixed number of pulses per burst. The coupling interval between the first pulse of the burst and the last spontaneous heart depolarization decreases by 5 ms from burst to burst. The process ends when the initial delay of the last burst is 80 ms shorter than the one corresponding to the first burst.

5.3.1. OPERATING PARAMETERS

The operating parameters of this method are the following:

- Initial Delay: the interval between the last sensed depolarization and the first pulse of the burst. The initial delay of the first burst is user- programmable from 200 to 400 ms. The default value is 260 ms. The initial delay diminishes by 5 ms from burst to burst.
- Coupled Delay: the interval between one stimulus in the burst and the following one. It is user-programmable from 100 to 400 ms. The default value is 260 ms.
- Number of Pulses per Burst: user programmable from 1 to 10. The default value is 8.

5.3.2. PROCEDURE

If the intrinsic rate of the patient is higher than the programmed Tachycardia Recognition Rate the ***PaceStar-T/LT*** signals the presence of tachycardia with the symbol "**T**" in the status area of the LCD, and an acoustic alarm if enabled.

The steps to apply the scanning method are the following:

- Press the *TACHY* key. On the LCD appears the message:
  HIGH RATE:<<
  ORTHORH.:
  SCANNING:
  Select the option SCANNING by moving the cursor with the arrow keys.
- Press *ENTER*. The following message will appear:
  DEFAULT:<<
  PROGRAMMED:
  Select the DEFAULT Option if you want to use the factory-programmed set of parameter values (ID= 260ms, CD= 260ms, Npul=5). Select the Programmed option if you want to use the data previously programmed by you through the *CONFIG* key (see Section 3.2). Press *ENTER*.
- The coupled delay (CD), the initial delay (ID) and the number of pulses (Npul) will be shown on the LCD. Then the message START REVERSION? will prompt to initiate the process.

- To start the reversion process press *ENTER*. If the sensed intrinsic rate is out of the range for tachycardia termination, the message
  TACHYCARDIA
  OUT OF RANGE!
  will appear on the LCD. On the contrary, if the tachycardia rate is accepted by the ***PaceStar-T/LT*** unit the termination process will start. The tachy cycle length (INT) and the initial delay of the burst currently generated will be shown on the LCD.

- If the tachycardia is terminated during the process the message SUCCESS! will be shown, and the message START REVERSION? following. If after finishing the process the tachycardia remains, the message NO SUCCESS! will be shown prior to returning to the START REVERSION? prompt.

- The termination process may be aborted by pressing any key. In such a case the message REVERSION HALTED will be shown before resuming the START REVERSION? prompt.

- If the termination process was successful, the initial delay that terminated the tachycardia will be stored in memory for future use. This value will be used as the Initial Delay of the First Burst in case a new tachy termination process using the scanning method is started. This value is overwritten by the programmed Initial Delay of the First Burst whenever the next termination process is unsuccessful, or one of the operating parameter values is modified.

- To quit the *TACHY* termination function, press the *CANCEL* key twice. If the *EMERG* key is pressed, the ***PaceStar-T/LT*** will enter the Emergency SSI Pacing Mode.

NOTE: The Scanning Method is non-Orthorhythmic. This means that the initial delay and the coupled delay should always be programmed in advance taking into account the clinical record of the patient. This minimizes the risk of accelerating the tachyarrhythmia if an unsuitable Initial Delay is used.

6. POTENTIAL COMPLICATIONS

6.1. ELECTROMAGNETIC INTERFERENCE (EMI)

The ***PaceStar-T/LT*** has been designed to reject EMI. This type of interference is generated by many devices (for instance: diathermy and electrosurgery units), and especially those operating on AC line current.

If the EMI level is high, an effective rejection is not possible. In such a case the ***PaceStar-T/LT*** switches to asynchronous mode pacing (SOO) at the selected rate. An "**N**" letter in the LCD Status Area will indicate the presence of "noise" on the leads (see Section 3.1).

6.2. DEFIBRILLATION

The ***PaceStar-T/LT*** is protected from defibrillation discharges of up to 400 Joules. Repeated defibrillator discharges or discharges directly on the pacing lead or connections to the lead may cause damage to the ***PaceStar-T/LT*** unit and/or tissue adjacent to the patient lead.

Placing the paddles at right angles to the line formed by the electrode lead will minimize the risk of damage to the ***PaceStar-T/LT*** unit and tissue at the electrode tip. The ***PaceStar-T/LT*** may occasionally require parameter reprogramming after defibrillation discharge.

6.3. LEADS

Lead displacement or fracture may cause intermittent or complete loss of sensing and/or pacing.

6.4. BATTERIES

The ***PaceStar-T/LT*** indicates when it is necessary to replace the batteries by means of a persistent acoustic alarm, the remaining battery life in the DATA menu (BL<6h) and LCD symbols. If battery replacement is delayed, the unit will continue operation until the ***PaceStar-T/LT*** Microprocessor decides to turn off the device.

If the 1.5V AA alkaline batteries are replaced sequentially, pacing will not be interrupted. The ***PaceStar-T/LT*** will operate temporarily with only one battery.

While turned-off, the ***PaceStar-T/LT*** drains a very small current (10 microamps typical). Fresh 1.5V alkaline batteries should be installed after 6 months regardless of the amount of usage.

6.5. STORAGE

For long-term storage, the batteries should be removed. The ***PaceStar-T/LT*** should be cleaned and placed with accessories in the storage handbag.

7. MAINTENANCE

WARNING: The GALIX ***PaceStar-T/LT*** does not contain user-serviceable components with the exception of the batteries. The Liquid Crystal Display must not be exposed to direct sun light. If damage to the unit is suspected, contact an authorized GALIX representative. The warranty is void in the case of detecting misuse, negligence or if the unit has been repaired or altered outside of an authorized facility.

7.1. CLEANING

The ***PaceStar-T/LT*** can be regularly cleaned with a sponge or cloth moistened with water or metyl/isopropyl alcohol. Ketone based solvents must not be used. Do not immerse the unit in any liquid.

7.2. STERILIZATION

The ***PaceStar-T/LT*** and its accessories can be sterilized in ethylene oxide gas.

8. SPECIFICATIONS

PROGRAMMABLE PARAMETERS

- **Pacing:**
  Rate, Pulse Amplitude, Sensitivity, Hysteresis, Refractory Period, Pulse Width.
- **Tachycardia Termination:**
  A) Orthorhythmic: Number of pulses in the initial burst (Ni) and Number of Pulses in the final burst (Nf)
  B) Scanning: Initial Delay (ID), Coupled Delay (CD) and Number of Pulses per burst (NP)

PACING

- **Normal Rate:** 30 ppm to 200 ppm; step: 5 ppm. Accuracy: +/- 0.5%.
- **High Rate (overdriving):** 120 ppm to 600 ppm; step: 10 ppm. Accuracy: +/- 3%.
- **Pulse Amplitude:** 0.2 V to 10 V; step: 0.2 V. Accuracy: +/- 0.2 V.
- **Sensitivity:** 0.2 mV to 12 mV; step: 0.2 mV. Accuracy: +/- 0.2 mV.
- **Hysteresis:** 0, 5, 10, 15 and 20 bpm.
- **Refractory Period:** 200 ms to 400 ms; step: 5 ms Accuracy: +/- 1.5%.
- **Pulse Width:** 0.1 ms to 2 ms; step: 0.1 ms Accuracy: +/- 0.02 ms.
- **Emergency:** SSI (AAI/VVI) - 70 ppm - 10 V - 2.4 mV - 1 ms.
- **Electromagnetic Interference (EMI) Protection:** auto-switching to AOO/VOO.
- **Defibrillation Protection:** up to 400 Joules.
- **Software Failure Protection:** auto-switching to Emergency Mode.

TACHYCARDIA TERMINATION

- **Overdrive:** Transitory high rate operation. Patient heart rate is measured automatically and the overdrive rate is set 30% higher. Overdrive rate up to 600 ppm. For safety reasons unit generates auto-quit if no key is pressed within 20 seconds.
- **Orthorrhythmic:**
  Ni = 5 to 10 pulses (8).
  Nf = 10 to 20 pulses (15).
- **Scanning:**
  ID = 200 ms to 400 ms (260).
  CD = 100 ms to 400 ms (260).
  NP = 1 to 10 (5).

Note: Default values in brackets.

MEASUREMENTS AND STATISTICS

- **R-R/P-P Interval:** 5 ms to 2 sec.
- **Patient Frequency:** 30 bpm to 300 bpm.
- **P-wave or R-wave amplitude.**
- **Pacing clock:** up to 10 days. Accuracy: +/- 0.005%.
- **Pacing Percentage:** ratio between the total number of paced beats, and total number of paced beats plus spontaneous beats.
- **Remaining Battery Life.**
- **Intracardiac ECG presentation**
- **Date and Time** (only ***PaceStar-LT***)

CONFIGURATION

- **Tachycardia Recognition Rate:** 100 bpm to 200 bpm; step: 5 bpm.
- **Reset of Stimulation Timer.**
- **Enabling/Disabling of sensing, pacing and key-pressed acoustic signals.**
- **Enabling/Disabling of tachycardia alarm.**
- **Setting of Display Contrast.**
- **Selection of Language (English, Spanish or Portuguese)**
- **Recorded Data Downloading** (only ***PaceStar-LT***)
- **Data Logging Enable** (only ***PaceStar-LT***)
- **Logging Buffer Clearing** (only ***PaceStar-LT***)

GENERAL

- **Case:** shock-resistant ABS plastic.
- **Dimensions:**
  Length: 6.53" (166 mm)
  Width: 3.46/2.75"(88/70 mm)
  Height: 0.87"(22 mm).
- **Weight:** 7.8 oz. (220 grams), batteries included
- **Power source:** Two 1.5V AA alkaline battery (Mallory Duracell MN1500 or equivalent).
- **Battery Life:** 20 days of continuous pacing at emergency parameters with 500ohm load (ECG, logging and acoustic indicators disabled).
- **Extension cable:** It is compatible with most standard external pacing lead wires.
- **Keyboard:** polycarbonate metal-dome tactile-feel membrane.
- **Display:** 26x47-mm 64x128-pixels graphic Liquid Crystal Display.
- **Serial number is programmed and shown on the LCD.**

ACCESSORIES

- The GALIX ***PaceStar-T/LT*** set includes a carrying handbag, two 1.5V AA alkaline batteries, one extension cable, one arm strap, one waist strap and instruction manual.
- In addition to this, the GALIX ***PaceStar-LT*** set also includes an USB ***O-Box*** (Optical Box) Interface, one USB O-Box/PC cable, one Optical PaceStar/O-Box cable and one ***PaceStar Data Logger*** Software Diskette

GALIX BIOMEDICAL INSTRUMENTATION, INC. reserves the right to make improvements or to change specifications in its products at any time and without notice.

9. WARRANTY

GALIX BIOMEDICAL INSTRUMENTATION

Limited Warranty

GALIX Biomedical Instrumentation provides to the original purchaser the following limited warranty from date of invoice.

All serialized parts	18 months
Accessories (patient cables, disposables)	90 days

GALIX Biomedical Instrumentation warrants each instrument to be free from defects in material and workmanship. Liability under this warranty covers servicing of the instrument when returned from the customer's facility prepaid to the factory. GALIX Biomedical Instrumentation will repair any component(s) or part(s) that are found to be defective during the period of this limited warranty. Should a defect become apparent, the original purchaser shall first notify GALIX Biomedical Instrumentation of the suspected failure. The instrument should be carefully packaged and shipped prepaid to:

Galix Biomedical Instrumentation, Inc.
Service Department
2555 Collins Avenue, Suite C-5
Miami Beach, FL 33140, U.S.A.

Your instrument will be repaired in the shortest possible time and returned by the same shipping method as received by the factory.

This limited warranty is void if the instrument has been damaged by accident, misuse, negligence, act of God, or if the instrument has been serviced or modified by any person not authorized by GALIX Biomedical Instrumentation.

Equipment distributed by GALIX Biomedical Instrumentation such as, but not limited to personal computers and printers will carry the original equipment manufacturer's warranty and will not be warranted by Galix Biomedical Instrumentation.

This limited warranty contains the entire obligation of GALIX Biomedical Instrumentation and no other warranties expressed, implied or statutory are given. No representative or employee of GALIX Biomedical Instrumentation is authorized to assume any further liability, or grant any further warranties except as set herein.

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