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VVIR Single-Chamber Pacemaker

CLYN-US-DES-DD-15

Rev: 3

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Calyan VVIR Single Chamber Pacemaker Programmer Software IFU



T E C H N O L O G I E S

VVIR Single Chamber Pacemaker Programmer Software Instructions For Use

CAUTION - Investigational Device. Limited by Federal (or United States) law to investigational use.



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1 Introduction

1.1 About this manual

This manual describes the operation and intended use of the Calyan VVIR Single Chamber Pacemaker Programmer software. The programmer software is intended to be used to interact with the Calyan VVIR Single Chamber Pacemaker model P200 implantable pacing system. The Programmer software is resident on the tablet provided by Calyan. The tablet is locked to prevent any installation of unknown software and similarly has its networking capabilities disabled.

1.2 Manual Conventions

Throughout this manual, the word “Device” refers to the Calyan VVIR single chamber implantable pacemaker.

1.3 Product Literature

Before implanting the Device, it is strongly recommended that you take the following actions:

- Read the product literature provided for information about prescribing, implanting, and using the Device, and for conducting a patient follow-up session
- Discuss the Device and implant procedure with the patient and any other interested parties

1.4 Technical Support

Calyan employs highly trained representatives and engineers to serve you and, upon request, to provide training to investigational sites personnel in the use of Calyan products. In addition, Calyan maintains a professional staff of consultants to provide technical consultation to product users. For more information, contact your local Calyan representative at the address below:

Calyan Technologies
7300 Hudson Blvd N, Oakdale, MN 55128 Suite 290
Support Email: info@calyantech.com
Website www.calyantech.com

1.5 Notice

The Patient Information screen of the programmer software application is provided as an informational tool for the end user. The user is responsible for accurate input of patient information into the software. Calyan makes no representation as to the accuracy or completeness of the patient information that end users enter into the Patient Information screen. Calyan SHALL NOT BE LIABLE FOR ANY DIRECT, INDIRECT, INCIDENTAL, OR CONSEQUENTIAL DAMAGES TO ANY THIRD PARTY WHICH RESULT FROM THE USE OF THE PATIENT INFORMATION SUPPLIED BY END USERS TO THE SOFTWARE.



1.6 Description

The Programmer is a handheld Android based tablet that communicates with the Device via Bluetooth Low Energy (BLE) to set the treatment parameters and read data events and treatment parameters stored in the pacemaker. The Calyan programmer and software are used to program the Device for implant testing and patient follow-up sessions. The use of a magnet is required for communication between the device and the programmer. Programmers from other manufacturers are not compatible with the Device but will not damage the Device. The Programmer is used only by physicians, cardiac clinicians, or Calyan Representatives and is supplied and customized by Calyan. The Programmer app allows you to program the Device settings and view stored Device data. Use the programmer app to perform the following tasks:

1. Program Device parameters
2. Verify the status of the implantable Device.
3. View or enter patient information.

For a complete system description, see the Calyan VVIR Single Chamber Pacemaker IFU.

1.7 Indications and Usage

The Calyan VVIR single chamber pacing system is indicated for use in patients who have Class I or IIa indication for implantation of a single-chamber ventricular pacemaker, according to ACC/AHA/HRS guidelines.

Rate-responsive pacing is intended to provide increased heart rate appropriate to increasing levels of activity.

This is an investigational Device, which should only be used for clinical investigations at participating investigational sites.

1.8 Contraindications

For a complete list of contraindications, see the Calyan VVIR Single Chamber Pacemaker IFU.

1.9 Abbreviations and Terminology

Term	Description
Programmer	Calyan Programmer App and Tablet
Device	Calyan VVIR pacemaker Device
BPM	Beats per minute
mV	Milli Volts
mSec	Milli Seconds



dBm	Decibels. (The closer that number is to 0, the stronger the signal)
EGM	Electrogram
IFU	Instructions for Use
BLE	Bluetooth Low Energy
RSSI	Received Signal Strength Indicator
milli-g	Milli-gravity, one thousandth of Earth standard gravity

Table 1: Terminology used in this document.

1.10 Warnings, Precautions, & Adverse Events

Refer to the Calyan VVIR Single Chamber Pacemaker IFU for a complete list of warnings, precautions, and adverse events.

Warning: Ensure that the pacing parameters are set to appropriate values for the patient. Entering incorrect values could result in harm to the patient.

Warning: Ensure the Sensitivity parameter is appropriately set, failure to do so can result in underpacing or overpacing of the patient. Setting the Sensitivity parameter too high will result in overdelivery of therapy, setting the Sensitivity parameter too low will result in underdelivery of therapy.

Warning: If an electrical reset occurs on the Device, this will not be displayed on the main programmer screen. To view the errors that are present active or historic errors on the Device, tap GET DEVICE STATUS and a dialog box will be invoked indicating an electrical reset has occurred. After the reset is confirmed, confirm the Device parameters are accurate.

Warning: Provide an adequate safety margin when selecting values for pacing amplitude. Calyan recommends that the Pacing Amplitude be programmed at 150% of the observed pacing capture threshold.

Warning: Do not use the Calyan Programmer Application when the Tablet is charging.

Warning: Do not use the Programmer to interrogate a Device or do patient follow-up while it is plugged into power

Warning: Throughout the entire implant procedure and when conducting electrical verifications, keep the Calyan Programmer out of the sterile field

Warning: Programming the Device to any mode incorporating sensitivity may result in increased risk to the patient due to electromagnetic interference.

Warning: The Programmer should only be used in a clinical setting.



Note: If extracardiac stimulation is observed during the implant procedure or post-implant, refer to the Calyan VVIR Single Chamber Pacemaker IFU.

1.10.1 Magnet, Device and Programmer App Interaction

- When the Device is active and magnet is present, the Device will pace with emergency setting as defined in Table 3: Emergency Pacing Parameters
- To wake up the Device and establish connection, swipe a magnet on the Device and scan with the programmer. When swiping the magnet over the Device, temporarily put the magnet in close proximity to the Device for less than one second.
- Do not leave the magnet on the Device when trying to program parameters into the Device.
- The programmer tablet must be within a foot from the Device to maintain reliable Bluetooth connection while programming session is active.
- If the programmer tablet moves out of communication range of the Device for more than 30 seconds, the Bluetooth connection between Device and programmer will be closed. In such a case, swipe the magnet on the Device to wake up the Device and scan with the programmer app to establish a communication connection.
- If the programmer tablet moves out of communication range of the Device and comes back in communication range within 30 seconds, the Bluetooth connection between the Device and the programmer will be reestablished without the need for the magnet.
- Excessive communication via Bluetooth with the pacemaker Device will cause the battery to drain more quickly. It is recommended to limit Bluetooth communication with the Device to only necessary communications.

1.10.2 Tablet App Interaction

Tablets operating system events such as notifications, alarms, and messaging can take priority and therefore move the Calyan Programmer app to the background. Tapping, pressing buttons, etc. on the tablet outside the application can move the implantable Device app to the background or close the app. For example, the Calyan Programmer app will move to the background if you lock the tablet. When the Calyan Programmer app moves to the background or closes, communication with the Calyan VVIR Device is paused or lost, in such a situation swipe the magnet on the Device to resume connection.

1.11 Network Requirements

1.11.1 Bluetooth

Bluetooth should be enabled on the tablet; the programmer communicates with the Device using Bluetooth.

1.12 Cybersecurity

Because the Calyan Pacemaker is an electronic device with wireless connectivity, there are cybersecurity risks that malicious actions may be taken by third parties to access patient treatment data or change the programming of the implantable device. Calyan has taken steps to minimize these risks to an acceptably low



level by allowing wireless access to the implantable device only when enabled by a physician with physical access and verbal consent from the patient and only using a secure, proprietary programming tablet controlled by the physician or a Calyan representative. This tablet has all wireless communications connections disabled (WiFi, LTE, etc) except for the short-range Bluetooth link necessary to communicate with the Calyan Pacemaker device. All information contained on the Calyan Pacemaker and programmer tablet and communicated over this Bluetooth link are de-identified, encrypted and stored securely. Measures are also in place to prevent unauthorized changes to Calyan Pacemaker parameters and software.

Warning: BLE security risks include eavesdropping, man-in-the-middle and brute force attacks that may lead to modification or capture of patient treatment parameters and data.

Warning: If there is a cybersecurity breach, please contact your local Calyan representative

1.13 Over-the-Air Updates

Over the air updates for the Device may be supported and limited to firmware updates on the Device. If an over-the-air update is required, please contact a Calyan representative.

Calyan Technologies
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Website www.calyantech.com

1.14 Quality of Service

Wireless communications typical of the intended use environment are unlikely to interfere with the communications between the Device and Programmer so long as they are kept a sufficient distance from the physical communications link.

- Wi-Fi, Bluetooth and Cellphone nodes operating in the 2.4-2.5GHz ISM band with Effective Isotropic Radiated Power (EIRP) below 10mW should be kept at least 0.35 meters away from the physical communications link.
- In-Band and Co-Channel signals of EIRP above 10mW should, if reasonable, be kept at least 1.11 meters from the physical communications link, and signals of EIRP above 100mW should be kept at least 3.51 meters away.

If the connection between Pacemaker and Programmer drops unexpectedly, it is likely caused either by an interfering wireless signal source or the Device and Programmer are too far away from each other. In this case, the Programmer should be moved closer to the Device. Any sources of interference should be identified and, if reasonable, either turned off or moved further away from the physical communications link. A Relative Signal Strength Indicator(RSSI) and a "CONNECTED"/"DISCONNECTED" status indicator are present on the Programmer User Interface to confirm connectivity. If the RSSI drops below -60, it is



recommended that the Programmer be moved closer to the Device. In the event that communications become disconnected, the Device will automatically revert to its last saved set of programmed parameters to continue delivering therapy to the patient. Communications can be re-established by swiping a magnet across the Device and connecting to its Bluetooth address via the Programmer.

The net result of these cybersecurity mitigation efforts is that the risks to the patient and patient data are acceptably low.

2 Setup Steps

2.1 To find and open the App.

1. Navigate to the apps on the tablet.
2. Find the Calyan Programmer App (Figure 1).
3. Tap on the app icon to open the app.

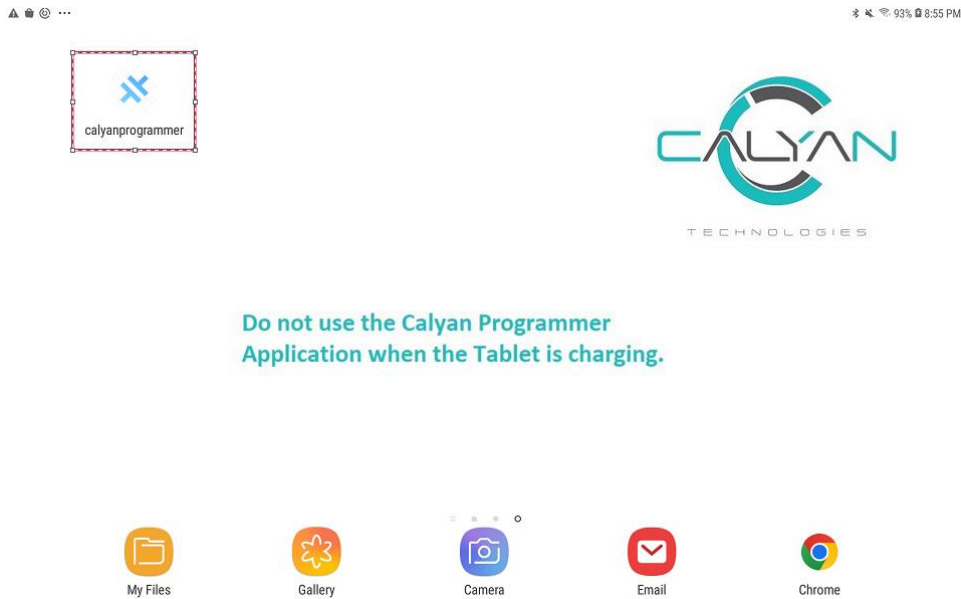


Figure 1: Calyan Programmer App

2.2 Programming Modes

Term	Description
Implant Mode	Mode selected in the Programmer Application during the implant. This mode provides the ability test lead Impedance during the implant
Follow Up Mode	Mode selected in the Programmer Application during the Follow up. This mode provides the ability set Rate response parameters into the Device.



1. Select a mode (Figure 2).
2. Confirm if you want to continue with mode selection or press back button if you want to change the selected mode (Figure 3).

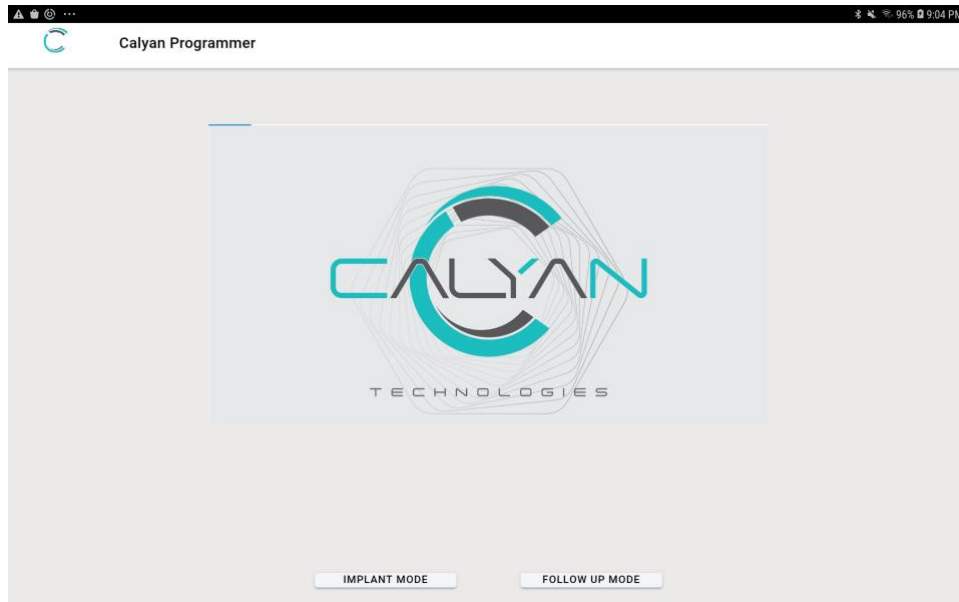


Figure 2: Programming modes

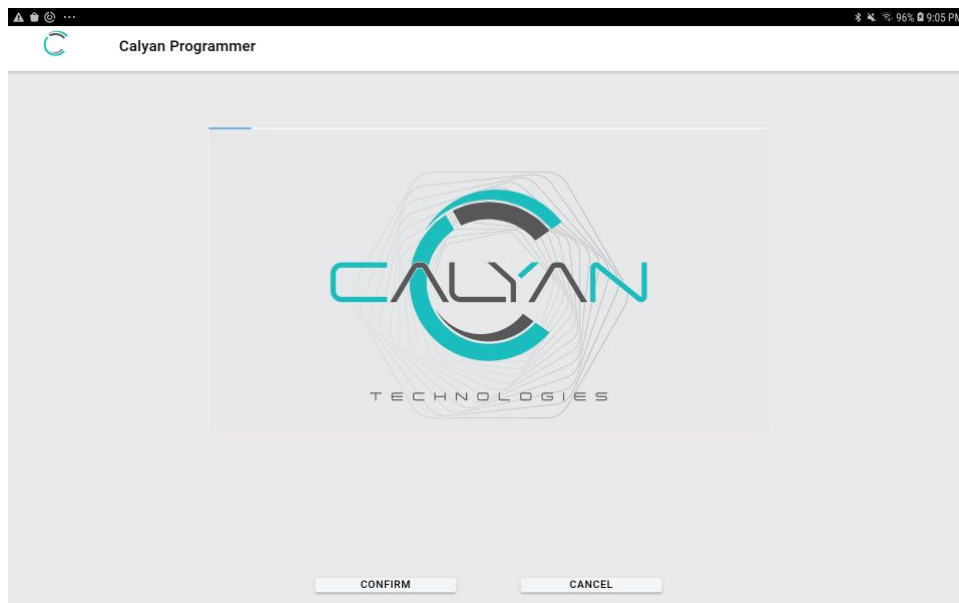


Figure 3: Confirm programming mode selection.

2.3 Scanning for the Device

1. Once the mode is confirmed, the programmer app transitions to scanning for Device over Bluetooth.
2. Swipe the magnet over the Device to wake the Device and advertise over BLE.



3. To initiate scanning, press the “Start Scan” button on top right corner. (Figure 5).
4. The Programmer will list all the Calyan Devices that are currently advertising (Figure 4 and Table 2: Device Advertisement).
5. The programmer app scans for the Devices for 10 seconds, if a Device is not found it stops scanning.
6. If at any point you want to clear the list of Devices, select the “Clear” button on the top right corner (**Error! Reference source not found.**).
7. Tap on any advertising Device appearing on the screen to initiate a connection.



Figure 4: Initiating scan for Device



Figure 5: Scanned List of Devices



Figure 6: Clear listed Devices.



2.4 Connecting to the Device

1. On successful connection, the programmer will display “CONNECTED” in blue and transition to the “DEVICE SESSION” screen (Figure).
2. On successful connection the programmer will interrogate the Device and fetch all the settings. This process may take some time. Please do not dismiss the dialog box (Figure 7), unless the process takes longer than 3 minutes.

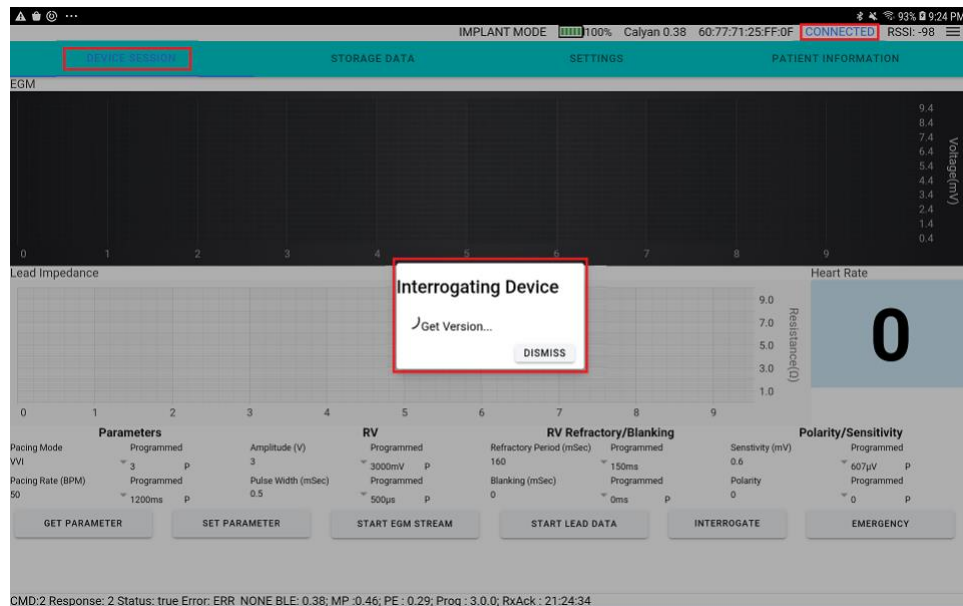




Figure 7: Interrogation

3. If the connection is unsuccessful at any point, a “DISCONNECT” status will be displayed in the top right of the screen in red with a reconnecting message in the bottom of the screen (Figure 8).
4. If this occurs, disconnect by tapping on the  icon, and tapping “Disconnect” (Figure). This will bring the user back to the Device scan screen (Figure 4). This button will also forcibly disconnect the Device from the application.
5. The user can scan for the Device and reinitiate connection once the Device is discovered.
6. Ensure the tablet is in proximity with the Device.
7. The  icon also gives the user the ability to exit the app entirely by tapping “Exit” (Figure 10).

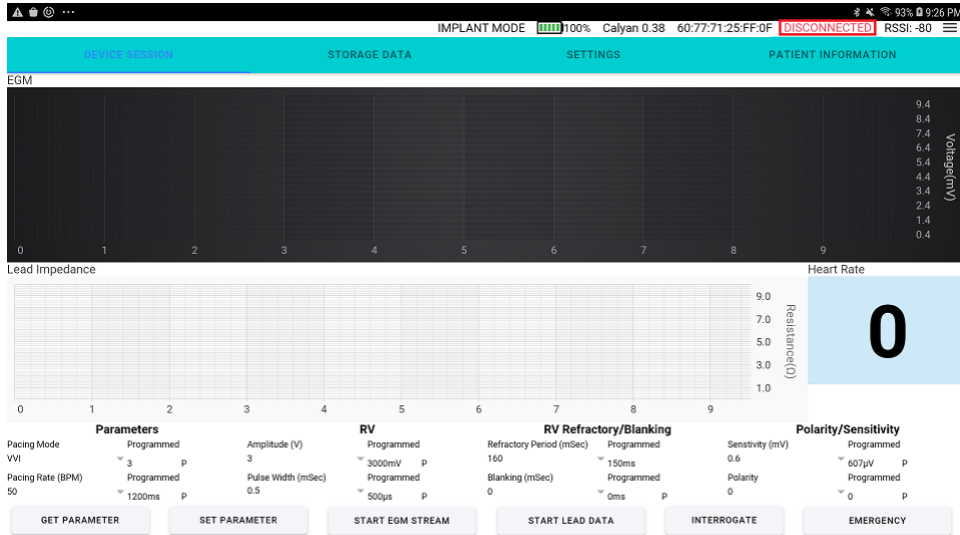


Figure 8: Connection Error - Disconnect

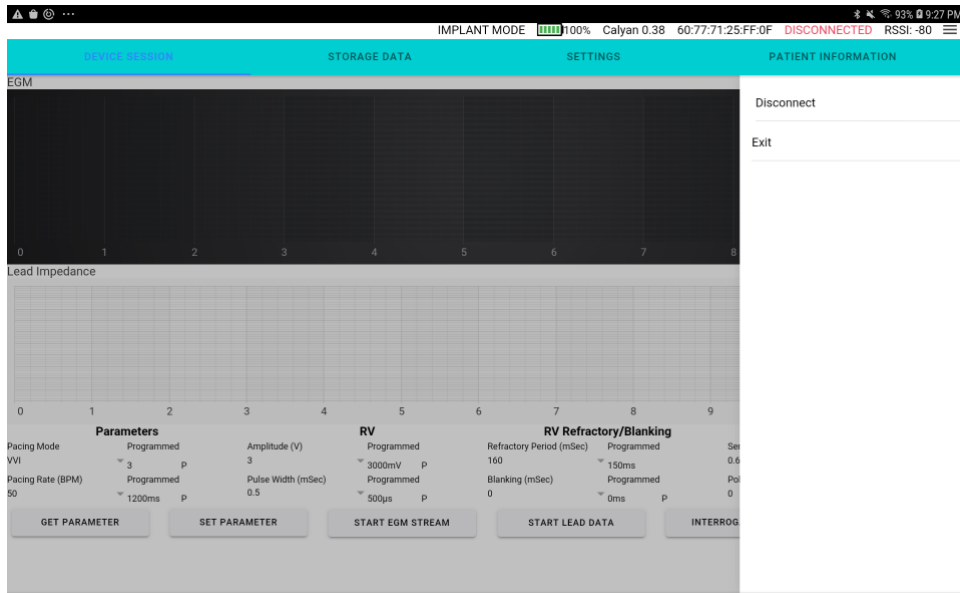


Figure 9: Disconnect Device from App

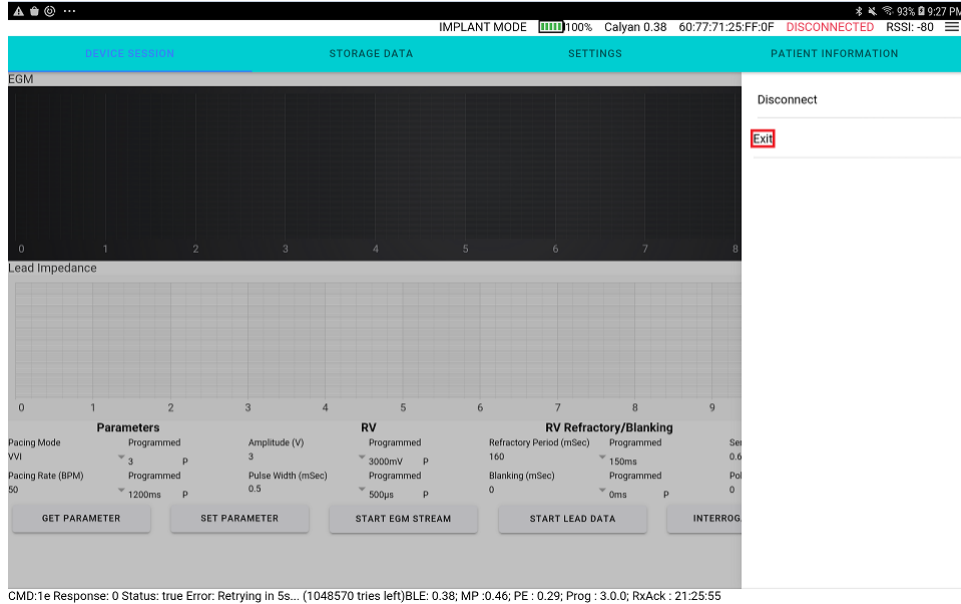


Figure 10: Exit App

3 Device Session

1. On Successful interrogation the Device settings will be displayed on the programmers “DEVICE SESSION” screen (Figure 7).
2. The Parameter range is defined in the Table 4: Device Programming Parameters.

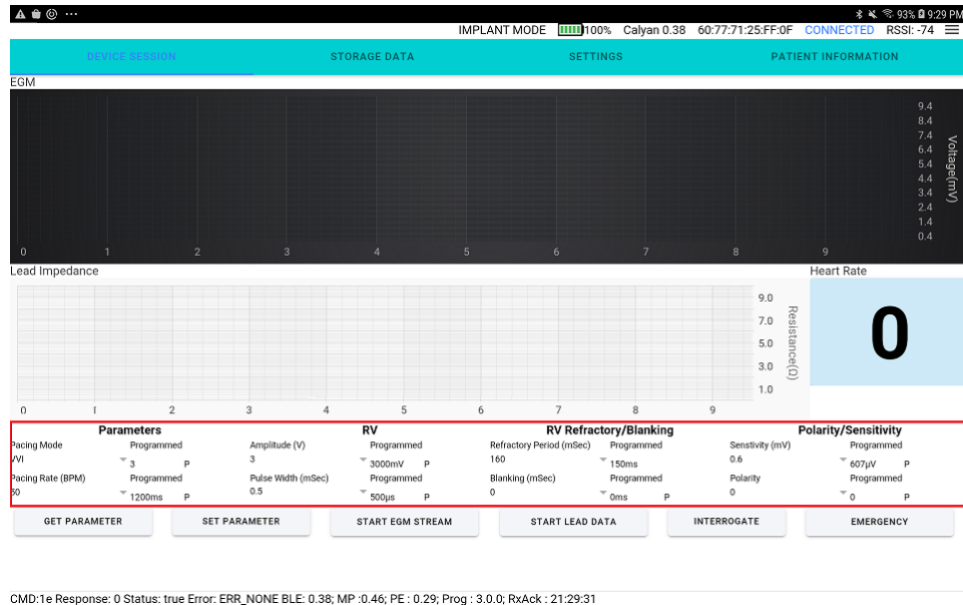


Figure 7: Device Session

The screen provide access to multiple operations:

3.1 Interrogation

1. Tap the button “INTERROGATE” to initiate and interrogate the Device.
2. Ensure the programmer is in proximity with the Device, and the Bluetooth connection is active, and the programmer displays “CONNECTED” in blue text on the top right of the status bar.
3. On interrogation the programmer fetches, the version data (Table 7), parameter data (Table 4), and the stored data (Table 6).
4. The programmer automatically initiates an interrogation.
 - a. On initial session connection with the Device.
 - b. Whenever a Bluetooth connection is broken and reestablished. If the programmer/Device moved out of range and loses connection but reenters Bluetooth range within 30seconds the programmer will reestablish the Bluetooth connection and interrogate the Device automatically.
5. Do not dismiss the dialog box during interrogation, wait for the communication to complete.

3.2 Programming Parameters

The screen displays the programmed values (highlighted in Blue - Figure 8) and the editable fields (highlighted in Red - Figure 8) for the parameters.

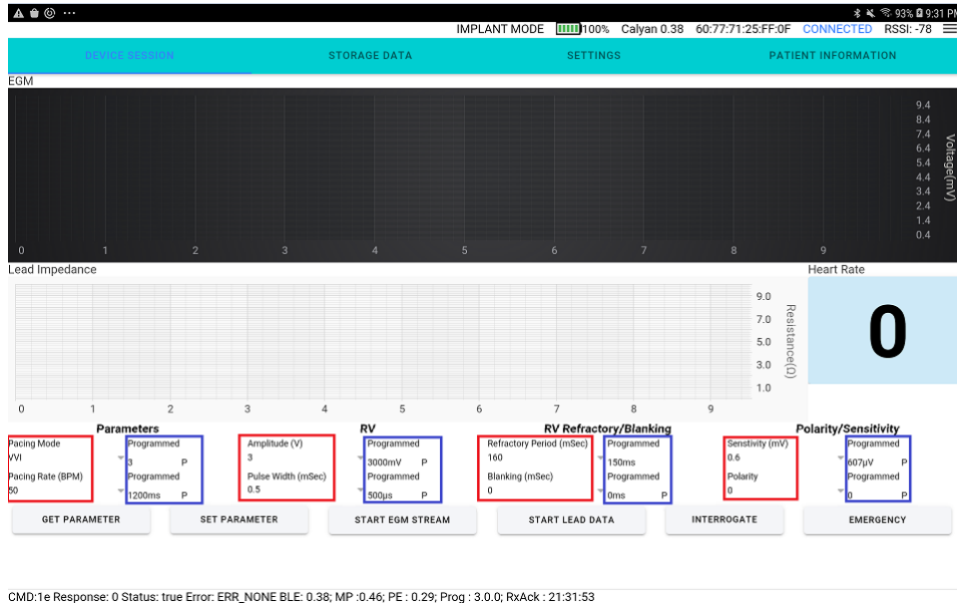


Figure 8: Programmable Parameters

1. Tap the “GET PARAMETER” button on the “DEVICE SESSION” screen any time during a session to fetch the programmed values from the Device.
2. To change the value of a parameter, tap on the ▼ icon adjacent to the parameter value intended to be changed.
3. This will bring up a dialog box with the allowed programmable values (Figure 9).
4. Tap on the desired value to select the value for programming (Figure 9).

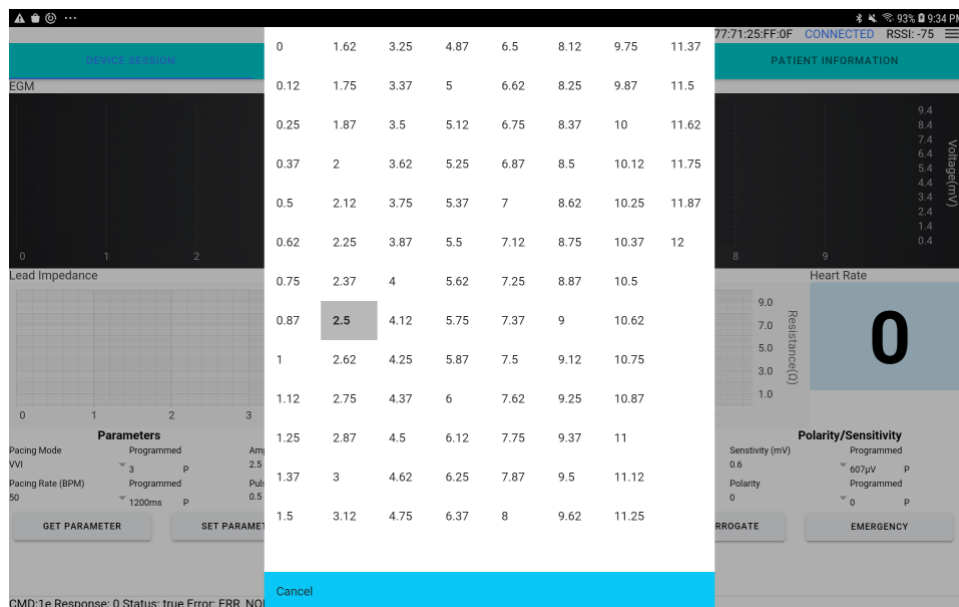


Figure 9: Selecting Parameter Values



- 5. Whenever the value of a parameter in the field does not match the programmed value, the “P” next to the programmed values disappears. The value that has changed has a blank in place of the programmed icon (Figure 10).

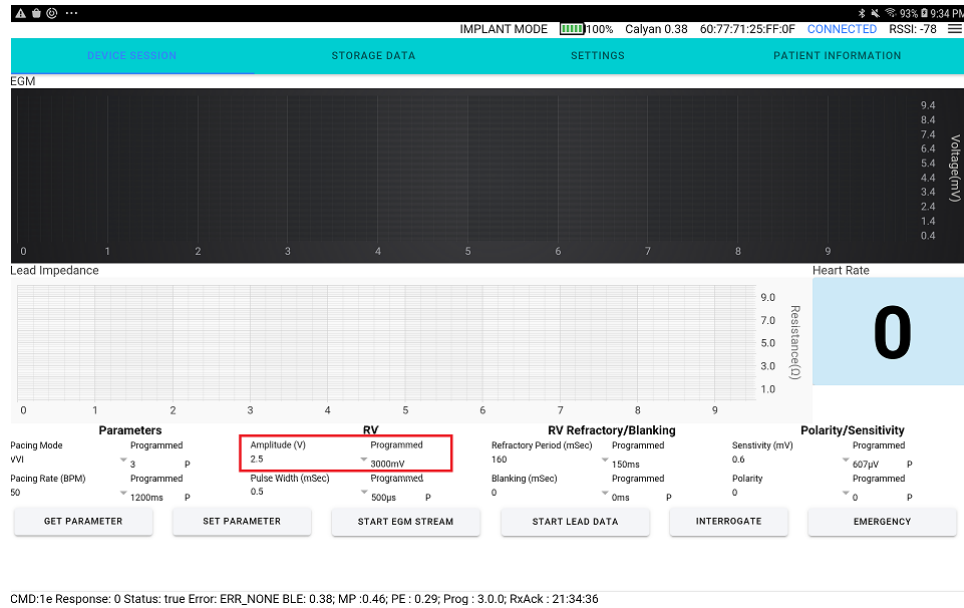


Figure 10: Highlight Change

- 6. Repeat the step with any parameters in need of update.
- 7. Make necessary changes to all desired parameters and tap the “SET PARAMETER” button to program the values into the Device. Note: VVIR Pacing mode should only be configured while in follow-up mode. VVIR requires that rate response be configured after setting parameters. (See Section 0.)
- 8. The set Parameter will take several seconds to conclude, a dialog box will appear indicating the task in progress. The dialog box will close after programming the parameters. Wait for the dialog box to close (Figure 11).

Note: Refer to the Calyan VVIR Single Chamber Pacemaker IFU for acceptable pacing parameters during the implant process and patient follow up.

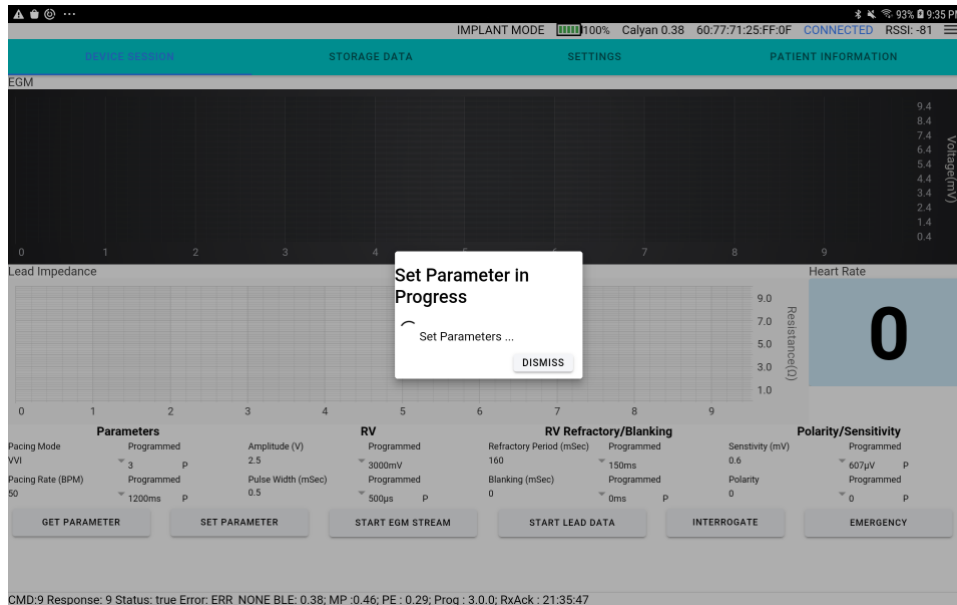


Figure 11 : Set Parameters.

3.3 R-Wave Sensing

The Device must sense the occurrence of intrinsic cardiac events while avoiding oversensing so that it can deliver pacing therapy appropriately. Effective sensing can reduce the effects of long depolarizations after paced events, oversensing the same event, sensing T-waves, noise, and interference. As the patient's condition changes, the sensing threshold may change, requiring the threshold to be monitored regularly and adjusted to intracardiac signals, if necessary.

Careful consideration should be given to patient exposure to external electromagnetic interference if programming a pacing inhibition sensitivity setting more sensitive than 2.0 mV. More sensitive settings than 2.0 mV are considered to represent an increased risk from sensing either inappropriate physiologic signals or non-physiologic electromagnetic interference from external sources. These more sensitive settings should therefore be programmed only for those patients requiring such sensitivity parameters rather than routine programming without further evaluation.

Note: Selecting a higher value for the sensing threshold reduces the sensitivity to lower amplitude signals.

Programmable blanking periods and refractory periods help to screen out extraneous sensing or to prevent the Device from responding to it. Both blanking periods and refractory periods follow pacing pulses and sensed events. Sensing is inhibited during blanking and refractory periods. Cardiac signals are disconnected during blanking. Sensing is inhibited during refractory periods. Refractory events have no effect on the timing of subsequent pacing events.



The Sensing value is determined by evaluating the electrogram and observing the mV value of the R-Wave. The R-Wave Amplitude is measured as the peak-to-peak measurement of the sense signal. The sense signals are denoted with the vs markers. If significant noise is observed on the electrogram, increase the sensitivity. If low amplitudes are observed on the QRS complex on the electrogram, reduce the sensitivity. The default sensitivity value is 2mV.

For example, in Figure 16 below, the R-Wave Amplitude is 14.4mV- 10.4mv = 4mV. The sensitivity is sufficient to detect the 4mV sense signal at a sensitivity of 0.6mV.

Note: If the R-wave amplitude is lower than the set sensitivity value, the programmer will not display any sense markers on the EGM stream in OVO, VVI, VVIR mode as shown in Figure 17 with a sensitivity value of 8mV.



CMD:3e Response: 0 Status: true Error: ERR_NONE BLE: 0.38; MP :0.46; PE : 0.29; Prog : 3.0.0; RxAck : 21:37:18

Figure 12 : R-Wave Amplitude Measurement



CMD:3e Response: 0 Status: true Error: ERR_NONE BLE: 0.38; MP: 0.46; PE: 0.29; Prog: 3.0.0; RxAck: 21:40:42

Figure 17: Sensitivity too large for sense markers to appear.

3.4 Blanking Period

Blanking periods follow paced and sensed events and are time intervals during which sensing in a chamber is disabled to avoid oversensing. Blanking periods help to prevent the Device from sensing pacing pulses, post-pacing depolarization, T-waves, and oversensing of the same event. The blanking periods after paced events are longer than or equal to those after sensed events to avoid sensing ventricular depolarizations. The blanking periods that follow sensed events and paced events cannot be programmed to be longer than the refractory periods. Blanking periods are set by the programmer by selecting the dropdown for Blanking and selecting a value from 0ms to 450ms (Figure 18, Figure 19).



Figure 18: Blanking dropdown location



Figure 19: Blanking programmable range.

3.5 Refractory Period

During a refractory period, the Device senses normally but classifies sensed events as refractory and limits its response to these events. The pacing refractory periods prevent inappropriately sensed signals, such as T-



waves or electrical noise, from triggering certain pacing timing intervals. Refractory periods are set by the programmer by selecting the dropdown for Refractory Period and selecting a value from 0ms to 500ms (Figure 20, Figure 21).



Figure 18: Refractory Period dropdown location

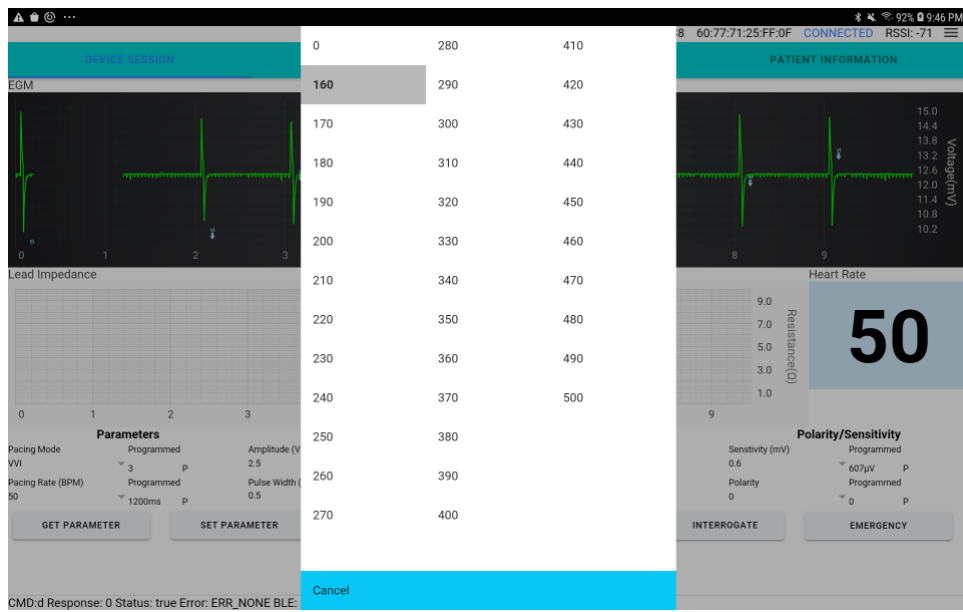




Figure 19: Refractory Period programmable range.



3.6 Streaming

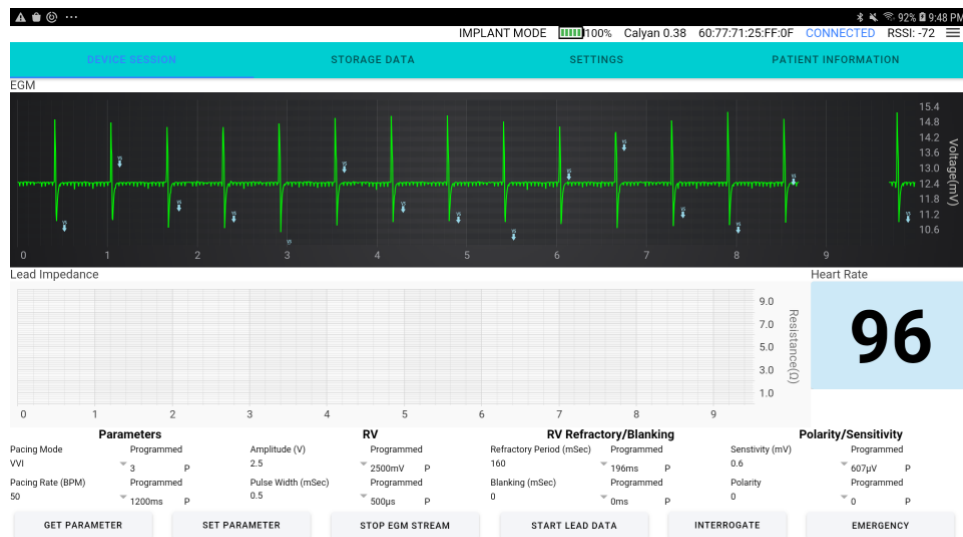
In Implant Mode the programmer can stream EGM and Lead Impedance. In Follow up Mode the programmer can only stream EGM.

3.6.1 EGM Streaming

1. Tap on the “START EGM STREAM” button to initiate EGM Streaming.
2. The EGM will be streamed under the “EGM” section of the “DEVICE SESSION” screen (Figure, Figure).
3.  denotes the pace marker on the EGM stream.
4.  denotes the sense markers on the EGM stream.
5. Tap on the “STOP EGM STREAM” button to stop EGM stream.

The start and stop EGM stream is the same button, its acts as a toggle based on the present state of EGM streaming.

NOTE: In case the Device and the programmer lose the Bluetooth link for more than 30 seconds, re-swiping the magnet is required to reinitiate connection. The EGM stream button will retain the previous state prior to losing connection, hence if the button displays “STOP EGM STREAM” tap the button once to reset the streaming state, and once again to reinitiate EGM streaming.



CMD:3e Response: 0 Status: true Error: ERR_NONE BLE: 0.38; MP :0.46; PE : 0.29; Prog : 3.0.0; RxAck : 21:47:55

Figure 20: EGM Streaming - Implant Mode

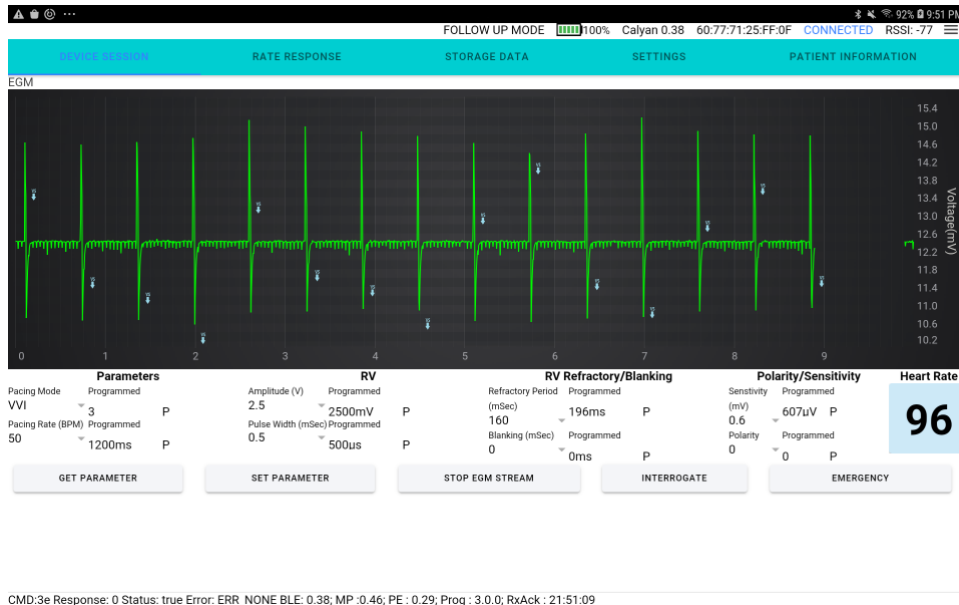


Figure 21: EGM Streaming - Follow up Mode.

3.6.2 Lead Impedance Streaming (Only in Implant Mode)

1. Tap on the “START LEAD DATA” button to initiate Lead Impedance Streaming.
2. The Lead Impedance will be streamed under the “Lead Impedance” section of the “DEVICE SESSION” screen (Figure 22).
3. Tap on the “STOP LEAD DATA” button to stop Lead Impedance stream.

The Start and stop Lead Impedance stream is the same button, its acts as a toggle button based on the state the Lead Impedance streaming is in.

NOTE: In case the Device and the programmer lose the Bluetooth link for more than 30 seconds, swiping of a magnet is require for reinitiating connection, the LEAD DATA stream button would retain the previous state prior to connection being lost. Hence if the button displays “STOP LEAD DATA” tap button once to reset the streaming state and again to initiate the start streaming Lead Impedance.

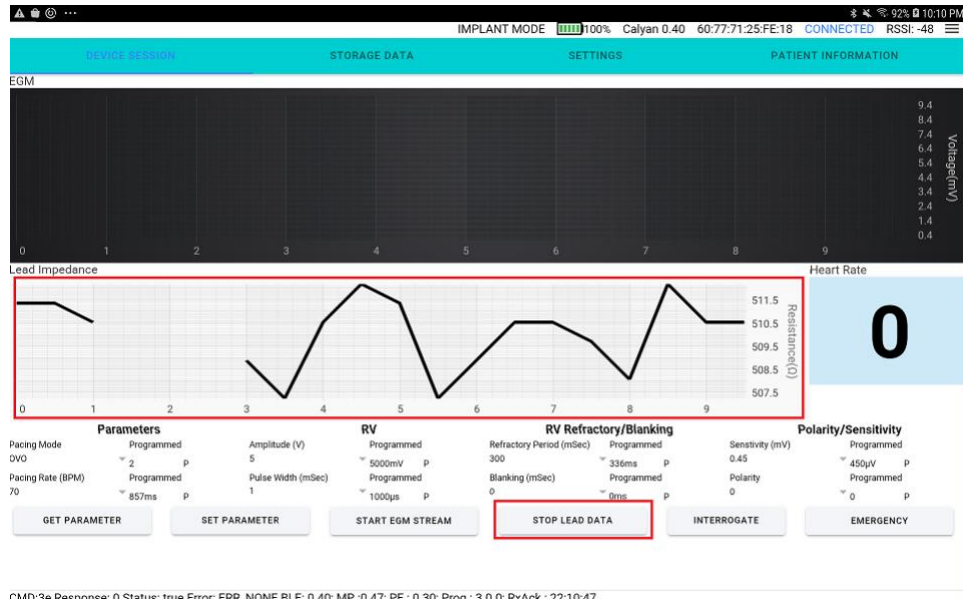


Figure 22: Lead Impedance Streaming

3.7 Programmer Initiated Emergency Mode

1. Tap on the “EMERGENCY” button to initiate Emergency mode.
2. The Device will be put into an Emergency mode and pace using the parameters defined in Table 3: Emergency Pacing Parameters.
3. An “EMERGENCY MODE ACTIVE” message will be displayed on the lower left corner of the programmer (Figure).
4. The “EMERGENCY” button will toggle and display the “EXIT EMERGENCY” button (Figure).
5. Tap “EXIT EMERGENCY” to exit the software emergency state and transition to the parameter settings as selected on the “DEVICE SESSION” Screen.

Note:

- The Exit Emergency in turn resets the parameters as selected by the user in the “DEVICE SESSION” screen. It would revert to the old, programmed parameters if none of the parameters were updated between programming of Emergency and Exit Emergency.
- The Device would also exit software emergency if “SET PARAMETER” was tapped.
- If the Bluetooth connection is lost or the programmer application was exited using the “DISCONNECT” button during software emergency, the user will need to swipe a magnet and open the programmer app. The “DEVICE SESSION “screen will display “EMERGENCY” in the Pacing Mode (**Error! Reference source not found.**) and will display the Emergency parameters values for all the other pacing attributes as defined in Table 3: Emergency Pacing Parameters. The user needs to reprogram the Device with the desired pacing mode and parameter values to exit emergency mode.

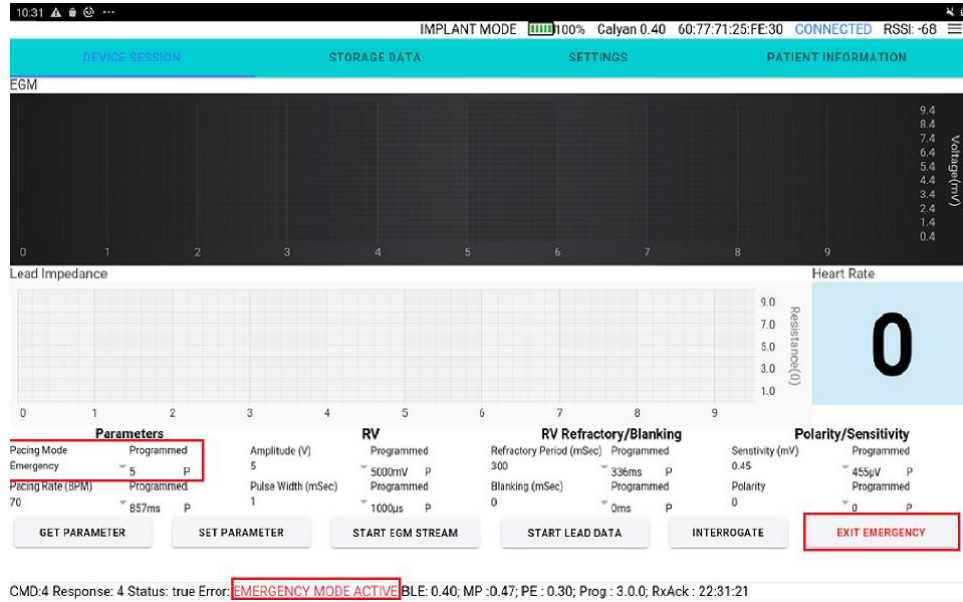
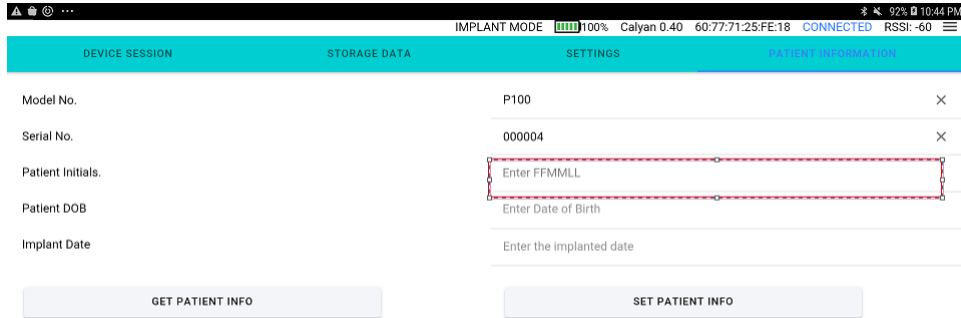


Figure 23: Software Initiated Emergency Mode

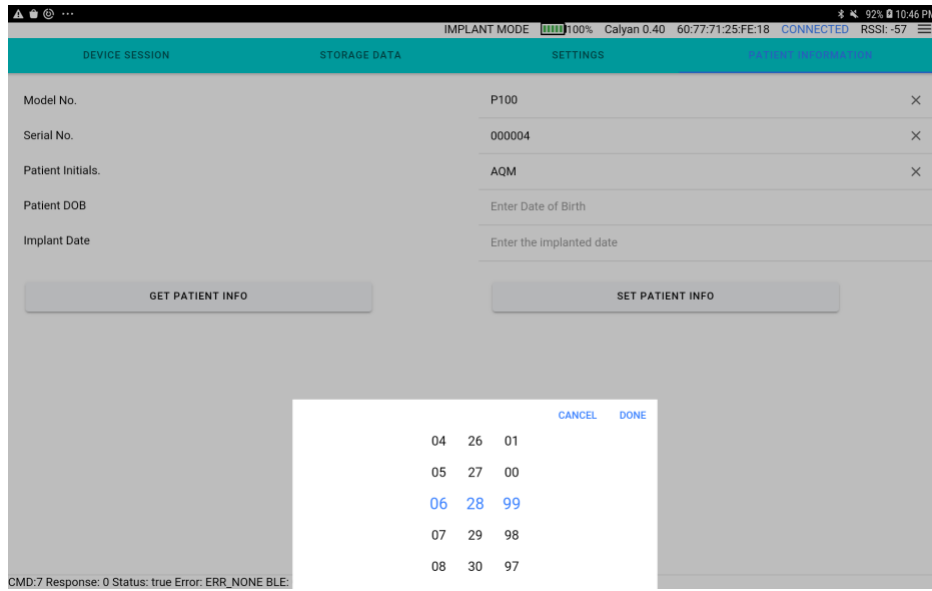
4 Patient Information

1. Patient Information needs to be updated during implant.
2. The Serial number and model number need to be preprogrammed.
3. Tap on the Patient Initials (FML) field and a keyboard will appear, select appropriate initials (Figure 13).
4. Tap on Patient DOB field or tap the “Next” button on the keyboard to transition to the next field (Figure 14).
5. Once the Implant date field is populated with values, tap on the “Done” button or tap anywhere outside the keyboard on the screen.
6. Tap “SET PATIENT INFO” to set the filed in detail into the Device.
7. Tap “GET PATIENT INFO” to retrieve the values stored on the Device.



CMD:1e Response: 0 Status: true Error: ERR_NONE BLE: 0.40; MP :0.47; PE : 0.30; Prog : 3.0.0; RxAck : 22:44:26

Figure 13: Patient Initials



CMD:7 Response: 0 Status: true Error: ERR_NONE BLE:

Figure 145: Patient Information: Entering the DOB.

5 Stored Data

1. The “STORED DATA” page displays (Figure 156)

- Weekly Impedance Trend
- R-wave Amplitude Trend
- Pacing and Sensing Histograms.

- Ventricular Markers
2. The Histogram data and the Ventricular markers are reset every time a parameter is programmed using the “SET PARAMETER” button on the “DEVICE SESSION” Screen.
 3. The stored data from the Device is fetched during interrogation.
 4. Tap “GET STORED DATA” to fetch the latest set of data from the Device.

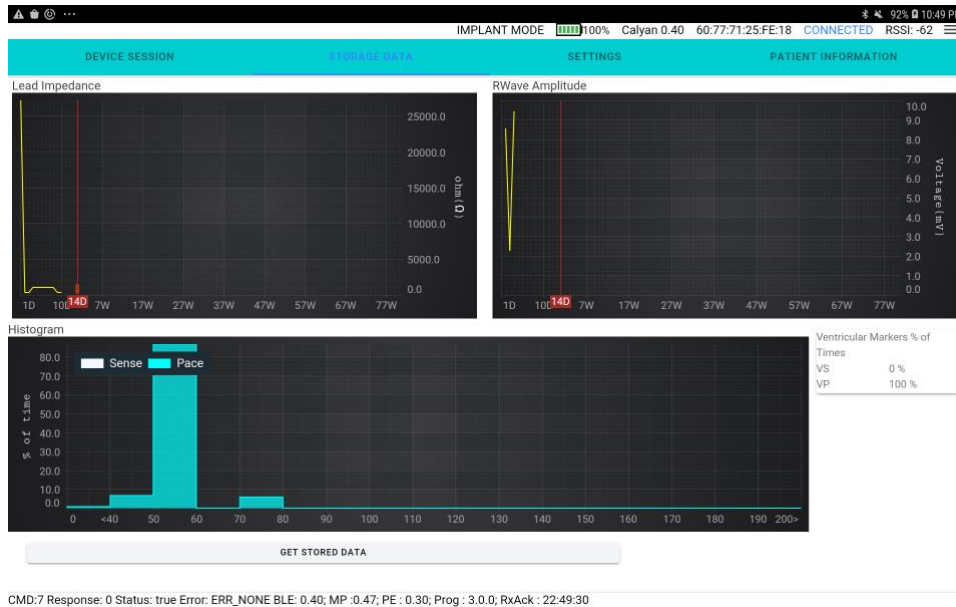


Figure 156: Stored Data

6 Settings Page

6.1 View errors

1. To view the errors that are presently active or historic errors on the Device tap the “GET DEVICE STATUS” button.
2. A dialog box with the following will appear (Figure 167).
 - Presently active Errors for Main Processor and Pacing Engine if any.
 - Historic errors for Main processor and Pacing Engine if any.
 - Reset Reasons for Main Processor and Pacing Engine if any.

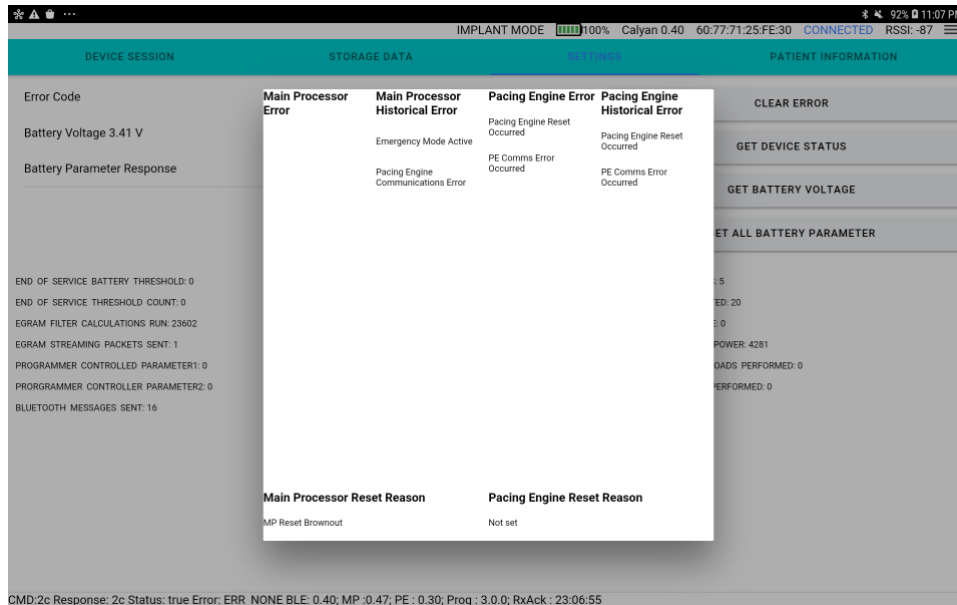



Figure 167: Device Error Screen

6.2 Clear errors

6.2.1 Clear Individual errors

The programmer application gives the user an option to clear specific errors.

1. Tap on the  icon to display a drop down of all the error codes besides the “CLEAR ERROR” button.
2. The drop down is scrollable (Figure 178).
3. Tap on the specific error that needs to be cleared.
4. Tap on the “CLEAR ERROR” button (Figure 189).

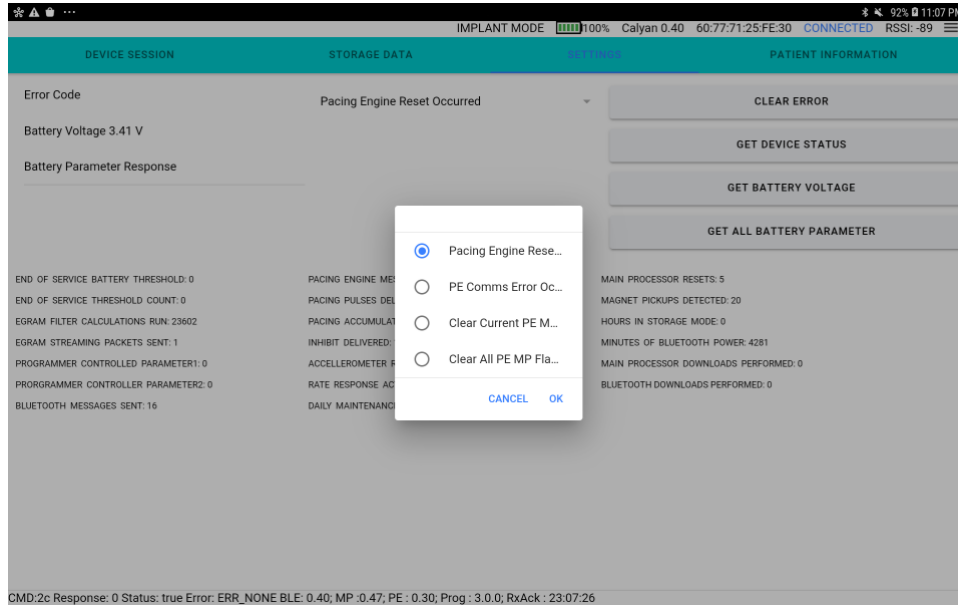


Figure 178: Error Code Dropdown

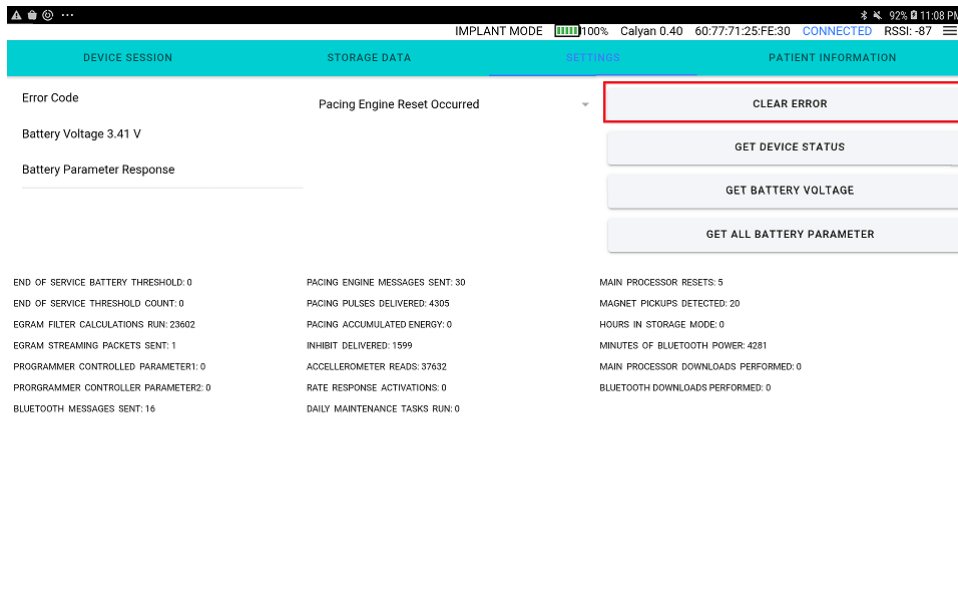



Figure 189: Clear Error

6.2.2 Clear all present errors.

The programmer application gives the user an option to clear all present errors.


1. Tap on the  icon to display a drop down of all the error codes.
2. The drop down is scrollable, Scroll to the end of the list.



- 3. Tap on the “Clear Current PE MP Flags”.
- 4. Tap on the “CLEAR ERROR” button (Figure 189).

6.2.3 Clear all present and historic errors.

The programmer application gives the user an option to clear all present and historic errors.

- 1. Tap on the  icon to display a drop down of all the error codes.
- 2. The drop down is scrollable, Scroll to the end of the list.
- 3. Tap on the “Clear all PE MP Flags”.
- 4. Tap on the “CLEAR ERROR” button (Figure 189).

6.3 Get Battery Voltage

Battery voltage and other stored data as defined in section 5 are measured and collected by the Device every day at 2:00am local time.

- 1. To view the last measured battery voltage, tap the “GET BATTERY VOLTAGE” button.
- 2. The results are displayed on the screen (Figure30).

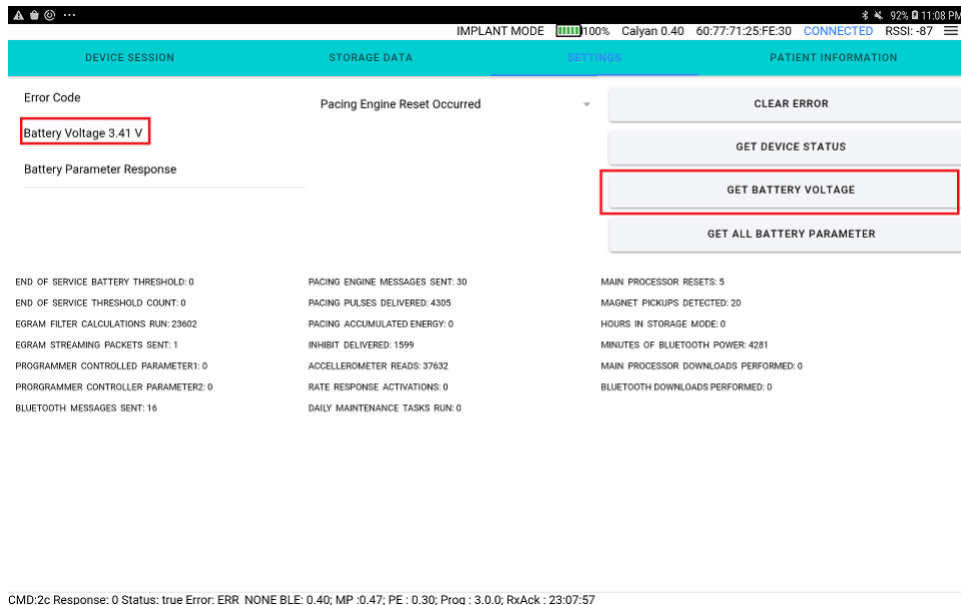


Figure 30: Battery Voltage

If you want to initiate a daily maintenance data collection and view the present Battery Voltage readings.

- 1. Tap “SET TIME FOR DAILY DATA” button
- 2. Tap the “GET BATTERY VOLTAGE” button.
- 3. The result displayed on the screen (Figure30).

Note: If you initiate Daily maintenance by taping the “SET TIME FOR DAILY DATA” button, the Device time is set to 2:00am and the Device does Battery voltage check, Lead impedance test and R Wave amplitude data collection. As a daily/weekly stored data values will get incremented.



6.4 Get All Usage Counters (Get all battery parameters)

The Programmer provides the ability to query and fetch all usage counters stored in the Device.

1. Tap the “GET ALL BATTERY PARAMETER” button (Figure 191).
2. The result is displayed in the scrollable area under “Battery Parameter Response” (Figure 191).

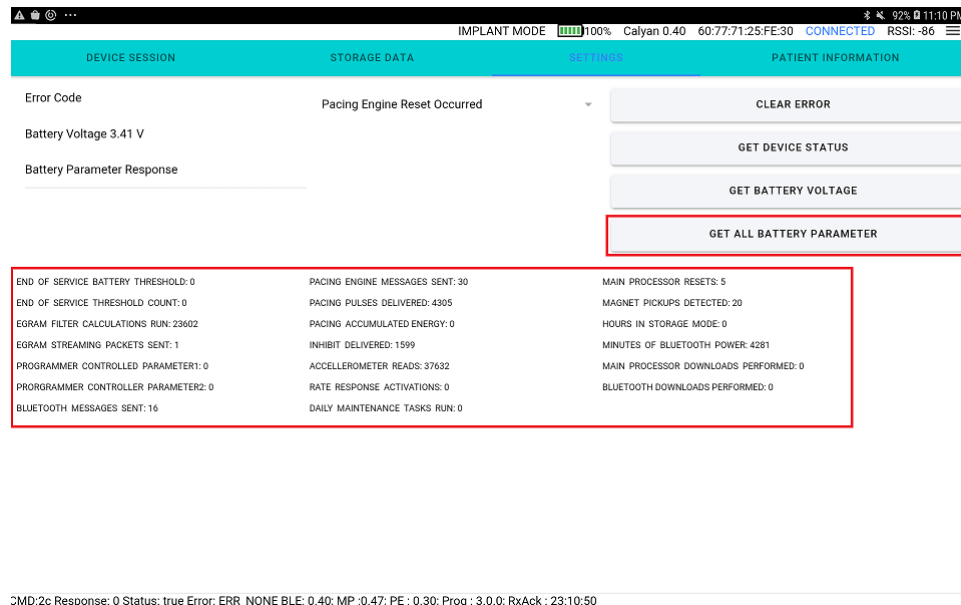


Figure 191: Get All Usage Counters

7 Rate Response

The adaptive rate response module takes in accelerometer samples to determine patient activity levels. If a pacing rate adjustment is required due to onset or offset of patient activity, an internal command is sent to initiate the ramp up or down to the new targeted pacing rate based on an internal algorithm. The Activity Level required to induce a pacing rate change and the maximum Activity Pacing Rate are the parameters adjustable by the physician via the programmer.

Rate Response Terminology

Activity Level	Intensity of patient activity as measured by on-board accelerometer.
Activity Threshold	Activity level required to increase the pacing rate.
Base Rate	Device pacing rate when activity threshold is not met due to low patient activity level. This is the programmed pacing rate, which is set by the pacing parameters.



Activity Pacing Rate	Maximum pacing rate when activity threshold is met due to high patient activity level. Maximum activity pacing rate is limited to 180 bpm or less for patient safety.
Activity Duration	Count of how long patient activity level has been above the activity threshold. Activity duration must exceed 15 seconds to enable an increase in pacing rate or fall below the activity threshold for more than 30 seconds to enable a decrease in pacing rate.

Rate Response Operation

The rate response algorithm tracks the most recent patient activity level, as measured by the on-board accelerometer. This is called the Activity Level and is compared against the Activity Threshold. If the activity level is greater than the activity threshold the activity duration is incremented, if not the activity duration is decremented. If the accumulated activity duration exceeds 15 seconds, the pacing rate is increased to accommodate increased patient activity. If activity slows or stops, for a duration that exceeds 30 seconds, the pacing rate is decreased to accommodate reduced patient activity.

Rate Response when Intrinsic are Detected

To reduce power consumption, the accelerometer primarily remains powered down when intrinsic heartbeats are detected and patient activity is below the Low Activity threshold. Once every two minutes, the accelerometer will power up and begin sampling for a period of time to look for activity. If activity is observed, the accelerometer will continue sampling and performing rate updates as needed. If no activity is observed, the accelerometer powers down after the sampling period.

Every time the pacing parameters are reconfigured in VVIR, the rate response setting must be updated afterward. The rate response screen is only available in follow up mode.


7.1 Rate Response Guidelines

Rate response is designed to advance the pacing rate based on the detected level of physical activity.

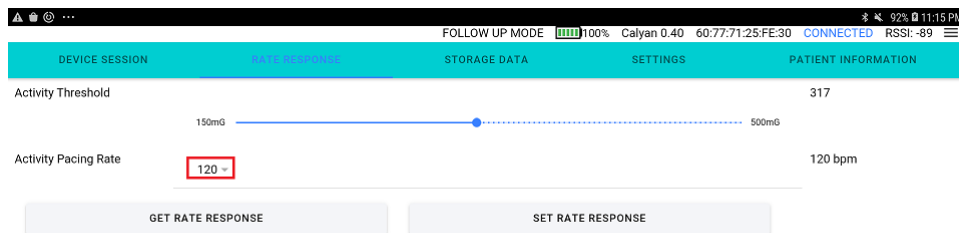
- The Activity Pacing Rate setting on the Rate Response screen will define the maximum pacing rate during the highest level of activity.
- The Activity Threshold defines the minimum sustained activity level to begin increasing pacing rate.
- Physicians should seek to set Activity Threshold to engage at a walking level of activity.
- As a guideline, an activity value around 325 milli-g is typical for walking, but this can vary widely from patient to patient.
- More strenuous activity will result in pacing at higher rates, up to the Activity Pacing Rate.



7.2 Get and Set Rate Response Parameters

1. To retrieve the rate response parameters programmed in the Device tap the “GET RATE RESPONSE” button.
2. The Activity Threshold value and the Activity Pacing Rate programmed for the Device are retrieved and displayed.
3. Move the slider to the left to decrease the Activity Threshold.
4. Move the slider to the right to increase the Activity Threshold.
5. Tap on the  icon next to Activity Pacing Rate edit field (Figure 202).
6. The scrollable list with programmable values is displayed (Figure 213).
7. Select the desired upper Activity Pacing Rate limit and tap OK (Figure 213).
8. The presently selected values of Activity Threshold and Activity Pacing Rate are displayed.
9. Once the desired values of each of the parameters is selected, tap the “SET RATE RESPONSE” button to program the values into the Device.

Note: Always do a “GET RATE RESPONSE” prior to making any changes to the rate response parameters.



CMD:2a Response: 0 Status: true Error: ERR_NONE BLE: 0.40; MP :0.47; PE : 0.30; Prog : 3.0.0; RxAck : 23:15:20

Figure 202: Rate Response Screen

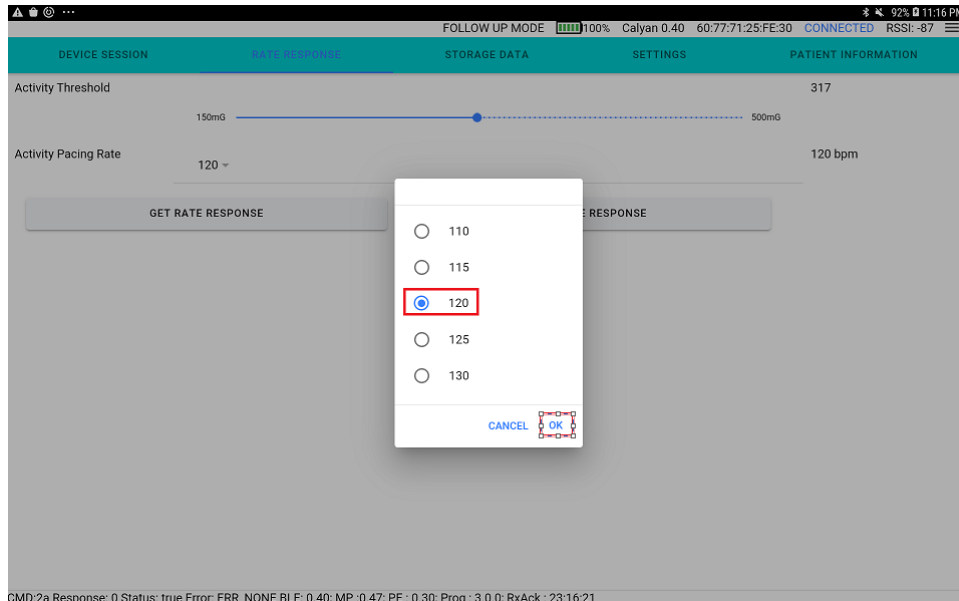


Figure 213: Rate Response: Pacing Rate Upper limit Selection

8 Magnet Initiated Emergency Mode

1. When a magnet is placed on the Device, the Device will enter a Hardware Emergency mode and transition to Pacing with values as defined in Table 3: Emergency Pacing Parameters
2. The Device remains in Emergency Mode for as long as the magnet is placed over the Device.
3. When the magnet is moved away from the Device, the Device transitions to the programmed pacing mode.
4. During hardware emergency if the programmer interrogates the Device, an “EMERGENCY MODE ACTIVE” is displayed on the bottom left of the programmer (Figure 224).

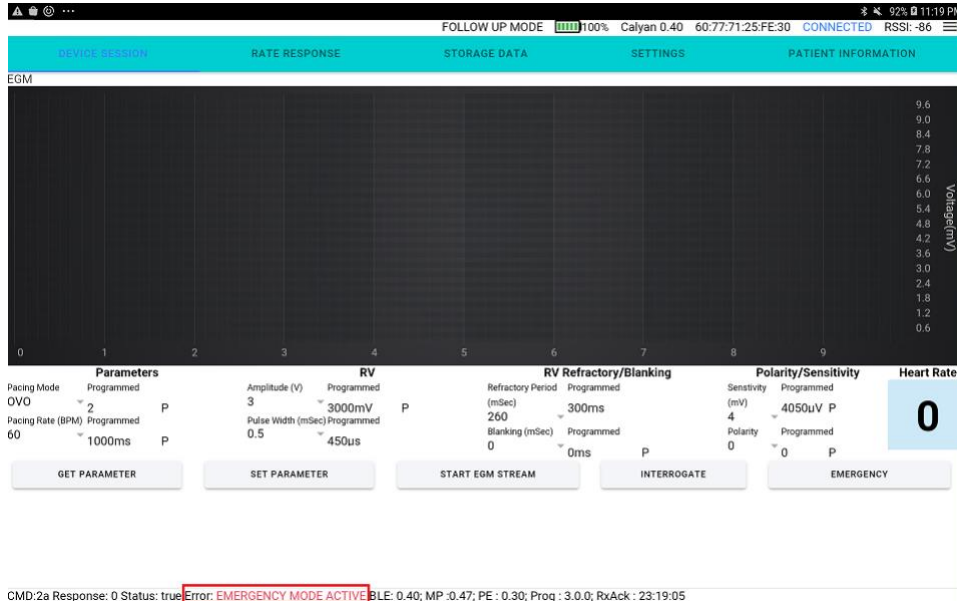


Figure 224: Emergency Mode Active

9 Device Error (Status Bar)

The programmer displays error code received from the Device as part of the response to its Bluetooth command on the status bar.

1. Tap on the error codes and a dialog box with all the errors presently returned from the Device will be listed (Figure 235).
2. Tap OK or Cancel to dismiss this dialog box after viewing the errors.
3. Errors are described in 12.8

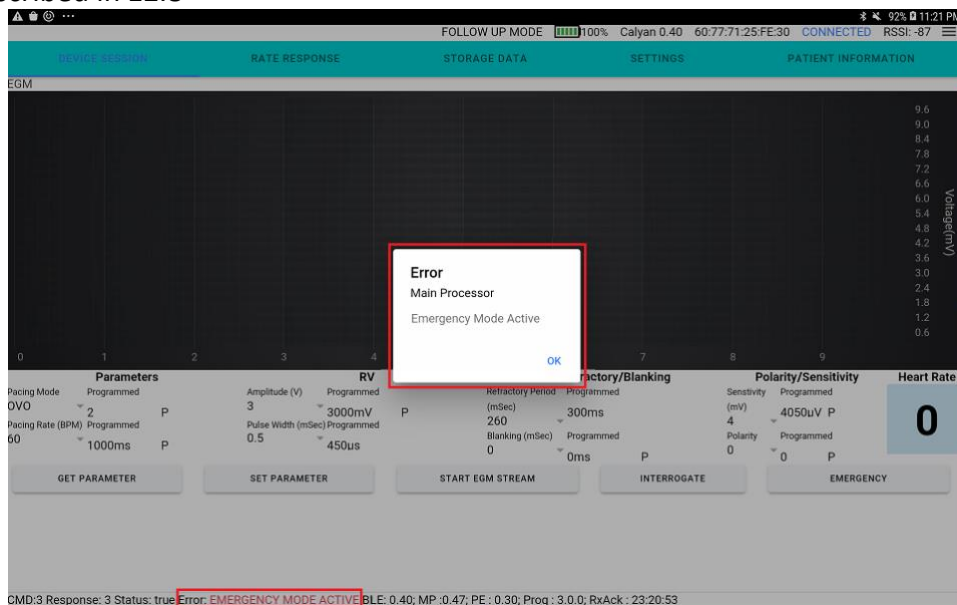


Figure 235: Device Error (Status Bar)



10 Menu Bar and Indications

The menu bar on the programmer app highlights the mode, Elective Replacement Indicator, the estimated remaining lifetime, the Device name, MAC Id connection status and the Bluetooth signal strength of the connection (Figure 246).

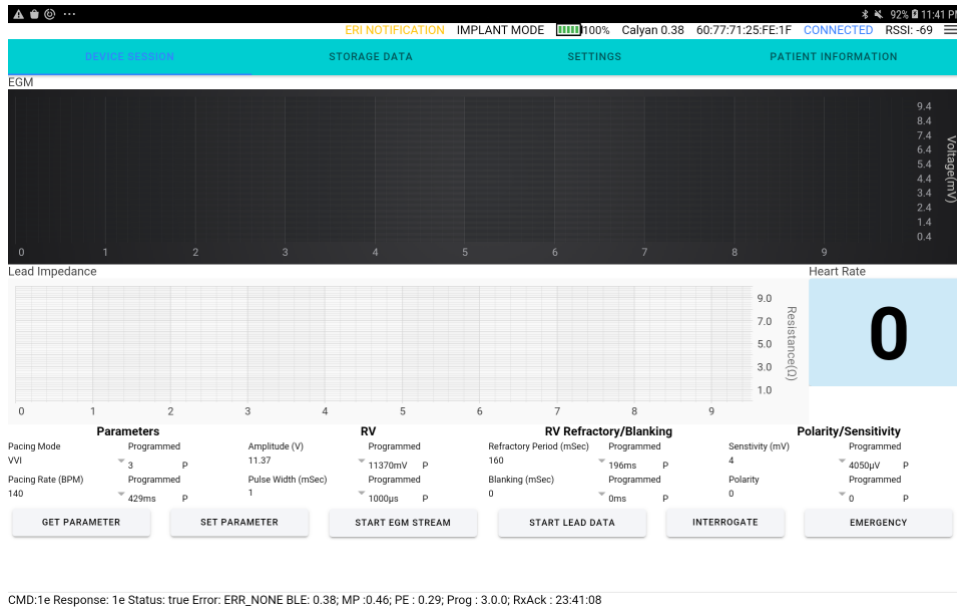


Figure 246: Menu bar

11 Troubleshooting

11.1 Multiple Devices Discovered

1. Multiple Calyan Devices can appear in the scan page if they are all activated for Bluetooth connection. Ensure you are selecting the appropriate Device based on the RSSI.
2. A progress spinner will appear next to the selected Device (Figure37).

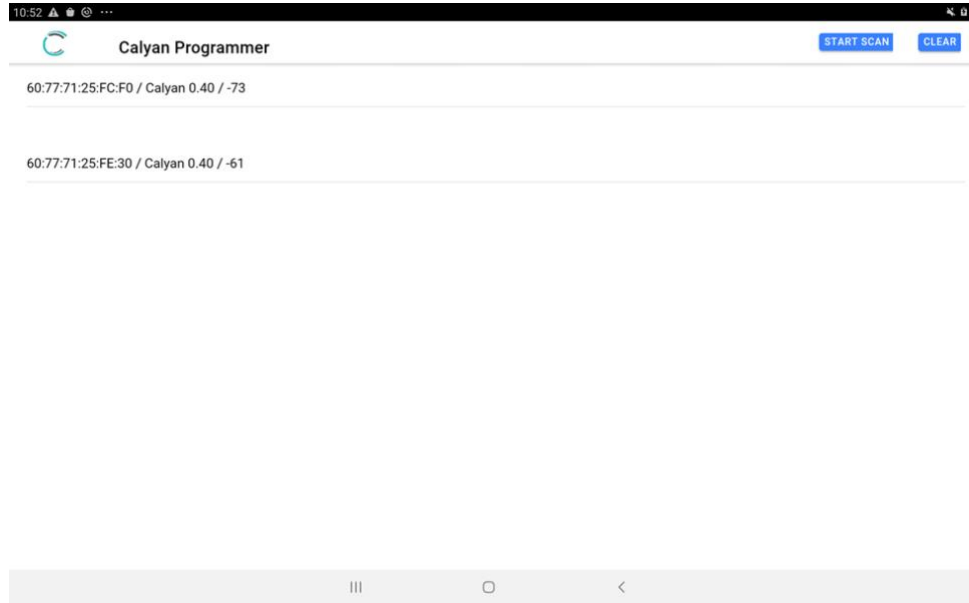


Figure 37: Multiple Device discovery

12 Appendix

12.1 Device Advertisement Details

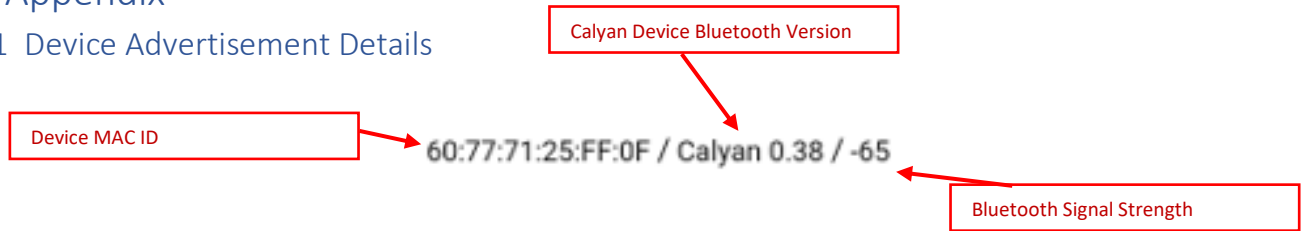


Figure 25: Device advertisement

Field	Description
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Calyan X.XX	Displays the Bluetooth version of the Device where X.XX will be replaced with the actual version numbers.
Device MAC ID	Displays the unique MAC Id of a Device.
Bluetooth Signal Strength	Displays the Bluetooth signal strength in dBm.

Table 2: Device Advertisement

12.2 Emergency Pacing Parameters

Emergency Mode can be initiated by swiping the Device with a magnet or by initiating Emergency Mode from the Programmer. The Device parameters are as below when in Emergency Mode and are non-configurable.

Parameter Description	Value
Pacing Mode	5
Pacing Rate	70bpm
Pacing Amplitude	5V
Pacing Pulse Width	1 mSec
Refractory Period	300mSec
Blanking	0mSec
Sensitivity	0mV
Polarity	0

Table 3: Emergency Pacing Parameters

12.3 Device Programming Parameters

Parameter	Description
Selectable Device Mode(s)*	000 , OVO, VOO, VVI, VVIR, Emergency
Pacing Rate	30bpm , 35 bpm, 40bpm, ..., 60bpm, ..., 70bpm , ..., 150bpm
Pacing Amplitude	0V , 0.12V, 0.25V, ..., 5V, ..., 12V
Pacing Pulse Width	0.1mSec , 0.15mSec, 0.24mSec, 0.4mSec, 0.5mSec, 0.75mSec, 1.0mSec, 1.15mSec, 1.24mSec, 1.4mSec, 1.5mSec
Refractory Period	0mSec , 25mSec, 50mSec, ..., 300 mSec, 325 mSec, 350 mSec
Blanking	0 mSec , 10 mSec, 20 mSec, ..., 130mSec, 140mSec, 150 mSec
Sensitivity	0.45mV , 0.6mV, 0.9mV, 1.5 mV, 2.0 mV, 2.8 mV, 4.0 mV, 5.6 mV, 8.0 mV, 11.3mV
Polarity	0, 1

Table 4: Device Programming Parameters

*An additional Storage mode is available; however, it is not a programmable Device mode.

Note: The default values are highlighted in Bold.



12.4 Rate Response Parameters

Parameter	Description
Activity Threshold (Acceleration)	150 milli-g, ..., 317 milli-g , ..., 500 milli-g
Activity Pacing Rate (Upper Limit)	65 bpm, 70bpm, ..., 120 bpm , ..., 150 bpm

Table 5: Rate Response Parameters

Note: The default values are highlighted in Bold.

12.5 Stored Data

Parameter	Description
Lead Impedance Trend Value	Lead Impedance measured over days and weeks
R wave Trend Value	R Wave Amplitude measured over days and weeks
Paced and Sensed Histogram	Pacing and sensing rate measured from the time of last programming.
Ventricular Markers.	Ventricular markers measured from the time of last programming as percentages.

Table 6: Stored Data

12.6 Version Data

Parameter	Description
BLE	Bluetooth Version
MP	Main Processor Version
PE	Pacing Engine Version
Prog	Programmer Application Version

Table 7: Version Data

12.7 Patient information

Field	Description
Model No.	Calyan VVIR pacemaker model number is "P100"
Serial No.	6-digit Serial Number of the Device XXXXXX
Patient Initials (FML)	Patient Initials (First name middle name last name) can take 3-character input.
Patient DOB(YMMDD)	Patient Date of Birth
Implant Date (YMMDD)	Date of implant

Table 8: Patient Information



12.8 Error Codes

12.8.1 Main Processor Status

Error Condition	Description
Emergency Mode Active	This flag is present when pacing is forced to emergency levels. It will be active when a magnet is present but can also be triggered due to other error flags.
Watchdog Reset	The main processor was forced to reset due to an error which prevented it from a normal operating sequence.
BT Comm Fault	Bluetooth communications suffered an error forcing the connection to reset.
Pacing Parameter Corruption	An error was detected in the pacing parameters. New parameters should be written.
Low Battery	The remaining energy in the pacemaker battery is low. After 30 days of consistent Low Battery status, the Device will automatically enter "END OF SERVICE".
Pacing Engine Activity Error	The pacing engine has ceased its indications of normal activity. (This may occur during firmware updates.)
Pacing Engine Communications Error	An internal communications error occurred preventing normal communications. This error will clear once normal communications resume.
Accelerometer Fault	The pacemaker is in VVIR mode, and the internal accelerometer feature failed to respond as expected. This will clear once normal communications resume.
End of Service Activated	The pacemaker has reached "END OF SERVICE". The ability for this Device to provide therapy is permanently disabled.
Pacing Parameter Corruption Corrected	An inconsistency was found within the programmed pacing parameters. The data was properly repaired.
POST Failure	The Device has failed its internal diagnostics. This failure will cause Device reset and is thusly logged in the historical flags only.
Non-Pacing Parameter Corruption	A corruption was detected in non-pacing parameters, such as patient info or manufacturing statistics.
EEPROM Memory Error	The pacemaker has encountered an error storing or retrieving memory from EEPROM.

Table 9: Error Codes- Main Processor Status

12.8.2 Main Processor Reset Reason

Reset Reason	Description
Unknown/Not Set	No reset has occurred, or the reason has not been populated
Power	The battery was previously detached, or shorted.



Brownout	Battery voltage dropped below an operable level.
Software	A reset was forced by software. This will occur in the case of a critical error, or during Device firmware update.
LPM Exit	The pacemaker was previously in low power (storage) mode.
Watchdog	A POST failure, or unexpected watchdog timeout occurred.
Password Violation	(Mfg use) An invalid attempt to access internal Device memory using the JTAG interface
Security Violation	(Mfg use) Attempt to write a secured internal vector
Uncorrectable Memory Error	An internal program memory error forced a reset.
Peripheral Error	An internal feature or function encountered a critical error.
MPU Error	The memory protection unit encountered a critical error.

Table 10: Error Code - Main Processor Reset Reason

12.8.3 Pacing Engine Status

Error Condition	Description
Emergency Mode Active	This flag is present when pacing is forced to emergency levels. It will be active when a magnet is present but can also be triggered due to other error flags.
Pacing Engine Reset Occurred	The pacing engine was reset. This can occur when exiting storage mode.
Watchdog Reset	The pacing engine was forced to reset due to an error which prevented it from a normal operating sequence.
Memory Repair Occurred	A successful repair occurred on an inconsistent internal parameter set.
Pacing Inhibit Ignored	Pacing therapy is being forced due to internal communications errors.
Digipot Error Occurred	An error occurred in communicating with the internal digipot Device.
Non-Volatile Parameter Corruption Detected	Programmed parameters have become corrupted.

Table 11: Error Code - Pacing Engine Status

12.8.4 Pacing Engine Restart Reason

Reset Reason	Description
PowerOn	Device was previously in storage mode.
Stack Overflow	An internal stack overflow fault caused a reset.
Stack Underflow	An internal stack underflow fault caused a reset.
Software Reset	The Device was forced to reset due to an error condition.
Watchdog Reset	A POST failure, or unexpected watchdog timeout occurred.
External Reset	The reset pin of the pacing engine was pulled low.



Brownout	Battery voltage dropped below an operable level.
Unknown Reset Cause	Reset reason was not populated.

Table 12: Error Code - Pacing Engine Restart Reason

12.8.5 Bluetooth Status

Error Condition	Description
Magnet Detected	The magnetic detection circuit indicates a magnet is present.
Watchdog Reset	A POST failure, or unexpected watchdog timeout occurred.
Main Processor Timeout	Main processor did not respond to Bluetooth communication.
Pacing Engine Non-Critical Parameters Corrupted.	The Non-Critical parameters in the pacing engine were not set or retried correctly and the data is corrupt.

Table 13: Error Code - Bluetooth Status

12.9 Menu bar

Fields	Description
Mode	The connection mode selected in the application. Implant Mode, Follow up Mode
Remaining Battery Status	The Battery indicator shows the percentage of battery life remaining.
Device Bluetooth Name	Defined as Calyan X.XX were X.XX is the Bluetooth firmware version
Mac ID	This is the unique ID of the Device that is connected to the programmer
Connection Status	CONNECTED, DISCONNECTED
RSSI Value (Bluetooth Signal Strength)	The Bluetooth Signal Strength value displayed in dBm.

Table 14: Menu Bar

13 Contact Information

Calyan employs highly trained representatives and engineers to serve you and, upon request, to provide training to investigational sites personnel in the use of Calyan products. In addition, Calyan maintains a professional staff of consultants to provide technical consultation to product users. For more information, contact your local Calyan representative at the address below:

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