Barostim

Outsmart the heart

IPG Model 2102 and 2104
Programming System
      Model 9010 and 9020

Programming
Guide

ABOUT THIS DOCUMENT

This document is a portion of the Instructions for Use (IFU) for the Barostim™ System. The full IFU consists of:

System Overview	900133-001
Surgical Procedures	900133-002
Programming	900133-003
Magnetic Resonance Imaging (MRI)	900133-004
Patient Instructions	900133-005

IFU documents are available at www.cvrx.com/ifu.

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System
Set Up

HOW SUPPLIED

Figure 1 9010 (left) and 9020 (right) Programmer System.

The Programmer System is supplied as either Model 9010 or Model 9020. Both are compatible with the Model 2100, 2102, and 2014 IPGs.

To simplify the display of information throughout this document, where the information is similar to all applicable models, photos of the model 9020 using the NEO2 device are shown. Where clarification of the differences is required, additional images are provided.

INTENDED USER

The programmer user is the physician, clinical staff or CVRx® support personnel trained in the operation of the programmer. All programmed final settings are under the authority and responsibility of the treating clinical staff.

SYSTEM INSTALLATION AND MAINTENANCE

There are no Installation, Commissioning or Modifications required for the proper use of the Programmer System. No installation measurements are required. Regular maintenance is also not required.

CLEANING THE PROGRAMMER SYSTEM

If the Programmer System requires cleaning, clean the system components with a soft cloth dampened with water. Do not allow pooling or ingress of liquid into the Programmer Interface enclosure.

NAVIGATING

Use the pointing device for the 9010 or your finger on the touchscreen for the 9020 to navigate the Programmer Software. In this document, the word "click" indicates depressing the left pointing device button for the 9010 or pressing the touchscreen for the 9020 to perform the required action.

PROGRAMMER SYSTEM SET UP

- Inspect the Programmer Interface, computer/tablet and cables prior to each use. Notify CVRx or your CVRx representative of any items that need replacement.
- If the programmer computer/tablet has been stored for an extended period without being charged, it is recommended to connect the recharging cable prior to turning on the computer/tablet.

Note: Avoid letting the battery discharge below 20%.

- Insert the USB I/O cable connector into the USB I/O port on the Programmer Interface by pushing the connector into the port. Make sure the connection is secure.

9020   9010

Figure 2 9020 USB C connection and 9010 USB connection

- Insert the other end of the USB I/O cable into a USB port on the computer/tablet. Make sure the connection is secure.

9020   9010

Figure 3 9020 USB C connection to Tablet and 9010 USB connection to Computer

- Turn on the computer / tablet by pushing its "power" button. located on side of tablet as shown.


- Check the tablet's battery capacity. Charge if the device has not been charged in the previous 6 months, or the capacity is less than 20%.
- Confirm that Programmer Interface is connected correctly by checking to see if the green light on the 9010 Programmer Interface is lit. On the 9020 Programmer Interface, the additional blue light indicates the interface is communicating properly on the USB-C interface. If the lights are not lighting properly, check the cable connection.

- Place the Programmer Interface in its upright position with no obstructions between the Programmer Interface and the IPG. Telemetry performance is best when the Programmer Interface front or back side label is facing the IPG and is a distance of 2 meters or less from the IPG.

USER LOGIN

After powering up the programmer you will be requested to login. Click the CVRxUser and enter the password provided by your CVRx representative.

STARTING THE APPLICATION
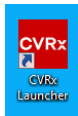
Select the **CVRx** icon labeled **CVRx Launcher** to start the software application.

DEVICE DISCOVERY

9020 Discovery Screen Shown

When the Device Discovery window appears, verify that the system time, date, and time zone on the programmer is correct. If not, click the **Set...** button to correct the time.

On the 9020 Discovery screen, select "Session Summary Patient ID" check box if you want the patient ID included on the session summary report. Note: For privacy reasons, the patient name does not appear on saved reports.

The Discovery status should indicate **In progress…** While Discovery is in progress, all CVRx devices in the area will be displayed in the list of IPGs discovered.

To establish communication, first select the device by clicking on the row containing the desired patient identification and serial number information. This will highlight the row.

Note: Devices that have no Patient Name and no Patient ID are new devices not yet implanted.

Ensure that the patient identification and serial number of the selected IPG matches that of the device implanted (or being implanted) in the patient being treated. Click on the **Connect** button to start communication.

While the programmer establishes connection with the IPG, the screen will display the IPG Serial Number, Patient Name and Patient ID, verify this is the correct patient. Once the connection has been made, the application will then display the Main Screen.

An automated adjustment of the IPG time takes place at the beginning of a session. The software sets the time of the IPG equal to the computer/tablet time, accounting for Daylight Saving Time, if necessary.

9020 Only: In the Device Discovery Window you may set the option for the programmer to display the Patient ID on the Session Summary Report generated by that programmer. Note – the Patient ID should not include private patient information.

2
Programmer
Screens

STATUS WINDOW
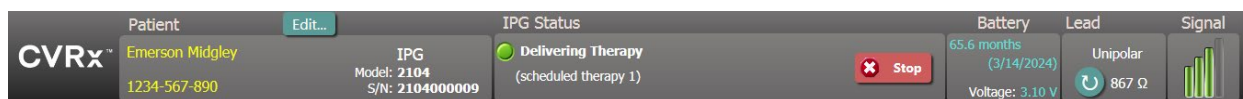
The Status window is always at the top of the screen and provides several pieces of information related to the current status of the IPG and communication link.

- Patient Identification: The software displays the patient identification along with IPG model and serial numbers in the Patient Identification window.
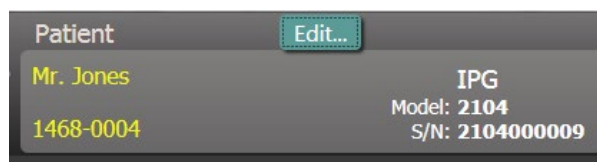
  The patient identification information can be changed by clicking on the **Edit…** button. Both Patient Name and Patient ID can be stored. Patient ID should not include private patient information. Note: For privacy reasons, the patient name does not appear on saved reports.

- IPG Status: The IPG Status is a real-time display that shows information about therapy being delivered by the IPG. **No Therapy** indicates that no therapy is being delivered.

Stop: While therapy is active, the **Stop** button is available. This allows the user to quickly and permanently stop all scheduled therapies.

Resume: While therapy is stopped, the **Resume** button is available. This allows the user to resume all scheduled therapies.
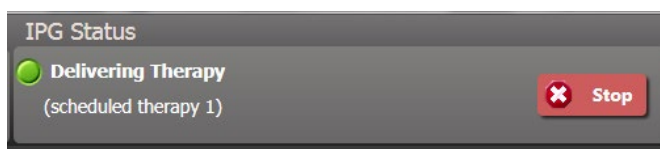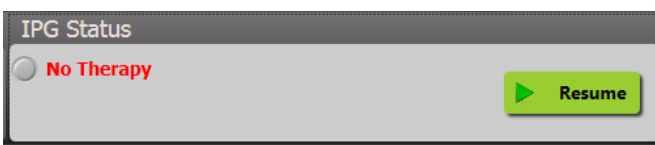

- Battery Life: The software displays an estimate of the expected life remaining of the IPG battery, the date of the **Recommended Replacement Time (RRT),** and the current battery voltage. The battery life estimation is based on the currently programmed permanent therapy and schedule settings. The device should be scheduled for replacement on or before the RRT to prevent loss of therapy. If the RRT

  date has already passed, the Battery status box turns yellow and indicates **RRT Alert**. If the device has reached EOS (End of Service), the status box turns red and indicates EOS; therapy is no longer being delivered and device should be replaced.

Note: The battery voltage displayed may decrease during a communication session due to the power requirements of telemetry as well as impacts of aggressive parameter settings used during testing of therapy efficacy.

Note: The Initial Battery Voltage is reported on the Session Summary Report. This is the voltage measured at the beginning of the session and is representative of the battery health coming into the programming session.

- Lead Impedance: The impedance of the lead is displayed in the Lead portion of Status. Make an immediate lead impedance measurement by clicking on the ↻ symbol. The lead impedance value provides a measure of lead integrity and can indicate whether therapy delivery is functioning properly (Model 2104 display shown)
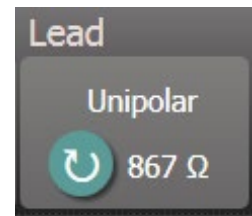
- Telemetry Link: The quality of the telemetry link between the Programmer Interface and the IPG is provided by the Link Quality Indicator on the Signal portion of Status.

- To get a good telemetry signal, ensure that the Programmer Interface is placed in its upright position with no obstructions between the Programmer Interface and the IPG. Telemetry performance is best when the Programmer Interface front or back side label is facing the IPG and is 2 meters or less from the IPG.
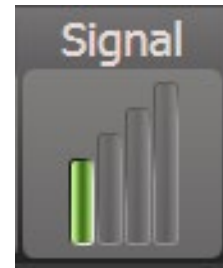
- Check the quality of the telemetry link between the Programmer Interface and the IPG by looking at the Link Quality Indicator as shown below. Two or more green bars are recommended to ensure that parameter updates occur in the IPG when requested. If the Link Quality Indicator is poor or inconsistent, reposition the Programmer Interface to improve the quality of the telemetry link.
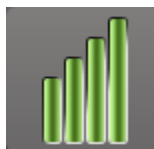
Link Quality Indicator (Excellent, Poor, No Link)

- The Programmer Interface has the option to be hung from an IV pole using the provided hook. This configuration may improve the quality of the telemetry link in situations where the link is difficult to maintain.

- If the communication link is lost while in a programming session, the IPG will revert to the previously permanently programmed therapy settings and the IPG status Window will indicate "no link" with grey background. The system will automatically re-connect to the device as soon as it is back in range of the communication. Once the device re-connects, you may continue programming.

-

MAIN SCREEN 9020
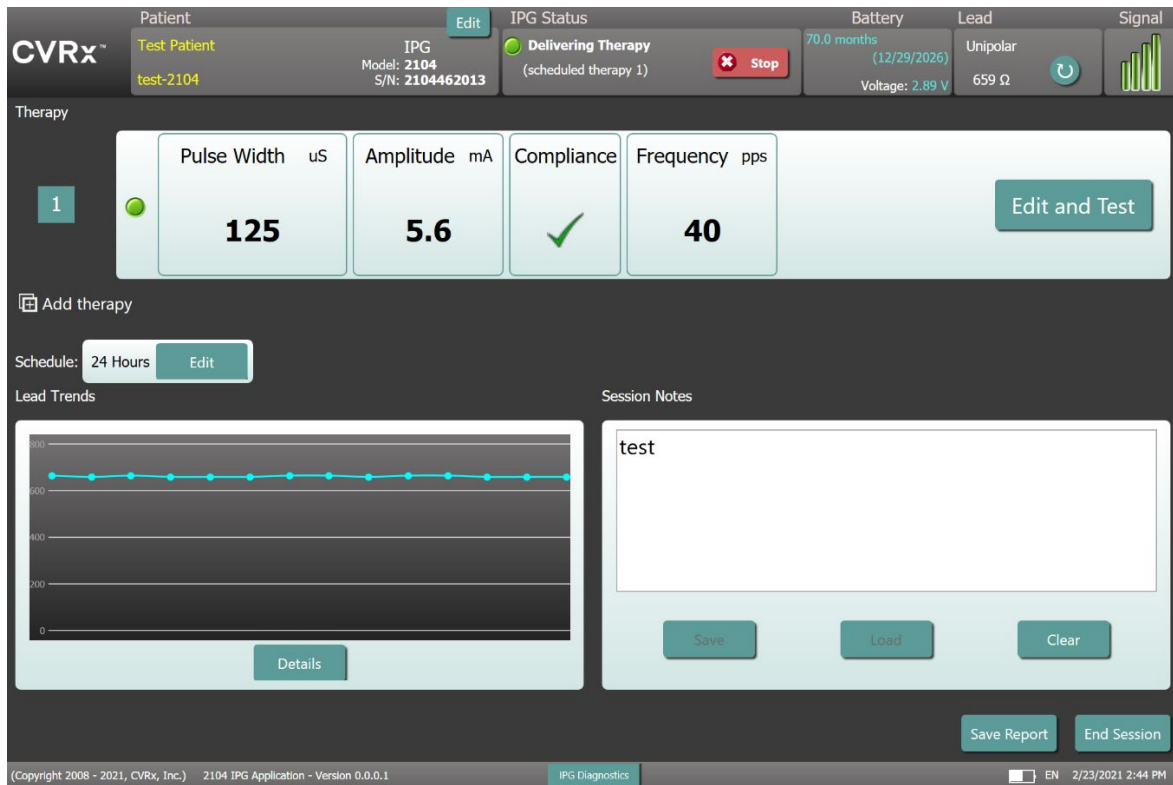
Model 2104 shown

MAIN SCREEN 9010
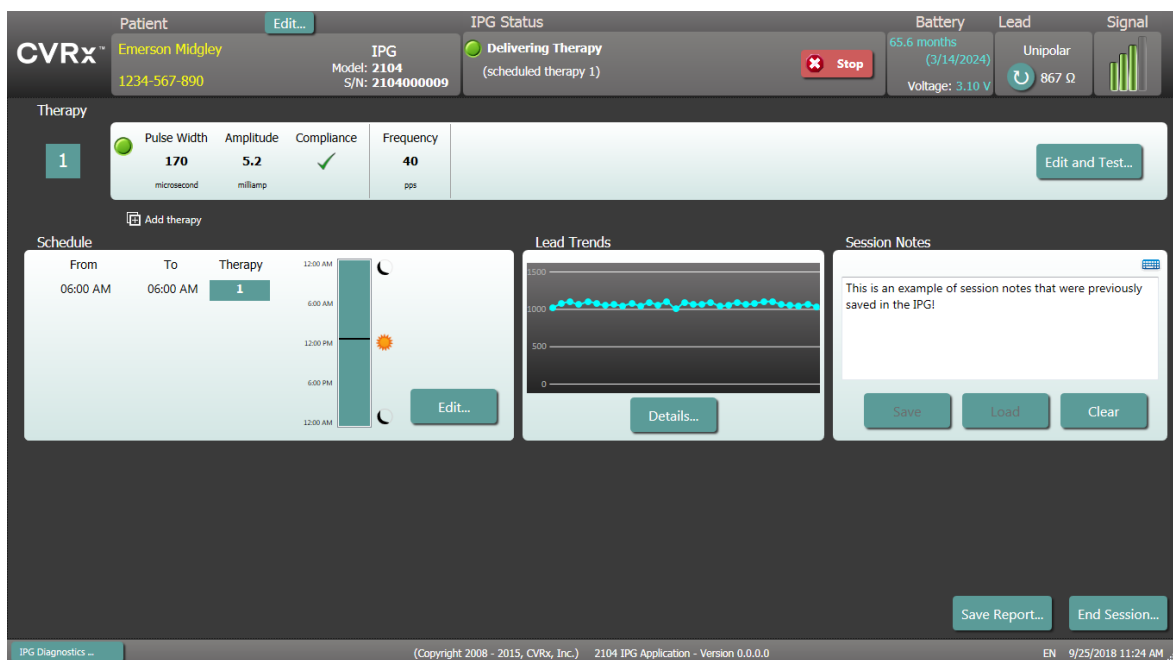
Model 2104 shown

Therapy Status Window(s)
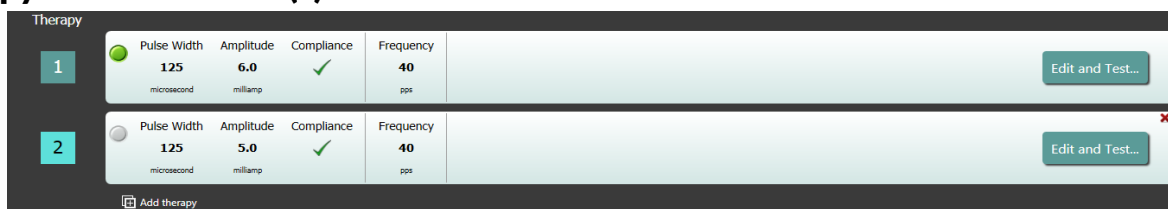
In some cases, a patient may require more, or less, therapy during a specific portion of the day than at other times. The system has up to three independently programmable therapies (Therapies 1, 2, 3). Each therapy has its own status window. Each Therapy status window contains a therapy status indicator, the therapy settings, and an **Edit and Test...** button. Therapy settings can be changed by clicking the **Edit and Test...** button. A new therapy can be added by clicking the **Add Therapy** button below the Therapy Status Window(s).

Schedule

The schedule status is displayed differently depending on the programmer model.

- For the 9010 programmer applications, the schedule is displayed on the home screen as shown in the "Schedule Window" below.

- For the 9020 Programmer applications the detail of the Schedule window is accessible by pressing Edit next to the Schedule:

  - If the therapy is programmed as one therapy scheduled all day, the schedule shows "24 hours".
  - If the therapy has a schedule other than one therapy scheduled all day, the schedule shows "Custom".
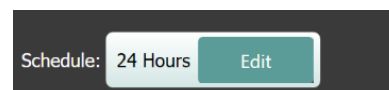
Schedule Window

The Schedule controls the portion of each day during which therapy is delivered. The Schedule is a 24-hour clock that is started at midnight each day. The current Schedule settings are displayed in the Schedule window. The Schedule contains a list of entries. Each entry is defined by a time period

and the Therapy assigned to it. Only Therapies in the list of Therapy Status Windows can be added to the Schedule. To add a therapy to the schedule, click on the **Edit...** button in the Schedule Window. Click on the **Add Time Period** button, then select the therapy and adjust the time of day when the therapy will be delivered. **Off** should be selected if periods of no therapy are desired. To remove a schedule entry, click the ✕ button. Click **Save** to program Schedule changes or **Cancel** to ignore changes.
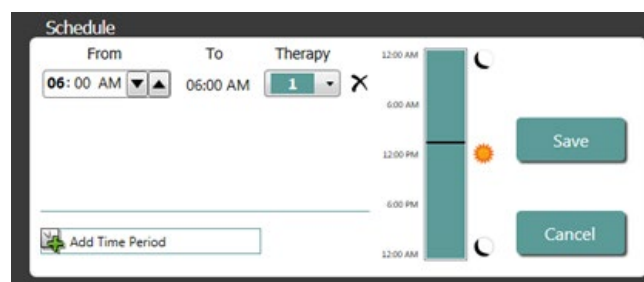
Lead Trends Window

Model 9020 programmer includes display of Lead Trends. The Lead Trends window displays the recent history of the available lead impedance measurements recorded in the IPG. To review the impedance trend, click **Details**.
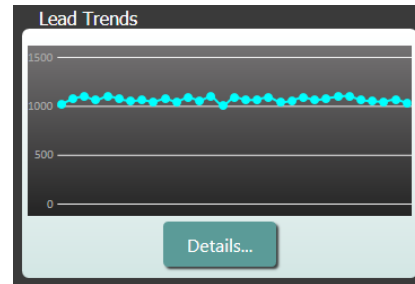
Session Notes Window

Enter any notes to be included in the Session Summary Report. For Model 2104 only, the text in this window may also be saved in the IPG to be available during the next programming session.

- To save the content of the Session notes to the IPG, verify the desired information is in the Session Notes text box and click **Save**. If the Save button is not available and there is a telemetry link, the content matches what is currently saved in the IPG.

- To clear the contents of the Session Notes, click **Clear**. As this changes the contents of the window, the user will be asked to confirm this operation.

- **Note** this does not remove the contents stored in the IPG, it only clears the contents on the screen and what will be reported on the Session Summary Report. To permanently erase what is stored in the IPG, click **Clear** and then **Save**.

- To load the Session Notes with information that was previously saved in the IPG, click the **Load** button. As this will change the contents of the notes window, the user will be asked to confirm this operation. If the Load button is not available and there is a telemetry link, the content matches what is currently saved in the IPG.

- To record Session Notes information on the Session Summary Report only – type the notes and click **Save Report** without clicking **Save** in the Session Notes window.
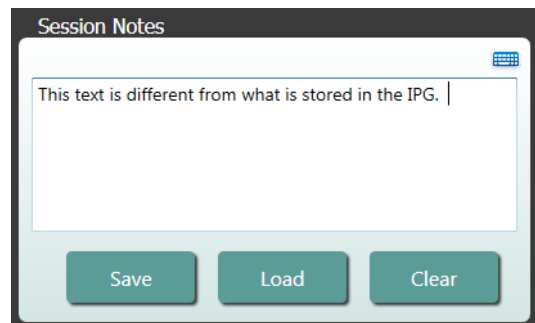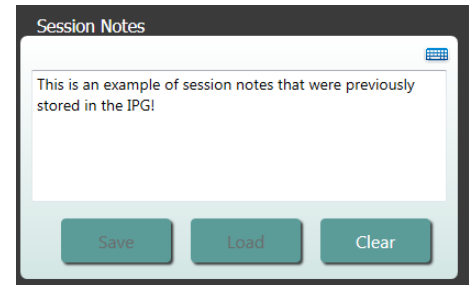
Save Report

The Session Summary Report, which contains the final therapy parameters and all pertinent session information, can be generated by clicking the **Save Report...** button. Note where the

file is saved so you can retrieve the file when needed. When saved, the file location is displayed on the screen to allow the user to open the file and review/verify the contents of the report.

The 9020 tablet is equipped with a Micro SD card to save reports to a portable memory device. The Micro SD slot is located under the Tablet Kick Stand as shown.

- o To insert SD / memory card: With the gold contacts facing down, insert the memory card into the opening as shown and press the card into the slot until it locks in place.

- o To remove SD / memory card: Press the memory card into the slot to unlock it then slide the card out with your fingers.

End Session

By clicking **End Session...** the software disconnects communication from the implanted device and returns to the Device Discovery window. Read any warnings or confirmations carefully and respond prior to dismissing the patient. For a list of some of these confirmations see the Troubleshooting section of this document.

LEAD TRENDS SCREEN

The Lead Impedance trend screen displays the history of the daily lead impedance stored in the IPG. The last 30 days are displayed in the Lead Trends summary screen and in the initial view of the details screen.

Note: Some early models of IPGs do not support this feature.
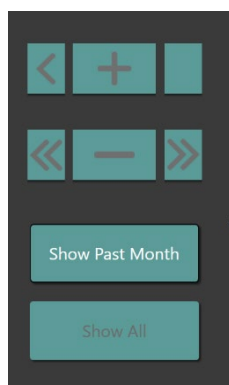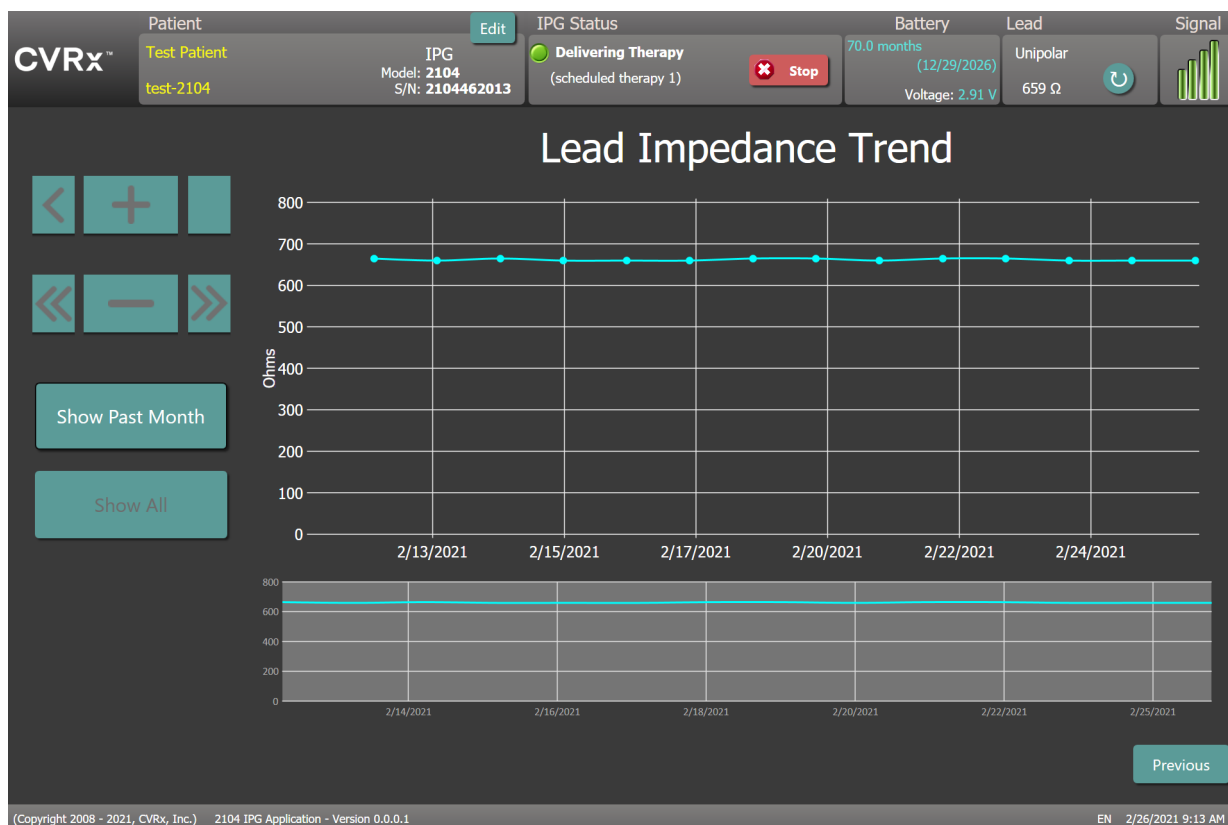
Use the navigation buttons to adjust what is visible in the data display.

Click Previous to return to the main screen.

EDIT AND TEST SCREEN

The **Edit and Test** Screen is used to adjust therapy settings and record therapy effectiveness.

Therapy Settings

Therapies have independent control of the parameters in the table below. For devices with therapy programmed on only one lead, Therapy Control includes two different programming controls views (⌂ and ✿). The availability of different parameters in the different programming controls is indicated. Models with therapy programmed on more than one lead display includes only the ✿ view.

Parameter	Description	Range of Values	⌂	✿
Amplitude	Determines the amplitude of the applied pulses.	1.0 milliamps to 20.0 milliamps	X	X
Pulse Width	Determines the width of the applied pulse. Can be configured individually for the left and right pathways.	15 microseconds to 500 microseconds		X
Therapy Frequency	Determines the frequency of applied pulses except during the Rest portion of the Burst Interval.	10 to 100 pulses per second		X
Burst	Determines whether therapy pulses are applied throughout the burst cycle in a continuous manner or if a cycle of active and rest periods is being used.	Not Checked / Checked		X
Burst Duration	Determines the length of the active portion of the burst cycle during which the Therapy Frequency is delivered. **NOTE:** This parameter is not shown if Burst is Not Checked.	50 milliseconds to 1950 milliseconds		X
Burst Interval	Determines the total length of the burst cycle including the active portion and the rest portion. **NOTE:** This parameter is not shown if Burst is Not Checked.	100 milliseconds to 2000 milliseconds		X

There are two ways to view the therapy settings.

This view contains the primary method of programming adjustments, the Therapy Amplitude (mA) (For devices with therapy programmed on only one lead)

Therapy 1 Adjust pulse parameters and select "Test Now"

Amplitude

6.0

milliamps

Test Now   Stop
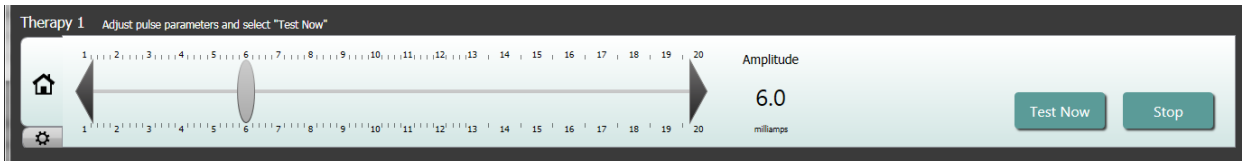
- Adjust the Amplitude by moving the slider left or right. The slider can be moved by clicking on the arrows on either end of the slider, clicking on either side of the indicator, grabbing the slider and moving with the pointing device, or by clicking once anywhere on the slider and using any of the arrow keys.

This view contains all detailed parameters of the therapy settings including access to Pulse Width, Frequency and Burst settings.

One therapy pathway programmed

Therapy 1 Adjust pulse parameters and select "Test Now"

Pulse Width	Amplitude	Frequency	☐ Burst
125 ▼▲	6.0 ▼▲	40 ▼▲	
microseconds	milliamps	pps	Test Now Stop

Devices with two therapy pathways programmed

Therapy 1 Adjust pulse parameters and select "Test Now"

	Pulse Width	Amplitude	Frequency	☐ Burst	Test Now
Left ☑	▼ 280 ▲	▼ 6 ▲	▼ 40 ▲		
Right ☑	▼ 280 ▲	▼ 6 ▲	pps	Edit Burst	Stop
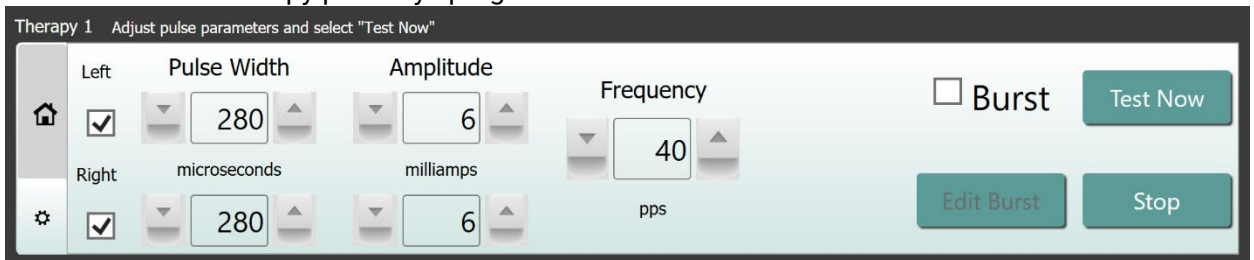
- Click the **Test Now** button to start delivery of the desired settings.
- Click **Stop Test** to stop therapy, allowing observation of the patient response without therapy.

Therapy 1 Adjust pulse parameters and select "Test Now"

Pulse Width	Amplitude	Freque
65 ▼▲	1.8 ▼▲	40 ▼
microseconds	milliamps	pps
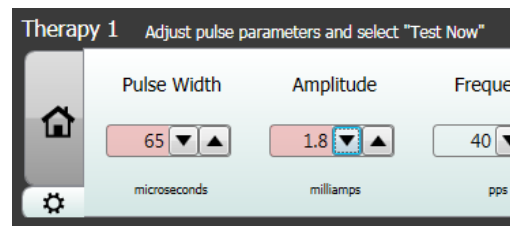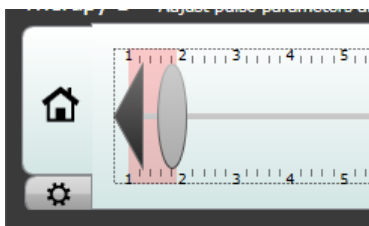
Note: When the settings in the window change to a red background or the slider enters a portion of the Amplitude range that has a red background (indicating that the current parameter combinations are not allowed) the settings cannot be tested.

Patient Response Log

Patient Response Log												
Pulse Width	Amplitude	Compliance		Frequency	Burst		Battery	Elapsed Time				
---	---	---		---			- month(s)	00:00				Record

Time	Width	Ampl.	Compl.	Imp.	Freq.	Dur/Int	Battery	Elapsed	Sys	Dias	HR	Notes	Edit
2:45:41 PM	235	4.8	---	590	40	100/200						Copy of Therapy 1	✎
2:45:47 PM	250	6.0	✓	590	40	N/A	48.6	00:04					✎
2:45:47 PM	250	6.0	✓	590	40	N/A	48.6	00:04					✎
2:45:47 PM	250	6.0	✓	590	40	N/A	48.6	00:05					✎

The Patient Response Log window records the sequence of therapy testing performed in the programming session. Each line of the log contains pertinent information for each test:

- Estimation of the battery life utilizing the parameters being tested. This estimate does not take the Therapy Schedule into account. Instead, therapies under test always assume a 24-hour schedule. This allows comparison of the current therapy settings to other therapy settings that have been tested. However, these estimates should not be compared to the Battery Life estimate in the IPG Status section at the top of the screen. The Battery Life estimate in IPG Status always represents the longevity of the currently programmed permanent therapy and schedule settings.

- Compliance status of each therapy. Compliance is measured when therapies are tested on the **Edit and Test...** screen. The Compliance indication can be one of the following:

  "---" No Compliance measurement has been taken

  "✓" IPG is able to deliver programmed amplitude

  "✗" IPG is not able to deliver programmed amplitude

Compliance is a measure of the ability of the IPG to deliver the programmed output amplitude. The IPG delivers output pulses that maintain a constant electrical current during the duration of each pulse. There are situations in which the device cannot maintain this constant current. When this occurs, the device will not deliver the programmed amplitude throughout the duration of the pulse and Compliance will fail. Settings that are out of Compliance cannot be saved in the IPG.

NOTE: All therapies in the schedule must be evaluated for Compliance at each follow-up so that the proper settings are sent to the IPG. This should be performed even if the therapy settings are not being changed. The currently active therapy is automatically updated for compliance during initial interrogation.

- Duration / Interval (Dur/Int) refers to the burst settings. Duration is the length of time of the active portion of the burst cycle during which the Therapy Frequency is delivered. Interval is the total length of the burst cycle including the active and rest portion.

- Clicking the **Record** button adds an entry to the Patient Response Log. If Compliance has passed, the recorded entry is selected (row is highlighted). Any entry can be selected by clicking somewhere on the desired entry in the log.

- Measured results for BP and Heart Rate, as well as any observational notes that are related to the therapy settings, can be entered by clicking on the box of interest and entering the information. (Note that the on-screen keyboard can be used to aid data entry.)

- To edit or delete an entry in the Patient Response log – select the pencil or X icon by toggling the "Edit" button. The selected entry can be removed by clicking the ✕

  button or edited by clicking the ✎ button. All edits and deletions are permanent.

4:26:14 PM	125	6.4	✓	805	40	N/A	67.1	14:45					✕
4:26:51 PM	125	6.8	✓	841	40	N/A	60.4	00:38					✕
4:28:29 PM	125	7.0	✓	712	40	N/A	64.1	01:11					✕

| Use Selected Log Entry for Test | | Save Selected Log Entry as Therapy 1 | Exit without Saving |

DEMO (Copyright 2008 - 2018, CVRx, Inc.)   CVRx2104TrainingProgrammer – Version 1.5.6.0 DEMO   8/7/2018 4:29 PM

- Click the **Use Selected Log Entry for Test** button to load the settings of the selected Patient Response Log entry into the **Therapy N** (N=1,2,3) window. This provides convenient access to prior settings if more testing is desired. To use these parameters, click Test Now.

- There are two options to return to the Main Screen.
  - Select the permanent therapy settings by choosing a Patient Log Entry that contains the desired settings and also indicates that Compliance has passed. Then press the **Save Selected Log Entry as Therapy N** (N=1,2,3) button.
  - If no permanent changes are to be made, choose **Exit without Saving**.

3
IPG
Programming

Goal

To achieve maximum efficacy of Barostim by maximizing the dose, while maintaining patient comfort and safety.

Dose

Is limited by extraneous stimulation, undesired symptoms (e.g., sensations, jaw or neck pain, difficulty speaking or swallowing), and stimulation capabilities of the device (i.e., failed compliance).

Settings

For most patients, modification of the Pulse Amplitude (in milliamperes) is all that is needed. In some circumstances, adjustment of Pulse Width (microseconds) or Pulse Frequency (pulses per second) may be required.

Approach

Dose is maximized by maximizing pulse amplitude at nominal pulse width and frequency settings. The dose may need to be titrated over time to achieve the goal.

Barostim dose and the threshold for extraneous sensations follow typical strength-duration curves.
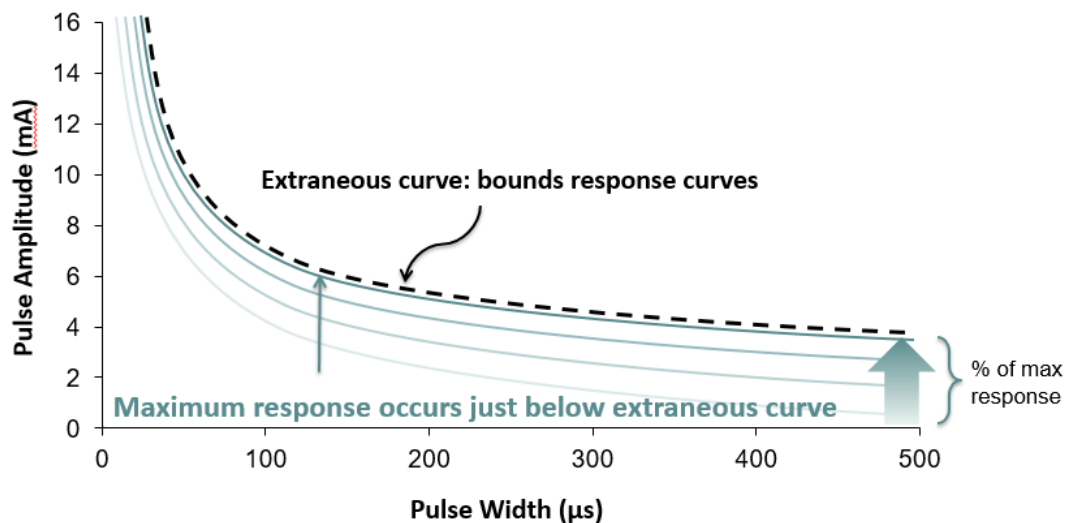
PERFORMING PROGRAMMING

Prior to Programming

- Ensure that the patient is prepared for the session
  - Ensure patient has achieved a steady hemodynamic state
  - Obtain baseline values of appropriate hemodynamic parameters (e.g., Blood Pressure and Heart Rate)

During Programming

- Take response measurements to ensure patient safety and understand therapeutic doses:
  - Record response measurements (e.g., Blood Pressure or Heart Rate) at set points within the programming algorithm
  - Record response measurements taken at set points on the Programmer Session Log on the Edit and Test screen
- When increasing parameters:
  - Use multiple, successive small increments
  - Wait only long enough at each setting to look for extraneous sensations and device compliance
- Add comments to the Programmer Session Log on the Edit and Test screen, especially when extraneous sensations are reported, so that these comments can be saved in the Programmer Session Report. If desired include this information in Session Notes and Save to the IPG for future reference.

PROGRAMMING APPROACH

The goal when programming Barostim Therapy is to identify the pulse amplitude just below the threshold for extraneous sensations at a nominal pulse width and pulse frequency.

Step 1: Identify Maximum Pulse Amplitude (i.e., dose)

- Start with a pulse amplitude of 2 mA
- Increase pulse amplitude in two steps until one of the following conditions is met:
  - Symptoms are encountered
    - Decrease pulse amplitude in two steps until symptoms resolve
  - Compliance fails
    - Decrease pulse amplitude in two steps until compliance is re-established
- If 2 mA causes symptoms, consider a reduction in pulse width (from 125uS to 65uS) combined with an increase in Pulse Amplitude.

  This setting is only available in the ⚙ screen.

Step 2: Therapy Titration

Barostim can be up-titrated in a similar fashion as other medications/therapy. Pulse Amplitude should not be more than 50% of the maximum tolerated dosage during the first two weeks after implantation. Plan programming visits in approximately 2-3 weeks, 1-2 months, 3 months and 6 months after initial implant to allow for optimization of Barostim.

## Step 3: Finalizing Programming

- Ensure optimal programming values are programmed for chronic use and that therapy is scheduled

- Obtain final values of relevant hemodynamic parameters such as blood pressure and heart rate
- Save Programmer Session Summary Report

# FOLLOWING-UP BAROSTIM THERAPY

Evaluate Lead Impedance

Review the lead impedance displayed in the upper right corner and in the **Lead Trends** window. The recent history of the Lead Trends is displayed in the Lead Trends window. To review more of the lead trend history, click the Lead Trends **Details…** selection.
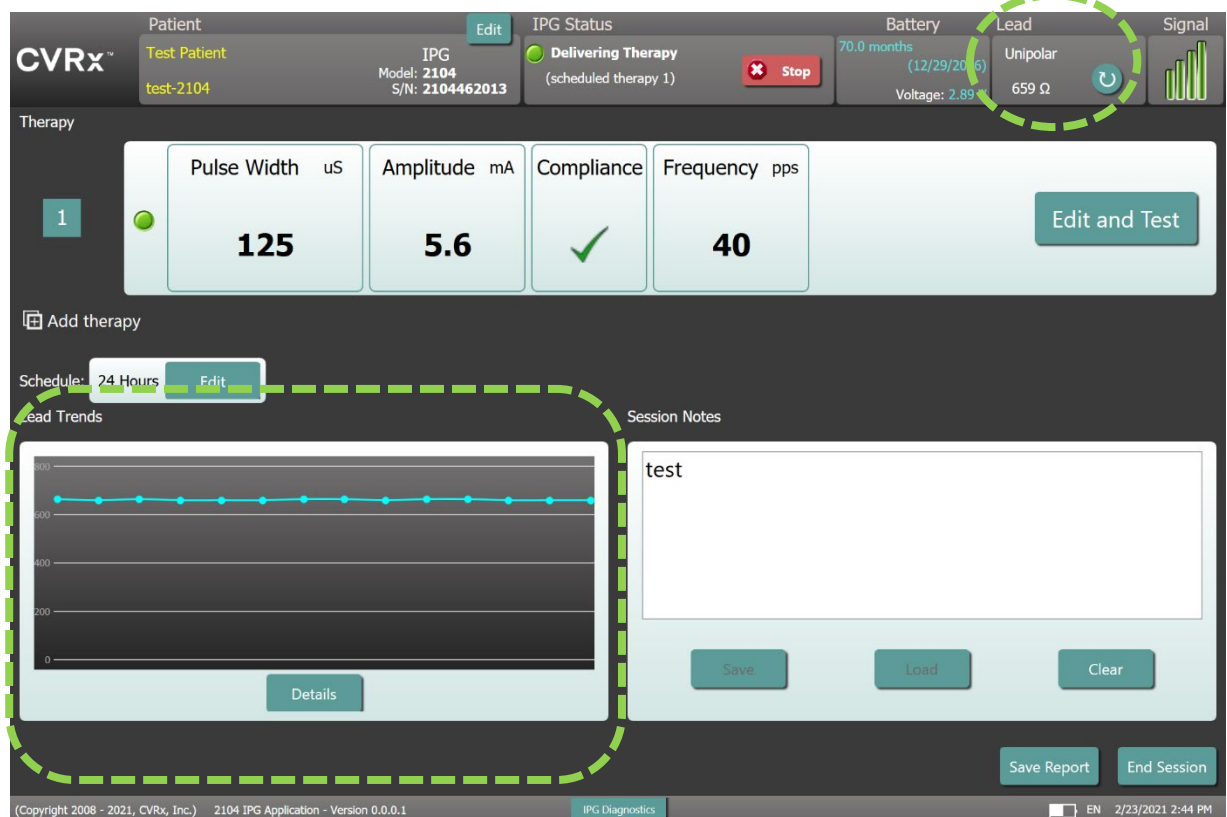

Precaution: If any of these 3 situations are observed, a CVRx representative should be contacted immediately.

- Low lead impedance, less than 300 Ohms, may indicate a short in the lead.
- High lead impedance, greater than 3000 Ohms, may indicate poor lead connection to IPG or a lead fracture.
- Drastic, abrupt or sudden changes in lead impedance may indicate a problem with a lead. Abrupt drops in impedance are expected immediately post implant of a new Carotid Sinus Lead (CSL). This is usually followed by a gradual increase in impedance until 2-4 weeks post implant.

For devices with therapy programmed on only one lead
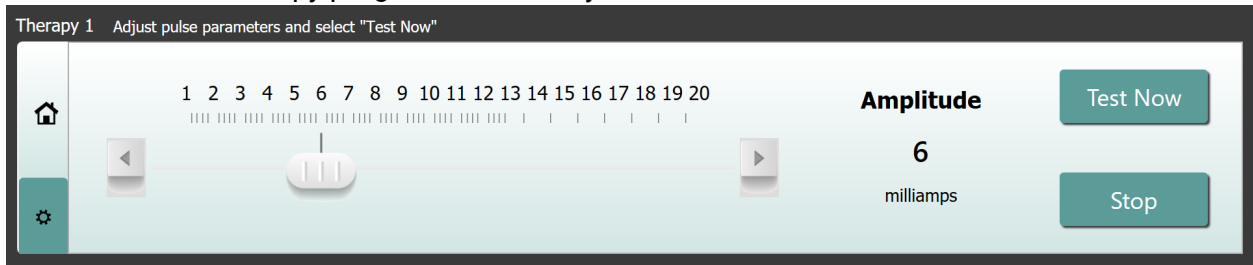
- Devices with two therapy pathways programmed
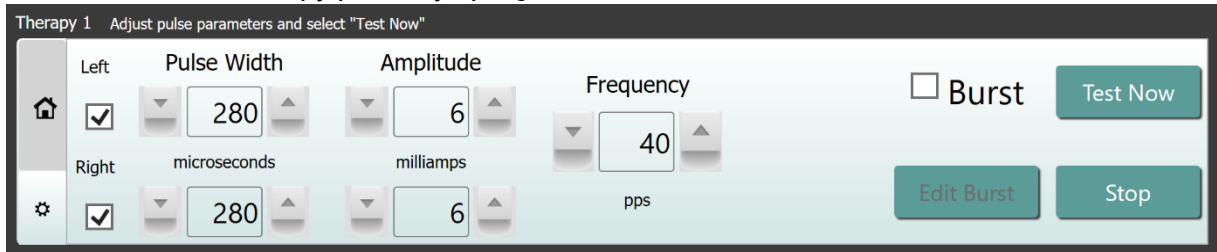
Adjust therapy as needed
- If chronic therapy results are greater than desired:
  - Reduce Pulse Amplitude
- If chronic therapy results are less than desired:
  - Increase Pulse Amplitude
- If device longevity is less than desired:
  - Consider variable daily therapy schedules (e.g., lower dose at night)

Adjust the Schedule if necessary
Edit the Schedule window to adjust time of day when therapy will be delivered.

Note: The IPG Schedule is in relation to the local time set by the programmer computer/tablet. Patients who travel to other time zones and have more than one therapy in their Schedule will experience therapy transitions based on the time zone in use at the time of IPG programming. If the patient travels to a different time zone, the IPG schedule does not change to the new time zone. Clinicians should take this behavior into consideration when programming multiple therapies.

Estimating Longevity
Review estimated longevity after adjusting therapies.
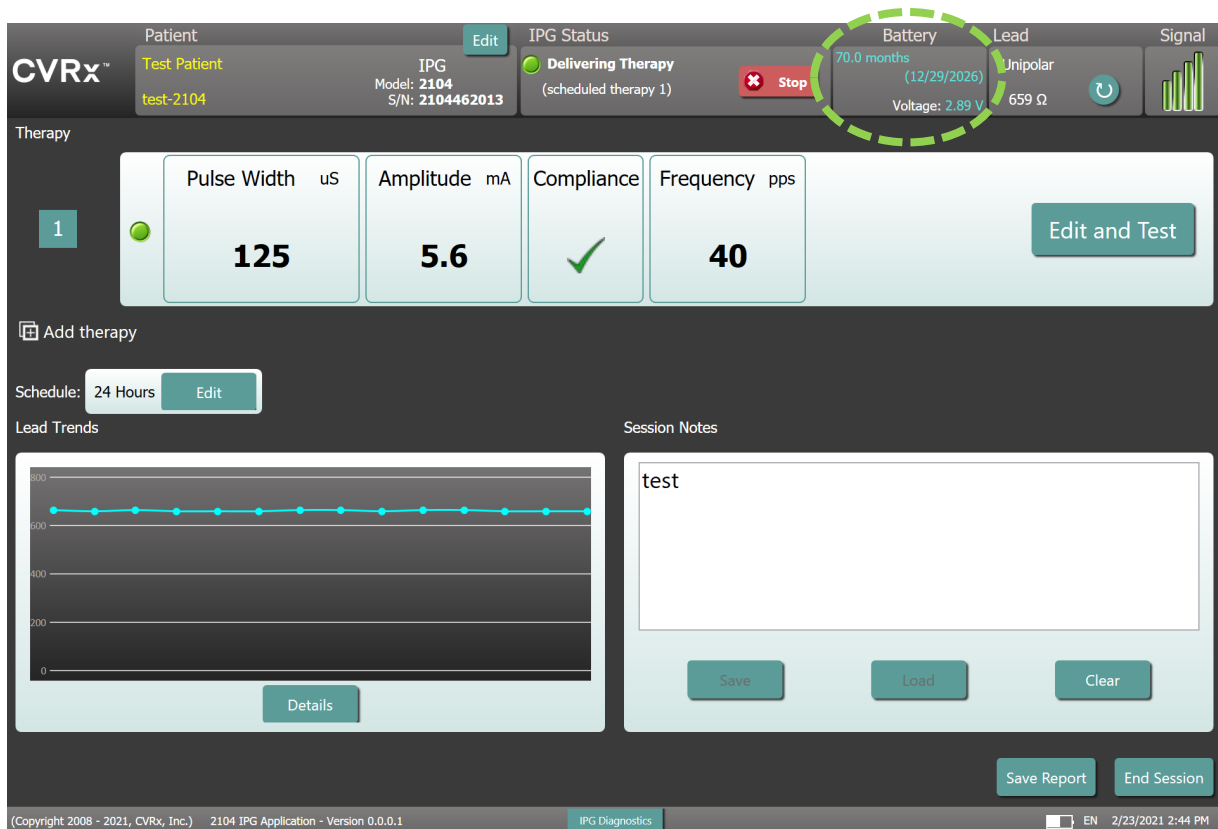
- **Adequate Follow-up frequency near RRT:** Follow-up frequency should be adjusted within 2 years of RRT such that the next follow-up occurs no later than half of the number of months to predicted RRT when RRT is at least 3 months away. For example, if RRT is expected in 14 months the next follow-up should be in 7 months. When RRT is less than 3 months away, it is recommended that replacement be scheduled on or before the RRT to prevent battery depletion.

ENDING PROGRAMMING

Once the Therapy Programming and the Schedule has been adjusted, review the Main Screen of the application to **verify all the desired settings are correct** (Patient Identification, IPG Status, Therapy Settings, and Schedule).

Session Notes

Enter information in the Session Notes to be stored on the Session Summary Report. Save Session Notes to the IPG to be displayed at the next Programming Session, if desired. This may be useful to record extraneous stimulation thresholds for future reference, as an example.

Save the Session Summary Report

The report contains the final therapy parameters and all pertinent session information for record keeping purposes.

System Shut Down

Once programming is completed:

- Exit Discovery Screen.
- For 9010: Shut down the computer using the Windows Start Menu and click Shut down.
- For 9020: Shut down the tablet using the Windows Power Menu or long press the power button and follow the onscreen instructions to shut down.

4
Troubleshooting

CVRX CONTACT INFORMATION

CVRx, Inc.

9201 West Broadway Avenue, Suite 650

Minneapolis, MN 55445 USA

Phone: (763) 416-2840

Fax: (763) 416-2841

Email: engineering@cvrx.com

www.cvrx.com

WARNING MESSAGES

The following table lists some of the common warning messages displayed in the user interface and a description of the conditions leading to the warning and the action required by the user to resolve.

Symptom or System/Warning Message	Possible Cause(s)	How to resolve
PGM005 - **Programmer Not Connected** PGM006 - **Programmer Connection Problem** PGM007 - **Programmer Failure** IPG013 - **Programmer Not Connected**	• Poor USB connection • Damaged Programmer Interface • Damaged Programmer Interface USB cable	1. Ensure Programmer Interface USB cable is properly connected. 2. Disconnect and reconnect the USB cable. 3. Ensure Programmer Interface USB cable is not cut or otherwise damaged. 4. Ensure green power indicator is lit on 9010 Programmer Interface. On 9020 verify the blue indicator light is on. 5. Disconnect, and then reconnect the USB cable. 6. If problem persists, exit and then restart application 7. If problem still persists, contact CVRx®

END SESSION WARNING MESSAGES

The following table lists warning messages that can occur when ending session. All these messages are in the IPG008 – End Session dialog. To resolve a message, click No to return to the programming session and make the appropriate changes.

Symptom or System/Warning Message	Possible Cause(s)	How to resolve
THERAPIES ARE DISABLED	• Therapies have been Stopped • No therapies are in the schedule	1. Resume Therapy 2. Make sure that the schedule contains one or more therapy entries.
A scheduled therapy has not passed a compliance test.	• One or more therapies in the therapy schedule do not have a **Compliance** check mark. ✔	1. For each therapy not in compliance click on the **Edit and Test** button to test and save therapy settings that pass the **Compliance** checks.
Patient Information has not been entered.	• The **Patient Name** and **Patient ID** fields have not been set.	1. Click the Patient Edit button and enter the information in at least one of the fields on the **Edit Patient** Information dialog. 2. Click Save.

TROUBLESHOOTING

The following table list some Symptoms, possible causes and the action required by the user to resolve.

Symptom or System/Warning Message	Possible Cause(s)	How to resolve
Implanted device does not appear on **Discovery** screen Unable to connect to selected IPG Poor or no telemetry signal while in session	• Loss of communication.	1. Ensure that the Programmer Interface is placed in its upright position with no obstructions between the Programmer Interface and the IPG. 2. Ensure the Programmer Interface is facing the IPG. 3. Ensure the distance from the Programmer Interface and the IPG is no more than 2 meters. 4. Disconnect and reconnect the USB cable. 5. If problem persists, exit and then restart application 6. If problem still persists, contact CVRx
Compliance failure ✗	• **Therapy settings** are too high • **Lead impedance** is too high • **Pulse width** is too high	1. Verify the **lead impedance** is in the normal range. 2. Reduce **Therapy Amplitude** 3. If further reduction of **Amplitude** is not desired, reducing **Pulse Width** may allow the **Compliance** check to pass.
The programmer computer operating system indicates a quick drop in battery capacity. Or Operating system displays a message indicating the battery needs to be replaced.	• Computer has been in storage for a long period of time – this behavior may not be an indication of a worn battery	1. Plug in the computer to allow the battery to charge. 2. After power up, allow the computer to charge for at least 15 minutes, then note the charge level of the battery. If the battery charge indicates greater than 60%, unplug the charging cable and monitor the battery charge percentage. If the battery depletes slowly from this higher charge level, it does not need to be replaced. If it depletes rapidly, then consider replacing the battery or ensuring the computer is plugged in anytime it is in use
Software stops responding to keyboard or pointer device input:	• Operating system error or Application errors	1. Use task manager (Computer: accessed by pressing ctrl-alt-delete) (Tablet: access by pressing the power and the volume up button) and close the CVRx application. 2. Restart the application. 3. If that is unsuccessful, the programmer computer or tablet can be restarted to recover functionality.

If there is still a problem after following the troubleshooting steps above, contact your CVRx representative or call CVRx.

DIAGNOSTIC FILE

A diagnostic file may be requested by CVRx for advanced trouble shooting support. To save a diagnostics file, open the CVRx Launcher application, go to the **Programmer Diagnostics** button and select **Save PGM Diagnostics** and indicate where to save the file. This file may be requested by CVRx.

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Fax: (763) 416-2841
www.cvrx.com

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