Monitoring Devices

Merlin™ Patient Care System
Merlin™ 2 Patient Care System

For the following devices:

SJM Confirm™ Implantable Cardiac Monitor

Confirm Rx™ Insertable Cardiac Monitor

Jot Dx™ Insertable Cardiac Monitor

Help Manual

Abbott

Contents

Introduction

Intended Purpose

The intended purpose of the Merlin™ Patient Care System (PCS) and Merlin 2 PCS is for programming implanted Abbott Medical devices by medical personnel.

For Indications, Intended Use, Contraindications, Precautions and Warnings related to the device, please refer to the appropriate device manual.

Summary of Safety and Clinical Performance

A summary of the safety and clinical performance for this device is available at https://ec.europa.eu/tools/eudamed. Search for the device using the UDI-DI provided on the outer packaging of the device. This is the SSCP location after the launch of the European Database on Medical Devices/Eudamed.

Symbols

The symbols below and harmonized symbols may be found on the product or product label. For harmonized symbols, refer to the Universal Symbols Glossary at medical.abbott/manuals.

Symbol	Description
CE 0123	European conformity, affixed according to the relevant provisions of European Council Regulation 2017/745 (NB 2797 and RE directive 2014/53/EU Annex III. Hereby, Abbott Medical declares that this device complies with the relevant provisions of this regulation and directive. The full text of the European Union RE directive 2014/53/EU declaration of conformity is available at the following internet address:www.cardiovascular.abbott/int/en/hcp/products/declarations-of-conformity.html.
medical.abbott/manuals	Follow instructions for use on this website
MD	Medical Device
UDI	Unique Device Identifier
	Importer
MCMC	Malaysian Communication and Multimedia Commission (MCMC) certification mark for products meeting applicable MCMC Technical Codes

Tools Menu

Contents:

? Button

The ? button opens a window that provides access to the Help manual. You can also access the manual if you select Tools (page 2) > Educational Materials > Help.

Accessed From: Help button

Tools

The Tools menu provides access to a number of programmer tools, including:

- **PSA**. Opens the PSA application (not supported within this software application).
- **Session Records**:
  - **Session Records**. Opens archived data.
  - **PDFs** (page 3). Opens the PDFs window to manage the reports stored as PDFs on the programmer's hard disk.
  - **Data Management**. Opens a window where you can choose to export or delete all patient data.
- **Educational Materials**:
  - **Help**. Opens links for on-line Help for all supported devices.
  - **Demos**. Opens device demonstrations.
- **Maintenance**. Opens utilities for programmer maintenance (for use by Abbott Medical personnel only).
- **Clinical Studies**. Opens information for studies (not supported by monitoring devices).
- **Preferences** (page 3). Opens the programmer settings.
- **Customer Support**. See Technical Support (page 30).
- **Print Screen** (page 4)
- **Export Scree**n (page 4). Exports an image to a USB flash drive.

Accessed From: Tools menu

Session Records

From the Session Records window, you can review (model 3650 programmers only) and export data acquired during previous programming sessions.

- View Session Records Stored on the Programmer Instructions (page 2)
- View Session Records on External Media Instructions (page 2) (model 3650 programmers only)

Accessed From: Tools menu > Session Records button

View Session Records Stored on the Programmer Instructions

To view data acquired during previous programming sessions and stored on the Merlin™ PCS or Merlin 2 PCS programmer:

1. Select Tools > Session Records.
2. Select a device to review.

   Session records can be sorted by model number, serial number, or patient name. To sort the available data, select a column heading.

   NOTE: You can filter by Patient Name and Patient ID only on model 3650 programmers.

   To copy all of the stored session records for the selected device to an external storage device, select the Export All button. Follow the instructions in the window to save comments with the session data.
3. Select a session to view (model 3650 programmer only).

   To view a session, select the session record. To view the most recent session, select the Review Most Recent button.
4. Select a file to review (model 3650 programmer only).

   The session file information is displayed at the top of the screen. Review the stored session data using standard parameter and diagnostic screens. To print reports, see Print Menu (page 31).

View Session Records on External Media Instructions

NOTE: You can view session records from external media only on the Merlin™ PCS programmer model 3650.

To view data acquired during previous programming sessions and stored on external media:

1. Select Tools > Session Records.
2. Select the Read Ext. Media button.
3. Select the media device that contains session data.

4. Select a session to view.
   To copy all of the stored session records for the selected session from an external storage device, select the Copy to Merlin™ PCS button.
5. Select a file to review.
   The session file information is displayed at the top of the screen. Review the stored session data using standard parameter and diagnostic screens. To print reports, see Print Menu (page 31).

PDFs

Every time you select any Print button to create a report, the Merlin™ PCS or Merlin 2 PCS programmer saves the report as a PDF (portable document file [1]). This file can be exported to a flash drive connected to one of the programmer's USB ports. You must install Adobe‡ Acrobat‡ Reader or Adobe Reader‡ on your PC to view the PDF.

From the PDFs window, you can:

- Check the number of PDFs stored on the programmer's hard disk that have not been exported.
- Export all the stored PDFs.
- Export the Most Recent PDFs (created in the last actual session or demo session, including your current session).
- Delete all PDFs.

On Merlin 2 PCS programmers, patient data is nominally set to be encrypted during data export. This data includes PDF reports, screen exports and PC database-compatible records. You may be prompted to enter a six-digit personal identification number (PIN) when exporting patient data to a USB flash drive.

NOTE:

- Be sure to document the PIN selected. This same PIN is later required to access the data from the USB flash drive on a separate computer.
- On Merlin 2 PCS programmers, you can select your Data Export preferences from Tools >Maintenance > Special Functions > Data Export Options.

When you select one of the Export buttons, the Export Data screen appears. The file naming and storing of the PDFs are as follows:

- Folder Name: "Date of PDF creation"
- Sub Folder Name: "Patient Name" (read from the Patient Data)
- File Name: "Device name_Device Model Number_Device Serial Number_Reportname.pdf"

Example: In the folder called "2008-03-22", a subfolder exists called "John Smith." Inside the sub folder is a file titled "PromoteRF_3207-36_201399_TestResults.pdf"containing the test results for John Smith on 3/22/2008.

Accessed From: Tools menu > Session Records > PDFs

Preferences

The Preferences windows set the following for the programmer:

- **Date and Time**
- **Language for Display and Help**
- **Date, Time, and Number Formats**
- **ECG Notch Filter Frequency**. The ECG Notch Filter Frequency reduces ECG interference from the programmer's AC power line frequency. Check with your local authorities for your power line frequency.
- **Audio Preferences** (page 3)
- **Printer Preferences** (page 3)

Accessed From: Tools menu > Preferences button

NOTE: It is important to set an accurate date and time because the device's diagnostics, tests, and other functions use the date and time from the programmer.

Audio Preferences

This screen contains two panels:

- **General Audio**. Select the On button to allow audio cues for programmer activity. You can also select a volume level. The Off button turns all sounds off (except Charging Audio).
- **Charging Audio** (Tachy devices only). Select the On button for an audio cue when the capacitors charge during a programming session.

Accessed From: Tools menu > Preferences button > Audio tab

Printer Preferences

Every time you select any Print button to create a report, the programmer saves the report as a PDF (portable document file [2]). This file can be exported to a flash drive connected to one of the programmer's USB ports. You must install Adobe‡ Acrobat‡ Reader or Adobe Reader‡ on your PC to view the PDF.

To view the number of stored PDFs and to export or delete PDFs, select Tools > Session Records > PDFs (page 3). This window contains two panels:

[1] The programmer does not create a PDF for Freezes printed from the Start-Up screen, real-time printing or when Session Record snapshots are printed.

[2] The programmer does not create a PDF for Freezes printed from the Start-Up screen, real-time printing or when Session Record snapshots are printed.

- **Selected Printer**. You have three choices:
  - PDF Only (Paperless). Sends reports to the programmer's hard disk as a PDF (paperless printing) with no paper documents.
  - Internal & PDF. Sends the report to the programmer's internal printer (available only in programmer model 3650) and simultaneously creates a PDF on the hard disk.
  - External & PDF. Sends the report to an external USB printer and simultaneously creates a PDF on the hard disk. Before reports can be sent to an external printer, you must first connect the external printer to any one of the USB ports on the programmer. For more information on connecting an external printer, see the Merlin™ PCS or Merlin 2 PCS User's Manual.
- **Number of Paper Copies**. This selects how many reports are printed whenever a Print button is selected.

  NOTE: Supported Printers. The programmer can print to many laser jet printers. For a list of compatible printers, contact your Abbott Medical Representative or Technical Support (page 30).

Accessed From: Tools menu > Preferences > Printer tab

Print Screen

The Print Screen button prints an image of the current screen. To send the image to an external printer, go to the Tools Menu > Preferences > Printer tab and select the External button.

This function does not create a PDF.

For more information on printing, see Print Menu (page 31).

Accessed From: Tools menu > Print Screen

Export Screen

The Export Screen button opens the Export Data window (page 29), which allows you to save the current screen as an electronic (.png) file and send the file to any storage device (flash drive) connected to one of the programmer's USB ports. The programmer detects all connected devices and asks you to select the device to receive the data.

On Merlin™ 2 PCS programmers, patient data is nominally set to be encrypted during data export. This data includes PDF reports, screen exports and PC database-compatible records. You may be prompted to enter a six-digit personal identification number (PIN) when exporting patient data to a USB flash drive.

NOTE:

- Be sure to document the PIN selected. This same PIN is later required to access the data from the USB flash drive on a separate computer.
- On Merlin 2 PCS programmers, you can select your Data Export preferences from Tools > Maintenance > Special Functions > Data Export Options.

Accessed From: Tools menu > Export Screen

New Device

The first time you interrogate a Confirm Rx™ or Jot Dx™ device, the New Device window [3] appears. Use the tabs of this window to enter the Reason for Monitoring and other required information. The selections for the Reason for Monitoring include the following:

- Syncope
- Seizures
- Palpitations
- Ventricular Tachycardia
- Suspected AF
- Post AF Ablation
- AF Management
- Cryptogenic Stroke
- Other

Certain device parameters are automatically programmed based on your selection for the Reason for Monitoring and the patient's date of birth. These parameters include the following:

- AF Duration
- AF EGM Trigger Priority
- Pause EGM Trigger Priority
- Tachy EGM Trigger Priority
- Brady EGM Trigger Priority
- Tachy Cutoff Rate

You can change the Reason for Monitoring and the device parameters at any time.

Accessed From: Main Programming window

Rhythm Display

Contents:

Rhythm Display

The Rhythm Display, seen on the Main Programming Window (page 30), shows up to five concurrent channels that can be individually configured, repositioned, and adjusted. You can also freeze the display or print it in real time.

Three types of waveforms can be shown in the Rhythm Display:

- ECG (page 6) (electrocardiogram)
- Markers (page 6)
- EGM (page 8) (subcutaneous electrogram)

The controls for the Rhythm Display include the:

	Channel Configuration labels, which identify the source shown on each channel
	Adjust Display button (page 8)
	Freeze Capture button (page 9)

See Rhythm Display Setup Instructions (page 8).

[3] Available in Confirm Rx and Jot Dx devices only.

ECG

The Rhythm Display can show up to five ECG waveforms simultaneously from seven possible ECG vectors. Select the Adjust Display button (page 8) to select the ECG waveform source and configuration.

A typical ECG setup is shown in the Merlin™ PCS or Merlin 2 PCS User's Manual. See ECG Configuration (page 9).

Markers

Markers are symbols that represent events, intervals, refractory periods, and algorithm activity.

You can choose markers as one of the five waveforms. Markers can be configured from the Adjust Display window (page 8) either as:

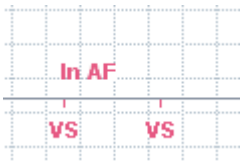
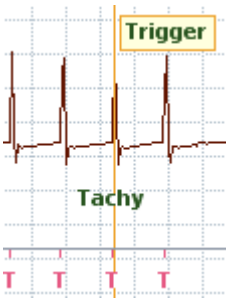
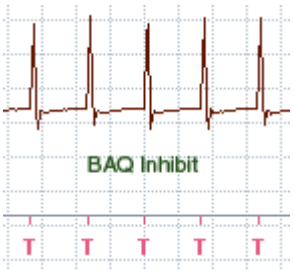
- **Basic**. Basic Event Markers (page 6) appear along a time line.
- **Full**. In addition to the Basic Event Markers, the Activity and Noise Markers (page 7) and Interval and Refractory Markers (page 7) appear.

The following markers always appear in both the Basic and Full marker configurations:

- Programmer Communication Markers (page 7)
- Waveform Channel Markers (page 8)

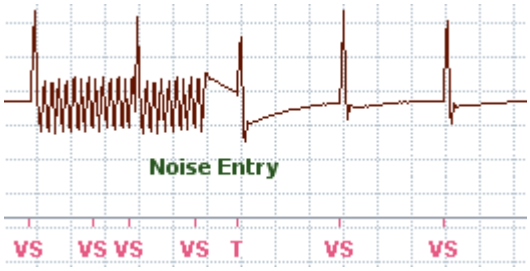
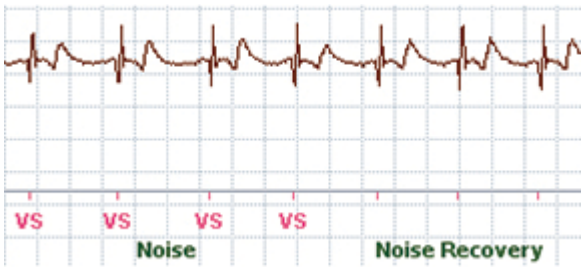
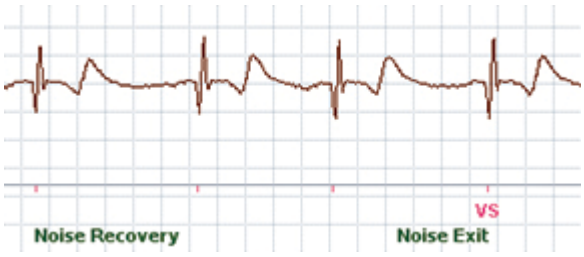
Basic Event Markers

Table 1. Basic event markers

Marker	Description	Example
AF Entry	AF entry	AF markers are only shown in stored EGMs and not on the real-time display.
In AF	AF ongoing	
AF Exit	AF exit	
T	Binned interval: Tachycardia	
B	Binned interval: Bradycardia	
A or P	Binned interval: Asystole or Pause	
VS	Ventricular sensed event	
Episode Exit	Episode exit	
Tachy	Tachy episode diagnosis	If an event triggers EGM storage, a vertical bar with a "Trigger" flag appears at the trigger point.
Brady	Brady episode diagnosis	
Asystole or Pause	Asystole or pause episode diagnosis	
Patient Activated or Symptom	Patient activated or symptom EGM storage	The Patient Activated or Symptom marker is only shown in stored EGMs and not on the real-time display.
BAQ Inhibit or Bigeminy	Diagnosis inhibited due to bigeminal rhythm	
DISC Inhibit or SVT	Diagnosis inhibited	
–	Unbinned interval (dash)	

Activity and Noise Markers

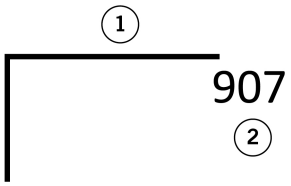
Table 2. Activity and noise markers

Markers	Description	Example
ACT or Act.	Activity Sensor Marker	
Act., Noise [4]	Activity and noise response ongoing	
Act., Noise Recovery [5]	Activity and noise response recovery	
Noise Entry	Noise response entry	
Noise	Noise response ongoing	
Noise Recovery	Noise response recovery	
Noise Exit	Noise response exit	

Interval and Refractory Markers

Interval and refractory markers are shown in the following diagram. These markers are available in Full marker configurations only.

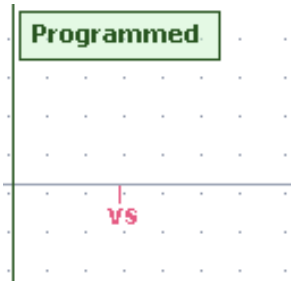
Figure 1. Interval and refractory markers



1. Refractory Period (Line)
2. R-R Interval

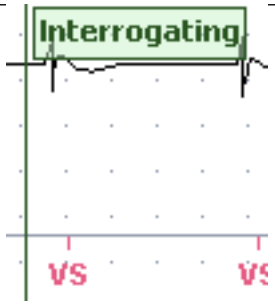
Programmer Communication Markers

Table 3. Programmer communication markers

Marker	Description	Example
Programmed	Device programming	The marker is a vertical bar with a flag. 
Interrogating	Device interrogation	

[4] Available in Confirm Rx and Jot Dx devices only.
[5] Available in Confirm Rx and Jot Dx devices only.

Table 3. Programmer communication markers

Marker	Description	Example
		

Waveform Channel Markers

Table 4. Waveform channel markers

Marker	Description	Example
[New Configuration]	The ECG or EGM channel configuration was changed	
+ Gain	An increase in the gain setting	
- Gain	A decrease in the gain setting	
Dynamic Range	A change in the dynamic range	

EGM

EGMs (electrograms) show the heart's electrical activity as sensed by the device. The shape and size of the waveform depend on the available EGM Configuration (page 9) and the Gain setting.

The Rhythm Display can show up to two EGM waveforms simultaneously in a variety of configurations. Select the Adjust Display button (page 8) to select the waveform source, configuration, and gain as well as the ECG Filter.

When episode retrieval is in progress for Confirm Rx™ or Jot Dx™ devices, the EGM display will be suspended. It will resume automatically once the episode retrieval is completed.

Rhythm Display Setup Instructions

1. Select the Adjust Display button to the right of the Rhythm Display.
   The Adjust Display window (page 8) appears.
2. Locate position 1.
3. Select the Source you want to see in position 1 (ECG (page 6), EGM (page 8), Markers (page 6), or Off).
   The programmer selects a default Configuration for the Source.
4. Select the Configuration button.
   If you select ECG or EGM for the Source, the ECG Configuration (page 9) or EGM Configuration (page 9) window opens. If you select Markers (page 6), select the Basic or Full button.
5. Choose the configuration.
6. Choose the Gain setting.
   The default setting for each Gain control is Auto.
7. Repeat these steps for the remaining waveforms.
8. To change the default sweep speed, select the Sweep Speed button and choose a speed.
9. To invert an EGM, select the Invert EGM button. [6]
10. To set the ECG filter (to reduce electromagnetic interference), select the ECG Filter button.
11. To refresh the Autogain settings, select the Update Auto Gains button.
    NOTE: The Rhythm Display settings for monitoring devices are stored in the programmer. The same Rhythm Display settings are used for the next monitoring device session, until you readjust the Rhythm Display settings.

Adjust Display

From the Adjust Display window, you can change the:

- **Source** for each waveform in the Rhythm Display window (ECG (page 6), Markers (page 6), or EGM (page 8))

[6] Available in Confirm Rx and Jot Dx devices only.

- **Configuration** of the waveform
- **Gain** to adjust the height of the waveform. The default setting is Auto.
- **Sweep Speed**
- **ECG Filter** to reduce electromagnetic interference
- **Invert EGMs** [7] to invert the peaks of the EGM.

The following buttons are also available:

- **Update AutoGains**. Recalculates the gain of waveforms currently displayed in the Rhythm Display and that are set to Auto.
- **? Marker Help**. See Markers (page 6).

See also:

- ECG Configuration (page 9)
- EGM Configuration (page 9)
- Rhythm Display Setup Instructions (page 8)

Accessed From: Rhythm Display > Adjust Display button or window

ECG Configuration

The ECG Configuration window changes the ECG vector on the Rhythm Display (page 5), Rhythm Display (page 5). See ECG (page 6) for a typical ECG setup.

To achieve the ECG vectors, select the following electrodes:

- **I**. L(+) – R(-)
- **II**. F(+) – L(-)
- **III**. F(+) – R(-)
- **aVR**. R(+) – L(-) + F(-)
- **aVL**. L(+) – R(-) + F(-)
- **aVF**. F(+) – R(-) + L(-)
- **Chest**. C

Accessed From: Adjust Display > Configuration button

EGM Configuration

The EGM Configuration window changes the EGM source on the Rhythm Display (page 5), Rhythm Display (page 5). The following EGM configurations are available depending on the device:

- **VEGM**. The ventricular EGM using a can to header vector.
- **ZOOM** [8]**.** The VEGM configuration with 3x amplification.
- **VSENSE**. A filtered VEGM configuration used for sensing.
- **ASC** [9]**.** The sensing threshold determined by the automatic sensitivity control algorithm.

Accessed From: Adjust Display > Configuration button

Freeze Capture

In SJM Confirm™ devices, the Freeze button captures the most recent 64 seconds of the waveform and shows the data in the Freeze Capture window. Once you close the Freeze Capture window, only the most recent 16 seconds of the waveform data are stored. The Presenting Rhythm (page 10) and up to 49 of the most recent Freeze Captures are stored.

In Confirm Rx™ and Jot Dx™ devices, the Freeze button captures the most recent 30 seconds of the waveform and shows the data in the Freeze Capture window. The most recent 15 seconds of the waveform data are stored, and you can view up to 6 of the most recent Freeze Captures in a session record.

The controls on the Freeze Capture window include the:

- **Adjust Channels button** [10]. Adjusts the characteristics of the Freeze Capture window. In Confirm Rx and Jot Dx devices, these adjustments are done through the EGM configuration.
- **Update AutoGains button**. Recalculates the gain of waveforms currently displayed in the Freeze Capture window and that are set to Auto.
- **Center Vertical button** [11]. Centers the waveforms currently displayed in the Freeze Capture window.
- **Sweep Speed button**
- **Show Calipers button**. Shows calipers that can be moved with button controls to display time measurements for a portion of the freeze.
- **Hide Calipers button**. Toggles to the Show Calipers button.
- **Reset Calipers button**. Resets the calipers to their default positions.
- **Print button**. Prints the channel information and the portion of the frozen waveform data displayed in the Freeze Capture window. The amount of EGM data printed is determined by the Sweep Speed setting.
- **Scroll buttons**
- **Restore Channels button.** Restores the hidden waveforms.

Select the Select for Printing button to print the most recent 16 seconds of the Freeze Capture at the end of the session.

See also Wrap-up™ Overview (page 29).

Accessed From: Freeze button

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[7] Available in Confirm Rx and Jot Dx devices only.
[8] Available in SJM Confirm devices only.
[9] Available in SJM Confirm devices only.
[10] Available in SJM Confirm devices only.
[11] Available in SJM Confirm devices only.

Presenting Rhythm

The Freeze Capture labeled Presenting Rhythm includes up to 16 seconds of waveform data captured immediately following the initial device interrogation. You can view the Presenting Rhythm in the Freeze Capture (page 9) window.

Accessed From: Freeze button

Adjust Channels

You can adjust certain characteristics of the Freeze Capture window. These characteristics include:

- **Display** [12] **or Restore Channels button** [13]. Shows or hides each channel.
- **Configuration**. Displays the source shown on each channel. You can set the Markers (page 6) to basic or full.
- **Gain buttons**. Adjusts the size of each waveform.
- **Sweep Speed button**
- **? Marker Help button**. See Markers (page 6).
- **Invert EGM button** [14]
- **ECG Filter button.** Reduces electromagnetic interference.

Accessed From: Freeze button > Freeze Capture window

[12] Available in SJM Confirm devices only.
[13] Available in Confirm Rx and Jot Dx devices only.
[14] Available in Confirm Rx and Jot Dx devices only.

FastPath™ Summary Screen

Contents:

FastPath™ Summary

Select any button on the FastPath™ Summary window for more detail.

- **Alerts** (page 11). Opens a list of conditions requiring attention.
- **Battery Status**. Shows the estimated longevity and a battery capacity status bar in SJM Confirm™ devices. You can retrieve the battery voltage measurement from the Real-Time Measurements window (page 17).

  Shows the battery capacity estimate in Confirm Rx™ and Jot Dx™ devices.
- **Parameters**. Shows the settings of parameters. In SJM Confirm™ devices, this button opens the Monitor Settings window (page 18). In Confirm Rx and Jot Dx devices, this button opens the Parameters Workspace window.
- **EGM Count**. [15] Shows a summary of EGMs and the percentage of EGM storage remaining in the device. In SJM Confirm Model DM2102, this button opens the Episode Statistics window (page 13). In SJM Confirm Model DM2100, this button opens the EGMs Directory window (page 13). In SJM Confirm Model DM2100, this button opens the EGMs Directory window (page 13). See also Episode Description (page 15).
- **Episode Count**. [16] Shows a summary of detected episodes. An alert appears when episode data needs to be cleared. Opens the Episodes Directory window (page 13).
- **AF Burden**. Shows a trend of the AF Burden diagnostics. Opens the AF Diagnostics window (page 16).
- **Test Results** [17]. Shows the current and last session signal amplitude measurements and the date of the last session in SJM Confirm devices. Opens the Real-Time Measurements window (page 17).
- **Sense Test Results**. [18] Shows the most recent R-wave measurement and the date that the measurement was obtained in Confirm Rx and Jot Dx devices. Opens the R-Wave Amplitude Measurement window (page 17).
- **Ventricular Heart Rate Histogram**. Shows the Ventricular Heart Rate Histogram. Opens the Heart Rate window (page 16).
- **End Session**. Opens a window to print Reports (page 31) that have not been printed and to end the session.
- **Print button**. Prints a Summary Report which includes all of the information on the Summary screen.

Accessed From: FastPath Summary button

Alerts

The Alerts window lists conditions detected in the current session. The list contains buttons that open related windows. In SJM Confirm devices, alerts that have not been viewed are listed in a red font with a red border around the alert box; alerts that have been viewed are listed in a black font with a green border around the alert box.

In Confirm Rx™ and Jot Dx™ devices, the border of the alert box corresponds to the type of alert that is detected. Red borders are for device alerts, yellow borders are for clinical alerts, and blue borders are for informational alerts.

Accessed From: FastPath Summary button

Patient Information

The Patient Information window displays device information and allows you to save additional data in the device's memory. In Confirm Rx™ and Jot Dx™ devices, you can also view the Reason for Monitoring (page 5) from here.

There are two types of patient information buttons:

- **Parameter Style**. A list of available settings.
- **Data Entry**. Type information using either the On-Screen Keyboard (page 11), which opens when you select a data entry button, or a USB keyboard connected to one of the USB ports. The data entry buttons have a keyboard icon on the button.

Accessed From: Main Programming window

Note

The Note window allows you to enter additional information about the patient. When you select the Highlight At Every Follow-up check-box, the pencil icon on the main programming window is highlighted and the information appears as an alert at the next programming session.

Accessed From: Main Programming window

On-Screen Keyboard

Use the On-Screen Keyboard to enter data.

- **Special Char key**. Select the Special Char key and then select another key to display the special character (labeled in green on the key).

[15] Available in SJM Confirm devices only.
[16] Available in Confirm Rx and Jot Dx devices only.
[17] Available in SJM Confirm devices only.
[18] Available in Confirm Rx and Jot Dx devices only.

- **Inactive Keys**. Inactive keys mean that the device does not support the character.
- **Repeating Keys**. If you press and hold most keys on the on-screen keyboard, they are not repeatedly typed. The exceptions are the arrow keys, the Space key, the Enter key, and the Backspace key.
- **External Keyboard**. You can use an external keyboard connected to the programmer through any of its USB ports. Both keyboards can operate simultaneously.

Episodes

In SJM Confirm™ devices, the Episodes button opens a window that contains the:

- EGMs Directory (page 13)
- Episode Statistics (page 13)

In Confirm Rx™ and Jot Dx™ devices, the Episodes button opens a window that contains the:

- Episodes Directory (page 13)
- Episode Statistics (page 13)

See also:

- Episode Description (page 15)

Accessed From: Episodes button

EGMs Directory

The EGMs window lists all EGMs recorded by the device since diagnostic data were last cleared, the date of the last programmer session, the date of the last device interrogation, and the date that diagnostic data were last cleared. Each item in the list is a button that opens an Episode Detail window.

From the EGMs window, you can:

- **View an EGM**. Select an EGM from the list. Each EGM in the list is a button that opens the Episode Detail window (page 14).
- **Sort the Directory**. Select a column heading.
- **Update the Directory**. Select the Update Directory button to retrieve data from the device and update the data shown. See Retrieve EGMs from the Device (page 14).
- **Print EGMs** (page 14). Select the Print Selected button to print a detailed report for EGMs selected for printing.

When an EGM is uploaded to the SJM Confirm™ patient activator (PA), the Uploaded to PA column shows it.

The Status column displays stored EGMs that have been retrieved from the device. As EGMs are retrieved, the EGM Retrieved icon is displayed.

See also:

- EGM Trigger Priority (page 25), EGM Trigger Priority (page 26)
- Episodes and Stored EGMs (page 15)
- Clear Diagnostics (page 29)
- Retrieve EGMs from the Device (page 14)
- Episode Description (page 15)

Available In: SJM Confirm™ devices

Accessed From: Episodes button > EGMs window

Episodes Directory

The Episodes window lists the episodes detected by the device since episode data were last cleared. It also gives the date of the last programmer session, the date that episode data were last read and cleared, and the date of the last remote session for Confirm Rx™ and Jot Dx™ devices. By default, the window lists all episodes with SEGMs since the last programmer session. Episodes without SEGMs can be viewed by selecting the Include All (old and non-EGM) checkbox. Each item in the list is a button that opens an Episode Detail window.

From the Episodes window, you can:

- **View an Episode**. Select an episode from the list. Each episode in the list is a button that opens the Episode Detail window (page 14).
- **Sort the Directory**. Select a column heading.
- **Update the Directory**. Select the Update Directory button to retrieve data from the device and update the data shown.
- **Print Episodes**. Select the Print Selected button to print a detailed report for episodes selected for printing.

The Additional Information column shows additional information about an episode. The additional information listed depends on the type of episode.

The Uploaded to Merlin.net column shows if that episode was uploaded to Merlin.net.

The Status column displays stored EGMs that have been retrieved from the device. As EGMs are retrieved, the EGM Retrieved icon is displayed.

See also:

- Episodes and Stored EGMs (page 15)
- Clear Diagnostics (page 29)
- Episode Description (page 15)

Available In: Confirm Rx and Jot Dx devices

Accessed From: Episodes button > Episodes window

Episode Statistics

The Episode Statistics window lists statistical data for all episodes recorded by the device since episodes and stored EGMs were last cleared, the number of inhibited VT diagnoses due to the bigeminal rhythm qualifier and rhythm discriminators, the date of the last programmer session, the date that episode data were last read, and the date that episodes and stored EGMs were last cleared.

In Confirm Rx™ and Jot Dx™ devices, the Episode Statistics window also lists the last remote session time stamp.

From the Episode Statistics window, you can:

- View Episodes. Select an episode type from the list to open the Episode Detail window (page 14) for the most recent episode of that type.

See also:

- Alerts (page 11)
- Episodes and Stored EGMs (page 15)
- Clear Diagnostics (page 29)
- Retrieve EGMs from the Device (page 14)
- Print EGMs (page 14)
- Episode Description (page 15)

Accessed From: Episodes button > Episode Statistics window

Print EGMs

You can print from the EGMs Directory window (page 13) (Print Selected button), from the Episode Detail window (page 14) (Print button), from the Wrap-up™ Overview window (page 29) (Print Reports button), and from the Print Menu (page 31).

To print all episodes or EGMs, select the Select All for Printing button from the Episodes or EGMs Directory. To print individual episodes or EGMs while viewing the directory, select the Print Selected button. The episode or EGMs can also be printed at a later time from the Wrap-Up Overview window.

To print a single episode or EGM:

1. Select the episode or EGM from the directory.
   The Select for Printing button is unchecked by default.
2. Close the episode or EGM to return to the Episodes or EGMs Directory.
3. To print the episode or EGM immediately, select the Print Selected button.
   If the episode or EGM is not printed from the Episodes or EGMs Directory window, it is stored in the print queue.

Accessed From: Episodes button > Episodes or EGMs window > Print Selected button

Episode Detail

The Episode Detail window shows the EGM (page 8) and Markers (page 6) data that precede and follow the recorded episode.

The Episode Details window also includes the:

- **Date, Time, and Type** of episode
- **Duration** of the episode
- **Caliper Controls**
  - **Show Calipers button**. Shows calipers that can be moved with button controls to display time measurements.
  - **Hide Calipers button**. Toggles to the Show Calipers button.
  - **Reset Calipers button**. Resets the calipers to their default positions.
- **Scroll buttons**
- **Sweep Speed button**
- **Adjust Channels button**
- **Update Auto Gains button**. Recalculates the gain for each source with Auto selected. This button is available if at least one displayed source is set to Auto gain.
- **Select for Printing button**. The EGM is stored for printing with the Wrap-up Summary Report.
- **Previous/Next controls**. Shows the previous or next EGM.
- **Print button**

Accessed From: Episodes button > EGMs window > Specific EGM button

Adjust Channels

You can adjust certain characteristics of the Episode Detail window (page 14). These characteristics include:

- **Display button**. Shows or hides each channel
- **Markers configuration**. Displays the basic or full markers
- **Gain buttons**. Adjusts the size of each waveform
- **Sweep Speed button**
- **? Marker Help button**. See Markers (page 6)

Accessed From: Episodes button > EGMs window > Specific EGM button

Retrieve EGMs from the Device

The device stores EGMs according to programmed criteria (see Episode Settings (page 25)) and transmits them to the programmer. The retrieval of stored EGMs begins after the initial interrogation. EGMs are retrieved beginning with the most recent EGM and continuing until the oldest EGM has been retrieved. EGMs are retrieved in the "background", which means that the real-time ECG and markers are active and limited navigation and telemetry operations function normally.

The background retrieval of EGMs pauses when:

- Telemetry is lost
- Another telemetry operation, such as retrieving measured data, is performed
- Manual EGM retrieval is initiated

The background retrieval of EGMs continues once the other telemetry operations are complete. The background retrieval of EGMs eventually retrieves all of the EGMs from the device. Once background retrieval is complete:

- Printing from the EGMs Directory becomes available
- Parameters may be programmed
- Wrap-Up Overview and Print Menu functions become available.

Stored EGMs can be retrieved individually when you select an EGM from the EGMs Directory window (page 13).

Episodes and Stored EGMs

A stored EGM includes the EGM, as well as episode date, time, and type of episode if available. EGM storage is dependent upon the Episode Settings (page 25) and the EGM Trigger Priority (page 25), EGM Trigger Priority (page 26).

In SJM Confirm™ Model DM2102 devices, up to 147 auto activated (Tachy, Brady, Asystole) and patient activated EGMs can be stored and an additional 147 AF episodes can be stored, with a total of 48 minutes of EGM storage time. Patient activated episodes have a higher storage priority than auto activated episodes and are stored first. Once the storage capacity is reached, patient activated episodes are retained and newer auto activated EGMs replace older auto activated EGMs.

In Confirm Rx™ and Jot Dx™ devices, up to 250 AF episodes and 250 auto activated (Tachy, Brady, Pause) and symptom episodes can be stored with a total of 60 minutes of EGM storage time. Symptom episodes have a higher storage priority than auto activated episodes and are stored first. Once the storage capacity is reached, symptom episodes are retained and newer auto activated EGMs replace older auto activated EGMs.

See also Episode Description (page 15).

Episode Description

- **AF Episode** [19]. An algorithm determines when an AF episode begins and ends. The EGM shows the beginning of the episode only.
- **Tachy Episode**. A tachy episode begins when the intrinsic rate exceeds the Tachy Cutoff Rate (page 18) for the programmed number of intervals (Tachy Count (page 18)) and ends with the detection of five sinus intervals or another rhythm.
- **Brady Episode**. A brady episode begins when the intrinsic rate is slower than Brady Cutoff Rate (page 18) for four intervals and ends with the detection of five sinus intervals or another rhythm.
- **Asystole or Pause Episode**. An asystole or pause episode begins when the Asystole (page 18) or Pause Duration (page 22) is exceeded without R-wave detection and ends with the detection of four consecutive non-asystole or non-pause binned intervals.
- **Patient Activated or Symptom Episode**. A patient activated [20] or symptom episode [21] captures the time surrounding manually activated recording using the external patient activator or myMerlin™ mobile application (app).

  NOTE: In Confirm Rx™ and Jot Dx™ devices, the symptom episode details include the symptoms selected by the patient in the app.

[19] Available in SJM Confirm (DM2102), Confirm Rx, and Jot Dx devices only.
[20] Available in SJM Confirm devices only.
[21] Available in Confirm Rx and Jot Dx devices only.

Diagnostics

Contents:

See also:

- Clear Diagnostics (page 29)

Accessed From: Diagnostics button

Heart Rate

The Heart Rate window contains the following:

- **Ventricular Heart Rate Histogram**. A bar graph of all recorded events by rate since the diagnostic data were last cleared. Shows the Tachy Cutoff Rate (page 18), Brady Cutoff Rate (page 18), and Pause Cutoff Rate [22] settings.
- **Read Diagnostics button**. Retrieves data from the device and updates the data shown.
- **View Counts button** [23]. Shows the diagnostic data in a table.
- **Last Session**. The date and time of the last programmer session.
- **Last Remote Session** [24]**.** The date and time of the last remote session.
- **Last Read**. The date and time that the diagnostic data were last read.
- **Last Cleared**. The date and time that the diagnostic data were last cleared.

Accessed From: Diagnostics button > Heart Rate tab

AF Diagnostics

The AF Diagnostics window contains the following:

- **AF Burden**. Shows the percentage of time that the patient was in AF since the AF diagnostics data were last cleared (see Clear Trend (page 29)). In Confirm Rx™ and Jot Dx™ devices, it shows the daily percentage over a 31 day period.
- **AF Summary**. Histograms of the Mean Ventricular Heart Rate and the Duration of AF episodes since AF diagnostic data were last cleared.
- **AF Statistics**. Statistical data for AF episodes stored since AF diagnostic data were last cleared.
- Read Diagnostics button. Retrieves diagnostic data from the device and updates the data shown.
- **Last Session**. The date and time of the last programmer session.
- **Last Remote Session**. [25] The date and time of the last remote session.
- **Last Read**. The date and time that the diagnostic data were last read.
- **Last Cleared**. The date and time that the diagnostic data were last cleared.

Available In: SJM Confirm™ (DM2102), Confirm Rx and Jot Dx devices

Accessed From: Diagnostics button > AF Diagnostics tab

[22] Available in Confirm Rx and Jot Dx devices only.
[23] Available in SJM Confirm devices only.
[24] Available in Confirm Rx and Jot Dx devices only.
[25] Available in Confirm Rx and Jot Dx devices only.

Tests

The Tests window contains the following:

- Real-Time Measurements (page 17) in SJM Confirm™ devices
- R-wave Amplitude Measurements (page 17) in Confirm Rx™ and Jot Dx™ devices

Accessed From: Tests button

Real-Time Measurements

The Real-Time Measurements window contains:

- **Battery Voltage**. The battery voltage and the date of the last valid measurement are shown. Select the checkbox next to the last valid measurement to update the battery voltage measurement. Battery specifications are listed with the Technical Data for each of the Supported Devices (page 30).
- **R-Wave Amplitude**. The median filtered R-wave amplitude from baseline to peak is shown. "N/A" appears until a successful measurement is made.
- **Number of Cycles button** (page 17)
- **Retrieve Selected button**

The real-time measurements are also shown on the FastPath™ Summary window (page 11).

Available In: SJM Confirm™ devices

Accessed From: Tests button > Real-Time Measurements tab

Number of Cycles

The Number of Cycles parameter determines the number of intervals used to evaluate the signal amplitude.

Settings: 3; 5 (Nominal: 3)

Accessed From: Tests button > Real-Time Measurements tab

R-Wave Amplitude Measurements

The R-wave Amplitude Measurements window contains:

- **R-Wave Amplitude**. The median filtered R-wave amplitude from baseline to peak is shown. "No Previous Result" appears until a successful measurement is made.
- **Number of Cycles**. The number of cycles is fixed at 5.
- **Measure Amplitude button**

The R-wave amplitude measurements are also shown on the FastPath™ Summary window (page 11).

Available In: Confirm Rx™ and Jot Dx™ devices

Accessed From: Tests button > R-Wave Amplitude Measurements tab

SJM Confirm Monitor Settings

The Monitor Settings window shows most of the programmable monitor parameters divided into groups. Select a button to change parameter settings. The buttons are:

- Detection (page 18)
- Tachy Criteria (page 18)
- Sensing (page 19)
- Detection Inhibitors (page 20)

Available In: SJM Confirm™ devices

Accessed From: Parameters button > Monitor Settings tab

Detection

From the Detection window, you can change the settings for the following parameters:

- AF Duration (page 18)
- Tachy Cutoff Rate (page 18)
- Tachy Count (page 18)
- Brady Cutoff Rate (page 18)
- Asystole Duration (page 18)

Available In: SJM Confirm™ devices

Accessed From: Parameters button > Monitor Settings tab > Detection button

AF Duration

The AF Duration parameter determines the shortest AF episode that will be stored.

Available In: SJM Confirm™ (DM2102) devices Settings: (min) 0.5; 1; 2; 5; 10 (Nominal: 2)

Accessed From: Parameters button > Monitor Settings tab > Detection button

Tachy Cutoff Rate

The Tachy Cutoff Rate parameter determines the rate that must be exceeded for a programmed number of intervals (Tachy Count (page 18)) to trigger episode storage.

Settings: (min^{-1}) 120; 125; … 250 (Nominal: 180)

Available In: SJM Confirm™ devices

Accessed From: Parameters button > Monitor Settings tab > Detection button

Tachy Count

The Tachy Count parameter sets the number of intervals that must be faster than the Tachy Cutoff Rate (page 18) to trigger episode storage.

Settings: 8; 9; … 25; 30; … 50 (Nominal: 12)

Available In: SJM Confirm™ devices

Accessed From: Parameters button > Monitor Settings tab > Detection button

Brady Cutoff Rate

The Brady Cutoff Rate parameter determines the rate at which four intervals at slower rates trigger episode storage.

Settings: (min^{-1}) 30; 40; 50 (Nominal: 50)

Available In: SJM Confirm™ devices

Accessed From: Parameters button > Monitor Settings tab > Detection button

Asystole Duration

The Asystole Duration parameter determines the length of time allowed without the detection of intrinsic rhythm before episode storage is triggered.

Settings: (s) 3.0; 3.5; … 5.0 (Nominal: 3.0)

Available In: SJM Confirm™ devices

Accessed From: Parameters button > Monitor Settings tab > Detection button

Tachy Criteria

From the Tachy Criteria window, you can change the settings for the following parameters:

- Bigeminy Qualifier (page 19)
- Sudden Onset (page 19)
- Onset Delta (page 19)
- Interval Stability (page 19)
- Stability Delta (page 19)
- Stability Window (page 19)

Available In: SJM Confirm™ (DM2102) devices

Accessed From: Parameters button > Monitor Settings tab > Tachy Criteria button

Bigeminy Qualifier

The Bigeminy Qualifier parameter enables an algorithm that requires more intervals to be identified as tachyarrhythmia intervals than sinus intervals before episode storage is triggered.

Available In: SJM Confirm™ (DM2102) devices Settings: On; Off (Nominal: Off)

Accessed From: Parameters button > Monitor Settings tab > Tachy Criteria button

Sudden Onset

The Sudden Onset parameter enables a discriminator that distinguishes between VT (abrupt onset) and sinus tachycardia (gradual onset) in patients whose maximum sinus rates can exceed their slowest ventricular tachyarrhythmia rates ("rate overlap").

Available In: SJM Confirm™ (DM2102) devices Settings: Off; On (Nominal: Off)

Accessed From: Parameters button > Monitor Settings tab > Tachy Criteria button

Onset Delta

The Onset Delta parameter determines the abruptness of a tachycardia's onset. When the percentage of change in the measured interval is equal to or greater than the programmed Onset Delta setting, the Sudden Onset discriminator (page 19) classifies the rhythm as VT and the event triggers episode storage.

Available In: SJM Confirm™ (DM2102) devices Settings: (%) 4; 6; … 86 (Nominal: 18)

Accessed From: Parameters button > Monitor Settings tab > Tachy Criteria button

NOTE: A larger Onset Delta percentage decreases the chance that the device indicates tachycardia.

Interval Stability

The Interval Stability parameter enables a discriminator that distinguishes between atrial fibrillation (AF) (more rate-variability) and VT (less rate-variability).

Available In: SJM Confirm™ (DM2102) devices Settings: Off; On (Nominal: Off)

Accessed From: Parameters button > Monitor Settings tab > Tachy Criteria button

Stability Delta

The Stability Delta parameter defines the acceptable difference between the second longest and the second shortest ventricular intervals in a recent group of intervals defined by the Stability Window (page 19). When the measured interval is shorter than the programmed Stability Delta setting, the Interval Stability discriminator (page 19) classifies the rhythm as VT.

Available In: SJM Confirm™ (DM2102) devices Settings: (ms) 30; 35; … 500 (Nominal: 80)

Accessed From: Parameters button > Monitor Settings tab > Tachy Criteria button

NOTE: A shorter Stability Delta interval decreases the chance that the device indicates tachycardia.

Stability Window

The Stability Window parameter determines the number of intervals prior to the detection of an arrhythmia that are used to evaluate the stability of an arrhythmia. The Interval Stability Window Size setting must be less than or equal to the selected Tachy Count (page 18).

Available In: SJM Confirm™ (DM2102) devices Settings: 8; 9; … 20 (Nominal: 12)

Accessed From: Parameters button > Monitor Settings tab > Tachy Criteria button

Sensing

From the Sensing window, you can change the settings for the following parameters:

- EGM Dynamic Range (page 19)
- Max Sensitivity (page 19)
- Sense Refractory Period (page 20)
- Decay Delay (page 20)
- Threshold Start (page 20)

See also:

- Ventricular Sensing Example (page 20)

Available In: SJM Confirm™ devices

Accessed From: Parameters button > Monitor Settings tab > Sensing button

EGM Dynamic Range

The EGM Dynamic Range parameter determines the maximum amplitude displayed when VEGM is the EGM source configuration setting.

See EGM Configuration (page 9) and Ventricular Sensing Example (page 20).

Settings: (mV) ±1.22; ±0.72; ±0.36; ±0.18 (Nominal ±0.72)

Available In: SJM Confirm™ devices

Accessed From: Parameters button > Monitor Settings tab > Sensing button

Max Sensitivity

The Max Sensitivity parameter determines the minimum amplitude of sensed signals used for sensing. The settings available are dependent upon the setting of the EGM Dynamic Range (page 19) parameter.

See Ventricular Sensing Example (page 20).

Table 5. Settings

EGM Dynamic Range	Max Sensitivity Settings (mV)	Nominal
± 1.22	0.09; 0.12; 0.16; 0.32; 0.48; 0.64; 0.80	--

Table 5. Settings

EGM Dynamic Range	Max Sensitivity Settings (mV)	Nominal
± 0.72	0.05; 0.07; 0.09; 0.12; 0.19; 0.28; 0.38; 0.47	0.19 [26]
± 0.36	0.05; 0.07; 0.09; 0.12; 0.16; 0.19; 0.24	--
± 0.18	0.05; 0.07; 0.09; 0.12	--

Available In: SJM Confirm™ devices

Accessed From: Parameters button > Monitor Settings tab > Sensing button

Sense Refractory Period

The Sense Refractory Period parameter determines the amount of time after a sensed event during which the device ignores subsequent sensed events.

See Ventricular Sensing Example (page 20).

Settings: (ms) 125;150; … 400 (Nominal: 250)

Available In: SJM Confirm™ devices

Accessed From: Parameters button > Monitor Settings tab > Sensing button

Decay Delay

The Decay Delay parameter determines the amount of time after the Sense Refractory Period (page 20) that the threshold remains at the programmed Threshold Start (page 20) setting before beginning its decay. Increasing the Decay Delay may prevent oversensing.

See Ventricular Sensing Example (page 20).

Settings: (ms) 0; 30; 60; 95; 125; 160; 190; 220 (Nominal: 60)

Available In: SJM Confirm™ devices

Accessed From: Parameters button > Monitor Settings tab > Sensing button

Threshold Start

The Threshold Start parameter determines the threshold at which events are sensed following the Sense Refractory Period (page 20) for a sensed event. This threshold is a percentage of the maximum peak amplitude sensed during the previous Sense Refractory Period. Threshold Start can be used to prevent oversensing.

After a sensed event, the device determines the maximum amplitude signal detected during the Sense Refractory Period. Upon expiration of the Sense Refractory Period, the sensing threshold automatically adjusts to the higher of either the Threshold Start or a percentage of that maximum amplitude with an absolute maximum value of the EGM Dynamic Range (page 19) setting.

See Ventricular Sensing Example (page 20).

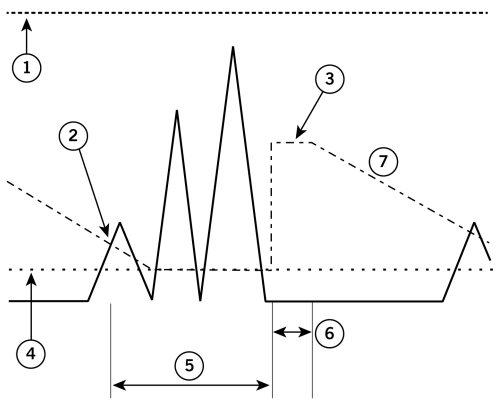
Settings: (%) 50; 62.5; 75; 100 (Nominal: 75)

Available In: SJM Confirm™ devices

Accessed From: Parameters button > Monitor Settings tab > Sensing button

Ventricular Sensing Example

Figure 2. An example of ventricular sensing for SJM Confirm™ devices



1. EGM Dynamic Range (page 19)
2. Sensed R-wave
3. Threshold Start (page 20)
4. Max Sensitivity (page 19)
5. Sense Refractory Period (page 20)
6. Decay Delay (page 20)
7. The sensing threshold determined by the automatic sensitivity control algorithm (dashed line). You can view the sensing threshold on the Rhythm Display (page 5), Rhythm Display (page 5). See EGM Configuration (page 9).

Detection Inhibitors

From the Detection Inhibitors window, you can change the settings for the following parameters:

- Noise Response (page 21)
- Activity Response (page 21)

Also available is the Calibrate Activity (page 21) button.

Available In: SJM Confirm™ devices

Accessed From: Parameters button > Monitor Settings tab > Detection Inhibitors button

[26] Nominal of 0.19 mV is based on EGM Dynamic Range nominal setting of ± 0.72 mV.

Noise Response

The Noise Response nonprogrammable parameter enables an algorithm that determines if sensed events are noise. When noise is detected EGM and data storage is inhibited.

See also EGM Trigger Priority (page 25), EGM Trigger Priority (page 26) and Markers (page 6).

Available In: SJM Confirm™ devices

Accessed From: Parameters button > Monitor Settings tab > Detection Inhibitors button

Activity Response

The Activity Response parameter enables an algorithm that determines if sensed events are activity. When activity is detected and the Activity Response setting is:

- Inhibit. EGM and data storage is inhibited. Activity markers are shown on the real-time display. Interval measurements are not shown.
- Monitor. EGM and data storage occurs. Activity markers and interval measurements are shown.
- Off. EGM and data storage occurs. Activity markers and interval measurements are not shown.

See also Markers (page 6).

Settings: Inhibit; Monitor; Off (Nominal: Monitor)

Available In: SJM Confirm™ devices

Accessed From: Parameters button > Monitor Settings tab > Detection Inhibitors button

Calibrate Activity

The Calibrate Activity button clears the automatically determined activity sensor threshold. After clearing, the device uses the next 30 seconds of sensor data to establish a new activity threshold, so the patient should remain at rest for 30 seconds. The activity sensor threshold is continuously updated and is based on the most recent 18 hours of activity sensor data.

Available In: SJM Confirm™ devices

Accessed From: Parameters button > Monitor Settings tab > Detection Inhibitors button

Confirm Rx and Jot Dx Parameter Settings

The Parameters Settings window shows most of the programmable parameters divided into groups. Select a button to change parameters settings. The buttons are:

- Episode & Alert Type (page 22)
- Detection Qualifiers (page 23)
- Sensing (page 23)

Available In: Confirm Rx™ and Jot Dx™ devices

Accessed From: Parameters button

Episode & Alert Type

- AF Duration (page 22)
- Tachy Cutoff Rate (page 22)
- Tachy Count (page 22)
- Brady Cutoff Rate (page 22)
- Pause Duration (page 22)

Available In: Confirm Rx™ and Jot Dx™ devices

AF Duration ICM

The AF Duration parameter determines the shortest AF episode that will be stored.

Settings: (min) 0.5; 1; 2; 6; 10; 20; 30; 60 (Nominal: 2)

Available In: Confirm Rx™ and Jot Dx™ devices

Accessed From: Parameters button > Episode & Alert Settings > AF Episode > AF Episode & Alert Detection

Tachy Cutoff Rate

The Tachy Cutoff Rate parameter determines the rate that must be exceeded for a programmed number of intervals (Tachy Count (page 22)) to trigger episode storage.

Settings: (min^{-1}) 120; 125; … 250 (Nominal: 180)

Available In: ConfirmRx™ and JotDx™ devices

Accessed From: Parameters button > Episode & Alert Settings > Tachy Episode > Tachy Detection

Tachy Count

The Tachy Count parameter sets the number of intervals that must be faster than the Tachy Cutoff Rate (page 22) to trigger episode storage.

Settings: 8; 9; … 25; 30; … 50 (Nominal: 12)

Available In: Confirm Rx™ and Jot Dx™ devices

Accessed From: Parameters button > Episode & Alert Settings > Tachy Episode > Tachy Detection

Brady Cutoff Rate

The Brady Cutoff Rate parameter determines the rate at which four intervals at slower rates trigger episode storage.

Settings: (min^{-1}) 30; 40; 50 (Nominal: 30)

Available In: Confirm Rx™ and Jot Dx™ devices

Accessed From: Parameters button > Episode & Alert Settings > Brady Episode > Brady Detection

Pause Duration

The Pause Duration parameter determines the length of time allowed without the detection of intrinsic rhythm before episode storage is triggered.

Settings: (s) 2.0; 3.0; … 8.0 (Nominal: 3.0)

Available In: Confirm Rx™ and Jot Dx™ devices

Accessed From: Parameters button > Episode & Alert Settings > Pause Episode > Pause Detection

AF Alerts

The AF Episode & Alert Detection window allows you to set the conditions for monitoring and notifying the patient of AF conditions. The alerts include:

- **Continuous AF**. The length of time a patient is in AF before triggering the alert.
- **AF Burden**. The time in AF for a given evaluation period.
- **V Rate During AF**. The ventricular rate above which monitoring and notification occurs and the duration of the high ventricular rates.

Available In: Confirm Rx™ and Jot Dx™ devices

Accessed From: Parameters button > Episode & Alert Settings > AF Episode > AF Episode & Alert Detection

DirectAlerts™ Notification

Merlin.net™ PCN DirectAlerts™ notifications are customizable through the Merlin.net portal only. For information on direct alerts, refer to the Merlin.net Patient Care Network Arrhythmia and Device Management Application help manual.

Detection Qualifiers

From the Detection Qualifiers window, you can change the settings for the following parameters:

- Bigeminy Qualifier (page 23)
- Sudden Onset (page 23)
- Onset Delta (page 23)
- Arrhythmia Detection during Activity (page 23)

Available In: Confirm Rx™ and Jot Dx™ devices

Bigeminy Qualifier

The Bigeminy Qualifier parameter enables an algorithm that requires more intervals to be identified as tachyarrhythmia intervals than sinus intervals before episode storage is triggered.

Settings: On; Off (Nominal: Off)

Available In: Confirm Rx™ and Jot Dx™ devices

Accessed From: Parameters button > Detection Qualifiers

Sudden Onset

The Sudden Onset parameter enables a discriminator that distinguishes between VT (abrupt onset) and sinus tachycardia (gradual onset) in patients whose maximum sinus rates can exceed their slowest ventricular tachyarrhythmia rates ("rate overlap").

The nominal value of the Sudden Onset parameter is set based on the Reason for Monitoring (page 5).

Settings: Off; On

Available In: Confirm Rx™ and Jot Dx™ devices

Accessed From: Parameters button > Detection Qualifiers

Onset Delta

The Onset Delta parameter determines the abruptness of a tachycardia's onset. When the percentage of change in the measured interval is equal to or greater than the programmed Onset Delta setting, the Sudden Onset discriminator (page 23) classifies the rhythm as VT and the event triggers episode storage.

Settings: (%) 4; 6; … 86 (Nominal: 18)

Available In: Confirm Rx™ and Jot Dx™ devices

Accessed From: Parameters button > Detection Qualifiers

NOTE: A larger Onset Delta percentage decreases the chance that the device indicates tachycardia.

Arrhythmia Detection during Activity

The Arrhythmia Detection during Activity parameter enables an algorithm that determines if sensed events are activity. When activity is detected and the Arrhythmia Detection during Activity setting is:

Off. Arrhythmias will not be detected when the patient is active.

On. Arrhythmias will be detected and stored as configured when the patient is active.

See also Markers (page 6).

Settings: On; Off (Nominal: On)

Available In: Confirm Rx™ and Jot Dx™ devices

Accessed From: Parameters button > Detection Qualifiers

Calibrate Activity

The Calibrate Activity button clears the automatically determined activity sensor threshold. After clearing, the device uses the next 30 seconds of sensor data to establish a new activity threshold, so the patient should remain at rest for 30 seconds. The activity sensor threshold is continuously updated and is based on the most recent 18 hours of activity sensor data.

Available In: Confirm Rx™ and Jot Dx™ devices

Accessed From: Parameters button > Detection Qualifiers

Sensing

From the Sensing window, you can change the settings for the following parameters:

- EGM Dynamic Range (page 23)
- Max Sensitivity (page 24)
- Sense Refractory Period (page 24)
- Sense Refractory Decay Delay (page 24)
- Threshold Start (page 24)

Available In: Confirm Rx™ and Jot Dx™ devices

EGM Dynamic Range

The EGM Dynamic Range parameter determines the maximum amplitude displayed when VEGM is the EGM source configuration setting.

See EGM Configuration (page 9) and Ventricular Sensing Example (page 24).

Settings: (mV) ±0.2; ±0.4; ±0.8; ±1.6 (Nominal: ±0.8)

Available In: Confirm Rx™ and Jot Dx™ devices

Accessed From: Parameters button > Sensing

Max Sensitivity

The Max Sensitivity parameter determines the minimum amplitude of sensed signals used for sensing. The settings available are dependent upon the setting of the EGM Dynamic Range parameter (page 23).

See Ventricular Sensing Example (page 24).

Table 6. Settings

EGM Dynamic Range	Max Sensitivity Settings (mV)	Nominal
±1.6	0.15; 0.175; 0.20; 0.225; 0.25; 0.30; 0.35; 0.40; 0.45; 0.50; 0.60; 0.70; 0.80	--
±0.8 (nominal)	0.075; 0.10; 0.125; 0.15; 0.175; 0.2; 0.225; 0.25; 0.30; 0.35; 0.40	0.125mV [27]
±0.4	0.05 [28]; 0.075; 0.10; 0.125; 0.15; 0.175; 0.20	--
±0.2	0.05 [29]; 0.075; 0.10	--

Available In: Confirm Rx™ and Jot Dx™ devices

Accessed From: Parameters button > Sensing

Sense Refractory Period

The Sense Refractory Period parameter determines the amount of time after a sensed event during which the device ignores subsequent sensed events.

See Ventricular Sensing Example (page 24).

Settings: (ms) 125;150; … 400 (Nominal: 250)

Available In: Confirm Rx™ and Jot Dx™ devices

Accessed From: Parameters button > Sensing

Sense Refractory Decay Delay

The Sense Refractory Decay Delay parameter determines the amount of time after the Sense Refractory Period (page 24) that the threshold remains at the programmed Threshold Start (page 24) setting before beginning its decay. Increasing the Decay Delay may prevent oversensing.

See Ventricular Sensing Example (page 24).

Settings: (ms) 0; 30; 60; 95; 125; 160; 190; 220 (Nominal: 60)

Available In: Confirm Rx™ and Jot Dx™ devices

Accessed From: Parameters button > Sensing

Threshold Start

The Threshold Start parameter determines the threshold at which events are sensed following the Sense Refractory Period (page 24) for a sensed event. This threshold is a percentage of the maximum peak amplitude sensed during the previous Sense Refractory Period. Threshold Start can be used to prevent oversensing.

After a sensed event, the device determines the maximum amplitude signal detected during the Sense Refractory Period. Upon expiration of the Sense Refractory Period, the sensing threshold automatically adjusts to the higher of either the Threshold Start or a percentage of that maximum amplitude with an absolute maximum value of the EGM Dynamic Range setting (page 23).

See Ventricular Sensing Example (page 24).

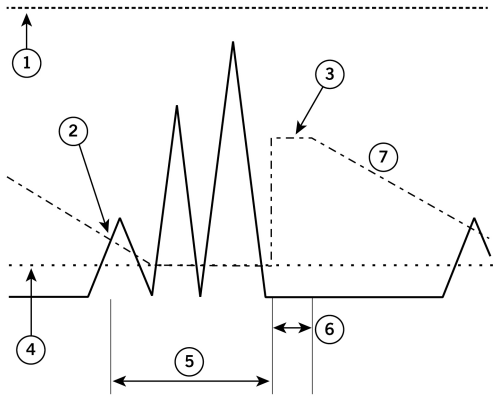
Settings: (%) 50; 62.5; 75; 100 (Nominal: 75)

Available In: Confirm Rx™ and Jot Dx™ devices

Accessed From: Parameters button > Sensing

Ventricular Sensing Example

Figure 3. An example of ventricular sensing for Confirm Rx™and Jot Dx™ devices



1. EGM Dynamic Range (page 23)
2. Sensed R-wave
3. Threshold Start (page 24)
4. Max Sensitivity (page 24)
5. Sense Refractory Period (page 24)
6. Decay Delay (page 24)
7. The sensing threshold determined by the automatic sensitivity control algorithm (dashed line). You can view the sensing threshold on the Rhythm Display (page 5), Rhythm Display (page 5). See EGM Configuration (page 9).

[27] Nominal of 0.125mV is based on EGM Dynamic range nominal setting of ±0.08.

[28] Max sensitivity setting of 0.05 mV may be more susceptible to false sensed events.

[29] Max sensitivity setting of 0.05 mV may be more susceptible to false sensed events.

SJM Confirm Episode Settings

The Episode Settings window shows most of the programmable episode parameters divided into two groups:

- Auto Activated Settings (page 25)
- Patient Activated Settings (page 26)

Available In: SJM Confirm™ devices

Accessed From: Parameters button > Episode Settings tab

Auto Activated Settings

EGM Trigger Priority

For SJM Confirm™ devices, you can use the EGM Trigger Priority parameters to prioritize episode triggers for EGM storage. The priority determines the number of EGMs stored for each episode trigger.

- **Off.** No EGMs are stored for an episode trigger.
- **Low**. At least one EGM is stored for an episode trigger. However, if a new trigger occurs after the memory is full, the device overwrites old episodes with an equal or higher priority.
- **High**. At least one EGM is stored for an episode trigger. Additional EGMs are stored for an episode trigger if there is space available in the device memory. Once the stored EGM memory is full, a new EGM for storage replaces the oldest stored EGM.

  NOTE: Only stored EGMs with a high priority setting are transmitted to the PA.

  NOTE: When a patient activated episode and an auto activated episode occur at the same time, the patient activated episode EGM takes precedence and is stored.

AF

The AF parameter triggers the storage of an EGM when an AF episode greater than the programmed AF Duration (page 18) is detected.

Available In: SJM Confirm™ (DM2102) devices

Settings: Off; Low; High (Nominal: High)

Accessed From: Parameters button > Episode Settings tab

Tachy

The Tachy parameter triggers the storage of an EGM when the intrinsic rate exceeds the Tachy Cutoff Rate (page 18) for the programmed number of intervals (Tachy Count (page 18)).

Settings: Off; Low; High (Nominal: Low)

Available In: SJM Confirm™ devices

Accessed From: Parameters button > Episode Settings tab

Brady

The Brady parameter triggers the storage of an EGM when the intrinsic rate is slower than the Brady Cutoff Rate (page 18) for four intervals.

Settings: Off; Low; High (Nominal: Low)

Available In: SJM Confirm™ devices

Accessed From: Parameters button > Episode Settings tab

Asystole

The Asystole parameter triggers the storage of an EGM when the Asystole duration (page 18) is exceeded without R-wave detection.

Settings: Off; Low; High (Nominal: High)

Available In: SJM Confirm™ devices

Accessed From: Parameters button > Episode Settings tab

Episode Settings

Using the Auto Activated Episode Settings, you can change the settings for the following parameters:

- Pre-Trigger Duration (page 25)
- Post-Trigger Duration (page 26)
- AF EGM Inhibit (page 26)

Available In: SJM Confirm™ devices

Accessed From: Parameters button > Episode Settings tab

Pre-Trigger Duration

The Pre-Trigger Duration parameter determines the amount of time recorded before non-patient activated episode storage.

See EGM Trigger Priority (page 25), EGM Trigger Priority (page 26).

Settings: (s) 10; 20; … 60 (Nominal: 20)

Available In: SJM Confirm™ devices

Accessed From: Parameters button > Episode Settings tab

Post-Trigger Duration

The Post-Trigger Duration parameter determines the amount of time recorded after non-patient activated episode storage.

See EGM Trigger Priority (page 25), EGM Trigger Priority (page 26).

Settings: (s) 10; 20; … 60 (Nominal: 20)

Available In: SJM Confirm™ devices

Accessed From: Parameters button > Episode Settings tab

AF EGM Inhibit

The AF EGM Inhibit parameter determines an absolute refractory period immediately following storage of an AF episode.

Available In: SJM Confirm™ (DM2102) devices

Settings: Off; 15 min; 30 min; 1 hr; 6 hr; 12 hr; 24 hr (Nominal: Off)

Accessed From: Parameters button > Episode Settings tab

Patient Activated Settings

In SJM Confirm™ devices, the patient activated episodes are stored when the Patient Activator is placed over the implanted device and EGM storage is manually initiated. Using the Patient Activated Episode Settings, you can change the settings for the following parameters:

- EGM Trigger Priority (page 25), EGM Trigger Priority (page 26)
- Pre-Trigger Duration (page 26)
- Post-Trigger Duration (page 25)
- Number of Stored EGMs (page 26)

Episode Settings

EGM Trigger Priority

The Patient Activated parameter triggers the storage of an EGM when the Patient Activator is placed over the implanted device and EGM storage is manually initiated. When this parameter is set to High, patient activated EGMs are stored for an episode trigger and have the highest priority over other types of episodes. When this parameter is set to Off, EGMs are not stored for a patient activated episode.

Settings: Off; High (Nominal: High)

Available In: SJM Confirm™ devices

Accessed From: Parameters button > Episode Settings tab

Pre-Trigger Duration

The Patient Activated Pre-Trigger Duration parameter determines the amount of time recorded before patient activated episode storage. This parameter is only available when EGM Trigger Priority (page 25), EGM Trigger Priority (page 26) is set to High.

See EGM Trigger Priority (page 25), EGM Trigger Priority (page 26).

Settings: (s) 60; 70; … 240 (Nominal: 240)

Available In: SJM Confirm™ devices

Accessed From: Parameters button > Episode Settings tab

Post-Trigger Duration

The Patient Activated Post-Trigger Duration parameter determines the amount of time recorded after patient activated episode storage. This parameter is only available when EGM Trigger Priority (page 25), EGM Trigger Priority (page 26) is set to High.

See EGM Trigger Priority (page 25), EGM Trigger Priority (page 26).

Settings: (s) 30; 40; 50; 60 (Nominal: 60)

Available In: SJM Confirm™ devices

Accessed From: Parameters button > Episode Settings tab

Number of Stored EGMs

The Number of Stored EGMs panel displays the number of patient activated stored EGMs. The number of stored EGMs changes according to the Episode Settings parameters (page 25). This panel is only displayed when EGM Trigger Priority (page 25), EGM Trigger Priority (page 26) is set to High.

Settings: First 9; ... First 30 (Nominal: First 9). (Nonprogrammable. The setting is automatically chosen depending on the Episode Settings.)

Available In: SJM Confirm™ devices

Accessed From: Parameters button > Episode Settings tab

Confirm Rx and Jot Dx Stored EGM Settings

The Stored EGM Settings window shows most of the programmable episode parameters divided into two groups:

- Auto Activated Settings (page 27)
- Symptom Settings (page 28)

Available In: Confirm Rx™ and Jot Dx™ devices

Accessed From: Parameters button > Episode & Alert Type > Stored EGM Settings

Auto Activated Settings

EGM Trigger Priority

For Confirm Rx™ and Jot Dx™ devices, you can use the EGM Trigger Priority parameters to prioritize episode triggers for EGM storage. The priority determines the number of EGMs stored for each episode trigger.

- **Off.** No EGMs are stored for an episode trigger. You can set the value to Off through the Monitoring column.
- **Low**. At least one EGM is stored for an episode trigger. However, if a new trigger occurs after the memory is full, the device overwrites old episodes with an equal or higher priority.
- **High**. At least one EGM is stored for an episode trigger. Additional EGMs are stored for an episode trigger if there is space available in the device memory. Once the stored EGM memory is full, a new EGM for storage replaces the oldest stored EGM.

  NOTE: All new EGMs are transmitted to the app.

  NOTE: When a symptom episode and an auto activated episode occur at the same time, the symptom episode EGM takes precedence and is stored.

  NOTE: The nominal values of the EGM Trigger Priority parameters are set based on the Reason for Monitoring (page 5).

AF

The AF parameter triggers the storage of an EGM when an AF episode greater than the programmed AF Duration (page 22) is detected.

Settings: Off; Low; High

Available In: Confirm Rx™ and Jot Dx™ devices

Accessed From: Parameters button > Episode & Alert Type > EGM Trigger Priority

Tachy

The Tachy parameter triggers the storage of an EGM when the intrinsic rate exceeds the Tachy Cutoff Rate (page 22) for the programmed number of intervals (Tachy Count (page 22)).

Settings: Off; Low; High

Available In: Confirm Rx™ and Jot Dx™ devices

Accessed From: Parameters button > Episode & Alert Type > EGM Trigger Priority

Brady

The Brady parameter triggers the storage of an EGM when the intrinsic rate is slower than the Brady Cutoff Rate (page 22) for four intervals.

Settings: Off; Low; High

Available In: Confirm Rx™ and Jot Dx™ devices

Accessed From: Parameters button > Episode & Alert Type > EGM Trigger Priority

Pause

The Pause parameter triggers the storage of an EGM when the Pause Duration (page 22) is exceeded without R-wave detection.

Settings: Low; High

Available In: Confirm Rx™ and Jot Dx™ devices

Accessed From: Parameters button > Episode & Alert Type > EGM Trigger Priority

Stored EGM Settings

Using the Stored EGM Settings, you can change the settings for the following parameters:

- AF Pre-Trigger Duration (page 27)
- AF Post-Trigger Duration (page 27)
- Other Pre-Trigger Duration (page 28)
- Other Post-Trigger Duration (page 28)

Available In: Confirm Rx™ and Jot Dx™ devices

Accessed From: Parameters button > Episode & Alert Type > Stored EGM Settings

AF Pre-Trigger Duration

The AF Pre-Trigger Duration parameter determines the amount of time recorded before an AF episode is detected.

See EGM Trigger Priority (page 27).

Settings: (s) 10; 20;… 60 (Nominal: 30)

Available In: Confirm Rx™ and Jot Dx™ devices

Accessed From: Parameters button > Episode & Alert Type > Stored EGM Settings

AF Post-Trigger Duration

The AF Post-Trigger Duration parameter determines the amount of time recorded after an AF episode is detected.

See EGM Trigger Priority (page 27).

Settings: (s) 10; 20; 30, 60… 120 (Nominal: 120)

Available In: Confirm Rx™ and Jot Dx™ devices

Accessed From: Parameters button > Episode & Alert Type > Stored EGM Settings

Other Pre-Trigger Duration

The Other Pre-Trigger Duration parameter determines the amount of time recorded before a tachy, brady, or pause episode is detected.

See EGM Trigger Priority (page 27).

Settings: (s) 10; 20; … 60 (Nominal: 30)

Available In: Confirm Rx™ and Jot Dx™ devices

Accessed From: Parameters button > Episode & Alert Type > Stored EGM Settings

Other Post-Trigger Duration

The Other Post-Trigger Duration parameter determines the amount of time recorded after a tachy, brady, or pause episode is detected.

See EGM Trigger Priority (page 27).

Settings: (s) 10; 20; … 60 (Nominal: 30)

Available In: Confirm Rx™ and Jot Dx™ devices

Accessed From: Parameters button > Episode & Alert Type > Stored EGM Settings

Symptom Settings

EGM Trigger Priority

For Confirm Rx™ and Jot Dx™ devices, symptom episodes are stored when the patient records their symptoms using the app. The Symptom EGM Trigger Priority parameter is fixed to High.

Stored EGM Settings

Using the Stored EGM Settings, you can change the settings for the following parameters:

- Symptom Pre-Trigger Duration
- Symptom Post-Trigger Duration
- Number of Stored EGMs

Available In: Confirm Rx™ and Jot Dx™ devices

Accessed From: Parameters button > Episode & Alert Type > Stored EGM Settings

Symptom Pre-Trigger Duration

The Symptom Pre-Trigger Duration parameter determines the amount of time recorded before a symptom episode is stored.

Settings: (min) 4; 6; … 14 (Nominal: 8)

Available In: Confirm Rx™ and Jot Dx™ devices

Accessed From: Parameters button > Episode & Alert Type > Stored EGM Settings

Symptom Post-Trigger Duration

The Symptom Post-Trigger Duration parameter determines the amount of time recorded after a symptom episode is stored.

Settings: (s) 30; 40; 50; 60 (Nominal: 60)

Available In: Confirm Rx™ and Jot Dx™ devices

Accessed From: Parameters button > Episode & Alert Type > Stored EGM Settings

Number of Stored EGMs

The Number of Stored EGMs panel displays the number of stored EGMs for symptom episodes. The number of stored EGMs changes according to the Stored EGM Settings parameters.

Settings: First 4; ... First 13 (Nominal: First 9). (Nonprogrammable. The setting is automatically chosen depending on the Episode & Alert Settings.)

Available In: Confirm Rx™ and Jot Dx™ devices

Accessed From: Parameters button > Episode & Alert Type > Stored EGM Settings

Wrap-Up™ Overview

The Wrap-up™ Overview window provides a place for your final review of session activities and includes the following:

- **Battery Information panel**. Shows the estimated battery longevity [30] and a battery capacity status bar.
- **Signal Amplitude panel**. Shows the measured R-wave amplitude.
- **Session Notes panel**. Reports the status of routine follow-up tasks.
- **Programming Changes**. Lists all changes in programmed parameter settings.
- **Selected Reports button**. Lists the reports that have been selected to print and opens the Print Menu window (page 31).
- **Restore Initial Values button** (page 29)
- **Clear Trend button** [31]
- **Export Data button** (page 29)
- **Clear Diagnostics button** (page 29)
- **Clear After Printing check-box**. Automatically clears the selected diagnostics after printing.
- **Print Reports button**. Prints all reports listed in the Selected Report button.

Accessed From: Wrap-up Overview button

Restore Initial Values

The Restore Initial Values button reprograms the settings that were read at the initial interrogation. When you press the Program button, all parameter changes made during the session are lost.

Accessed From: Wrap-up Overview button > Restore Initial Values button

Clear Trend

The Clear Trend button clears the AF Diagnostics data (page 16) (including the AF Burden trend data), Heart Rate histogram (page 16), episode data, and stored EGMs from the device memory.

Available In: SJM Confirm™ (DM2102) devices

Accessed From: Wrap-up Overview button > Clear Trend button

Export Data

The Export Data window lists the data formats available for export. To export data:

1. Insert the USB connector from a media device into one of the three USB ports on the programmer.
2. Select the Export Data button.
3. Select the format for the exported data.
4. Select the desired media device. If a media device hasn't been detected, select the Redetect Media button.
5. Select the Export button.

If you are using a Merlin™ 2 PCS programmer model MER3700, you can use a six-digit Personal Identification Number (PIN) when exporting data. Avoid the following when creating the PIN:

- Repeating a number six times in succession, for example 555555
- Consecutive numbers in either ascending or descending order, for example 123456 or 654321

  NOTE:
  - Document the PIN you selected. The PIN will be required later to access the data from the media device.
  - On Merlin 2 PCS programmers, you can select your Data Export preferences from Tools > Maintenance > Special Functions > Data Export Options.
  - If you need assistance importing data into a computer database, contact Technical Support.

Accessed From: Wrap-up Overview button > Export Data button

Clear Diagnostics

In SJM Confirm™ devices, from the Clear Diagnostics window you can selectively clear episode data and stored EGMs, and the Heart Rate histogram (page 16) from the device memory.

In Confirm Rx™ and Jot Dx™ devices, from the Clear Diagnostics window you can clear episode data and stored EGMs, diagnostics, and AF Burden trend data.

Select the Save Selections button to store your preferences for future programming sessions.

Accessed From: Wrap-up Overview button > Clear Diagnostics button

[30] Available in SJM Confirm devices only.
[31] Available in SJM Confirm devices only.

Additional Programming Information

Contents:

Technical Support

Abbott Medical maintains 24-hour phone lines for technical questions and support:

- 1 818 362 6822
- 1 800 722 3774 (toll-free within North America)
- + 46 8 474 4147 (Sweden)
- + 61 2 9936 1200 (Australia)
- medical.abbott/manuals

For additional assistance, call your local Abbott Medical representative.

If, in the course of use of this device, you have reason to believe that a serious incident occurred, please report it to the manufacturer. For customers in the European Union, report the serious incident to your national authority as well as to the manufacturer.

Supported Devices

The devices listed in the table below are supported by the Merlin™ Patient Care System equipped with Model 3330 Software or the Merlin 2 Patient Care System with MER3400 software.

Table 7. Supported devices

Name	Model Number
SJM Confirm™ (page 32)	DM2102 (only available on the Merlin PCS programmer)
Confirm Rx™	DM3500
Jot Dx™ (page 35)	DM4500

Main Programming Window

The Main Programming window is the upper portion of the screen that contains the following:

- **? button**. Opens the on-screen help menu.
- **Tools menu** (page 2). Opens a menu for preferences and other functions.
- **Monitor Enable/Disable button** (page 30). Opens a window to temporarily disable data collection.
- **Patient Information button** (page 11). Opens a window to write and edit patient information into the device memory.
- **Note button** (page 11). Opens a window for additional patient data.
- **Measured Heart Rate**
- **Rhythm Display** (page 5), **Rhythm Display** (page 5). Shows the real-time waveforms.
- **Adjust Display button** (page 8). Opens a window to adjust the Rhythm Display.
- **Freeze Capture button** (page 9). Freezes the Rhythm Display and opens a window to adjust and print the frozen waveform.
- **Print Settings button** (page 31). Opens the Print Settings window. An icon without a cord indicates the programmer is using the internal printer (only available on the 3650 programmer). An icon with a cord indicates the programmer is connected to an external printer (see figure below). The PDF icon indicates that a PDF report is available for export. See PDFs (page 3). To change printers, select Tools > Preferences > Printer (Printer Preferences (page 3)).

Figure 4. Printer icons

1. Internal printer in use (only available on the 3650 programmer)
2. External printer connected
3. Paperless or PDF printing selected

Monitor Enable/Disable

Select the Monitor Enable/Disable button on the main programming window to temporarily disable data collection. This is useful for noise-generating medical procedures such as electrocautery, where the device could detect noise from the equipment, interpret it as an arrhythmic episode, and record an EGM and episode data.

- **Monitoring is Disabled**. The device cannot detect and diagnose an arrhythmic episode. Diagnostic data are not updated or cleared.

- **Monitoring is Enabled**. The device can detect and diagnose episodes and diagnostic data is updated.

Since the previously programmed parameters are stored in the device, it is not necessary to use the same programmer to disable and enable monitoring.

Accessed From: Main Programming window

NOTE: In SJM Confirm™ devices, when monitoring is disabled and you initiate data recording with the PA, the PA responds as if it has successfully recorded data, however no data is recorded.

Device Parameters and Settings Selection

To change the setting for any parameter, select the desired parameter button. A setting selection window appears. The range of settings is usually indicated at the top and bottom of the scroll bar. The current permanently programmed setting is marked with a small device icon.

Select the desired setting. Once a setting is selected, you can select the following buttons:

- **Program** permanently programs the setting.
- **Preview** opens the Preview window containing the manually selected and autoprogrammed settings.
- **Discard Changes** on the Preview window removes the changes and retains the programmed parameter settings.

Console Buttons

The console has two emergency buttons, the Shock button and the VVI button. These buttons are not supported by the monitoring devices.

Print Menu

The Print Menu window contains two tabs:

- Reports (page 31)
- Settings (page 31)

To send the image to an external printer, go to the Tools Menu > Preferences > Printer tab and select the External button.

Reports

The Reports window allows you to select or deselect any report in the print queue.

To choose a report to print, select the check-box on the left. Select the button to the right of the Episodes checkbox to choose episodes for printing. Select the button to the right of the Freeze Captures checkbox (page 9) to choose freeze captures for printing.

The Discard Pending button clears the reports in the print queue.

Accessed From: Print button > Reports tab

Settings

The Settings window allows you to set print preferences.

Select the Printer Preferences button (page 3) to change the report destination (internal or external printer) and the number of copies of each report.

Select the appropriate check-mark boxes to:

- Add the patient's name to the printed report headers. The information comes from the device's memory and is entered in the Patient Information window (page 11).
- Add the Clinic Name to the printed report header. Select the blue button to open the on-screen keyboard to enter the information into the programmer's memory.
- Automatically print the Summary Report on initial interrogation.

Accessed From: Wrap-Up Overview button > Selected Reports button > Settings tab or Main Programming window > Print Menu button > Settings tab

Hardware Reset

If the microprocessor in the device ceases to function, the device operates in Hardware Reset mode, independent of software function. This is different from a device software reset. Contact Abbott Medical immediately if a hardware reset occurs.

When the device operating in the Hardware Reset mode is interrogated, a message shows that a hardware reset has been detected. The monitoring function of the device is disabled.

The reset settings are listed with the Technical Data for each of the Supported Devices (page 30).

SJM Confirm Devices Technical Data

The tables below are applicable to the following SJM Confirm™ device models:

- SJM Confirm DM2102

The technical data below include:

- Physical Specifications (page 32)
- Battery Specifications (page 32)
- Reset Settings (page 32)
- X-ray Identification (page 33), X-ray Identification (page 37)

Physical Specifications

Table 8. Physical specifications for SJM Confirm™ devices

Specification [32]	**Data**
Dimensions (h x l x t) (cm)	5.6 x 1.8 x 0.8
Weight (g)	12
Displacement volume ($cm^{3)}$	6.5
Surface area of can electrode (mm^2)	76
Surface area of header electrode (mm^2)	30
Shortest distance between electrodes (mm)	39
Can and electrode material	Titanium
Header material	Epoxy
Coating	Parylene
Noise detection rate	100 or more sensed events per second

Battery Specifications

Table 9. Battery voltage for SJM Confirm™ devices

Parameter	**Data**
Manufacturer	Eagle Picher
Model	LTC-3PN
Chemistry	Lithium-thionyl chloride
Number of cells	One cell
Battery voltage (beginning of service)	3.60 V
Elective replacement voltage (ERI)	3.30 V
End-of-service voltage (EOS)	3.00 V
Longevity (after 12 months shelf life)	3 years

Reset Settings

Table 10. Reset settings for SJM Confirm™ devices

Parameter	**Software**
Monitor Enable/Disable	As programmed
AF Duration (min)	2
Tachy Cutoff Rate (min^{-1})	180
Tachy Count (intervals)	12
Brady Cutoff Rate (min^{-1})	50
Asystole Duration (s)	3.0
Bigeminy Qualifier	Off
Sudden Onset	Off

[32] The dimensions, weight, and displacement volume are nominal values based on engineering model measurements.

Table 10. Reset settings for SJM Confirm™ devices

Parameter	Software
Onset Delta (%)	18
Interval Stability	Off
Stability Delta	80
Stability Window (intervals)	12
EGM Dynamic Range (mV)	± 0.72
Max Sensitivity (mV)	0.19
Sense Refractory Period (ms)	250
Decay Delay (ms)	60
Threshold Start (%)	75
Noise Response	Inhibit
Activity Response	Monitor
Auto Pre-trigger Duration (s)	20
Auto Post-trigger Duration (s)	20
Patient Activated Pre-trigger Duration (s)	240
Patient Activated Post-trigger Duration (s)	60
AF EGM Inhibit	OFF
EGM Trigger: AF	High
EGM Trigger: Tachy	Low
EGM Trigger: Brady	Low
EGM Trigger: Asystole	High
EGM Trigger: Patient Activated	High

X-ray Identification

Table 11. X-ray ID codes for SJM Confirm™ devices

Device Model	X-ray ID Model Code
DM2102	AM

SJM Confirm Devices Clinician Use Information

Contents:

Patient Selection

Before implanting a device, assess the patient's current and anticipated clinical needs and select a device that fulfills those needs.

Patient Counseling Information

Physicians should consider the following in counseling the patient about this device:

- Give the patient a copy of the Patient Activator manual, which includes instructions for using the Patient Activator. Go over the manual with the patient. Explain which symptoms he or she should record.
- Encourage patients to use ID cards (issued by Abbott Medical) and/or ID bracelets documenting their implanted system.

Implanting The Device

Due to the nature of the implantation procedure, the physician and support staff should be familiar with all of the components of the system and the material in this manual before beginning the procedure.

Implant Preparation

You can determine an optimal device implant site and orientation before implanting the device with surface ECG measurements in the locations and orientations of interest. Use standard surface ECG electrodes and an ECG measurement system such as the Merlin™ PCS or Merlin™ 2 PCS with the ECG cables.

Consider the following when selecting the implant site:

- Observe the desired R-wave, P-wave, and T-wave visibility.
- Minimal device movement due to body and arm movement. An implant site parallel to the midline, closer to the sternum and away from the lower half of the pectoral region and breast area may help minimize device movement. Also, consider patient comfort.

Choosing the Implant Site

General Site Mapping

Mapping may be beneficial to determine the best location for the ICM based on surface R-wave measurements. To determine the best location:

1. Set up the programmer or 12-lead ECG to view Leads I and II in the real-time display.
2. Place the Right Leg (RL) electrode on the torso and either the electrodes from Option 1 or Option 2 as shown in the figure below.
3. Print a real-time tracing and check the ECG for R-wave amplitude, and R-wave/T-wave ratio.
4. Note the best electrode configuration or use a skin marker to indicate the preferred electrode position before surgical prep.

   NOTE: Place the conductive portion of the ECG pads 4 cm apart. This distance approximates the SJM Confirm ICM interelectrode spacing.

Option 1: Mapping in the V2-V3 Location

There are two mapping locations within V2-V3:

- Vertical
- Angled

Mapping in the V2-V3 Location - Vertical

The preferred mapping location is between the parasternal line and the midclavicular line.

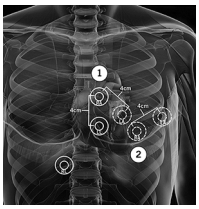
1. Place the Right Arm (RA) electrode about 2.5 cm from the inferior sternum and approximately 1 cm to the patient's left.
2. Place the Left Leg (LL) electrode vertically underneath the Right Arm (RA) electrode as shown in the figure below.

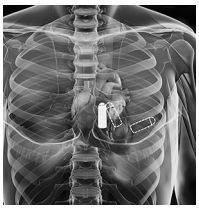
Mapping in the V2-V3 Location - Angled

1. Follow the instructions in section Mapping in the V2-V3 Location- Vertical above.
2. Place the Left Arm (LA) electrode about 4 cm along a lead II vector slanting downward from the patient's right shoulder. This may result in improved signal amplitude in some patients.

Option 2: Mapping in the Apical Location

Figure 5. Mapping options 1 and 2





1. Option 1
2. Option 2

Another mapping location is anterolateral, inframammary between the 5th and 6th ribs.

1. Place the Right Arm (RA) electrode and the Left Arm (LA) electrode as shown in the figure above.

For more information see:

van Dam P, van Groeningen C, Houben RP, et al. Improving sensing and detection performance in subcutaneous monitors. J Electrocardiol. 2009;42:580-3.

Chrysostomakis, S. I., N. C. Klapsinos, E. N. Simantirakis, M. E. Marketou, and P. E. Vardas. 2003. Sensing issues related to the clinical use of implantable loop recorders. Eurospace 2003;5:143-148.

Forming the Pocket and Inserting the Device

1. Create a subcutaneous pocket that is slightly narrower than the width of the device.

   WARNING: For reliable data transmission, implant the device at a depth not to exceed 4 cm.
2. Insert the device into the pocket so that the can end of the device enters the pocket first. Orient the device such that the header electrode faces away from the body and the can electrode faces the muscle.

   The device should enlarge the pocket to create a snug fit.
3. Place the programming wand over the device to confirm adequate R-wave detection and to ensure there is no inappropriate T-wave sensing.
4. Use both suture holes in the device header to secure the device in the pocket to minimize device movement within the pocket and promote sensing and episode detection.

   One suture hole is located behind the header electrode on the side of the header facing the muscle. The other suture hole is located on side of the header facing away from the body.
5. Close the pocket.
6. Select programmable parameters and program the device.
7. Clear any stored EGMs and episode data from the device.

See Clear Diagnostics (page 29).

Confirm Parameter Settings

At the end of the programming session, interrogate the device and confirm that the final parameter settings are correct.

Implant/Patient Registration Form

Fill out and return both the Implant/Patient Registration Form and the device registration card to register the patient and facilitate patient tracking.

Patient Follow-up

Patients should be seen for follow-up every three months. The frequency of follow-up visits depends on the patient's condition.

A follow-up visit should include (at a minimum):

- Review of the FastPath™ Summary screen
- Review of stored episodes and real-time EGMs
- Confirmation that the final parameter settings are correct.

See also:

- Battery Status (page 35), Battery Status (page 38)

Battery Status

The battery status is based on battery capacity, not battery voltage. It is determined primarily by device usage and is shown on the FastPath™ Summary window (page 11) and on the Wrap-up™ Overview window (page 29). The battery voltage measurement (see Real-Time Measurements (page 17)) should be used as a secondary indicator of battery status.

See also Battery Specifications (page 32).

Explanting the Device

WARNING: Before explanting the device program the device Off. In the event of the patient's death, deactivate the device before post-mortem examination.

Before returning the explanted device to Abbott Medical, clean it with disinfectant solution, but do not submerge it.

WARNING: Devices contain sealed chemical power cells and therefore should never be incinerated.

Out-of-Service/Explant/Patient Death Form

Whenever a device is explanted, complete an Out-of-Service/Explant/Patient Death form and return it to Abbott Medical with the explanted products. If possible, send along a printout of the programmed settings of the device. For information on printing reports, see Print Reports.

SJM Confirm External Patient Activator

Contents:

- Reading Transmitted Data (page 35)

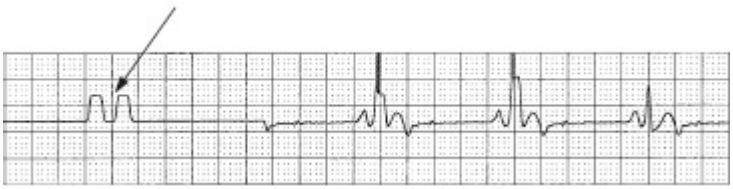
  NOTE: The PA and the programming wand should not be placed over the SJM Confirm device at the same time. Doing so may produce enough EMI to interfere with the operation of the device and the PA.

Reading Transmitted Data

ECG recordings transmitted by the PA contain distinctive markings that identify the beginning of an ECG. The PA holds a maximum of five minutes of ECG waveforms. Only waveform data is transmitted by the PA. Additional data such as the patient's name, device information, parameter settings, waveform markers, and date and time of events is retained in the implanted device and is only available when you interrogate the device with the programmer. The transmitted waveform data is also retained in the device and is available with the corresponding episode information.

Any additional information on the transmission report is generated by the service provider. Below is an example of transmitted data.

Figure 6. ECG separation marks



The EGMs Directory (page 13) on the programmer shows if an episode was uploaded to the PA.

Confirm Rx and Jot Dx Devices Technical Data

The tables below are applicable to the Confirm Rx™ model DM3500 device and the Jot Dx™ DM4500 device.

The technical data below include:

- Physical Specifications (page 36)
- Battery Specifications (page 36)
- Reset Settings (page 36)
- X-ray Identification (page 33), X-ray Identification (page 37)

Physical Specifications

Table 12. Physical specifications for Confirm Rx™ and Jot Dx™ devices

Specification [33]	Data
Dimensions (h x l x t) (mm)	49 x 9.4 x 3.1
Weight(g)	3.0
Displacement volume (cm^3)	1.4
Surface area of can electrode (mm^2)	105.9
Surface area of header electrode (mm^2)	10.8
Shortest distance between electrodes (mm)	39.85
Can and electrode material	Titanium
Header material	Polyurethane and epoxy
Coating	Parylene

Battery Specifications

Table 13. Battery voltage for Confirm Rx™ and Jot Dx™ devices

Parameter	Data
Manufacturer	Eagle Picher
Model	ICM Battery
Chemistry	CFx
Number of cells	One cell
Battery voltage (beginning of service)	3.40 V
Elective replacement voltage (ERI)	2.81 V
End-of-service voltage (EOS)	2.67 V
Longevity	2 years, under the usage scenarios: ▪ Average of 1 auto detected episode per day ▪ Average of 1 patient activated symptom episode per month ▪ Up to 6 month shelf storage time NOTE: At a maximum shelf storage time of 18 months, longevity is reduced by approximately 5 months.

Reset Settings

Table 14. Reset settings for Confirm Rx™ and Jot Dx™ devices

Parameter	Software
Monitor Enable/Disable	Enabled
AF Duration (min)	2
Tachy Cutoff Rate (min^{-1})	180
Tachy Count (intervals)	12
Brady Cutoff Rate (min^{-1})	50
Pause Duration (s)	3
Bigeminy Qualifier	Off
Sudden Onset	Off
EGM Dynamic Range (mV)	±0.8

[33] The dimensions, weight, and displacement volume are nominal values based on engineering model measurements.

Table 14. Reset settings for Confirm Rx™ and Jot Dx™ devices

Parameter	Software
Max Sensitivity (mV)	0.15
Sense Refractory Period (ms)	250
Decay Delay (ms)	62.5
Threshold Start (%)	75
Arrhythmia Detection during Activity	On
EGM Trigger: AF	High
AF Pre-trigger Duration (s)	30
AF Post-trigger Duration (s)	120
Other Pre-trigger Duration (s)	30
Other Post-trigger Duration (s)	30
Symptom Pre-trigger duration (min)	8
Symptom Post-trigger duration (s)	30
EGM Trigger: Tachy	Low
EGM Trigger: Brady	Low
EGM Trigger: Pause	High
EGM Trigger: Patient Activated	High

X-ray Identification

Table 15. X-ray ID code for Confirm Rx™ and Jot Dx™ devices

Device Model	X-ray ID Model Code
DM3500; DM4500	CC

Confirm Rx and Jot Dx Devices Clinician Use Information

Patient Counseling Information

Physicians should consider the following when counseling a patient about this device:

- Advise the patient not to touch the implant site.
- Give the patient a copy of the myMerlin Mobile Application User's Manual, which includes instructions for using the mobile device application.

  Go over the manual with the patient. Explain which symptoms the patient should record.
- Encourage the patient to use the ID card issued by Abbott Medical and/or an ID bracelet documenting their implanted system.

Implanting The Device

Due to the nature of the implantation procedure, the physician and support staff should be familiar with all of the components of the system and the material in this manual before beginning the procedure.

Choosing an Insertion Site

For recommended insertion sites, refer to the Confirm Rx™ User’s Manual or Jot Dx™ User's Manual. Before implanting the device, you can confirm the suitability of an insertion site or determine an alternative optimal device insertion site and orientation by performing surface ECG measurements in the locations and orientations of interest. Use standard surface ECG electrodes and an ECG measurement system such as the Merlin™ PCS or Merlin 2 PCS with the ECG cables. For instructions on how to use the programmer to perform this task, see General Site Mapping (page 34), General Site Mapping (page 37).

Consider the following desired signal characteristics when evaluating potential implant positions:

- High amplitude R-wave that demonstrates minimal variation in different patient positions, such as sitting versus lying down.
- High R-wave to T-wave ratio

General Site Mapping

Mapping may be beneficial to determine the best location for the device based on surface R-wave measurements, especially when considering an anterolateral, inframammary insertion location between the 5th and 6th ribs. To determine the best location that will suit the needs of the patient:

1. Set up the programmer or 12-lead ECG to view Lead I in the real-time display.
2. Place the Right Leg (RL) electrode on the torso and the Right Arm (RA) and Left Arm (LA) electrodes at the desired device location.
3. Print a real-time tracing and check the ECG for R-wave amplitude, and R-wave/T-wave ratio.

4. Note the best electrode configuration or use a skin marker to indicate the preferred electrode position before surgical prep.

   NOTE: Place the conductive portion of the ECG pads 4 cm apart. This distance approximates the Confirm Rx™ ICM and Jot Dx™ ICM interelectrode spacing.

Inserting the Device

1. Prior to opening the sterile packaging, apply a magnet to the Confirm Rx™ device or Jot Dx™ device for at least three seconds.
2. Use the programmer to interrogate the device.
3. Select a Reason for Monitoring and any other applicable information. You will be prompted to insert the device before continuing. See New Device (page 5).
4. Insert the device. Refer to the Confirm Rx User's Manual or Jot Dx User's Manual for insertion instructions.
5. Measure the R-wave amplitudes and observe the signal quality.
6. Consider body position and arm movement as part of this assessment. If signals are small or unstable, revise the device positioning.
7. Determine device sensing parameters to ensure there is adequate R-wave detection and no inappropriate oversensing of T-waves or P-waves.
8. The max sensitivity of the device should be selected in accordance with the smallest observed R-wave amplitudes.
9. Close the incision site.
10. Select programmable parameters and program the device.
11. Calibrate the activity sensor threshold.
12. Clear any stored EGMs and episode data from the device.

Atrial Fibrillation Detection Algorithm and Performance Statistics

The SJM Confirm™ implantable cardiac monitor, Model DM2102, and Confirm Rx™ insertable cardiac monitor detect AF episodes using an automatic detection algorithm that monitors for irregular ventricular rhythm, commonly known to occur during AF.

The algorithm uses Hidden Markov Chains and Euclidian distance calculations of similarity to assess the transitionary behavior of one R-wave (RR) interval to another and compare the patient's interval transitions to the known interval transitions during AF and non-AF episodes obtained from many patients. The algorithm uses additional rhythm discrimination criteria to reduce the frequency of false positives in AF detections due to other irregular rhythm types such as PACs, PVCs, bigeminy, etc.

The algorithm is capable of detecting AF episodes over a short number of RR intervals with high sensitivity. It has a positive predictive value for episodes >30 seconds as well as >120 seconds in duration.

The QRS detection performance of the DM2102 device was evaluated using well-known, publicly available arrhythmia databases that allow us to test the QRS detection performance over 285,000 beats.

Table 16. Device QRS detection performance results (%) [34]

	Se	PPV
Median	99.4	99.4

The performance of the AF detection algorithm was also evaluated using well-known, publicly available arrhythmia databases.

Table 17. AF detection algorithm performance results (%) [35]

	ESe	E+P	DSe	D+P
All Events	86	89	89	83
Events >30 s	97	83	94	82
Events >120 s	98	85	94	81

Confirm Parameter Settings

At the end of the programming session, interrogate the device and confirm that the final parameter settings are correct.

Patient Follow-Up

The frequency of patient remote monitoring and follow-up visits depends on the patient's condition and should be determined by the healthcare practitioner.

A follow-up visit should include (at a minimum):

- Review of the FastPath™ Summary screen
- Review of stored episodes and real-time EGMs
- Confirmation that the final parameter settings are correct.

See also:

- Battery Status (page 35), Battery Status (page 38)

Battery Status

The battery status is based on battery capacity, not battery voltage. It is determined primarily by device usage and is shown on the FastPath™ Summary window (page 11) and on the Wrap-up™ Overview window (page 29).

See also Battery Specifications above.

[34] Se = Sensitivity; PPV = Positive Predictive Value

[35] Ese = Episode Sensitivity; E+P = Episode Positive Predictivity; DSe = Duration Sensitivity; D+P = Duration Positive Predictivity

Explanting the Device

WARNING: Before explanting the device program the device Off. In the event of the patient's death, deactivate the device before post-mortem examination.

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Index

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