ZOOM® LATITUDE® Programming System

USB Data Management Utility
USB DATA MANAGEMENT UTILITY

Description

The ZOOM® LATITUDE® Programming System, which includes the Model 3120 Programmer/Recorder/Monitor (PRM), is a portable cardiac rhythm management system designed to be used with Boston Scientific implantable pulse generators.

The PRM allows you to save patient data to a USB pen drive for use in later sessions. Boston Scientific pulse generator System Guides include a chapter titled “Using the Programmer/Recorder/Monitor,” which describes how to perform disk operations using the PRM. This document supplements those System Guides by describing how to perform patient data operations with a USB pen drive.

Saving Patient Data to the USB Pen Drive

Saving patient data to the USB pen drive is a two-step process: (1) The PRM allows you to save pulse generator data to the hard drive or a removable floppy data disk. (2) Data saved to the hard drive can then be transferred to a removable USB pen drive.

If a floppy disk is not inserted in the PRM disk drive, any disk operations initiated within any application will be performed on space allocated on the PRM hard drive. Data saved to the hard drive can then be exported to the USB pen drive through the Export Data feature of the USB Data Management Utility, accessible from the PRM startup screen.

USB Data Management Features

The USB Data Management utility allows you to export, read, and delete patient data. Select the Utilities button and then the Data Storage tab, to access these features.

Note: Versions 1.05 and earlier of the 2868 (COGNIS/TELIGEN) pulse generator application do not support USB Data Management functionality.

Export Data

Patient data on the PRM hard drive can be exported to a USB pen drive.

Initializing the Pen Drive

If a pen drive is being used to store patient data for the first time, you must initialize it with a new password to encrypt the Protected Health Information
that will be stored on it. When the system prompts you with the Initialize USB Drive dialog box, enter and confirm a password of your choosing, then select the Initialize button. If the password does not meet system requirements, the system displays the Password Creation Failed dialog box and prompts you to try again. You will need to re-enter this password only when using a non-Boston Scientific system (e.g., a clinic PC) to access the patient data stored on the pen drive.

Exporting Data
1. Select the Export tab on the USB Data Management interface. The system displays a list of patient records currently saved on the PRM hard drive.
2. Select the patient records you want to export. You can select all patient records by selecting the Select All button, or select specific patient records by selecting the checkbox next to a patient's name. You can also undo your selections by selecting the Deselect All button.
3. Select the Export button to initiate the export operation. When the operation initiates successfully, the system displays a message stating that Protected Health Information is being exported to the USB pen drive. To protect patient privacy, pulse generator data is encrypted before it is transferred to the USB pen drive.
4. Do not remove the USB pen drive during the export operation. If the export operation fails for any reason, the system displays an error message prompting you to select Try Again or Cancel.
5. If the storage capacity of the USB pen drive is reached during the export operation, the system displays a message stating that the export failed. Insert another pen drive and select the Try Again button to continue with the export.

Read Data
You can read patient data from the PRM hard drive or the USB pen drive.
1. When you attempt to read data from the PRM hard drive or the USB pen drive, the appropriate application is initiated. If the operation is unable to read the patient data, the system displays a message indicating that the application could not be started in Disk Mode or that the data could not be read from the USB pen drive. You can then select Try Again or Cancel to continue.
2. When the read operation initiates successfully, the system displays a message stating that Protected Health Information is being read from the USB pen drive or the PRM hard drive.
Note: The Read Data feature is unavailable on the following pulse generator applications which do not support reading patient data from removable storage media: 2865 (CONTAK RENEWAL TR®), 2880 (VIGOR), 2881 (DELTA/VISTA), 2890 (PULSAR/DISCOVERY®/MERIDIAN®/CONTAK TR®), 2891 (PULSAR II/DISCOVERY II®/VIRTUS II/INTELIS II), 2892 (ALTRUA®/INSIGNIA I®/NEXUS I).

Delete Data
You can manage the contents of the patient data archive on the PRM hard drive or the USB pen drive with the delete data operation.

1. Select the Delete tab on the USB Data Management interface.
2. Select the USB Drive or Programmer option to indicate the location from which you want to delete patient records.
3. Select the patient records you want to delete. You can select all patient records by selecting the Select All button, or select specific patient records by selecting the checkbox next to a patient's name. You can also undo your selections by selecting the Deselect All button.
4. Select the Delete button to initiate the deletion of selected patient records. The system displays the Delete Confirmation dialog box asking you to confirm that you want to delete the selected patient records. Select the Confirm button to continue with the delete operation, or the Cancel button to cancel the operation.
5. When the delete operation initiates successfully, the system displays a message stating that Protected Health Information is being deleted from the system.
6. Do not remove the USB pen drive during the delete operation. If the delete operation fails for any reason, the system displays an error message prompting you to select Try Again or Cancel.

Saving Episodes from Legacy Pulse Generators
When saving patient episodes from a legacy pulse generator, if a record already exists on the PRM hard drive for that patient, new episodes are added to the patient record. The patient record, however, contains an episode index file which lists only the episodes saved during the most recent patient session.

When you start a new patient session using QUICK START® to interrogate the pulse generator, saving patient data will replace the episode index file in the patient record.
When you start an existing patient session by reading the patient record into the pulse generator application, saving patient data will add to the episode index file in the patient record.

In either case, when reading the patient record back into the pulse generator application, only the episodes listed in the episode index file are displayed. When exporting the patient record to a USB pen drive, all episodes are exported.

**Processing Considerations**

- When performing multiple patient follow-ups, be sure to start a new session for each patient through the QUICK START® or Select PG options (rather than the application’s New Patient option). This will ensure that data saved to the PRM hard drive during the previous session is not lost.

- Be sure to save all pulse generator data to either a floppy disk or USB pen drive before returning a PRM to Boston Scientific, as all patient and pulse generator data will be erased from the PRM when it is returned for service.

- No more than 400 unique patient records may be saved to the PRM. When a pulse generator is interrogated, the PRM evaluates if there is a record on file for that pulse generator, or if a new record needs to be created. If a new record is needed, and the PRM is at the 400 record capacity, the oldest record on file will be deleted to create space for the new patient record.

- Up to 200 episodes can be saved to the PRM hard drive during a session with a patient. Performing the Save All to Disk operation with a patient who has more than 200 episodes will save only the oldest 200 episodes. The system will then notify you that the disk is full and you will need to restart the session and save up to 200 selected episodes.

- If a patient has more than 200 episodes, it is recommended that you perform a selective save operation instead of the Save All to Disk operation.

- With VITALITY® applications, ensure a floppy disk is inserted when saving profile data to Disk. Otherwise, the system will not prompt you to insert a floppy disk and the profile data will be lost.

**Symbols on Packaging**

The following symbols are used in this document (Table 1).
Table 1. Symbols on packaging

<table>
<thead>
<tr>
<th>Symbol</th>
<th>Definition</th>
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<tr>
<td><img src="image" alt="Symbol" /></td>
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