A Closer Look

Boston Scientific

SUMMARY

The Boston Scientific Model 3120 Programmer/Recorder/Monitor (PRM) allows the user to save patient data to a USB pen drive for use in later sessions. The Patient Data Management utility allows patient data to be exported, read, and deleted. The Read Disk option allows patient data to be read and deleted.

This article provides an overview of how to perform patient data operations with a USB pen drive for those PG software applications that support the use of the Patient Data Management Utility.

Products Referenced
ALTRUA, DISCOVERY, DISCOVERY II INSIGNIA Entra, INSIGNIA I Plus, INSIGNIA AVT, INSIGNIA Ultra, PULSAR MAX II, PULSAR MAX, PULSAR, MERIDIAN, VENTAK PRIZM®, VITALITY®, CONTAK® RENEWAL, CONFIENT™ LIVIAN™, COGNIS™*, and TELIGEN™*

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

Products referenced herein may not be approved in all geographies. For comprehensive information on device operation and indications for use, reference the appropriate product labeling.

CRT-D: Cardiac Resynchronization Therapy Defibrillator
ICD: Implantable Cardioverter Defibrillator#

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Saving and Managing Patient Data on a USB Pen Drive

Patient and device data from many Boston Scientific implantable devices can be downloaded from device memory and stored on a USB pen drive. This enables later review and/or electronic transmission of data to another location for further review and storage. Data can be reviewed on any computer that has Adobe Reader installed and the PDF files can be attached to Electronic Medical Records in the clinic's patient record system. One USB drive can store up to 400 unique patient records; records are encrypted and password-protected to ensure patient data is safe during the export process.

The following types of data are saved:

- Current programmed parameter values
- Battery status and lead measurements
- Paced/sensed counters and histograms
- Therapy history (including stored electrograms)
- Trending values
- Heart Rate Variability data (if applicable)

Selecting and Initializing the Pen Drive
Either a USB drive from Boston Scientific or a commercially available USB drive may be used for this process. If a USB drive not provided by Boston Scientific is used, it must:
- have a capacity of greater than 100 Mb
- be formatted as a FAT file system
- not be password protected

The first time a pen drive is inserted into a USB port on the Programmer/Recorder/ Monitor (PRM) and an export is attempted, an "Initialize USB" system prompt will appear. Create and enter a valid password (i.e. minimum of 6 alphanumeric characters) and select the Initialize button. Password use will be required when using a system other than the 3120 PRM (e.g., a clinic computer) to access the data. ***NOTE: Passwords cannot be reset on the pen drive and data stored on the USB cannot be accessed in the absence of a password. Passwords are case sensitive and will be in lower case unless the shift button is pressed upon password creation.***

Saving Patient Data to the PRM Hard Drive
Important: Data must first be saved to the PRM hard drive before it can be exported to the USB drive. ***NOTE: In order to save to the hard drive, the floppy disk drive must be empty. If the floppy disk drive is not empty when a "save to hard drive" is attempted, data storage will default to the floppy disk.***

*To save **all** episodes to the PRM hard drive:*
- Confirm that there is no floppy disk inserted in the programmer.
- Select the 'Save All to Disk' button. All episodes are automatically saved. The Save All to Disk feature may be accessed via the Utilities menu on the programmer. This feature is also available by selecting the Quick Check, New Patient or Quit options (with the exception of COGNIS and TELIGEN).

*To save **select** episodes to the PRM hard drive:*
- Confirm that there is no floppy disk inserted in the programmer
- Select Desired Episodes and select Save to Disk; or (when available)
- Select the Save to Disk feature, located in the Arrhythmia Logbook

Data saved to the hard drive can be exported to the USB pen drive through the Export feature of the Patient Data Management utility, accessible from the PRM startup screen.

Exporting Data to the USB Drive
1. Select the Patient Data Management interface on the main PRM screen. This will default to the Export tab on the Patient Data Management screen. The system displays a list of patient records currently saved on the PRM hard drive.
2. Select the patient records to be exported. Choose 'Select All' or refine the selection by checking the box next to a patient's name. The Deselect All button will clear the checkboxes. The files will be stored in folders labeled with the device model and serial numbers. Select the reports to be exported. The selected reports are created as a PDF file from the data for each selected patient. One or more reports may be generated and exported from each selected patient record. ***NOTE:*** *Selecting a report is not required to initiate the export operation. To export patient records only, leave the reports selection unchecked and proceed to the next step.*
3. Select the export button to initiate the export operation. When the operation successfully initiates, a message stating that Protected Health Information is being exported to the USB drive is displayed. To protect patient privacy, data is encrypted before it is transferred to the USB drive.
   NOTES:
   - 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 the user to select 'Try Again' or 'Cancel'.
   - 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. Data collection and storage will continue where it left off.

Transferring Data to the Clinic Personal Computer (PC)
Files can be extracted from the USB and saved, e-mailed or attached to an Electronic Medical Record.
1. Insert the pen drive into any USB port on the PC and open Windows Explorer.
2. Navigate to the folder titled 'bsc' (in the root directory of the pen drive) and double-click to access the sub-folders.
3. Double-click the "ExtractAll.bat" file.
4. When prompted, enter the pen drive password and choose a destination directory.
5. When ready, press the 'Extract All' button.
6. Each patient record on the pen drive will be extracted to a folder that is titled with the device model and serial number. PDF files of selected reports will be placed in the 'report' folder and titled with the name of the report and the date saved.

Print
For those PG software applications that support the use of the Patient Data Management Utility, patient data can be saved to the programmer hard-drive and exported to a USB pen drive. PDF reports can then be printed to an external printer.*

NOTE: *The* Print Data *to PDF option is only available with the following pulse generator applications: ALTRUA, INSIGNIA I, NEXUS I), PRIZM and PRIZM 2, VITALITY, VITALITY DS, VITALITY 2, VITALITY HE, CONFIENT, CONTAK CD2, RENEWAL, LIVIAN*

Read Data
Data may be read on the 3120 PRM from the PRM hard drive or the USB pen drive. To view a list of available records:

- Select the Read tab and check the "Programmer" option; or,

- Insert the USB drive, select the Read tab and check the "USB Drive" option

After these steps are performed, the PRM will initiate the device-specific application. For devices other than COGNIS and TELIGEN, the "Read Disk" must be pressed. 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. Select Try Again or Cancel to continue. 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 option is not available with the following pulse generator applications: 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

The Delete function manages contents of patient data archived on the programmer hard drive or a USB Drive.

1. Select the Delete tab on the Patient Data Management interface.
2. Select the USB Drive or Programmer option to indicate the location from which to delete patient records.
3. Select the patient records to be deleted. All patient records can be chosen by selecting the Select All button, or specific patient records can be chosen by selecting the checkbox next to a patient's name. Undo selections by selecting the Select All button.
4. Select the Delete button to initiate the deletion of selected patient records. The system displays the Delete Confirmation dialog box asking for confirmation to delete the selected patient records. Select the Confirm button to continue, 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.
   NOTE: 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 the user to select 'Try Again' or 'Cancel'.

Tips for Saving Patient Data to the PRM Hard Drive and USB Pen Drive

- 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 this 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 issue notification that the disk is full; the session may be restarted to save remaining episodes.
- If a patient has more than 200 episodes, it is recommended that a selective save operation be performed instead of the Save All to Disk operation.
- In VITALITY devices, the "My Patient Profile" file can only be saved to floppy disk. It will not save to a USB drive**. All other exportable data can be saved to a USB drive.
- In ALTRUA and INSIGNIA devices, Save Memory must go to a floppy disk**.

*For additional information regarding printing from a USB drive, please see the appropriate device system guide. Printing information is also summarized in the *A Closer Look* article "Print Guide for the ZOOM® LATITUDE® Programmer".

**If data is saved from an unsupported device or to an unsupported medium, the data will be lost with no warning issued. This is also the case with deletion of data due to the "first in, first out" storage algorithm.