

SUMMARY

The Boston Scientific Model 3120 Programmer/Recorder/Monitor (PRM) allows the user to save patient data from Boston Scientific ICDs and CRT-Ds to a floppy drive using Save All to Disk and Save to Disk. The Read Disk option allows patient data to be read.

This article provides an overview of the Save All to Disk and Save to Disk tools including copying and reading disks and saving to multiple disks.

Products Referenced

VENTAK PRIZM[®], VITALITY[®], CONTACT[®]
RENEWAL, CONFIENT[™], LIVIAN[™],
COGNIS[™], and TELIGEN[™]

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#

Contact Information

Americas

(Caribbean, and Central, North, and South America)

www.bostonscientific.com

Technical Services

LATITUDE[®] Clinician Support

1.800.CARDIAC (227.3422)

+1.651.582.4000

Patient Services

1.866.484.3268

Europe, Japan, Middle East, Africa

Technical Services

+32 2 416 7222

eurtechservice@bsci.com

LATITUDE Clinician Support

latitude.europe@bsci.com

Asia Pacific

Technical Services

aptechservice@bsci.com

LATITUDE Clinician Support

latitude.asiapacific@bsci.com

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Saving Patient Data to Floppy Disk

Patient and device data from Boston Scientific ICD and CRT-D systems can be downloaded from device memory and stored on a Model 6627 Patient Data Disk or a properly formatted 3.5-inch floppy disk. This enables later review and/or electronic transmission of data to another location for further review and storage. 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 Formatting the Floppy Disk

If a disk other than a Model 6627 Patient Data Disk is used, it must be properly formatted prior to use. (**NOTE:** *Formatting a disk will remove all data from the disk*). To format a disk:

- Insert a floppy disk into disk drive on the right side of the Programmer/Recorder/Monitor (PRM).
- Open an application other than COGNIS/TELIKEN (if disk will be used in a COGNIS or TELIGEN device, it can be formatted in another device's demo mode application, then the COGNIS/TELIKEN application can be started).
- Select the Format Disk option from the Disk Operations button.
- When formatting is complete, insert another disk and select the Format Another Disk button or select the Cancel button to exit the format tool.

Saving Patient Data to a Floppy Disk

Two options are available to save the data to a disk:

1. **Save All to Disk**—Saves all patient data and all stored episodes.
2. **Save to Disk**—Saves all patient data and selected episodes.

The time required to perform a Save All to Disk can be lengthy, particularly if there are a significant number of episodes stored in memory, since each episode needs to be fully interrogated from the implanted device before it can be transferred to a disk. Consider limiting use of this tool to the first time patient and device data is saved. The Save to Disk tool provides a faster alternative for saving data. The Save to Disk tool (when available), located within the Arrhythmia Logbook, allows saving of selected, rather than all, episodes (e.g. save only episodes in which tachy therapy was delivered and skip non-therapeutic episodes).

To save all episodes to the disk:

- Insert a floppy disk into the disk drive on the right side of the PRM).
- Confirm that the write-protect tab is closed (i.e., the black tab is covering the hole).
- Select the 'Save All to Disk' button. All data and episode information are automatically saved. The Save All to Disk tool may be accessed via the Utilities menu on the programmer. This option 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 disk:

- Insert a floppy disk into the disk drive on the right side of the PRM.
- Select desired episodes.
- Select Save to Disk.

When the progress bar on the PRM reaches 100% and the green light on the disk drive is off, the save process is complete and the disk can safely be removed from the disk drive. **CAUTION:** Make sure the disk drive light is off before removing the patient data disk from the disk drive. Removing the disk while the drive heads are engaged can damage the disk and/or the drive.

Episodes saved to disk during the current interrogation will be indicated in the Saved column of the Arrhythmia logbook. If data are saved during the interrogation session using either of the above methods, an asterisk (*) or disk icon (📀), populates the field corresponding to the episode(s) saved during that session (Figure 1).

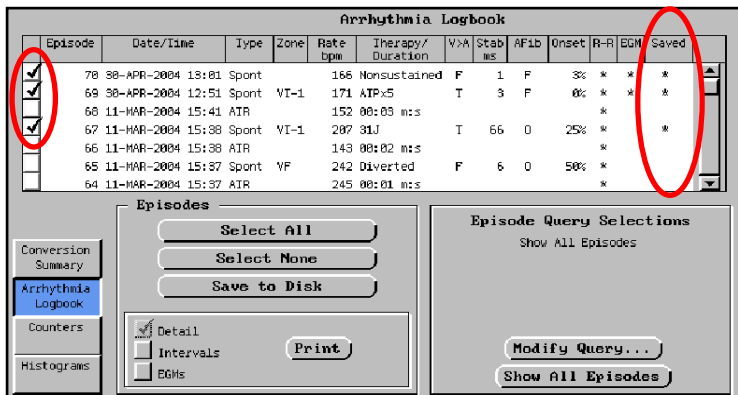


Figure 1. Episodes identified as saved during an interrogation session.

Either method (i.e. Save to Disk or Save All to Disk) allows data from one patient to be saved to an individual disk. If the user attempts to save data from two different patients using the same disk, the programmer will display an error message reading: "Incorrect patient data disk. Insert another disk and try again."

If the amount of data to be stored exceeds the storage limits of a single patient disk, the programmer will prompt the user to insert another disk to complete the download process.

- With COGNIS and TELIGEN devices, after inserting a new disk, select the Try Again button to initiate saving data to the new disk.
- With all other devices, users must select the Close button from the "Patient data disk is full" window, insert a new disk, and then select the Save All to Disk button again. The programmer then resumes the save process from where it left off.

If an episode is in progress during the Save All to Disk or Save to Disk process, that episode will *not* be saved; all episodes except the one in progress will save to the disk. If an episode is in-progress during a save, the programmer will display the message "Episode in progress. Try again when complete." Once the episode in progress has ended, users should perform another save in order to include the most recent episode on the disk. **NOTE:** The "Episode in progress. Try again when complete" message will **not** be displayed with COGNIS and TELIGEN devices.

Notes on Save to Disk

- Save to Disk is only activated when one or more episodes are selected
- In COGNIS and TELIGEN devices, individual episodes may also be saved to a disk from the Summary, EGM, or Intervals tabs on the Event Detail screen.
- When available, the Modify Query option within the Arrhythmia Logbook provides an efficient way to locate and display specific types of episodes, which can then be selected for saving.

Copying a Disk

Duplicate copies of patient data may be saved to disk without re-interrogating the device. To make disk copies:

- Select the Copy Disk option from the Utilities menu.
- Insert the source disk (containing the patient data to be copied) into the disk drive on the right side of the PRM.
- Select the Read Disk button.
- The PRM will read the information from the disk. When complete, a message will indicate that the destination disk should be inserted.
- Eject the source disk and insert a new patient data disk into the disk drive (any data on the disk will be overwritten).
- Select the Write Disk button and the information will be copied on the disk.

Read Data

Patient data disks can be read via a Boston Scientific programmer; the disks cannot be read via a computer, although the icons of the files saved to the disk may be viewed from a PC. To read a patient data disk on the programmer, insert a floppy disk into disk drive on the right side of the PRM. Launch the correct software application from the Select PG screen, then select Read Disk from the application options. For example, if the data disk contains patient data from a VITALITY AVT® device, the user must first select the VITALITY AVT application from the Select PG menu before selecting the Read Disk button. 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. 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.

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

Reformatting the disk, on the PRM (except with COGNIS/TELIGEN applications) or a PC, will remove all data from the disk. It is possible to delete individual files from the disk; however, deleting incorrect files could render the disk unreadable.

Transmit Data Electronically

Depending on the type of data necessary for analysis, Technical Services may request electronic transmission of either the Save All to Disk or Save to Disk files or a Memory (Hex) Dump. All three store device data onto a disk; however, each is intended to retrieve different device-related information. The Save All to Disk and Save to Disk store patient and device data that is available from the device through the programmer. A Memory Dump downloads the binary code from the device memory and can only be read by an engineering-level programmer, which can decipher the code. A Memory Dump is typically done only when requested by CRM Technical Services.

To send the disk data electronically:

- Insert the floppy disk containing data into a computer disk drive.
- Without opening the individual files, compress the files using a program such as WinZip®.
- Insert the compressed files into an e-mail message.
- Send e-mail message to the requesting Technical Services department (Tech.Services@bsci.com or eurtechservice@bsci.com)

To ensure data integrity when sending disk contents electronically, do not attempt to open or view any of the files contained on the disk from a computer, either prior to sending or upon receipt. Additionally, the complete patient disk should be sent; do not attempt to send only selected files from the disk. Finally, due to file and disk size, users should only send the files from one patient data disk per e-mail message.

Tips for Saving Patient Data to Disk

- *Consider using the same disk for a given patient every time a Save All to Disk is performed. This enables the programmer to interrogate and copy only those episodes that have not previously been saved to the disk rather than interrogating and copying all episodes in memory. All current device data (parameter values, battery status, histograms, etc.) will always be saved.*
- *For COGNIS and TELIGEN, if programmer software has recently been upgraded, use a new disk to save patient data rather than reusing a previous disk. Disks recorded with older programmer software can be read with the new software. However, prior to reading a used patient data disk, to ensure data is secure, slide the “write-protect” tab to its read only position.*
- *For COGNIS and TELIGEN, if an Unexpected Disk Error is encountered, reduce the number of events to save to fewer than 108. This error is the result of insufficient directory space on the disk; disk space is still available for event storage.*