

Saving ICD and CRT-D Data

SUMMARY

Boston Scientific ICD and CRT-D systems offer the ability to save patient and device data to disk using the Save All to Disk and Save to Disk features.

This article provides an overview of the Save All to Disk and Save to Disk features as well as other related features, including the ability to copy disks, read disks, and save to multiple disks.

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

CRM PRODUCTS REFERENCED*

The following device families:

VENTAK MINI®, VENTAK PRIZM®, VITALITY®, CONTACT® CD, CONTACT RENEWAL®, CONFIENT™, LIVIAN™, COGNIS™, TELIGEN™.

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

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Boston Scientific ICD and CRT-D systems offer the ability to download patient and device data from device memory and store the data to a Model 6627 Patient Data Disk or any formatted floppy disk. This enables clinicians to review data at a later time and/or transmit data electronically to another location for further review and storage. The following types of data may be 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)

Two features are available to save the patient and device data to a disk:

1. **Save All to Disk**—Saves the above data and **all** stored episodes
2. **Save to Disk**—Saves the above data and **selected** episode(s).

Save All to Disk

The Save All to Disk feature may be accessed via the Utilities menu on the programmer. With the exception of COGNIS™ and TELIGEN™, Save All to Disk is also available by selecting the Quick Check, New Patient or Quit options.

Upon selecting the Save All to Disk button, all data and episodes are automatically saved to a floppy disk. 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.

Accessing Save All to Disk	
VENTAK MINI®, VENTAK PRIZM®, VITALITY®, CONTACT® CD, CONTACT RENEWAL®, CONFIENT™, and LIVIAN™ device families	COGNIS and TELIGEN

Save to Disk

The Save to Disk feature (when available), located within the Arrhythmia Logbook, allows clinicians to save selected episodes rather than **all** episodes (e.g., save only episodes in which tachy therapy was delivered and skip non-therapeutic episodes). A Save to Disk can be performed by selecting the desired episode(s) and then the Save to Disk button.

NOTES:

- Save to Disk is only activated when one or more episodes are selected.
- With 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.
- Choosing the Select All button and then the Save to Disk button via the Arrhythmia Logbook screen results in saving of **all** episodes and yields the same results as performing a Save All to Disk.
- When available, the Modify Query feature within the Arrhythmia Logbook provides an efficient way to locate and display specific types of episodes, which can then be selected for saving.

Accessing Save to Disk	
VENTAK MINI®, VENTAK PRIZM®, VITALITY®, CONTAK® CD, CONTAK RENEWAL®	COGNIS and TELIGEN

Tips for Using Save All to Disk and Save to Disk


- Consider using the same disk (rather than a new disk) for a given patient every time a Save All to Disk is performed as 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 reuse 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.
- Consider limiting use of the Save All to Disk feature to situations in which patient and device data is saved for the first time, since the process can be lengthy. The Save to Disk feature provides a faster alternative for saving data.

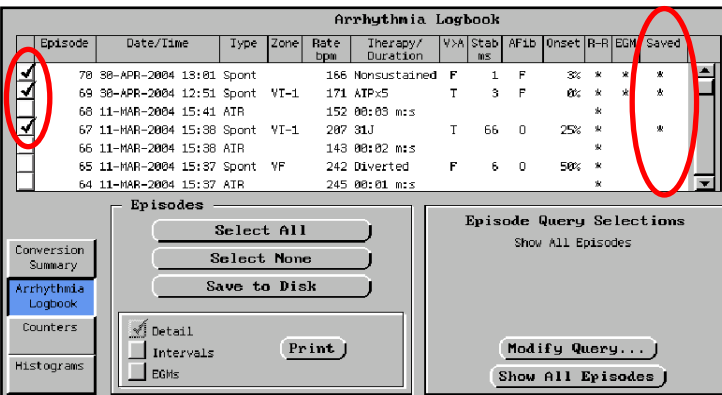
Frequently Asked Questions

Q1. How do clinicians know when the save process is complete?

A1. The save process is complete when the progress bar reaches 100% and the green light on the disk drive is off, at which time the disk can safely be removed from the disk drive.

Q2. What does the *Saved* column in the Arrhythmia Logbook represent?

A2. The *Saved* column (when available) indicates those episodes that have been saved to disk during the current interrogation session (episodes saved to disk in a previous session will not be marked in the *Saved* column). At the start of each new interrogation session, the column is blank. If data are saved during the interrogation session using either Save All to Disk or Save to Disk, an asterisk (*) or disk icon () populates the field corresponding to the episode(s) saved during that session (Figure 1).



Episode	Date/Time	Type	Zone	Rate type	Therapy/Duration	V/A	Stab ms	AFib	Unset	R-R	EGM	Saved
78	38-APR-2004 18:01	Spont		166	Nonsustained	F	1	F	3%	*	*	*
69	38-APR-2004 12:51	Spont	VT-1	171	ATP×5	T	3	F	0%	*	*	*
68	11-MAR-2004 15:41	ATR		152	00:03 mss						*	
67	11-MAR-2004 15:38	Spont	VI-1	207	31J	T	66	0	25%	*	*	*
66	11-MAR-2004 15:38	ATR		143	00:02 mss						*	
65	11-MAR-2004 15:37	Spont	VF	242	Diverted	F	6	0	50%	*	*	*
64	11-MAR-2004 15:37	ATR		245	00:01 mss						*	

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

Q3. Can a patient data disk be copied?

A3. Two methods are available to copy patient data disks, both of which utilize a programmer rather than a computer:

1) When available, the Copy Disk feature (accessed via the Utilities pull-down menu) is the recommended method for making duplicates of patient disk data.

2) The contents of a disk may also be copied without re-interrogating the implanted device, by completing the following steps:

Step 1: Insert the disk to be copied in the programmer disk drive.

Step 2: Launch the appropriate software application from the Select PG screen.

Step 3: Select the Read Disk button from the application options. All patient and device data from the disk will automatically populate the programmer screens.

Step 4: Remove the original disk and insert a new disk in the drive.

Step 5: From the Utilities menu, select the Save All to Disk option to save data on the new disk.

Q4. Can an individual disk be used to save patient data for more than one patient?

A4. No. The software application is designed to save only one patient's data per disk. If the user attempts to save data from two different patients using the same disk, the programmer will display an error message "Incorrect patient data disk. Insert another disk and try again."

Q5. What happens when data will not fit on a single disk?

- A5. 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. This may occur if the patient experienced a significant number of episodes since the last time data was saved to disk.
- 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, such that the new disk contains only the next sequential episodes. When the save process is complete, the disk can be removed from the programmer.

Q6. How can clinicians read a patient data disk?

- A6. Patient data disks can be read via a Boston Scientific programmer; the disks cannot be read via a computer. To read a patient data disk on the programmer, first 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.

Q7. Can patient data be transmitted electronically?

- A7. Yes, electronic transmission is typically done when requested by CRM Technical Services. To send the disk data electronically, the following should be done:

- Step 1: Insert the floppy disk containing data into a computer disk drive.
- Step 2: Without opening the individual files, compress the files using a program such as WinZip[®].
- Step 3: Insert the compressed files into an e-mail message.
- Step 4: Send e-mail message to 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.

Q8. Is it possible to save data to a disk while an episode is in progress?

- A8. Yes. However, if an episode is currently 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 that episode on the disk.

NOTE: *The “Episode in progress. Try again when complete” message will not be displayed with COGNIS and TELIGEN devices.*

Q9. Does a disk need to be formatted before it can be used for a Save to Disk or a Save All to Disk?

- A9. Yes, a disk must be formatted in order to store data. Disks can be purchased from many stores pre-formatted or can be formatted using a computer. Disks can also be formatted on the programmer using the Format Disk function (when available), which is accessed via the Utilities pull-down menu.

Q10. How do Save All to Disk and Save to Disk differ from a Memory Dump (Hex Dump)?

- A10. All three features 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. On the other hand, 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.