Boston Scientific

OPERATOR'S MANUAL

Patient Data Management

Application for use with the LATITUDE™ Programming System

REF 3931 Patient Data Management

REF 3300 LATITUDE™ Programming System

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INFORMATION FOR USE

Trademark Statement

LATITUDE is a trademark of Boston Scientific Corporation or its affiliates.

Bluetooth® is a registered trademark of Bluetooth SIG.

Description and Use

Patient Data Management is an application of the LATITUDE™ Programming System, Model 3300, which is a portable cardiac rhythm management system designed to be used with Boston Scientific (BSC) systems, i.e. implantable pulse generators (PG) and leads.

NOTE: *The screen images used in this manual are representative and may not exactly match your screens.*

Intended Use

The LATITUDE Programming System is intended for use in hospital and clinical environments to communicate with Boston Scientific implantable systems. The software in use controls all communication functions for the pulse generator. For detailed software application instructions, refer to the associated product literature for the pulse generator being interrogated.

Intended Audience

The Model 3300 Programmer device is intended for use by health care professionals trained or experienced in device implant and/or follow-up procedures.

Required Expertise and Knowledge

Users must be thoroughly familiar with electrotherapy of the heart. Only qualified medical specialists having the special knowledge required for the proper use of the device are permitted to use it.

Physician Supervision

The LATITUDE Programming System may only be operated under the constant supervision of a physician. During a procedure, the patient must be continuously monitored by medical personnel with the aid of a surface ECG monitor.

Medical Product Operator's Ordinance

National regulations may require that the user, manufacturer or manufacturer representative perform and document safety checks of the device during installation. They may also require that the manufacturer or its representative provide training to users on the proper use of the device and its accessories.

If you do not know the national regulations in your country, please contact your local Boston Scientific representative.

Contraindications

The LATITUDE Programming System is contraindicated for use with any pulse generator other than a Boston Scientific pulse generator.

The Patient Data Management application is contraindicated for use with any programming system other than the Boston Scientific Model 3300 LATITUDE™ Programming System.

For contraindications for use related to a specific Boston Scientific pulse generator, refer to the associated product literature for that pulse generator.

WARNINGS AND PRECAUTIONS

Refer to the *LATITUDE Programming System Operator's Manual, Model 3300*.

PATIENT DATA MANAGEMENT CAPABILITIES

The Patient Data Management application of the LATITUDE Programming System provides the ability to print, save, or transfer related data (via Bluetooth or USB pen drive), during or after an implant/follow-up session, to a clinic computer for processing/transferring data to external systems (e.g., the LATITUDE Link system).

The LATITUDE Programming System:

- Exports saved patient data from the Programmer hard drive to one of the following:
  - Removable USB pen drive
  - Via Bluetooth® wireless technology to another computer (e.g. for use with the LATITUDE Link system)
- Stores patient data to the Programmer hard drive or to a USB pen drive that can be retrieved later
- Generates printable reports that detail pulse generator functions, stored patient data, and test results
- Provides the option to encrypt patient data prior to exporting to a USB pen drive
- Creates PDF report(s) from saved patient data and saves the report(s) to the hard drive or to a USB pen drive

Processing Considerations

- Save data before powering down. Powering down removes all unsaved data. When the system is powered down all real-time patient and pulse generator data is removed from the Model 3300 Programmer memory. Existing patient data on the hard drive remains. Patient data is saved to the hard drive or a USB pen drive only when the user selects and explicitly saves patient data. As needed, save patient and pulse generator data to the hard drive or a USB pen drive before powering down.

- Be sure to save all pulse generator data to a USB pen drive before returning a LATITUDE Programming System to Boston Scientific, as all patient and pulse generator data will be erased from the LATITUDE Programming System when it is returned for service.
- Up to 400 patient records for non S-ICD devices (e.g. transvenous PGs, AST) and up to 50 S-ICD patient records may be saved to the LATITUDE Programming System.
  - For non S-ICD device patient records: When the pulse generator is interrogated, the Model 3300 Programmer evaluates if there is a record on file, or if a new record is requested by the user. If a patient record is needed, and the LATITUDE Programming System is at record capacity, the oldest non S-ICD device patient record on file will be automatically deleted to create space for the new record.
  - For S-ICD device patient records: When the S-ICD device is interrogated, the Model 3300 Programmer evaluates if there is an S-ICD patient record on file, or if a new record is requested by the user. If a patient record is needed, and the LATITUDE Programming System is at record capacity, the oldest S-ICD device patient record on file will be automatically deleted to create space for the new record.
- Use the Selective Save option as a best practice to maintain only those records desired and to optimize storage space.

PATIENT DATA MANAGEMENT SECURITY

All patient data on the Model 3300 Programmer hard drive is encrypted using Advanced Encryption Standards (AES)[a]. The length of time that patient data can be stored on the Programmer is limited. The Programmer limits patient data stored on the hard drive by automatically deleting it after 14 days for transvenous PGs and 90 days for S-ICD devices[b]. When patient data is removed from the Programmer, it is completely erased so that it is no longer recoverable.

For transvenous PGs, this 14 day check of patient data is performed when the Programmer is powered on, but not more than once each day.

For S-ICD devices, this 90 day check of patient data is performed whenever the S-ICD application is started.

For all transvenous PGs and S-ICD devices, if the "Purge" button is pressed from the Data Management application, then all patient data will be deleted.

NOTE: *There is no notification to the user that the deletion has occurred.*

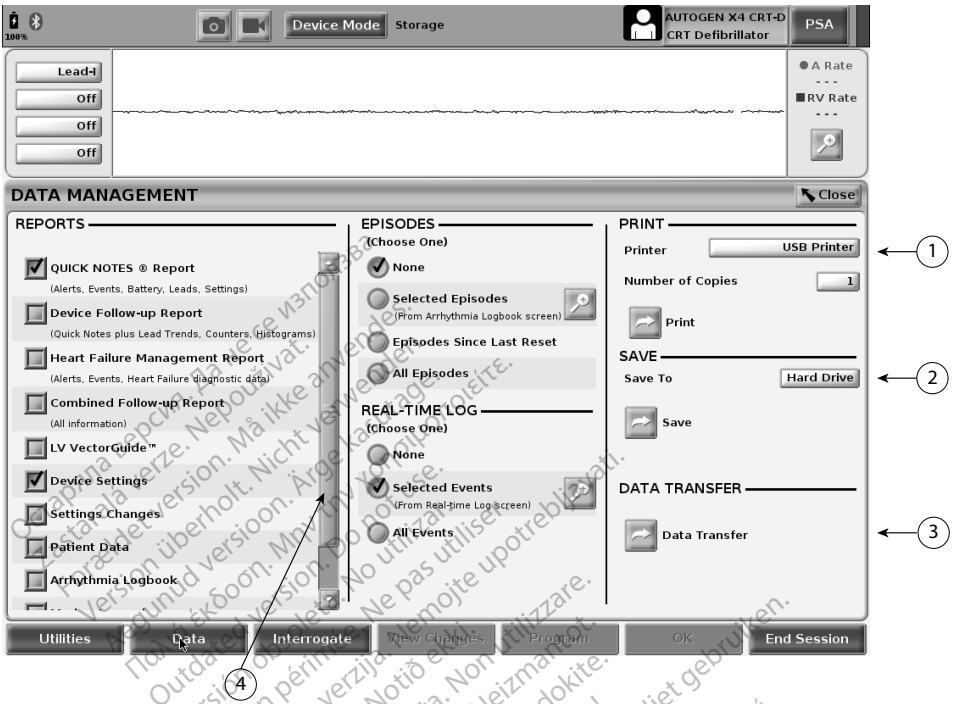
Only connect to known Bluetooth® devices, as patient data could be transmitted to inappropriate printers or devices if guidance is not followed. Delete all patient data before shipping the Model 3300 Programmer or at any time when the Programmer will be leaving the clinic's direct control.

a. The Programmer hard drive uses AES-256 encryption and, when selected by the user, the USB ports use AES-128 encryption.

b. If the Programmer is turned off, patient data cannot be deleted. For transvenous PGs, if the Programmer is not turned on when the 14 day time limit expires, the data will be deleted the next time the Programmer is turned on. For S-ICD devices, if the Programmer is not turned on when the 90 day time limit expires, the data will be deleted the next time the S-ICD application is started.

PRINT, SAVE, AND TRANSFER DATA FROM A PG OR PSA SESSION

This section describes how to Print, Save, and Transfer patient data while in a PG or PSA session.



[1] Print function [2] Save function [3] Bluetooth® Transfer function [4] Scroll bar to view additional report options

Figure 1. PG/PSA Session - Data tab - Data Management

Print Patient Data

To print patient data perform the following:

1. Select the Data button at the bottom of the screen to display the Data Management screen (Figure 1 on page 4).
2. Select the desired Report(s), Episode(s), and/or Real-time Log(s).
3. Select the desired printer source, by clicking on the Printer bar (see call-out 1 in Figure 1 on page 4).
4. Click the Print button to begin printing the patient data.

Save Patient Data

To save patient data to the Programmer hard drive or a USB pen drive perform the following:

1. Select the Data button at the bottom of the screen to display the Data Management screen (Figure 1 on page 4).
2. Select the desired Report(s), Episode(s), or Real-time Log(s).

3. Select the desired source, by clicking on the Hard Drive bar and choosing Hard Drive or USB.

   NOTE: ***If saving to USB, ensure that a USB pen drive is inserted into a USB port on the Programmer before pressing the Save button.***

4. Click the Save button to begin saving the patient data.

NOTE: *Use the Selective Save option as a best practice to maintain only those records desired and to optimize storage space.*

NOTE: *The length of time that patient data can be stored on the Programmer hard drive is limited. The Programmer limits patient data stored on the hard drive by automatically deleting it after 14 days.*

NOTE: *Patient data may be saved throughout the day. Reports and Real-time Logs are saved separately and add to the existing saved reports and Real-time Logs. However, multiple saves of programming and parameter settings replace the current saved versions. Only the most recently saved programming and parameter settings are kept.*

Transfer Patient Data via Bluetooth®

Patient data (for selected or all patients) can be transferred to another computer via Bluetooth® where the data can be viewed, saved, e-mailed, or attached to an Electronic Medical Record (for example for use with the LATITUDE Link system).

NOTE: *For Bluetooth setup and configuration information, refer to the LATITUDE Network and Connectivity Operator's Manual, Model 3294.*

1. Select the Data button at the bottom of the screen to display the Data Management screen (Figure 1 on page 4).
2. Select the Data Transfer button (Figure 1 on page 4).
3. Click the receiving computer bar to select the receiving computer as illustrated in Figure 2 on page 6. Then, press the Continue button to begin the patient data transfer
4. The transfer progress bar displays (Figure 3 on page 6).
5. When the PC authorizes the transfer, the PC dialogue includes where to store the transferred data.

   NOTE: *The default location on a Windows PC is My Documents/Bluetooth Exchange Folder*

6. When the transfer completes, the Programmer displays a confirmation message.

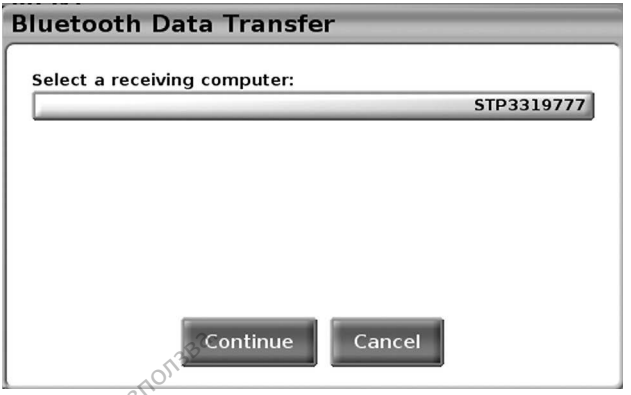


Figure 2. PG/PSA Session - Data Transfer

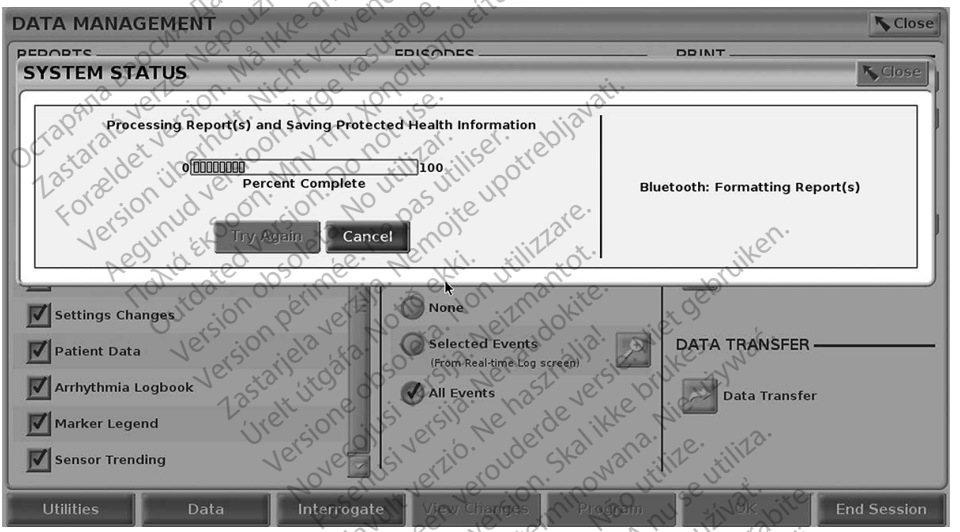


Figure 3. PG/PSA Session - Data Transfer Progress

PATIENT DATA MANAGEMENT APPLICATION

The Patient Data Management application allows you to export, transfer, print, read, and delete patient data, which has been saved to the Programmer hard drive.

Privacy Notice: By exporting data from the LATITUDE Programming System, you are assuming responsibility for the privacy and security of that data. Printing, storing, transferring, reading, and deleting of patient data must be performed in compliance with applicable data privacy and security laws. Using the available secure export methods is recommended.

From the Main screen, select the Patient Data Management button to access this application.

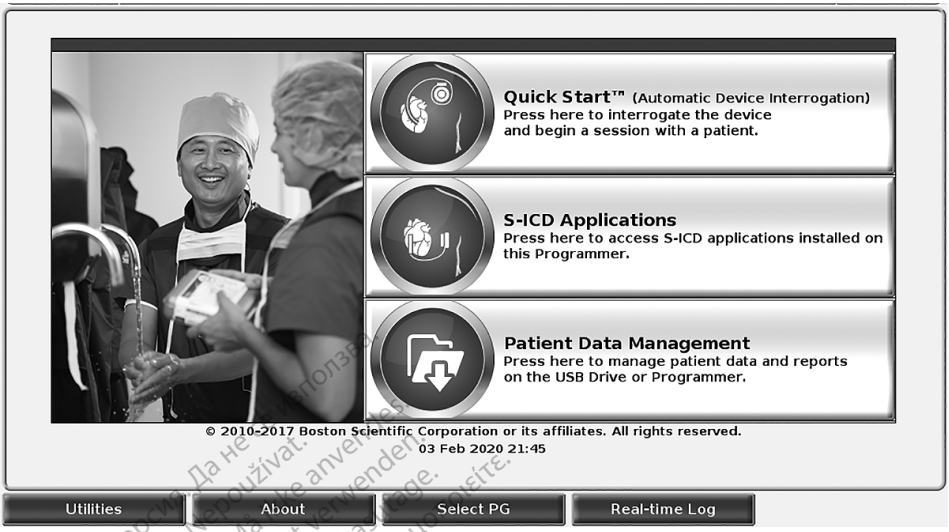


Figure 4. Main screen with Patient Data Management button

Export Feature

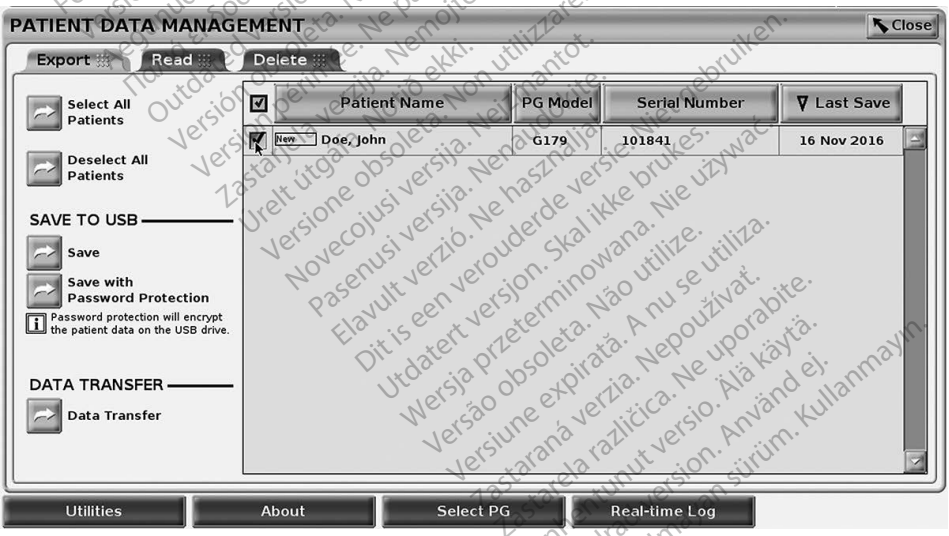


Figure 5. Patient Data Management - Export tab

Export - Save to USB

Patient data (for selected or all patients) stored on the Model 3300 Programmer hard drive can be exported to a USB pen drive.

1. Insert a pen drive into one of the USB ports on the left side of the Programmer.

2. From the Main screen, select the Patient Data Management button (Figure 4 on page 7.)
3. Select the Export tab on the Patient Data Management screen. The system displays a list of patient records currently saved on the Programmer hard drive.
4. Select the patient data you want to export. You can select all patient records by selecting the Select All Patients button, or select specific patient records by selecting the check box next to a patient's name. You can also undo your selections by selecting the Deselect All Patients button, or undo a specific selection by clicking on its check box.
5. Select the SAVE TO USB method:
   a. To initiate export of the selected patient data to a USB pen drive, select the Save button. Patient data is neither encrypted nor compressed on the USB pen drive.
   b. To initiate export of the selected patient data with encryption to a USB pen drive, select the Save with Password Protection button. Password protection encrypts Protected Heath Information on the USB pen drive.
      If a USB pen drive is being used to store patient data for the first time, the system will prompt you to enter and confirm a password:
      i. Enter and confirm the password (see Figure 6). The password must be alpha-numeric and contain at least six characters.
      ii. Select the Initialize button.

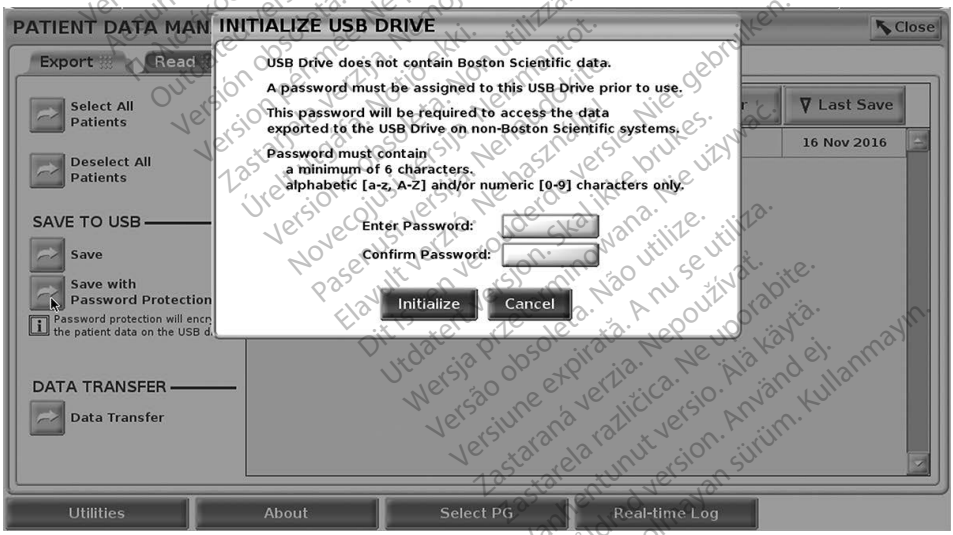


Figure 6. Password for USB

If the password does not meet the system requirements, the system displays the Password Creation Failed dialog box and prompts you to try again.

NOTE: *The USB pen drive used to store exported patient data cannot contain both encrypted and non-encrypted patient data. To copy the data onto another*

pen drive, insert original pen drive into Programmer and save the data to the Programmer hard drive, then re-export to another pen drive.

NOTE: *The data on the pen drive is encrypted, not the pen drive itself.*

6. 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.
7. 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 USB pen drive with greater capacity and select the Try Again button to continue with the export.

   NOTE: *Exported patient data cannot span multiple USB pen drives.*
8. If the exported data is unreadable, erase the USB pen drive and try again, or use another USB pen drive and re-export the data.

NOTE: *When using a computer (e.g., a clinic PC), to access encrypted patient data stored on the USB pen drive, enter the password you created during the export process. If you forget the password, then use a new USB pen drive. Passwords are not recoverable.*

Export - Data Transfer

Patient data (for selected or all patients) can be transferred to another computer via Bluetooth® where the data can be viewed, saved, e-mailed, or attached to an Electronic Medical Record (for example for use with the LATITUDE Link system).

NOTE: *For Bluetooth setup and configuration information, refer to the LATITUDE Network and Connectivity Operator's Manual, Model 3294.*

1. From the Main screen, select the Patient Data Management button (Figure 4 on page 7.)
2. Select the desired patient(s) displayed on the Export screen.
3. Select the Data Transfer button on the Export tab (Figure 5 on page 7).
4. Select the receiving computer bar to select the receiving computer as illustrated in Figure 7 on page 10. Then, press the Continue button to begin the patient data transfer
5. The transfer progress bar displays (Figure 8 on page 10).
6. When the PC authorizes the transfer, the PC dialogue includes where to store the transferred data.

   NOTE: *The default location on a Windows PC is My Documents/Bluetooth Exchange Folder*
7. When the transfer completes, the Programmer displays a confirmation message.

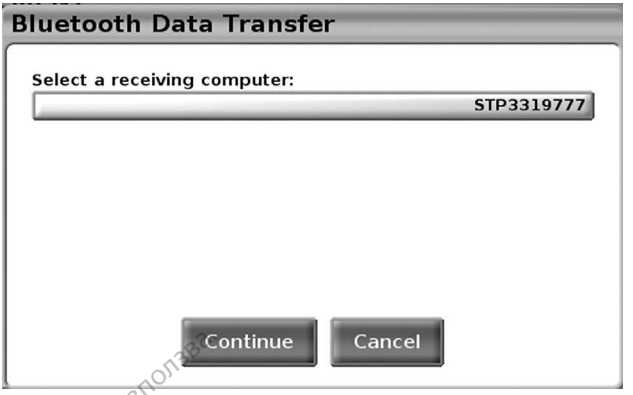


Figure 7. Patient Data Management - Data Transfer

Figure 8. Patient Data Management - Data Transfer Progress

Read Feature

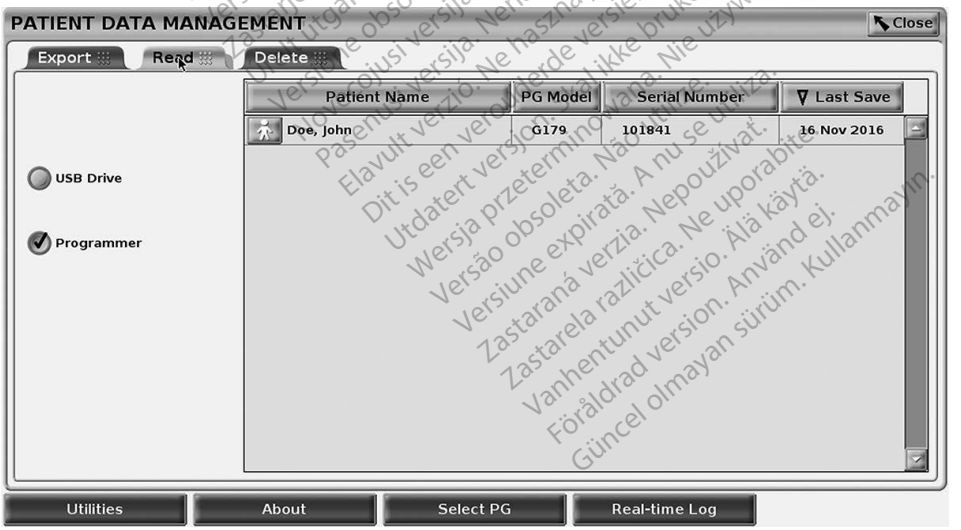


Figure 9. Patient Data Management - Read tab

You can read patient data from the Programmer hard drive or the USB pen drive.

1. From the Main screen, select the Patient Data Management button (Figure 4 on page 7.)
2. Select the Read tab on the Patient Data Management screen (Figure 9).
3. Select the USB Drive or Programmer button to indicate the location from which you want to read patient records.
4. When you attempt to read data from the 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 or that the data could not be read from the USB pen drive or hard drive. You can then select Try Again or Cancel to continue.
5. 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 hard drive.
6. If using a USB pen drive, **do not** remove the USB pen drive during the read operation.
7. If the Read operation fails, the system displays an error message prompting you to select Try Again or Cancel.

Delete Feature

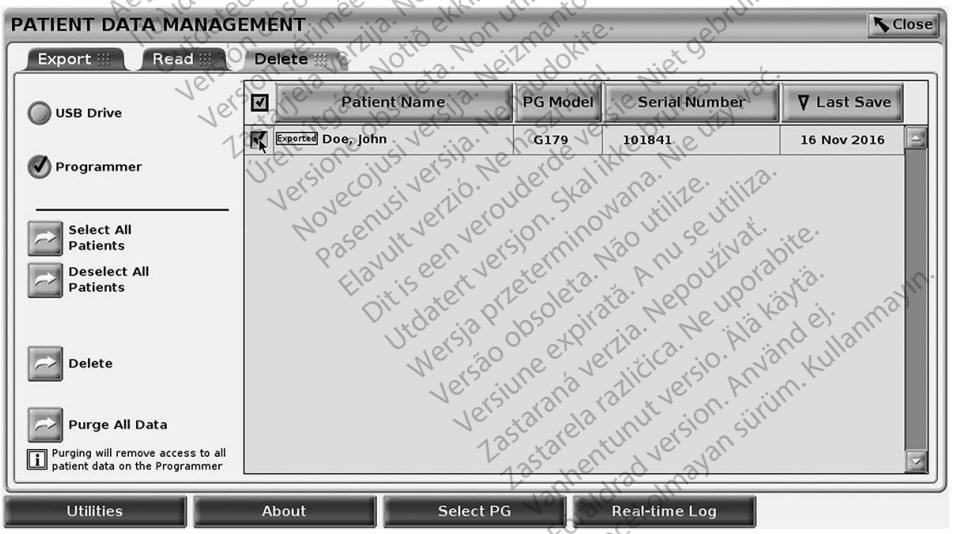


Figure 10. Patient Data Management - Delete tab

You can delete the contents of the patient data records archived on the hard drive or a USB pen drive.

NOTE: *The Delete feature deletes the reference(s) to the patient data on the hard drive. Use the Purge All Data feature to cryptologically erase the patient data from the Programmer.*

1. Select the Delete tab on the Patient Data Management screen (Figure 10).
2. Select the USB Drive or Programmer option to indicate the location from which you want to delete patient data.
3. Select the patient data that you want to delete. You can select all of the patients by selecting the Select All Patients button, or select a specific patient's data by selecting the check box next to a patient's name. You can also undo your selections by selecting the De-select All Patients button, or undo a specific selection by clicking on its check box.
4. Select the Delete button to initiate the deletion of the selected patient data. 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. If deleting data from a USB pen drive, **do not** remove the USB pen drive during the delete operation.
7. If the delete operation fails, the system displays an error message prompting you to select Try Again or Cancel.

Purge All Data Feature

You can delete the entire contents of all patient data records stored on the hard drive. This ensures that all patient data is cryptologically erased and no longer accessible. Use the Purge All Data button shown in Figure 10 on page 11.

NOTE: *The Purge All feature cryptologically erases all patient data from the Programmer.*

NOTE: *Boston Scientific recommends using the Purge All Data feature before returning the Programmer for repair or before moving the Programmer to another clinic or hospital.*

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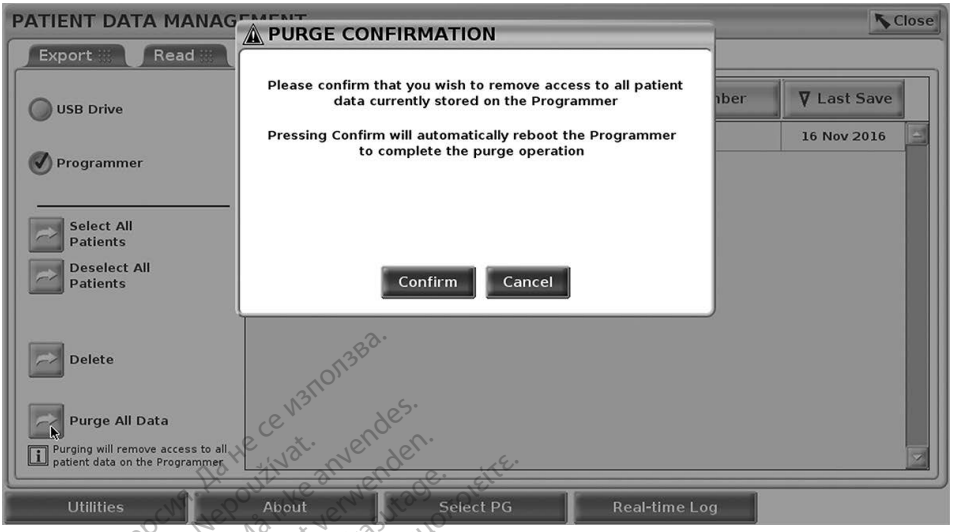

Figure 11. Patient Data Management - Purge All Data

MAINTENANCE, TROUBLESHOOTING, HANDLING, AND SPECIFICATIONS

For questions regarding operation or repair of the LATITUDE Programming System, contact Boston Scientific using the information on the back cover of this manual. The LATITUDE Programming System must be serviced by Boston Scientific personnel only.

For all other Maintenance, Troubleshooting, Handling, and Specifications information, refer to the LATITUDE Programming System Operator's Manual, Model 3300.

NOTE: *Be sure to save all patient and pulse generator data to a USB pen drive before returning the LATITUDE Programming System to Boston Scientific. Boston Scientific recommends using the Purge All Data feature before returning the Programmer. All patient and pulse generator data will be erased from the LATITUDE Programming System when it is returned for service.*

WARRANTY INFORMATION

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Zastarela različica. Ne uporabi.
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