CIT200 CardiolInsight™
Cardiac Mapping System

Operator’s Manual
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General Description
CardioInsight™ Cardiac Mapping System is a noninvasive, single beat cardiac mapping system that provides three dimensional (3D) electroanatomic maps of the heart. CardioInsight™ combines body surface potential measurements with cardiac anatomy to generate panoramic, bi-atrial or bi-ventricular 3D electroanatomic maps. The system is mobile and can be used for mapping bedside or in the electrophysiology (EP) lab.

Indications for Use
The CardioInsight™ Cardiac Mapping System is intended for acquisition, analysis, display and storage of cardiac electrophysiological data and maps for analysis by a physician.

Contraindications
There are no known contraindications.

Principles of Operation
Electrocardiographic potentials are measured from the torso using 252 silver-silver chloride electrocardiogram (ECG) sensors on the surface of the body. Each measured ECG signal is amplified and digitized. A computerized tomography (CT) scan of the thorax is segmented to obtain the three-dimensional location of each sensor and the detailed anatomy of the epicardial surface of the heart. From these data, the system uses mathematical algorithms to use the geometrical information to transform the measured body surface signals into epicardial signals via solving the cardiac inverse problem. The mathematical computation of epicardial potential maps, 3D rendering of maps and plots and clinically relevant signal processing is accomplished using a computer workstation.

Warnings and Precautions
Read these warnings and precautions carefully before using CardioInsight™ Cardiac Mapping System (CardioInsight™, CardioInsight™ System).

⚠️ WARNINGS
⚠️ Read all documentation prior to using CardioInsight™, and use CardioInsight™ in accordance with the documentation provided.
⚠️ Do not modify the attachment plug or use a power adapter. This could cause an electrical hazard. If you require a different electrical socket plug, contact your local Medtronic Representative. CardioInsight™ must always be connected to the power source properly.
⚠️ Ensure that all power sources are appropriately rated and are properly grounded or earthed. If the CardioInsight™ system is not properly grounded or earthed, it becomes a possible electric shock hazard. Protection against electrical shock has been provided through an isolation transformer and chassis grounding via a plug to an appropriate power source.
⚠️ Before connecting the CardioInsight™ system, ensure that the power cord is undamaged.
⚠️ Electroanatomical mapping with CardioInsight™ should ONLY be performed after the risks of the entire procedure, including radiation exposure and time required for signal collection, have been adequately considered for each patient.
⚠️ If CardioInsight™ comes into contact with hazardous chemicals or biological materials, take appropriate cautions to minimize personnel interaction with CardioInsight™ until the system can be cleaned.
⚠️ Do not use the Sensor Array if the patient has sensitivity, open sores, or a severe skin condition or disease of the thorax area.
\* Do not perform magnetic resonance (MR) imaging with the Sensor Array on the patient. The Sensor Array may cause harm to the patient if used in MR imaging. Remove Sensor Array prior to performing MR imaging studies.

\* Operation of CardioInsight™ in a manner not specified in this Operator’s Manual voids the terms of the product warranty.

\* PRECAUTIONS

\* The installation and setup of CardioInsight™ and its software should ONLY be performed by trained Medtronic personnel.

\* Portable or mobile RF communications equipment may affect CardioInsight™.

\* Connect the system ONLY as indicated in the Operator’s Manual.

\* Extension cords and electrical power bars should NEVER be used with CardioInsight™.

\* CardioInsight™ should not be connected to any equipment that is not supported by or part of the system.

\* The Sensor Array should only be connected to the CardioInsight™ Cardiac Mapping System.

\* The isolation transformer should NEVER be placed on the floor for use.

\* Do not stack other equipment on the mapping amplifier or the system cart.

\* Do not use the cart for any other purpose than storing and using CardioInsight™.

\* Avoid running over power cords or cables connected to the system.

\* The workstation that is supplied as part of CardioInsight™ is not intended for use without the isolation transformer.

\* Do not connect the CardioInsight™ system to a network or to any other devices which are not components of CardioInsight™ or accessories approved by Medtronic. Introducing unapproved connections or devices may introduce viruses or compromise system security, and may affect the accuracy and usability of CardioInsight™.

\* Devices that connect to CardioInsight™ via Universal Serial Bus (USB) such as an external hard drive should be used ONLY after approval by Medtronic as they may introduce computer viruses.

\* Installation of software not authorized by Medtronic on the CardioInsight™ workstation can cause the system to display inaccurate results or otherwise malfunction, and will void the terms of the product warranty.

\* Do not replace the amplifier fuses while the system is in use or connected to the patient.

\* Assembly, repair, and modifications of the system over its service life will be evaluated based on the requirements of IEC 60601-1 prior to implementation.

\* Disconnect the system from the supply mains and the patient before cleaning the system or performing any maintenance operations.

\* CardioInsight™ should ONLY be used by trained personnel or under the guidance of trained Medtronic personnel.

\* CardioInsight™ should ONLY be used in an institution’s environment.

\* Do not expose CardioInsight™, the Sensor Array, or electrical connectors to fluids or solvents, except when following cleaning instructions in this Operator’s Manual.

\* Do not use CardioInsight™ in the presence of flammable anesthetic mixtures with air, oxygen, or nitrous oxide.

\* The Sensor Array is meant to be used only during CT imaging procedures that use legally marketed CT scanners.

\* The CardioInsight™ acquisition should be performed on the same day as the completion of the CT scan. The Sensor Array should not be removed or repositioned between the CT scan and the acquisition.

\* The Sensor Array is not sterile and cannot be sterilized. Care should be taken to keep the Sensor Array outside of any sterile field.

\* The Sensor Array is intended for single use ONLY. Reusing the Sensor Array may result in poor system performance or transmission of infection.

\* The system cables, including the Sensor Array signal cables and patient ground reference
cable are provided non-sterile. DO NOT sterilize the cables.

- Store Sensor Array flat (parallel to the floor) with the correct side facing up, as labeled, according to the environmental storage conditions.
- Inspect the packaging and Sensor Arrays prior to use.
- DO NOT use Sensor Array if pouches are opened or damaged.
- Panels from different Sensor Array sizes should NEVER be mixed and matched for use.
- Store Sensor Array panels in their sealed protective pouches until use.
The CardioInsight™ System is comprised of the following components:

1. **Cart**: Holds the CardioInsight™ components including workstation, mapping amplifier, isolation transformer, monitor, operator’s manual, and connecting cables.
2. **Workstation**: Includes the computer, mouse, and keyboard. The keyboard tray can be adjusted for height and tilt. The mousepad can swivel out from under the keyboard tray.
3. **Mapping Amplifier**: Acquires data from the Sensor Array via the four Sensor Array signal cables along with the patient ground reference cable. It is docked on the cart but can be removed from the cart to be placed closer to the patient.
4. **Isolation Transformer**: Provides isolation from supply mains to the workstation and mapping amplifier.
5. **Monitor**: Can be adjusted for preferred user height, tilt, and swivel.
6. **Operator’s Manual**: This document is stored in the drawer.
7. **Connecting cables** (not pictured): Includes two sets of Sensor Array signal cables, two patient ground reference cables, Ethernet cables, display cables, and power cables.

**Note**: The cart has two green casters that can be engaged to lock wheel alignment and two gray casters that can be engaged to lock wheel rotation.

**Note**: The cart drawer is a storage space for the Operator’s Manual, an extra set of signal cables, an extra patient ground reference cable, display cables, the optional mapping amplifier power cable, and additional Ethernet cables.

**Note**: The CardioInsight™ Cardiac Mapping System is provided with two sets of signal cables. It is highly recommended to keep a spare set of cables in the cart drawer to be placed into service as needed. When a cable set has been damaged or reached end-of-service, contact your local Medtronic Representative to order a replacement so that a spare set may be maintained.

The following components are not included in the CardioInsight™ system delivery:

- **CardioInsight™ Sensor Array**: A Multi-Electrode Mapping Vest containing 252 electrodes is
fitted on the patient. It can be connected to the CardioInsight™ System for signal acquisition via the mapping amplifier using the four signal cables and the patient ground reference cable.

- **Second Display:** The CardioInsight™ System can support a 1080p resolution (1920x1080) second display. This second display will mirror the content displayed on the main monitor. Use ONLY a Medtronic supplied display cable for the second display.

⚠️ **Note:** Some displays may not be compatible with the CardioInsight system. When connecting a second display, ensure that the resolution on both the second display and main monitor are maintained at 1080p resolution (1920x1080).

The following components are not supplied but are required for use with CardioInsight™:

- Electrode patches for patient ground reference cable
- Skin preparation materials
- System cleaning materials
- Protective signal cable sleeves
- CT scanner

⚠️ **Note:** The use and performance of the CardioInsight™ system in conjunction with commercially available navigation systems could result in signal noise.

**Patient Preparation**

Upon confirming the patient’s rhythm, prepare the patient according to the Sensor Array Technical Manual that is provided with each CardioInsight™ Sensor Array. The Sensor Array Technical Manual contains instructions for patient skin preparation and Sensor Array application in preparation for a CardioInsight™ procedure. Once the patient is fitted with the Sensor Array, he or she can either go through the CT scan protocol first and then be connected to the CardioInsight™ System to be recorded, or he or she can be recorded first and then go through the CT scan protocol.

⚠️ **Precaution:** The CT scan must be performed with the same Sensor Array placement configuration that will be used for the associated EP procedure.

⚠️ **Note:** It is helpful to secure the Sensor Array cable connectors by tucking them in between the patient sides and arms for the duration of the CT scan.

**CT Scan Requirements**

All information related to the geometry of the surfaces and positions of electrodes is dependent on the image data produced by the CT scanner. After the Sensor Array has been placed on the patient, the patient is ready to undergo a CT scan to register the locations of each electrode with respect to the body surface. The CT scan must occur prior to map creation.

CT scans must be performed on legally marketed CT scanners. For consistent image resolution and quality, the CT scan parameters must be set to meet the following minimum requirements:

- 250 milliamperage second (mAs)
- 80 peak kilovoltage (kVp)
- 3 mm slice thickness
- 1.5 recon increment (overlap)
- 64 slices
- Supine with arms at side
- Field of View: 5 cm (2 in) above the shoulder line to the bottom of Sensor Array and from mid-arm to mid-arm laterally to include the entire width of the torso. If the user is not confident with
the lower boundary for the field of view, secure a radiopaque marker to the bottom of the lowest panel of the Sensor Array to act as the lower boundary.

- Follow standard of care for cardiac gating and contrast enhancement

**System Operation**

**System Users**
The system is intended for use only by persons trained or under the guidance of trained Medtronic personnel.

**System Connections**
Before connecting the CardioInsight™ system to power, ensure that the system components are properly connected (refer to Figure 2).

**Getting Started**
When accessing the workstation with the intent to record signals, first follow the instructions in the Sensor Array Technical Manual to prepare the patient for acquisition. The signal acquisition can be performed with the mapping amplifier either docked on the system cart, or in cases where the cart cannot be in close proximity to the patient bedside, the mapping amplifier can be removed off of the system cart and placed at patient bedside. The patient should remain in a supine position, similar to their CT scan position, during all signal acquisition.
Amplifier Setup

When accessing the workstation without the intent to acquire signals, the mapping amplifier may be left powered off.

When accessing the workstation with the intent to acquire signals, the mapping amplifier may be set up on the cart or removed from the cart to be set up near the patient. To remove the mapping amplifier off of the cart, ensure that the mapping amplifier is powered off and that the power and Ethernet cables are disconnected from the mapping amplifier. Stand so that you are facing the back of the cart and the mapping amplifier is in front of you (Figure 2.1). Grasp the integrated hand grip on the mapping amplifier with your left hand and rotate the mapping amplifier out and towards the floor so that it is rotated at around 45 degrees (Figure 2.2). The pivot lock will detach from the mating feature on the cart (Figure 2.3). Carefully pull the mapping amplifier out of the pivot block until it comes off the cart (Figure 2.4). The mapping amplifier can now be set up at patient bedside using the mapping amplifier power cable from the cart drawer. Connect a provided Ethernet cable to the mapping amplifier and run it to the CardioInsight™ workstation.

To place the mapping amplifier back on the cart frame, ensure that the mapping amplifier is powered off and that the power and Ethernet cables are disconnected. Stand in front of the mapping amplifier with the logos facing you and the power switch on the left side. Grasp the integrated hand grip on the mapping amplifier with your left hand and lift the mapping amplifier to bring it to the cart. Angle the bottom edge of the mapping amplifier at around 45 degrees and tip it onto the pivot block on the cart. With the mapping amplifier riding on the pivot block, gently rotate the mapping amplifier enclosure.
forward until it clicks and locks into place on the cart. Connect the on-board mapping amplifier power and Ethernet cables to the mapping amplifier.

**System Power On**
Once the mapping amplifier is set up in the desired configuration, plug the isolation transformer power cable into a supply mains with protective earth and press on the isolation transformer power switch.

⚠️ **Warning**: To avoid the risk of electric shock, this equipment must ONLY be connected to a supply mains with protective earth.

The computer and monitor may now be powered on. Log into Windows with the given username and password and launch the CardioInsight™ application using one of the following two methods:

- Double-click on the CardioInsight™ icon on the desktop
- Select Start | All Programs | CardioInsight | CardioInsight™

After launching the software, a splash screen appears while the software loads.

![CardioInsight™ Login Screen](image)

**Figure 3: Login Screen**

The *Login screen* (Figure 3) is displayed once the software loads. Users must enter a valid username and password to gain access to CardioInsight™. Several functions can be performed at the *Login screen*, including logging into the software, changing a password, and exiting the software.

⚠️ **Note**: The password is case-sensitive.

⚠️ **Note**: The Admin password cannot be changed.

**Changing a Password**

To change a password:

1. Click *Change password*?
2. Enter Username, Old password, New password, and Confirm new password
3. Click **Save** to save the new password or click **Cancel** to cancel changing the password

**Home Screen**

Once successfully logged in, the user is presented with the *Home screen* (Figure 4). The following buttons can be accessed on the *Home screen*:

- **Noninvasive Mapping**: Loads the noninvasive mapping workflow and opens the *Patient screen*.
- **Maintenance**: Accesses the *Physician List*. Administrators can access system information and settings.
- **Log Off**: Exits the user account and returns to the *Login screen*.
- **About**: Displays product information, including the software version number.
- **Exit**: Exits the CardioInsight™ software.

![Figure 4: Home Screen](image)

**Physician List**

Users can view and manage physician profiles from the *Physician List* (Figure 5). This screen can be accessed from the *Home screen* by clicking on the **Maintenance** button.
Noninvasive Mapping Workflow Bar
At the top of each of the proceeding screens in the CardiolInsight™ System, there is a Workflow Bar (Figure 6) that allows the user to navigate through the screens in the workflow. By selecting the different icons on the Workflow Bar, the system will load the corresponding screen. Each of the screens and their workflows are described in this Operator’s Manual.

Figure 6: Workflow Bar

Patient Screen
From the Home screen, clicking on the Noninvasive Mapping button will load the Patient screen (Figure 7). The Patient screen contains the patient information stored on CardiolInsight™. Each patient may have one or more studies stored. Patient records may be sorted by Name, Medical Record Number (MRN), Date of Birth (DOB), or Sex by clicking the sorting icons above the Patients list. The Patients list may also be filtered by search criteria, which can be entered in the Patients search box (Table 3). Study records may also be filtered by search criteria by using the Studies search box. The user may select a patient from the list to view associated studies for that patient or select New Patient to add a new patient to the system.
The following buttons can be accessed on the Patient screen:

1. **New Patient**: Add a new patient record. User can enter patient data or import patient data from a DICOM (Digital Imaging and Communications in Medicine) file.

2. **Restore Patient from Archive**: Load a patient record and corresponding studies from an archive file.

⚠️ **Note**: When attempting to restore a patient record with an MRN that already exists in the system, a message will display that informs the user that the MRN already exists. Two different patients with the same MRN cannot both exist in the system at the same time.

3. **Archive Patient**: Save a patient record and corresponding studies to an archive file.

⚠️ **Note**: Patient records that have been archived will be indicated with the Archive icon in white unless they were anonymized when they were archived. Patient records that have not been archived will have the same icon grayed out.

⚠️ **Note**: If a user attempts to delete a patient record, a message will appear either indicating the date and time of when the patient record and studies were last archived, or stating that the patient record has not been archived. Continuing with the deletion function will display a confirmation message stating that deleting a patient record will permanently remove all signal data and calculated maps. Confirm that the desired patient record is selected before continuing with deletion.

4. **Delete Patient**: Delete a patient record and all corresponding studies.

5. **New Study**: Create a new study for the selected patient.

6. **Edit**: Edit the patient record and study information.
7. **Copy Study**: Create a copy of the acquired data from the selected study. This function does not create a copy of geometries or maps created in the study.

   🔄 **Note**: If a user attempts to delete a study, a message will appear either indicating the date and time of when the patient record and studies were last archived, or stating that the patient record related to the study has not been archived. Continuing with the deletion function will display a confirmation message stating that deleting a study will permanently remove all signal data and all calculated maps. Confirm that the desired study is selected before continuing with deletion.

8. **Delete Study**: Delete the selected study.

9. **Open Study**: Launch the selected study.

   🔄 **Note**: Studies that have a geometry set associated with them will be indicated with the *Geometry icon* in white. 🔄 Studies that do not have an associated geometry set will have this icon grayed out.

**New Patient**

To create a new patient record, complete the following steps:

1. Click on **New Patient**. The **New Patient** dialog displays (Figure 8).
2. Enter the patient name, date of birth, sex, MRN, and comments.

   🔄 **Note**: If the patient’s DICOM files are loaded in the computer or their CD is in the CD-drive, CardioInsight™ can import the patient’s information from the DICOM files. Click on **Import from DICOM** to use this feature. The user can modify the patient name, date of birth, sex, MRN, and any comments in the **New Patient** dialog.

   🔄 **Note**: Each patient must have a unique MRN. Entering an existing MRN will prompt the message “*MRN is already in use.”

![Figure 8: New Patient](image)

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Existing Patient
If the patient record already exists in the Patients list, click on the patient’s row to display all associated studies in the Studies list.

New Study
All information related to an electrocardiographic (EC) mapping session is stored in a single study. Studies and related files are stored on the local hard drive of the CardiolInsight™ workstation. After selecting the patient from the Patients list, click New Study to open the New Study dialog.

⚠️ Note: Before creating a new study, ensure that the physician profile exists in the Physician List within Maintenance.

To create a new study:
1. Select the patient record from the Patients list.
2. Click on New Study.
3. Enter the study name, arrhythmia type, physician name, and study notes.
4. Choose to either create Geometry, continue with Acquisition (and segment later), or Cancel.

When creating a new study, the user may choose to create a geometry or continue to signal acquisition. Selecting Geometry will proceed to the Geometry screen where a new active geometry set can be created. Selecting Acquisition will proceed to the Acquisition screen without segmenting.

⚠️ Note: Segmentation must be performed before CardiolInsight™ maps can be created.

Figure 9: New Study

Archive and Restore Functions
The user can create backup files of CardiolInsight™ records using the archive function. The user can also restore a record to the system using the restore function. The CardiolInsight™ (.archive) file contains complete patient and study information. An archived patient record and its affiliated studies are uniquely identified by a system-generated identity.
Note: ONLY Medtronic trained users are permitted to restore data to a CardioInsight™ system from an archived file.

Note: Restoring an archive that was created on a system that is prior to CIT200 will not automatically reprocess maps in CIT200.

Note: Studies loaded with Phase Maps that were created on legacy systems prior to CIT200 should be used for reference only. Refer to Appendix H, item 73. Studies loaded with Beat Maps that were created on legacy systems prior to CIT200 should be used for reference only.

To archive a patient record:
1. Select a patient in the Patients list.
2. Select Archive Patient. The Save As dialog is displayed.
3. Browse to the destination for the file and enter a file name for the .archive file and click Save.
4. The Archive Patient dialog is displayed. If the archive file is to be anonymized, check the Anonymize box. The patient fields are now editable.
5. Select Start. The progress of the archive operation will display until the archive is complete.

To restore a patient record into the CardioInsight™ system:
1. Select Restore Patient from Archive. The Select Archive File dialog is displayed.
2. Browse to the folder containing the archive file.
3. Select the archive file to be restored.
4. Select Open. The Restore Patient from Archive dialog is displayed, indicating the patient associated with the selected archive file. Verify data and check the Anonymize box if the patient information should be anonymized upon restoration.
5. Select Start to continue with restoration. The progress of the restore operation will display until the restore is complete. The patient information and study information will be added to the Patients list and Studies list respectively.

Note: When restoring an archive that is affiliated with a physician who does not exist in the system, the physician will be automatically added to the Physician List within Maintenance.

Note: When restoring an archive of a patient that already exists in system but the archive contains a study that is not on the system, a confirmation message will appear stating non-duplicate studies from the archive will be added to the patient without anonymization.

Editing or Deleting a Patient Record
To delete a patient record, complete the following steps:
1. Select a patient from the Patients list.
2. Select Delete Patient.
   a. If the patient has been previously archived, a dialog will appear that displays the date and time of the last archival. Click OK. A second dialog will appear to confirm patient deletion. Click OK to continue or Cancel to abort deletion.
   b. If the patient has not been previously archived, a dialog will appear that displays the patient information and allows the user to archive the file or to delete the file without archiving. Click Archive to archive the file. Click Delete Without Archiving to continue deletion without archiving. Click Cancel to abort deletion.

To edit a patient or study record, complete the following steps:
1. Select a patient record from the Patients list.
2. Click **Edit**. Edits can now be made to the patient and study attributes.
3. Click **Save** to save and exit the editing mode. Edits made to patient and study attributes appear immediately in the *Patients list* or *Studies list*.

⚠️ **Note:** Study notes can be accessed and edited for any loaded study by clicking on the **Study Notes** button:

### Deleting a Study

To delete a study record, complete the following steps:

1. Select the patient record associated with the desired study from the *Patients list*.
2. Select the desired study from the *Studies list*.
3. Select **Delete Study**.
   a. If the patient record has been previously archived, a dialog will appear that displays the date and time of the last archival. Click **OK**. A second dialog will appear to confirm study deletion. Click **OK** to continue or **Cancel** to abort deletion.
   b. If the patient record has not been previously archived, a dialog will appear that displays the patient information and allows the user to archive the file or to delete the file without archiving. Click **Archive Patient** to archive the file. Click **Delete Without Archiving** to continue deletion without archiving. Click **Cancel** to abort deletion. A second dialog will appear to confirm study deletion. Click **OK** to continue or **Cancel** to abort deletion.

### Geometry Screen

The *Geometry screen* (Figure 10) displays the active geometry set, indicates whether the geometry set is current, and allows the user to manage geometry sets and their details.

⚠️ **Note:** If the active geometry set is not the most recent, the following message will appear to notify the user:

⚠️ **Geometry Set: Not Most Recent**
A new geometry set can be created from a DICOM series. Click **New Geometry** to open the **Segmentation** dialog. The dialog prompts the user to insert a CT Data CD. A Medtronic approved USB drive may also be used. Click **Start Segmentation** to begin the segmentation process. A second dialog will notify the user that the segmentation is in progress and will launch the **3Di Patient Browser**. Refer to “**Segmentation**” section for details.

**Edit Geometry**
Click **Edit Geometry** to load the active set into the **CISH** application. The user can now make edits to the cardiac and electrode segmentation. Refer to “**Introduction to CISH**” section for details.

**Manage Geometry**
Click **Manage Geometry** to select the active geometry set, delete selected geometry sets, and delete structures. Deleting a geometry set will permanently remove all geometry set data and all associated calculated maps.

**Segmentation**
CardioInsight™ segmentation extracts cardiac geometry and CardioInsight™ Sensor Array electrode positions from the CT scan of the patient. Segmentation may occur before or after signal acquisition, but it must occur before CardioInsight™ map generation. Segmentation is performed only on the chambers (atria or ventricles) and all associated geometric landmarks and valves to which the study arrhythmia type applies.

**3Di Patient Browser**
The CardioInsight™ system uses segmented CT data to produce maps. Segmentation is performed using **CISH** segmentation software included in the CardioInsight™ system. When
creating a new geometry, click **Start Segmentation** to launch the 3Di Patient Browser (Figure 11) from the Geometry screen. The 3Di Patient Browser is used to select the DICOM format image series for segmentation.

Use the **Folder** button or the D:\ button from the Sources tab to select the image series location. Once the location containing the image series is selected, an image preview will be generated inside the 3Di Patient Browser along with the patient data, list of series, and list of images. Select the desired image series from the list of series and preview the images. When satisfied with the image series and preview, click the **CISH** button on the left side of the screen to launch the segmentation application.

![Figure 11: 3Di Patient Browser](image)

**Introduction to CISH**

Load **CISH** by clicking the **CISH** button within the 3Di Patient Browser for a new geometry workflow, or by clicking **Edit Geometry** from the Geometry screen for a previously created geometry. There are two main tabs within **CISH** to allow for the segmentation of the cardiac structures and the registration of CardioInsight™ Sensor Array electrodes on the torso.

⚠️ **Note:** The spatial resolution of CardioInsight™ from published studies is a mean of 6.8±2 mm [References 1-8].

⚠️ **Note:** The physician, as the licensed medical practitioner, is responsible for verifying segmentation quality. If necessary, all segmentation can be cancelled and restarted.

**CISH Cardiac Segmentation**

The **CISH Cardiac Segmentation Tab screen** and tool layout is depicted below (Figure 12).
The following tools and ports are shown in the CISH Cardiac Segmentation Tab screen:

1. **Tissues List**: Displays the names of all created structures. Indicates if structures are displayed on the Segmentation Port. Transparency can be toggled and each structure’s color can be set.
2. **New**: Creates a new structure. New structures can be created by selecting a name from the list or typing in a custom name.
3. **Edit**: Toggles editing mode for the selected structure in which the Define and Edit Toolbar is available. The geometry cannot be edited in Mesh Mode.
4. **Sculpt Free Form**: Deletes a volume of the selected structure in the Segmentation Port.
5. **VOI (Volume of Interest)**: Adds user-identified volume to the selected structure in the Segmentation Port.
6. **Erase**: Deletes a volume of the selected structure in the Axial CT Slice Port. The Erase tool has a spherical shape. The tool’s size can be adjusted by scrolling the mouse wheel. The size will affect adjacent slices. This tool can be toggled with Ctrl + E.
7. **Add**: Adds a volume to the currently selected structure in the Axial CT Slice Port. The Add tool has a spherical shape. The tool’s size can be adjusted by scrolling the mouse wheel. The size will affect adjacent slices. This tool can be toggled with Ctrl + A.
8. **Define Curve**: Creates a curved cylindrical shape on the Axial CT Slice Port.
9. **Erase Tissue**: Deletes the entire geometry of the selected structure.
10. **Tissue Mode**: Allows the user to edit the cardiac structures. Tissue Mode is a rendering mode.
11. **Mesh Mode**: Allows the visualization of all cardiac structures as they will appear in CardiolInsight™ maps. Mesh Mode is a rendering mode.
12. **Scroll**: Enables the left mouse button to scroll through the Axial CT Slice Port. The left mouse button will rotate the Segmentation Port.
13. **Zoom**: Enables the left mouse button to zoom in and out of both ports.
14. **Pan**: Enables the left mouse button to pan on both ports.
15. **Rotate**: Enables the left mouse button to rotate the Segmentation Port. The left mouse
button will scroll through the *Axial CT Slice Port*.
16. **Relate**: Clicking on any point on the cardiac structure in the *Segmentation Port* or *Axial CT Slice Port* will relate that point to a point in the opposite port.
17. **Axial**: Sets the *Segmentation Port* orientation to an axial view.
18. **Coronal**: Sets the *Segmentation Port* orientation to a coronal view.
19. **Sagittal**: Sets the *Segmentation Port* orientation to a sagittal view.
20. **Flip**: Flips the *Segmentation Port* orientation.
21. **Segmentation Port**: Displays all displayed cardiac structures.
22. **Axial CT Slice Port**: Displays the series of axial CT slices.
23. **Cardiac Tab**: Displays the Cardiac Tab. Cardiac structures are segmented here.
24. **Electrodes Tab**: Displays the Electrodes Tab. Sensor Array electrodes are segmented here.

![Image](image.png)

**Figure 13: CISH Cardiac Segmentation Advanced Tab**

The following tools and ports are shown in the CISH Cardiac Segmentation Advanced Tab (Figure 13):

1. **Flip Vert**: Flips the *Axial CT Slice Port* vertically.
2. **Flip Horz**: Flips the *Axial CT Slice Port* horizontally.
3. **Straight Line**: Selects from multiple measurement tools to measure a length (in millimeters) on either port.
4. **Inject**: Increases the volume of a structure by clicking and holding on the structure.

The program will load the DICOM image series into *CISH* and will first complete automated segmentation in an attempt to segment the atria, ventricles, and aorta. Upon completion, the segmentation will be displayed in the *Segmentation Port*.

There are many tools that can be used to add or edit geometries. To add a new structure, select a new structure from the **New** list or type in a custom structure name. A selected tissue will turn a light grey color in the *Segmentation Port* and more opaque in the *Axial CT Slice Port*. When the tissue has been selected, it will automatically be placed into edit mode, and the Define and Edit toolbar will become available. The Manipulation toolbar buttons (**Scroll**, **Zoom**, **Pan**, **Rotate**, **Relate**) can be selected to change the function of the mouse when manipulating the image.

**Note**: Double clicking on either port will enlarge it to fit over both ports. Double click again on the port to restore it to the default view.

**Manual Segmentation of Cardiac Structures**

In order to manually segment, the user may begin identifying chamber boundaries with one of the following two options:

- The **VOI** tool allows a user to manually define the borders of a structure in the *Axial CT Slice Port*. Once borders have been defined on two separate slices, the tool will automatically interpolate the volume between the defined regions. The VOI tool is best used to define structure edges at intervals of several slices (every 4-5 axial images). This interval allows for a smooth interpolation of the structure edges in the non-defined
images. For example, the user selects VOI and begins tracing the posterior left atrial wall, completing an oval shape in one slice. The user then scrolls 4 slices forward in the image series, and traces the posterior left atrial wall by completing an oval shape. The user then clicks the Edit button to allow rendering of their progress, and views the result in the Segmentation Port. The VOI tool works best when sequential outlines are drawn in the same convex shape with slight changes in diameter. It is best to use the tool in a manner that avoids growing and shrinking a diameter within the same operation. A good method is to use two VOI operations – one growing a region, then another shrinking a region in the opposite direction. The VOI tool is only additive – overlap with a previously defined operation is allowed and encouraged for image continuity.

- The Add tool allows a user to add tissue with a spherical tracing. The spherical tracing appears as a circle in the Axial CT Slice Port, but adds tissue both above and below the current slice based on the diameter of the circle being used. Therefore, adding a circle in the Axial CT Slice Port will add a sphere in the 3D cardiac structure on the Segmentation Port. The size of the added sphere can be adjusted by scrolling the mouse wheel. The Add tool is useful for adding protruding structures, such as the appendages and the pulmonary veins. It is also useful for “smoothing” structures that were added using the VOI tool. A good method for using the Add tool for pulmonary veins is to select the tool and position it inside the left atrial body, and adjust the circle size to the pulmonary vein size as it exits the atrium. Holding down the left-click mouse button will trace the pulmonary vein outward. Release the left-click mouse button to stop adding volume to the pulmonary vein. If the vein ostium is large, repeat the tracing from the other side of the vein ostium. Then click Edit to render the operation in the Segmentation Port, and examine the result.

If desired for reference, the esophagus and left anterior descending artery (LAD) should be added to the segmented geometries by using the Define Curve tool in the Define and Edit toolbar. When selected, this tool allows the user to click the center of a structure at many points through the axial image stack. When the Define Curve operation is complete, click Define Curve to deselect the function and show the structure as a curving, narrow tube on the Segmentation Port.

Two additional tools are available which will delete portions of surfaces that have been previously added. These tools are the Sculpt Free Form and Erase tools within the Define and Edit toolbar.

- The Sculpt Free Form tool allows the user to erase areas of the 3D cardiac structure in the Segmentation Port that is selected for editing. The erasing occurs inside of a user-defined region that is set by left-clicking, holding, and dragging the mouse cursor around the area. The tool will erase all selected structure tissue that is within the defined area, including the tissue that is behind the surface in view (e.g. the z-axis of user perspective). For example, if the user views the ventricles in the RAO view and uses Sculpt Free Form to modify the anterior portion of the heart, tissue may be erased from both ventricles rather than the right ventricle alone. The Sculpt Free Form tool is useful for “smoothing” chamber edges, outflow tracts, distal vein portions, and appendages. The Sculpt Free Form tool can only be used on the 3D cardiac structure in the Segmentation Port.

- The Erase tool works much like the Add tool. A spherical area of the selected tissue is erased depending on where the user clicks and holds the cursor. Clicking and creating a circle in the Axial CT Slice Port will remove a sphere in the 3D cardiac structure on
the Segmentation Port. The size of the erased sphere can be adjusted by scrolling the mouse wheel. The Erase tool is useful for removing structure volume that has been segmented outside of the heart’s surface.

Valves are manually defined by using the Add tool to paint the valves directly on the rendered structure in the Segmentation Port.

¹ Note: Ensure that the cardiac structure that is being edited is the same structure as the name appearing in the Tissues List. For example, do not paint on the mitral annulus when the selected structure appears as tricuspid annulus in the Tissues List.

**CISH Electrode Segmentation**

Proper segmentation of CardioInsight™ Sensor Array electrodes is integral to the accuracy of the CardioInsight™ system. The Electrodes tab may be selected on the left side of the CISH screen. The system will complete an automated segmentation in an attempt to identify and label all Sensor Array electrodes. Upon completion, a 3D volume rendering of the patient’s torso segmentation is displayed in the Left Patient Port, and a reference Sensor Array is displayed in the Right Reference Port. The Right Reference Port should be used as a guide to complete the electrode identification and labeling on the Left Patient Port. Most electrodes will automatically be identified with a red dot, and some may be automatically labeled. CardioInsight™ automatically labels electrodes based on detection of the hexagonal arrangement. The system will continue the automatic labeling as hexagons are completed by manual electrode segmentation and labeling.

The CISH Electrodes Segmentation Tab screen and tool layout is displayed below (Figure 14).

![Figure 14: CISH Electrodes Segmentation Tab Screen](image)

The following tools and ports are shown in the CISH Electrodes Segmentation Tab screen:

1. **VR CT Protocols List**: Displays the selected and available visualization protocols including Electrodes and Bones.
2. **Show/Hide Toolbar**: Toggles electrode numbering labels, electrode hexagon detections, and automatic labeling.
3. **Add**: Toggles Add mode which allows the user to identify electrode points with red dots.
4. **Continuous labeling Toolbar**: Toggles continuous labeling mode in which the user can set the Current Label number and upon labeling an electrode point with that number, the Current Label number will be updated to the next chronological unlabeled electrode number.
5. **UnLabeled Electrodes Toolbar**: Setting an unlabeled electrode number and advancing to the previous or next chronological unlabeled electrode number.
6. **Scroll**: Enables left mouse button to rotate the volume rendering on both ports.
7. **Zoom**: Enables left mouse button to zoom in and out of both ports.
8. **Pan**: Enables left mouse button to pan the volume rendering on both ports.
9. **Rotate**: Enables left mouse button to rotate the volume rendering on both ports.
10. **Axial**: Sets both port orientations to an axial view.
11. **Coronal**: Sets both port orientations to a coronal view.
12. **Sagittal**: Sets both port orientations to a sagittal view.
13. **Flip**: Flips the volume rendering orientation on both ports.
14. **Left Patient Port**: Port displays a 3D rendering of the patient’s torso with the electrodes' locations and labels.
15. **Right Reference Port**: Port displays a reference of the Sensor Array electrodes.
16. **Cardiac Tab**: Cardiac structures are segmented here.
17. **Electrodes Tab**: Current tab displayed. Sensor Array electrodes are segmented here.

**Figure 15: CISH Electrodes Segmentation Advanced Tab**

1. **Sculpt Free Form**: Tool used to delete volume from the Left Patient Port.
2. **Straight Line**: Select from multiple measurement tools to measure a distance (in millimeters) on the ports.
3. **Segmentation Toolbar**: Toggle Tissue Mode and Subtract Mode. In Tissue Mode, cardiac segmentation structures can be selected from the accompanying tissue list and viewed.

**Adding Electrodes**
Electrodes that are not identified and labeled must be manually added and labeled. The user may add an electrode by selecting the Add tool and clicking once on Left Patient Port in the desired location. A red dot appears to indicate the new electrode identification.

**Deleting Electrodes**
Electrodes that are incorrectly identified or incorrectly labeled must be deleted or relabeled. The user may delete an electrode which has been added erroneously by selecting it with the mouse cursor (electrode will highlight yellow), right clicking, and selecting Delete. If the electrode was part of a hexagonal group, the group is reset. It is good practice to ensure that all electrodes are added and all incorrectly identified electrodes are deleted before the user proceeds to electrode labeling.
Labeling Electrodes

To add label numbers to unlabeled electrodes, type in the lowest unlabeled electrode number into the Current Label box in the Continuous labeling Toolbar. Use the Right Reference Port as a reference to find this electrode location and then click on the corresponding red dot in the volume rendering of the Left Patient Port. Alternatively, right click on an unlabeled electrode and enter the electrode number in the Label number box and press enter.

Saving Segmentation

In order to properly save segmentation, the following tissues listed in the checklist below need to be segmented. The checklist is divided between atrial study types and ventricular study types. Follow the checklist for the selected study type.

<table>
<thead>
<tr>
<th>Table 1: Minimum Required Segmentation Tissues Checklist</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Atrial Study Tissue List</strong></td>
</tr>
<tr>
<td>□ Right and Left Atria</td>
</tr>
<tr>
<td>□ Mitral Valve</td>
</tr>
<tr>
<td>□ Tricuspid Valve</td>
</tr>
<tr>
<td><strong>Ventricular Study Tissue List</strong></td>
</tr>
<tr>
<td>□ Right and Left Ventricle</td>
</tr>
<tr>
<td>□ Mitral Valve</td>
</tr>
<tr>
<td>□ Tricuspid Valve</td>
</tr>
</tbody>
</table>

Upon finishing cardiac and electrode segmentation within CISH, the user may save the segmentation and exit CISH by one of the following methods:

- Click **Menu** indicated by the icon 📋 | Click **Save Results** | Click **OK**
- Click on the **Save** button indicated by the icon 📋 | Click **OK**

If CISH was not loaded from the 3Di Patient Browser but instead loaded by clicking **Edit Geometry** from the Geometry screen, closing CISH will return the user to the Geometry screen. If CISH was loaded from the 3Di Patient Browser, once CISH is exited the user is presented again with the 3Di Patient Browser. The 3Di Patient Browser can be closed by one of the following methods to be returned to the Geometry screen.

- Click **Menu** indicated by the icon 📋 | Click **Close**
- Click on the red X in the top right corner

If the DICOM matches the patient details entered at the start of the study, the segmentation data will be saved as the current geometry set and loaded into the current study. If the DICOM data does not match the patient details entered at the start of the study, the Patient Information Comparison dialog will display (Figure 16).
The Patient Information Comparison Dialog will display the current patient information alongside the patient information obtained from the DICOM. Select the radio button next to each correct detail and click Continue when finished. The segmentation data will be saved as the current geometry set and loaded into the current study.

**Acquisition**

**Setting Up For Acquisition**

ECG signals may be acquired after successful application of the CardioInsight™ Sensor Array, connection of the Sensor Array to the mapping amplifier, and successful setup of a patient study. The Acquisition screen allows the user to visualize the Sensor Array electrodes, record live ECG signals, and create and manage time events.

⚠️ **Note:** For more information on setting up the system and maintaining good signals, refer to Appendix E: Minimizing Signal Noise

⚠️ **Note:** Creating an active geometry is not required prior to navigating to the Acquisition screen. However, the user cannot continue the workflow past the Acquisition screen without an active geometry set.

⚠️ **Precaution:** Patient should be in a supine position during signal acquisition, similar to their position during the CT scan.

When it is necessary to connect the Sensor Array signal cables and the patient ground reference cable to the mapping amplifier, complete the following steps:

1. Open the mapping amplifier door to access the mapping amplifier cable connectors.
2. Carefully connect each color-coded Sensor Array signal cable to its respective color-coded mapping amplifier cable connector.
3. Close the mapping amplifier door.
4. Connect the patient ground reference cable to its socket on the mapping amplifier.
When it is necessary to disconnect the Sensor Array signal cables and the patient ground reference cable from the mapping amplifier, complete the following steps:

1. Carefully pinch and pull up on the connector end of the patient ground reference cable to disconnect the cable from its socket on the mapping amplifier.
2. Open the mapping amplifier door to access the mapping amplifier cable connectors.
3. Carefully lift up the color coded pull tabs on the Sensor Array signal cables and pull each one straight up to disconnect each one from its respective mapping amplifier cable connector.
4. Close the mapping amplifier door.

⚠️ Note: When using the system during an EP procedure, take care to ensure that the signal cables, the patient ground and reference cable, and the connectors are placed securely under the drape to limit potential for contamination. Use medical tape if needed.

⚠️ Note: It is recommended that a protective barrier (similar to Medtronic 6177 Programmer Head Sleeve) be used to separate the signal cables and connector joints from potential contamination sources.

To acquire CardioInsight™ body surface signals, complete the following steps:

1. Connect the signal cables from the amplifier to the Sensor Array cable connectors on the CardioInsight™ Sensor Array according to their matching colors. The vest panel labels refer to the patient’s front left, front right, back left, and back right (Figure 2).
2. Apply the ground electrode (green cable) of the patient ground reference cable on the lower front right of the patient’s torso just below the Sensor Array panel.
3. Apply the reference electrode (red cable) of the patient ground reference cable on the lower front left of the patient’s torso just below the Sensor Array panel.
4. Ensure that the patient ground reference cable is securely connected to the amplifier. Be sure that the Sensor Array cable connectors fit snugly with the signal cables.

⚠️ Precaution: Do not try to force the Sensor Array signal cables into the Sensor Array cable connectors or the mapping amplifier cable connectors. Connect and disconnect the signal cables using a straight insertion and withdrawal motion without any sort of twisting, tilting, rocking, or peeling.

⚠️ Note: Position the ground and reference electrodes completely below the Sensor Array so that they are symmetrical on the torso. The electrodes should not be in contact or overlapping with the Sensor Array.
When the CardioInsight™ Sensor Array signal cables and the patient ground reference cable are connected, the amplifier may be powered on and data acquisition can begin. The user can navigate to the **Acquisition screen** upon opening a study (Figure 18).

ℹ️ **Note:** When switching patients and opening a study with the intent to acquire data, it is recommended to restart the application.

**Acquisition Screen**

The following are the different plots and buttons on the **Acquisition screen**:

1. **Workflow Bar:** Navigate through the different screens in the workflow.
2. **Patient Information Bar:** Displays current patient and study information.
3. **Study Notes:** Opens the study notes.
4. **Start/Stop Acquisition, Test Again:** Starts and stops signal acquisition when the amplifier is connected. Also the **Test Again** button tests the connection to the amplifier.
5. **Enable/Disable R-R Detection:** Toggles R-R Detection to help detect map intervals and premature beats.
6. **Acquisition Vest Display:** Displays all Sensor Array electrodes and their status during acquisition. The expander can be expanded or collapsed.
7. **Deselect All:** Deselects all Sensor Array electrodes and removes them from the **Acquisition Plot Display**.
8. **Acquisition Plot Controls:** Adjusts the display size of the x-axis and y-axis of the **Acquisition Plot Display**. Also, user can navigate around the study and pause live signal display.
9. **Acquisition Plot Display:** Displays selected Sensor Array electrode channels and time events.
10. **Study Timeline:** Displays the time events indicators on a timeline of the total study recording time. Green triangles represent bookmarks, purple lines represent phase
maps, blue lines represent beat maps, green lines represent QT events, yellow lines represent stops in acquisition, and the thick white line displays the clock time at the current study location. Thin white lines represent map intervals detected using the minimum threshold set in the Map Intervals list after setting a QT event. The longer white lines represent longer map intervals and the shorter white lines represent the shorter map intervals.

11. **Events Display**: Displays the four buttons for creating events and displays the three event tabs. The Events Display expander can be expanded or collapsed.

12. **QT**: Create a QT event.

13. **Phase Map**: Create a new phase map event.

14. **Beat Map**: Create a new beat map event.

15. **Bookmark**: Create a new bookmark.

16. **Maps Tab**: Displays the map events (Figure 19).

17. **Map Intervals Tab**: Displays the map intervals (Figure 20).

18. **Premature Beats Tab**: Displays the premature beats (Figure 21).

**Figure 19: Maps Tab**

1. **Delete Event(s)**: Delete all events marked for deletion.
2. **Search Box**: Search the map events list by keyword (Table 3).
3. **Time Sort**: Sort map events list by time.
4. **Label Sort**: Sort map events list by label.
5. **Length Sort**: Sort map events list by length.
6. **Filter**: Filter map events list by the type of event.
7. **Mark Event for Deletion**: Mark an event for deletion.
8. **Flag Beat Map**: Mark a beat map with a flag.

![Map Intervals Tab](image)

**Figure 20: Map Intervals Tab**

1. **Minimum Threshold**: Set the minimum threshold for a map interval length of a pause measured between the end of a T-wave to the beginning of the next QRS. (No less than 800ms).
2. **Refresh List**: Manually refreshes the map intervals list if the minimum threshold is changed. The map intervals list will refresh automatically every 10 seconds if acquisition is live.
3. **Detected Map Intervals**: Displays the number of detected map intervals based on the minimum threshold set.
4. **Ignore Map Interval(s)**: Ignore all map intervals marked for ignoring.
5. **Filter**: Filter map intervals list by the type of event.
6. **Length Sort**: Sort map intervals list by length.
7. **Time Sort**: Sort map intervals list by time.
8. **Mark Ignore**: Mark a map interval to be ignored.
Figure 21: Premature Beats Tab

1. **R-R Interval**: Set the duration for the average R-R interval in milliseconds.
2. **Threshold (%)**: Set a threshold percentage to only show detected premature beats that are equal to or less than the R-R interval reduced by the threshold percentage.
3. **Refresh List**: Manually refreshes the premature beats list if the R-R interval or threshold is changed. The premature beats list will refresh automatically every 10 seconds if acquisition is live.
4. **Detected Premature Beats**: Displays the number of detected premature beats based on the R-R interval and threshold set.
5. **Ignore Premature Beat(s)**: Ignore all premature beats marked for ignoring.
6. **Filter**: Filter premature beats list by the type of event.
7. **Length Sort**: Sort premature beats list by length.
8. **Time Sort**: Sort premature beats list by time.
9. **Mark Ignore**: Mark a premature beat to be ignored.

The Acquisition screen can display live signals from all 252 electrodes of the Cardiolnslt™ Sensor Array. The x- and y- axes of the signal plots are adjustable and the Acquisition Vest Display and Events List can be toggled or collapsed. The user may choose which Sensor Array electrode channels to display. To display or hide a channel on the Acquisition Plot Display, click on the corresponding channel number on the Acquisition Vest Display. The channel number of each channel added to the plot will be shown to the left of the Acquisition Plot Display. Channels are added in the order they are clicked. There is no limit to the number of channels that may be added and displayed at one time. To deselect all channels from the Acquisition Plot Display, click on the Deselect All button. Channels may also be rearranged by holding Ctrl while clicking on the signal of interest, then clicking on the desired location to
rearrange the channel on the Acquisition Plot Display. The y-axis of the Acquisition Plot Display can also be modified by scrolling the mouse wheel while hovering the mouse over the plot. Any communication or noise problems should be resolved before proceeding with data recording.

Once the Acquisition screen is displayed, the user can start acquisition. To start ECG data acquisition, click the Start acquisition button. To stop ECG data acquisition, click the Stop acquisition button.

⚠️ Note: System plots are relative to the displayed scales.

⚠️ Note: If Start button is not selectable and the system displays “Amplifier Self-Test Failed”, check amplifier, Ethernet cable, and Sensor Array connections and click Test Again to try to reconnect to the amplifier. If the system does not reconnect to the amplifier, power cycle the amplifier.

Acquisition Vest Display
When actively acquiring data, each channel in the Acquisition Vest Display is shown as green if it is connected and giving a good signal, red if it is connected but giving a poor signal, gray if it is disconnected, and yellow if it is selected to be displayed on the Acquisition Plot Display. When acquisition is stopped, all channels are shown in gray except for the channels that are selected to be displayed on the Acquisition Plot Display.

R-R Detection
During acquisition, the R-R Detection can be disabled or enabled (Figure 18, item 5). When R-R Detection is enabled, the system will detect R peaks and use that data to identify premature beats. These premature beats will be listed based on the parameters set in the Premature Beats tab (Figure 21). The system will also use R peak detection in conjunction with the QT event set by the user to identify map intervals. Based on the Minimum Threshold set, these map intervals will be displayed in the Map Intervals tab (Figure 20). The R-R Detection should only be enabled when acquiring data from a patient who is lying supine and not being paced. When pace mapping during signal acquisition, disable the R-R Detection so that map intervals which contain pacing spikes are not displayed.

Event Management
Depending on the type of study being performed, the user may want to interact with the Acquisition screen a little differently. If the type of study being performed is a phase mapping study, the user can set a QT event to base the determination of longer R-R intervals in order to more easily identify atrial signals to be used for phase mapping. However, it is also permissible to manually identify signals and create Phase Map events. In other study types, the user can manually identify signals and create Beat Map events. In all study workflows, it is possible to set and rename Bookmarks for signals and events of interest.

To create a QT event, complete the following steps:
1. Click on the QT button to display green calipers.
2. Set the green calipers to encompass the entire QRST interval.
3. Click on the Confirm QT button.
4. Rename the QT event if desired.

⚠️ Note: Manually creating QT events, Phase Map events, or Beat Map events will pause live acquisition on the Acquisition Plot Display. While the plot is paused, data will continue to be acquired in the background.
Note: If multiple QT events are created in one study, each QT event will become the determinant for the R-R interval detection from that QT event until the next chronological QT event. The first chronological QT event will also act as the determinant for the R-R interval detection from the beginning of the study to the next chronological QT event.

Once the QT event is set, the system will begin to calculate and detect R-R interval lengths. For atrial phase mapping, if good signals (green) are observed on the Sensor Array channels, the user may navigate to the Phase Map Processing screen to continue with phase mapping.

The user may remain on the Acquisition screen and choose to create manual time events including additional QT events, Phase Map events, Beat Maps, and Bookmarks. The user may also remain on the Acquisition screen to monitor the Sensor Array channels during acquisition and review signals.

Note: During manual QT event, Phase Map event, and Beat Map event creation, events are not created until they are confirmed. Clicking on the navigation, play, or pause buttons on the Acquisition Plot Controls will automatically cancel the event creation.

To manually create a Phase Map event, complete the following steps:
1. Click on the Phase Map button to display purple calipers.
2. Set the purple calipers to encompass the desired signal from the beginning of the first QRS complex to the end of the second T-wave.
3. Click on the Confirm Phase Map button.
4. Rename the Phase Map event if desired.

Note: During manual creation of a Phase Map event, the user should extend the purple calipers slightly before the beginning of the first QRS complex and slightly beyond the end of the second QT complex to ensure that both QRST complexes are encompassed by the calipers.

Note: The minimum Phase Map event length is 1200ms.

To manually create a Beat Map, complete the following steps:
1. Click on the Beat Map button to display blue calipers.
2. Set the blue calipers to encompass the desired signal.
3. Click on the Confirm Beat Map button.
4. Rename the Beat Map if desired.

To create a bookmark at the live signal location during live acquisition, complete the following steps:
1. Click on the Bookmark button or use a Bookmark Hotkey to drop a bookmark at the live signal location.
2. Rename the Bookmark if desired.

To create a bookmark at the live signal location during paused acquisition, complete the following steps:
1. Use a Bookmark Hotkey.
2. Rename the Bookmark if desired.

To create a bookmark at a live signal location during live or paused acquisition when the Events Display is collapsed, complete the following steps:
1. Use a **Bookmark** Hotkey to display the *Add Bookmark* dialog box.
2. Rename the Bookmark if desired.
3. Click **Save** or press **Enter**.

To create a bookmark at a desired location during paused acquisition, complete the following steps:
1. Click on the **Bookmark** button to display a green cursor.
2. Set the green cursor at the desired bookmark location.
3. Click on the **Confirm Bookmark** button.
4. Rename the Bookmark if desired.

To create a bookmark at a desired location during stopped acquisition, complete the following steps:
1. Click on the **Bookmark** button or Use a **Bookmark** Hotkey to display a green cursor.
   - Set the green cursor at the desired bookmark location.
2. Click on the **Confirm Bookmark** button.
3. Rename the Bookmark if desired.

Right-clicking on the Acquisition Plot Display over a channel of interest will open a menu with the following commands:
- **X-Axis Measurement**: Opens x-axis measurement calipers that display time in milliseconds.
- **XY-Measurement Cursor**: Opens an adjustable red cursor that displays the potential of every displayed channel in millivolts and the current location of the cursor within the study recording.
- **Y-Axis Measurement**: Open y-axis measurement calipers for the selected channel and displays the potential in millivolts.

**Acquisition Screen Keyboard Hotkeys:**
The following table shows the keyboard hotkeys associated with creating events on the Acquisition screen and the other sequential screens. The keyboard hotkeys are particularly useful when the Events Display is collapsed.

<table>
<thead>
<tr>
<th>Table 2: Keyboard Hotkeys</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Hotkey Action</strong></td>
</tr>
<tr>
<td>---------------------</td>
</tr>
<tr>
<td>Bookmarking at the live signal location during live or paused acquisition on either the <strong>Acquisition screen</strong> or the <strong>Single Beat Mapping screen</strong>.</td>
</tr>
<tr>
<td><strong>Bookmark</strong> Cursor if live acquisition is stopped on either the <strong>Acquisition screen</strong> or the <strong>Single Beat Mapping screen</strong>.</td>
</tr>
<tr>
<td>Bookmarking at the live signal location during live or paused acquisition and displaying an Add Bookmark dialog box if the Events Display is collapsed on the <strong>Acquisition screen</strong>.</td>
</tr>
<tr>
<td>Bookmarking at the live signal location during live or paused acquisition and displaying an Add Bookmark dialog box if the Mapping Controls is collapsed on the <strong>Single Beat Mapping screen</strong>.</td>
</tr>
<tr>
<td>Bookmarking at the live signal location during live or paused acquisition from either the <strong>Geometry screen</strong>, <strong>Phase Map Processing screen</strong>, or the <strong>Phase Map Analysis screen</strong>.</td>
</tr>
<tr>
<td><strong>QT Calipers</strong></td>
</tr>
</tbody>
</table>
Search Box Functionality

The search box appearing on the Acquisition screen and on the other sequential screens has advanced functionality that allows for input of conditional search criteria. The table below describes the search box functionality.

Table 3: Search Box Functionality

<table>
<thead>
<tr>
<th>Search Criteria</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>map</td>
<td>Selects records that contain the “map” string in any search column.</td>
</tr>
<tr>
<td>phase map 1</td>
<td>Selects records that contain either “phase” OR “map” OR “1” strings in any search column.</td>
</tr>
<tr>
<td>“phase map”</td>
<td>Selects records that contain “phase map” in any search column.</td>
</tr>
<tr>
<td>phase +“map 1”</td>
<td>Selects records that contain both “phase” AND “map 1” in search columns.</td>
</tr>
<tr>
<td>Label:phase</td>
<td>Selects records that contain “phase” in the column that starts with “Label”.</td>
</tr>
<tr>
<td>Label:phase map</td>
<td>Selects records that contain “phase” in the column that starts with “Label”, AND also contain “map” in any search column.</td>
</tr>
<tr>
<td>phase +map -1</td>
<td>Selects records that contain both &quot;phase&quot; AND &quot;map&quot; in search columns, excluding records that contain &quot;1&quot;.</td>
</tr>
<tr>
<td>phase map -1</td>
<td>Selects records that contain &quot;phase&quot; OR &quot;map&quot;, excluding records that contain &quot;1&quot;.</td>
</tr>
<tr>
<td>Length:&quot;1&quot;</td>
<td>Selects records that contain &quot;1&quot; in the column that starts with &quot;Length&quot;, AND also contain &quot;phase map&quot; in the column that starts with &quot;Label&quot;.</td>
</tr>
<tr>
<td>Label:&quot;phase map&quot;</td>
<td>Selects records that contain &quot;phase map&quot; in any search column, excluding records that contain &quot;1&quot; in the column that starts with &quot;Length&quot;.</td>
</tr>
</tbody>
</table>

⚠️ Note: Searches performed are case insensitive. Precede a condition with “+” to display only records that match this condition. Precede a condition with “-“ to display only records that exclude this condition. If the expression contains the “-“ character, quotation marks are ignored.

Automatic Interruptions of Signal Acquisition

If hard disk space is insufficient for study recording, a message will be displayed and data acquisition may not start. If during the study, disk space becomes too low for continued use, acquisition will automatically stop. If the amplifier loses power during data acquisition, the acquisition will stop automatically. Returning to the Home screen or Patient screen will automatically stop acquisition.

Phase Map Processing

After starting acquisition and setting a QT event, the next steps in a phase mapping study workflow occur in the Phase Map Processing screen. The user may navigate to the Phase Map Processing screen any time after data acquisition begins, although it is recommended to first create a QT event in the Acquisition screen. In addition, Phase Map events can be created manually before continuing to the Phase Map Processing screen.
The following are the different plots and buttons on the *Phase Map Processing screen*:

1. **Workflow Bar**: Navigate through the different screens in the workflow.
2. **Patient Information Bar**: Displays current patient and study information.
3. **Study Notes**: Opens the study notes.
4. **Start/Stop Acquisition, Test Again**: Starts and stops signal acquisition when the amplifier is connected. Also the Test Again button tests the connection to the amplifier.
5. **Enable/Disable R-R Detection**: Toggles R-R Detection to help detect map intervals and premature beats.
6. **Phase Map Vest Display**: Displays all Sensor Array electrodes and their status for the selected Phase Map event.
7. **Phase Map Information Bar**: Displays the name, clock time, map interval duration (in milliseconds), and map processing status of the currently loaded Phase Map event.
8. **Composite Signal Plot**: Displays selected Phase Map event signals and QT calipers. When hovering over or selecting a Sensor Array electrode, the bottom plot displays the selected electrode signal.
9. **Selected Electrode Display**: Displays the selected electrode number(s).
10. **Areas of Low Resolution Map**: Displays geometry with highlighted areas of poor electrode coverage or signal. The geometry can be set to one of the eight standard views (AP, PA, LAO, RAO, CRA, CAU, RL, and LL).
11. **Areas of Low Resolution Map Menu**:
   - **Reset View**: Resets the zoom and pan on the Areas of Low Resolution Map to default.
   - **Show Orientation Arrows**: Toggles the orientation arrows.
12. **Composite Signal Plot Controls**: Adjusts the display size of the x-axis and y-axis of the Composite Signal Plot.
13. **Add/Remove Electrodes**: Selected electrode(s) will be added or removed from the Composite Signal Plot.
14. **Clear Selection**: Deselects all electrodes.
15. **Reset**: Resets all channels to their original settings in the Composite Signal Plot.
16. **Calculate Phase Map**: Begins to calculate the Phase Map from the current Phase Map event.
17. **Delete Phase Map & Start Over**: If a Phase Map has previously been created, it can be deleted and processing on the Phase Map event can start over.

18. **Filters**: Toggle the Assisted Bad Channel Detection (ABCD) and Low-Pass filters. The ABCD filter detects and displays noisy or saturated channels from the Sensor Array for review and correction during map processing.

19. **Study Timeline**: Displays the time events indicators on a timeline of the total recording time.
   - Purple lines represent phase maps, yellow lines represent stops in acquisition, and white lines represent the lengths of detected map intervals based on the minimum threshold.

20. **Map Intervals**: Displays the total number of map intervals detected above the set minimum threshold and lists them (Figure 20).

21. **Phase Maps**: Displays total duration and total number of created Phase Maps. Also displays a list of all created Phase Maps, calculating Phase Maps, and Phase Map events.

22. **Search Box**: Search the Phase Maps list by keyword.

23. **Delete Phase Map(s)**: Delete all Phase Maps marked for removal.

24. **Filter**: Filter the Phase Maps list by the status of Phase Maps.

25. **Mark Phase Map for Removal**: Mark Phase Maps to be removed.

### Managing Map Intervals

The system will use the most recently defined QT event (set in the **Acquisition screen**) to calculate the pause lengths of Map Intervals. These are calculated based on the interval between QT detections. The user may set the **Minimum Threshold** to filter the Map Intervals list and show those intervals above the set threshold. Double click on a Map Interval to add it to the Phase Maps list and load it into the Composite Signal Plot.

⚠️ **Note**: It is highly recommended that Phase Maps be calculated on at least 3-4 cycles. It is also important that enough Phase Maps (example ten or more) are analyzed to ensure that the mapped data is representative of the fibrillatory rhythm under investigation.

⚠️ **Note**: The Map Intervals list displays the estimated length of each detected map interval based on the previously created QT event. The Phase Maps list displays the estimated length of each selected Phase Map interval based on the QT matching during the processing of the actual signal. The two calculated lengths may be different. The Phase Map Interval is finalized when the Phase Map calculation begins.

### Creating Phase Maps

To create a Phase Map from a Phase Map event (refer to Event Management), complete the following steps:

1. Double click the Phase Map event in the Phase Maps list (Figure 22, item 21).
2. Verify the ABCD filter results. This is performed by viewing electrode signals which were systematically removed from the Composite Signal Plot. Additional signals may be added or removed by clicking on the signal or its associated electrode, and clicking the **Add** or **Remove** button (Figure 22, item 13). Multiple channels can be selected simultaneously by holding Ctrl while clicking.
3. Review the Composite Signal Plot (Figure 22, item 8). Verify that the QT interval is correctly defined. The QT interval calipers can be adjusted by clicking and dragging the “Set QT” interval calipers to the correct location on the segment. The “Auto QT” interval will automatically update to match the “Set QT” interval for the second QT interval on the segment.

⚠️ **Note**: When it is necessary, the “Auto QT” interval can be manually adjusted by clicking and dragging the “Auto QT” interval calipers to the desired location on the segment. Manually
adjusting the “Auto QT” interval will unlink it from the “Set QT” interval and characterize it as a second “Set QT” Interval.

⚠️ **Note:** The minimum phase map interval which will be accepted by the system is 200ms. The user will not be able to create phase maps for phase map intervals shorter than this length. It is not recommended to create phase maps from phase map intervals shorter than 800ms, and the caliper area will turn red if the caliper width is shorter than 800ms.

4. Verify that the **Areas of Low Resolution Map** (Figure 22, item 10) is acceptable. If there are too many or substantially large areas of low resolution, consider using another phase map event for the creation of a Phase Map.

5. Once satisfied with the signal selection, click **Calculate Phase Map** (Figure 22, item 16). The map may take several minutes to process. Refer to map status icons below.

The Phase Maps list can display the three types of Phase Maps encountered during Phase Map creation denoted by the following icons:

- **Phase Map Event:** A map interval that has been marked as a candidate to become a Phase Map.
- **Calculating Phase Map:** A Phase Map Event that has been processed and is calculating into a Phase Map.
- **Phase Map:** Is a completed Phase Map and can be viewed in the **Phase Map Analysis screen**.

⚠️ **Note:** If a Phase Map cannot be calculated, it is denoted by this icon: 🚨

⚠️ **Note:** Phase Maps are calculated based on the geometry set provided at the time of phase map creation. If the geometry set is changed and a previously created Phase Map is attempted to be reprocessed, the map processing status in the Phase Map information bar (Figure 22, item 7) will read “Mapped in Other Geometry”. Phase Maps that are calculated in other geometry sets do not allow editing of processing inputs for channel and filter selections, unless the maps in the other geometry sets are deleted. A map calculation using the same processing input settings may still be performed.

**Phase Map Vest Display**
The Phase Map Vest Display indicates in green, high integrity signals calculated by the ABCD filter. In red are low-integrity signals which are non-zero. In grey are zero signals, indicating electrode disconnection from the skin. Black indicates the electrode was not detected and labeled during segmentation. The user can review signals and add or remove individual electrode signals before map creation.

**Composite Signal Plot**
The Composite Signal Plot mirrors that of Sensor Array electrodes, only showing high integrity (green) signals. The user can select signals and remove them from the Composite Signal Plot. Signals which were added from the Phase Map Vest Display will show in the Composite Signal Plot.

**Areas of Low Resolution Map**
The Areas of Low Resolution Map indicates, in red, whether an area of the heart is
compromised because too many Sensor Array electrodes are not sensing high integrity signal. The operator can continue to create electroanatomic maps with known locations of 'low resolution,' or identify and map another interval with better electrode coverage.

⚠️ **Precaution:** The Areas of Low Resolution Map is intended to inform user of the impact of the detected bad or disconnected channels on the map resolution. These areas of maps should be very carefully analyzed before they are considered in any arrhythmia analysis.

**Filters and Noise**
There are two filters displayed on the *Phase Map Processing screen*. The *ABCD* filter is “on” by default and can be turned off. This filter detects and displays noisy or saturated channels from the Sensor Array for review and correction during map processing. Turning this filter off will add back in all available electrodes to the *Composite Signal Plot*. The *Low-Pass* filter is “on” by default and cannot be turned off. This filter removes high frequency signals in the currently loaded phase map displayed in the *Composite Signal Plot*.

**Phase Map Analysis**
Following the phase mapping workflow, once Phase Maps are created in the *Phase Map Processing screen* the user may continue to the *Phase Map Analysis screen* to view, analyze and manage Phase Maps.

![Figure 23: Phase Map Analysis Screen](image)

The following are the different ports and buttons on the *Phase Map Analysis screen*:

1. **Workflow Bar:** Navigate through the different screens in the workflow.
2. **Patient Information Bar:** Displays current patient and study information.
3. **Study Notes:** Opens the study notes.
4. **Start/Stop Acquisition, Test Again:** Starts and stops signal acquisition when the amplifier is connected. Also the **Test Again** button tests the connection to the amplifier.
5. **Enable/Disable R-R Detection**: Toggles R-R Detection to help detect map intervals and premature beats.

6. **Composite Map**: Displays all Phase Map detections for the selected Phase Map(s). The geometry can be set to one of the eight standard views (AP, PA, LAO, RAO, CRA, CAU, RL, and LL). The **Composite Map** tab can be expanded/collapsed.

7. **Composite Map Menu**:
   a. **Reset View**: Resets the zoom and pan on the **Composite Map** to default.
   b. **Show Orientation Arrows**: Toggles the orientation arrows.
   c. **Show Only Consecutive Focals**: Toggles showing only the focals occurring consecutively in a Phase Map on the Composite Map.
   d. **Show Trajectories**: Toggles the entire trajectory line for each stable rotation on the Composite Map.
   e. **Show Rotation Counts**: Toggles the rotation counts.

8. **Focal and Rotation Colormap Scales**: Displays the scales for the number of focals and the rotation count for rotations.

9. **Rotation Threshold**: The gray bar on the rotation colormap scale can be dragged to set the value for the minimum number of rotations displayed on the **Composite Map**.

10. **Composite Map Details**: Toggle between Unreviewed, Updated, and All detections displayed on the **Composite Map**. Clicking on the **Composite Map** will display the detected activity in that region in a sortable list. In Figure 23, a rotation detection is selected and the green trajectory is displayed on the **Composite Map** while the detection is listed in the Display list. Each detection can be marked as ignored or reviewed. The **Composite Map Details** tab can be expanded/collapsed.

   a. **Unreviewed Display Mode**: Displays detections that have not been marked as reviewed.
   b. **Updated Display Mode**: Displays detections that have not been marked as ignored.
   c. **All Display Mode**: Displays all detections.

11. **Phase Map**: Displays the selected Phase Map. The playback speed can be set by adjusting the slider cursor next to the play button. The geometry can be set to one of the eight standard views (AP, PA, LAO, RAO, CRA, CAU, RL, and LL). The **Phase Map** tab can be expanded/collapsed.

12. **Display Single Composite Map**: Toggles the synchronization between the Phase Map and the Composite Map. Only detections from the loaded Phase Map will be shown when the sync is on and more than one Phase Map will not be selectable.

13. **Phase Map Menu**:
   a. **Reset View**: Resets the zoom and pan on the Phase Map to default.
   b. **Show Orientation Arrows**: Toggles the orientation arrows.
   c. **Electrogram Cursor**: Toggles the electrogram cursor. Clicking on the geometry displayed in the Phase Map will also toggle on the electrogram cursor. Hold Ctrl and click anywhere on the geometry displayed in the Phase Map to remove it.
   d. **Show Trajectories**: Toggles the trajectory lines for stable rotations on the Phase Map.
   e. **Loop Phase Map Ciné**: Sets the ciné to play in a continuous loop five times.

14. **Phase Map Colormap Scale**: Displays the scale from $-\pi$ to $\pi$ for the Phase Map.

15. **Current Sample**: Displays the ciné cursor location in milliseconds from the beginning of the Phase Map.

16. **Cursor Electrogram Plot**: Displays the reconstructed unipolar electrogram (blue) and the phase signal (yellow) that represents signal from the hover mouse or the electrogram cursor location on the Phase Map. When a rotation detection is selected from the Display list, the detection period is bounded by the red lines on the **Cursor Electrogram Plot**. The **Cursor Electrogram Plot** can be expanded/collapsed.

17. **Ciné cursor**: The ciné can be controlled by clicking and dragging the white ciné cursor.
clicking on the ciné cursor and using the mouse scroll wheel, or clicking on the ciné cursor and pressing the backward and forward arrow keys on the keyboard. When the **Cursor Electrogram Plot** is collapsed, the ciné cursor can still be seen and manipulated with any of the three methods described.

18. **Cursor Electrogram Plot Controls**: Adjusts the display size of the x-axis and y-axis of the Cursor Electrogram Plot.

19. **Cycle Length (CL)**: Displays phase map cycle length at the location of either the hover mouse or the electrogram cursor.

20. **Electrograms Plot**: Displays the electrogram signals surrounding the rotation detection. The electrogram signals are color coded and represented by their respective electrogram points on the Phase Map. The **Electrograms Plot** opens when a rotation detection is double-clicked from the **Display List**. Once it is open, the **Electrograms Plot** can be collapsed.

21. **Electrograms Plot Controls**: Adjusts the display size of the x-axis and y-axis of the Electrograms Plot.

22. **Phase Map Details**: Displays the Phase Maps List along with the **Total Selected Phase Time**. The Phase Map Details tab can be expanded/collapsed.

23. **Total Selected Phase Time**: Displays the total cumulative selected phase time of all selected Phase Maps in milliseconds.

24. **View All**: Checks all Phase Maps and displays their detections on the Composite Map.

25. **View None**: Unchecks all Phase Maps and removes their detections from the Composite Map.

26. **Delete Phase Map(s)**: Delete all Phase Maps marked for removal.

27. **Search Box**: Search the Phase Maps list by keyword.

28. **Phase Maps List**: Displays a sortable list of all Calculating Phase Maps and Phase Maps. Toggle view to display each Phase Map on the Composite Map.

29. **Mark Phase Map for Removal**: Mark Phase Maps to be removed.

30. **Structures**: Displays a sortable list of structures. Toggle whether these structures are displayed on the Phase Map and Composite Map by checking the View box. Set transparency by moving the slider cursor.

The **Phase Map Analysis screen** contains the **Composite Map** tab, the **Phase Map** tab, and the **Phase Map Details** tab which contains the complete list of Phase Maps which have been mapped in the **Phase Map Processing screen**.

**Composite Map**

The **Composite Map** (Figure 23, item 6) on the left side of the **Phase Map Analysis screen** displays areas on the heart surface that have been identified as Phase Map detections in at least one Phase Map selected from the **Phase Maps List** (Figure 23, item 28). Rotation detections are displayed as gradients of red, orange, and yellow color against a solid color heart surface. Focal detections are displayed as colored points ranging from orange to red on the heart surface. Both focal and rotation detections have values associated with their colors that are displayed in the **Focal and Rotation Colormap Scales** (Figure 23, item 8). The Composite Map can be manipulated and settings can be toggled by selecting them from the **Composite Map Menu** (Figure 23, item 7). The **Composite Map Details** tab (Figure 23, item 10) allows the user to click on any point on the Composite Map to display a list of rotation detections from that region of the heart or click on any focal detection to display a list of focal detections from that region of the heart. Double clicking on a detection from this list will load the detection in the Phase Map. Each detection can be marked as ignored or marked as reviewed.
Phase Map

The Phase Map (Figure 23, item 11) on the right of the Phase Map Analysis screen displays a single phase map for review of detected activity. This map displays the phase of the yellow phase signal at all locations on the heart’s surface. As the user navigates the mouse over this map, the Cursor Electrogram Plot (Figure 23, item 16) updates to show signals at the mouse location. The Phase Map can be played in ciné format with adjustable playing speed, or manually played by clicking and dragging on the ciné cursor or by using the mouse scroll wheel. The Phase Map can be manipulated and settings can be toggled by selecting them from the Phase Map Menu (Figure 23, item 13). Phase Maps can be selected for display either by double clicking on the desired Phase Map in the Phase Maps List (Figure 23, item 28) or by double clicking on a detection from the Composite Map Details tab (Figure 23, item 10).

⚠️ Note: The phase computation algorithms implemented in the system include special filtering tailored to the mapped band of physiological frequencies and are important for the accuracies of phase computation.

⚠️ Note: The clinical significance of solely utilizing phase maps to classify arrhythmia mechanisms has not been validated by clinical investigations.

⚠️ Note: Confirm the area and signal of interest with a mapping catheter as appropriate.

Reviewing Phase Maps

Once Phase Maps have been created and appear on the Phase Maps list, they can be viewed and managed through the Composite Map Details tab.

1. Select View All from the Phase Maps list.
2. Select Unreviewed view from the Display feature in Composite Map Details.
3. Click on a region in the Composite Map to call up the detections from that region into the Composite Map Details list.
4. Double click on one of the detections from the Composite Map Details list to load the related Phase Map and queue the ciné cursor in the Cursor Electrogram Plot to the start of the detection. Review the ciné and cursor electrograms for that detection.
5. Mark the detection as “Review” if the detection is acceptable or mark the detection as “Ignore” if the detection is not acceptable. Detections marked as “Review” will appear in the Updated view and the All view. Detections marked as “Ignore” will only appear in the All view.
6. Repeat steps 3-5 for all detections displayed in the Unreviewed view.
7. Select Updated view from the Display feature in Composite Map Details to view the Updated Composite Map that displays all detections except those marked as “Ignore”.

Single Beat Mapping

When map creation is desired for organized rhythms, the Single Beat Mapping screen is used to acquire, select, process, and display a selection of different map types. The Single Beat Mapping screen allows for the display of up to 6 map ports simultaneously and also has full functionality for live acquisition as well as for Beat Map processing. The Vest Expander on the left side of the screen has two tabs labeled Acquisition and Processing. The Acquisition tab contains the Acquisition Vest Display, which displays all Sensor Array electrodes during acquisition, and the Processing tab contains the Beat Map Processing Vest Display, which displays all Sensor Array electrodes and their status for the selected Beat Map. The Mapping Controls Expander is on the right side of the screen and has two tabs labeled Maps and
Premature Beats. The Maps tab contains a sortable list of created Beat Map events with their respective maps. The Maps tab also contains bookmarks and shows the total number of potential maps. The Premature Beats tab contains parameters that can be set to identify heartbeats that fall outside a patient’s usual rhythm. These beats can then be viewed and mapped all from the Single Beat Mapping screen. The Beat Map Processing Expander, Acquisition Plot Expander, and Study Timeline at the bottom of the screen allows for live signal review, bookmarking, beat map event creation, signal integrity verification, Beat Map creation, and complete study event overview without leaving the Single Beat Mapping screen.

Figure 24: Single Beat Mapping Screen, View 1

The following are the different plots and buttons on the Single Beat Mapping Screen, View 1:
1. **Workflow Bar**: Navigate through the different screens in the workflow.
2. **Patient Information Bar**: Displays current patient and study information.
3. **Study Notes**: Opens the study notes.
4. **Start/Stop Acquisition, Test Again**: Starts and stops signal acquisition when the amplifier is connected. Also Test Again button tests the connection to the amplifier.
5. **Enable/Disable R-R Detection**: Toggles R-R Detection to help detect map intervals and premature beats.
6. **Vest Expander**: Displays the Acquisition Vest Display tab and the Processing Vest Display tab. The Vest Expander can be expanded/collapsed.
7. **Acquisition Vest Display**: Displays all Sensor Array electrodes and their status during acquisition.
8. **Deselect All**: Deselects all Sensor Array electrodes and removes them from the Acquisition Plot Display.
9. **Acquisition Plot Expander and Acquisition Plot Controls**: Displays the Acquisition Plot Display, toggle to show 3 or 4 channels at a time on the Acquisition Plot Display, and adjust the display size of the x-axis and y-axis of the Acquisition Plot Display. Also, user can navigate around the study and pause live signal display. The Acquisition Plot Expander can be expanded/collapsed.
10. **Acquisition Plot Display**: Displays selected Sensor Array electrode channels and time events.
11. **Bookmark**: Create a new bookmark.
12. **Beat Map**: Create a new beat map.
13. **Study Timeline**: Displays the time events indicators on a timeline of the total study recording time. Green triangles represent bookmarks, blue lines represent beat maps, yellow lines represent stops in acquisition, and the thick white line displays the clock time at the current study location.
14. **Mapping Controls**: Displays the Maps tab and the Premature Beats tab. Also displays the Structures toolbar. This expander can be expanded/collapsed.
15. **Maps Tab**: Displays a list of bookmarks, beat map events, and beat maps including expandable lists of associated map types. The Maps Tab has a Search Box (Table 3) and a sortable list with filtering functionality. Beat maps can also be flagged.
16. **Potential Map Count**: Displays the number of potential maps created. This is the same number of beat maps created.
17. **Delete Event(s)**: Delete all events marked for removal.
18. **Bookmark Icon**: This icon indicates a bookmark was created.
19. **Beat Map Icon**: This icon indicates a beat map was created. Created beat maps have expandable lists to show all the map types that have been created.
20. **Potential Map Type**: This indicates that a potential map has been created for the associated beat map.
21. **Beat Map Event Icon**: This icon indicates a beat map event was created.
22. **Structures**: Displays a sortable list of structures. Toggle whether these structures are displayed on the Beat Maps by checking the View box. Set transparency by moving the slider cursor.

The following are the different plots and buttons on the Single Beat Mapping Screen, View 2:

1. **Beat Map Processing Vest Display**: Displays all Sensor Array electrodes and their status for the selected Beat Map.
2. **Beat Map Processing Expander**: Displays the label, clock time, map interval duration (in
milliseconds) and status of the currently loaded beat map. Also displays the Composite Signal Plot and the Areas of Low Resolution Map along with the Signal Averaging button and filters. The Beat Map Processing tab can be expanded/collapsed.

3. **Selected Electrode Display**: Displays the selected electrode number(s).
4. **Add/Remove Electrodes**: Selected electrode(s) will be added or removed from the Composite Signal Plot.
5. **Clear Selection**: Deselects all electrodes.
6. **Reset**: Resets all channels to their original settings in the Composite Signal Plot.
7. **Composite Signal Plot**: Displays selected Beat Map signals. When hovering over or selecting a Sensor Array electrode, the bottom plot displays the selected electrode signal.
8. **Areas of Low Resolution Map Menu**: Lists the controls for the Areas of Low Resolution Map.
   a. **Reset View**: Resets the zoom and pan on the Areas of Low Resolution Map to default.
   b. **Show Orientation Arrows**: Toggles the orientation arrows.
9. **Areas of Low Resolution Map**: Displays geometry with highlighted areas of poor electrode coverage or signal. The geometry can be set to one of the eight standard views (AP, PA, LAO, RAO, CRA, CAU, RL, and LL).
10. **Activation Map**: Selecting this and clicking **Calculate Maps** will generate an Activation Map in addition to the Potential Map.
11. **Calculate Maps**: Processes the selected Beat Map event and generates a Potential Map. Also generates an Activation Map if the Activation Map box is checked.
12. **Composite Signal Plot Controls**: Adjusts the display size of the x-axis and y-axis of the composite signal plot display.
13. **Signal Averaging**: Opens signal averaging toolbar for the currently loaded beat map (Figure 29).
14. **Filters**: Toggle ABCD and Low-Pass filters.
15. **Premature Beats Tab**: Displays the premature beats list and the associated premature beats parameters (Figure 21).

Figure 26: Single Beat Mapping Screen, View 3
The following are the different plots and buttons on the Single Beat Mapping Screen, View 3:

1. **1-UP**: Displays only the first map port.
2. **2-UP**: Displays only the first two map ports.
3. **4-UP**: Displays only the first four map ports. This will minimize the *Beat Map Processing Expander* if it is open.
4. **6-UP**: Displays all six map ports. This will minimize the *Vest Expander* if it is open.
5. **Sync Ports**: Synchronizes the view and movement of all map ports.
6. **Clear All Ports**: Unloads all beat maps from the displayed map ports.
7. **Add Electrograms**: Toggles the left mouse click to add virtual electrograms on all maps.
8. **Clear All Electrograms**: Removes all electrograms from all maps. Electrograms can be individually removed by holding Ctrl and clicking on the desired electrogram on the map.
9. **Potential Map Type Menu**: Only available in Potential Maps and is used for creating Activation, Voltage, Slew Rate, and Propagation maps. Refer to “Creating Beat Maps” for details.
10. **Create New Map**: Creates the selected map type from the Map Type menu.
11. **Play Map Ciné**: Animate the map and control the playback speed. This is only available for potential and propagation map types.
12. **Map Port Menu**: Lists the map menu functions.
   a. **Reset View**: Resets the zoom and pan on the map port to default.
   b. **Show Orientation Arrows**: Toggles the orientation arrows.
   c. **Show Colormap Contour Lines**: Toggles the contour lines on the current map.
   d. **Show Torso**: Available only in the Potential Map. Toggles the torso as the displayed geometry.
   e. **Show Directional Activation Arrows**: Available only in the Directional Activation Map. Toggles the activation arrows on the current map.
   f. **Show Solid Map Color**: Available only in the Directional Activation Map. Toggles the current map as a solid color.
13. **Standard View Buttons**: Change the orientation of the map port to one of the standard views (AP, PA, RAO, LAO, RL, LL, CRA, CAU).
14. **Map Port**: Displays the map type and map name next to each map port number. The map itself and corresponding virtual electrograms are shown in each map port. The virtual electrograms can be reordered by holding Ctrl while clicking on the virtual electrogram on the plot, then clicking on the desired location for that virtual electrogram on the plot. The map port also displays the current map’s colormap scale. Right clicking on the scale will give the option to switch between a Histogram and a Min/Max colormap scale. Available only on a Voltage Map, the option to toggle the Multi-Layer Colormap.
15. **Min/Max**: Adjusts the minimum and maximum values of the colormap scale. The user can reset the scale. The user can also sync the scale so that other displayed maps of the same type will sync to the selected map.
16. **Activation Map Type Menu**: Only available in Activation Maps and is used for creating Directional Activation Maps. Refer to “Creating Beat Maps” for details.
17. **Edit Activation Time**: Only available in Activation Maps. Opens activation time editing. Refer to “Edit Activation Times for an Activation Map” for details.
18. **Go to Beat Signal**: Loads the Beat Map location on the Acquisition Plot Display.
19. **Set the map port as a base for copying caliper locations**: Toggles the current map port as the base for copying the caliper locations to be applied to other map ports.
20. **Adjusts the calipers to match the map port set as the copying base**: Adjusts the calipers in the current map port to match the calipers from the map port set as the copying base.
21. **Maximize**: Maximizes the map to be displayed in a maximized single beat mapping plot (Figure 27).
22. **Close**: Closes the currently loaded map in that map port.

![Maximized Single Beat Mapping Plot](image)

**Figure 27**: Maximized Single Beat Mapping Plot

The following are the different plots and buttons on the Maximized Single Beat Mapping Plot:

1. **Minimize Map Port**: Minimize the current map port.
2. **Map Electrogram**: Adding an electrogram to the map will add a color coded point to the map surface. The corresponding color electrogram’s signal is displayed on the Electrogram Signal Plot.
3. **Electrogram Signal Plot**: Displays the color coded electrogram signal shown on the map. The electrogram signals can be rearranged by holding Ctrl while clicking on a signal and then releasing Ctrl and clicking on the desired location to place the electrogram signal.
4. **Potentials List**: Toggles between Potentials view and DV/DT view for the Hover Electrogram signal.
5. **Hover Electrogram**: Displays the reconstructed surface electrogram signal at the location of the hover mouse.

**Premature Beats**

The Premature Beats tab in the Mapping Controls Expander (Figure 25, item 15) assists in identifying signals of interest based on R-R Interval detection. It allows the user to set an average **R-R Interval** in milliseconds and a **Threshold (%)** to start populating the list with intervals that match these criteria. Clicking **Refresh** after changing these values will update this list to display only those detected premature beats that follow these parameters. The list will also refresh automatically every 10 seconds if acquisition is live. Double-clicking on a premature beat will load its location on the Acquisition Plot Display and open Beat Map calipers. The user may set the calipers and confirm the Beat Map event or double-click on another premature beat to cancel Beat Map event creation for the current premature beat and move on to new premature beat. Confirming the Beat Map event will add it to the events list in the Maps tab and load the beat into the Beat Map.
Processing Expander. Refer to *Creating Beat Maps* for instructions on completing Beat Map creation.

**Event Management**

Beat Map events and bookmarks that are manually created on the *Acquisition screen* will be listed in the Maps tab under Mapping Controls Expander on the right side of the screen. Additional Beat Map events and bookmarks can be created from the *Single Beat Mapping screen* the following ways.

To manually create a Beat Map Event:
1. Click on the Beat Map button or use the Beat Map Hotkey to display blue calipers.
2. Set the blue calipers to encompass the desired signal.
3. Click on the Confirm Beat Map button.
4. Rename the Beat Map Event if desired.

To create a bookmark at the live signal location during live acquisition:
1. Click on the Bookmark button or use a Bookmark Hotkey to drop a bookmark at the live signal location.
2. Rename the Bookmark if desired.

To create a bookmark at the live signal location during paused acquisition:
1. Use a Bookmark Hotkey.
2. Rename the Bookmark if desired.

To create a bookmark at a live signal location during live or paused acquisition when the Mapping Controls expander is collapsed:
1. Use a Bookmark Hotkey to display the *Add Bookmark* dialog box.
2. Rename the Bookmark if desired.
3. Click Save or press Enter.

To create a bookmark at a desired location during paused acquisition:
1. Click on the Bookmark button to display a green cursor.
2. Set the green cursor at the desired bookmark location.
3. Click on the Confirm Bookmark button.
4. Rename the Bookmark if desired.

To create a bookmark at a desired location during stopped acquisition:
1. Click on the Bookmark button or Use a Bookmark Hotkey to display a green cursor. Set the green cursor at the desired bookmark location.
2. Click on the Confirm Bookmark button.
3. Rename the Bookmark if desired.

Right-clicking on the Acquisition Plot Display over a channel of interest will open a menu with the following commands:
- X-Axis Measurement: Opens x-axis measurement calipers that display time in milliseconds.
- XY-Measurement Cursor: Opens an adjustable red cursor that displays the potential of every displayed channel in millivolts and the current location of the cursor within the study recording.
- Y-Axis Measurement: Open y-axis measurement calipers for the selected channel and displays the potential in millivolts.
Creating Beat Maps

To complete Beat Map creation, the user must:

1. Double-click on the desired Beat Map event in the Maps list so that the map signals are loaded into the Beat Map Processing Expander.
2. (Optional) If desired, Signal Averaging can be performed by clicking Signal Averaging. (Refer to Signal Averaging).
3. Verify signal integrity and add back any removed good integrity signals by clicking on the corresponding electrode in the Beat Map Vest Display and clicking Add. Multiple electrodes can be selected by holding the Ctrl key while left-clicking on electrodes that are either on the Beat Map Vest Display or on the Beat Map Processing Expander. The user may also remove signals which contain electrical artifact or noisy signal by clicking on the electrode or signal and clicking Remove.
4. Review low resolution areas, and select filters to apply. The ABCD filter and the Low-Pass filter may be applied to all signals according to the needs in that particular lab setting. The user should review the Areas of Low Resolution Map in the Beat Map Processing Expander to ensure a minimal amount of areas of low resolution will exist in that map. Areas of low resolution are identified in red. If the user is unable to resolve large areas of low resolution by adding signals or applying filters, a different beat should be chosen for map creation.

⚠️ **Precaution:** The Areas of Low Resolution Map is intended to inform the user of the impact of the detected bad or disconnected channels on the map resolution. These areas of maps should be very carefully analyzed before they are considered in any arrhythmia analysis.

5. (Optional) Check the Activation box in the Beat Map Processing Expander in order to create both a Potential and an Activation Map.
6. Click Calculate Maps.

⚠️ **Note:** The number of maps displayed depends on whether the user has selected 1-UP, 2-UP, 4-UP, or 6-UP in the Map Ports Toolbar.

Though Potential and Activation Maps are the only map types available for initial creation, the other map types may be created directly from a Potential or Activation Map once it is displayed in a map port.

⚠️ **Note:** Before creating a Voltage Map, Slew Rate Map or an Activation Map from a Potential map, there must be at least one virtual electrogram set on the displayed Potential Map so that the green calipers can be toggled and set to the desired location.

To create a Voltage Map, Slew Rate Map, Propagation Map, or an Activation Map:

1. Set a virtual electrogram on the displayed Potential Map if there is not one set already.
2. Set the green calipers to the desired locations on the displayed Potential Map electrogram.
3. Click on the Map Type menu in the same map port.
4. Select the type of map desired.
5. Click the Create New Map button. The new map will be created, displayed in an available map port, and listed in the Maps list on the right side of the screen.

To create a Directional Activation Map:

1. First create or display an Activation Map.
2. Set a virtual electrogram on the displayed Activation Map if there is not one set already.
3. Set the green calipers to the desired location on the displayed Activation Map.
4. Click on the Map Type menu in the same map port.
5. Select the Directional Activation Map.
6. Click the Create New Map button. The new map will be created, displayed in an available map port, and listed in the Maps list on the right side of the screen.

⚠️ **Note:** Confirm the area and signal of interest with a mapping catheter as appropriate.

**Filters and Noise**

There are two filters displayed on the Single Beat Mapping screen. The ABCD filter is “on” by default and can be turned off. This filter detects and displays noisy or saturated channels from the Sensor Array for review and correction during map processing. Turning this filter off will add back in all available electrodes to the Composite Signal Plot. The Low-Pass filter is “on” by default and can be turned off. This filter removes high frequency signals in the currently loaded beat map displayed in the Composite Signal Plot. Turning this filter off will allow for mapping of signals containing high frequency signals such as a pacing spike.

**Modify Interval for an Activation Map, Voltage Map, Propagation Map or Slew Rate Map**

To modify a map interval, reposition the green calipers on the electrogram plot for the desired map. The map is recalculated based on the selected interval as defined by the green calipers and is saved with the study. The colormap scale will adjust according to the map values in the selected interval.

**Edit Activation Times for an Activation Map**

The user is able to edit the activation times for an Activation Map by selecting a single point, a combination of single points, or a region of points and recalculating the activation time for those selected points.

To edit activation times for an Activation Map:
1. Ensure that the desired Activation Map is loaded into a map port and the green calipers are set as desired.
2. Click on the Edit Activation Time button (Figure 21, item 4) in the same map port as the desired Activation Map. The Activation Time Editing window will open and display the Activation Map on the left and the electrogram signal plot on the right.
3. Select Place Single Electrogram if one electrogram marker is desired to be placed at a time. Select Place Multi Electrograms if multiple electrogram markers are desired to be placed at a time. Use the mouse wheel scroll to change the quantity of multi electrogram markers to be placed.
4. Hover over the Activation Map to view the quantity and location of the electrogram marker(s). When the desired location for the electrogram marker(s) is achieved, click on the Activation Map to drop the electrogram marker(s). The virtual electrogram(s) will appear on the electrogram signal plot. The activation time marker (white vertical line) is shown for each electrogram displayed on the electrogram signal plot.
5. When necessary, electrograms and the corresponding electrogram markers can be removed. Select Remove All Electrograms to clear all electrograms and electrogram markers. To manually remove individual electrogram markers or a group of electrogram markers, hover over the Activation Map and hold **Ctrl** while
clicking on the desired electrogram marker(s).

6. Adjust the green calipers on the electrogram signal plot to recalculate the white activation time marker for each electrogram displayed.

7. Subsequent clicks on the Activation Map will add additional electrogram markers on the Activation Map and the corresponding electrograms are added on the electrogram signal plot.

8. Select **Save** to save the activation time edits and return to the *Single Beat Mapping screen* or select **Cancel** to revert to the original Activation Map.

---

**Figure 28: Activation Time Editing**

**Signal Averaging**

Signal Averaging averages several beats of the same kind. To begin Signal Averaging:

1. Click **Signal Averaging**.
2. Click **Begin Signal Averaging**.
3. Review the Original and Averaged ports and wait for Signal Averaging to run. The status is displayed above the Averaged port (‘x’ segments in ‘y’ iteration(s)).
4. Signal averaging will stop automatically when averaging is completed or the user clicks **End Averaging Early**.
5. Keep the results and proceed by selecting **Accept & Continue**.
6. To reject signal averaging results and start over, select **Reset to Original**.
7. To cancel Signal Averaging click **Cancel Signal Averaging**.
Map Types
Several types of maps are available to the user. The 3D electroanatomical maps produced by CardiolInsight™ are calculated onto the epicardial surface. Body surface potential maps (BSPM) can be reviewed to ensure accurate registration of sensors. A description of each map type is included here for reference.

Phase Map
A Phase Map displays the phase of the yellow phase signal at all locations on the surface of the heart. A white line is represented at the π/2 phase value, which is a surrogate for activation time. This map is most often used for displaying electroanatomical activation of arrhythmias that have local areas of varying cycle lengths.

Potential Map
A Potential Map displays electrical potentials, in mV, at all locations on the surface of the heart at any point in time within the map interval. A ciné of the map interval may be played.
to show potential changes over time. The potentials are displayed in a color gradient where white defines most negative potential values, and dark green defines those areas with most positive potential values.

![Potential Map of the Ventricle](image)

**Figure 31: Potential Map of the Ventricle**

**Activation Map**

An Activation Map displays activation time, in ms, for all locations on the surface of the heart. Activation is marked as the maximum $-dV/dt$ within the user-defined signal window, and the activation time is recalculated and displayed according to any user changes to the signal window. Earliest activation is represented by red, and latest by dark blue.

![Activation Map of the Ventricle](image)

**Figure 32: Activation Map of the Ventricle**

**Directional Activation Map**

A Directional Activation Map displays the information of the activation map, described above, combined with spatial information. The Directional Activation map also has the ability to show arrows that describe the direction of increasing potential measurements at all points on the epicardial surface.
Voltage Map

A Voltage Map displays the largest magnitude of the unipolar electrograms at all locations on the surface of the heart for a user-defined map interval. Areas with the highest voltage are displayed as purple, while areas of lowest voltage are displayed as red. The minimum and maximum values for these colors can be adjusted by the user.
Slew Rate Map

A Slew Rate Map displays the magnitude of the maximal $-dV/dt$ values of unipolar electrograms at all locations on the surface of the heart for a user-defined map interval.

Propagation Map

A Propagation Map displays an animation of activation times over a selected map interval. Activation is displayed as a fading white wavefront against a blue epicardial surface.
Shut Down Procedure
When setting up the CardioInsight™ equipment be sure to position so equipment may be easily disconnected if necessary.

To disconnect the equipment, perform the following steps:

1. Power off the monitor and workstation.
2. Power off the mapping amplifier and isolation transformer.
3. Unplug the isolation transformer power cord.
4. If applicable, unplug the optional mapping amplifier power cord.

When CardioInsight™ is no longer in use, the user may Shut Down CardioInsight™ software to close the application. To do this, click Home then click Exit. A confirmation prompt will ask “Exit Application?” Click OK and the CardioInsight™ application will close. The user may then shut down the workstation via the Start menu.

Once the workstation is shut down, the user may turn off the monitor and turn power switches off for the mapping amplifier and isolation transformer. Once the equipment is all powered off, the user may disconnect power cords from power sources and store CardioInsight™ until the next use. If the system will be turned on again after powering down, wait one (1) minute before powering on the isolation transformer. Close the CardioInsight™ application at the end of daily use.

Installation
The initial installation of CardioInsight™ and its software should ONLY be performed by trained Medtronic personnel. Contact your local Medtronic Representative for more information on installation.

Technical Description
Electrical
Per IEC 60601-1, this system (CIT200) and Amplifier (CIT200AMP) are a Class I, defibrillation-proof type CF applied part.

NEMA IEC 60529 degrees of protection provided by enclosures – ingress protection rating of IPX0.
Power Input – Computer
- 100/120/220/240 VAC
- 50/60 Hz
- 6.3/5.3/2.9/2.75 A

Power Input – Amplifier (CIT200AMP)
- 100-240 VAC
- 50/60 Hz
- 1.0-0.4 A
- 250 V F3AL AGC Fuses (2)

Power Input – Isolation Transformer
- 115/230 VAC
- 50/60 Hz
- 13.0/6.5 A

⚠️ **Warning:** The isolation transformer is ONLY for use with the components of CardioInsight™. Do not plug other equipment into the isolation transformer. Connecting electrical equipment to the isolation transformer effectively leads to creating a Medical Electrical (ME) System and the result can be a reduced level of safety. The isolation transformer isolates the system and user from supply mains.

⚠️ **Warning:** Do not modify the CardioInsight™ equipment in any manner, or use accessories, power cords, or cables that are not specified for use with CardioInsight™. The use of accessories, power cords, and cables other than those specified and sold by Medtronic may result in electric shock, increased emissions, or decreased immunity of the equipment. The use of other accessories may also cause the system to be non-compliant with IEC 60601-1-2.

**Mechanical**

**System Dimensions:**
- MIN: 615mm x 664mm x 1300mm (24.21in x 26.14in x 51.18in)
- MAX: 696mm x 862mm x 1461mm (27.40in x 33.94in x 57.52in)

**System Mass:**
- 102kg (225lbs)

⚠️ **Note:** The maximum load for the cart drawer is 4.53kg (10lbs)

<table>
<thead>
<tr>
<th>Cable</th>
<th>Maximum Length</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ethernet data cable</td>
<td>30.48m (100ft)</td>
</tr>
<tr>
<td>DVI-A to VGA cable</td>
<td>3m (9.84ft)</td>
</tr>
<tr>
<td>DVI-D cable</td>
<td>7.62m (25ft)</td>
</tr>
</tbody>
</table>

**Environmental Conditions**

**System Storage**
- Temperature: +15°C to +30°C (+59°F to +86°F)
- Relative Humidity, non-condensing: 15%-90%
- Pressure: >700 hPa

**System Transport**
- Temperature: -30°C to +60°C (-22°F to +140°F)
Relative Humidity, non-condensing 15%-90%

**System Usage**
- Temperature +15°C to +30°C (+59°F to +86°F)
- Relative Humidity, non-condensing 20%-80%
- Pressure >724 hPa

**Storage and Transport**
CardioInsight™ should be stored according to the environmental conditions above, when not in use. When getting the system ready for transport or storage, power down the system completely (refer to "Shut Down Procedure"). Position the monitor so that it rests on the center of the top shelf. Push the keyboard and mouse tray under the top shelf into its storage position. Store the mouse on the pivot arm of the keyboard tray above the keyboard. Store all but the on-board Ethernet cables inside the cart drawer. Store the signal cables and the patient ground reference cable around one end of the mapping amplifier. Store the isolation transformer power cable by wrapping it around the cart handle. All cables should be wrapped in their designated locations and the components of CardioInsight™ should remain securely in place on the CardioInsight™ cart.

⚠️ Precaution: Do not use the cart for any other purpose than storing and using CardioInsight™.

⚠️ Precaution: Move the CardioInsight™ system using the handle designed on the cart. Ensure at least one hand remains on the cart during transport.

**Cleaning, Maintenance, and Disposal**
**Cleaning and Maintenance**
Ensure connections are secure. Signal cables and the patient ground reference cable should be wiped down after each use. Refer to Appendix D for step by step cleaning instructions.

⚠️ Precaution: Prior to each use, inspect the cables for wear and visual evidence of damage. Do not use the cables if they are damaged.

**Disposal**
Disposal of equipment and accessories should be made in accordance with local regulation. Contact your sales representative for complete end-of-service information on applicable products.

**Operational**
When a defibrillator must be used during the procedure, CardioInsight™ requires at least five minutes to restart and return to normal function.

⚠️ Warning: Remove or peel back front Sensor Array panels prior to using an external defibrillator on the patient.

**References**

3. Cuculich et al, "Noninvasive Characterization of Epicardial Activation in Humans With Diverse Atrial Fibrillation"


Appendix A: Consumables
The Sensor Array and accessories can be purchased from Medtronic. Contact your local Medtronic Representative to place an order for these parts.

Table 4: Consumables

<table>
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<tr>
<th>Item</th>
<th>Re-order number</th>
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</thead>
<tbody>
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<td>CardioInsight™ Sensor Arrays</td>
<td>CITVST0001S (1), CITVST0002M (2), CITVST0003L (3), CITVST0004XL (4)</td>
</tr>
<tr>
<td>Vest Signal Cable Pack</td>
<td>CIT200AMP0006</td>
</tr>
<tr>
<td>Patient Ground Reference Cable</td>
<td>CIT200AMP0021</td>
</tr>
<tr>
<td>All other parts</td>
<td>Contact your local Medtronic Representative.</td>
</tr>
</tbody>
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Appendix B: System Symbols
The following table describes the symbols used in the labeling of CardioInsight™ and the software icons contained in this operator’s manual.

Table 5: Symbols used on CardioInsight™

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<thead>
<tr>
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<tr>
<td>Precaution</td>
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</tr>
<tr>
<td>Note</td>
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</tr>
<tr>
<td>Package contents</td>
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</tr>
<tr>
<td>Icon</td>
<td>Description</td>
</tr>
<tr>
<td>------</td>
<td>-------------</td>
</tr>
<tr>
<td><img src="image" alt="Cardiac Mapping System" /></td>
<td>Cardiac Mapping System</td>
</tr>
<tr>
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<td>Multi-Electrode Mapping Vest</td>
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</tr>
<tr>
<td><img src="image" alt="Sensor Array Front Right Panel" /></td>
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</tr>
<tr>
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<td>Mapping Amplifier or Signal Recorder</td>
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<td>![Nationally Recognized Symbol]</td>
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<td>![This Way Up Symbol]</td>
<td>This way up</td>
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<tr>
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<tr>
<td>![Do Not Use Symbol]</td>
<td>Do not use if package is damaged</td>
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<tr>
<td>![Do Not Stack Symbol]</td>
<td>Do not stack</td>
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<tr>
<td>![Output Power Symbol]</td>
<td>Output power (non-ionizing electromagnetic radiation)</td>
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<tr>
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<td>Description</td>
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<td>Consult instructions for use</td>
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<td>Patient ground (green) reference (red) cable configuration</td>
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# Appendix C: Electromagnetic Compatibility Declaration

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<th>Emissions test</th>
<th>Compliance</th>
<th>Electromagnetic environment – guidance</th>
</tr>
</thead>
<tbody>
<tr>
<td>RF emissions CISPR 11</td>
<td>Group 1</td>
<td>The equipment uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.</td>
</tr>
<tr>
<td>RF emissions CISPR 11</td>
<td>Class A</td>
<td>The equipment is suitable for use in all establishments other than domestic, and may be used in domestic establishments and those directly connected to the public low-voltage power supply net- work that supplies buildings used for domestic purposes, provided the following warning is heeded: Warning: This equipment/system is intended for use by only by order of a physician. This equipment/ system may cause radio interference or may disrupt the operation of nearby equipment. It may be necessary to take mitigation measures, such as re-orienting or relocating the equipment or shielding the location.</td>
</tr>
<tr>
<td>Harmonic emissions IEC 61000-3-2</td>
<td>Class A</td>
<td></td>
</tr>
<tr>
<td>Voltage fluctuations/ flicker emissions IEC 61000-3-3</td>
<td>Complies</td>
<td></td>
</tr>
</tbody>
</table>
Table 7: Guidance and manufacturer’s declaration – electromagnetic immunity

<table>
<thead>
<tr>
<th>Immunity test</th>
<th>IEC 60601 Test level</th>
<th>Compliance level</th>
<th>Electromagnetic environment – guidance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Electrostatic discharge (ESD) IEC 61000-4-2</td>
<td>±6 kV contact ±8 kV air</td>
<td>±6 kV contact ±8 kV air</td>
<td>Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.</td>
</tr>
<tr>
<td>Electrical fast transient/burst IEC 61000-4-5</td>
<td>±2 kV for power supply lines ±1 kV for input/output lines</td>
<td>±2 kV for power supply lines ±1 kV for input/output lines</td>
<td>Mains power quality should be that of a typical commercial or hospital environment.</td>
</tr>
<tr>
<td>Surge IEC 61000-4-5</td>
<td>±1 kV line(s) to line(s) ±2 kV line(s) to earth</td>
<td>±1 kV line(s) to line(s) ±2 kV line(s) to earth</td>
<td>Mains power quality should be that of a typical commercial or hospital environment.</td>
</tr>
<tr>
<td>Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11 UT = 230 Vac</td>
<td>&lt;5 % UT (&gt;95 % dip in UT) for 0.5 cycle 40 % UT (60 % dip in UT) for 5 cycles 70 % UT (30 % dip in UT) for 25 cycles</td>
<td>&lt;5 % UT (&gt;95 % dip in UT) for 0.5 cycle 40 % UT (60 % dip in UT) for 5 cycles 70 % UT (30 % dip in UT) for 25 cycles</td>
<td>If the user of the equipment requires continued operation during power mains interruptions, it is recommended that the equipment be powered from an uninterruptible power supply or a battery.</td>
</tr>
<tr>
<td>Power frequency (50 Hz) magnetic field IEC 61000-4-8</td>
<td>3 A/m</td>
<td>3 A/m</td>
<td>Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.</td>
</tr>
</tbody>
</table>
Table 8: Guidance and manufacturer’s declaration – electromagnetic immunity

<table>
<thead>
<tr>
<th>Immunity test</th>
<th>IEC 60601 Test level</th>
<th>Compliance level</th>
<th>Electromagnetic environment – guidance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Conducted RF</td>
<td>3 Vrms 150 kHz to 80 MHz</td>
<td>3 Vrms</td>
<td>Portable and mobile RF communications equipment should be used no closer to any part of the equipment including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance</td>
</tr>
<tr>
<td>Radiated RF</td>
<td>3 V/m 80 MHz to 2.5 GHz</td>
<td>3 V/m</td>
<td>$d = 1.2\sqrt{P}$</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>$d = 1.2\sqrt{P}$ 80 MHz to 800 MHz</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>$d = 2.3\sqrt{P}$ 800 MHz to 2.5 GHz</td>
</tr>
</tbody>
</table>

where $P$ is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and $d$ is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,$^{(a)}$ should be less than the compliance level in each frequency range.$^{(b)}$

Interference may occur in the vicinity of known RF transmitting devices and equipment marked with the following symbol:

NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

a) Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the equipment is used exceeds the applicable RF compliance level above, the equipment should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the equipment.

b) Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.
Table 9: Guidance and manufacturer's declaration – electromagnetic immunity

CardioInsight™ is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of CardioInsight™ can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and CardioInsight™ as recommended below, according to the maximum output power of the communications equipment.

<table>
<thead>
<tr>
<th>Rated maximum output power of transmitter W</th>
<th>Separation distance according to frequency of transmitter m</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>150 kHz to 80 MHz</td>
</tr>
<tr>
<td>0.01</td>
<td>0.12</td>
</tr>
<tr>
<td>0.1</td>
<td>0.38</td>
</tr>
<tr>
<td>1</td>
<td>1.2</td>
</tr>
<tr>
<td>10</td>
<td>3.8</td>
</tr>
<tr>
<td>100</td>
<td>12</td>
</tr>
</tbody>
</table>

NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

Table 10: Applied Parts

<table>
<thead>
<tr>
<th>Applied Parts: Parts that may come into contact with the patient in normal use</th>
<th>Re-order number</th>
</tr>
</thead>
<tbody>
<tr>
<td>CardiOInsight™ Sensor Array</td>
<td>CITVST0001S (1)</td>
</tr>
<tr>
<td></td>
<td>CITVST0002M (2)</td>
</tr>
<tr>
<td></td>
<td>CITVST0003L (3)</td>
</tr>
<tr>
<td></td>
<td>CITVST0004XL (4)</td>
</tr>
<tr>
<td>Vest Signal Cable Pack</td>
<td>CIT200AMP0006</td>
</tr>
<tr>
<td>Patient Ground Reference</td>
<td>CIT200AMP0021</td>
</tr>
</tbody>
</table>
Appendix D: Maintenance and Cleaning

Maintenance
- CardioInsight™ has specified consumable components that can be replaced by Medtronic trained personnel.
- CardioInsight™ must be serviced by Medtronic trained personnel.
- The CardioInsight™ system requires no adjustments or calibrations.
- Contact your local Medtronic Representative for evaluation of the CardioInsight™ system if exposed to excessive shock, vibration, or any mishandling.
- Local standards and regulations should be followed with respect to periodic performance verification.

Cleaning
Prior to each study, inspect the cables for wear and secure connections. If components of the system are soiled, follow the cleaning process described in Table 12. Use a liquid crystal display (LCD) cleaner or a 50% isopropyl alcohol solution when cleaning the monitor.

Precaution: Disconnect the system from the supply mains and the patient before cleaning the system or performing any maintenance operations.

Table 12: Cleaning Instructions

<table>
<thead>
<tr>
<th>Step</th>
<th>Instructions</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Prepare a mild detergent solution by mixing 4.9 mL (1 tsp) of concentrated liquid detergent into 3785.4 mL (1 gal) of lukewarm tap water.</td>
</tr>
</tbody>
</table>
| 2    | Wet a clean, lint-free wipe in the prepared cleaning solution and squeeze out excess liquid.  

† Note: The wipe should be wet but not dripping. |
| 3    | Use the damp wipes to thoroughly clean the signal cables for a minimum of one (1) minute and until all visible soil is removed. Discard and replace soiled wipes, as needed. Pay close attention to each connector and associated strain relief to ensure the uneven surfaces and area under the switches are thoroughly cleaned. |
| 4    | Wet clean, lint-free sharp tip cotton swab in the prepared cleaning solution and squeeze out excess liquid.  

† Note: The swab and the wipe or cloth should be wet but not dripping. |
| 5    | Use the damp swab to thoroughly clean the lead strain reliefs, until all visible soil is removed. Discard and replace soiled cotton swabs, as needed. |
| 6    | Use a new solution-dampened wipe (see Step 2) to thoroughly wipe the cables for a minimum of one (1) minute and until all visible soil is removed. Discard and replace soiled wipes, as needed. Pay close attention to each connector and associated strain relief to ensure the uneven surfaces and area under the switches are thoroughly cleaned. |
| 7    | Wet a new clean, soft, lint-free wipe with lukewarm tap. Squeeze out excess liquid.  

† Note: The wipe should be wet but not dripping. |
<table>
<thead>
<tr>
<th>Step</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>8</td>
<td>Use the damp wipe to thoroughly wipe the cables for a minimum of 30 seconds to remove cleaning residue. Pay close attention to each connector and associated strain relief to ensure the uneven surfaces and area under the switches are thoroughly cleaned.</td>
</tr>
</tbody>
</table>
| 9    | Wet a second new clean, soft, lint-free wipe with lukewarm tap. Squeeze out excess liquid.  
**Note:** The wipe should be wet but not dripping. |
| 10   | Use the damp wipe to thoroughly wipe the cables for a minimum of 30 seconds to remove cleaning residue. Pay close attention to each connector and associated strain relief to ensure the uneven surfaces and area under the switches are thoroughly cleaned. |
| 11   | Thoroughly dry the cables with a clean, dry, lint-free wipe. Visually inspect the cables in a well-lit area to confirm the absence of any soil. |
Appendix E: Minimizing Signal Noise

In order to obtain the best possible signal quality with a minimal amount of noise, care must be taken in the positioning of the CardioInsight™ amplifier and cabling (patient ground reference cable, Sensor Array signal cables). Both the amplifier and cabling should be kept away from metal surfaces, power cords, and electric or magnetic fields generated by other equipment.

⚠️ Warning: DO NOT stack the system components.

⚠️ Warning: DO NOT use the system adjacent to other equipment.

When setting up for a patient study:
- Position the amplifier either on the cart or on the floor underneath the patient table.
- Move all power cords (from all equipment) away from the vicinity of the amplifier.
- Keep all cables from touching the table and away from power cords and other equipment.
  - Run them along the side of the table up to the patient OR;
  - Clip them along the sheet OR;
  - Run them diagonally from the amplifier on the floor to the point of clipping them on the sheet.

⚠️ Precaution: DO NOT place the amplifier on the patient table while in use if the patient table is made of metal.

⚠️ Precaution: DO NOT wrap the patient ground reference cable around the amplifier or the power cord while in use.

⚠️ Note: The patient ground reference cable should exit the amplifier in the same direction as the Sensor Array signal cables; they should not run back towards the area of the amplifier where the power cord is attached. All of the cables should run together and be secured along most of their length.

⚠️ Note: Clip the cables to the sheets as it will relieve the strain on the Sensor Array signal cable connection points due to the weight of the cables.

The mapping amplifier also has a DIN 42801 potential equalization conductor terminal marked with the symbol . When signal noise is suspected to be coming from other devices in the environment, the mapping amplifier can be connected to the potential equalization bus bar of the electrical installation. This connection should only be made by trained personnel in accordance with relevant national regulations. Additional information is available in IEC-60601-1.

![Figure 38: Potential Equalization Conductor Terminal](image-url)
Appendix F: Troubleshooting

The following guide is intended to help a user troubleshoot system problems. In any case that the user requires further assistance, please contact your local Medtronic Representative. Please have the product name and version number being used available when contacting your local Medtronic Representative. The software version number can be accessed by clicking the About button on the Home screen.

Hardware Troubleshooting

If there is a problem in a hardware component of CardioInsight™, check all power connections and connections between the Sensor Array, Amplifier, Workstation, and Workstation components. Many hardware problems can be identified and resolved by checking status lights and connections.

- **Amplifier Power:** the amplifier will have a green status indicator light on when it is connected to power and properly functioning. If the amplifier does not power on, try a different power outlet. If the amplifier still does not power on, the power cable may need replacement or the amplifier may need service. Please contact your local Medtronic Representative.

- **Workstation Power:** the workstation will have status lights at the isolation transformer, amplifier, computer, and monitor when power is being correctly distributed. If any of these lights are not functioning properly, check the connections between these components (Table 13). If all of the lights indicate there is no power, try plugging the isolation transformer into a different power outlet. If the isolation transformer will not power on after trying a different power outlet, contact your local Medtronic Representative and report the issue. DO NOT rearrange power cords to use CardioInsight™ without the isolation transformer.

- **Communication between Amplifier and Workstation:** if the amplifier test continues to fail, yet both the amplifier and the workstation are powered on correctly and CardioInsight™ software is running, check the Ethernet cable connection between the workstation and the amplifier. Verify that the Ethernet cable connectors at each end are intact and that the cable is not severed or compromised at any location between the connectors. If connection problems persist, a replacement Ethernet cable may be required and can be ordered by contacting your local Medtronic Representative.

- **CardioInsight™ Sensor Array is not providing signals:** if all components are connected correctly, and the amplifier test in CardioInsight™ passes and shows a green status light, there may be a connection issue between the CardioInsight™ Sensor Array and the Mapping Amplifier. Check the integrity of the connections between the amplifier and the vest connectors. If just one part of the CardioInsight™ Sensor Array, e.g. the front left panel, is demonstrating problems with signals, it is highly likely that the connection to that portion of the CardioInsight™ Sensor Array requires attention. In the rare occasion that the issue is not resolved by verifying the cable connections, attempt to replace the Sensor Array signal cables. If there is signal baseline drift or all signals are saturated, check the patient ground reference cable connections. Replacement cables may be ordered by contacting your local Medtronic Representative.

- **Amplifier light is flashing red:** if the amplifier light is flashing red, check the Ethernet connection to ensure that the Ethernet is plugged in to the amplifier at one end and to the workstation computer at the other end. If the amplifier light continues to flash red, power cycle the amplifier. If the amplifier light still continues to flash red, power cycle the system. If the amplifier light continues to flash red, contact your local Medtronic Representative.
<table>
<thead>
<tr>
<th>Component</th>
<th>Specification</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Mapping Amplifier</strong></td>
<td></td>
</tr>
<tr>
<td>□ Solid Green and Red</td>
<td>Amplifier is booting</td>
</tr>
<tr>
<td>□ Solid Green</td>
<td>Amplifier is idle</td>
</tr>
<tr>
<td>□ Flashing Green</td>
<td>Amplifier is acquiring</td>
</tr>
<tr>
<td>□ Flashing Red</td>
<td>Amplifier is indicating a fault</td>
</tr>
<tr>
<td><strong>Isolation Transformer</strong></td>
<td></td>
</tr>
<tr>
<td>□ Solid Green</td>
<td>Isolation Transformer is on</td>
</tr>
<tr>
<td><strong>Workstation Computer Power Button Light</strong></td>
<td></td>
</tr>
<tr>
<td>□ Solid White</td>
<td>Computer is operating normally</td>
</tr>
<tr>
<td>□ Flashing White</td>
<td>Computer is on standby</td>
</tr>
<tr>
<td>□ Flashing Amber</td>
<td>Indicates a problem has occurred with the system board</td>
</tr>
<tr>
<td>□ Solid Amber</td>
<td>Computer does not start, indicating a problem with the system board or the power supply</td>
</tr>
<tr>
<td>□ Solid Green</td>
<td>Computer malfunction</td>
</tr>
<tr>
<td><strong>Workstation Computer Drive Activity Light</strong></td>
<td></td>
</tr>
<tr>
<td>□ Flashing White</td>
<td>Computer is reading data from, or writing data to the hard drive</td>
</tr>
<tr>
<td><strong>Workstation Computer Network Link Integrity Light (Back Panel)</strong></td>
<td></td>
</tr>
<tr>
<td>□ Solid Green</td>
<td>Good connection at 10 Mbps exists between the network and the computer</td>
</tr>
<tr>
<td>□ Solid Orange</td>
<td>Good connection at 100 Mbps exists between the network and the computer</td>
</tr>
<tr>
<td><strong>Workstation Computer Network Activity Lights (Back Panel)</strong></td>
<td></td>
</tr>
<tr>
<td>□ Solid Yellow</td>
<td>Good connection at 1000 Mbps exists between the network and the computer</td>
</tr>
<tr>
<td>□ Flashing Yellow</td>
<td>There is a network activity on the connection</td>
</tr>
<tr>
<td><strong>Monitor</strong></td>
<td></td>
</tr>
<tr>
<td>□ Solid White</td>
<td>Monitor is on</td>
</tr>
</tbody>
</table>
Software Troubleshooting
Software issues within CardioInsight™ are often resolved by referring to the Instructions for Use to be sure that the desired action is occurring within a designated workflow of system operation. In the occasion that the user believes the CardioInsight™ software is malfunctioning, please contact your local Medtronic Representative to report the issue and obtain assistance for a solution.

- Hard drive has run out of space: The user must archive past patient records to DVD or a Medtronic-approved storage device, and then delete those patient records from the workstation.

- Excessive noise appears in the signals from the CardioInsight™ Sensor Array: Attempt to identify the source of the noise, and turn that source off if possible. If this is not possible, attempt to re-route the CardioInsight™ Sensor Array signal cables in parallel, but away from the noise source. If the noise is still too abundant, consider repreparing the patient skin directly underneath the patient ground reference electrodes or moving the patient to a different location for signal recording.

- Features of the software are disabled and un-clickable: The user must perform or correctly finish other tasks before attempting to click the desired feature. For example, the Phase Map Analysis tab will not be available to click until after Phase Map Processing is complete for one or more maps. Another example is that Phase Map Intervals must meet the minimum required length before the “Calculate Phase Map” button may be clicked. The user may remedy these situations by referring to this user manual and following all instructions in the relevant section pertaining to the tasks they are performing.

- Phase Maps are created, but there are no detections visible: The user must change their selection from “Unreviewed” or “Updated” to “All” in order to display all the detections which have been identified in Phase Maps.

- An on-screen warning or error message appears: Most user messages that are system-generated are self-explanatory in nature. The user must read any messages that are generated, and either acknowledge the message or choose to cancel their desired action. A list of warnings may be found at the beginning of this Operator’s Manual. A list of software user messages can be found in Appendix H.

- CardioInsight™ stops running for a prolonged period of time: Should CardioInsight™ freeze, the user may be required to restart the software. CardioInsight™ can take several seconds to switch between screens and manipulate maps during normal operation. This is especially true if signal acquisition is occurring simultaneously as other software operations. The user may, if necessary, perform a manual restart of the software by pressing Alt + Ctrl + Delete on the keyboard, selecting Task Manager, finding the CardioInsight™ application or CISH application in the list of Applications, and then clicking End Task. If Alt + Ctrl + Delete is non-responsive, the user may as a last resort hold down the power button on the workstation. Once the workstation is powered off, the user may re-start the workstation by waiting several seconds and pressing the power button again. Due to the nature of the hard drive redundant array of independent disks (RAID), using a hard power shut down sequence may result in slowing of the system after the reboot for several hours.

- Error message saying that heart surface failed to segment: The “arrhythmia type” defined is associated with either atria or ventricular surfaces of the heart. If the user encounters this message after segmenting the heart geometry, there are two likely scenarios: the user failed to segment electrodes on the body surface, or the user segmented structures different from those in the arrhythmia type (e.g. they segmented the atria for a PVC arrhythmia type). The only solution
for this is to re-segment the heart and electrodes, and to ensure that the arrhythmia type matches the chambers being defined.
Appendix G: Snagit®

Overview

Snagit allows the user to capture, edit, and publish high-quality screen captures. The following gives an overview of the Snagit editor:

1. Several profiles are available for the user to select a region, entire window, or full screen. Hovering over a profile displays the profile capture properties.

2. The Profile Toolbar allows one to create and edit profiles.

3. Displays tips when hovering over buttons, tools, and icons.

4. Press the hotkey, PrtSc, to initiate screen capture.

5. Capture mode is the type of capture you want to acquire.

6. Customize capture options.

7. Change Profile Settings to select the capture mode, input, output, and effect.

8. Convert images, turn on OneClick, organize profiles, or manage accessories in Related Tasks.

9. Quick Launch the snagit editor, or the library view.
Taking a screen capture

Follow these procedures to take a capture:
1. Decide the region of interest on your screen that you would like to capture.
2. Open Snagit.
3. Select a capture profile.

4. Click Capture

5. A dialog box with an explanation of how to complete the capture will appear:
   a. Click and drag to select a region.
   b. Release the button to capture.
   c. To cancel, right click or press ESC.

6. When you complete the capture, your capture will automatically appear in Editor.

⚠️ Note: After step 1, instead of opening Snagit, pressing the hotkey will automatically launch Snagit, and you can proceed directly to step 5.

Snagit Editor

Once you complete the screen capture, Snagit Editor will automatically launch. To open Snagit Editor manually, follow these instructions:

1. Select Windows Start menu | All Programs | Snagit 9 | Snagit 9 Editor.

The following window will open:
1. Snagit Button accesses basic program commands such as: New, Open, Save, Save As, Print, Delete & Close.

2. Tools and options needed to complete most tasks are located on the ribbon.

3. Quick Access Toolbar: Frequently used tools can be added by right clicking the mouse on the icon & selecting add to Quick Access Toolbar.

4. Quick Start Gallery offers access to ready-made styles and effects. Select a style and then click on the canvas to use the style.

5. Canvas: All screen captures can be reviewed on the canvas.

6. Search Pane: Search for screen captures by date, keywords, filename, flags or folders.

7. Flags: Can be used to help search for and identify certain files.

8. Library: Allows the user to find, view & manage files captured.

9. Zoom slider allows the user to increase/decrease zoom quickly.

10. Open Captures Tray allows the user to view recently captured images.

Snagit Hotkeys

<table>
<thead>
<tr>
<th>Function</th>
<th>Hotkey</th>
</tr>
</thead>
<tbody>
<tr>
<td>Screen capture</td>
<td>PrtSc</td>
</tr>
<tr>
<td>Hide / Unhide Snagit</td>
<td>Ctrl + X</td>
</tr>
<tr>
<td>Repeat Last Capture</td>
<td>Ctrl + Shift + R</td>
</tr>
</tbody>
</table>
Appendix H: Software User Messages

Overview
The following table contains the software user messages found in CardioInsight™ software along with the description and action associated with each message. Curly brackets with a number between them (for example \{0\}), indicate that a value will be supplied by the software, such as a number, name, or other calculated information.

Table 14: Software User Messages

<table>
<thead>
<tr>
<th>#</th>
<th>User Message</th>
<th>Description and Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>*Calculation requires QT</td>
<td>The calculation of the suggested phase intervals list requires a QT to be set. Set a QT interval to display the list.</td>
</tr>
<tr>
<td>2</td>
<td>*Enter bookmark label.</td>
<td>Adding a bookmark requires a non-empty text field. Type in a value and retry.</td>
</tr>
<tr>
<td>3</td>
<td>*Enter new password. Passwords must contain at least 5 characters.</td>
<td>While changing a password, entering a value into the password field is required. Enter and retry.</td>
</tr>
<tr>
<td>4</td>
<td>*Error in configuration parameter(s). Edit or restore to default.</td>
<td>A valid configuration parameter must be entered to save changes.</td>
</tr>
<tr>
<td>5</td>
<td>*First name is empty or contains invalid characters '/' or ''.</td>
<td>Editing a patient requires entering a first name. Enter and retry.</td>
</tr>
<tr>
<td>6</td>
<td>*Invalid user name. User names must contain at least three characters.</td>
<td>While changing a username entering a value into the username field is required. Enter and retry.</td>
</tr>
<tr>
<td>7</td>
<td>*Invalid user name. User names must not contain spaces.</td>
<td>While changing a username the username must not contain spaces. Re-enter and retry.</td>
</tr>
<tr>
<td>8</td>
<td>*Last name is empty or contains invalid characters '/' or ''.</td>
<td>Editing a patient requires entering a last name. Enter and retry.</td>
</tr>
<tr>
<td>9</td>
<td>*Medical Record Number is already in use.</td>
<td>The medical record number field must be unique. Enter a unique value and retry.</td>
</tr>
<tr>
<td>10</td>
<td>*Medical Record Number is empty or contains invalid characters '/' or ''.</td>
<td>The medical record number field must contain a non-empty value with alphanumeric characters. Enter a valid value and retry.</td>
</tr>
<tr>
<td>11</td>
<td>*Medical Record Number is not anonymized. Anonymize and retry.</td>
<td>When anonymizing a patient record, it is not permitted to use the original medical record number. Anonymize the MRN and retry.</td>
</tr>
<tr>
<td>12</td>
<td>*Middle name contains invalid characters '/' or ''.</td>
<td>Only alphanumeric characters are supported for middle name. Enter a valid text value and retry.</td>
</tr>
<tr>
<td>13</td>
<td>*MRN from CT scan is already in use. Cancel and import the study for the existing patient, or use the new medical record number.</td>
<td>The medical record number must be unique for each patient. Cancel and import the study under the existing patient, or use the new medical record number.</td>
</tr>
<tr>
<td>14</td>
<td>*One or more study names are empty or contain invalid characters '/' or ''.</td>
<td>Editing a study requires entering a study name. Enter and retry.</td>
</tr>
<tr>
<td>15</td>
<td>*Password contains one or more spaces.</td>
<td>While changing a password, the password must not contain spaces. Re-enter and retry.</td>
</tr>
<tr>
<td>16</td>
<td>*Passwords cannot include spaces.</td>
<td>While changing a password, the password must not contain spaces. Re-enter and retry.</td>
</tr>
<tr>
<td>17</td>
<td>*Passwords do not match.</td>
<td>While changing a password, the new and confirm password fields must match. Re-enter both values and retry.</td>
</tr>
<tr>
<td>18</td>
<td>*Physician name already exists.</td>
<td>Physician names must be unique. Enter a unique physician name and retry.</td>
</tr>
<tr>
<td>19</td>
<td>*Physician name is empty or contains invalid characters '/' or ''.</td>
<td>Adding a physician requires a non-empty text value with alphanumeric characters. Enter a valid value and retry.</td>
</tr>
<tr>
<td>20</td>
<td>*Select a date of birth.</td>
<td>Editing a patient requires selection of date of birth. Select and retry.</td>
</tr>
<tr>
<td>21</td>
<td>*Select a physician.</td>
<td>Editing a study requires selection of a physician. Select and retry.</td>
</tr>
<tr>
<td>22</td>
<td>*Select a sex.</td>
<td>Editing a patient requires selection of sex. Select and retry.</td>
</tr>
<tr>
<td>23</td>
<td>*Select arrhythmia type.</td>
<td>Creating a study requires selection of an arrhythmia. Select and retry.</td>
</tr>
<tr>
<td>Number</td>
<td>Message</td>
<td>Description</td>
</tr>
<tr>
<td>--------</td>
<td>-------------------------------------------------------------------------------------------------------------------</td>
<td>--------------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>24</td>
<td>*Study name is empty or contains invalid characters '/' or ''.</td>
<td>Editing a study requires entering a study name. Enter and retry.</td>
</tr>
<tr>
<td>25</td>
<td>*User name already in use.</td>
<td>Usernames must be unique. Enter a unique username and retry.</td>
</tr>
<tr>
<td>26</td>
<td>*Username or password is incorrect.</td>
<td>Login information supplied was incorrect. Retry.</td>
</tr>
<tr>
<td>27</td>
<td>{0} creation is in progress for {1}.</td>
<td>Exiting the screen is not allowed during creation of beat maps. Wait for map calculation to complete and then retry.</td>
</tr>
<tr>
<td>28</td>
<td>ABCD channel selections not available for maps that were created in previous versions of the software.</td>
<td>A restored map from a study created prior to v3.0 does not persist channel selection information. ABCD has been run on the mapping event, but it is not guaranteed that the calculated map and the current ABCD settings match.</td>
</tr>
<tr>
<td>29</td>
<td>Acquiring signal data. Stop acquisition?</td>
<td>Performing the requested action will cause acquisition to stop. Confirm this is desired before continuing.</td>
</tr>
<tr>
<td>30</td>
<td>Acquisition stopped. Insufficient disk space. Archive and remove studies, and re-start acquisition.</td>
<td>There is not enough space to continue acquisition of data. Archive and remove studies from the system, and then retry.</td>
</tr>
<tr>
<td>31</td>
<td>After CD is inserted, click Start Segmentation.</td>
<td>The software is ready to read CT information for segmentation. Insert the data media and proceed.</td>
</tr>
<tr>
<td>32</td>
<td>Amplifier disconnected, attempting reconnection.</td>
<td>The amplifier has faulted and is automatically attempting self-recovery of the connection.</td>
</tr>
<tr>
<td>33</td>
<td>Amplifier is disconnected. Check connections or restart amplifier, and then retry.</td>
<td>The amplifier is disconnected. Check connections, test again. Reboot and retry if necessary.</td>
</tr>
<tr>
<td>34</td>
<td>Amplifier re-connected. Acquisition will re-start in {0} seconds, unless cancelled.</td>
<td>After disconnecting, the amplifier has recovered and will automatically start acquisition again unless cancelled.</td>
</tr>
<tr>
<td>35</td>
<td>Amplifier Self-Test Failed</td>
<td>The amplifier self-test failed. Restart the amplifier and retry.</td>
</tr>
<tr>
<td>36</td>
<td>An unknown application error occurred. Continue to use the system. If the problem persists, reload the study or restart the application. An unknown application error has occurred. Continue to use the system. Reload the study or restart the application if the problem persists.</td>
<td></td>
</tr>
<tr>
<td>37</td>
<td>Anonymizing CT File {0} of {1}:</td>
<td>The software is anonymizing the underlying CT DICOM files associated with the study.</td>
</tr>
<tr>
<td>38</td>
<td>Anonymizing CT Files...</td>
<td>The software is anonymizing the underlying CT DICOM files associated with the study.</td>
</tr>
<tr>
<td>39</td>
<td>Attempting to acquire data into a previously closed study. Confirm patient and study information is correct before proceeding. Last acquisition: {0} DAYS AGO Continue?</td>
<td>A study with data previously acquired has been selected for further acquisition. Check patient and study information and date prior to continuing acquisition to ensure that the correct study is selected.</td>
</tr>
<tr>
<td>40</td>
<td>Calculation of phase maps is not allowed on studies with phase maps calculated prior to version 3.0.</td>
<td>Studies restored from systems prior to software version 3.0 use a different method of composite map display. Deletion of old and calculation of new phase maps on an old study is restricted to prevent mixed views.</td>
</tr>
<tr>
<td>41</td>
<td>Canceling geometry set creation...</td>
<td>The geometry set creation is being cancelled.</td>
</tr>
<tr>
<td>42</td>
<td>Cancelled</td>
<td>A user operation has been cancelled.</td>
</tr>
<tr>
<td>43</td>
<td>Cancelling</td>
<td>A user operation is cancelling.</td>
</tr>
<tr>
<td>44</td>
<td>Cannot communicate with amplifier. Wait 15 seconds or restart amplifier, and then retry.</td>
<td>The amplifier is in a faulted state. Check connections, test again. Reboot and retry if necessary.</td>
</tr>
<tr>
<td>45</td>
<td>Cannot display more electrograms. To add electrograms, first remove some existing electrograms.</td>
<td>The maximum number of electrograms for display is 16. Remove electrograms in order to add more.</td>
</tr>
<tr>
<td>46</td>
<td>Cannot restore patient. Insufficient disk space. Archive, remove studies, and then retry.</td>
<td>There is not enough space to restore the patient. Archive and remove studies from the system, and then retry.</td>
</tr>
<tr>
<td>47</td>
<td>CardiolInsight application already running. Use ALT-TAB to find window.</td>
<td>An instance of the application is already running. Click OK, and use ALT-TAB to go to that instance.</td>
</tr>
<tr>
<td>48</td>
<td>Changing a physician’s name will permanently update all associated previous studies. Continue?</td>
<td>All prior studies associated with this physician will be edited with a physician name change. Only change a physician name based on a legal name change or to correct spelling errors. New staff should not replace prior staff using the edit tool.</td>
</tr>
<tr>
<td>49</td>
<td>Closing the study may cause the following calculations to stop: {0} Select 'OK' to close the study and stop operations. Select 'Cancel' to keep the study open.</td>
<td>Exiting the study is not allowed during creation of phase maps. Wait for map calculation to complete or cancel the calculation and retry.</td>
</tr>
<tr>
<td>50</td>
<td>Complete or cancel signal averaging to proceed.</td>
<td>The signal averaging view must be cancelled or completed on the currently loaded beat before loading a different beat map for processing.</td>
</tr>
<tr>
<td>51</td>
<td>Configuration error. Cannot start application. Contact Medtronic.</td>
<td>The software configuration has been modified incorrectly, and the application will not start. Contact your local Medtronic Representative.</td>
</tr>
<tr>
<td>52</td>
<td>Correct the patient information to proceed.</td>
<td>Entered patient information and the CT DICOM records do not exactly match. Select the correct values for the patient.</td>
</tr>
<tr>
<td>53</td>
<td>Could not detect valve segmentation. Re-segment mitral and tricuspid valves.</td>
<td>The software could not create valve holes due to an invalid definition. Retry segmentation.</td>
</tr>
<tr>
<td>54</td>
<td>Could not detect valve segmentation. Re-segment mitral and/or tricuspid valves.</td>
<td>The software could not create valve holes due to an unknown error. Retry segmentation.</td>
</tr>
<tr>
<td>55</td>
<td>Could not Segment. Retry segmentation.</td>
<td>The software could not segment the CT study due to an unknown error. Retry segmentation.</td>
</tr>
<tr>
<td>56</td>
<td>Creating geometry set...</td>
<td>The geometry set is being created.</td>
</tr>
<tr>
<td>57</td>
<td>Deleting a geometry set will permanently remove all geometry set data AND all associated calculated maps. Continue with Delete?</td>
<td>Deletion of a geometry set will delete all created maps for that geometry. Ensure no previously created maps are needed prior to deletion.</td>
</tr>
<tr>
<td>58</td>
<td>Deleting a map event will delete the event and any associated maps for all geometries. Events with maps in other geometries to be DELETED: {0} Continue with Delete?</td>
<td>Deletion of a map event will delete all created maps for all geometries. Ensure no previously created maps are needed prior to deletion. Alternatively, only delete individual map calculations to retain the event and other geometries’ maps.</td>
</tr>
<tr>
<td>59</td>
<td>Deleting a patient will permanently remove all signal data AND all calculated maps. Patient: {0} Continue with Delete?</td>
<td>Deletion of a patient will delete all patient information and all studies for that patient. Ensure the correct patient is selected prior to deletion.</td>
</tr>
<tr>
<td>Page</td>
<td>Text</td>
<td>Details</td>
</tr>
<tr>
<td>------</td>
<td>-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------</td>
<td>--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>60</td>
<td>Deleting a study will permanently remove all signal data AND all calculated maps. Patient: {1} Study: {0}</td>
<td>Deletion of a study will delete all acquisition data and all geometries and maps associated with that study. Ensure the correct patient is selected prior to deletion.</td>
</tr>
<tr>
<td>61</td>
<td>Deleting a user will permanently remove the user. Username: {0}</td>
<td>Deletion of a user will remove the record. Ensure the selected user should no longer have access to the system prior to deletion.</td>
</tr>
<tr>
<td>62</td>
<td>Deletion of phase map calculations is not allowed on studies with phase maps calculated prior to version 3.0.</td>
<td>Studies restored from systems prior to this software version use a different method of composite map display. Deletion of old and calculation of new phase maps on an old study is restricted to prevent mixed views.</td>
</tr>
<tr>
<td>63</td>
<td>Disk space low. Acquisition can only continue for {0} minutes. Archive and then delete patient data to create more room on the disk.</td>
<td>The user notification threshold for disk storage space time remaining has been met. Archive and delete patient data to create more room on the disk for this and future acquisition.</td>
</tr>
<tr>
<td>64</td>
<td>Disk space low. Acquisition can only continue for {0} minutes. Archive and then delete patient data to create more room on the disk. Continue acquisition? Select 'OK' to continue acquisition. Select 'Cancel' to stop acquisition.</td>
<td>The user notification threshold for disk storage space time remaining has been met. Archive and delete patient data to create more room on the disk for this and future acquisition.</td>
</tr>
<tr>
<td>65</td>
<td>Error, Reconnecting</td>
<td>The amplifier has faulted and is automatically attempting self-recovery of connection.</td>
</tr>
<tr>
<td>66</td>
<td>Exit application?</td>
<td>The software will exit after user acknowledgement.</td>
</tr>
<tr>
<td>67</td>
<td>Geometry Set: Most Recent</td>
<td>The geometry set is the most recently created set.</td>
</tr>
<tr>
<td>68</td>
<td>Geometry Set: Not Most Recent</td>
<td>The geometry set is not the most recently created set. Confirm this is the desired set for mapping.</td>
</tr>
<tr>
<td>69</td>
<td>Insert CT Data CD</td>
<td>The software is ready to read CT information for segmentation. Insert the data media and proceed.</td>
</tr>
<tr>
<td>70</td>
<td>Interval too short for low pass filtering. Select interval &gt; 40ms.</td>
<td>A mapping event is 40 milliseconds or less, and the low pass filter is disabled.</td>
</tr>
<tr>
<td>71</td>
<td>Invalid login information. Restart application.</td>
<td>A valid login username and password combination was not detected due to an unknown software error. Restart the application and retry.</td>
</tr>
<tr>
<td>72</td>
<td>Invalid patient information: {0}</td>
<td>Editing a patient requires valid fields as specified. Enter valid fields and retry.</td>
</tr>
<tr>
<td>73</td>
<td>Maps prior to v3.0 are unsupported. Color bar is time-based. See IFU.</td>
<td>Studies restored from prior systems use a different method of composite map display for time-based rotations, and do not support selection of rotations and focals for detail analysis on a per-detection basis. Contact your local Medtronic Representative with questions.</td>
</tr>
</tbody>
</table>
| Page | Missing electrodes do not match current geometry:  
| • Electrodes Added: {0}  
| • Electrodes Removed: {1}  
| Map calculation results will be deleted for all geometry sets if missing electrodes list is changed.  
<p>| Select 'Delete Maps' to proceed. Select 'Re-Import' to import different data or modify missing channels. |
|---|---|
| 74 | If the missing electrodes list changes, due to addition or removal of missing electrodes during a geometry set change, all existing maps must be deleted due to processing constraints. Mapping events will be retained for future calculations. Ensure deletion of maps is acceptable prior to making a change to the set of missing electrodes. |
| 75 | If the missing electrodes list changes, due to addition or removal of missing electrodes during a geometry set change, all existing maps must be deleted due to processing constraints. Mapping events will be retained for future calculations. Ensure deletion of maps is acceptable prior to making a change to the set of missing electrodes. |
| 76 | If the missing electrodes list changes, due to addition or removal of missing electrodes during a geometry set change, all existing maps must be deleted due to processing constraints. Mapping events will be retained for future calculations. Ensure deletion of maps is acceptable prior to making a change to the set of missing electrodes. |
| 77 | If the missing electrodes list changes, due to addition or removal of missing electrodes during a geometry set change, all existing maps must be deleted due to processing constraints. Mapping events will be retained for future calculations. Ensure deletion of maps is acceptable prior to making a change to the set of missing electrodes. |</p>
<table>
<thead>
<tr>
<th>No.</th>
<th>Error Description</th>
<th>Solution/Advice</th>
</tr>
</thead>
<tbody>
<tr>
<td>78</td>
<td>The geometry set is the most recently created set.</td>
<td></td>
</tr>
<tr>
<td>79</td>
<td>Moving away from this screen may cause the following operations to stop: (0)</td>
<td>Exiting the screen is not allowed during certain operations, for example, creation of beat maps. Wait for operations to complete and then retry.</td>
</tr>
<tr>
<td></td>
<td>Select 'OK' to move away from this screen and stop operations. Select 'Cancel' to remain on this screen.</td>
<td></td>
</tr>
<tr>
<td>80</td>
<td>No valves detected. Segment both mitral and tricuspid valves to proceed.</td>
<td>The software requires 2 valves to be defined. Retry segmentation, ensuring that 2 valves are defined.</td>
</tr>
<tr>
<td>81</td>
<td>Not Most Recent</td>
<td>The geometry set is not the most recently created set. Confirm this is the desired set for mapping.</td>
</tr>
<tr>
<td>82</td>
<td>Number of channels insufficient for signal averaging. Select a valid beat, and then retry.</td>
<td>The software cannot perform signal averaging on a beat with too few good channels. Select a valid beat and retry.</td>
</tr>
<tr>
<td>83</td>
<td>Off, Amplifier Offline</td>
<td>Acquisition is off. The amplifier is off line and not active. Turn on the amplifier to enable acquisition.</td>
</tr>
<tr>
<td>84</td>
<td>Off, Amplifier Ready</td>
<td>Acquisition is off. The amplifier is ready to start acquisition.</td>
</tr>
<tr>
<td>85</td>
<td>Only mitral and tricuspid valves must be segmented. Retry segmentation.</td>
<td>The software requires 2 valves to be defined. Retry segmentation, ensuring that 2 valves are defined.</td>
</tr>
<tr>
<td>86</td>
<td>Only one valve detected. Re-segment both mitral and tricuspid valves to proceed.</td>
<td>The software requires 2 valves to be defined. Retry segmentation, ensuring that 2 valves are defined.</td>
</tr>
<tr>
<td>87</td>
<td>Patient already exists. Non-duplicate studies from archive will be added to the patient without anonymization.</td>
<td>If choosing to restore a patient that already exists with anonymization, non-duplicate studies will restore into the original patient record.</td>
</tr>
<tr>
<td></td>
<td>Name: {0}</td>
<td></td>
</tr>
<tr>
<td></td>
<td>MRN: {1}</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Select 'OK' to continue restoring the patient. Select 'Cancel' to cancel.</td>
<td></td>
</tr>
<tr>
<td>88</td>
<td>Patient already exists.</td>
<td>It is not possible to restore a study that already exists in the system. If restoration is desired, archive and remove the existing study first.</td>
</tr>
<tr>
<td></td>
<td>Name: {0}</td>
<td></td>
</tr>
<tr>
<td></td>
<td>MRN: {1}</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Archive and delete the existing patient, and then retry patient restore.</td>
<td></td>
</tr>
<tr>
<td>89</td>
<td>Patient and studies were last archived on (0).</td>
<td>If edits have been made to the study after the last archival date, re-archive the latest study prior to deletion.</td>
</tr>
<tr>
<td></td>
<td>If changes were made after this date, re-archive the patient before deleting.</td>
<td></td>
</tr>
<tr>
<td>90</td>
<td>PATIENT has NOT been archived.</td>
<td>The user has requested deletion of a patient that has not been previously archived. Ensure that the record is not needed before proceeding with delete action.</td>
</tr>
<tr>
<td></td>
<td>All PATIENT data will be PERMANENTLY removed.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Continue?</td>
<td></td>
</tr>
<tr>
<td>91</td>
<td>Patient information from CT does not match the current patient information.</td>
<td>Entered patient information and the CT DICOM records do not exactly match. Select the correct values for the patient.</td>
</tr>
<tr>
<td>92</td>
<td>Press Alt-Tab to resume segmentation. Press 'Stop Segmentation' to close the segmentation program. Note: All segmentation work will be lost.</td>
<td>The segmentation program is open, and the user has switched screen views to show the main application. Use Alt-Tab to return to the segmentation program window. If Stop Segmentation is selected, segmentation work will be lost and the segmentation program will close.</td>
</tr>
<tr>
<td>93</td>
<td>QRST processing failed. Adjust QRST calipers before and after map interval, and then retry. Note: To re-enable auto-adjustment of the 2nd QRST calipers based on manual adjustment of the 1st QRST, reload the phase map.</td>
<td>During phase map processing, caliper settings and data did not allow successful QRST processing prior to phase mapping. Adjust calipers and retry. Reload the phase map for processing to allow the system to auto-adjust the 2nd QRST calipers based on manual adjustment of the 1st QRST, which may result in more successful QRST processing.</td>
</tr>
<tr>
<td>94</td>
<td>Reconnection of amplifier failed. Check connections, and then retry.</td>
<td>Self-recovery of connection to the amplifier failed. Troubleshoot connection to amplifier and retry.</td>
</tr>
<tr>
<td>95</td>
<td>Restarting Acquisition</td>
<td>Acquisition is off and attempting to restart automatically.</td>
</tr>
<tr>
<td>96</td>
<td>R-R interval detections are incomplete. Detection is optional and may take several minutes. Cancel at any time.</td>
<td>A restored study from a software version prior to 3.0 does not include R-R data to calculate suggested phase intervals and premature beats. Select to perform this processing or cancel to skip. This processing is long-running and may take several minutes, depending on the length of acquired data.</td>
</tr>
<tr>
<td>97</td>
<td>Segment at least {0} electrodes to proceed.</td>
<td>Less than the minimum number of electrodes are defined during segmentation. Retry segmentation.</td>
</tr>
<tr>
<td>98</td>
<td>Segmentation aborted.</td>
<td>The segmentation program has been closed.</td>
</tr>
<tr>
<td>99</td>
<td>Segmentation complete.</td>
<td>Segmentation process is complete.</td>
</tr>
<tr>
<td>100</td>
<td>Segmentation in Progress</td>
<td>The segmentation program is open, and the user has switched screen views to show the main application. Use Alt-Tab to return to the segmentation program window. If Stop Segmentation is selected, segmentation work will be lost and the segmentation program will close.</td>
</tr>
<tr>
<td>101</td>
<td>Segmentation ready.</td>
<td>The segmentation program is ready.</td>
</tr>
<tr>
<td>102</td>
<td>Segmentation running.</td>
<td>The segmentation program is running.</td>
</tr>
<tr>
<td>103</td>
<td>Segmentation software is not installed correctly. Contact Medtronic.</td>
<td>CISH segmentation software could not start because it is not installed correctly. Contact your local Medtronic Representative.</td>
</tr>
<tr>
<td>104</td>
<td>Self-Test In Progress</td>
<td>The amplifier self-test is in progress. Wait for it to complete prior to taking further action.</td>
</tr>
<tr>
<td>105</td>
<td>Signal averaging is complete on all available data.</td>
<td>Signal averaging is complete due to reaching the end of the dataset while looking for averaging matches.</td>
</tr>
<tr>
<td>106</td>
<td>Signal averaging is complete. Maximum matches found.</td>
<td>Signal averaging is complete due to reaching the maximum number of matches for averaging.</td>
</tr>
<tr>
<td>107</td>
<td>Starting Acquisition</td>
<td>The amplifier is responding to a command to start acquisition.</td>
</tr>
<tr>
<td>108</td>
<td>Stopping Acquisition</td>
<td>The amplifier is responding to a command to stop acquisition.</td>
</tr>
<tr>
<td>109</td>
<td>This physician record is not associated with any studies and may be deleted. Deletion will permanently remove the physician record. Physician: {0} Continue with Delete?</td>
<td>Deletion of a physician will remove the record. Note: Physicians associated with studies cannot be deleted.</td>
</tr>
<tr>
<td>Error Description</td>
<td>Solution</td>
<td></td>
</tr>
<tr>
<td>----------------------------------------------------------------------------------</td>
<td>--------------------------------------------------------------------------------------------</td>
<td></td>
</tr>
<tr>
<td>This will delete a STUDY for a patient that has NOT been archived.</td>
<td>The user has requested deletion of a study for a patient that has not been previously archived. Ensure that the record is not needed before proceeding with delete action.</td>
<td></td>
</tr>
<tr>
<td>All STUDY data will be PERMANENTLY removed.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Ensure that the STUDY record is not needed before proceeding with delete action.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Unable to add new patient. Restart application, and then retry.</td>
<td>Software could not add a new patient due to an unknown error. If problem persists, contact your local Medtronic Representative.</td>
<td></td>
</tr>
<tr>
<td>Unable to add selected channels. Restart application, and then retry.</td>
<td>The software could not add channels during beat processing due to an unknown error. Restart the application and retry. If problem persists, contact your local Medtronic Representative.</td>
<td></td>
</tr>
<tr>
<td>Unable to archive patient. Restart application, and then retry.</td>
<td>The software could not archive the patient due to an unknown error. Restart the software and retry. If problem persists, contact your local Medtronic Representative.</td>
<td></td>
</tr>
<tr>
<td>Unable to cancel segmentation. Restart application, and then retry.</td>
<td>The software could not cancel segmentation. Restart the application. If problem persists, contact your local Medtronic Representative.</td>
<td></td>
</tr>
<tr>
<td>Unable to change password. Restart application, and then retry.</td>
<td>The software could not change the password due to an unknown error. Restart the application and retry. If problem persists, contact your local Medtronic Representative.</td>
<td></td>
</tr>
<tr>
<td>Unable to close window. Restart application, and then retry.</td>
<td>The software could not close the segmentation window due to an unknown error. Restart the software and retry. If problem persists, contact your local Medtronic Representative.</td>
<td></td>
</tr>
<tr>
<td>Unable to complete signal averaging. Adjust caliper settings, and then retry.</td>
<td>The software could not complete signal averaging due to an unknown error. Adjust the caliper settings and retry. If problem persists, contact your local Medtronic Representative.</td>
<td></td>
</tr>
<tr>
<td>Unable to create a new physician. Restart application, and then retry.</td>
<td>The software could not create a physician due to an unknown error. Restart the software and retry. If problem persists, contact your local Medtronic Representative.</td>
<td></td>
</tr>
<tr>
<td>Unable to create a new user. Restart application, and then retry.</td>
<td>The software could not create a user due to an unknown error. Restart the software and retry. If problem persists, contact your local Medtronic Representative.</td>
<td></td>
</tr>
<tr>
<td>Unable to create activation map. Restart application, and then retry.</td>
<td>The software could not create a map due to an unknown error. Restart the software and retry. If problem persists, contact your local Medtronic Representative.</td>
<td></td>
</tr>
<tr>
<td>Unable to create Directional Activation map. Adjust interval, and then retry.</td>
<td>The directional activation map calculation is sensitive to inputs, and could not converge. Adjust caliper settings and retry.</td>
<td></td>
</tr>
<tr>
<td>Unable to create new geometry set. Restart application, and then retry.</td>
<td>The software could not create a geometry set due to an unknown error. Restart the software and retry. If problem persists, contact your local Medtronic Representative.</td>
<td></td>
</tr>
<tr>
<td>Unable to create phase map. Restart application, and then retry.</td>
<td>The software could not create a map due to an unknown error. Restart the software and retry. If problem persists, contact your local Medtronic Representative.</td>
<td></td>
</tr>
<tr>
<td>Unable to create potential map. Restart application, and then retry.</td>
<td>The software could not create a map due to an unknown error. Restart the software and retry. If problem persists, contact your local Medtronic Representative.</td>
<td></td>
</tr>
<tr>
<td>Unable to create study. Restart application, and then retry.</td>
<td>The software could not create a study due to an unknown error. Restart the software and retry. If problem persists, contact your local Medtronic Representative.</td>
<td></td>
</tr>
<tr>
<td>Unable to delete geometry set. Restart application, and then retry.</td>
<td>The software could not delete a geometry set due to an unknown error. Restart the software and retry. If problem persists, contact your local Medtronic Representative.</td>
<td></td>
</tr>
<tr>
<td>Unable to delete maps. Restart application, and then retry.</td>
<td>The software could not delete a map due to an unknown error. Restart the software and retry. If problem persists, contact your local Medtronic Representative.</td>
<td></td>
</tr>
<tr>
<td>Unable to delete physician. Restart application, and then retry.</td>
<td>The software could not delete a physician due to an unknown error. Restart the software and retry. If problem persists, contact your local Medtronic Representative.</td>
<td></td>
</tr>
<tr>
<td>Error Code</td>
<td>Description</td>
<td></td>
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<tr>
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<td></td>
</tr>
<tr>
<td>129</td>
<td>Unable to delete physician. Remove or unlink all studies linked to the physician, then retry.</td>
<td></td>
</tr>
<tr>
<td>130</td>
<td>Unable to delete selected bookmark. Restart application, and then retry.</td>
<td></td>
</tr>
<tr>
<td>131</td>
<td>Unable to delete selected events. Restart application, and then retry.</td>
<td></td>
</tr>
<tr>
<td>132</td>
<td>Unable to delete selected phase interval. Restart application, and then retry.</td>
<td></td>
</tr>
<tr>
<td>133</td>
<td>Unable to delete selected segmented structure. Restart application, and then retry.</td>
<td></td>
</tr>
<tr>
<td>134</td>
<td>Unable to delete selected user. Restart application, and then retry. Username: {0}</td>
<td></td>
</tr>
<tr>
<td>135</td>
<td>Unable to display phase map. Restart application, and then retry.</td>
<td></td>
</tr>
<tr>
<td>136</td>
<td>Unable to exit the application. To exit the application, use Task Manager.</td>
<td></td>
</tr>
<tr>
<td>137</td>
<td>Unable to import patient DICOM data from disk. Retry with a different DICOM file from the series.</td>
<td></td>
</tr>
<tr>
<td>138</td>
<td>Unable to load map. Restart application, and then retry.</td>
<td></td>
</tr>
<tr>
<td>139</td>
<td>Unable to load physicians. Restart application, and then retry.</td>
<td></td>
</tr>
<tr>
<td>140</td>
<td>Unable to load potential map. Restart application, and then retry.</td>
<td></td>
</tr>
<tr>
<td>141</td>
<td>Unable to load users. Restart application, and then retry.</td>
<td></td>
</tr>
<tr>
<td>142</td>
<td>Unable to remove selected channels. Restart application, and then retry.</td>
<td></td>
</tr>
<tr>
<td>143</td>
<td>Unable to restore patient. Restart application, and then retry.</td>
<td></td>
</tr>
<tr>
<td>144</td>
<td>Unable to save and close study notes.</td>
<td></td>
</tr>
<tr>
<td>145</td>
<td>Unable to save changes to user credentials. Restart application, and then retry. Username: {0}</td>
<td></td>
</tr>
<tr>
<td>146</td>
<td>Unable to save new geometry set. Restart application, and then retry.</td>
<td></td>
</tr>
<tr>
<td>147</td>
<td>Unable to save new physician. Restart application, and then retry.</td>
<td></td>
</tr>
<tr>
<td>148</td>
<td>Unable to select channel. Delete and redefine mapping interval. If problem persists, restart the application, and then retry.</td>
<td></td>
</tr>
<tr>
<td>Page</td>
<td>Issue Description</td>
<td>Solution</td>
</tr>
<tr>
<td>------</td>
<td>-------------------</td>
<td>----------</td>
</tr>
<tr>
<td>149</td>
<td>Unable to shut down application. To exit the application, use Task Manager.</td>
<td>The software could not exit due to an unknown error. Use the Task Manager to exit the application. If problem persists, contact your local Medtronic Representative.</td>
</tr>
<tr>
<td>150</td>
<td>Unable to start acquisition. Restart application, and then retry.</td>
<td>The software could not start acquisition due to an unknown error. Restart the application and amplifier, and retry. If problem persists, contact your local Medtronic Representative.</td>
</tr>
<tr>
<td>151</td>
<td>Unable to start the application. Restart workstation, and then retry.</td>
<td>The software could not start due to an unknown error. Restart the workstation, wait 5 minutes for initialization, and retry. If the problem persists, contact your local Medtronic Representative.</td>
</tr>
<tr>
<td>152</td>
<td>Unable to stop acquisition. Close application to disconnect.</td>
<td>The software could not stop acquisition due to an unknown error. Close the software to disconnect. If problem persists, contact your local Medtronic Representative.</td>
</tr>
</tbody>
</table>