## Explanation of packaging and product symbols

Refer to the package label and product to see which symbols apply to this product.

<table>
<thead>
<tr>
<th>Item</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td><img src="image" alt="Warning" /></td>
<td>Warning</td>
</tr>
<tr>
<td><img src="image" alt="Precaution" /></td>
<td>Precaution</td>
</tr>
<tr>
<td><img src="image" alt="Note" /></td>
<td>Note</td>
</tr>
<tr>
<td><img src="image" alt="Consult instructions for use" /></td>
<td>Consult instructions for use</td>
</tr>
<tr>
<td><img src="image" alt="Package contents" /></td>
<td>Package contents</td>
</tr>
<tr>
<td><img src="image" alt="Product documentation" /></td>
<td>Product documentation</td>
</tr>
<tr>
<td><img src="image" alt="Re-order number" /></td>
<td>Re-order number</td>
</tr>
<tr>
<td><img src="image" alt="Lot number" /></td>
<td>Lot number</td>
</tr>
<tr>
<td><img src="image" alt="Date of manufacture" /></td>
<td>Date of manufacture</td>
</tr>
<tr>
<td><img src="image" alt="Manufacturer" /></td>
<td>Manufacturer</td>
</tr>
<tr>
<td><img src="image" alt="Use by" /></td>
<td>Use by</td>
</tr>
<tr>
<td><img src="image" alt="Do not reuse" /></td>
<td>Do not reuse</td>
</tr>
<tr>
<td><img src="image" alt="Keep away from sunlight" /></td>
<td>Keep away from sunlight</td>
</tr>
<tr>
<td><img src="image" alt="Keep dry" /></td>
<td>Keep dry</td>
</tr>
</tbody>
</table>
Fragile: handle with care

Storage temperature

Transit temperature

Humidity limitation

This way up

Do not use if package is damaged

Caution: Federal law (USA) restricts this device to sale by or on the order of a physician.

Multi-Electrode Mapping Vest (Sensor Array)

Sensor Array size code

Sensor Array Front Left Panel

Sensor Array Front Right Panel

Sensor Array Back Panel
Before use, refer to the documentation provided with the system.

**General Description**
The Sensor Array is a Multi-Electrode Mapping Vest composed of three panels and contains a total of 252 electrodes. It is fitted on the patient and then connected to the CardiolInsight™ Cardiac Mapping System for signal acquisition via the mapping amplifier.

**Packaging Contents:**
One of the following Sensor Array Sizes:
- CITVST0001S (1)
- CITVST0002M (2)
- CITVST0003L (3)
- CITVST0004XL (4)

**Sensor Array Use**
The Sensor Array is to be used only with the CardiolInsight™ Cardiac Mapping System to provide a means of acquiring electrocardiographic signals in order to process and display virtual epicardial maps.

**Indications for Use**
The CardiolInsight™ 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.

**Sensor Array Sizing Chart**
Use the sizing chart to select the correct Sensor Array size using the ratio of the patient's height and weight.

<table>
<thead>
<tr>
<th>Ratio (cm/kg)x100</th>
<th>Ratio (in/lb)x100</th>
<th>Recommended size</th>
</tr>
</thead>
<tbody>
<tr>
<td>&gt;290</td>
<td>&gt;50</td>
<td>1</td>
</tr>
<tr>
<td>250-290</td>
<td>46-50</td>
<td>2</td>
</tr>
<tr>
<td>190-250</td>
<td>34-45</td>
<td>3</td>
</tr>
<tr>
<td>&lt;190</td>
<td>&lt;34</td>
<td>4</td>
</tr>
</tbody>
</table>
WARNINGS

⚠️ 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.

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

PRECAUTIONS

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

⚠️ The Sensor Array is meant to be used only during computed tomography (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.

⚠️ DO NOT expose the Sensor Array to organic solvents such as alcohol. If an organic solvent is used on patient, allow to dry for at least one minute prior to applying Sensor Array.

⚠️ DO NOT expose the Sensor Array and electrical connectors to fluids or solvents, except when following the cleaning instructions in the Operator’s Manual.

⚠️ Store Sensor Array flat (parallel to the floor) with the correct side facing up, as labeled, according to the environmental storage conditions.

⚠️ Store Sensor Array panels in their sealed protective pouches until use.

⚠️ Inspect the packaging and Sensor Arrays prior to use.

⚠️ DO NOT use Sensor Array if pouches are opened or damaged.

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

⚠️ Panels from different Sensor Array sizes should NEVER be mixed and matched for use.

⚠️ DO NOT cut or fold the circuitry on the Sensor Array.
Environmental Conditions

Sensor Array Storage
Temperature: +15°C to +30°C (+59°F to +86°F)

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

Instructions
CardioInsight™ Sensor Array is to be applied by trained personnel only.

Follow the instructions below for skin preparation and Sensor Array placement and refer to Appendix A as indicated below.

Skin Preparation
The patient will require skin preparation prior to Sensor Array placement. This includes cleaning of the skin to reduce impedance and enhance signal quality. Cleaning of the patient shall be done with a product containing the following properties:
- Either a liquid or a wipe
- Non-abrasive
- Hypoallergenic
- Non-staining
- Non-alcoholic

Step 1. Ensure that the patient’s torso is completely shaved (refer to Appendix A, step 1,2 for an illustration of the area to be shaved).

Step 2. Apply the cleaning solution to the patient’s torso according to the cleaning product instructions (refer to Appendix A, step 1,2 for an illustration of the area to be cleaned).

Sensor Array Placement
The Sensor Array must be applied after skin preparation.

Step 3. Have the patient carefully lie down on his or her back on a flat bed.

Step 4. Remove the plastic backing from the “Front Left” panel, and position the medial edge of the panel such that it lines up with the patient’s sternum. This panel should also be positioned on the torso so that the medial end of the left clavicle is between sensors 65 and 66 (refer to Appendix A, step 4).
Step 5. Remove the plastic backing from the “Front Right” panel. Position the medial edge of the “Front Right” panel along the medial edge of the “Front Left” panel, staggered in such a manner that it fits like a “puzzle” with the “Front Left” panel. The “Front Right” panel should be staggered slightly higher than the “Front Left” panel (refer to Appendix A, step 5,6).

Step 6. After placing both front panels, place three equally distributed strips of medical tape horizontally across the two panels along the sternum (refer to Appendix A, step 5,6).

Step 7. Have the patient carefully stand up, or sit up with his or her back straight if they are unable to stand, for placement of the “Back” panel.

Step 8. Remove the plastic backing from the “Back” panel and position the panel so that it is symmetrical on the patient’s back. This panel should also be positioned on the back so that sensor 192 rests at the level where the neck meets the shoulders. First, adhere the top center of the panel to the patient’s back and continue down through the bottom. Next, adhere the left and right sides of the “Back” panel to cover the left and right lateral sides of the torso, respectively. Lastly, drape the shoulder straps on top of the shoulders (refer to Appendix A, step 8).

⚠️ Note: If the “Back” panel shoulder electrodes overlap with the “Front Left” panel shoulder electrodes, give priority to adhering the “Front Left” panel electrodes onto the skin.

⚠️ Note: If the “Back” panel shoulder electrodes overlap with the “Front Right” panel shoulder electrodes, give priority to adhering the “Front Right” panel electrodes onto the skin.

Step 9. Have the patient lie back down on the flat bed taking care that all four Sensor Array cable connectors are accessible on either side of the patient.

Step 10. Place two strips of medical tape horizontally across the panels to secure the lateral side of the “Front Left” panel with the “Back” panel (refer to Appendix A, step 10,11).

Step 11. Place two strips of medical tape horizontally across the panels to secure the lateral side of the “Front Right” panel with the “Back” panel (refer to Appendix A, step 10,11).

Step 12. Place two perpendicular strips of medical tape across each shoulder to secure the “Back” panel shoulder straps with the Front panels (refer to Appendix A, step 12).
Compatible Device Placement
The following steps are not required to operate the device but will allow for compatibility with other equipment such as a patient return electrode, ECG electrodes, and defibrillator patches.

Patient return electrode placement
When there is a need to use a patient return electrode, follow the manufacturer’s instructions for placement. Within these guidelines, there is a preference for the patient return electrode to be placed low on the back.

It is preferred not to have the ECG electrodes or defibrillator patches attached to the patient during signal acquisition. Whenever possible, acquire the signals prior to ECG electrode and defibrillator patch placement to optimize Sensor Array electrode contact and minimize outside noise.

Defibrillator patch placement
Step 13. Gently peel back the nearest edge of the Sensor Array that corresponds to the defibrillator patch location. Apply the defibrillator patch and route the DCC (direct current cardioversion) cables to the nearest edge of the Sensor Array. Refer to Figure 1 for suggested defibrillator patch placement.
Step 14. Return the peeled edge of the Sensor Array back to its previous location on the patient’s torso.

Figure 1: Defibrillator patch placement
**ECG electrode placement**

**Step 15.** Identify locations between the Sensor Array electrodes for the desired ECG electrodes.

**Step 16.** Gently peel the nearest edge of the Sensor Array off of the patient’s skin and apply the ECG electrodes. Avoid placing the ECG electrodes directly beneath Sensor Array electrodes and circuitry.

**Step 17.** Return the peeled edge of the Sensor Array back to its previous location on the patient’s torso. Cut holes in the spandex just large enough for connecting ECG cables to the electrode snaps, making sure to avoid cutting the Sensor Array circuitry.

**Step 18.** Connect the ECG cables to the electrode snaps.

**Disposal**

Dispose of the Sensor Array and its residual elements or waste items according to institution’s biohazard requirements.

For additional education and materials for Sensor Array sizing and placement, please contact your local Medtronic Representative.

**Medtronic Limited Warranty**

For Sensor Array warranty information, see the accompanying limited warranty document.
Appendix A: Steps