The Carnation Ambulatory Monitor (CAM) is a continuously recording P-wave centric™ ambulatory ECG patch monitor that records for up to the prescribed wear time.

### Instructions For Use

**CAUTION:**
This section lists general cautions. Those pertaining to the CAM out of the direct stream of water. Avoid contact with other conductive parts if the LED does not blink, contact Customer Service.

NOTE: The activated 10 second LED blinking will only occur while the CAM is being worn. Contact Customer Service if the LED continues to blink.

**APPLICATION INSTRUCTIONS**
- **Step 4**
  - Record the date and time of CAM activation, which is a required field to complete patient registration.

- **Step 5**
  - Gently peel the liner from the CAM by grasping the tab at the top of the device and peeling downward. Avoid contact with the adhesive.
  - **CAUTION:** Touching the adhesive can reduce adhesive performance. Hold onto tabs at the end of the CAM.

**REVIEW**
- **Step 8**
  - Give the patient the Patient Diary and CAM box and explain their use. Review of instructions and Cautions and advise patient to avoid showering, bathing, or exercise immediately following application, and thereafter avoid activities or environments that result in excessive perspiration, as this may result in a decreased period of monitoring.

**LINK THE CAM TO PATIENT INFORMATION**
- **Step 9**
  - Barcode stickers with the CAM identification number are found inside the CAM box and must be placed on the patient’s chart or typed into the patient’s EMR.

**IMPORTANT:** Fill in all information on the front page of the Patient Diary, including the patient name, date/time when the CAM is activated, physician name and hospital/clinic.

**Packet Registration**
- **Step 10**
  - Register the patient as early as possible on the BDxCONNECT patient management portal.

### Technical Specifications

- **EMC Guidelines**
- **General Cautions**
- **Operational Instructions**
- **Patient Population**
- **Preparation of Skin**
- **Preparation of Recorder**
- **Patient Diary**
- **Preparation of CAM**
- **Patient Diary Insert**
- **Procedure**
- **Quick Reference Instructions**
- **Technical Specifications**
- **Disclaimer**

**PREPARE THE SKIN**
- **Step 1**
  - Remove all hair over the xiphoid process. This is a prescribed medical device. Keep device and packaging away from young children.

**PREPARE THE CAM**
- **Step 3**
  - On a flat, hard surface insert the narrow end of the Battrode into the CAM first, and then click the Battrode into place with the event button facing up.
**EMC GUIDELINES**

The CAM requires special cautions regarding EMC and needs to be put into service according to provided information.

**CAUTION:** Electromagnetic interference (EMI)

Portable and mobile wireless communications equipment such as wireless home network devices, mobile phones, cordless telephones and their base stations, and walkie-talkies can affect the CAM and should be kept at least a distance of 30 centimeters away from the equipment. Position the CAM away from other electrical or electronic equipment, if possible. The presence of strong EMI fields, or electronic, surgical, or diathermy instruments in close proximity to the ECG device may cause trace noise or input overload conditions.

The ECG device is compliant with IEC 60601-1-2 EMC immunity requirements.

**EMC GUIDELINES**

When the CAM is returned to the processing center, it will be functional after the first use.

**PROCESSING CAUTIONS**

When the CAM is returned to the reading center, it will have been in contact with human skin. Follow the facility’s procedures for appropriate handling.

**CAUTION:** Contaminated surfaces

The CAM contains a battery. Properly dispose of batteries in accordance with local regulations.

**CAUTION:** Electronic waste may present environmental hazard

The CAM is considered medical electrical equipment. Properly dispose of electronic waste in accordance with local regulations.

**CAUTION:** Single use only

The Bardy Diagnostics CAM is not intended for reuse, as local regulations.

Properly dispose of electronic waste in accordance with environmental hazard.

Battery may present environmental hazard.

Contaminated surfaces

When the CAM is returned to the reading center, it will have been in contact with human skin. Follow the facility’s procedures for appropriate handling.

**DESCRIPTION**

The Bardy Diagnostics products display one or more of these symbols and warning labels.

**SYMBOL**

- **Attention:** Consult accompanying documents
- **Warning and caution symbol**
- **TYPE BF APPLIED PART:** Type BF applied part
- **IP23**

solid by prescription only

**CAUTION:** Federal law (USA) restricts this device to sale by or on the order of a licensed healthcare practitioner.

- **Single use only**
- **Manufacturer**
- **Use-by date**

**TECHNICAL SPECIFICATIONS**

**ITEM**

- **Physical Characteristics**
  - Approximate dimensions: 178mm x 38mm x 14mm
  - Weight: 125g
  - Enclosure material: Medical grade thermoplastic polymer
  - Flammability rating: UL-HB

- **Classification**
  - Type of protection: Internally powered
  - Degree of protection: Type BF applied part
  - Protection against objects and water ingress: IP23 (Protected against intrusion from fingers and small objects, and from water falling as a spray at an angle of up to 6° from vertical)

- **Electrode Characteristics**
  - Number of electrodes: 2
  - Type: Electrode incorporating electrode gel and internal lead wire
  - Supplied as: Disposable, non-sterile
  - Lead wire length: 11.6 cm (no patient contact)
  - Materials: Electrode gel: Medical grade conductive synthetic Adhesive: Medical grade skin adhesive

**Symbols**

- **SYMBOL**
  - **DESCRIPTION**
    - Do not expose to temperatures outside of these limits. For more information on environmental parameters refer to the Technical Specifications section.
    - Atmospheric pressure must be within these limits. For more information on environmental parameters refer to the Technical Specifications section.
    - Humidity must be within these limits. For more information on environmental parameters refer to the Technical Specifications section.
    - Contains electronic equipment. Dispose of property in accordance with local regulations.
    - Serial number
    - Orderable part number
    - Batch code
    - MRI Unsafe
    - CE Mark signifying conformity to EU regulations
    - EU authorized representative
    - Symbols

**Technical Specifications**

**Ambulatory Monitor**

**Bardy Diagnostics, Inc.**
316 Occidental Ave S, Ste B310
Seattle, WA 98104
USA

**EU Customer Service:**
(844) 422-7393

For assistance in setting up, using, and maintaining the device, or to report unexpected operations or events:

**EC REP**

Medical Product Service GmbH
Bormaaweg 20
35619 Braunfels
Germany

**EU Customer Service:** +31 (0)46 7630422

**Instructions For Use**

For additional instructions and Frequently Asked Questions visit www.bardydx.com

**Technical Specifications**

**Environmental Specifications (ECG Device)**

- Operating temperature: 50°F to 113°F (10°C to 45°C)
- Operating pressure: 700 to 1060 hPa
- Operating humidity: 10% to 95% (non-condensing)
- Transport temperature: 14°F to 130°F (-10°C to 55°C)
- Storage temperature: 59°F to 77°F (15°C to 25°C)
- Transport / Storage humidity: 10% to 95% (non-condensing)
- Transport / Storage pressure: 500 to 1060 hPa
- Standards compliance: Applicable sections of IEC local regulations, 60601-1, 60601-1-2, 60601-1-11, 60601-2-47

**A/D sampling rate**

0.67 Hz to 25 Hz

**Differential range**

4 mV

**Frequency response**

171 Hz

**ECG channels**

1 channel

**Recording capacity**

Up to 2 or 7 days

**Recording format**

Continuous

**Service life**

Up to 2 or 7 days

**Shelf life**

24 months

**Weight**

<125g

**Electrical Characteristics**

- Battery type: Lithium primary (coin cell)
- Lithium content: Lithium content < 1 g
- Heavy metal content: Within weight limits of 2006/66/EC
- UN compliance: Complies with UN 3900

**Approximate dimensions**

178mm x 38mm x 14mm

**Electrode Characteristics**

- Number of electrodes: 2
- Type: Electrode incorporating electrode gel and internal lead wire
- Supplied as: Disposable, non-sterile
- Lead wire length: 11.6 cm (no patient contact)
- Materials: Electrode gel: Medical grade conductive synthetic Adhesive: Medical grade skin adhesive

**Notes:**

- **CAUTION:** Federal law (USA) restricts this device to sale by or on the order of a licensed healthcare practitioner.
- **Single use only**
- **Manufacturer**
- **Use-by date**

**Technical Specifications**

**Equipment Specifications**

- Operating temperature: 50°F to 113°F (10°C to 45°C)
- Operating pressure: 700 to 1060 hPa
- Operating humidity: 10% to 95% (non-condensing)
- Transport temperature: 14°F to 130°F (-10°C to 55°C)
- Storage temperature: 59°F to 77°F (15°C to 25°C)
- Transport / Storage humidity: 10% to 95% (non-condensing)
- Transport / Storage pressure: 500 to 1060 hPa
- Standards compliance: Applicable sections of IEC local regulations, 60601-1, 60601-1-2, 60601-1-11, 60601-2-47

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- **Single use only**
- **Manufacturer**
- **Use-by date**
Electromagnetic Emissions Declarations

Guidance and manufacturer’s declaration – electromagnetic emissions

The CAM is intended for use in the electromagnetic environment specified below. The customer or the user of the CAM should assure that it is used in such an environment.

<table>
<thead>
<tr>
<th>Emissions test</th>
<th>Compliance</th>
<th>Electromagnetic environment - guidance</th>
</tr>
</thead>
<tbody>
<tr>
<td>RF emissions</td>
<td>Group 1</td>
<td>The CAM 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>Harmonic emissions</td>
<td>Group B</td>
<td>The CAM has No AC Mains, and is suitable for use in all establishments, including domestic, and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.</td>
</tr>
<tr>
<td>Voltage fluctuations/</td>
<td>Not Applicable</td>
<td></td>
</tr>
<tr>
<td>flicker emissions</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Electromagnetic environment - guidance

Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.

Power frequency magnetic fields should be that of a typical commercial or hospital environment.

Portable and mobile RF communications equipment should be used no closer than 30 cm to any part of the CAM.

Interference may occur in the vicinity of equipment marked with the following symbol: 😵

Guidance and manufacturer’s declaration – electromagnetic immunity

The CAM is intended for use in the electromagnetic environment specified below. The customer or the user of the CAM should assure that it is used in such an environment.

<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)</td>
<td>± 8 kV contact</td>
<td>± 8 kV contact</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>IEC 61000-4-2</td>
<td>± 15 kV air</td>
<td>± 15 kV air</td>
<td></td>
</tr>
<tr>
<td>Power frequency (50/60 Hz) magnetic field</td>
<td>30 A/m</td>
<td>30 A/m</td>
<td>Power frequency magnetic fields should be that of a typical commercial or hospital environment.</td>
</tr>
<tr>
<td>IEC 61000-4-8</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Radiated RF</td>
<td>10 V/m 80 MHz to 2,7 GHz</td>
<td>10 V/m 80 MHz to 2,7 GHz</td>
<td>Portable and mobile RF communications equipment should be used no closer than 30 cm to any part of the CAM.</td>
</tr>
<tr>
<td>IEC 61000-4-3</td>
<td>9 V/m - 28 V/m per</td>
<td>9 V/m - 28 V/m per</td>
<td>Interference may occur in the vicinity of equipment marked with the following symbol: 😵</td>
</tr>
<tr>
<td>Proximity Fields (per IEC 60601-1-2 Ed. 4)</td>
<td>IEC 60601-1-2 Ed. 4,</td>
<td>IEC 60601-1-2 Ed. 4,</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Table 9</td>
<td>Table 9</td>
<td></td>
</tr>
</tbody>
</table>
**Instructions For Use**

The Carnation Ambulatory Monitor is a single patient use, continuous recording ambulatory ECG monitor that records for up to 7 Days.

**Indications for Use**
The Carnation Ambulatory Monitor is designed to provide extended duration cardiac monitoring for people who are suspected of having cardiac arrhythmias.

**Patient Population**
The intended patient population includes both males and females not weighing less than 10 kg (22lbs) who may have cardiac arrhythmias.

Read all instructions before using this product

By prescription only

For assistance in setting up, using, and maintaining the device, or to report unexpected operations or events. Contact us:

Barry Diagnostics Inc.
316 Occidental Ave
Ste B310
Seattle, WA 98104 USA

US Customer service: (844) 422-7393
EU Customer service: +31 (0) 46 7630422

**Symbols**

- CAUTION: Touching the adhesive can reduce adhesive performance.
- CAUTION: Inability to diagnose if patient and physician data is missing.
- GENERAL Cautions
- Processing Cautions
- EMC Guidelines
- Symbols
- Technical Specifications

**Prepare the Skin**

**STEP 1**

Read all instructions before using the device, or to report unexpected operations or events. Contact us:

Barry Diagnostics Inc.
316 Occidental Ave
Ste B310
Seattle, WA 98104 USA

US Customer service: (844) 422-7393
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Patient Population

The intended patient population includes both males and females not weighing less than 10 kg (22lbs) who may have cardiac arrhythmias.

**STEP 2**

Prepare the Carnation Ambulatory Monitor. Such as the device coming loose from the patient’s chest. Scrub skin with wipe or wipes until wipe remains clean after use. IMPORTANT: Ensure skin is completely dry before monitor application.

**STEP 3**

Remove the Recorder and Battrode. If hair is present, shave the hair as close to the skin as possible.

**STEP 4**

On a flat, hard surface, snap the Recorder into the Battrode by inserting the narrow end first. Within 2-3 seconds you should hear a confirmation buzz. If there is no buzz see Operational Instructions on this page.

**STEP 5**

Use both hands to find the edge of the ribcage where it meets the abdomen. Slide both hands down towards the center of the body until they meet in a little notch.

Ask the patient to inhale and exhale — after exhaling you should feel a pointed bone. This is the xiphoid process.

**STEP 6**

Peel the liner from the back of the Carnation Ambulatory Monitor. CAUTION: Touching the adhesive can reduce adhesive performance. Hold onto the tabs at the ends of the Carnation Ambulatory Monitor.

**STEP 7**

Apply the CAM to the patient’s chest with the bottom of the electrode sitting over the xiphoid. Press firmly on patch adhesive for 1 minute to ensure adhesion.

**STEP 8**

Tell patient to gently press the button when they feel symptoms, and record the time/date in the Patient Diary.

If the Carnation Ambulatory Monitor becomes soiled, patients may gently wipe exterior of device, using a clean, dry cloth.

**STEP 9**

Fill in all information on the front page of the Patient Diary, including start time/date, patient initials, and physician name and phone number.

**STEP 10**

Barcode stickers with the device’s unique serial number are found inside the mailer box and can be placed on the patient chart, or be typed into the patient’s EMR.

**Instructions to Patient**

Avoid activities or environments that result in severe perspiration, as this may result in the device failing to maintain adherence to the skin.

**STEP 11**

Link the Carnation Ambulatory Monitor to the patient’s information. CAUTION: Inability to diagnose if patient and physician data is missing. The patient diary card must be kept with the Carnation Ambulatory Monitor to ensure proper diagnosis.

**STEP 12**

Give the patient the Patient Diary and Return Mailer and explain their use. Review all Instructions and Cautions in case there is a change in performance of the Carnation Ambulatory Monitor, such as the device coming loose from the patient’s chest.

**Operational Instructions**

If the Carnation Ambulatory Monitor becomes soiled, patients may gently wipe exterior of device, using a clean, dry cloth.

If Carnation Ambulatory Monitor becomes loose or detached from skin, patient should press the monitor back in place.

If you do not hear a confirmation buzz, place the monitor up to your ear and press the button to confirm. If no buzz, return to manufacturer.
Safety Alert Descriptions
The symbol shown below identifies a potential hazard category.

⚠️ CAUTION
This alert identifies hazards that may cause minor personal injury, product damage, or property damage.

General Cautions
This section lists general cautions. Those pertaining to specific functions and procedures are included in the text where appropriate.

⚠️ CAUTION: Contains ECG Electrodes which can damage skin if used improperly.
This device should be used by or in consultation with a health care provider familiar with their proper placement and use. Apply electrodes to intact, clean skin only. Do not apply over an open wound, lesion, infected or inflamed skin.

⚠️ CAUTION: Skin irritation
Patients with sensitive skin or with known skin conditions should use this device with caution. If irritation such as redness, severe itching or allergic symptoms (i.e. hives) develop, instruct patients to remove the device immediately and have them contact their physician.

⚠️ CAUTION: Allergic skin reaction
Do not use this device on patients with known skin allergies or family history of skin allergies.

⚠️ CAUTION: Damage to skin
Instruct patients to remove electrodes carefully to avoid damaging their skin.

⚠️ CAUTION: Choking hazard
This is a prescribed medical device. Keep device and packaging away from young children.

⚠️ CAUTION: Equipment damage
Use only as directed. Tampering with the Carnation Ambulatory Monitor may render it unusable. There are no user serviceable parts.

⚠️ CAUTION: Equipment damage
Use only with approved Bardy Diagnostics download station.

⚠️ CAUTION: May interfere with defibrillation therapy
To avoid ineffective defibrillation therapy, remove the Carnation Ambulatory Monitor before applying any external cardiac defibrillators.

⚠️ CAUTION: May interfere with MRI scanning
This device is not intended for use with MRI equipment and could reduce effectiveness of diagnostic scanning. Remove before any MRI scan.

⚠️ CAUTION: Ineffective electronic imaging
This device is not intended for use with imaging equipment and could reduce effectiveness of diagnostic imaging. Remove before using electronic imaging systems.

⚠️ CAUTION: Enclosure damage
Do not use any parts that appear damaged. Check the Carnation Ambulatory Monitor for damage before using and reject any parts that have been damaged in shipping.

CAUTION: Electrical shock
This Carnation Ambulatory Monitor contains electrodes for monitoring ECG. Do not allow conductive parts of the electrodes on this device to come in contact with other conductive parts (including earth).

Processing Cautions
When the ECG device is returned to the processing center, these additional cautions apply.

⚠️ CAUTION: Contaminated surfaces
When this device is returned to the reading center it will have been in contact with human skin. Follow the facility’s procedures for appropriate handling.

⚠️ CAUTION: Battery may present environmental hazard
This device contains a battery. Properly dispose of batteries in accordance with local regulations.

⚠️ CAUTION: Electronic waste may present environmental hazard
This device is considered medical electrical equipment. Properly dispose of electronic waste in accordance with local regulations.

⚠️ CAUTION: Single use only
The Bardy Diagnostics Carnation Ambulatory Monitor is not intended for reuse, as the monitor becomes non-functional after the first use.

EMC Guidelines
The Carnation Ambulatory Monitor needs special cautions regarding EMC, and needs to be put into service according to provided information.

⚠️ CAUTION: Electromagnetic interference (EMI)
Portable and mobile wireless communications equipment such as wireless home network devices, mobile phones, cordless telephones and their base stations, and walkie-talkies can affect the Carnation Ambulatory Monitor and should be kept at least a distance of 3.3 meters away from the equipment. Position the Carnation Ambulatory Monitor away from other electrical or electronic equipment, if possible. The presence of strong EMI fields, or electronic, surgical, or dialthermy instruments in close proximity to the ECG device may cause trace noise or input overload conditions.

The ECG device is compliant with IEC 60601-1-2 EMC immunity requirements.

EMC Guidelines

Symbols
Bardy Diagnostics products display one or more of these symbols and warning labels.

<table>
<thead>
<tr>
<th>SYMBOL</th>
<th>DESCRIPTION</th>
</tr>
</thead>
<tbody>
<tr>
<td>🚭</td>
<td>Attention: Consult accompanying documents</td>
</tr>
<tr>
<td>⚠️</td>
<td>Warning and caution symbol</td>
</tr>
<tr>
<td>🌊</td>
<td>TYPE BF APPLIED PART: F-TYPE APPLIED PART complying with the specified requirements of 60601-1 to provide a higher degree of protection against electric shock than that provided by TYPE B APPLIED PARTS.</td>
</tr>
<tr>
<td>🍄</td>
<td>Note: TYPE BF APPLIED PARTS are not suitable for DIRECT CARDIAC APPLICATION.</td>
</tr>
<tr>
<td>⚠️</td>
<td>Protected against intrusion from fingers and small objects, and from water falling as a spray at an angle of up to 60° from vertical. Do not immerse in bathtub or swimming.</td>
</tr>
<tr>
<td>🔥</td>
<td>Sold by prescription only</td>
</tr>
<tr>
<td>🚭</td>
<td>Single use only</td>
</tr>
<tr>
<td>🚭</td>
<td>Manufacturer</td>
</tr>
<tr>
<td>🛑</td>
<td>Use-by date.</td>
</tr>
<tr>
<td>💦</td>
<td>Do not expose to temperatures outside of these limits. For more information on environmental parameters refer to the Technical Specifications section.</td>
</tr>
<tr>
<td>🚭</td>
<td>MR Unsafe</td>
</tr>
</tbody>
</table>

Symbols

<table>
<thead>
<tr>
<th>SYMBOL</th>
<th>DESCRIPTION</th>
</tr>
</thead>
<tbody>
<tr>
<td>🌊</td>
<td>Atmospheric pressure must be within these limits. For more information on environmental parameters refer to the Technical Specifications section.</td>
</tr>
<tr>
<td>💦</td>
<td>Humidity must be within these limits. For more information on environmental parameters refer to the Technical Specifications section.</td>
</tr>
<tr>
<td>📅</td>
<td>Date of manufacture</td>
</tr>
<tr>
<td>🍄</td>
<td>Contains electronic equipment. Dispose of properly in accordance with local regulations.</td>
</tr>
<tr>
<td>🍄</td>
<td>Serial number</td>
</tr>
<tr>
<td>🎁</td>
<td>Orderable part number</td>
</tr>
<tr>
<td>🤝</td>
<td>Batch code</td>
</tr>
<tr>
<td>🌊</td>
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<tr>
<td>🌊</td>
<td>EU authorized representative</td>
</tr>
<tr>
<td>🚭</td>
<td>MR Unsafe</td>
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</table>
Technical Specifications

PHYSICAL CHARACTERISTICS

- 178mm x 38mm x 14mm
- <25g
- Medical grade thermoplastic polymer

CLASSIFICATION

- Type of protection: Internally powered
- Degree of protection: Type BF applied part
- Protection against objects and water ingress: IP23 (Protected against intrusion from fingers and small objects, and from water falling as a spray at an angle of up to 60° from vertical)

PERFORMANCE CHARACTERISTICS

- 1 channel
- Continuous
- ECG channels
- Recording capacity
- Recording format Continuous
- Service life 7 days
- Shelf life 24 months

ELECTRICAL CHARACTERISTICS

- Frequency response: 0.67 Hz to 25 Hz
- Differential range: 4 mV
- A/D sampling rate: 171 Hz

POWER REQUIREMENTS

- Battery type: Lithium primary (coin cell)
- Lithium content: Lithium content < 1 g
- Heavy metal content: Within weight limits of 2006/66/EC
- UN compliance: Complies with UN 3090

ENVIRONMENTAL SPECIFICATIONS (ECG DEVICE)

- Operating temperature: 50 °F to 113°F (10 °C to 45 °C)
- Operating pressure: 700 to 1060 hPa
- Operating humidity: 10% to 95% (non-condensing)
- Transport temperature: 14°F to 130°F (-10 °C to 55 °C)
- Storage temperature: 59°F to 77°F (15 °C to 25 °C)
- Transport/Storage humidity: 10% to 95% (non-condensing)
- Transport/Storage pressure: 500 to 1060 hPa

ELECTRODE CHARACTERISTICS

- Number of electrodes: 2
- Type: Electrode incorporating electrode gel and internal lead wire
- Supplied as: Disposable, non-sterile
- Lead wire length: 11.6 cm (no patient contact)
- Materials: Electrode gel: Medical grade conductive synthetic Adhesive: Medical grade skin adhesive

Guidance and manufacturer’s declaration – electromagnetic emissions

The CAM is intended for use in the electromagnetic environment specified below. The customer or the user of the CAM should assure that it is used in such an environment.

<table>
<thead>
<tr>
<th>Emissions test</th>
<th>Compliance</th>
<th>Electromagnetic environment - guidance</th>
</tr>
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<tbody>
<tr>
<td>RF emissions CISPR 11</td>
<td>Group 1</td>
<td>The CAM 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>Harmonic emissions IEC 61000-3-2</td>
<td>Group B</td>
<td></td>
</tr>
<tr>
<td>Voltage fluctuations/</td>
<td>Not Applicable</td>
<td></td>
</tr>
<tr>
<td>Flicker emissions IEC 61000-3-3</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Guidance and manufacturer’s declaration – electromagnetic immunity

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<th>IMMUNITY test</th>
<th>IEC 60601 test level</th>
<th>Compliance level</th>
<th>Electromagnetic environment - guidance</th>
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</thead>
<tbody>
<tr>
<td>Electrostatic discharge (ESD) IEC 61000-4-2</td>
<td>± 8 kV contact</td>
<td>± 8 kV contact</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>
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<td>Power frequency (50/60 Hz) magnetic field IEC 61000-4-8</td>
<td>± 15 kV air</td>
<td>± 15 kV air</td>
<td>Power frequency magnetic fields should be that of a typical commercial or hospital environment.</td>
</tr>
<tr>
<td>Radiated RF IEC 61000-4-3</td>
<td>30 A/m</td>
<td>30 A/m</td>
<td>Portable and mobile RF communications equipment should be used no closer than 30 cm to any part of the CAM.</td>
</tr>
<tr>
<td>Radiated RF Proximity Fields IEC 61000-4-3 (per IEC 60601-1-2 Ed. 4)</td>
<td>10 V/m - 28 V/m per IEC 60601-1-2 Ed. 4, Table 9</td>
<td>10 V/m - 28 V/m per IEC 60601-1-2 Ed. 4, Table 9</td>
<td>Interference may occur in the vicinity of equipment marked with the following symbol: 📡</td>
</tr>
</tbody>
</table>