The Carnation Ambulatory Monitor (CAM) 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 (22 lbs) who may have cardiac arrhythmias.

**TABLE OF CONTENTS**

<table>
<thead>
<tr>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>2</td>
</tr>
<tr>
<td>3</td>
</tr>
<tr>
<td>4</td>
</tr>
<tr>
<td>5</td>
</tr>
<tr>
<td>6</td>
</tr>
<tr>
<td>7</td>
</tr>
<tr>
<td>8</td>
</tr>
</tbody>
</table>

**CAUTIONS**

The symbol below identifies a potential hazard category.

**CAUTION:** This legend 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.

**CONTAINS ECG Electrodes, which can damage skin if used improperly. The CAM should be used by or in consultation with a health care provider familiar with its proper placement and use. Apply electrodes to intact, clean skin only. Do not apply over an open wound, lesion, infected or irritated skin.**

**Damage to skin**

Instruct patients to remove electrodes carefully to avoid damaging their skin.

**APPLICATION:**

**Step 6**

Locate the bone at the bottom of the sternum. This is the xiphoid process.

**APPLY THE CAM**

Apply the CAM to the patient’s sternum with the bottom part sitting over the xiphoid process. Push firmly around the edges of the patch for 1 minute to ensure adhesion. Place two fingers under the event button and press down firmly to adhere the top of the CAM to the patient’s chest.

**RECORD SYMPTOMS**

Step 7

Instruct patients to gently press the button only once each time they feel symptoms, and record the date/time in the Patient Diary (included). Do not press button repeatedly or forcefully.

**PREPARING THE SKIN**

- Remove all hair over sternal area by shaving close to the skin. Do not merely clip hair. The prepared area should extend 2 inches past where the CAM will be placed.
- Use all prep pads provided in the box to clean area shown. SCRUB the skin with the prep pads until they appear clean after use. Skin should be scrubbed well enough to be slightly reddened. Allow the skin to dry for 1 minute prior to applying.
- On a flat, hard surface insert the narrow end of the Battrode into the CAM first, then click the Battrode into place with the event button facing up.

**CAUTIONS:**

- Proper skin prep required to achieve full length of prescribed monitoring duration.
- Do not allow conductive parts of the electrodes on the CAM to come in contact with other conductive parts (including ear).
- The CAM is not intended for use with imaging equipment and could reduce effectiveness of diagnostic scanning. Remove before any MRI scan.
- This is a prescribed medical device. Keep device and packaging away from young children.
- Use only as directed. Tampering with the CAM may render it unusable. There are no user serviceable parts.
- Do not use the CAM on patients with known skin allergies or family history of skin allergies.

**PREPARE THE SKIN**

**Step 1**

Remove all hair over sternal area by shaving close to the skin. Do not merely clip hair. The prepared area should extend 2 inches past where the CAM will be placed.

**Step 2**

Use all prep pads provided in the box to clean area shown. SCRUB the skin with the prep pads until they appear clean after use. Skin should be scrubbed well enough to be slightly reddened. Allow the skin to dry for 1 minute prior to applying.

**PREPARE THE CAM**

**Step 3**

On a flat, hard surface insert the narrow end of the Battrode into the CAM first, then click the Battrode into place with the event button facing up.

**PREPARATION OF THE SKIN**

- Remove all hair over sternal area by shaving close to the skin. Do not merely clip hair. The prepared area should extend 2 inches past where the CAM will be placed.
- Use all prep pads provided in the box to clean area shown. SCRUB the skin with the prep pads until they appear clean after use. Skin should be scrubbed well enough to be slightly reddened. Allow the skin to dry for 1 minute prior to applying.
- On a flat, hard surface insert the narrow end of the Battrode into the CAM first, then click the Battrode into place with the event button facing up.

**APPLY THE CAM**

**Step 6**

Locate the bone at the bottom of the sternum. This is the xiphoid process.

**APPLY THE CAM**

Apply the CAM to the patient’s sternum with the bottom part sitting over the xiphoid process. Push firmly around the edges of the patch for 1 minute to ensure adhesion. Place two fingers under the event button and press down firmly to adhere the top of the CAM to the patient’s chest.

**RECORD SYMPTOMS**

Step 7

Instruct patients to gently press the button only once each time they feel symptoms, and record the date/time in the Patient Diary (included). Do not press button repeatedly or forcefully.

**PREPARING THE SKIN**

**Step 1**

Remove all hair over sternal area by shaving close to the skin. Do not merely clip hair. The prepared area should extend 2 inches past where the CAM will be placed.

**Step 2**

Use all prep pads provided in the box to clean area shown. SCRUB the skin with the prep pads until they appear clean after use. Skin should be scrubbed well enough to be slightly reddened. Allow the skin to dry for 1 minute prior to applying.

**PREPARE THE CAM**

**Step 3**

On a flat, hard surface insert the narrow end of the Battrode into the CAM first, then click the Battrode into place with the event button facing up.

**CAUTIONS:**

- Proper skin prep required to achieve full length of prescribed monitoring duration.
- Do not allow conductive parts of the electrodes on the CAM to come in contact with other conductive parts (including ear).
- The CAM is not intended for use with imaging equipment and could reduce effectiveness of diagnostic scanning. Remove before any MRI scan.
- This is a prescribed medical device. Keep device and packaging away from young children.
- Use only as directed. Tampering with the CAM may render it unusable. There are no user serviceable parts.
- Do not use the CAM on patients with known skin allergies or family history of skin allergies.

**PREPARE THE SKIN**

**Step 1**

Remove all hair over sternal area by shaving close to the skin. Do not merely clip hair. The prepared area should extend 2 inches past where the CAM will be placed.

**Step 2**

Use all prep pads provided in the box to clean area shown. SCRUB the skin with the prep pads until they appear clean after use. Skin should be scrubbed well enough to be slightly reddened. Allow the skin to dry for 1 minute prior to applying.

**PREPARE THE CAM**

**Step 3**

On a flat, hard surface insert the narrow end of the Battrode into the CAM first, then click the Battrode into place with the event button facing up.

**CAUTIONS:**

- Proper skin prep required to achieve full length of prescribed monitoring duration.
- Do not allow conductive parts of the electrodes on the CAM to come in contact with other conductive parts (including ear).
- The CAM is not intended for use with imaging equipment and could reduce effectiveness of diagnostic scanning. Remove before any MRI scan.
- This is a prescribed medical device. Keep device and packaging away from young children.
- Use only as directed. Tampering with the CAM may render it unusable. There are no user serviceable parts.
- Do not use the CAM on patients with known skin allergies or family history of skin allergies.

**PREPARE THE SKIN**

**Step 1**

Remove all hair over sternal area by shaving close to the skin. Do not merely clip hair. The prepared area should extend 2 inches past where the CAM will be placed.

**Step 2**

Use all prep pads provided in the box to clean area shown. SCRUB the skin with the prep pads until they appear clean after use. Skin should be scrubbed well enough to be slightly reddened. Allow the skin to dry for 1 minute prior to applying.

**PREPARE THE CAM**

**Step 3**

On a flat, hard surface insert the narrow end of the Battrode into the CAM first, then click the Battrode into place with the event button facing up.

**CAUTIONS:**

- Proper skin prep required to achieve full length of prescribed monitoring duration.
- Do not allow conductive parts of the electrodes on the CAM to come in contact with other conductive parts (including ear).
- The CAM is not intended for use with imaging equipment and could reduce effectiveness of diagnostic scanning. Remove before any MRI scan.
- This is a prescribed medical device. Keep device and packaging away from young children.
- Use only as directed. Tampering with the CAM may render it unusable. There are no user serviceable parts.
- Do not use the CAM on patients with known skin allergies or family history of skin allergies.

**PREPARE THE SKIN**

**Step 1**

Remove all hair over sternal area by shaving close to the skin. Do not merely clip hair. The prepared area should extend 2 inches past where the CAM will be placed.

**Step 2**

Use all prep pads provided in the box to clean area shown. SCRUB the skin with the prep pads until they appear clean after use. Skin should be scrubbed well enough to be slightly reddened. Allow the skin to dry for 1 minute prior to applying.

**PREPARE THE CAM**

**Step 3**

On a flat, hard surface insert the narrow end of the Battrode into the CAM first, then click the Battrode into place with the event button facing up.

**CAUTIONS:**

- Proper skin prep required to achieve full length of prescribed monitoring duration.
- Do not allow conductive parts of the electrodes on the CAM to come in contact with other conductive parts (including ear).
- The CAM is not intended for use with imaging equipment and could reduce effectiveness of diagnostic scanning. Remove before any MRI scan.
- This is a prescribed medical device. Keep device and packaging away from young children.
- Use only as directed. Tampering with the CAM may render it unusable. There are no user serviceable parts.
- Do not use the CAM on patients with known skin allergies or family history of skin allergies.

**PREPARE THE SKIN**

**Step 1**

Remove all hair over sternal area by shaving close to the skin. Do not merely clip hair. The prepared area should extend 2 inches past where the CAM will be placed.

**Step 2**

Use all prep pads provided in the box to clean area shown. SCRUB the skin with the prep pads until they appear clean after use. Skin should be scrubbed well enough to be slightly reddened. Allow the skin to dry for 1 minute prior to applying.

**PREPARE THE CAM**

**Step 3**

On a flat, hard surface insert the narrow end of the Battrode into the CAM first, 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.

DESCRIPTION
When the CAM is returned to the processing center, these additional cautions apply.

CAUTION: 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.

CAUTION: Battery may present environmental hazard
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.

The CAM is considered medical electrical equipment.

ENVIRONMENTAL SPECIFICATIONS

- Storage temperature: 10° C to 55° C (50° F to 113° F)
- Transport temperature: 14° F to 180° F (10° C to 85° 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

TECHNICAL SPECIFICATIONS

- 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
- Frequency response: 0.05 Hz to 25 Hz
- Differential range: ±4 mV
- A/D sampling rate: 171 Hz
- Battery type: Lithium primary (coin cell)
- Lithium content: Lithium content < 1 g
- Heavy metal content: Within weight limits of 2006/666/EC
- UN compliance: Complies with UN 3090

SYMBOLS

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

SYMBOL DESCRIPTION

- Warning and caution symbol

- TYPE BF APPLIED PART: F-TYPE APPLIED PART complying with the specified requirements of 60601-1 to provide a higher degree of protection against electronic shock than that provided by TYPE B APPLIED PART.

- Note: TYPE BF APPLIED PARTS are not suitable for DIRECT CARDIAC APPLICATION.

- 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. Do not immerse in bathtub or swimming.

- Single use only

- Manufacturer

- Use-by date

TECHNICAL SPECIFICATIONS

- Physical Characteristics
  - Approximate dimensions: 178mm x 38mm x 14mm
  - Weight: <25g
  - Enclosure material: Medical grade thermoplastic polymer
  - Flammability rating: UL-HB

- Classification
  - Type of protection: Internally powered
  - Degree of protection: Type BF applied part

- Electrode Characteristics
  - Number of electrodes: 2
  - Type: Electrode incorporating electrode gel and internal lead wire

- Electrode Characteristics
  - Number of electrodes: 2
  - Type: Electrode incorporating electrode gel and internal lead wire

- Lead wire length: 11.6 cm (no patient contact)

- Materials: Electrode gel: Medical grade conductive synthetic Adhesive: Medical grade skin adhesive

- Other features
  - Single use only
  - Single use only

- 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.

- 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.

- Battery may present environmental hazard
The CAM contains a battery. Properly dispose of batteries in accordance with local regulations.

- Electronic waste may present environmental hazard
The CAM is considered medical electrical equipment. Properly dispose of electronic waste in accordance with local regulations.

- Single use only
The Bardy Diagnostics CAM is not intended for reuse, as local regulations.

- Medical electrical equipment.

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.
### 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 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>RF emissions CISPR 11</td>
<td>Group B</td>
<td></td>
</tr>
<tr>
<td>Harmonic emissions IEC 61000-3-2</td>
<td>Not Applicable</td>
<td></td>
</tr>
<tr>
<td>Voltage fluctuations/ ficker emissions IEC 61000-3-3</td>
<td>Not Applicable</td>
<td></td>
</tr>
</tbody>
</table>

### 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) 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>
</tr>
<tr>
<td></td>
<td>± 15 kV air</td>
<td>± 15 kV air</td>
<td></td>
</tr>
<tr>
<td>Power frequency (50/60 Hz) magnetic field IEC 61000-4-8</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>Radiated RF IEC 61000-4-3</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>Radiated RF Proximity Fields IEC 61000-4-3 (per IEC 60601-1-2 Ed. 4)</td>
<td>9 V/m - 28 V/m per IEC 60601-1-2 Ed. 4, Table 9</td>
<td>9 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>
Instructions For Use

The Carnation Ambulatory Monitor is a single patient use, continuous recording ambulatory ECG monitor that records for up to 48 hours.

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

Prepare the Carnation Ambulatory Monitor

STEP 1
Remove the Recorder and Battrode from the packaging.

STEP 2
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 3
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 4
Apply the Carnation Ambulatory Monitor 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 5
Ask the patient to inhale and exhale – after exhaling you should feel a pointed bone. This is the xiphoid process.

STEP 6
Tell patient to gently press the button when they feel symptoms, and record the time/date in the Patient Diary.

STEP 7
Tell patient to keep the Patient Diary and return Mailer with device for mailing back to manufacturer.

STEP 8
If hair is present, shave the hair as close to the skin as possible. 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. If there is no buzz see Operational Instructions on this page.

STEP 9
If hair is present, shave the hair as close to the skin as possible. 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.

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.

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 11
Fill in all information on the front page of the Patient Diary, including start time/date, patient initials, and physician name and phone number.

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

Carnation Ambulatory Monitor Instructions For Use  DWS006149H 04/2019

NOTE: Be sure that the prepared area extends over 1 inch larger than where the patch will sit.
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.

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 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.

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.

Specifications section.

<table>
<thead>
<tr>
<th>SYMBOL</th>
<th>DESCRIPTION</th>
</tr>
</thead>
<tbody>
<tr>
<td><img src="image" alt="Attention: Consult accompanying documents" /></td>
<td>Attention: Consult accompanying documents</td>
</tr>
<tr>
<td><img src="image" alt="Warning and caution symbol" /></td>
<td>Warning and caution symbol</td>
</tr>
<tr>
<td><img src="image" alt="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>
<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><img src="image" alt="Note: TYPE BF APPLIED PARTS are not suitable for DIRECT CARDIAC APPLICATION." /></td>
<td>Note: TYPE BF APPLIED PARTS are not suitable for DIRECT CARDIAC APPLICATION.</td>
</tr>
<tr>
<td><img src="image" alt="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>
<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><img src="image" alt="Sold by prescription only" /></td>
<td>Sold by prescription only</td>
</tr>
<tr>
<td><img src="image" alt="CAUTION: Federal law (USA) restricts this device to sale by or on the order of a licensed healthcare practitioner." /></td>
<td>CAUTION: Federal law (USA) restricts this device to sale by or on the order of a licensed healthcare practitioner.</td>
</tr>
<tr>
<td><img src="image" alt="Single use only" /></td>
<td>Single use only</td>
</tr>
<tr>
<td><img src="image" alt="Manufacturer" /></td>
<td>Manufacturer</td>
</tr>
<tr>
<td><img src="image" alt="Use-by date." /></td>
<td>Use-by date.</td>
</tr>
<tr>
<td><img src="image" alt="Do not expose to temperatures outside of these limits. For more information on environmental parameters refer to the Technical Specifications section." /></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>
</tbody>
</table>
### Technical Specifications

**ITEM** | **SPECIFICATION**
---|---
**PERFORMANCE CHARACTERISTICS**
ECG channels | 1 channel
Recording capacity | 48 hours
Recording format | Continuous
Service life | 48 hours
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

**PHYSICAL CHARACTERISTICS**
Approximate Dimensions | 178mm x 38mm x 14mm
Weight | <25g
Enclosure material | Medical grade thermoplastic polymer
Flammability rating | UL- HB

**ENVIROMENTAL 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 60601-1, 60601-1-2, 60601-1-11, 60601-2-47

### ELECTRODE CHARACTERISTICS

| **ITEM** | **SPECIFICATION** |
---|---
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.

**Emissions test** | **Compliance** | **Electromagnetic environment - guidance**
---|---|---
RF emissions CISPR 11 | Group 1 | 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.
RF emissions CISPR 11 | Group B | 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.
Harmonic emissions IEC 61000-3-2 | Not Applicable |
Voltage fluctuations/ flicker emissions IEC 61000-3-3 | Not Applicable |

### 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.

**IMMUNITY test** | **IEC 60601 test level** | **Compliance level** | **Electromagnetic environment - guidance**
---|---|---|---
Electrostatic discharge (ESD) IEC 61000-4-2 | ± 8 kV contact ± 15 kV air | ± 8 kV contact ± 15 kV air | 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 (50/60 Hz) magnetic field IEC 61000-4-8 | 30 A/m | 30 A/m | Power frequency magnetic fields should be that of a typical commercial or hospital environment.
Radiated RF IEC 61000-4-3 | 10 V/m 80 MHz to 2,7 GHz | 10 V/m 80 MHz to 2,7 GHz | Portable and mobile RF communications equipment should be used no closer than 30 cm to any part of the CAM.
Radiated RF Proximity Fields IEC 61000-4-3 (per IEC 60601-1-2 Ed. 4) | 9 V/m - 28 V/m per IEC 60601-1-2 Ed. 4, Table 9 | 9 V/m - 28 V/m per IEC 60601-1-2 Ed. 4, Table 9 | Interference may occur in the vicinity of equipment marked with the following symbol: [Symbol]