CAM™ Quick Reference Instructions

1 SKIN PREP

SHAVE
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 Carnation Ambulatory Monitor (CAM) will be placed.

CLEAN
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.

2 CAM PREP

NOTE: The activated 10 second LED blinking will only occur when the Recorder is connected to the Battrode. No additional blinking should occur while the CAM is being worn. Contact Customer Service if the LED continues to blink.

3 APPLY

CONNECT
On a flat, hard surface insert the narrow end of the Recorder into the Battrode first with the event button facing up, and then click the Recorder into place. A green LED light will blink for 10 seconds to confirm activation. Following the LED activation sequence, push down on the event button once to ensure the Recorder is clicked firmly in place. If the LED does not blink, contact Customer Service.

DOCUMENT
Record the time of CAM activation, which will be required to complete patient registration.

PEEL
Gently peel the liner from the CAM by grasping the tab at the top of the device and peeling downward, carefully avoiding contact with the adhesive.

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

Apply the CAM to the patient’s sternum with the bottom part sitting over the xiphoid process. Rub 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

**PRESS BUTTON**
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.

**REVIEW**
Give the patient the Patient Diary and CAM box and explain their use. Review all 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.

**IN THE BOX**
- Battrode™ (packaged inside CAM box)
- Recorder (packaged inside CAM box)
- Patient Diary and Quick Reference Instructions (inside CAM box)

The Carnation Ambulatory Monitor is a continuously recording ambulatory ECG monitor that records for up to the prescribed duration of wear time.

**Indications for Use**
The 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.

**CAUTION STATEMENTS**
- **CAUTION:** Proper skin prep required to achieve duration of prescribed wear time.
- **CAUTION:** Touching the adhesive can reduce adhesive performance. When peeling the liner from the back of the Battrode, hold onto the tabs at both ends.
- **CAUTION:** Inability to diagnose if patient and physician data is missing. The Patient Diary card must be kept with the CAM to ensure proper diagnosis.

4 RECORD SYMPTOMS

5 TRACKING

**LINK THE CAM ID NUMBER TO PATIENT**
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.

**REGISTER**
Register the patient as early as possible on the BDxCONNECT patient management portal.

**OPERATIONAL INSTRUCTIONS**
If the CAM becomes soiled, patient may gently wipe exterior of device, using a clean, dry cloth. If Battrode becomes loose or detached from skin, patient should press the adhesive portions of monitor back in place.

If you do not see the confirmation blinking LED upon initial connection of the Battrode and Recorder, contact Bardy Diagnostics Customer Service.

**TROUBLESHOOTING**
See Operational Instructions above OR Visit www.bardydx.com for more information.

**FAQS**
If you have questions regarding the Carnation Ambulatory Monitor, visit our website: www.bardydx.com

**CARNATION AMBULATORY MONITOR QUICK REFERENCE INSTRUCTIONS DWG000476A 06/2019**

- **EC REP**
  - MPS Medical Product Service GmbH
  - Borngasse 20
  - 35619 Braunfels
  - Germany

- **Contact us:**
  - Bardy Diagnostics, Inc.
    - 316 Occidental Ave S, Suite B310
    - Seattle, WA 98104
    - USA
    - US Customer Service: (844) 422-7393
    - EU Customer Service: +31 (0)46 7630422

- **ONLY By prescription only**

- **Ce0459**

**For assistance in setting up, using, and maintaining the CAM, or to report unexpected operations or events.**

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**PATIENT PREP**

**SHAVE**
The prepared area should extend 1 inch past where the CAM will be placed. Remove all hair over sternal area by shaving close to the skin. Do not merely clip hair.

**CLEAN**
Use the skin prep pads provided in the CAM box to clean area shown below. SCrub the skin with the prep pads until they appear clean after use. Skin should be scrubbed well enough to be slightly reddened. Ensure skin is dry prior to applying (1-2 minutes).

**APPLY**

**LOCATE XIPHOID**
Locate the bone at the bottom of the sternum. This is the xiphoid.

Apply the CAM to the patient’s sternum with the bottom part sitting over the xiphoid. Press firmly around the edges of the patch for 1 minute to ensure adhesion.

**RECORD SYMPTOMS**

**PRESS BUTTON**
Tell patients to gently press the button once when they feel symptoms and record the date/time in the included Patient Diary. Do not press button repeatedly or forcefully.

**TRACKING**

**LINK THE CAM IDENTIFICATION NUMBER TO PATIENT**
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 applied, patient initials, physician name and phone number.

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**CAM PREP**

**CONNECT**
Remove the Battrode™ and Recorder from their packaging. On a flat surface, snap the pieces together.

You should hear the confirmation buzz within 2-3 seconds. 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.

**PEEL**
Gently peel the liner from the CAM by grasping the tab at the top of the device and peeling downward, carefully avoiding contact with the adhesive.

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**Quick Reference Instructions**

Review complete Instructions for Use online at www.bardydx.com/CAMInstructions before using this product.
The Carnation Ambulatory Monitor is a continuously 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.

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

If Battrode becomes loose or detached from skin, patient should press the adhesive portions of monitor back in place.

If a high pitch tone continuously repeats, patient should remove the device and notify doctor.

**TROUBLESHOOTING**
See Operational Instructions above OR Visit www.bardydx.com for more information.

**FAQs**
If you have questions regarding the Carnation Ambulatory Monitor, visit our website:
www.bardydx.com

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**CAUTION STATEMENTS**

**CAUTION:** Proper skin prep required to achieve 48 hours wear.

**CAUTION:** Touching the adhesive can reduce adhesive performance. When peeling the liner from the back of the Battrode, hold onto the tabs at its ends.

**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.