



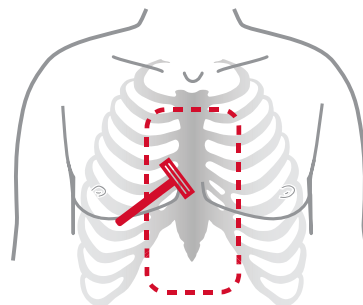
CAM™ Quick Reference Instructions

⚠ Review complete Instructions For Use online at www.bardyd.com/CAMinstructions before using this product.



Carnation
Ambulatory Monitor™

1 SKIN PREP



prep pads



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.

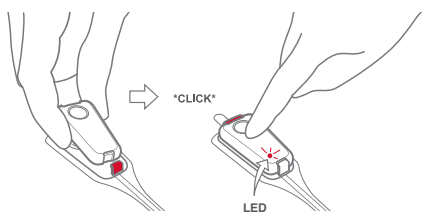
CLEAN

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.

Skin Prep

One

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.

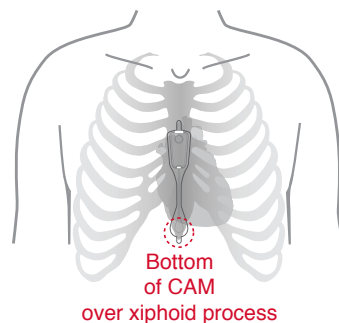
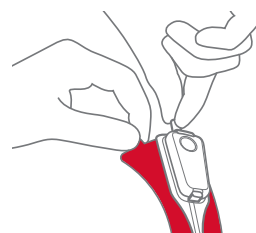
CONNECT

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.

3 APPLY



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.

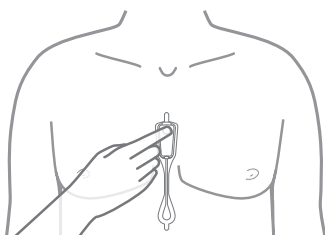
Apply the CAM to the patient's sternum with the bottom part sitting over the xiphoid process. Rub firmly around the edges of the patch for 1 minute to ensure adhesion. Place two fingers under the event button and press down firmly to adhere the top of the CAM to the patient's chest.

Apply

Three

CAM Prep

Two



RECORD SYMPTOMS	
Symptoms include:	
1) Palpitations	5) Shortness of Breath
2) Dizziness / Lightheadedness	6) Exercise-Related
3) Fainted	7) Other
4) Chest Discomfort / Pain	
Example	
Date/Time:	02 / 25 / 12 10:27 AM
Symptom:	2 Dizziness getting out of bed
Date/Time:	02 / 25 / 12 10:27 AM
Symptom:	1

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.



PATIENT HEALTH RECORD	
NAME:	DOB:
ADDRESS:	PHONE:
ALLERGIES:	PHYSICIAN:
ADDITIONAL INFORMATION:	

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.

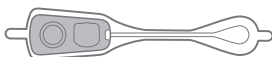
IMPORTANT: Fill in all information on the front page of the Patient Diary, including the patient name, date/time when the CAM is activated, physician name, and hospital/clinic.

REGISTER

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



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.

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

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



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35619 Braunfels
Germany

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.bardyd.com for more information.

R ONLY By prescription only

FAQS

If you have questions regarding the Carnation Ambulatory Monitor, visit our website:

www.bardyd.com

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