

PATIENT QUICK START GUIDE

Customer Service: (844) 77P-WAVE

Note: Please review this guide completely to ensure you understand all the steps and the order in which they must be performed. If you do not understand any steps, or may need assistance in applying, ask a friend or family member for help.

The Carnation Ambulatory Monitor

is a continuously recording P-wave centric™ ambulatory ECG patch monitor that records for up to the prescribed wear time.

Intended Use Population

The Carnation Ambulatory Monitor (CAM) is intended to be used by males and females not weighing less than 10 kg (22 lbs), who are suspected of having cardiac arrhythmia.

Indications for Use

The Carnation Ambulatory Monitor (CAM) is designed to provide extended duration cardiac monitoring for people who are suspected of having cardiac arrhythmias.

1 WATCH VIDEO

- ❑ **Important:** Prior to applying your Carnation Ambulatory Monitor (CAM) patch, please watch application video by visiting our website or scanning the QR code:

www.bardydex.com/patients



Need help?

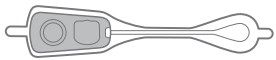
Visit our Frequently Asked Questions on our website or call our patient support hotline:

1-844-777-9283

2 OPEN BOX

- ❑ Lay out contents of box on a hard, flat surface.

If any item is missing from the box, contact the phone number listed above. Note that bar code stickers are included in the box but are not needed for at-home use.



CAM Patch
(packaged inside white pouch)



Recorder
(packaged inside silver pouch)



Patient Diary



(3) Alcohol Prep Pads



(1) Clear Sticker



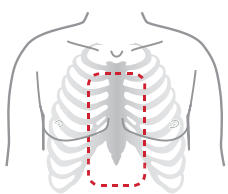
(1) Adhesive Removal Wipe

Supplies for application

Supplies for later

3 PREPARE SKIN

- ⚠ **CAUTION:** Proper skin prep required to achieve full length of prescribed monitoring duration.



- ❑ If you have any chest hair, use a razor to shave all hair in the center of your chest.

- ❑ Using all 3 prep pads, scrub the skin above your chest bone in the area outlined in the red box until pads appear clean after use. Your skin should be slightly reddened.

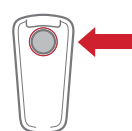
- ❑ Allow skin to dry at least **2 minutes** before applying your monitor.



- ❑ To confirm activation, look for a **green light** that will blink for 10 seconds (Note: Pay attention as this will only happen once).

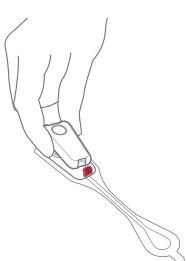


Note: If you do not see the green light, or it continues to blink, call 1-844-777-9283.



- ❑ Note date and time of activation.
- ❑ Press silver button down **once** firmly with your finger for 5 seconds.

4 PREPARE CAM PATCH

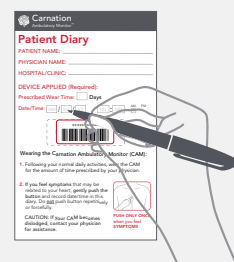


- ❑ Carefully remove CAM Patch from the white pouch and Recorder from the silver pouch without touching the gold colored metal pins. (Keep the box and white pouch to return the CAM Patch after you are finished.)

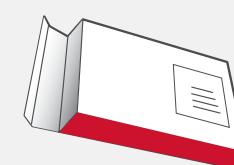


- ❑ **On a hard, flat surface**, firmly snap Recorder into CAM Patch narrow end first and arrow pointing down. The silver button should be facing up.

5 RECORD DATE & TIME



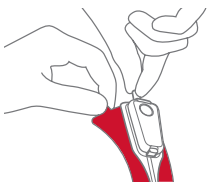
- ❑ **Important:** Record the Date and Time of activation in your Patient Diary.



- ❑ **Important:** Record the Date and Time of activation on the sticker located on the outside of the box.

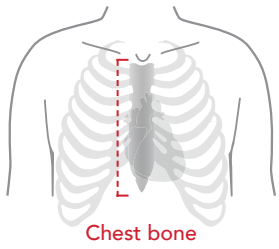
➔ MORE STEPS ON BACK

6 ATTACH CAM PATCH



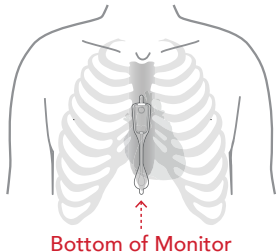
- Straighten your posture for application.
- Locate the bottom of your chest bone in between your rib cage.

Note: Recorder should be connected to CAM Patch **PRIOR** to peeling off plastic backing.



- Hold the top tab of the CAM Patch, and **slowly and carefully** peel off the clear plastic backing.

- Place the **bottom** of the CAM Patch on the bottom of your chest bone, with the Recorder pointed upward.



- Rub along the CAM Patch edges for **2 minutes** to confirm it has been firmly adhered to your chest.

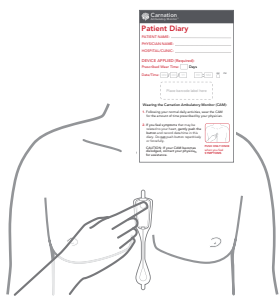
- Place two fingers under the silver button and gently press it against the chest for 15 seconds.

7 CALL 1-844-777-9283



- Please call us at 1-844-777-9283 to confirm receipt of your CAM Patch. Representatives are available to help if you have any questions about applying your CAM Patch.

8 RECORD SYMPTOMS



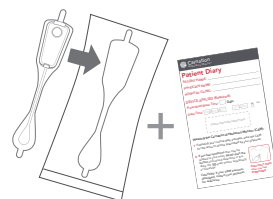
- In addition to the start date and time, fill in your name, prescribing clinician, and doctor's office on your diary.

- Gently press the silver button once if you feel symptoms, and document symptoms with **both** date and time in diary.

9 REVIEW INSTRUCTIONS

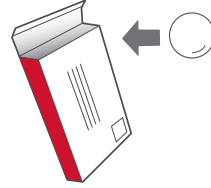
- Refrain from showering or engaging in heavy activity for at least 24 hours after application.
- When showering, do not stand with the water stream directly on the CAM Patch.
- Do not immerse in water such as a bathtub or swimming pool while wearing the monitor.
- Avoid saunas, steam rooms and extremely humid environments.
- If the CAM Patch loosens, press and rub the adhesive portions of the CAM Patch back in place. First-aid tape and band-aids may be used to secure the monitor.
- Avoid wearing necklaces that may hit the Recorder.
- If possible, refrain from wearing underwire bras. Sports bras and tank tops are recommended during wear.

10 REMOVE & RETURN



REMOVAL

- Remove by **pulling the tab** at the top of the CAM Patch and peeling downward. Stick entire CAM Patch on footprint of white pouch. Use the provided **Adhesive Remover Wipe Pad** to wipe away any adhesive remaining on your skin.



RETURN

- Place the CAM and Patient Diary back in box. Seal box with the Mailer Sticker and return as directed.

CAUTION: Proper skin prep required to achieve full length of prescribed monitoring duration.

CAUTION: If the Patient Diary does not contain all of the information requested as directed, the ECG report may not be prepared or may be delayed getting to your physician. The completed Patient Diary must be returned with the CAM and contain all requested information in order to prepare the ECG report for your physician.

CAUTION: Choking Hazard
Keep the CAM and the packaging away from unsupervised children.

CAUTION: Contains ECG Electrodes and the gel they require to record an ECG. If these Instructions for Use are not followed correctly, your skin could be damaged by the application and/or removal of the CAM. Apply the CAM to intact, clean skin only. Do not apply over hair or an open wound, lesion, infected or inflamed skin.

CAUTION: Damage to skin
Remove the CAM carefully to avoid damaging your skin.

CAUTION: Skin irritation
People with sensitive skin or with known skin conditions should use the CAM with caution. If irritation such as redness, severe itching or allergic symptoms (i.e. hives) develop, remove the CAM immediately and contact your physician.

CAUTION: Allergic skin reaction
Do not use the CAM if you have known skin allergies or family history of skin allergies. Contact your physician for guidance.

CAUTION: Single use only
The CAM is not intended for reuse by any individual or for use by multiple people. The CAM will become inoperable after its initial use. If multiple people apply or wear the CAM, the ECG report will be of no value.

CAUTION: Equipment damage
Use only as directed. Tampering with the components may render the CAM unusable. There are no user serviceable parts.

If seeing a physician while wearing the CAM, please provide the following Cautions to your health care provider:

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

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

CAUTION: Ineffective electronic imaging
The CAM 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 each of the Battrode and Recorder for damage before using. If any have been damaged in shipping, do not apply or use the CAM.

CAUTION: Electrical shock
The Battrode contains electrodes for recording ECG signals. Do not allow exposed electrodes on the Battrode to come in contact with any conductive parts/surfaces (including grounding to earth).

CAUTION: Battery may present environmental hazard
The Battrode contains a battery. Properly dispose of batteries in accordance with local regulations (if the CAM is not returned for analysis).

CAUTION: Electronic waste may present environmental hazard
The CAM is considered medical electrical equipment. Properly dispose of electronic waste in accordance with local regulations (if the CAM is not returned for analysis).

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 3.3 meters 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.