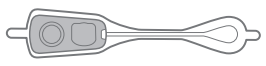
CAM® Instructions For Use

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

Carnation Ambulatory Monitor®

IN THE BOX



Battrode®
(packaged inside CAM box)

Recorder
(packaged inside CAM box)

Patient Diary and Quick Reference Instructions
(inside CAM box)

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.

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

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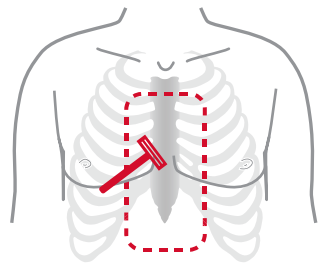
PREPARE THE SKIN

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



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.

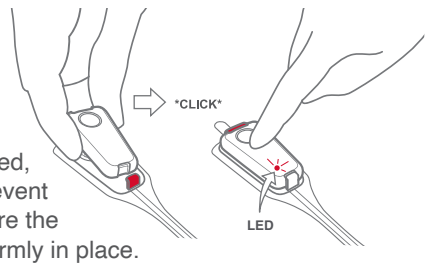
Step 2
Use all prep pads provided in the box to clean area shown. SCRUB the skin with the prep pads until they appear clean after use. Skin should be scrubbed well enough to be slightly reddened. Allow the skin to dry for 2 minutes prior to applying.

prep pads

PREPARE THE CAM

Step 3
On a flat, hard surface insert the narrow end of the Recorder into the Battrode first with the event button facing up, and then push the Recorder down firmly.

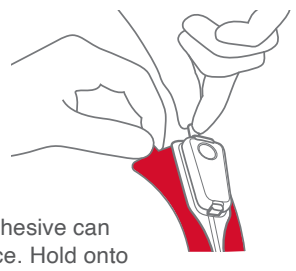
A green LED light will blink for 10 seconds to confirm activation. After the LED activation is confirmed, press down on the event button once to ensure the recorder is clicked firmly in place.



NOTE: *The LED light may take a few seconds to initiate. The LED blinking will only occur when the Recorder is first connected to the Battrode. No additional blinking should occur while the CAM is being worn. Contact Customer Service if the LED does not blink as described.*

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

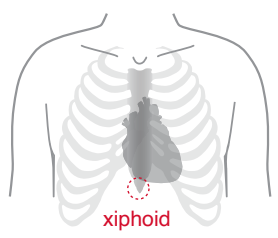
Step 5
Gently peel the liner from the CAM by grasping the tab at the top of the device and peeling downward, carefully avoiding contact with the adhesive.



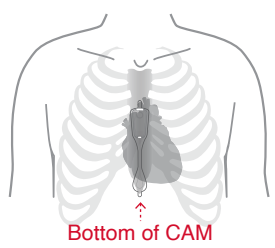
⚠ **CAUTION:** Touching the adhesive can reduce adhesive performance. Hold onto tabs at the end of the CAM.

APPLY THE CAM

Step 6
Locate the bone at the bottom of the sternum. This is the xiphoid process.



xiphoid process

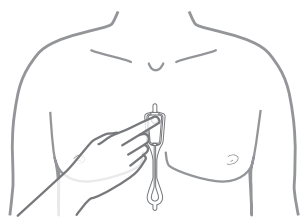


Bottom of CAM over xiphoid process

Apply the CAM to the patient's sternum with the bottom electrode of the patch sitting over the xiphoid process. Press along the entire edge of the patch for 2 minutes and rub firmly around the edges of the patch for 1 minute to ensure adhesion. Place two fingers below the event button and press down firmly to adhere the top of the CAM to the patient's chest.

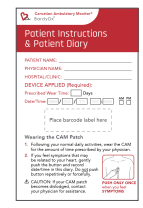
RECORD SYMPTOMS

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.



REVIEW

Step 8
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 exercising for 24 hours 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

⚠ **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.

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.

Step 10
Register the patient as early as possible on the BDxCONNECT patient management portal.

BDxCONNECT

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.

Remind the patient to return the monitor following the prescribed period of wear.

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.** 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 inflamed skin.

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

⚠ **CAUTION: Post-application activity**
Instruct patients to avoid showering, bathing, or exercising for 24 hours following application, and thereafter avoid activities or environments that result in excessive perspiration, as this may result in a decreased period of monitoring.

⚠ **CAUTION: CAM adhesive swelling**
It is normal for the CAM adhesive material to swell in humid environments or when exposed to moisture. Instruct patients to allow adhesive to dry following activities such as showering or exercise. If desired, patient can gently pat with a dry towel, but should not attempt to reposition the CAM.

⚠ **CAUTION: Submersion**
Submersion (such as during swimming or bathing) is not advised. Instruct patients to keep showers brief and the CAM out of the direct stream of water.

⚠ **CAUTION: Poor skin contact**
Poor contact of the CAM with the skin can negatively affect monitoring performance. Instruct patients to secure the CAM back in place if it becomes loose or detached.

⚠ **CAUTION: Skin irritation**
Patients 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, instruct patients to remove the CAM immediately and have them contact their physician.

⚠ **CAUTION: Allergic skin reaction**
Do not use the CAM on patients with known skin allergies or family history of skin allergies.

⚠ **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 CAM may render it unusable. There are no user serviceable parts.

⚠ **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 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: Equipment damage**
Use only with approved Bardy Diagnostics BDxStation.

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

⚠ **CAUTION: Electrical shock**
The CAM contains electrodes for monitoring ECG. Do not allow conductive parts of the electrodes on the CAM to come in contact with other conductive parts (including earth).

PROCESSING CAUTIONS

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 the monitor becomes non-functional after the first use.

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.

SYMBOLS

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

SYMBOL	DESCRIPTION
	Attention: Consult accompanying documents
	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 PARTS. 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.
℞ ONLY	Sold 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

SYMBOL	DESCRIPTION
131°F (55°C) 32°F (0°C)	Do not expose to temperatures outside of these limits. For more information on environmental parameters refer to the Technical Specifications section.
1060hPa 500hPa	Atmospheric pressure must be within these limits. For more information on environmental parameters refer to the Technical Specifications section.
95% 10%	Humidity must be within these limits. For more information on environmental parameters refer to the Technical Specifications section.
	Date of manufacture
	Contains electronic equipment. Dispose of properly in accordance with local regulations.
SN	Serial number
REF	Orderable part number
LOT	Batch code
MR	MR Unsafe
CE	CE Mark signifying conformity to EU regulations
EC REP	EU authorized representative

TECHNICAL SPECIFICATIONS

ITEM	SPECIFICATION
Performance Characteristics	
ECG channels	1 channel
Recording capacity	Up to 2, 7, or 14 days
Recording format	Continuous
Service life	Up to 2, 7, or 14 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

ITEM	SPECIFICATION
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
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)
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

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 60601-1, 60601-1-2, 60601-1-11, 60601-2-47

BardyDx®

We're close to your heart®

Instructions For Use

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

Carnation Ambulatory Monitor®

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

Bardy Diagnostics, Inc.®
220 120th Avenue NE, Ste 100
Bellevue, WA 98005
USA

US Customer Service:
(844) 422-7393

EC REP
Medical Product Service GmbH
Borngasse 20
35619 Braunfels
Germany

EU Customer Service:
+44 1625 668811

℞ ONLY By prescription only

Read all instructions before using this product

This device is provided non-sterile.

CE 0459

www.bardydx.com

DWG000781B 03/23

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.

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 Radiated RF Proximity Fields IEC 61000-4-3 (per IEC 60601-1-2 Ed.4)	10 V/m 80 MHz to 2,7 GHz 9 V/m - 28 V/m per IEC 60601-1-2 Ed.4, Table 9	10 V/m 80 MHz to 2,7 GHz 9 V/m - 28 V/m per IEC 60601-1-2 Ed.4, Table 9	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: