Clinical Summary
CAM vs. Holter Study

STUDY PURPOSE
To compare simultaneous recordings to determine diagnostic efficacy between an external patch system specifically designed to ensure better P-wave recordings and a standard Holter monitor.

STUDY METHODS
• Prospective comparison of a single-channel patch monitor and a standard 3-lead Holter monitor:
  – Carnation Ambulatory Monitor (CAM™) (Bardy Diagnostics, Inc.)
  – Standard DR180 Series 3-channel (leads V1, II, and V5) Holter monitor (NorthEast Monitoring, Inc.)
• 50 consecutive patients enrolled from a single center:
  – Both devices simultaneously applied and removed after 24 hours
  – Each patient served as their own control
• Holter and CAM reports were read in a blinded fashion by two electrophysiologists unaware of the findings in the other corresponding ECG recording
• All patients, technicians, and physicians completed a questionnaire on comfort, ease-of-use, and potential complications

OUTCOME MEASURES
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<th>Primary</th>
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| • Impact on Clinical Decision-Making When Comparing Rhythm Findings | • Patient Assessment
  - Device Preference
  - Comfort
  - Skin Irritation
  - Discreetness
  - Effect on Daily Activities
  - Effect on Sleeping
  • Clinician Assessment
  - Device Stability
  - Ease of Attachment |

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The single-channel CAM patch demonstrated to be comfortable, easy-to-use, and designed to reliably capture the P-wave. As a result of the superior ECG clarity, it resulted in significantly improved rhythm diagnoses and avoided inaccurate diagnoses made by the standard 3-lead Holter.


Indications for Use: The Carnation Ambulatory Monitor is designed to provide extended duration cardiac monitoring for people who are suspected of having cardiac arrhythmias. Please refer to the Instructions for Use for further information. © 2022 Bardy Diagnostics. All rights reserved. Bardy Diagnostics, Bardy Diagnostics logo, and Carnation Ambulatory Monitor (CAM) are trademarks of Bardy Diagnostics.

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