Beaty

Medical Feedback Technologies LTD

# TECHNICAL SPECIFICATIONS

## Indication For Use

BEATY is to be used during CPR in cases of cardiac arrest, allowing the rescuer to perform effective chest compressions as suggested in the current guidelines. BEATY gives an audible feedback when adequate force is applied on a patient's chest during CPR. The given feedback increases sense of capability among rescuers and chances of survival among victims, due to effective CPR.
The device can be used by any person familiar with CPR.

BEATY is not to be used in the following cases:
Children- BEATY is to be used only on victims 8 years of age and above
If there is no indication for chest compressions or chest compressions are unlikely to help the patient

## Device Specification

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|---|---|
| Power Requirements | Rated input voltage: 3v lithium coin battery |
| Dimensions | Height: 50mm, 1.96"<br>Width: 50mm, 1.96"<br>Depth: 24mm, 0.94" |
| Package Size | 95mmx120mmx30mm, 3.74"x4.72"x1.18" |
| Weight | Total device weight: 34g |
| Operating enviroment | Ambient temperatures: Between 32° and 102.2° F (0°and 39° C) and in normal conditions<br>Relative Humidity: 10% to 90% RH<br>Atmospheric Pressure: (Up to 2000m above sea level (700hpa) |
| Ingress protection | IP22: Resistant to solid objects greater than 12.5mm such as finger and vertically falling drops over an actuator tilted 15° |

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## Device Specification

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|---|---|
| Applied parts | Type BF: Electrically connected to Patient but not directly to heart |
| FDA | Class 2 (PMJ) |
| CE | Class 1<br>MHRA Reference Number: CA016844 |

## Compliance with international standards

CE-labelled device; complies with all appropriate performance standards as specified in Annex II of the European Medical Device Directive MDD 93/42/EEC.

BEATY is classified as class I medical device per the MDD. It classified as Class I by the International Standard IEC 60601-1 and as Class II Medical device by the Department of Health and Human Services of The Food and Drug Administration. (21CFR8750.5210)

The device is designed to comply with current revisions of the following international standards:

- IEC 606011:2005 (Third Edition) + CORR. 1:2006 + CORR. 2:2007 + A1:2012 or IEC 60601-1: 2012 reprint): General requirements for Basic Safety and) Essential Performance.
- IEC 606011-2 (4th edition); sections 7 & 8
  - Sec. 7.1 & CISPR 11: radiated emission
  - IEC 61000-4-2: Immunity from electrostatic discharge (ESD)
  - IEC 61000-4-3: Immunity from electromagnetic fields
- IEC 60601-1-6: Medical Electrical Equipment – Part 1-6: General Requirements for Basic Safety and Essential Performance – Collateral Standard: Usability.
- IEC 62366-1 Medical devices – application of usability engineering to medical devices
- RoHS: Restriction of Hazardous Substances DIRECTIVE 2011/65/EU.
- WEEE: Waste Electrical and Electronic Equipment Directive.