



English



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CPR Feedback Device

User Manual

Manufactured by Medical Feedback Technologies Ltd.

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Important user information

BEATY is a medical device developed by Medical Feedback Technologies LTD. and is used during real time CPR. BEATY gives an audio feedback regarding the effectiveness of chest compressions performed during CPR, allowing adjustments to the recommended compression depth (for more info. See page 4; section 1.1)

Before using BEATY, users must read and fully understand all information and instructions provided with the device. In case of any questions please contact our team.

It is strongly recommended that BEATY will be used by a person familiar with basic CPR principles. (visit our website www.imbeaty.com)

Users must follow local guidelines for CPR when using BEATY. In case of technical issues that are not solved despite implementation of recommended actions in page 15; section 5, continue CPR without using the device.

Using the device in any way other than described in the user manual provided with the device or in conjunction with other external devices may reduce the reliability of the audible feedback thus the effectiveness of chest compressions.

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1. Introduction

1.1 Background

Sudden Cardiac Arrest (SCA) refers to the sudden cessation of cardiac mechanical activity with hemodynamic collapse. 88% of SCA cases occur at home and survival rates are less than 10% but can be doubled or even tripled if Cardio-Pulmonary Resuscitation (CPR) is initiated immediately by a bystander or EMS.

Worldwide efforts are invested in educating the general population regarding the importance of CPR. The current American Heart Association guidelines, which are based on extensive evidence published by the International Liaison Committee on Resuscitation (ILCOR), emphasize the importance of rapid identification of cardiac arrest and initiation of high quality chest compressions. A rate of 100-120 compressions per minute and a depth of 5-6cm are suggested. The main goal of effective chest compressions is restoration of blood flow to the brain thus prevention of permanent damage. For untrained bystanders, "Hands only" CPR algorithm was developed based on similar survival rates with either "Hands only" CPR or CPR with both chest compressions and mouth to mouth ventilation.

Assessment of CPR quality and adherence to the CPR guidelines was the objective of many studies and high frequency of inadequate compressions depth compared to guidelines has been reported. The evaluation of the exact depth (5-6cm) is challenging, even for a trained rescuer.

BEATY is a feedback device that provides audible feedback regarding the effectiveness of chest compressions during CPR. With every chest compression, BEATY will tell its user whether the performance is effective or not. The real-time given feedback will increase sense of capability among users and the effectiveness of chest compressions.

Since most crises happen to people close to us, BEATY was designed to fit anywhere within reach. It can be stored in first aid kits, glove compartment or can even be used as a key chain. It's extremely easy for use and very affordable.

We believe in simplicity. We believe in accessibility.

We believe in saving lives.

1.2 Intended use

BEATY is to be used during CPR in cases of cardiac arrest, allowing the user to perform effective chest compressions as suggested in the current AHA guidelines. BEATY is placed between rescuer's palm and victim's chest while performing chest compressions. BEATY gives an audible feedback with each adequate chest compression, reaching a depth of 5 cm, thus increasing victim's chances of survival as well as the user's sense of capability.

1.3 Contraindications

BEATY is not to be used in the following cases:

- Children- BEATY is to be used only on victims 8 years old and above
- If there is no indication for chest compressions or chest compressions are unlikely to help the victim

1.4 Adverse effects

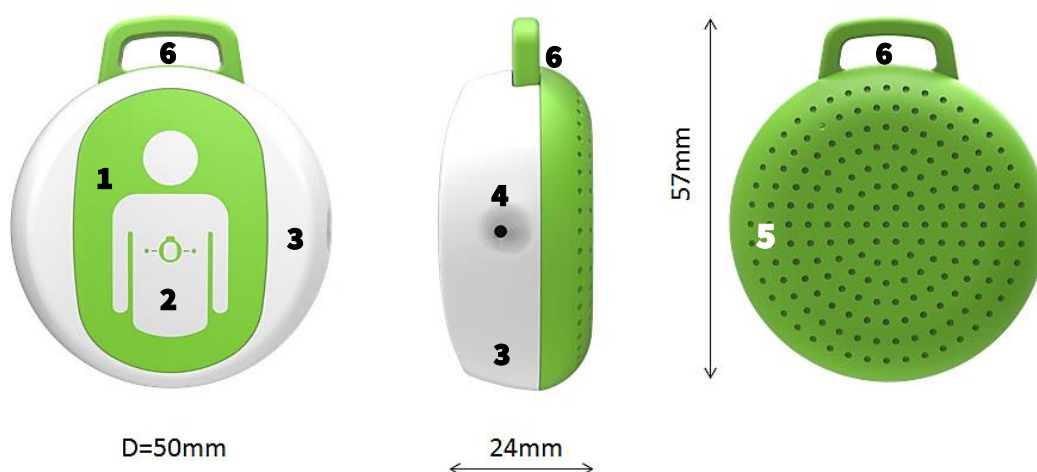
Various rates of skeletal and non-skeletal injuries due to effective chest compressions were reported in several studies. Nevertheless, it has been concluded that the injuries were in by and large non-fatal. It is important to remember that deeper compressions increase survival and that potential injuries are an acceptable alternative for death due to cardiac arrest. **NOTE!** BEATY is not the resuscitator. It is only there to give an audio feedback during real time CPR that is performed according to guidelines.

1.5 BEATY description

Restoring effective blood flow to the brain is achieved by compressing the victim's chest to a depth of 5 cm. BEATY provides audible feedback regarding the correct depth. BEATY was designed to fit anywhere within reach in cases of medical emergencies. BEATY can be stored easily in first aid kits, glove compartments or may be used as a key chain.

The device has no software.

External View



1. Upper concave soft pad (*TPU- ELASTOLLAN Soft 45A ESD*) designed to fit perfectly to your palm
2. Schematic drawing describing correct placement of BEATY
3. Hard lid made of high-quality materials (*MACROLON 2407 POLYCARBONATE*) capable of enduring high forces applied on the device when performing chest compressions
4. Sound output
5. Lower soft pad (*TPU- ELASTOLLAN Soft 45A ESD*) that comes in contact with victim's chest
6. Keychain hole made for easy attachment of the device allowing it to be within reach in case of medical crises

Internal View

1. PCB containing BEATY'S electrical components
2. 3V lithium battery
3. Buzzer
4. Sensor

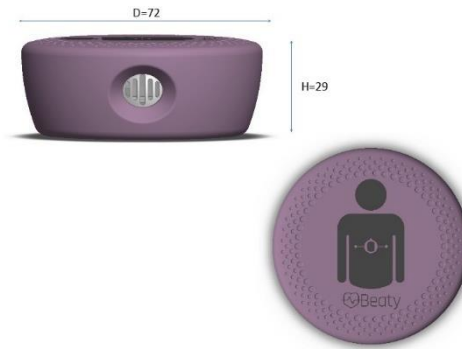


Silicone adapter

A silicone adapter is provided with each product.

The silicone adapter adds protection to your device. In addition, due to a larger surface area (7.2cm diameter) it increases user's comfort when prolonged CPR is required (rural areas, medical teams etc.).

NOTE! The silicone adapter is not mandatory for the proper utilization of BEATY and does not increase its effectiveness. The adapter can be used at user's choice and preference.



Using the silicone adapter

When opening the package, you should find BEATY correctly inserted into the silicone adapter- BEATY's bottom part (silicon cushion with embedded symbols) is seen on the open part of the silicon adapter. This is the component that comes in direct contact with patient's chest (See fig. 1 next page).

You can use BEATY with or without the adapter.

Extracting BEATY from the silicone adapter-

1. Hold the silicon adapter using both hands with upper part facing up.
2. Apply pressure on the middle of the silicon adapter, using both thumbs. The device should easily come out from the other side (See fig. 2 next page).
3. Use the device according to instructions (Page 10; Section 2)

Inserting BEATY into the silicone adapter-

1. Hold the silicon adapter with hollow part facing up.
2. Align BEATY according to the silicon adapter using buzzer output and keychain holes as reference points (See arrows in fig. 1 next page). **NOTE** that BEATY's bottom part (silicon cushion with embedded symbols) should also face upwards.
3. Use the device in the same often as when using it without the silicone adapter.

*fig. 3 next page describes correct and incorrect BEATY position within the silicone adapter.

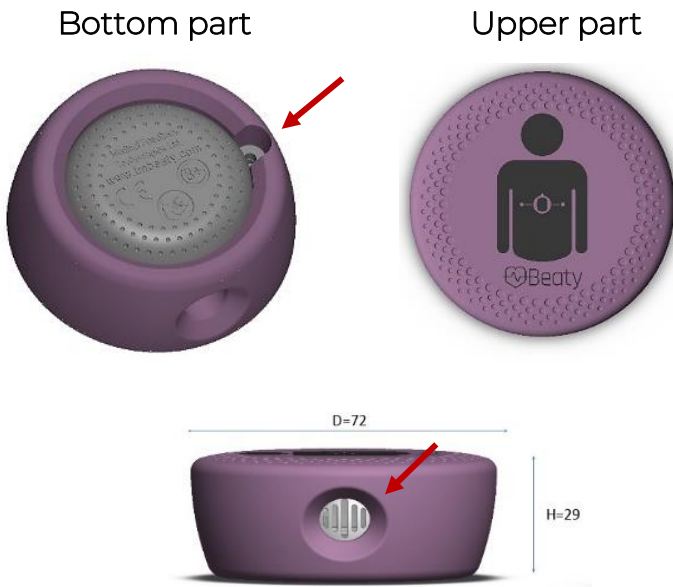


Figure 1

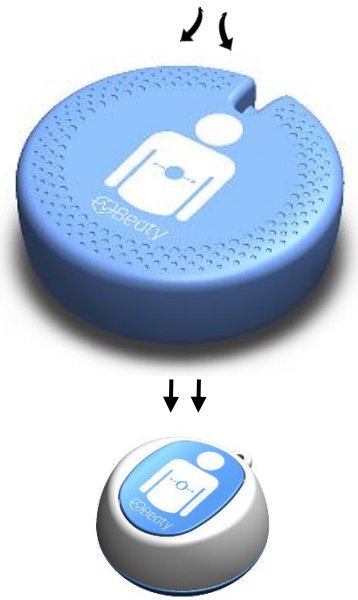











Figure 2



Figure 3

1.6 Symbols on the device

 CE Compliant	 Restriction of Hazardous Substances Directive Compliant (materials and components)	 Waste Electrical and Electronic Equipment Directive Compliant	 Refer to User Instruction Guide	 Handle with care
 Manufacturer	 Manufacturing date	 Type BF applied part	 Ingress property- Degree of protection provided by enclosure per IEC 60529	

1.7 Delivered items

Each delivered product contains the following items:

1. BEATY device in your preferred color
2. Silicon Adapter
3. 3V lithium battery installed within the device
4. User manual



2. Using Beaty

The use of BEATY is subject to the routine indications and guidelines for CPR. BEATY is there to give you an audible feedback regarding the effectiveness of routinely performed chest compressions.

2.1 Approaching the Victim

- Secure your area- move the victim and yourself away from hazardous factors (i.e. - road, electricity etc.)
- Confirm cardiac arrest- check for consciousness and breathing
- Call for help

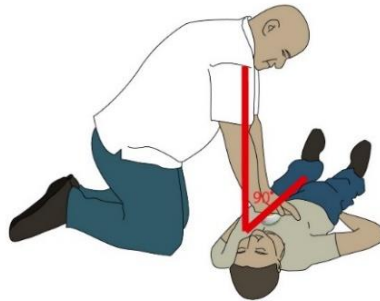
2.2 If CPR is indicated

Start chest compressions according to CPR guidelines

- Place BEATY in the middle of the victim's chest as shown in the sketch on top of the device. It is recommended not to use the device above clothes.

- Place your palms above the device. The base of your palms should fit perfectly to a concave soft pad on top of the device.
- Start compressing- with each effective chest compression, BEATY will produce a sound. If no sound is heard follow instructions in section 6. Principles for effective chest compressions:
 - Perpendicular alignment to the victim
 - Locked elbows
 - Chest compressions rate should be 120/min.
 - Full chest recoil- after BEATY produces a sound, it is crucial to allow full chest recoil before next compression

*If AED (Automatic External Defibrillator) is within reach use it according to instructions.



3. After use care/maintenance

The device is categorized as ingress/international IP22 according to IEC 60529

3.1 Cleaning

Use alcohol pad or wet wipe to clean the device. When cleaning, focus on the lower soft pad that comes in contact with Victim's chest. Do not immerse in water or disinfectant solution as liquids of any type can damage the internal mechanism of the device.



3.2 Change of battery

When changing battery, only UL approved batteries are allowed (list of UL approved batteries is described below)

1. Remove upper soft pad
2. Unscrew upper screw
3. Open the device using rotation movement
4. Change battery



List of possible UL approved 3v lithium coin cell batteries*

GP CR2032
Energizer CR2032
Panasonic CR2032
Sony CR2032

*The list provided above is **NOT** a full list of UL approved batteries. The list contains only several options. For UL verification for your battery, visit:

http://database.ul.com/cgibin/XYV/template/LISEXT/1FRAME/index.html?utm_source=button&utm_medium=ulcom&utm_campaign=ulwebsite_oed_referral

3.3 Routine checks

It is recommended to check the device by pressing the device against any stationary object and producing a sound. Battery life time is 3 years in standby mode or 15 hours of use. We recommend changing the device every 5 years.



3.4 Storage

Avoid exposing the device to excessive moist or dirt.



4. Warnings and precautions

4.1 General safety precautions

CAUTION- APPROVED ACCESSORIES

Use only UL approved batteries. If you use other batteries, you can cause permanent damage to Beaty. This also voids the warranty,

CAUTION- LIQUIDS

Do not immerse Beaty in liquids as direct liquids can damage the device

4.2 Operation warnings and precautions

CAUTION- ROUTINE CHECKS AND AFTER USE CARE

It is important to follow instructions regarding routine checks and after use care (provided within this user manual).

WARNING - INCORRECT POSITION OVER CHEST

If Beaty is not in the correct position in relation to the sternum, there is a possibility that it does not function properly. Place the device in the middle of victim's chest as shown on the sketch on top of the device.

WARNING - UNSATISFACTORY OPERATION

If the use of Beaty delays or interrupts with effective CPR. Continue CPR without the device.

WARNING - SOUND

If no sound is heard despite taking actions as recommended in troubleshooting section, continue CPR without the device.

WARNING- EXTERNAL DAMAGE

If external damage is seen, do not use Beaty as it can result in user and victim injury as well as malfunction of the device.

WARNING- DO NOT OPEN THE DEVICE IF UNESSECERY

Open the device only for battery replacement. You should follow the exact instructions provided within this user manual. Do not touch any other electrical component as it can damage the device.

5. Troubleshooting

Users must be familiar with the possible technical problems and their solution. For any questions please contact our team.

Arising problem	Possible cause	Solution	Prevention
No sound is heard before use/ sound is not loud enough	-Not enough pressure applied -Battery ran out -Audio inlet is covered by user's palm -Broken device	<ol style="list-style-type: none">1. Make sure audio inlet is not covered by hand2. Make sure compressing perpendicularly to victim's chest3. Push deeper by applying more pressure4. Change battery as instructed in page 12; section 3.25. Contact our customer service	<ol style="list-style-type: none">1. Check routinely for propriety (see page 12; section 3.3)2. Follow 'after use care' instructions (page 11; section 3)

<p>No sound is heard during CPR use/ sound is not loud enough</p>	<ul style="list-style-type: none"> -Loud environment -Not enough pressure applied -Battery ran out -Audio inlet is covered -Broken device 	<ol style="list-style-type: none"> 1. Make sure audio inlet is not covered by hand 2. Make sure compressing perpendicularly to victim's chest 3. Push deeper by applying more pressure 4. Change battery as instructed in page 12; section 3.2 5. Contact our customer service 6. If no solution found – remove BEATY and start compressing without the device 	<ol style="list-style-type: none"> 1. Check routinely for propriety (see page 12; section 3.3) 2. Follow 'after use care' instructions (page 11; section 3)
<p>Continuous sound during CPR</p>	<p>Improper chest recoil</p>	<ol style="list-style-type: none"> 1. With each sound produced by the device. Allow victim's chest to fully recoil 2. As chest is fully recoiled, repeat chest compression 3. Note that rate should be 100-120/min 	

<p>External damage to the device</p>	<p>-Improper storage -Dropping the device</p>	<p>If damage prevents compressing effectively d/t user discomfort or in case no sound is heard despite actions in section 2 in this table- continue CPR w/o using BEATY</p>	<ol style="list-style-type: none"> 1. Check routinely for propriety (see page 12; section 3.3) 2. Follow storage and after 'use care' instructions (page 11; section 3)
<p>Discomfort in user's palm</p>	<p>Improper location of palm over the device</p>	<ol style="list-style-type: none"> 1. Change palms position over the device. BEATY has an upper concave soft pad that should fit the base of your palms. NOTE! Do not change position of the device regarding victim's chest 2. If discomfort prevents effective chest compressions. Continue CPR w/o BEATY 	

6. Technical specifications

Item	Specification	Technical Data
Power Requirements	Rated input voltage	3V lithium coin battery
Dimensions	Width*length*height(cm)	5*5*2.4(cm)
Weight	Total device weight (battery included)	34g
Operating environment	Ambient temperatures	Between 32° and 102.2° F (0° and 39° C) and in normal conditions
	Relative Humidity	10% to 90% RH
	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°

7. Electromagnetic Compatibility

Test	Standard	Class/Severity level	Test result
Emission (IEC 60601-1-2 section 7)			
Radiated emission Freq. range: 30-1000 MHz	Sec. 7.1 & CISPR 11	Group 1 Class B	Complies
Immunity (IEC 60601-1-2 section 8)			
Immunity from Electrostatic discharge (ESD)	IES 61000-4-2	8 kV contact discharges & 15 kV air discharges	Complies
Immunity from radiated electromagnetic fields	IES 61000-4-3	10.0 V/m 80 MHz ÷ 2.5 GHz, 80% AM, 1kHz	Complies

8. FAQ

Q: When should I start performing CPR?

A: If victim is unconscious (does not respond to shaking or calling his name), look for breathing or only gasps. If not breathing, call for help and start compressing his chest to a depth of 5cm. Beaty will help you perform effective chest compressions.

Q: What does CPR do?

A: When the heart stops from beating, blood flow to the brain and vital organs ceases. Within 4 minutes the damage to the brain is irreversible. Effective CPR allows blood flow to the brain, preventing permanent damage. CPR can triple chances of survival.

Q: When should I use Beaty?

A: Beaty should be used in every case where CPR is indicated. As gauging the exact compression depth is almost impossible, Beaty will help you by providing real-time audible feedback when applying adequate force during chest compressions.

Q: Do I have to be well trained before using Beaty?

A: Beaty was designed to be very intuitive so any individual is able to use it in case of a medical emergency. A sketch upon the device will guide you where to place it. After locating the device between your palms and victim's chest- start compressing until audio feedback is achieved. The sound provided by the device indicates you are compressing effectively.

Q: What about ventilation? Is it unnecessary?

A: Based on extensive research, the current CPR guidelines put an emphasis on effective chest compressions. If you are trained and feel safe with ventilating the victim, combining chest compressions and ventilation is recommended at a rate of 30 compressions followed by 2 rescue breaths. For untrained rescuers or in case you don't feel safe or comfortable with ventilating the victim - chest compression only CPR is recommended (based on similar survival rates with either "Hands only" CPR or CPR with both chest compressions and mouth to mouth ventilation)

Q: What is the recommended compression rate?

A: The recommended compression rate is 100-120/min. This can be estimated by following the rhythm of the song *"Stayin' alive/Bee Gees"*.

It is important to pay attention that pushing fast does not result in shallower depth.

Q: How about other parameters not provided by the device (rate, chest recoil etc.)?

A: Effective CPR is composed from several parameters and not only compression depth. It is important to understand though, that medical emergencies are very stressful (especially when it comes to our loved ones). Too much information provided by a feedback device, during real time CPR can confuse lay rescuers and result in ineffective CPR. The major gap nowadays is in estimating compression depth (rate can be estimated by using other means) and many studies show suboptimal compression depth, even among professionals.

Beaty provides an effective, simple and affordable solution and was confirmed in experiments for effectiveness and

usability that were conducted by our team of doctors and engineers.

Q: Does the use of Beaty replace an AED?

A: NO! An AED is always recommended as part of CPR and is necessary in case of cardiac arrest due to an arrhythmia. Beaty should be used alongside the use of an AED- chest compressions should be performed before and after the use of the AED, regardless of its action (shock advice).

It should be noted that recent studies showed better survival rates following cardiac arrest due to arrhythmia, when effective chest compressions were performed before and after defibrillation.

Q: Can Beaty be used on children?

A: Beaty is designed to be used on victims 8 years old and above.

Q: What if during CPR, ribs are fractured?

A: It is important to understand that deeper compressions increase survival rate. During effective CPR, skeletal injuries may happen but none of them are fatal. Rib fractures are an acceptable alternative for death due to cardiac arrest.

As mentioned, Beaty is set to provide feedback in line with the recommended CPR guidelines.

Q: What if no sound is heard when using Beaty?

A: If no sound is heard, this can be due to several reasons (for more information follow instructions provided in page 15; section5). If using Beaty delays or interrupts with effective CPR- continue CPR without the device. We make significant efforts to provide the best product and encourage users to inform us of any malfunction or inconvenience caused by the use of the device.

Q: Can Beaty be used for training?

A: Beaty Is designed for real-time CPR on a real person. As some manikins differ from human skeletal structure as well as chest recoil, Beaty may not work properly on these manikins. A 'Demonstration Only' sample, calibrated to a desired manikin can be provided. Contact our team for more information (info@imbeaty.com)