

# Spektikor™ - disposable ECG-indicator

## USER MANUAL DHBI-1™ and DHBI-2™ Rev 3.0 23.03.2015

### Manufacturer

Spektikor Oy  
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CE 0598

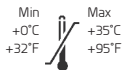
The product is classified as a medical device in compliance with directives 2002/96/EC (WEEE), 93/42/EEC and 2002/95/EC (ROHS).

### Usage Time and Temperature

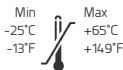
- DHBI-1 over 20 hours -35 - +50 °C (-31 - +122 °F).
- DHBI-2 over 6 hours -35 - +50 °C (-31 - +122 °F).

### Storage

- Long term storage: 4 years between +0 - +35 °C (+32 - +95 °F).
- Short term storage: 2 weeks between -25 - +65 °C (-13 - +149 °F).



Long term storage



Short term storage



Not for children  
weight less than 10 kg.



Read instructions  
before use

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Patents and patents pending FI 20106249,  
EP11190444.7 and 13/303,744-USA NATO CAGE  
Code A653G, NATO Stock Numbers 6515-58-000-  
6107, -7434, -7435, -7436, -7437 and -7438

Spektikor DHBI-1™ and DHBI-2™ are trademarks  
of Spektikor Oy.

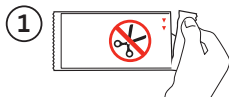
Spektikor™ is the tool for professionals to easily monitor and detect changes to a patient's heart rate. Spektikor™ is adhered to the patient like regular ECG-electrode with the adhesive located in the base of the device. The LED unit can be detached and moved to a spot in good view. The device indicates the ECG curve by flashing the light whenever it recognizes the R-peak. A blue LED indicates that the heart rate is over 40 but below 120 beats per minute. In case the heart rate is not within the set limits, this is indicated with red LED.

### Warning!



- Do not use the device in conjunction with a defibrillator or within the vicinity of MRI equipment.
- Too much body hair may disrupt electrode operation.
- Do not use any wireless communication devices in proximity of the device.
- A strong electric or magnetic field may cause false heart beat indication.
- May cause mild skin irritation to those with a sensitive skin.
- Modification of the device is strictly forbidden.
- Patient movements may cause false heart beat indication.
- Fast or irregular heart beats may cause temporary red heart beat indication turning into blue. Blue heart beat indication may take several seconds.
- Tall T-wave may cause erroneous heart beat indication.

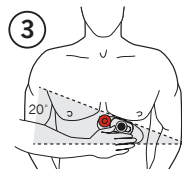
## Using the Device



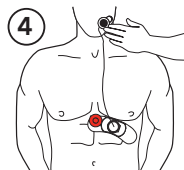
**Picture 1** Open the package by tearing.



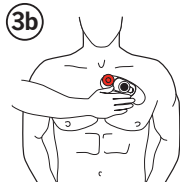
**Picture 2** Remove the sticker's protective film from the base of the device.



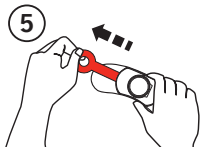
**Picture 3** Adhere the device to the patient with the sticker. The recommended installation location is the patient's left side of the chest between the pectoral muscle and the costal arch at a 20 degree angle.



**Picture 3b** Alternative installation location



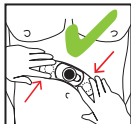
**Picture 4** Move the detachable LED unit to a place in clear view such as the patient's face, the edge of the stretcher or above the patient's clothing. Leave some slack in the unit's cable and ensure that the cable does not rub against a zipper for instance.



**Picture 5** Remove activation sheet. After removal, the blue LED of the LED unit should remain lit for 5 seconds. In a model DHBI-2™ the numeric display shows "----". Check whether the LED unit's light indication functions correctly – 10 seconds after activation a red or a blue light should blink on every heart beat.

If after activation the device does not detect the patient's heart beat, check the heart beat by removing the device and installing it again at the left side of the chest between the collarbone and the pectoral muscle as in picture 3b. In these cases patient's heart beat should be checked with alternative means.

The device may be faulty if the lights do not turn on or they turn on in the other order. Discard the faulty device and use one that functions correctly.



**Warning!** When you are installing the device, avoid pressing directly on the top of the electrodes. When the hydrogel in the electrode pad is pressed it can suffuse the sticker area and remove the sticker from the skin. The product will adhere well when you press the sticker from the side of the electrodes.

**Note!** The device may temporarily be removed and re-adhered to allow patient treatment.




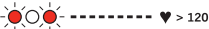


**Note!** The device turns off automatically after it has been detached for more than 10 minutes. Product can be reattached within two hours.

## Heart Beat Indication

Upon activation of the device first the blue LED remains lit for 5 seconds followed by continuously lit red LEDs. When after installation the heart beat is detected, a blue LED or two red LEDs (DHBI-1™) or one red LED (DHBI-2™) blink on every heart beat. In case no heart beat is detected the red LEDs remain continuously lit.







In case the batteries are running low or when the device detects a technical failure, the blue and red LEDs blink simultaneously with one second intervals.

### DHBI-1™

	The device is ready for use.
	The heart rate is within the normal range.
	Slow heart rate..
	Fast heart rate.
	No heart beat detected.
	Battery empty or technical failure.

DHBI-2™ contains the three-digit numeric heart rate display: a blue LED and a red one. During operation the display shows the current heart rate value: beats per minute (bpm). If the device does not detect a heart rate this is indicated by three lines ("---"). If the battery alarm is activated the screen lights up the code "-E-".

### DHBI-2™

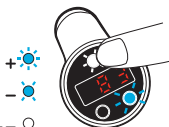
	The device is ready for use.
	The heart rate is within the normal range.
	Slow heart rate.
	Fast heart rate.
	No heart beat detected.
	Battery empty or technical failure.

## Use in low/dark light



### DHBI-1™

DHBI-1™/2013 includes a button that can help you regulate the brightness level of the heart rate indication. The first press will dim the indication light. Normal brightness will return if you press it again.



### DHBI-2™ -- ○






DHBI-2™ includes a button that can help you regulate the brightness level of the heart rate indication. The indication light and screen will dim if you use the dimmer button. The first press will dim the indication light and the heart rate display. The second press will dim the indication light completely while the heart rate display will stay in the dim mode. The display and its normal brightness will return if you press it again.

## End of Use

After removing the device from the patient, the red LEDs remain lit for 10 minutes and then switch off automatically.

After use normally dispose of the product as electrical and electronic waste. Devices contaminated by blood or other secretions have to be disposed of as biologically contaminated electrical or electronic hazardous waste.

## Symbols

	Individually packaged.
	The device is for single use only.
	Protected against spraying water.
	For waste disposal the device is classified as an electronic device according to WEEE directive 2002/96/E4.
	BF Type applied part.

## Technical Specifications

### Key Features

- Disposable.
- Activates when the activation sheet is removed.
- Adjustable LED brightness.
- Visualizes the patient's heart beat with a light.
- Long usage time.

### Technology

- Single use.
- ECG-based heart rate measurement.
- Measurement range of 20-300 BPM.
- Heart rate measurement accuracy  $\pm 2$  BPM.
- Three ECG-electrodes (AgCl) on the electrode membrane.
- Integrated heart rate measuring electronics.
- LED-unit's cable length 45 cm.
- Packaged hermetically.
- Battery-powered.