

ENGLISH



Spektikor – disposable ECG-indicator

USER MANUAL

1.4 - 2013

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The Spektikor disposable ECG-indicator has been developed for use by first aid and medical staff to speed up the follow-up in emergency situations.



**MULTI-PATIENT
SITUATIONS**



NOISY ENVIRONMENTS



EMERGENCIES



TRANSPORT

Patents pending FI 20106249, EP11190444.7 and 13/303,744-USA

General

Manufacturer

Spektikor Oy
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CE 0537

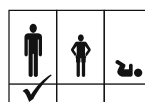
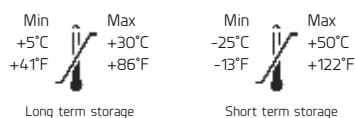
The product is classified as a medical device in compliance with directives 2002/96/EC (WEEE), 93/42/EEC and 2002/95/EC (ROHS).

Usage Time

- 10 hours.

Storage

- Long term storage: 2 years between +5 – +30 °C (+41 – +86 °F).
- Short term storage: 1 week between -25 – +50 °C (-13 – +122 °F).



Read instructions
before use

For use on adults
only (above 10kg).

Warning!

Do not use the device in conjunction with a de-fibrillator or within the vicinity of MRI equipment.

Too much body hair may disrupt electrode operation.

Do not use a cell phone in proximity of the device.

A strong electric field may cause false heart beat indication.

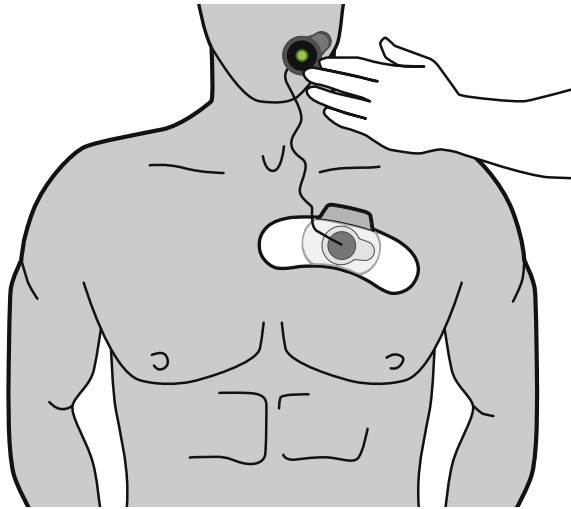
May cause mild skin irritation to those with a sensitive skin.

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 green. Green heart beat indication may take several seconds.

Instructions

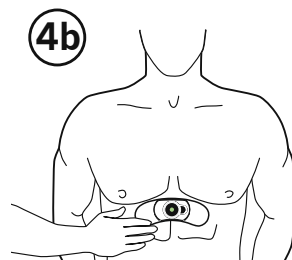


Spektikor - disposable ECG-indicator DHBI-1

Spektikor is the tool for professionals to easily monitor and detect changes to a patient's heart rate. Spektikor is adhered to the patient's chest like regular ECG-electrodes with the sticker 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 green 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 two red LEDs.

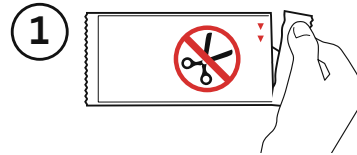
Note! The device may temporarily be removed and re-adhered to allow patient treatment.

Note! The device turns off automatically after it has been detached for more than 10 minutes.

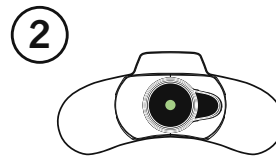


Picture 4b Alternate installation location.

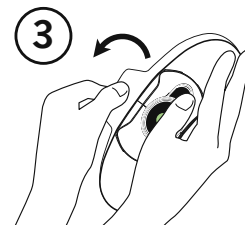
Using the Device



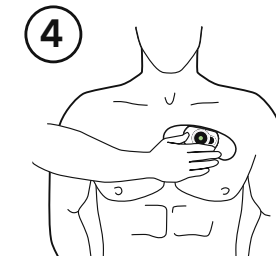
Picture 1 Open the package by tearing.



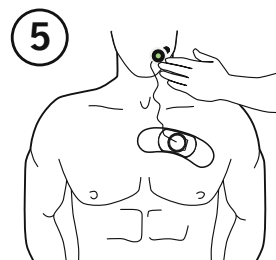
Picture 2 After removal of the packaging, the green LED of the top unit should remain lit for 5 seconds. Wait until the red LEDs are also lit before removing the protective film. The device is faulty if only one color is visible or if the lights do not turn on in the specified order. Discard the faulty device and use one that functions correctly.



Picture 3 Remove the sticker's protective film from the base of the device.



Picture 4 Adhere the device to the patient's chest with the sticker. The recommended installation location is the patient's left side of the chest between the collarbone and the pectoral muscle at a 25 degree angle. If after installation the device does not immediately detect the patient's heart beat, check the heart beat by removing the device and installing it again at the top of the costal arch as in picture 4b.









Picture 5 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. Check whether the LED unit's light indication functions correctly - immediately after installation a red or a green light should blink on every heart beat.

Heart Beat Indication

Upon activation of the device first the green LED remains lit for 5 seconds followed by two continuously lit red LEDs. When after installation the heart beat is detected, a green LED or two red LEDs 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 green and red LEDs blink simultaneously with one second intervals.








	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.

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.
	Keep away from heat.
	Protected against spraying water.
	For waste disposal the device is classified as an electronic device according to WEEE directive 2002/96/E4.
	The product does not contain latex.
	BF Type applied part

Technical Specifications

Use

Adhere the heart beat indicator to the patient's chest. Alternatively the device can be adhered to the top of the costal arch (picture 4b, p. 3). After installation detach the LED unit and move to a place in view.

The product can be used in the rain or in the sun.

Operating temperature range: -35 – +50 °C (-31 – +122 °F).

Heart Beat Indication

The normal range is 40 – 120 beats per minute. This is indicated with a green light.

Two red LEDs indicate the heart rate is outside the normal range.

The heart rate measurement is ECG based.

Size

Width: 149 mm

Length: 54 mm

Height: 15 mm

Weight: 40 g

Packaging Size

The product is available in packages of 10.

Key Features

- Disposable.
- Activates automatically when the packaging is removed.
- No buttons and no need to turn the device on.
- Visualizes the patient's heart beat with a light.
- Usage time 10 hours.

Technology

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

Storage

- Long term storage: 2 years between +5 – +30 °C (+41 – +86 °F).
- Short term storage: 1 week between -25 – +50 °C (-13 – +122 °F).



Spektikor

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