

custo guard holter

[blocked URL](#)

Intended use

custo guard holter is a wearable Holter recording device with an internal powersupply, and is used to record a 3-channel ECG signal in accordance with Holter standards. custo guard holter includes pacemaker detection. In addition to the ECG signal, the patient’s movement data (walking, running, prone, seated, etc.) is also recorded and later displayed in the custo diagnostic evaluation.

The recording time is 24 up to 120 hours. The recording is saved directly in the custo guard holter recording device.custo guard holter can be used safely on patients with pacemakers.

The system is intended for use by trained specialist staff or physicians in clinics and medical practices. Patients are only allowed to use the recording device after receiving instruction by trained specialist staff.

Patients who are not capable of understanding and following the instructions given are not allowed to use the device. This applies in particular to senile patients or patients suffering from dementia. The system is not suitable for electrocardiographic monitoring of patients as per DIN EN 60601-2-27, e.g. use in intensive care.

The device is not suitable for intracardiac use.

Technical specifications

Number of channels	3
Sampling Frequency (Depending on recording duration)	• 533 Hz (24 h, high resolution) • 400 Hz (24 h, 48 h, 72 h) • 100 Hz (5 days, 7 days, unlimited duration)
Resolution	18 bit
3-dB bandwidth ECG amplifier (depending on sampling frequency)	• f0 Hz – 105 Hz (with a sampling frequency of 533 Hz) • 0 Hz – 80 Hz (with a sampling frequency of 400 Hz) • 0 Hz – 20 Hz (with a sampling frequency of 100 Hz)
Minimum detection threshold (depending on sampling frequency)	• 10.46 µV (with a sampling frequency of 533 Hz) • 5.51 µV (with a sampling frequency of 400 Hz) • 5.51 µV (with a sampling frequency of 100 Hz)
ECG measurement range	+/- 685.7 mV.
Radio frequency band	ISM 2.4 GHz
Radio transmission power	• 10 mW
Radio communication	FHSS Frequency Hopping Spread Spectrum
Running Time	• internal rechargeable Battery approx. 10h • AAA-Batteries approx. 5h
Radio modulation	GFSK
Radio transmission rate	1Mbit/s
Connection to PC	via custo guard base charging and communication unit (USB) and Bluetooth
Power supply	Lithium polymer battery

Battery runtime) ¹	up to 168 h/7 days
Battery charging time	approx. 2 hours, charging current max. 130 mA
Status display	LED indicators for ECG quality and charging status
Dimensions	approx. 70 * 42 * 12 mm (L * W * H)
Weight	approx. 30 g
Ingress protection level	IP 65
Operating life	approx. 5 years (after this time has elapsed, the recording duration of up to 168 h can no longer be guaranteed)
Operating conditions	• Temperature: +5°C ... +45°C • Humidity: 10 ... 95 % rH • Air pressure: 700 ... 1060 hPa
Transport and storage conditions) ²	Temperature: -20°C ... +45°C Humidity: 10 ... 95 % rH Air pressure: 700 ... 1060 hPa Only for storage in a medical environment, under consideration of the conditions mentioned here.
Classification	Device with internal power supply, Class IIa, Type BF
Applied standards	DIN EN ISO 13485, DIN EN ISO 14971, DIN EN ISO 20417, DIN EN ISO 15223-1, DIN EN 60601-1, DIN EN 60601-1-2, DIN-IEC 60601-1-6, DIN EN 62304, DIN EN 62366-1, DIN EN ISO 10993-1, DIN EN 60601-2-47, DIN EN 60601-1-11, DIN EN ISO 10993-5, DIN EN ISO 10993-10