Operating Manual

Holter

1 Safety | 2 Hardware | 3 Software | 4 Hygiene

Part 2: Hardware, description of device for custo flash 500/510/510V/501/501L

Operating characteristics:
for 3-channel holter recordings,
24 hours to 7 days

MHW 0007 – DK 1694
Version 002 – 15/07/2019

CE 0123

custo·med
EXCELLENCE IN DIAGNOSTICS

The manufacturer reserves the right to change the information in this Operating Manual without prior notice. The current version can be downloaded from our website: www.customed.de.

CAUTION:
This Operating Manual is part of a modular system, consisting of four parts. All four parts must be downloaded from the Internet or from a CD to ensure the Operating Manual is complete.

Operating Manual

Holter

1 Safety | 2 Hardware | 3 Software | 4 Hygiene

Part 2: Hardware, description of device for custo flash 500/510/510V/501/501L

Table of contents

2.1 Symbols on the device

Manufacturer: custo med GmbH, Maria-Merian-Str. 6, 85521 Ottobrunn, Germany	
CE mark	
Observe the Operating Manual	
Separate collection of electrical and electronic equipment, do not dispose with domestic waste	
Recyclable material	
Medical electrical equipment classification according to DIN EN 60601-1 (Type BF)	
The device is not suitable for children weighing under 10 kg	
Labels in the recorder indicating the correct direction of insertion of the custo multiday card	

2.2 Intended use

custo flash 500/510/510V/501/501L is a portable Holter device with an internal power supply which is used to record a 3-channel ECG signal over a period ranging from 24 hours to seven days.

custo flash 500/510/510V/501/501L is perfectly safe for patients with a pacemaker. The ECG recording is not affected by pacemaker pulses.

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.

custo flash 500/510/510V/501/501L is not suitable for intracardiac use.

custo flash 500/510/510V/501/501L is not suitable for children weighing less than 10 kg.

Characteristics of the recorder types

custo flash...	500	510	510V	501	501/L
recording time max. 24 h	✓	✓	✓	✓	✓
recording time max. 7 Tage	✓	✓	✓	✗	✗
pacemaker detection	✗	✓	✓	✗	✗
ANS diagnostics	✗	✗	✓	✗	✗
for holter online (sender)	✗	✗	✗	✓	✗
with Software custo diagnostic light	✗	✗	✗	✗	✓

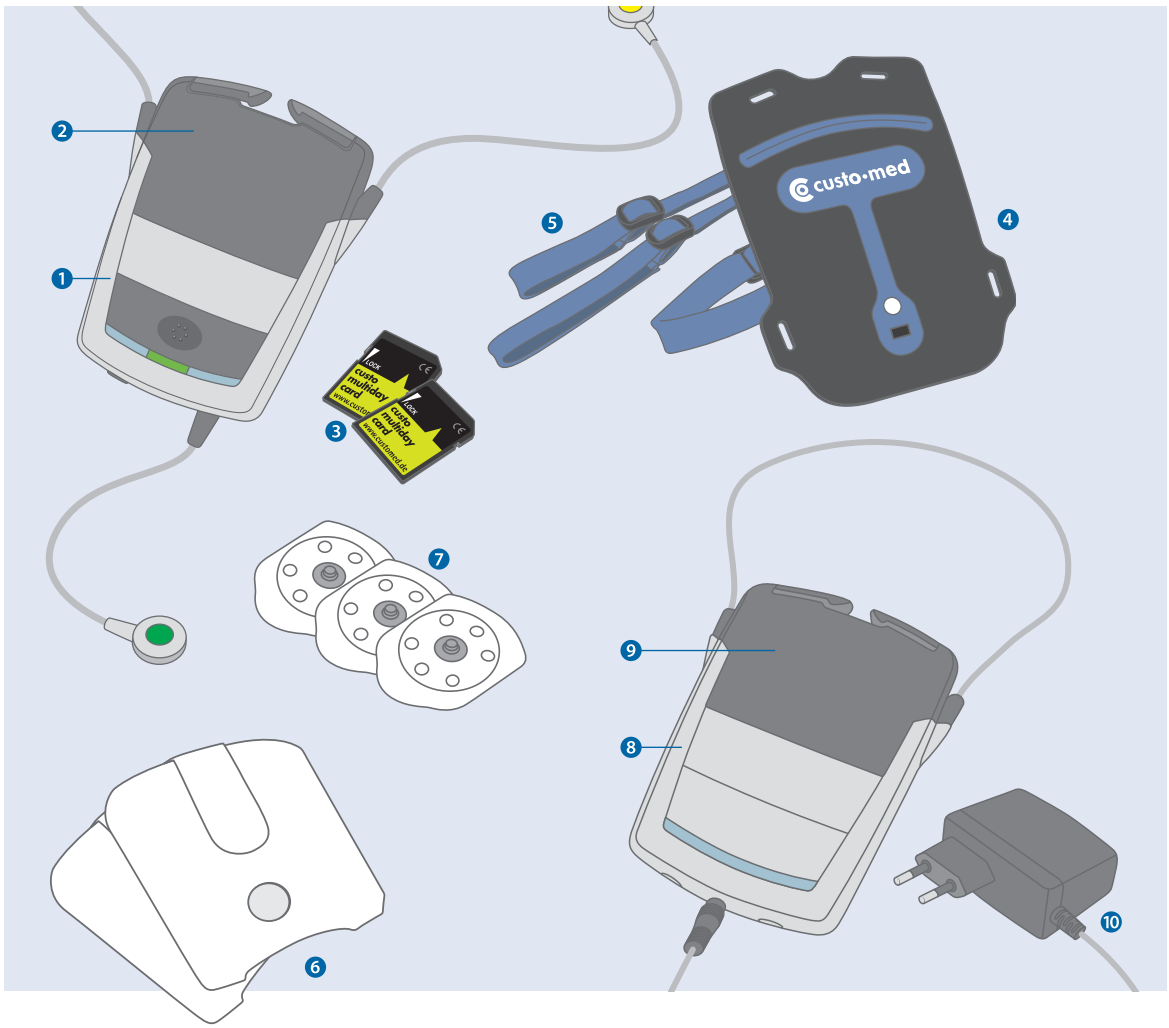
2.3 Part names, components for the recording

1. custo flash 500/510/510V/501/501L holter recorder[1)]
2. Rechargeable battery for custo flash 5xx
3. custo multiday card (standard SD card 256 MB)
4. Carrying case
5. Neck strap
- Chest belt for carrying case, standard 60 – 110 cm
6. custo flash 5xx protect
7. custo sensive disposable electrodes

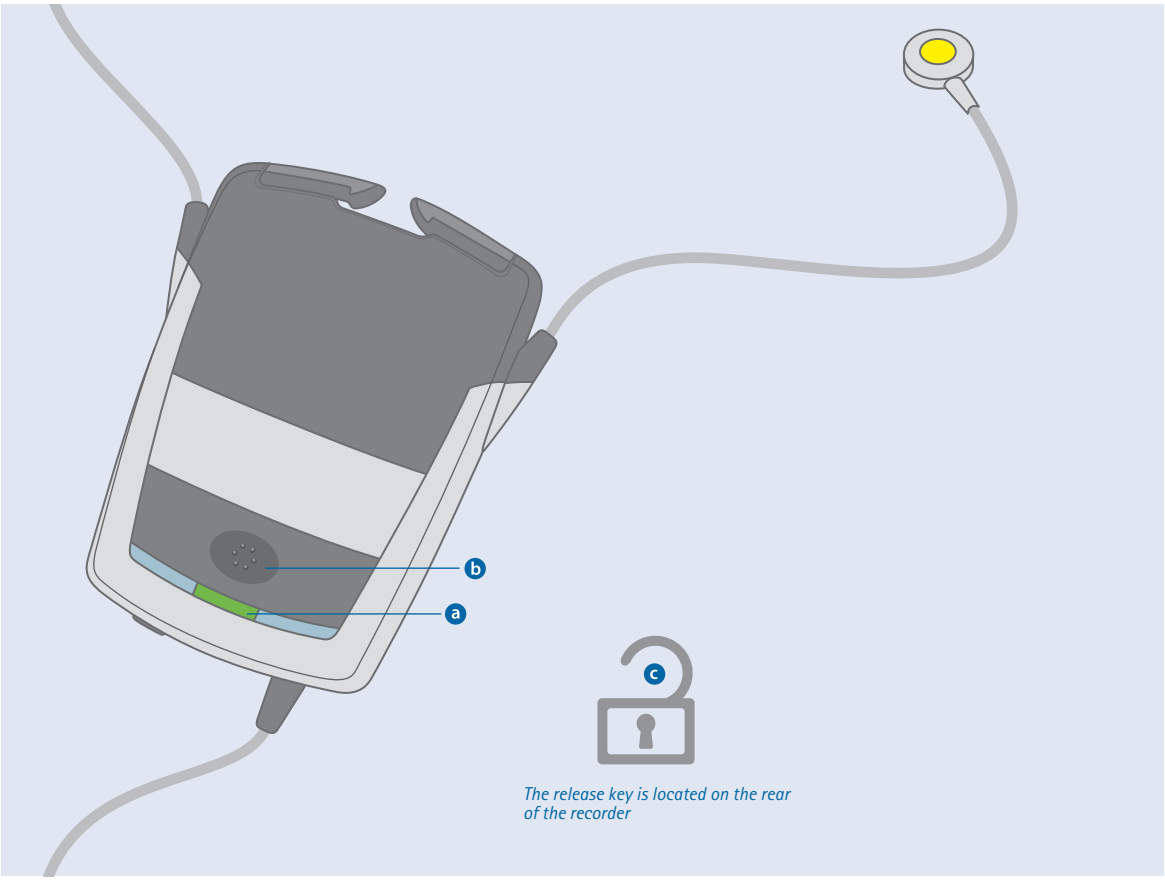
Starterkit (for custo flash 500/510/510V)

8. Charger for custo flash 5xx rechargeable battery
9. Rechargeable battery for custo flash 5xx
10. Power supply unit custo flash 5xx
- USB card reader with extension cable

1) Depending on the recorder type, the scope of delivery varies, see chapter „2.11 List of product components and accessories". For custo flash 501 and 501/L, e.g. charger and power supply unit are included in the set, in other versions, these parts are available separately as a starter kit.



2.4 Display and control elements on the recorder



The release key is located on the rear of the recorder

a LED display

The LED display provides information on the status of the recorder, the rechargeable battery, the custo multiday card and the recording. A table with the possible LED display states and their meaning can be found on the next page.

b Event key

This key can be pressed to mark events during the recording. The patient should make a note of the reason for pressing this key in his recording diary – e.g. health problems, stress, agitation or similar.

c Release key (located on the rear of the recorder)

This key is used to remove the rechargeable battery from the recorder. Firmly press the release key and pull the rechargeable battery upwards.

Note on the rechargeable battery

Always remove the rechargeable battery when the recorder is not in use.
The recorder starts as soon as the rechargeable battery is inserted.

LED display during a normal recorder start

RED	2 x flashing	custo multiday card was detected.
GREEN	fast flashing (2- 3 times / sec.)	The custo multiday card configuration is in progress, the process may take several minutes.
RED	8 x flashing	The custo multiday card configuration is complete.
GREEN	slow flashing (1 time / 2 sec.)	The device is in recording mode.

Further LED states, error display

RED	slow flashing	The rechargeable battery is almost empty.
RED	steady	When starting for the first time: The custo multiday card is defective, recording not possible. With very many new starts: The maximum number of starts has been reached (60). Recording is only possible after reading the custo multiday card.
GREEN	steady	Software error, the custo multiday card does not respond
	no LED	The custo multiday card is full, the maximum recording duration has been reached or the capacity of the rechargeable battery is exhausted.

2.5 Charging the rechargeable battery, operating the charger

Notes on the rechargeable battery

It is a lithium ion battery without memory effect. The rechargeable battery can be charged at any time, irrespective of the discharging times. A fully charged rechargeable battery lasts for a recording of seven days.

Always use a fresh and fully charged rechargeable battery for a recording.

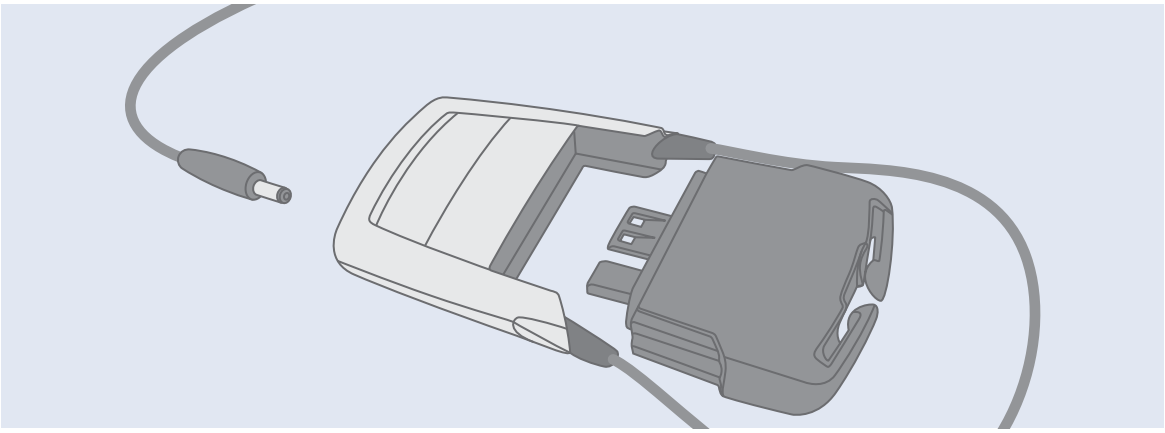
The rechargeable battery must only be charged at an ambient temperature between 10 – 45°C. The rechargeable battery must not be charged when exposed to direct sunlight or on the radiator.

Charging the rechargeable battery

- Connect the charger to the mains using the power supply unit
- Insert the rechargeable battery into the charger as shown below
- The LED display of the charger shows the state of the rechargeable battery:

Yellow LED	Green LED	Battery state	Charger state
×	×	without battery	PSU inserted?
✓	×	without battery	Ready for operation
✓	✓	battery inserted, charging in progress	
✓	×	battery inserted, completely charged	

- The maximum charging time is approx. 4 hours
- To remove the rechargeable battery, keep pressed the release key on the rear of the charger and pull out the rechargeable battery.



2.6 Starting the recorder and applying it to the patient

Material for the recording

For a recording you need: a custo flash 5xx recorder, a programmed custo multiday card (see *„Part 3, Software Description"*), a freshly charged battery, a clean neck strap, a clean carrying case, three electrodes.
For multi-day recordings (additional material for the patient): three electrodes per day, one hygiene bag per day, quick guide for patients.

Deactivating the custo multiday card write protection

❶ Make sure that the custo multiday card is writable. If the write protection is active, no ECG can be saved on the SD card. To save data to the SD card, the write protect lock must be in the upper position as shown.

❷ Insert the programmed custo multiday card into the recorder. Make sure that the direction of insertion is correct (see the label in the recorder).

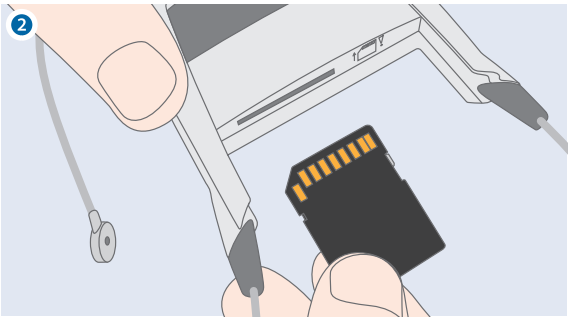
Assembling and starting the recorder

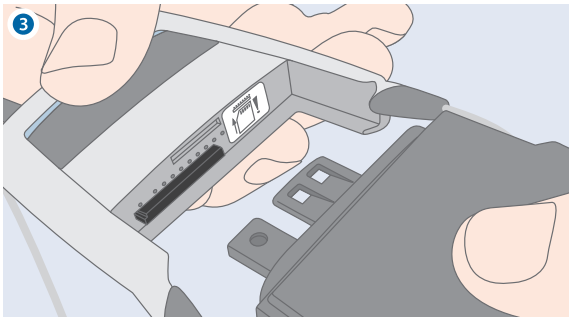
❸ Assemble the rechargeable battery and the recorder (press until the rechargeable battery engages). The direction of insertion is based on the position of the contacts. Once the device has been put together, it takes approx. one minute for the recording to start. During this period the custo multiday card is configured. LED display during configuration:

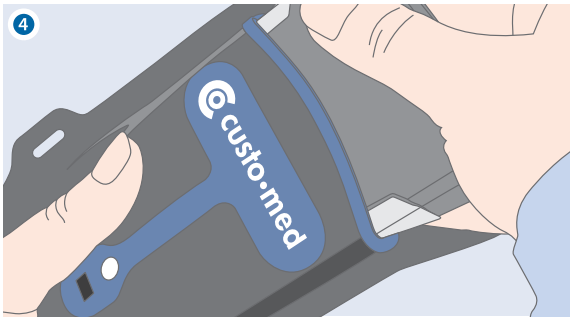
2 x red ..... custo multiday card detected
green, fast ..... custo multiday card configuration
8 x red ..... Configuration completed
green, slow ..... Recording in progress

Carrying case and neck strap

❹ Put the recorder into its case. Make sure that the inspection window of the case is on the front of the recorder and that the LED display is visible through the inspection window.







Carrying case and neck strap

❺ Attach the neck strap to the recorder. If a fabric carrying case is used, pull the loops of the neck strap through the holes at the top of the carrying case. To do so, feed the length adjusters of the strap loops through the holes. Place the loops around the strap holders of the rechargeable battery and pull them tight. Place the recorder around the patient's neck. Adjust the neck strap so that the recorder is placed centrally on the patient's chest.

Applying the electrodes

❻ Shave, clean (e.g. with custo prep ECG cream) and dry the electrode application points. Connect the electrodes to the ECG leads of the recorder. We recommend using custo sensive electrodes. Adhesive electrodes of other manufacturers can also be used, provided that they are approved by the respective manufacturer for this purpose.

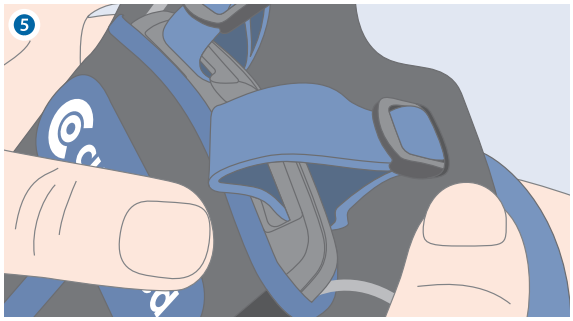
❼ Remove the protective films from the electrodes. Apply the top two electrodes (ⓐ, ⓑ) under the collarbone, if possible not on a muscle. Apply the bottom electrode (ⓒ) below the heart or on the breastbone. The electrodes can be applied at a slightly different position within the blue frame.

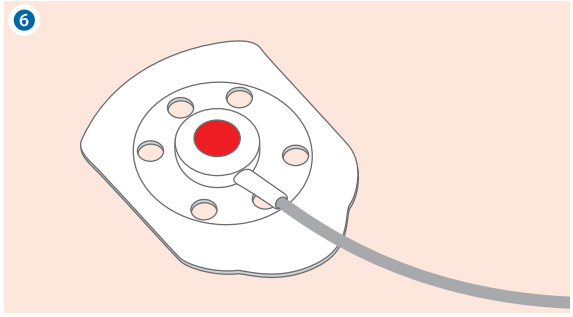
Hints for the quality of recording

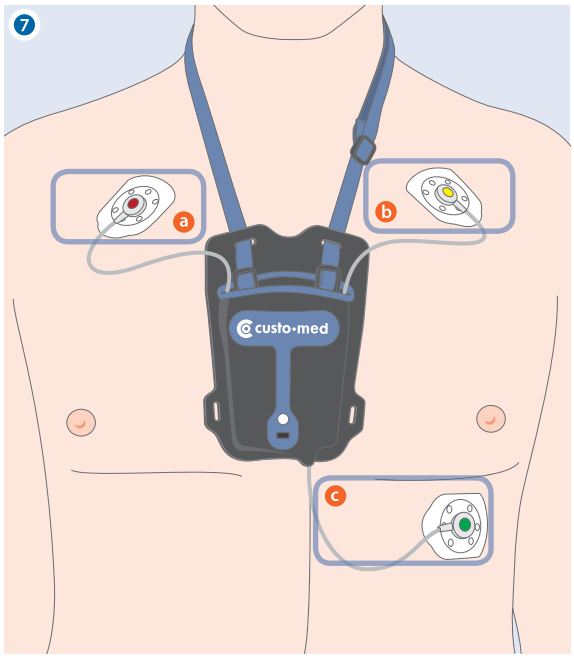
IMPORTANT: High grade electrodes, careful preparation of the patient and correct electrode application improve the quality of the recording and facilitate evaluation.

Provide the patient with a printout of the patient diary (print via custo diagnostic or use the provided master copy) and explain how to use the event key. Explain the patient instructions.

Tip for fixing the recorder: To reduce movement artefacts in the recording, you can fix the recorder to the patient. To do so, use adhesive strips with low adhesive residue, e.g. Leukosilk.







2.7 Patient instructions

Handling the recorder

The recording period selected should be as normal as possible (not a holiday, no out-of-the-ordinary events).

Protect the recorder against humidity and spray water. Do not immerse the recorder in liquids. Do not wear the recorder in the shower, bath, sauna or similar wet environments. Protect the recorder against extreme cold, heat, excessive dust development and impact or being dropped.

The patient is not allowed to remove the rechargeable battery, or modify the device in any way.

During the recording no radiological examinations must be performed. The quality of the recording may be influenced by other electrical devices (e.g. mobile phones).

Do not leave small children unattended with the device. Risk of strangulation with provided cables and belts, risk of suffocation from small parts that could be swallowed.

The LED display flashes green during recording (approximately once every 2 seconds). If this is not the case, contact the medical practice. To avoid incorrect recordings the LED display should be checked regularly.

Notes on applying the electrodes

In the case of known allergies, e.g. against substances in the adhesive electrodes, the further procedure must be agreed with the physician before the commencement of recording.

In the case of multi-day recordings, the electrodes and the hygiene case must be replaced daily. To achieve correct measuring results, the electrodes must be applied according to the specified electrode positions.

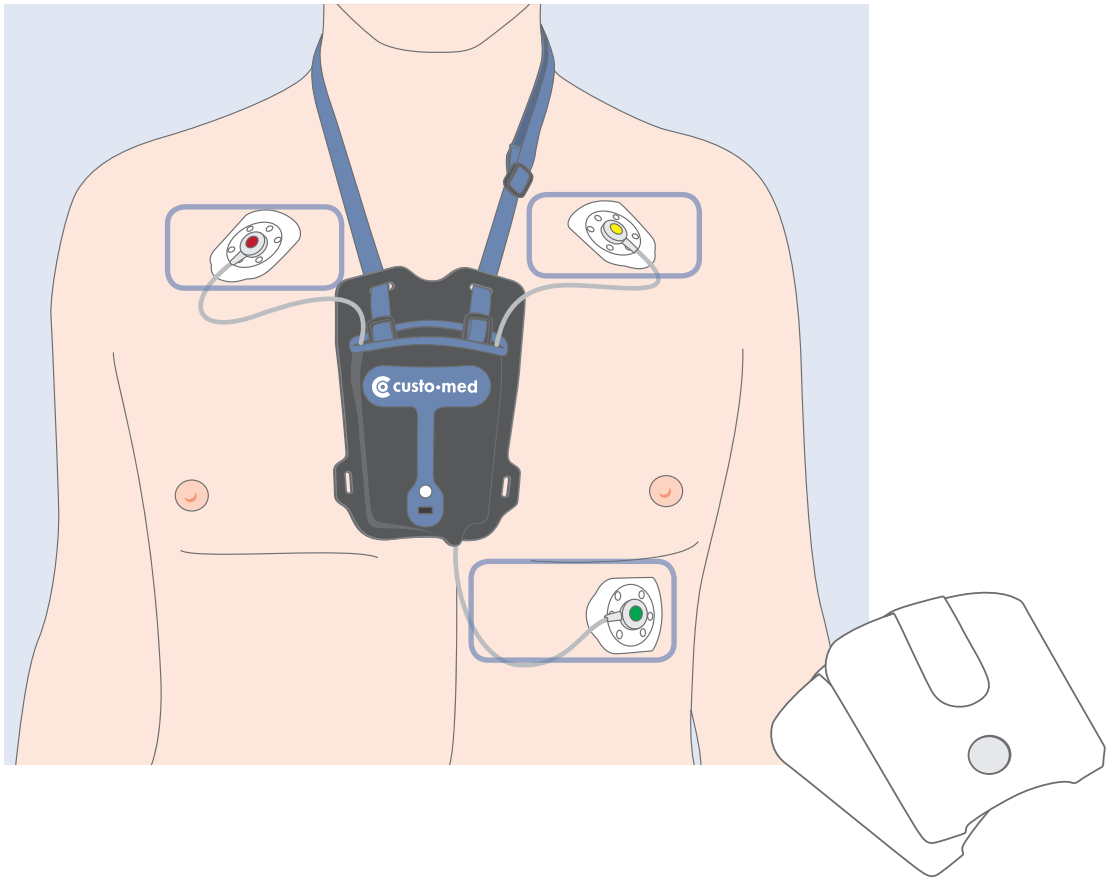
If electrodes become detached during the recording, they must be attached again. Otherwise the ECG recording will not be possible. Patients should contact their medical practice for assistance with reattaching the electrodes.

The electrodes must not be applied to moist skin. The application positions for the electrodes must be dry and free of grease. The application positions must be free of personal care products.

If patients experience physical problems (e.g. severe skin irritations) or any other form of discomfort during the recording, the recorder can be taken off and they should contact their physician.

Taking off and putting on the recorder, during multi-day recordings, e.g. for taking a shower or bath

- Detach the ECG leads from the electrodes, do not pull on the cables!
- Remove the neck strap together with the recorder over the head. Store the recorder in a safe and dry place.
- Remove the electrodes from the body.
- Dry thoroughly after taking a shower or a bath.
- Apply new electrodes as shown and attach them firmly.
- Change the hygiene case; the inspection window must be on the front of the recorder so that the LED display is visible.
- Put on the recorder and connect the ECG leads with electrodes.



2.8 Technical data and system requirements

custo flash 500/510/510V/501/501L

Recording channels	3	
Sampling rate	2.5 ms ± 0.1 % per channel	
Amplitude quantification	5.6 µ V/Bit ± 1 % at a total of 10 bit	
Frequency response	0.05 – 45 Hz	
Input resistance	≥10 MΩ	
Common-mode rejection at 50 Hz	80 dB	
Power supply	Rechargeable lithium-ion battery 3.7 V, >1800 mAh	
Rechargeable battery lifespan	approx. 500 charging cycles	
Dimensions	approx. 95 * 65 * 17 mm (L * W * H)	
Patient leads	160 mm	
Weight	approx. 105 g (including rechargeable battery and belt)	
Operating conditions	Temperature	+10°C ... 45°C
	Air humidity	10 ... 95 % rH without condensation
	Air pressure	700 ... 1060 hPa
Transport and storage conditions	Temperature	-20°C ... +40°C
	Air humidity	10 ... 95 % rH without condensation
	Air pressure	700 ... 1060 hPa
Classification	Device with internal power supply	
	Class IIa	
	Type BF	
Applied standards	DIN EN 60601-1	
	DIN EN 60601-2-47	
	DIN EN 60601-1-11	

General system requirements

Operating system	Windows 7 SP1 – with current updates (32 bit and 64 bit operating system) Windows 8 (32 bit and 64 bit operating system) Windows 8.1 (32 bit and 64 bit operating system) Windows 10 (32 bit and 64 bit operating system) Windows Server 2003 (32 bit and 64 bit operating system) Windows Server 2008 (32 bit and 64 bit operating system) Windows Server 2008 R2 Windows Server 2012 Windows Server 2012 R older versions are not supported	
PC	The PC hardware should meet the minimum requirements of the operating system used. Provide additional RAM (1 GB) for custo diagnostic. Please ensure that there is sufficient free space on the hard disk for the custo diagnostic evaluations. The PC must meet the requirements of the safety standard DIN EN 60950 for information technology equipment.	
File sizes of the evaluations	Holter	approx. 15 MB (max. 60 MB)
	ABPM:	approx. 128 KB (max. 512 KB)
	Holter ABPM:	approx. 20 MB (max. 25 MB)
	Resting ECG:	approx. 200 KB (for an ECG of approx. 10 sec.)
	Stress ECG:	approx. 6 MB (for an ECG of approx. 20 min.)
	CPET:	refer to stress ECG
	Spirometry:	approx. 50 KB (max. 256 KB)
	Rehab:	approx. 6 MB (for approx. 45 min. of exercise)
Hardware & ports	DVD or CD-ROM drive, USB port	

Recommended system requirements

Computer	Intel Core i3-CPU with HD graphics 4400
	4 GB RAM
	256 GB SSD or SSHD (for single-position systems 2TB HDD)
	1 GBit network connection (not for single-position systems)
	Fanless Dual-DVI (or DP) graphics card (for CPET)
	Windows 8.1 x64 (PRO version for joining a domain)
Ports	One USB 2.0 port per USB device (preferably not USB 3.0)
	One COM port each for ergometer and treadmills (serial)
	At least Version 4.0 if Bluetooth is installed
	otherwise can be deactivated in the BIOS
Monitor	20" TFT with DVI or DP port
	Full HD resolution
	Dual-TFT for CPET
Printer	600 dpi
	Monochrome (colour recommended for CPET)
	USB 2.0 port or network connection
	PCL-enabled (increases printing speed with the suitable driver)

2.9 Manufacturer's declaration regarding EMC (electromagnetic compatibility) according to DIN EN 60601-1-2:2016-05

Length of the patient leads: 160 mm

Manufacturer's declaration – electromagnetic emissions

The custo flash 500/510/510V/501/501L holter recorder is designed for use in the electromagnetic environment stated below. The customer or user of the custo flash 500/510/510V/501/501L should make sure that it is used in such an environment.

Emission measurements	Compliance	Electromagnetic environment – guidelines
RF emissions according to CISPR11	Group 1	custo flash 500/510/510V/501/501L uses RF energy only for its internal function. Its level of RF emission is therefore very low and is unlikely to be sufficient to interfere with other electronic devices.
RF emissions according to CISPR11	Class B	custo flash 500/510/510V/501/501L is designed for use in all establishments, including domestic establishments and those directly connected to the public low voltage power supply network that supplies buildings used for domestic purposes.
Harmonics according to IEC61000-3-2	Not applicable	
Voltage fluctuations/flickers according to IEC61000-3-3	Not applicable	

Manufacturer's declaration – electromagnetic immunity

The custo flash 500/510/510V/501/501L holter recorder is designed for use in the electromagnetic environment stated below. The customer or user of the custo flash 500/510/510V/501/501L should make sure that it is used in such an environment.

Immunity tests	IEC 60601- test level	Compliance level
Static electricity discharge (ESD) according to IEC 61000-4-2	± 8 kV contact discharge ± 15 kV air discharge	± 8 kV contact discharge ± 15 kV air discharge
Quick transient electric interference factors / bursts according to IEC 61000-4-4	± 2 kV for net wires ± 1 kV for input and Output leads (SIP/SOP)	Not applicable
Surges according to IEC 61000-4-5	± 1 kV lead against lead ± 2 kV lead against end	Not applicable
Voltage drops, brief interruptions and fluctuations in supply voltage according to IEC 61000-4-11	< 5 % U_T for 0.5 periods (> 95 % drop) 40 % U_T for 5 periods (60 % drop) 70 % U_T for 25 periods (30 % drop) < 5 % U_T for 5 s (> 95 % drop)	Not applicable
Magnetic field at supply frequency (50/60 Hz) according to IEC 61000-4-8	30 A/m	30 A/m

COMMENT: U_T is the alternating supply voltage prior to application of test levels

Manufacturer's declaration – electromagnetic immunity

The custo flash 500/510/510V/501/501L holter recorder is designed for use in the electromagnetic environment stated below. The customer or user of the custo flash 500/510/510V/501/501L should make sure that it is used in such an environment.

Immunity tests	IEC 60601- test level	Compliance level
Conducted disturbances, induced by high-frequency fields according to IEC61000-4-6	3 $V_{effective\ value}$ 0.15 MHz to 80 MHz 6 $V_{effective\ value}$ in ISM frequency bands[1)] between 0.15 MHZ and 80 MHz 80% AM at 1 kHz	not applicable
Radio-frequency electromagnetic fields according to IEC61000-4-3	10 V/m 80 MHz to 2.7 GHz 80 % AM at 1 kHz	10 V/m 80 MHz to 2.7 GHz 80 % AM at 1 kHz

1) The ISM bands (EN: Industrial, Scientific and Medical, i.e. frequency bands used for industrial, scientific and medical purposes) between 0.15 MHz and 80 MHz are 6.765 to 6.795 MHz; 13.553 MHz to 13.567 MHz; 26.957 MHz to 27.283 MHz; and 40.66 MHz to 40.70 MHz.
The amateur radio bands between 0.15 MHz and 80 MHz are 1.8 MHz to 2.0 MHz; 3.5 MHz to 4.0 MHz; 5.3 MHz to 5.4 MHz; 7 MHz to 7.3 MHz; 10.1 MHz to 10.15 MHz; 14 MHz to 14.2 MHz; 18.07 MHz to 18.17 MHz; 21 MHz to 21.4 MHz; 24.89 MHz to 24.99 MHz; 28 MHz to 29.7 MHz and 50 MHz to 54.0 MHz.

Recommended protective distances between portable and mobile RF telecommunication devices and custo flash 500/510/510V/501/501L

custo flash 500/510/510V/501/501L is designed for use in an electromagnetic environment in which the RF transients can be controlled. The user can help avoid electromagnetic interference by maintaining the minimum distance between portable and mobile RF telecommunication devices (transmitters) and the device – depending on the power output of the communication device, as indicated below.

WARNING: Wearable RF communication devices (radio devices) (including their accessories, e.g. antenna cables and external antennas) should not be used at distances of less than **30 CM** (12 inches) from the custo flash 500/510/510V/501/501L parts and leads described by the manufacturer. Failure to observe this warning can compromise the performance of the device.

WARNING: Use of this device directly next to other devices or stacked together with other devices should be avoided, as this could result in fault operation. If the devices must nonetheless be used as described above, this device and the other devices should be monitored to ensure proper functionality.

Frequency band[a] MHz	Radio service[a]	Maximum output in W	Clearance in m	Immunity test level in V/m
380 to 390	TETRA 400	1.8	0.3	27
430 to 470	GMRS 460, FRS 460	2	0.3	28
704 to 787	LTE Band 13, 17	0.2	0.3	9
800 to 960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	2	0.3	28
1700 to 1990	GSM 1800, CDMA 1900, GSM 1900, DECT, LTE Band 1, 3, 4, 25, UMTS	2	0.3	28
2400 to 2570	Bluetooth, WLAN 802.11 b/g/n RFID 2450, LTE Band 7	2	0.3	28
5100 to 5800	WLAN 802.11 a/n	0.2	0.3	9

a) For some radio services, on the frequencies for the radio connection of mobile communication devices to the base station (uplink) were included in the table.

COMMENT on protection clearances: The minimum clearances for increased immunity test levels must be calculated using the following equation:

$$E = \frac{6}{d} * \sqrt{P}$$

where P is the maximum output in Watt (W), d the minimum clearance in metres (m) and E the immunity test level in Volt per metre (V/m).

General COMMENTS:
These guidelines may not apply in every case. The propagation of electromagnetic variables is influenced by absorptions and reflections of buildings, objects and people.

2.10 EC Declaration of Conformity

EG-Konformitätserklärung
EC Declaration of Conformity

Hersteller / *manufacturer*: custo med GmbH | Maria-Merian-Str. 6 | 85521 Ottobrunn, Germany

Wir erklären hiermit in alleiniger Verantwortung, dass die
We hereby declare under our sole responsibility that the

Langzeit-EKG-Systeme	custo diagnostic Software Version 4.x & 5.x
Holter ECG Systems	custo flash 500/501/510
	custo watch
	custo guard 1/3

auf die sich diese Erklärung bezieht, mit den grundlegenden Anforderungen,
gemäß Anhang I der Richtlinie für Medizinprodukte 93/42/EWG, übereinstimmen.
to which this declaration relates are in conformity with the basic requirements according to Annex I of the Medical Device Directive 93/42/EEC.

Die Konformitätsbewertung entspricht dem Verfahren von Anhang II (ohne Abschnitt 4),
Richtlinie für Medizinprodukte 93/42/EWG.
The conformity assessment procedure is based on Annex II (excluding section 4), Medical Device Directive 93/42/EEC.

Die Produkte gehören zur Klasse IIa nach der Richtlinie für Medizinprodukte 93/42/EWG,
Anhang IX, Regel 10.
All units are class IIa according to MDD 93/42/ECC appendix IX rule 10.

Benannte Stelle / *Notified Body*	TÜV SÜD Product Service GmbH Ridlerstr. 65, 80339 München, Germany
Kenn-Nummer / *ID number*	0123
EG Zertifikat Nr. / *EC Certificate no.*	G1 012998 0010 Rev. 00
Ausstellungsdatum / *Date of issue*	2019-05-31
Ablaufdatum / *Expiry date*	2024-05-30

Seite/*page* 1 von/*of* 2

Zusätzlich erklären wir in alleiniger Verantwortung, dass das
Additionally, we declare under our sole responsibility that the

Produkt	**custo watch**
Product	**custo guard 1/3**

mit den grundlegenden Anforderungen der Funkanlagen-Richtlinie 2014/53/EU übereinstimmt.
is in conformity with the basic requirements of the Radio Equipment Directive 2014/53/EU.

Das Produkt entspricht folgenden Normen:
The product is compliant with the following standards:

SICHERHEIT / *SAFETY* (Artikel / Article 3.1a)	EN 60601-1:2006 + Cor.:2010 + A1:2013
EMV / *EMC* (Artikel / Article 3.1b)	EN 60601-1-2:2015
EFFIZIENZ DES FUNKSPEKTRUMS / *RADIO SPECTRUM EFFICIENCY* (Artikel / Article 3.2)	EN 300 440-1 V1.4.1

Gültig bis / *Valid until*: 2024-05-30

Ort / *City*
Ottobrunn, 31.05.2019

Hans-Jörg Hoffmann
Geschäftsführer / *Director*

custo·med
EXCELLENCE IN DIAGNOSTICS

Seite/*page* 2 von/*of* 2

2.11 List of product components and accessories

Set no.	Set name	Part no.	Qty.	Set/product designation
55501	custo flash 500			
		55500	1	custo flash 500 holter recorder
		55521	1	Rechargeable battery for custo flash 5xx
		55536	2	SD card for custo flash 5xx (256 MB)
		55543	1	Carrying case for custo flash 5xx
		55551	1	Neck strap for custo flash 5xx, adjustable
		55553	1	Chest belt for carrying case standard, 60 – 110 cm
		55541	7	custo flash 5xx protect
		40007	1 PCK30	custo sensive disposable electrodes
55503	custo flash 510			
		55502	1	custo flash 510 holter recorder with pacemaker detection
		55521	1	Rechargeable battery for custo flash 5xx
		55536	2	SD card for custo flash 5xx (256 MB)
		55543	1	Carrying case for custo flash 5xx
		55551	1	Neck strap for custo flash 5xx, adjustable
		55553	1	Chest belt for carrying case standard, 60 – 110 cm
		55541	7	custo flash 5xx protect
		40007	1 PCK30	custo sensive disposable electrodes
55512	custo flash 510/V			
		55513	1	custo flash 510/V holter recorder for ANS diagnostics
		55521	1	Rechargeable battery for custo flash 5xx
		55536	2	SD card for custo flash 5xx (256 MB)
		55543	1	Carrying case for custo flash 5xx
		55551	1	Neck strap for custo flash 5xx, adjustable
		55553	1	Chest belt for carrying case standard, 60 – 110 cm
		55541	7	custo flash 5xx protect
		40007	1 PCK30	custo sensive disposable electrodes
12168	Starter kit for flash 5xx			
		55520	1	Charger for custo flash 5xx rechargeable battery
		55521/Z	1	Rechargeable battery for custo flash 5xx
		55522	1	Power supply unit for custo flash 5xx
		16031[1)]	1	Card reader PNY black USB 2.0

1) The part numbers of the IT accessories or consumables may change.

Set no.	Set name	Part no.	Qty.	Set/product designation
55100	custo flash 501			
		55001	1	custo flash 501 holter recorder for holter online
		55520	1	Charger for custo flash 5xx rechargeable battery
		55522	1	Power supply unit for custo flash 5xx
		55521	1	Rechargeable battery for custo flash 5xx
		55536	2	SD card for custo flash 5xx (256 MB)
		55543	1	Carrying case for custo flash 5xx
		55551	1	Neck strap for custo flash 5xx, adjustable
		55553	1	Chest belt for carrying case standard, 60 – 110 cm
		55541	7	custo flash 5xx protect
		40007	1 PCK30	custo sensive disposable electrodes
55200	custo flash 501/L (light version, with reduced software functionality)			
		55002	1	custo flash 501/L holter recorder light
		55520	1	Charger for custo flash 5xx rechargeable battery
		55522	1	Power supply unit for custo flash 5xx
		55521	1	Rechargeable battery for custo flash 5xx
		55536	2	SD card for custo flash 5xx (256 MB)
		55543	1	Carrying case for custo flash 5xx
		55551	1	Neck strap for custo flash 5xx, adjustable
		55553	1	Chest belt for carrying case standard, 60 – 110 cm
		55541	7	custo flash 5xx protect
		40007	1 PCK30	custo sensive disposable electrodes

Manufacturer's contact details:
custo med GmbH
Maria-Merian-Straße 6
85521 Ottobrunn
Germany

Phone: +49 (0) 89 710 98 - 00
Fax: +49 (0) 89 710 98 - 10
E-mail: info@customed.de
Internet: www.customed.de

custo•med
EXCELLENCE IN DIAGNOSTICS