



Operating Manual

# Resting and Stress ECG

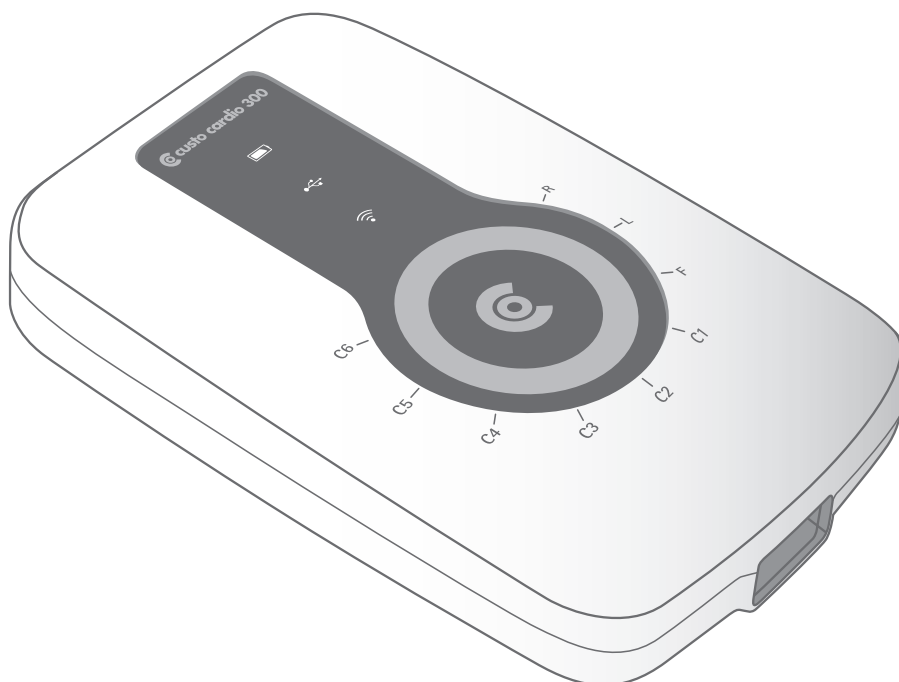
1 Safety

2 Hardware

3 Software

4 Hygiene

Part 2: Hardware, description of device for custo cardio 300



## Operating characteristics:

12-Channel PC ECG,  
Resting & Stress ECG

MHW 0013 - DK 1716  
Version 005 - 09/08/2021

CE 0123

 **custo-med**  
EXCELLENCE IN DIAGNOSTICS



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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](http://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

# Resting and Stress ECG

1 Safety

2 Hardware

3 Software










4 Hygiene

## Part 2: Hardware, description of device for custo cardio 300

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## 2.1 Symbols on the device

Manufacturer: custo med GmbH, Maria-Merian-Str. 6, 85521 Ottobrunn, Germany	
Serial number	
CE mark, notified body	
Manufacturing date, batch	
Observe the Operating Manual	
Safety class classification of medical electrical equipment according to DIN EN 60601-1 (type CF, defibrillation protected)	
Non-ionising electromagnetic radiation, device contains a HF transmitter (the radio unit is only active with Bluetooth models)	
Separate collection electrical and electronic equipment, do not dispose with domestic waste	
Follow the Operating Manual (applies to adapter cable suction system)	

## 2.2 Intended use

custo cardio 300 is a 12-channel PC ECG device designed for the creation, analysis and evaluation of ECG recordings in medical practices and hospitals. The system is intended for use by trained specialist staff or physicians.

custo cardio 300 is perfectly safe for patients with a pacemaker. ECG recording is not compromised by pace maker pulses. custo cardio 300 is not suitable for intra-cardial application.

## 2.3 Part names, components for the recording

- ❶ custo cardio 300 (different versions)
- ❷ Carrying case incl. belt for custo cardio 300
  - USB connection cable A-A, 3 m
  - Batteries AAA (for BT-B version)
  - USB universal power supply unit (for charging custo cardio 300 BT-A)
  - Bluetooth 4.0 USB Adapter (for connecting the bluetooth versions to the PC)
  - USB extension cable A-A, 1,8 m (for the Bluetooth 4.0 USB Adapter)
- ❸ Patient cable 10-wire with banana plugs
- ❹ Patient cable 10-wire with clips, long  
Patient cable 10-wire with clips, short
  - Disposable electrodes for banana plugs or clips
- ❺ D-Sub Adapter for suction system

Sets and accessories list with item numbers


see chapter „2.10 List of product components and accessories“.




## 2.4 Device operation custo cardio 300

### 2.4.1 Display- and operating elements

#### On/off button

The device is switched on and off with the large button in the middle  ①. To switch on, keep the button pressed for at least one second. Switch on the device shortly before recording.

Power off is effected automatically after 15 minutes of inactivity or manually by pressing the on/off button  for at least three seconds.

#### Status display

When switched on, information on the device status is indicated with the LED ②, ③ and ④:

#### ② State of charge rechargeable batteries (BT-A) or batteries (BT-B)

green:	good
yellow:	medium
red:	low

If custo cardio 300 BT-A (version with rechargeable battery) is charged, the LED ② flashes and indicates the state of charge with the corresponding color.

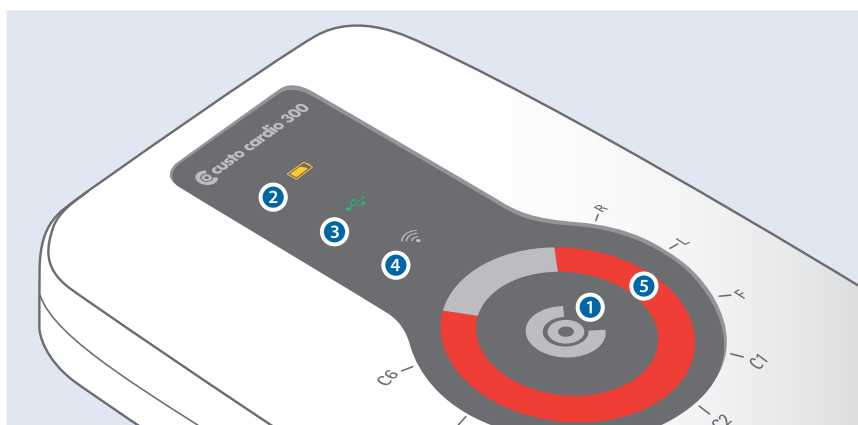
If the LED flashes red quickly: recharge battery / change battery <sup>1)</sup>.

1) Operating time  
 • Rechargeable battery & Bluetooth operation, 4 kHz sampling rate: max. 10 h (WiFi 4 h)  
 • Battery & bluetooth operation, 4 kHz sampling rate: max. 5 h (WiFi 90 min)


③ USB connection between device and PC: if the connection is established, the LED lights up green. If not connected, the LED is off.

④ Radio connection between device and PC: In radio mode, the LED lights up blue. The device can now be connected via Bluetooth or WLAN (depending on the version) or is already connected. During data transfer, the LED flashes. If not connected, the LED is off. For a change of connection, e.g. from Bluetooth to USB, the device must first be switched off and on again.


⑤ LED ring: Quality control of the electrode attachment or display of the recording progress, [see next page](#).




## 2.4.2 Sequences after switching on

Immediately after switching on (keep the on/off button  pressed for at least 1 s), all LEDs will light up. The device starts and can be used.


### Electrode control

After switching on, the LED ring indicates the quality of the electrode attachment. If the electrodes are not applied to the patient, all LEDs light up red. When properly attached to the patient, the corresponding LEDs will light green  (Figure 1). This check also works without connection to custo diagnostic.

### Start/stop recording on the device

An ECG recording can be triggered not only via the software interface, but also by pressing the on/off button  on the device. To do this, custo diagnostic must be configured accordingly, a patient must be selected and custo cardio 300 must be connected to custo diagnostic. The following types of recording are possible:

#### ► Automatic ECG by pressing the on/off button :

With the automatic ECG, the recording duration (at least 10 s) as well as the sequences after the recording are preset. After pressing the on/off button the recording starts. The LED ring lights up blue and shows the progress of the recording. When the preset recording time has elapsed, the entire LED ring lights up blue  (Figure 2).

#### ► Manual ECG by pressing the on/off button :

The manual ECG is recorded in any length. The recording must be started and stopped manually with the on/off button. The blue LED ring behaves as in the automatic ECG recording during the first 10 s. Afterwards, the LED ring lights up inverted and needs 10 s per additional cycle (Figure 2). The recording can be stopped by pressing the on/off button.

Figure 1: electrode control  
after switching on the device

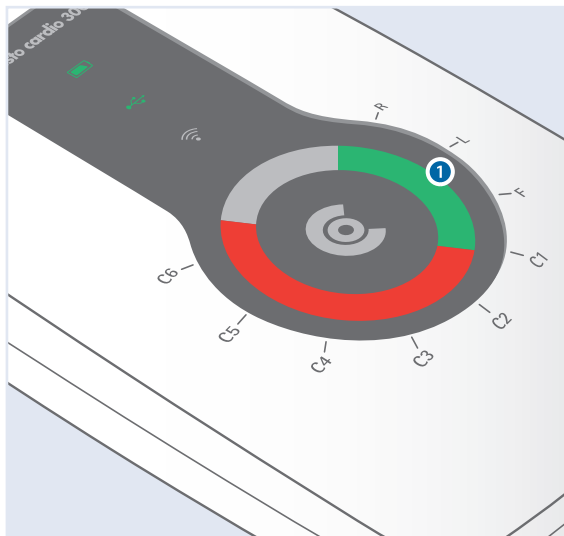


Figure 2:  
Recording progress





### 2.4.3 custo cardio 300 power supply

#### Recharge custo cardio 300 BT-A battery (version with rechargeable battery)

The custo cardio 300 with integrated battery is charged via the USB cable. The connection is located at the lower edge of the housing of the device ❶.

If custo cardio 300 is connected to a powered-on PC via USB cable, the device automatically charges. Charging via USB universal power supply is also possible. Connect the custo cardio 300 to the universal USB power supply and plug in the power adapter. The battery symbol indicates the charge status. In pure charging mode (without ECG recording), the maximum charging time is 3 hours.

#### Replacing custo cardio 300 BT-B batteries (version with batteries)

The battery compartment is located on the back of the housing. To change the batteries, open the battery compartment cover. Insert two fresh micro-batteries (AAA).



### 2.4.4 Connecting the patient cable or D-sub adapter

The connection for the patient cable or for the D-Sub adapter cable for connecting a suction system is located on the upper edge of the housing ❷.

Only suction systems with integrated 10 or 100 k $\Omega$  protective resistors may be connected to the adapter cable. Otherwise, the defibrillation strength can not be guaranteed.

## 2.5 Examination procedure

### Prerequisites for an examination:

Proper installation, configuration and commissioning of the system.

### Resting ECG

- Make sure that the ECG device is connected to the PC and the power supply of the device is guaranteed.
- Check that your patient is lying comfortably and is not cold.
- Shave, clean and dry the electrode application points thoroughly.
- Place the electrodes on the patient according to the placement diagram, See [2.6.1 Applying the electrodes](#).
- Connect the patient leads to the electrodes.
- Start custo diagnostic and click:  
[Examination, Resting ECG, New Resting ECG](#) see [Software description...](#)
- Start the recording.
- The patient must keep still during the recording process.

### Stress ECG

- Make sure that the ECG device is connected to the PC and the power supply of the device is guaranteed.
- When using an ergometer, make sure that the patient is in the optimal seating position (the extended leg should be slightly bent).
- When using a treadmill, make sure to follow the instructions in [2.6.2 Instructions for stress ECG with treadmill](#).
- Shave, clean and dry the electrode application points thoroughly.
- Place the electrodes on the patient according to the placement diagram, See [2.6.1 Applying the electrodes](#).
- Connect the patient leads to the electrodes.
- Wait some minutes so that the contact between the skin and the electrodes can develop optimally.
- Apply the blood pressure cuff.
- Start custo diagnostic and click:  
[Examination, Stress ECG, New Stress ECG](#) see [Software description...](#)
- Start the recording.

## 2.6 Attaching the device to the patient

### 2.6.1 Applying the electrodes

#### 1 Thoracic wall resting and stress ECG, standard according to Wilson

V1 (C1)	red	4. Intercostal space at the right sternal border
V2 (C2)	yellow	4. Intercostal space at the left sternal border
V3 (C3)	green	on left-hand side of the 5th rib between C2 and C4
V4 (C4)	brown	5th intercostal space on the left midclavicular line
V5 (C5)	black	on the left-hand side of the anterior axillary line, at the same height as C4
V6 (C6)	purple	on the left-hand side of the midaxillary line, at the same height as C4

#### 2 Extremities resting ECG

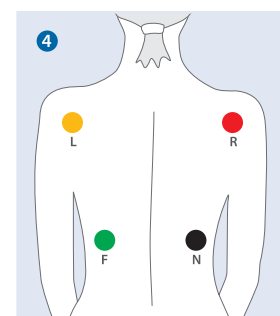
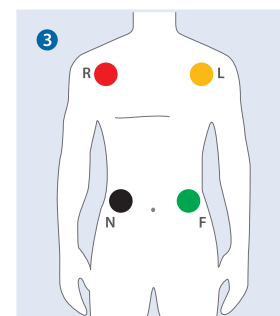
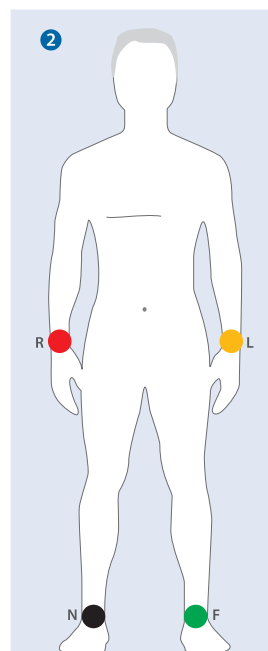
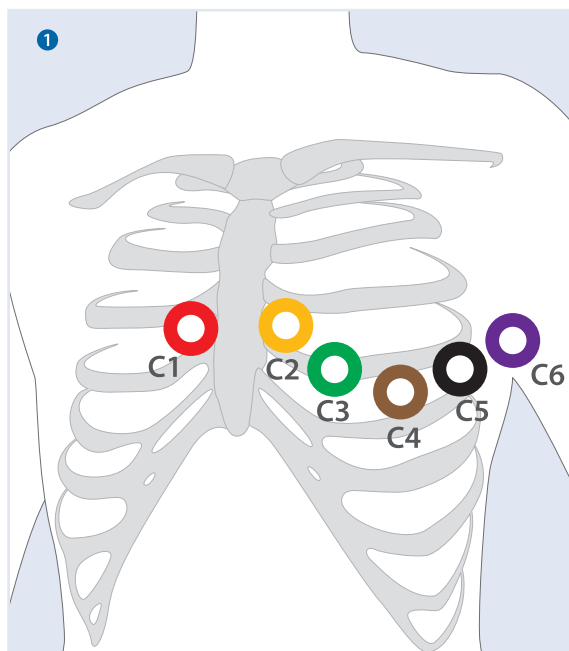
R	red	right arm
L	yellow	left arm
F	green	left leg
N	black	right leg

#### 3 Extremities stress ECG (lying or standing)

R	red	on the right below the collarbone
L	yellow	on the left below the collarbone
F	green	on the left above the hip
N	black	on the right above the hip

#### 4 Extremities stress ECG (sitting position)

R	red	attach to the deltoid muscle on the right
L	yellow	attach to the deltoid muscle on the left
F	green	9. left rib
N	black	9. right rib



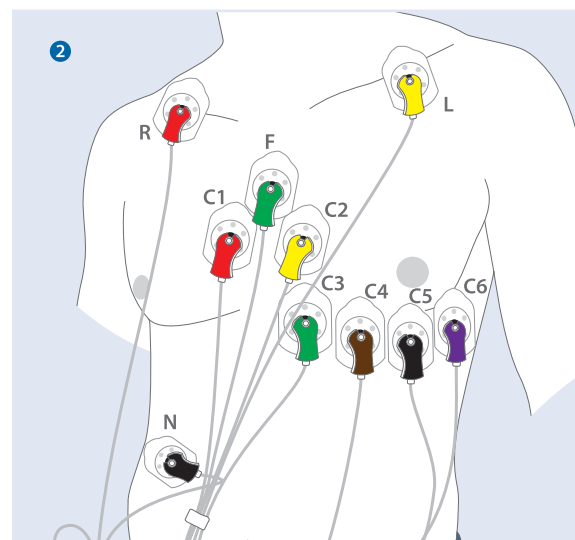
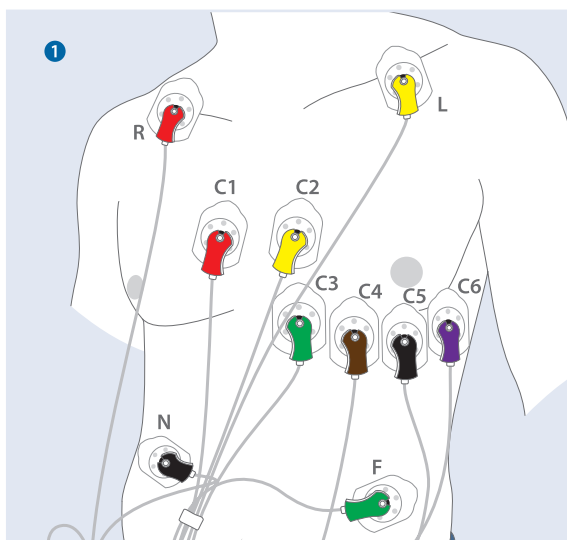
### 2.6.2 Instructions for stress ECG with treadmill<sup>1)</sup>

- The patient should ideally be wearing running shoes or trainers.
- The patient should not hold onto the handles of the treadmill during the recording process. This will lead to muscle tension which will affect the ECG signal.
- Missing skin tension, in interaction with shoulder movement, will increase artefacts in the ECG signal.
- The extremity leads should if possible be applied on taut skin areas in order to avoid excessive movement artefacts and therefore interference in the other electrode leads.
- During the ECG recording, the electrode leads must not come into contact with the patient, the treadmill or other objects.
- Fix any overlong trailing leads to the carrying case. No tension must be exerted on the electrodes. Make sure that no lead passes over the contact of an electrode.
- Tip: To fix electrodes and cables to the patient's body and therefore reduce interference in the ECG signal, the patient should wear a stretchable ECG mesh shirt.

1) For stress ECG with treadmill we recommend the use of custo cardio 300 with ergometry cable, carrying case and custo sensitive electrodes.

- ① Normal electrode application,
- ② Artefact reduced electrode application<sup>2)</sup>

2) Artefact reduced electrode application results in smaller amplitudes in the extremity derivations.



### Safe use of treadmills with stress ECG

Always set the treadmill so that the patient can safely move on the device. Ensure that the acceleration, speed and inclination of the treadmill are adjusted to the patient's physical constitution, stamina and skill. Observe the manufacturer's safety instructions.

Always inform the patient before you change the acceleration, speed or inclination. Otherwise, the patient may become injured, e.g. also due to an unexpected, abrupt stopping or starting of the treadmill.

## 2.7 Technical data and system requirements

### custo cardio 300

Number of ECG channels	12	
Frequency response	0 to 0.262 * sampling frequency [HZ]	
Sampling frequency	1000, 2000, 4000, 8000, 16000 (only with USB), 32000 (only with USB) Hz	
Sampling rate	Identical for all channels, possible settings: 1.0 ms/0.5 ms/0.25 ms/0.125 ms/0.0625 ms (only with USB)/0.03125 ms (only with USB)	
Deviation	< 1.5 %	
A/D converter	24 bit	
Input impedance	> 50 MΩ	
Amplitude quantification	1.526 μV/bit	
CMRR	> 93 dB	
Impedance measurement	at all electrode leads (not N) with automatic quality indication	
Defibrillation protection	Electrical strength 5000 V	
Recovery time after defibrillation	< 5 s	
Power supply	USB devices	USB cable (standard connection to PC)
	USB/BT devices	Lithium-ion rechargeable battery / 2 x AAA batteries
	USB/WLAN devices	Lithium-ion rechargeable battery / 2 x AAA batteries
Max. power consumption	max. 1.5 Watt	
Operating time Li-ion battery (BT-A)	Bluetooth mode and 4 kHz	max. 10 hours
Operating time AAA batteries (BT-B)	Bluetooth mode and 4 kHz	max. 5 hours
Charging time	max. 3 hours in pure charging mode	
Service life	approx. 5 years	
IT connection	USB (cable length 3000 mm), Bluetooth	
Patient connection	patient cable 10-wire with banana plugs / patient cable 10-wire with clips / D-Sub Adapter	
Bluetooth frequency	2.4 GHz ISM frequency band	
Bluetooth range	generally 10 m, depending on ambient conditions	
Dimensions	custo cardio 300 USB / BT-A	approx. 118 * 78 * 23 mm (L * W * H)
	custo cardio 300 BT-B	approx. 118 * 78 * 27 mm (L * W * H)
	weight	approx. 130 g
Patient leads	long	approx. 1050 mm (extremities) approx. 700 mm (chest wall)
	short	approx. 600 – 700 mm (extremities)
		approx. 500 – 650 mm (chest wall)
Operating conditions	temperature	+10°C ... +40°C
	air humidity	25 ... 95% rH
	air pressure	700 ... 1060 hPa
Transport and storage conditions	temperature	+5°C ... +45°C
	air humidity	30 ... 93% rH
	air pressure	700 ... 1060 hPa
Classification	custo cardio 300 USB	protection class II
	custo cardio 300 USB/BT	device with internal power supply
	custo cardio 300 USB/WLAN	device with internal power supply
	class IIa, type CF	
Underlying standards	DIN EN 60601-1, DIN IEC 60601-2-25	

## General system requirements

Operating system	<p>The custo diagnostic software is suitable for installation only on Microsoft Windows systems.</p> <p>custo diagnostic 5 is a client/server combination.</p> <p>The custo diagnostic 5 server only runs on 64-bit systems.</p> <p>For optimum performance, only use the operating systems/software combination (including the custo diagnostic server and client for custo diagnostic 5) that have been tested and approved by custo med.</p> <p>Refer to your custo med distributor or directly to custo med for information on these.</p>	
PC	<p>The PC's hardware must be compatible with Intel products and fulfil the minimum requirements for the operating system used.</p> <p>Provide additional RAM (1 GB) for custo diagnostic.</p> <p>Please ensure that there is sufficient free space on the hard disk for the custo diagnostic evaluations.</p> <p>The PC must comply with the DIN EN 62368 safety standard for information technology equipment.</p>	
File sizes of the evaluations	<p>Holter: approx. 15 MB (max. 60 MB)</p> <p>ABPM: approx. 128 KB (max. 512 KB)</p> <p>Holter-ABPM: approx. 20 MB (max. 25 MB)</p> <p>Resting ECG: approx. 200 KB (for an ECG of approx. 10 seconds)</p> <p>Stress ECG: approx. 6 MB (for an ECG of approx. 20 minutes)</p> <p>CPET: refer to stress ECG</p> <p>Spirometry: approx. 50 KB (max. 256 KB)</p> <p>Rehab: approx. 6 MB (for approx. 45 minutes of exercise)</p>	
Hardware Et ports	<p>DVD or CD-ROM drive,</p> <p>USB port</p>	

## Recommended system requirements

Computer	<p>Intel Core i3 CPU with HD Graphics 4400</p> <p>4 GB RAM</p> <p>256 GB SSB or SSHD (for single-position systems 2 TB HDD)</p> <p>1 Gbit network connection (not for single-position systems)</p> <p>Fanless Dual-DVI (or DP) graphics card (for CPET)</p> <p>We recommend the current Windows version with all updates.</p> <p>Observe the specifications listed under</p> <p>"General system requirements, operating system"</p> <p>on the previous page for this!</p>
Ports	<p>One USB 2.0 port per USB device (preferably not USB 3.0)</p> <p>One COM port each for ergometer and treadmills (serial)</p> <p>At least Version 4.0 if Bluetooth is installed</p> <p>otherwise can be deactivated in the BIOS</p>
Monitor	<p>20" TFT with DVI or DP port</p> <p>Full HD resolution</p> <p>Dual-TFT for spiroergometry</p>
Printer	<p>600 dpi</p> <p>Monochrome (colour recommended for spiroergometry)</p> <p>USB 2.0 port or network connection</p> <p>PCL-enabled (increases printing speed with the suitable driver)</p>

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

### Lengths of the patient leads and the USB cable

Patient leads	approx. 1050 mm and approx. 700 mm approx. 600 – 700 mm and approx. 500 – 650 mm
USB cable	approx. 3000 mm

### Manufacturer's declaration – electromagnetic emissions

The custo cardio 300 ECG device is designed for use in the electromagnetic environment stated below.  
The customer or user of custo cardio 300 should make sure that it is used in such an environment.

Emission measurements	Compliance	Electromagnetic environment – guidelines
RF emissions according to CISPR11	Group 1	<p>custo cardio 300 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.</p> <p>custo cardio 300 BT-A/BT-B uses the frequency band in the range 2.4 GHz to communicate with the PC. Its level of RF emission is very low and is unlikely to be sufficient to interfere with other electronic devices.</p>
RF emissions according to CISPR11	Class B	custo cardio 300 is suitable 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 cardio 300 ECG device is designed for use in the electromagnetic environment stated below.  
The customer or user of custo cardio 300 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)	± 2 kV for net wires ± 1 kV for input and Output leads (SIP/SOP)
Surges according to IEC 61000-4-5	± 1 kV lead against lead ± 2 kV lead against end	± 1 kV lead against lead ± 2 kV lead against end
Voltage drops, brief interruptions and fluctuations in supply voltage according to IEC 61000-4-11	<p>&lt; 5% <math>U_T</math> for 0.5 periods (&gt; 95 % drop)</p> <p>40% <math>U_T</math> for 5 periods (60 % drop)</p> <p>70% <math>U_T</math> for 25 periods (30 % drop)</p> <p>&lt; 5% <math>U_T</math> for 5 s (&gt; 95 % drop)</p>	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 cardio 300 ECG device is designed for use in the electromagnetic environment stated below.  
The customer or user of custo cardio 300 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	$3 V_{\text{effective value}}$ 0.15 MHz to 80 MHz $6 V_{\text{effective value}}$ in ISM frequency bands <sup>1)</sup> between 0.15 MHz and 80 MHz 80 % AM at 1 kHz	$3 V_{\text{effective value}}$ 0.15 MHz to 80 MHz $6 V_{\text{effective value}}$ in ISM frequency bands <sup>1)</sup> between 0.15 MHz and 80 MHz 80% AM at 1 kHz
Radio-frequency electromagnetic fields according to IEC61000-4-3	3 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 cardio 300

custo cardio 300 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 cardio 300 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 <sup>a)</sup> MHz	Radio service <sup>a)</sup>	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.

## 2.9 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*

<b>EKG-Systeme</b>	<b>custo diagnostic Software Version 4.x &amp; 5.x</b>
<b>ECG Systems</b>	<b>custo cardio 300 / 300 BT</b>

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 Produkte custo cardio 300 / 300 BT erfüllen die Vorschriften der Richtlinie 2011/65/EU des Europäischen Parlaments und des Rates vom 8. Juni 2011 zur Beschränkung der Verwendung bestimmter gefährlicher Stoffe in Elektro- und Elektronikgeräten (inkl. Änderungsrichtlinie (EU) 2015/863).

*The products custo cardio 300 / 300 BT are in conformity with Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment (incl. delegated directive (EU) 2015/863).*

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/EEC appendix IX rule 10.*

Benannte Stelle / <i>Notified Body</i>	TÜV SÜD Product Service GmbH Ridlerstr. 65, 80339 München, Germany
Kenn-Nummer / <i>ID number</i>	0123
EG Zertifikat Nr. / <i>EC Certificate no.</i>	G1 012998 0010 Rev. 01
Ausstellungsdatum / <i>Date of issue</i>	2021-05-25
Ablaufdatum / <i>Expiry date</i>	2024-05-26

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

**Produkt** **custo cardio 300 BT**  
*Product*

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 300 328 V2.1.1

Gültig bis / Valid until: 2024-05-26

Ort / City  
Ottobrunn, 25.05.2021

  
Hans-Jörg Hoffmann  
Geschäftsführer / Director



## 2.10 List of product components and accessories

Set no.	Set name	Part no.	Qty.	Set/product designation
12202	custo cardio 300 set	12201	1	custo cardio 300 (USB version)
		12213	1	Carrying case custo cardio 300 incl. belt
		12221	1	USB connection cable A-A, 3 m for custo cardio 300
12204	custo cardio 300 BT-A set	12203	1	custo cardio 300 BT-A (Bluetooth-USB & rechargeable battery)
		12213	1	Carrying case custo cardio 300 incl. belt
		12221	1	USB connection cable A-A, 3 m for custo cardio 300
		12212	1	USB universal power supply unit for custo cardio 300
		55050	1	Bluetooth 4.0 USB adapter
		16018	1	USB extension cable 1.8 m, plug A - socket A
12206	custo cardio 300 BT-B set	12205	1	custo cardio 300 BT-B (Bluetooth-USB & batteries)
		12213	1	Carrying case custo cardio 300 incl. belt
		12221	1	USB connection cable A-A, 3 m for custo cardio 300
		20033	2	AAA LR03 Micro 1.5 V batteries
		55050	1	Bluetooth 4.0 USB adapter
		16018	1	USB extension cable 1.8 m, plug A - socket A
12215	Patient cable set, banana plug	12214	1	Patient cable 10-wire with banana plugs for custo cardio 300
		40004	1 pck.60	ECG electrodes blue sensor for ECG device with banana plugs
12217	Patient cable set, clip (long)	12216	1	Patient cable 10-wire with clip (long) for custo cardio 300
		40007	1 pck.30	custo sensitive disposable electrodes
12219	Patient cable set, clip (short)	12218	1	Patient cable 10-wire with clip (short) for custo cardio 300
		40007	1 pck.30	custo sensitive disposable electrodes
		12220	1	D-Sub Adapter for custo cardio 300

All items listed here are available separately as accessories.



**Manufacturer's contact details:**

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