Operating Manual

Resting and stress ECG

custo cardio 400 accu
custo diagnostic 5.8

cus͡to·med
EXCELLENCE IN DIAGNOSTICS

Table of Contents

1 Safety

1.1 General notes

1.1.1 Symbols used in this Operating Manual

⚠	Safety warning symbol, in case of dangerous situations with high and medium risk level, which may result in personal injuries
❗	**IMPORTANT:** absolutely necessary working steps
ⓘ	**INFORMATION:** for the correct and safe use of the system.
★	**TIP:** contains practical information to assist you with your work
custo	Words highlighted in colour indicate buttons or click paths to the corresponding program point, e.g.: Examination, Settings

1.1.2   Laws and regulations applicable to the product

INFORMATION:

Strict compliance with the safety instructions protects against personal injury and property damage during device operation. This Operating Manual is designed to accompany the product and must be kept ready to hand close to the device. As either the operator or user of this device you should have read and understood the Operating Manual, in particular the safety instructions.

Should serious incidents occur in connection with a custo med product, they must be reported by the user and/or patient to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.

custo med devices are designed in accordance with the Medical Device Directive 93/42/EEC and Medical Devices Regulation (MDR 2017/745), class IIa and meet the requirements of protection class I or II, depending on the power supply unit used or they are devices with an internal power supply, type BF or CF according to IEC 60601-1. Other devices which are part of the system must meet the requirements of the Standard for Information Technology Equipment (IEC 62368) or the Standard for Electrical Medical Devices (IEC 60601-1).

The electrical installations in the rooms in which the system is used must meet the requirements of the applicable safety standards.

For users outside the Federal Republic of Germany, the respective national accident prevention measures, regulations and requirements apply.

1.1.3   Disclaimer

The manufacturer will not be held liable for improper operation, non-compliance with safety instructions and negligently skipped instructions.

custo med only assumes responsibility for the safety and reliability of the device if all changes, enhancements, repairs and other work on the device or system have been performed by an authorised custo med distributor or custo med and the Operating Manual has been observed during device operation.

1.1.4   Warranty

Our product philosophy is committed to providing you with faultless products which meet your expectations. Should you have reason to complain we aim to rectify any defects immediately or provide a replacement delivery.

This does not include damage that can be attributed to usual wear and tear, improper use, unauthorised modification of parts and the use of violent force.

After the warranty period has expired, only use original spare parts and accessories supplied by custo med. Only this will ensure the safe and problem-free operation of your device.

1.1.5   Support

If you have any questions or problems which are not dealt with here, please do not hesitate to contact your authorised custo med distributor. A list of authorised custo med distributor can be found on the Internet at:

www.customed.de, under Contact, Distributors.

You can also contact custo med GmbH directly at any time. We will be pleased to provide you with information about your authorised custo med distributor or contact your authorised custo med distributor and forward your queries.

1.2   Safety installations and safe working

1.2.1   Putting into operation, setup

custo med systems must only be used in a technically perfect condition. Regularly carry out a visual inspection of the devices and their associated components. Only use accessories approved by custo med. The use of accessories other than those specified may result in increased emissions or decreased immunity.

A PC with peripherals is required to operate the custo med devices. For assembly it is recommended to use portable multiple socket outlets approved by custo med, e.g. medical protector. The following must be noted:

→   Portable socket outlets must not be laid on the ground.
→   Portable multiple socket outlets which are supplied with the system are to be used only for supplying devices which are part of the system.
→   Additional portable multiple socket outlets, lines and other equipment, which are not part of the system, must not be connected to the system.
→   When using a multiple socket outlet, the maximum permitted load is 3200 VA.
→   Slots which are not used in the delivered system (portable multiple socket outlets) must be provided with covers.

1.2.2   Ambient conditions, handling of the devices

Emissions

The custo med devices/systems are not suitable for use in rooms or areas with a risk of explosion.

For installation and operation of the devices/systems, the EMC (electromagnetic compatibility) instructions in the Operating Manual must be observed.

Strong electromagnetic sources in the immediate vicinity of the custo med device/system may result in recording errors. The custo med device/system must not be stored or used in the vicinity of X-ray equipment, diathermy units or magnetic resonance devices (MRT). Other electrical devices such as mobile phones or radio transceivers may impair the quality of the recording.

Other devices may interfere with the custo med devices/systems, even if the other devices comply with the applicable emissions requirements according to CISPR.

Mechanical impact

No modifications may be made to the custo med devices/systems. Contact your authorised custo med distributor for repairs.

custo med devices for outpatient use (recorder, transmitter) must be protected from heat, moisture, dust and dirt. The devices may not function properly if they come into contact with liquid.

It is not permitted to wear the devices in a swimming pool, in the sauna, bathtub, shower or similar wet rooms. Do not submerge the custo med devices.

The custo med devices must be protected from mechanical impact, such as falls or transport damage. Avoid heavy mechanical loads.

Rechargeable batteries

Some custo med devices contain an integrated lithium polymer battery (permanently installed in the housing). Any mechanical stress which is beyond the intended use must be avoided. Do not use force to open the devices.

Some custo med devices contain a lithium-ion battery or other batteries that can be removed. Remove the rechargeable battery when the device is not in use. Do not expose the rechargeable battery to extreme temperatures, fire and moisture. Do not immerse in liquids. Observe the operating and storage conditions. Do not subject the rechargeable battery to strong shocks or drop it. The rechargeable battery must not be disassembled, modified or short circuited. Only use the supplied charger to charge the rechargeable batteries. Do not remove battery compartment covers or other covers during use.

USB cable

Some custo med devices have a USB cable. This cable must not be kinked. Do not step on the USB cable, only roll up the cable loosely and allow it to hang freely during operation. Always hold the USB cable by the plug in order to disconnect it from the PC.

Memory cards

Some custo med devices contain memory cards. custo med recommends that you leave the supplied memory cards (if present) in the respective recorders to ensure that they cannot get lost and to prevent dirt from entering the opening.

Do not insert or remove memory cards unless the device is switched off. The supplied memory cards are only intended for the respective device. Do not use the card to store any other data.

Only use the original memory card. Additional memory cards are available as accessories.

Use the supplied memory card case to send in defective memory cards. If using multiple recorders and/or memory cards, be careful not to confuse them.

1.2.3 Patient safety

Fig. 1: Safety distances at the patient area

Without medical protective devices, for example medical protector, the PC and all the non-medical devices connected to the system (e.g. the monitor and printer) must be set up and used at a distance of at least 1.5 m to the patient unit (see the orange area in the figure) as leakage currents can occur.

During examination or routine maintenance, do not touch non-medical equipment and the patient at the same time (risk of electric shock). Make sure that the electrode contacts do not come into contact with other conductive parts.

All results achieved by automatic analysis and the resulting unconfirmed reports produced by the system must be considered as suggestions only. For diagnosis and therapy purposes it is essential that the results are checked and assessed by a qualified physician.

1.2.4   System and data security

> **IMPORTANT:** Patient data must be handled in accordance with the legal requirements of the respective country (this includes the General Data Protection Regulation (GDPR)). custo diagnostic offers functions to help you meet these requirements (e.g., user administration, password assignment).

Manufacturer's note for users/customers for the integration of programmable electronic medical systems (PEMS) into existing IT networks

The custo med products and systems are programmable electronic medical systems (PEMS). The integration of custo med products into an IT network that includes other devices can lead to risks for patients, operators or third parties that were not previously known. The responsible organisation should identify, analyse, evaluate and control these risks. Subsequent changes to the IT network can lead to new risks, and therefore require additional analysis.

Changes to the IT network include the following: Changes to the IT network configuration, connecting additional items to the IT network, removing items from the IT network, updates/upgrades of devices that are connected to the IT network.

custo diagnostic

The device must only be used with the supplied custo med software (custo diagnostic).

As the operator you are responsible for ensuring regular data backups (patient databases, evaluations etc.) and system backups. We recommend that you backup the data at the latest before new installations, updates and far-reaching system configurations.

custo diagnostic new installations, updates and system configurations may only be performed by your authorised custo med distributor.

Only change data generated in custo diagnostic within custo diagnostic itself and not in your surgery IT system or your hospital information system (HIS). custo med does not accept any responsibility for any changes to data in your IT system or your HIS which were made after the export from custo diagnostic.

To ensure the safe operation of custo diagnostic, deactivate the screensaver and energy management options on your PC. Set up your operating system in such a way to prevent the PC from being switched off either accidentally or automatically during the examination (standby mode/idle mode).

custo connect

When you use custo connect to integrate additional medical devices in the custo med system, for automatic PDF printouts from the connected medical device, check whether the PDF file belongs to the current patient. Do not trigger any PDF printouts in other programs during the PDF printout in the connected medical device.

If you use custo connect to integrate additional medical devices in the custo med system, on starting the connected medical device check whether the patient's name was taken over correctly.

Allocation of case and job numbers

If case or job numbers are manually entered into the system or they are changed in the system, there is a risk of confusing patients and subsequent misdiagnosis if an incorrect entry is made by a user. Always make sure that case or job numbers are entered correctly!

Scanning or manually entering patient, case or job numbers does not relieve the user of the obligation to check the patient to be physically treated.

Data management in custo diagnostic: Assign evaluation (allocate evaluation)

If an examination was conducted with incorrect patient data, the evaluation can be subsequently allocated to the correct patient. Make sure that the evaluation is definitely allocated to the correct patient. Incorrect allocation can lead to misdiagnosis. Please note that data which has already been exported to an external system (e.g., surgery IT system) cannot be changed.

custo diagnostic is preset with the Assign evaluation function deactivated; however, it can be reactivated via user rights if necessary. Only the Supervisor can configure user rights. If the Assign evaluation function is activated, it can be found in the evaluation search or in open evaluations in the Options menu.

We recommend configuring user rights in custo diagnostic so that only authorised persons can execute the Assign evaluation function.

1.2.5   Information on EMC (Electromagnetic Compatibility)

The use of other accessories, other converters and leads than those indicated, except for the converters and leads sold by custo med as spare parts for inner components, can lead to increased electromagnetic emissions or to a reduced electromagnetic immunity of the system. For connecting the device to other equipment, only specially screened cables supplied by custo med must be used.

1.2.6   Maintenance (regular safety checks)

The operator is responsible for maintenance.

Observe the legal regulations for checking electrical systems and equipment (e.g., Regulation 3 "Accident Prevention Regulation" of the German Social Accident Insurance (DGUV) in the Federal Republic of Germany).

The functionality and the state of accessories must be checked at regular intervals. If damaged or heavily soiled, the complete system must no longer be used.

After each system or device repair, modification or conversion, your authorised custo med distributor must perform a safety and conformity assessment.

1.3 Safety instructions for resting and stress ECGs

The device must be protected from dust and liquids.

The custo med ECG devices are protected against defibrillation only in connection with the manufacturer's patient cable.

In the event of defibrillation, take note of the manufacturers' instructions regarding the safe and proper use of the defibrillator.

Defibrillation has an interfering effect on the ECG recording. custo cardio ECG devices have a recovery time of less than five seconds.

For ECG recordings with custo cardio 400 in connection with the extension arm, the plug coupling (power supply cable at the bottom end of the extension arm) and the patient must NOT be touched at the same time.

Make sure that the electrode contacts do not come into contact with other conductive parts.

If electrodes become detached from the patient during an ECG recording or the electrode contact is too weak, a red signal line will be displayed on the corresponding ECG channel in custo diagnostic. Below the ECG recording a hint will appear (in red letters) indicating which electrodes are concerned. Reattach them. The appearance of red signal lines in custo diagnostic does not indicate that the patient has an asystole.

custo diagnostic provides pacemaker detection. Here, the pacemaker pulse from the ECG signal (in two channels at least) is detected and then projected into the ECG recording as an (artificial) spike, precisely timed.

However, the pulse width of the pacemaker is not calculated with the pacemaker detection in custo diagnostic in conjunction with custo cardio 100/110/130/200. These devices are not suitable for binding pacemaker checks. In case of doubt, use the device approved by the pacemaker manufacturer (see the patient's pacemaker record).

custo cardio 400 accu is not suitable for intracardiac use.

custo cardio 400 accu has no protection against possible influences from high-frequency (HF) surgical devices.

custo cardio 400 accu must not be used in the vicinity of HF surgical devices.

Use of the custo cardio 400 accu in conjunction with life-support equipment is not permitted. The device is not suitable for intensive care or as an alarm system for life-sustaining body functions.

1.4 Residual risks resting and stress ECG

CAUTION

Skin irritations and hematomas due to negative pressure.

Skin irritations and hematomas due to negative pressure possible during operation with higher suction levels.

→ Ensure that the suction level is set correctly.

→ If the patient suffers from diseases, e.g. arterial occlusive disease or severe blood coagulation disorders, the physician must decide on the use of the device

WARNING

Risk of injury due to changes in acceleration, speed or incline of the treadmill.

Unexpected, abrupt stopping or starting of the treadmill can cause injury to the patient. Bruises, strains or fractures from tripping and falling.

→ Inform patient before making any change in acceleration, speed or incline.

→ Do not make changes until the patient has adjusted.

2   Hardware

2.1   Intended use

custo cardio 400 accu is a 12-channel PC ECG device designed for the creation, analysis and evaluation of ECG recordings in medical practices and hospitals.

custo cardio 400 accu has an integrated electrode application system. The electrode application system uses underpressure to attach the electrodes to the body of the patient.

The device must be operated by suitably trained and qualified personnel in medical practices, laboratories, rehab centres and hospitals. This includes, in particular, doctors and medical-technical assistants.

custo cardio 400 accu can be used safely on patients with pacemakers.

custo cardio 400 accu is not suitable for intracardiac use.

Use of the custo cardio 400 accu in conjunction with life-support equipment is not permitted. The device is not suitable for intensive care or as an alarm system for life-sustaining body functions.

2.1.1   Indications and contraindications

Sauer, G. et al. (2005) '[Position paper to the taking of quality controls for resting, exercise, and long-term-ECG].', Zeitschrift fur Kardiologie, 94(12), pp. 844–857. doi: 10.1007/s00392-005-0320-4.

Indications Resting ECG

→   Suspected cardiovascular system disorder (e.g. MI, CHD, cardiac insufficiency, arterial hypertension, hypertrophy, myocarditis, pericarditis)
→   Supervision and monitoring of patients with acute or chronic cardiovascular disorders (e.g. MI, CHD, cardiac insufficiency, arterial hypertension, hypertrophy, myocarditis, pericarditis)
→   To assess a preoperative risk
→   To assess a postoperative intervention
→   To assess and supervise medication therapy (in particular for cardiologically active substances such as tricyclic antidepressants, neuroleptics, etc.)
→   To assess structural heart problems with cardiac arrhythmia (especially sinus tachycardia and sinus bradycardia)
→   Suspicion or monitoring of (cardiac) hypertrophy
→   To check for comorbidities (for example with chronic respiratory disease)
→   As part of pacemaker therapy
→   For angina pectoris
→   For suspected or diagnosed arterial sclerosis
→   For suspected or diagnosed PAD (peripheral arterial disease)
→   For diagnosed renal arterial stenosis
→   To assess patients as part of a rehabilitation program
→   Acute coronary syndrome with no ST segment elevation (NSTE-ACS)

Indications Stress ECG

→   For CHD diagnosis
→   Post-myocardial infarction
→   Before and after revascularisation measures for progress monitoring

→ For patients with diagnosed or suspected arrhythmia
→ For patients with arterial hypertension
→ To record physical resilience

Contraindications Stress ECG

Absolute:
→ Acute myocardial infarction
→ Unstable angina pectoris
→ Cardiac arrhythmia with symptomatology and/or impaired haemodynamics
→ Symptomatic severe aortic stenosis
→ Decompensated cardiac insufficiency
→ Acute lung embolism
→ Acute myocarditis
→ Acute perimyocarditis
→ Acute aortic dissection

Relative:
→ Main stem stenosis
→ Moderate valvular disease
→ Diagnosed electrolyte disorder
→ Arterial hypertension (syst. 200, diast. > 110 mmHg)
→ Tachyarrhythmia or bradyarrhythmia
→ Hypertrophic obstructive cardomyopathy and other outflow tract obstructions
→ Higher-degree atrioventricular blockage
→ Physical and/or mental impairments

2.1.2 Device types and functions

Type	Connection to PC	Power supply
custo cardio 400 BT	USB (3 m) and Bluetooth 2.1 EDR	12 V power supply
custo cardio 400 accu	USB (3 m) and Bluetooth 2.1 EDR	Lithium polymer battery, 12 V power supply unit

2.2 Symbols on the devices and packaging

	Manufacturer: custo med GmbH, Maria-Merian-Str. 6, 85521 Ottobrunn, Germany
	Date of manufacture (YYYY-MM, e.g., 2022-01)
CE 0123	CE mark
SN	Serial number
	Follow the Operating Manual!
	Protection class designation of a medical electrical device 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 of electrical and electronic equipment, do not dispose with domestic waste.
	Hygiene seal of the German Society of Hospital Hygiene

2.3   Technical data and system requirements

1) In standby mode, the pump and valve are deactivated. Communication via USB/BT and manual configuration of the system is still possible. Standby mode is not activated during an ECG recording.

custo cardio 400 accu

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	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
Suction output	Level 0 = 0 mbar
	Level 1 = 60 mbar
	Level 2 = 100 mbar
	Level 3 = 140 mbar
	Level 4 = 180 mbar
	Level 5 = 220 mbar
	Level 6 = 280 mbar
Power supply	Lithium-polymer battery/12 V power supply
Battery specifications	Charging time: approx. 4.5 hours at 1.5 A charging current in standby, extended charging time with simultaneous operation
	Running time: approx. 9 hours (at pressure level 3), varies depending on pressure level and leaks
	Service life: at least 500 charging cycles
Max. Power consumption	19 watts (charging in standby)
IT connection	USB (3 m) and Bluetooth 2.1 EDR
Radio frequency band	Bluetooth 2.1 EDR: 2.402 - 2.480 GHz (ISM band)
Radio transmission power	Bluetooth 2.1 EDR: max. 10 dBm
Bluetooth range	typ. 10 m, depending on ambient conditions
Time to standby mode[1]	after disconnection from USB: 30 min
	after last BT communication: 30 min
	after last manual configuration: 30 min
Energy saving mode	after 1 minute of inactivity
IP protection class	IPX0 (not protected against water penetration)
Dimensions	250 * 110 * 60 mm (L * W * H)
Weight (without cables)	approx. 940 g
Electrode suction tubes	approx. 1200 mm, approx. 1450 mm, approx. 1650 mm
Operating conditions	Temperature +10°C ... +40°C
	Humidity 30 ... 75 % rH
	Air pressure 700 ... 1060 hPa
Transport and storage conditions	Temperature -20°C ... +45°C
	Humidity 30 ... 95 % rH
	Air pressure 700 ... 1060 hPa
Classification	Device with internal power supply
	Class IIa, application part type CF
Applied standards	DIN EN 60601-1, DIN EN 60601-1-2, DIN IEC 60601-2-25

General system requirements

Operating system	The custo diagnostic software is only suitable for installation on Microsoft Windows systems.
	custo diagnostic 5 is a client/server combination. The custo diagnostic 5 server can only run on 64-bit systems.
	For proper operation it is necessary to use the operating system/software combinations tested and approved by custo med for the respective custo diagnostic version (also custo diagnostic server and client for custo diagnostic 5). These can be obtained from the authorised custo med dealer or directly from custo med.
PC	The PC's hardware must be compatible with Intel products and fulfil the minimum requirements for the operating system used.
	Provide additional RAM (1 GB) for custo diagnostic. 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 62368 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 connection

Resting and stress ECG · custo cardio 400 accu

Recommended system requirements

Computer	Intel Core i3-CPU with HD graphics 4400, 4 GB RAM, 256 GB SSD or SSHD (for single-user workstations 2TB HDD), 1 GBit network connection (for single-user workstations), fanless Dual-DVI (or DP) graphics card (for CPET)
	We recommend the current Windows version with all updates. Observe the specifications listed under "General system requirements, operating system" on the previous page for this!
Ports	One USB 2.0 port per USB device (preferably no USB 3.0), one COM port (serial) each for ergometers and treadmills, with built-in Bluetooth at least version 4.0, otherwise deactivatable in 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)

2.4 Putting out of operation, storage, transport, disposal

Putting out of operation and storage

→ Clean and disinfect the devices and their components before putting them out of operation.

→ Make sure that the storage location is dust-free, dry and away from direct sunlight.

→ After a long period of non-operation, the devices may only be used again if a technical safety check has been carried out by your authorised custo med distributor.

Transport

→ Clean and disinfect the devices and their components before transport.

→ Use the original packaging for transport. These devices are sensitive pieces of electronic equipment. If the original packaging is not available, pack the devices in such a way that they are protected against impact, moisture and dust.

→ The devices must comply with the operating conditions when they are put into operation again, e.g. operating temperature.

Disposal

→ The devices and all their components must be disposed of in a proper manner in compliance with applicable regulations (that is, in accordance with the valid laws governing waste electrical and electronic equipment).

→ The devices must not be disposed of as normal domestic waste.

→ Observe the disposal instructions for consumables.

→ The original packaging is recyclable (cardboard/waste paper).

Symbols for transport, storage and disposal

	Fragile, handle with care
	Keep dry
	Protect from sunlight
	Separate collection of electrical and electronic equipment, do not dispose with domestic waste.

2.5 Components for the recording

1 custo cardio 400 accu ECG application system
2 6 electrode suction tubes, length 1.45 m
4 electrode suction tubes, length 1.65 m
3 Electrode "hair", optionally other versions
4 Spacer 2-fold
5 Spacer 3-fold
6 Extension arm custo move for custo cardio 400 accu incl. USB cable
(holder for the extension arm included in the custo move scope of delivery)
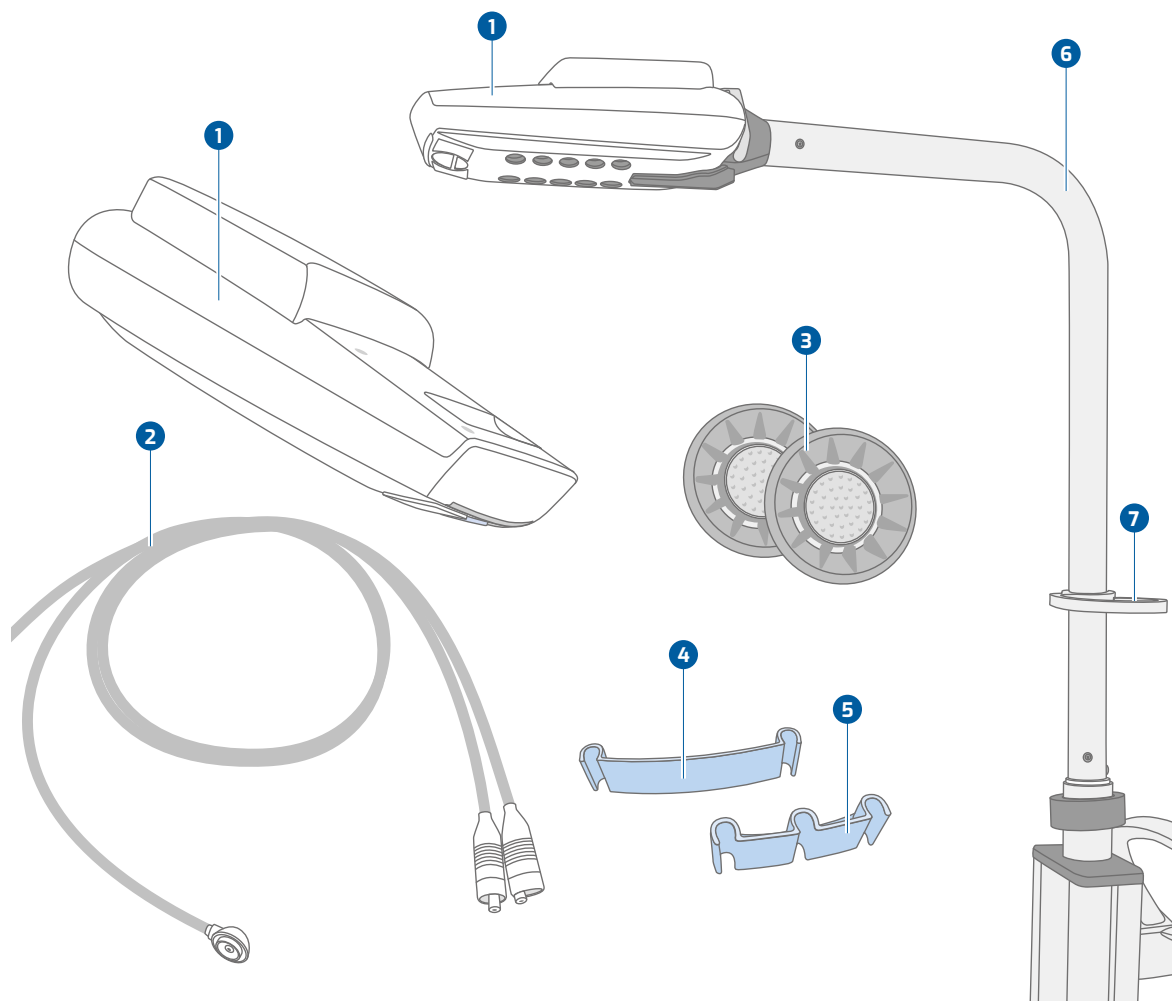**7** Cable hook for custo move extension arm

Fig. 2: custo cardio 400 accu part designation

Not shown

→ Bluetooth 4.0 USB adapter
→ USB extension cable 1.8 m, plug A-socket A
→ Power supply unit for custo cardio 400
→ Power cable 1 m for power supply unit

2.6 Mounting, preparing the device

2.6.1 Getting to know the operating elements on the custo move extension arm

Operating elements on the custo move extension arm

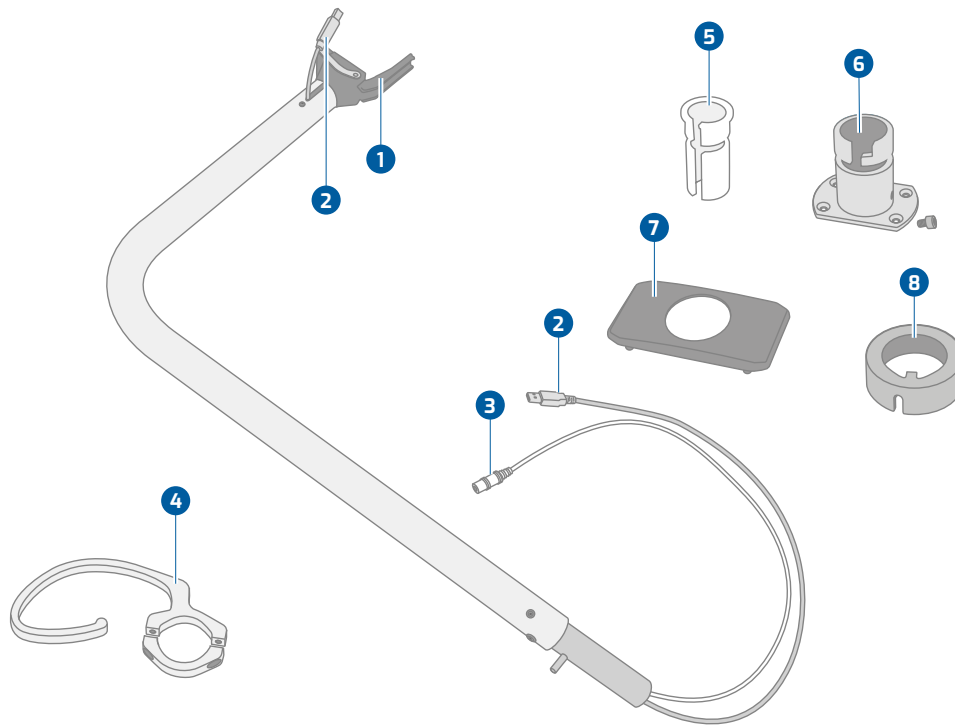*Fig. 3: custo move extension arm for custo cardio 400 accu*

1. Bracket for custo cardio 400 accu with safety bar
2. USB connection
3. Power cable
4. Cable hook for electrode suction tubes
5. Insert for the bracket
6. Bracket for custo move, with screw
7. Cover plate
8. Rotation collar

Attaching the cable hook

→ Attach the cable hook ④ to the custo move extension arm at the desired position using the screws supplied.

2.6.2   Mounting the custo move extension arm

Mounting the bracket for custo move extension arm

> **IMPORTANT:** The bracket **4** for the custo move extension arm is included in the scope of delivery of the extension arm. custo move must only be mounted with this bracket (with radial groove).

Preparing the custo easy plus 1 device trolley:

→   Remove the black cover plate **2** from the top of the custo easy plus.

→   Remove the four screws **3** of the extension arm holder already fitted to the custo easy plus and remove the extension arm holder.

Preparing the custo move bracket 4:

→   Remove the fixing screw from the custo move bracket.

→   Remove the white insert **5** contained in the custo move bracket (press out from below).

→   Screw the custo move bracket **4** onto the device trolley with the vertical groove facing backwards. Use the screws supplied.

→   Then attach the cover plate **2** (included with custo move). To do this, slide the round opening over the bracket **4** so that the column of the device trolley is closed at the top.

→   Then fit the insert **5** for the custo move extension arm into the bracket **4** from above.

→   The vertical groove of the insert **5** is aligned to the rear, corresponding to the groove in the bracket **4**.
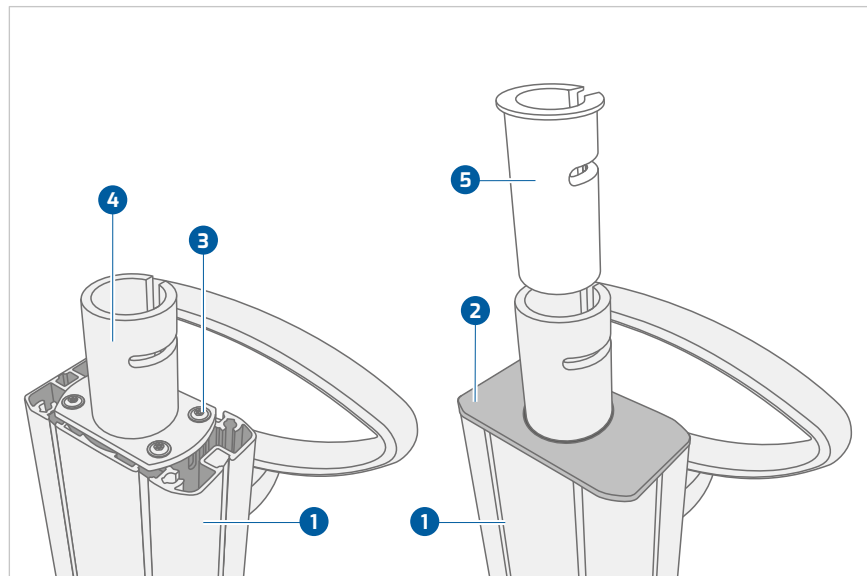

Fig. 4: Mounting the bracket for custo move extension arm

1   custo easy plus device trolley
2   Cover plate
3   Screws for attaching the bracket
4   Bracket for the extension arm
5   Insert for custo move extension arm

Inserting the custo move extension arm into the bracket

→ Thread the rotation collar onto the USB and power cable. The recess in the rotation collar points to the lower end of the extension arm.

→ Insert the USB and power cable of the custo move extension arm into the column of the device trolley via the opening in the bracket.

→ Align the custo move extension arm so that the shaft screw on the rear of the extension arm can be guided through the vertical grooves of the insert and bracket.

→ Insert the custo move extension arm.

→ Slide the rotation collar onto the insert and bracket. The upper edge of the rotation collar is below the upper edge of the bracket.

→ Bring the rotation collar into the "swivel position". The rectangular element inside the rotation collar must be at the upper right edge of the bracket.
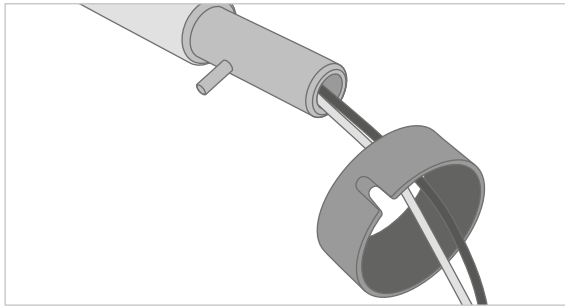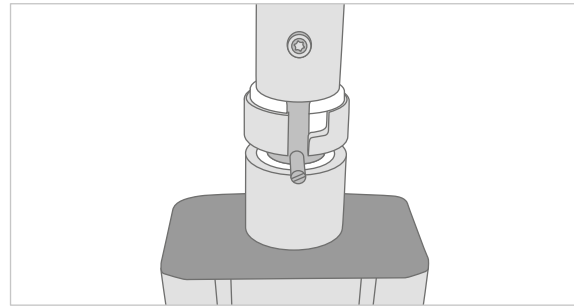

Fig. 5: Thread the rotation collar

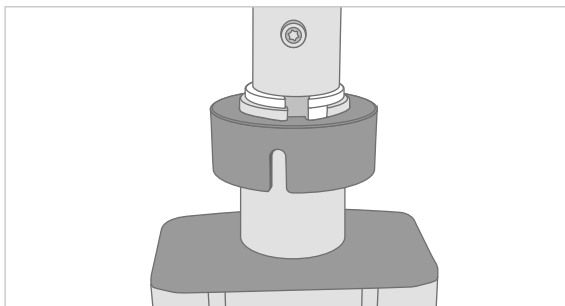*Fig. 6: Insert extension arm, shaft screw in vertical groove*

Fig. 7: Slide rotation collar onto bracket
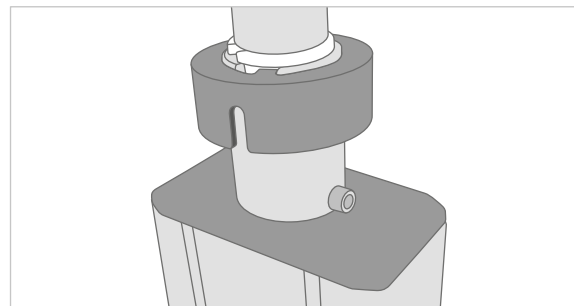

Fig. 8: Rotation collar in "swivel position"

Securing the custo move extension arm in the bracket

→ Viewed from above, turn the custo move clockwise as far as it will go in the bracket.

→ Then fasten the insert in the bracket using the screw supplied (on the left side of the holder as viewed from the front).

→ The custo move extension arm is now fully mounted.

Inserting the custo cardio 400 accu into the custo move extension arm

→ Pull the safety bar backwards **1**.

→ Insert the custo cardio 400 accu into the bracket on the extension arm from above **2**.

→ Press the device into the bracket until it clicks into place, so that the safety bar folds forward again **3**.

→ Important: Only connect the USB cable to the PC after installing the custo diagnostic software.
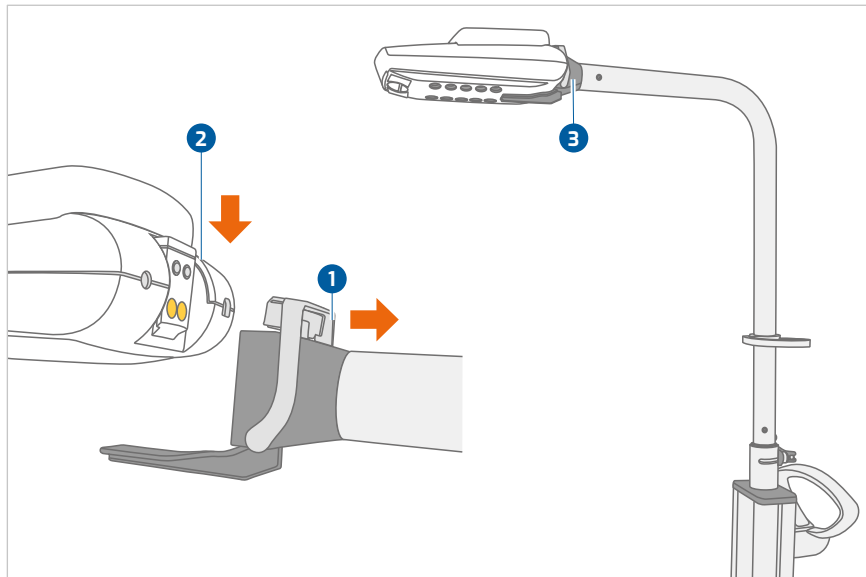

Fig. 9: custo cardio 400 accu on the custo move extension arm

2.6.3   Operating the custo move extension arm

Using the swivel range, rotating custo move:

→   Bring the rotation collar into the "swivel position". The rectangular element inside the rotation collar must be at the upper right edge of the bracket. The swivel range can be used.

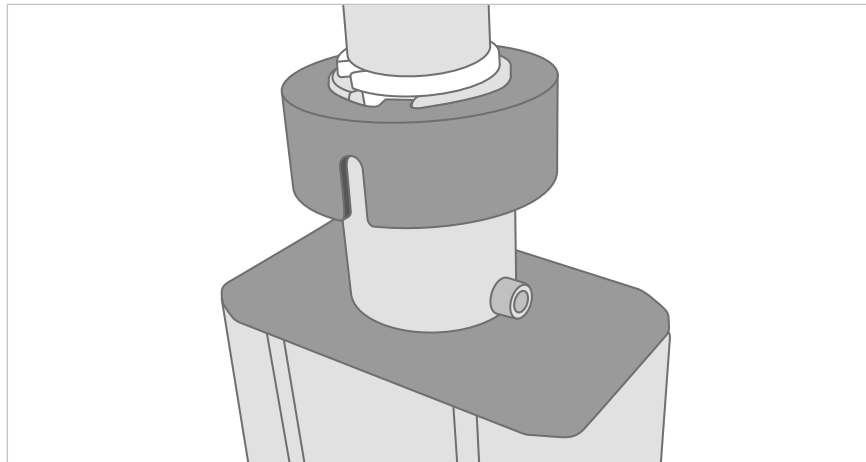→   Rotate the custo move extension arm into the desired position.

Fig. 10: Rotation collar in "swivel position"

Using the swivel range, fixing custo move in place:

→   To move custo move safely from one location to another, it is necessary to lock the rotation.

→   Turn the rotation collar clockwise so that the rectangular element inside the rotation collar is on the left edge of the vertical groove.

→   Slowly rotate the custo move extension arm until the rotation collar slides down and locks into place.

→   When the rotation collar is in the correct position, the custo move extension arm can no longer be rotated.

2.6.4   Removing the custo move extension arm, disassembly

Disassembly, removing custo move from the bracket

→   Remove the custo cardio 400 accu from the custo move extension arm.
→   To do this, disconnect the USB cable and, if necessary, the external power supply from the custo cardio 400 device.
→   Pull the safety bar backwards and remove the device upwards.
→   Remove the screw that holds the custo move extension arm in place (on the left side of the bracket as viewed from the front).
→   Bring the rotation collar into the "swivel position". The rectangular element inside the rotation collar must be at the upper right edge of the bracket.
→   Align the custo move extension arm straight forwards.
→   Pull the custo move and the USB and power cable upwards out of the bracket.
→   Remove the white insert from the extension arm.
→   Replace the white insert in the bracket.

2.6.5   Attaching electrode suction tubes to the device

→   Attach the coding stickers to the ends of the electrode suction tubes ❶.

→   Stickers "C1 to C6"
on the shorter electrode suction tubes:
with custo cardio 400 BT 1.20 m long,
with custo cardio 400 accu 1.45 m long.

→   The stickers "R, L, F and N"
on the longer electrode suction lines:
with custo cardio 400 BT 1.45 m long,
with custo cardio 400 accu 1.65 m long.

→   Connect the electrode suction tubes to the device according to
the coding ❷.

→   Press the electrodes onto the ends of the electrode suction tubes until you
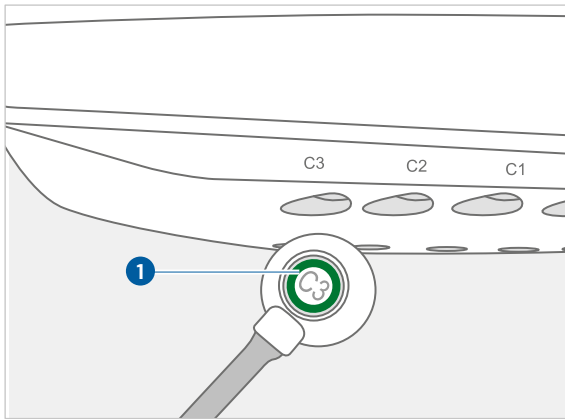hear a click ❸.

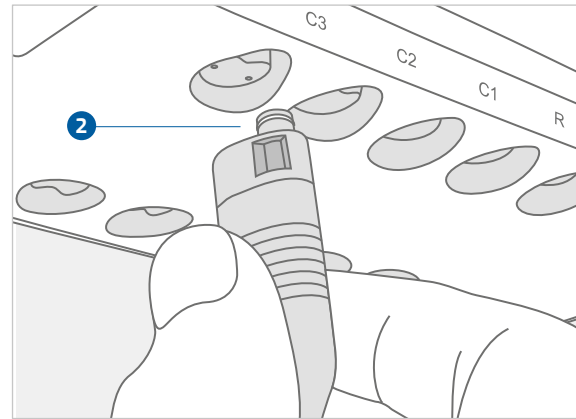*Fig. 11: Attaching the coding sticker*
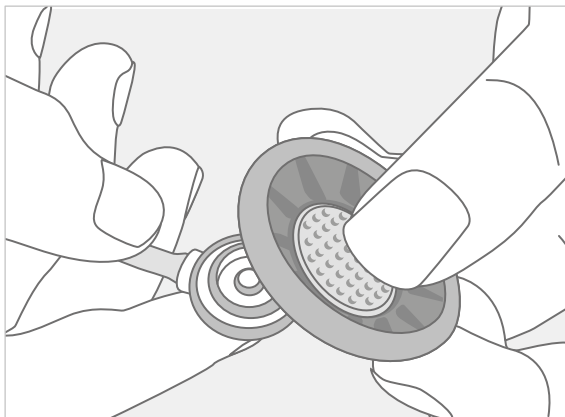

Fig. 12: Connect electrode suction tube to the device
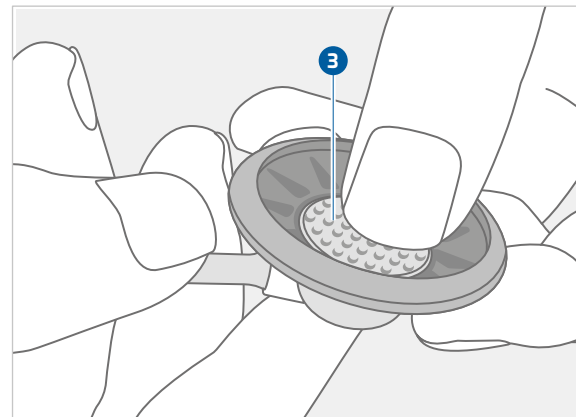

Fig. 13: Place electrode on the suction tube

Fig. 14: Attach electrode to the suction tube

Resting and stress ECG · custo cardio 400 accu

2.7 Device operation

2.7.1 Charging custo cardio 400 accu

The custo cardio 400 accu device type has a lithium polymer battery located on top of the housing ❶. The battery is permanently mounted and cannot be removed. To replace the battery, contact your authorized custo med dealer.

i

> **INFORMATION:** Observe the operating and storage conditions and only use the power supply unit supplied for charging.

Commissioning and charging in normal operation

On delivery, custo cardio 400 accu is in shipping mode to protect the battery (no illuminated displays, all keys inactive). To cancel the shipping mode and charge the device, connect custo cardio 400 accu to a power supply. Either directly via the supplied power supply unit ❷ or via the power supply of the extension arm ❸ if it is connected to the mains via the supplied power supply unit.

As soon as the power supply is plugged in, the pressure level display of the custo cardio 400 accu device lights up in orange for approx. three seconds, or flashes three times in orange ❹, depending on the device status (e.g., Stand-by mode, Energy-saving mode, Cleaning mode …). This provides feedback on whether the required charge current is supplied and the device is being charged. Only if the pressure level display of the custo cardio 400 accu device lights/flashes orange for approx. three seconds directly after plugging in the power supply, the charging current is available.
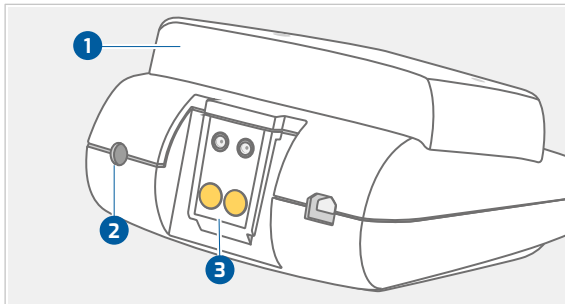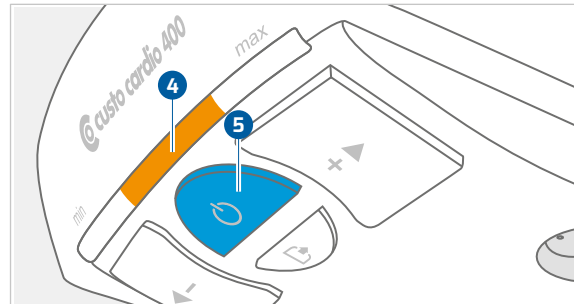

Fig. 15: custo cardio 400 power supply

Fig. 16: Status after plugging in the power supply unit

Afterwards, the device is in standby mode, the On/Off button is constantly illuminated blue ❺. When inactive, the device is put into energy-saving mode after one minute – the On/Off button flashes blue and the battery charge status is indicated by a light indicator in the middle of the front of the housing: purple below 20 %, blue 20 % to 80 %, green above 80 %.

custo cardio 400 accu is charged as soon as the device is connected to a power supply.

Loading and running times

Charging time	approx. 4.5 hours at 1.5 A charging current in standby, extended charging time during simultaneous operation, e.g. cleaning
Running time	approx. 9 hours (at suction level 3), depending on the suction level and leakages the running time varies!!

IMPORTANT: Fully charge custo cardio 400 accu before first use.

2.7.2   Restoring shipping mode

custo cardio 400 accu can be reset to shipping mode, e.g., in case of prolonged non-use, to protect the battery and the electronics. To restore the shipping mode, press and hold the On/Off button ❶ and the cleaning button ❷ simultaneously for three seconds. The complete pressure level display then lights up orange and goes out bit by bit (countdown). When the light has gone out completely, custo cardio 400 accu is again in shipping mode.

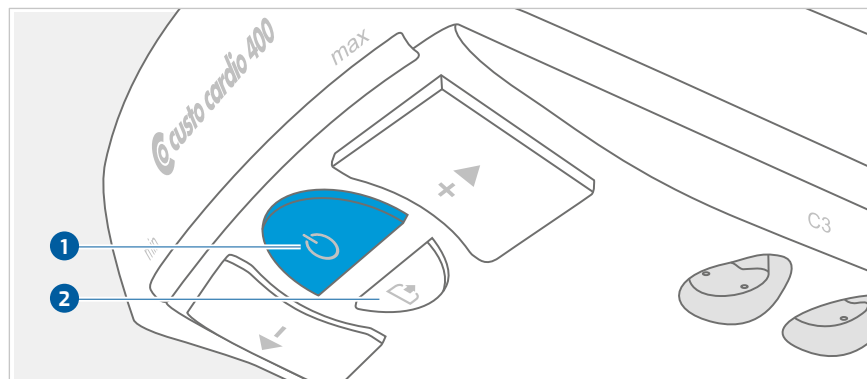3 seconds On/Off key + cleaning button = shipping mode

Fig. 17: On/Off button and cleaning button

2.7.3   Safety mode

If the custo cardio 400 accu device is not used for a longer period of time and the battery is discharged, the device may be put into safety mode to protect the battery. All keys are inactive and no LEDs are displayed.

To use custo cardio 400 accu again, connect it to a power supply. If a mobile use of the device is planned, make sure that the battery is sufficiently charged.

To ensure availability for mobile use, we recommend connecting custo cardio 400 accu to a power supply when not in use (e.g. overnight or at weekends).

2.7.4   Display and control elements

INFORMATION

Prerequisite for an examination: proper installation, configuration and commissioning of the system by your authorized custo med dealer.

The display and operating elements are located in the front area of the bottom of the housing. The display and operating elements provide feedback on the device status with different light states.

1. On/off button
2. Suction level and status display (for operating mode and battery, if applicable)
3. Suction level control: controls how firmly the electrodes are seated on the patient's skin (manually adjustable level 1 to 6)
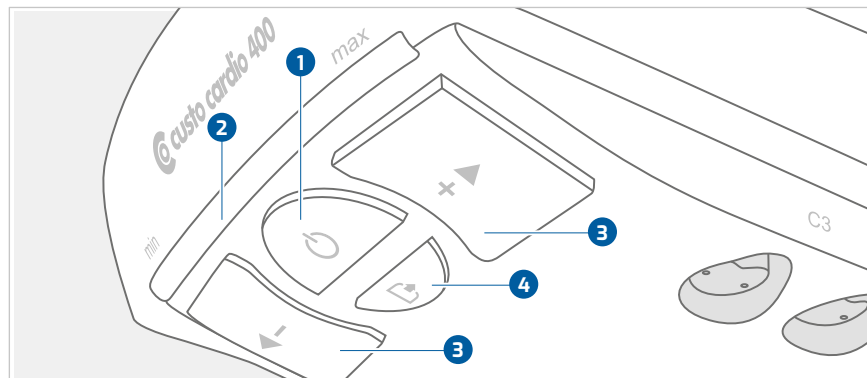4. Cleaning button: for manually blowing out the leads

Fig. 18: custo cardio 400 accu display and operating elements

2.7.5   States of the suction level and status display

During operation, when performing an ECG recording, the suction level and status display ❶ provides information about the current operating mode.

With custo cardio 400 accu the suction level and status display also shows the battery charging status.

Operating modes and states of the suction level and status display

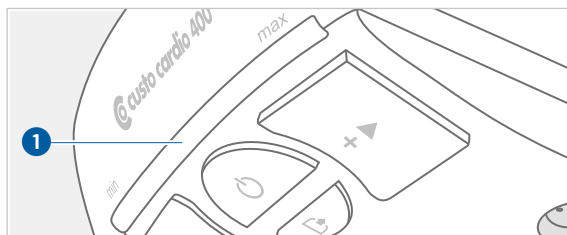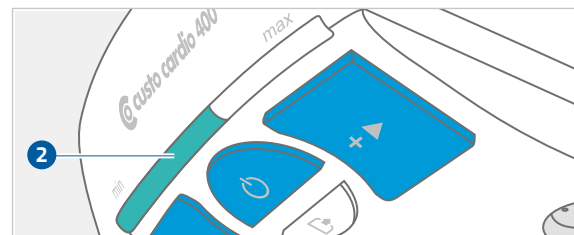|	
Turquoise	USB operation ❷
Blue	Bluetooth/WLAN operation
Orange	Manual recording by pressing a button
Green	Blowing out the electrode suction tubes
Yellow	Warning
Red	Error, service case

Fig. 19: Suction level and status display

Fig. 20: USB operation

Charging status display in energy-saving mode

Green	Battery charging level over 80 % **③**
Blue	Battery charging level between 20 % and 80 %
Purple	Battery charging level below 20 % **④**

Charging level warning during operation

If the charging level is below 20 %, the suction level indicator **①** lights up purple **④** during operation at the level of the set suction level instead of the colour of the operating mode (e.g., turquoise for USB). Even during the release time (short blow-out of the electrode suction tubes after completion of an ECG recording), the suction level display lights up purple instead of green in this case.
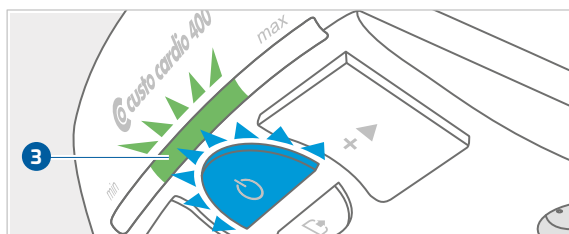

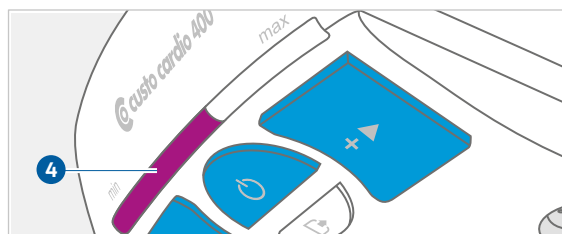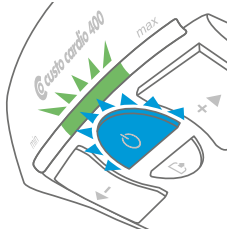Fig. 21: custo cardio 400 accu Battery charging level over 80%.

Fig. 22: custo cardio 400 accu Battery charging level below 20%.

Resting and stress ECG · custo cardio 400 accu

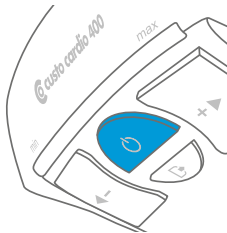### 2.7.6 Device states in standard operation

Energy saving mode

The On/Off button flashes blue and the charging status is shown in the suction level and status display. Briefly pressing the On/Off button puts custo cardio 400 accu into standby mode. The device can also be activated directly via custo diagnostic, by calling up the ECG interface.

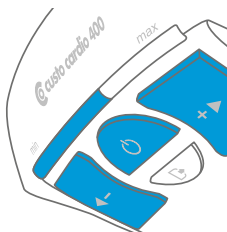custo cardio 400 accu is switched back to energy-saving mode after one minute of inactivity.

Standby

The On/Off button is constantly illuminated in blue. The device functions are active. The suction level control can be activated by briefly pressing the On/Off button, e.g. to apply the electrode suction tubes to the patient. Otherwise, the suction level control is activated automatically when the ECG surface is called up.

The cleaning can be started by pressing the cleaning button (prolonged blowing out of the electrode suction tubes, e.g., for 30 minutes).
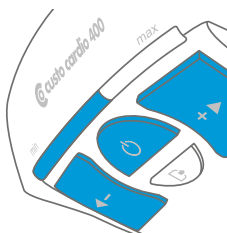
Monitoring, status before an ECG recording

When the ECG interface is called up in custo diagnostic, the suction level control is activated and the electrode suction tubes can be applied to the patient. The patient's ECG signal is displayed on the screen.

In this state, the On/Off button and suction level control light up blue. The suction level and status display shows the preset suction level in the colour of the operating mode. The suction level can be adjusted manually by pressing the +/- buttons (in this case, the automatic suction level control is deactivated).

ECG recording

Recording is triggered in custo diagnostic with the Start or Autostart button. Manual start by pressing a button on the device is also possible, *see 2.7.7 Further states and special functions, p. 37*. The indicator lights during a recording corresponds to the display during the monitoring.

If the charge level is below 20 %, the suction level and status display lights up purple during operation at the level of the set suction level instead of the colour of the current operating mode. Recharge the device as soon as possible!

Status at the end of ECG recording

When the ECG recording is ended, the electrodes are discarded and the electrode suction tubes are briefly blown out. During this process, the On/Off button and the cleaning button light up blue, and the suction level and status display lights up green for the duration of the blow-out.

The green suction level and status display decreases in accordance with the elapsed release time (if the total duration of the release time is less than one minute).

Resting and stress ECG · custo cardio 400 accu

2.7.7 Further states and special functions

Changing the operating mode

If a USB connection is available, this will be prioritized over the wireless connection due to the higher data rate. The connection can only be changed by the device (e.g. from Bluetooth to USB) if there is no recording.

Figure: USB connection, suction level and status display changes from blue (Bluetooth) to turquoise (USB connection).

Manual start and stop

An ECG recording can be triggered not only via the custo diagnostic ECG interface, but also by pressing the On/Off button on the device. To do this, open the ECG interface in custo diagnostic and press the On/Off button on the device. The status display lights up orange and the ECG recording takes place according to the custo diagnostic configuration. In the case of recordings with no time limit, the On/Off button must be pressed again to end the recording (e.g. with rhythm strips).

Figure: manual start of a recording, suction level and status display lights up orange.

Automatic suction level control

For this function, the suction power in custo diagnostic must be at least set at level 3. With the automatic suction level control, the suction level is increased until the system is tight or the electrodes are sufficiently tight against the patient's skin. If the suction level is set manually, the automatic suction level control is deactivated.
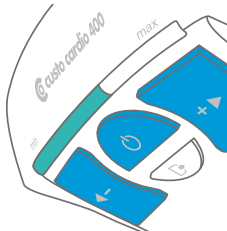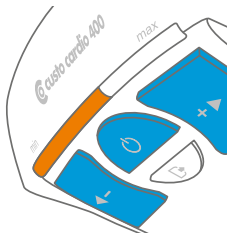
Permanently deactivate or activate automatic suction level control

The automatic suction level control is activated by default. To deactivate the automatic suction level control permanently, press the left arrow key and the On/Off button simultaneously for 3 seconds. To confirm, the middle LEDs of the suction level display light up orange. The next time an ECG recording is started in custo diagnostic, the automatic suction level control will be omitted. In the operating mode "without automatic suction level control", the on/off button flashes every second (slowly pulsating) during an ECG recording.

To reactivate the automatic suction level control, press the left arrow key and the on/off button simultaneously for 3 seconds. Deactivating and activating the automatic suction level control may only be done in the stand-by state, not during an ECG recording.

Cleaning the electrode suction tubes

The cleaning function should be used regularly, e.g. always at the end of a working day. Pressing the cleaning button causes the moisture to be blown out of the electrode suction tubes for a longer period of time. Process according to settings in custo diagnostic, factory setting: 30 minutes. After the cleaning time has elapsed, the device switches to standby mode.

With the custo cardio 400 accu device, it is recommended to activate the cleaning function in mains operation when the device is connected to a power supply via the supplied power supply unit. Cleaning in battery mode leads to increased battery consumption.

Figure: Illuminated display during cleaning of the device. On/Off button and cleaning button light up blue

Warning messages of the device

In case of technical problems, the left LED of the suction level and status display lights up yellow or red. Some problems can be solved by the user, *see 2.7.8 custo cardio 400 accu troubleshooting, p. 39*. Otherwise, contact your authorized custo med dealer.

Restarting the device and resetting the Bluetooth connection

When commissioning or when using the device on a mobile basis, the existing Bluetooth connection may have to be reset (e.g. to enable a connection to another workstation). To do this, press the "+" and "-" buttons simultaneously for approx. 3 seconds. The device switches off briefly and starts again.

2.7.8   custo cardio 400 accu troubleshooting

In the event of an error, the custo cardio 400 accu suction level display lights up yellow or red. The cause of a warning display is stored in the custo cardio 400 accu error log file and can be viewed there. To open the error log file, the custo cardio 400 accu device must be connected to the PC via USB. In this case, the device is displayed as custo cardio 400 mass storage. Open the directory of the custo cardio 400 mass storage device via Windows Explorer. The file is called "error.log" and can be opened with a text editor.

Warning display lights up yellow ❶ , ❷

The system is leaking

The device tries to reach the preset pressure, e.g. 280 mbar (suction level 6) for five minutes. If this is not successful, the warning display lights up yellow ❶. The ECG recording can still be continued. ECG recording with a leaky system, however, results in poor ECG quality!

→ Start the device without a patient (press On/Off button).
→ If the device controls extremely often (engine noise), there is a mechanical problem:
  → One or more sealing rings on the electrode suction tubes are missing/stuck in the housing.
  → The electrodes are not tight (dirt, e.g. from hair).
  → The unit has an internal defect (service case).
→ If the unit is tight without a patient, check and correct the following points during use on the patient:
  → Selection of the appropriate electrode type (child, normal, hair).
  → Placing the electrodes on a less hairy part of skin/shave patient.
  → Selection of a lower suction level which is more easily achieved. Note: electrodes adhere less strongly, possibly reduced quality of the derivations.

Fig. 23: System leaking

The pressure in the system is too high

The system may be clogged, e.g. too much moisture in the electrode suction tubes – the yellow warning indicator ❷ appears.

→   Start a cleaning cycle with the cleaning button (longer blowing out of the electrode suction tubes).

→   If this error still occurs or if the red light indicator appears during cleaning, contact your authorised custo med dealer.

Fig. 24: Pressure in the system too high

Warning indicator lights up red ❸

Defect on the device. The device must be sent in for repair. Contact your authorised custo med dealer.

Fig. 25: Defect on the device

2.8   Procedure of an examination

IMPORTANT:

Note on contact spray

Never spray the contact spray onto the electrodes or into the electrodes or leads. Do not use water or contact gel!

Recommended contact sprays from C+V Pharma Depot GmbH or GE Medical Systems. Only use recommended contact sprays. Residues of other products can damage the electrodes.

INFORMATION

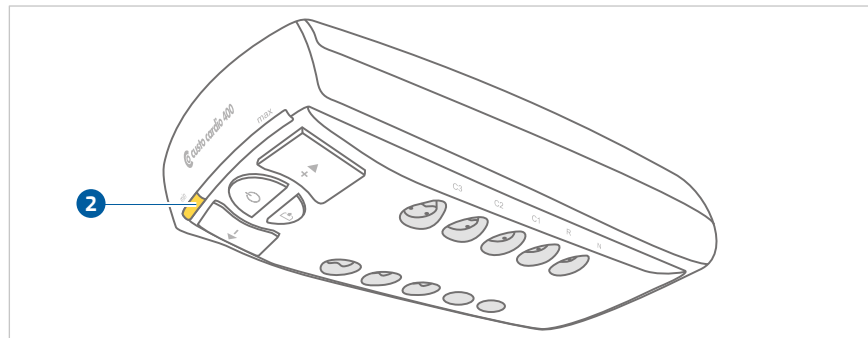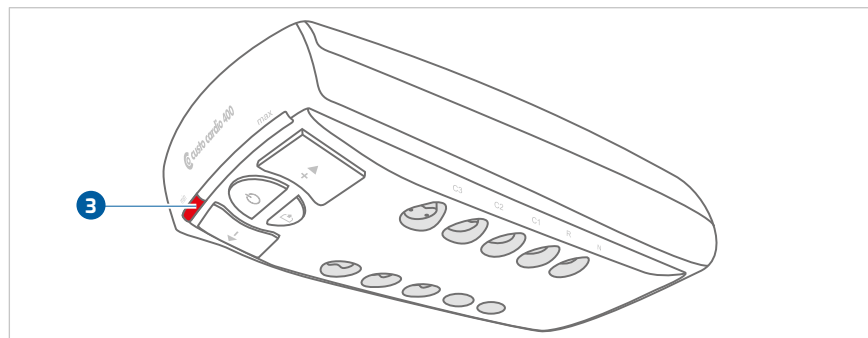Prerequisite for an examination: proper installation, configuration and commissioning of the system by your authorized custo med dealer.

Resting ECG

→ Ensure that the ECG device is connected to the PC and that power is supplied to the device.
→ Check that your patient is lying comfortably and is not cold.
→ Start custo diagnostic and click on Examination, Resting ECG, New Resting ECG.
→ Spray contact spray on the electrode contact points.
→ Apply the electrodes to the patient according to the application diagram, *see 2.9.1 Positions of the electrodes, p. 43*.
→ Start the recording.
→ The patient should remain calm during the recording.

Stress ECG

→ Ensure that the ECG device is connected to the PC and that power is supplied to the device.
→ The battery charging level should be > 20% (charging level indicator blue or green, not purple). Recharge device if necessary or use mains power!
→ When using an ergometer, make sure that the patient is in the optimal sitting position (the outstretched leg slightly bent).
→ When using a treadmill, be sure to follow the instructions for stress ECG with treadmill, *see 2.9.2 Notes on stress with treadmill, p. 44*.
→ Start custo diagnostic and click on Examination, Exercise Stress ECG, New Stress ECG.
→ Spray contact spray on the electrode contact points.
→ Apply the electrodes to the patient according to the application diagram, *see 2.9.1 Positions of the electrodes, p. 43*.
→ Wait a few minutes so that the contact between the skin and the electrodes can develop optimally.
→ Apply the blood pressure cuff.
→ Start the recording.

CAUTION

Skin irritations and hematomas due to negative pressure.

Skin irritations and hematomas due to negative pressure possible during operation with higher suction levels.

→   Ensure that the suction level is set correctly.

→   If the patient suffers from diseases, e.g. arterial occlusive disease or severe blood coagulation disorders, the physician must decide on the use of the device

Resting and stress ECG · custo cardio 400 accu

2.9 Attaching the recorder to the patient

2.9.1 Positions of the electrodes

Thoracic wall resting and stress ECG, standard according to Wilson

V1 (C1)	⭕	red	4th intercostal space at the right sternal border
V2 (C2)	⭕	yellow	4th intercostal space at the left sternal border
V3 (C3)	⭕	green	On the left on the 5th rib between C2 and C4
V4 (C4)	⭕	brown	5th intercostal space on the left midclavicular line
V5 (C5)	⭕	black	On the left on the anterior axillary line, on the level of C4
V6 (C6)	⭕	purple	On the left on the midaxillary, on the level of C4

Resting ECG extremities

R	🔴	red	Right arm
L	🟡	yellow	Left arm
F	🟢	green	Left leg
N	⚫	black	Right leg

Stress ECG (lying or sitting position): extremities

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

Stress ECG (sitting position): extremities

R	🔴	red	Attach to the deltoid muscle on the right
L	🟡	yellow	Attach to the deltoid muscle on the left
F	🟢	green	9th rib left
N	⚫	black	9th rib right

Fig. 26: C1 to C6

Fig. 27: R, L, F, N

2.9.2   Notes on stress with treadmill

→ The patient should ideally be wearing running shoes or trainers.

→ The patient should not hold on to the handles of the treadmill during recording. This causes muscle tension which affects 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 terminal lines.

→ The electrode cables should not touch the patient, the treadmill or other objects during ECG recording.

Fig. 28: Normal electrode application

Fig. 29: Artefact reduced electrode application

⭐ **TIP:** *Artefact reduced electrode application results in smaller amplitudes in the extremity derivations.*

2.9.3   Safe use of treadmills

WARNING

Risk of injury due to changes in acceleration, speed or incline of the treadmill.

Unexpected, abrupt stopping or starting of the treadmill can cause injury to the patient. Bruises, strains or fractures from tripping and falling.

→   Inform patient before making any change in acceleration, speed or incline.

→   Do not make changes until the patient has adjusted.

> **IMPORTANT:**
>
> 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.

3 Software

3.1 custo diagnostic program structure

The custo diagnostic program is divided into three areas: User, Patient and Examination. This structure ensures that you can always recognise who (which user) is carrying out what type of examination with whom (which patient).

The main menus of each area can be reached by clicking on User ❶, Patient ❷ or Examination ❸.

The user of the system can be selected in the main menu of the User ❶ area. User administration is performed in the custo diagnostic service center (create user, user rights, user-specific settings).

Patient administration takes place in the main menu of the Patient area ❷. The most important functions include Find patient, New patient and Find evaluation.

In the main menu of the Examination area ❸, all examination types that are possible with custo diagnostic are listed. Modules that have already been purchased are active (black font), all others are inactive (light grey font). This menu is also linked to the Settings area. This area is for making cross-program, examination-related and user-specific settings.

Fig. 30: custo diagnostic main menu

3.2   custo cardio 400 accu connection to the PC

IMPORTANT: Prerequisite - custo diagnostic is installed on your PC and ready for operation. The custo med devices and components may only be connected to the PC after custo diagnostic has been installed. The required device drivers are installed on the PC via the custo diagnostic standard setup or by specific selection during the custo diagnostic setup.

3.2.1   Connecting and configuring custo cardio 400

Connect the supplied power supply unit to the custo cardio 400 ECG device or to the custo cardio 400 supply line of the boom/extension arm. Connect the power supply unit to the mains. Either both connections (BT and USB) or only one connection can be configured as necessary. The order of configuration is left up to the user.

Setting up the Bluetooth connection

→   Plug the Bluetooth USB stick into the PC.
→   The driver installation starts automatically.
→   Check whether the Bluetooth driver has been installed correctly:
→   On your Windows desktop right-click on Workspace or Computer.
→   Select Manage in the context menu.
→   In the left half of the window click Device Manager.
→   In the right half of the window, open the Bluetooth Radios item.
→   Here you should see the items Broadcom BCM20702 Bluetooth 4.0 USB Device and Microsoft Bluetooth Enumerator.

Bluetooth connection between ECG device and PC

→   Switch on the unit by pressing the On/Off button.
→   Open the Windows Control Panel.
→   There, click on Devices and Printers, Add Device.
→   The ECG device is found.
→   Select the entry custo cardio 400... in the "Add device" dialogue box and click Next.
→   The device is added without pairing code.

Setting up the custo cardio 400 USB connection

Connect the ECG device to the PC using the USB cable supplied. The Windows driver installation for the new hardware starts automatically. After the driver installation is complete, the device is configured in custo diagnostic.

Device configuration for resting and stress ECG

→ Start custo diagnostic.
→ Open the screen Examination, Resting ECG or Stress ECG, Settings, Device **1**, ECG Device **2**.
→ The ECG device is shown in the "ECG devices" section: cardio 400 BT / cardio 400 USB **3**.
→ If it is not displayed, click Scan **4** (search process).
→ Select the device: cardio 400 BT / cardio 400 USB **3**.
→ A device can be identified by the serial number on the identification plate and in the software interface (e.g., SN: EAS 0001).
→ Only for Resting ECG: Later on, the ECG recording can also be started pressing a button on the device instead of using the software interface. Define the type of recording: Auto Start **5** (automatic ECG 10 s) or Start **6** (manual recording).
→ Save **7** your input. Close the screen with End **8**.
→ The device is ready for operation.
→ For stress ECG: section for configuring the training device.

Fig. 31: Configuring the ECG device in custo diagnostic (resting ECG)

3.2.2   Further device settings for custo cardio 400

The settings for the device pump (suction power, etc.) can also be found under Examination, Resting ECG or Stress ECG, Settings, Device ❶, ECG Device ❷.

❸ **Suction power**

Level 3 is the default setting for resting ECG, level 5 is the default setting for stress ECG. You can change the suction power at a later time on the device or use the automatic suction level control. With automatic suction power control, the suction level is increased until the system is airtight and the electrodes rest tightly enough against the skin of the patient. If the suction level is set manually, automatic suction level control is deactivated.

❹ **Detachment time**

Blow the moisture out of the electrode cables after an examination is "Detach electrodes at end of test automatically" is selected.

❺ **Cleaning time**

Extended blowing-out of moisture out of the electrode cables, e.g. at the end of a working day. This process is started manually, by keypress on the device.

❻ **Detach electrodes at end of test automatically**

Selecting this option automatically detaches the electrodes from the patient after an examination and the length of time set under "Blowing after test" runs as specified. Disable this option in the resting ECG settings if a stress ECG is to be performed immediately following a resting ECG.

Click on Save (bottom left) to apply your settings. Close the screen with End (bottom right). The device is ready for operation.

Fig. 32: Settings for the device pump

3.2.3   Connecting training devices for stress ECG

1) The number of serial ports on the PC can be expanded with USB-to-serial converters or a PCI plug-in card with serial ports.

→   Connect the training device to the PC with the supplied cable (serial port)[1].

→   Make a note of the serial port number, see Windows Device Manager. The number of the serial port will be needed later in custo diagnostic.

→   Some devices (e.g., ergometer ec5000 and treadmill er2100) can be connected to the PC using a network cable.

→   Start custo diagnostic.

→   Open the screen Examination, Settings, Interface, Devices ❶.

→   In the left half of the window, select the device, e.g., Ergometers, No. 1 ❷.

→   In the right side of the window, change the device settings as required.
  →   If the device type is known, select the Device option ❸ and in the "Device" dropdown list select the device type, e.g. ec5000 ❹.
  →   If the device type is not obviously recognizable, select the Protocol option ❺ and in the "Protocol" dropdown list select the connected device, e.g., customed/ergoline.

→   In the "Options" dropdown list ❻, set the device options.

→   Details about the device connection are entered in the "Interface" ❼ area.

→   Use the Test button ❽ to check whether the connection between the device and the PC is working.

→   If the connection is successful, "Status: O.K. started" appears in the test dialogue box.

→   Save ❾ your input. Close the screen with End ❿.

Fig. 33: Connecting training devices with custo diagnostic

3.2.4   Configuring a training device for stress ECG

→ In custo diagnostic, open the screen Examination, Stress ECG, Settings, Device ❶ , Training device ❷ .

→ Select the previously set Ergometer ❸ or Treadmill ❹ .

→ Select the blood pressure module of the ergometer or the previously connected and set sphygmomanometer ❺ .

→ Select the SPO2 module of the ergometer or the previously connected and set SPO2 meter ❻ .

→ Click on Save ❼ to apply your input.

→ Close the screen with End ❽ .

→ The training device is ready for operation.

Fig. 34: Configure training devices

3.2.5   Extended ECG settings

Changing the ECG colour scheme:

The ECG colours are preset in custo diagnostic and can be changed under Examination, Settings, System, ECG colour. Click on Save to apply your changes.

ECG Grid:

The ECG grid in custo diagnostic corresponds to normal ECG paper. The small boxes measure 1 * 1 mm, the large boxes 5 * 5 mm. To ensure the graph paper is correctly displayed on the screen, the screen diagonal of the monitor must be specified in the custo service center. Contact your authorized custo med dealer.

Resting ECG, automatic ECG procedures:

Under Examination, Resting ECG, Settings, Menu/Functions, Workflow procedures for automatic ECG recordings can be set in the "Automatic ECG" area. For example, recording duration and procedures after recording. Click on Save to apply your changes.

Procedures for manual resting ECG recordings and stress ECG:

Under Examination, Resting ECG or Stress ECG, Settings, Menu/Functions, Workflow procedures after recording and the display options in the evaluation can be set in the "Workflow" area. Click on Save to apply your changes

Print settings for resting ECG:

On the Examination, Resting ECG, Settings, Print, Print pages screen, you can set the contents for various printouts. Select the desired entry in the "Type of printout" list, for example automatic printout (Automatic ECG). In the "Printout" area, select the contents for the printout after an automatic ECG. Click Save to apply your changes.

Print settings for stress ECG:

On the Examination, Stress ECG, Settings, Print, Print pages screen, you can specify the contents for different printouts. Select the desired entry in the "Type of printout" list and compose the contents of the printout. Important: This setting is only required if the automatic ECG print pages contains content other than the standard printout (see "Type of printout" Standard). Click on Save to apply your changes.

Maximum load:

The maximum load achieved is displayed in the evaluation and in the printout and is used for comparison with the target load. The criteria for determining the maximum load are defined on the screen Examination, Stress ECG, Settings, Diagnostic, Calculation. For example, load levels that fall below a certain duration can be excluded.

3.3 Perform resting ECG recording

> **NOTE** on the procedure
>
> The steps necessary to record and evaluate ECG data in custo diagnostic are shown without a surgery IT system or HIS connection.

→ Apply the ECG device to the patient.
→ Observe the correct sequence of work steps.

Starting the program, calling up resting ECG

→ Start custo diagnostic and log in.
→ Click on Examination, Resting ECG, New Resting ECG.

Selecting a patient

→ Select a patient for the examination. Enter the patient's name into the input fields in the search mask.
→ Select the patient from the list.
→ Confirm the selection with Select Patient. The patient can also be selected by double-clicking on the name.

Tip for entries in the patient menu: Press the tab key to move the cursor to the next input field.

Creating a new patient

→ If the patient does not yet exist in your database:
    Click on New Patient.
→ Enter the patient data. The fields marked with an asterisk are mandatory.
→ Save the data.
→ The patient is entered into the database.

Selecting ECG device

→ If several ECG devices are connected to the workstation, the "Select ECG Device" dialogue box ❶ is displayed.
→ Select the ECG device ❷ and click on Confirm ❸.
→ If only one ECG device is connected, this step can be omitted.

Fig. 35: Select ECG device

Monitoring and electrode control

The patient's ECG signal will be shown on the display but not recorded (monitoring). Work steps before the start:

→ Change the type of lead ❶ if necessary.

→ If there are red lines on the screen, the contact between the skin and electrode(s) is insufficient. The corresponding electrodes will need to be reattached.

→ For ECG devices with USB connection, you can obtain a graphical representation of the signal quality via the Electrodes button ❷.

→ Set the required Filters ❸ (Options menu ❹).

Fig. 36: Monitoring and electrode control, resting ECG

IMPORTANT

Note on recording with a tablet PC: Before starting a recording, the system asks for the battery capacity. If this is less than 15%, no new recording can be performed.

INFORMATION:

The preset standard procedures for automatic ECG and manual recordings are described here. These sequences can be changed in the custo diagnostic settings, see Examination, Settings, Resting ECG, Menu/Functions, Workflow.

Automatic ECG – Autostart button

→ Click on Autostart **1** to start the automatic recording.

→ The default setting for the duration of automatic recording is ten seconds.

→ After the ten seconds have elapsed, the recording is automatically ended, saved, measured and printed out.

Manual recording – Start button or Enter key:

→ If you want to perform a recording without a time limit (e.g., if you suspect irregularities), trigger the recording with Start **2**.

→ At least ten seconds of ECG must be recorded before a recording can be ended.

→ Stop ends the recording, the ECG interface remains open.

→ Further sections can be recorded with Start and Stop.

→ End **3** closes the recording.

→ Click on Confirm in the End dialogue box so that the recording is saved, measured and displayed as an evaluation.

Fig. 37: Start resting ECG recording

Tip: Keyboard shortcut "Change amplitude (mm/mV)".

Editing options during the recording process

→ Mark ECG automatically: Clicking the Mark button ❶ automatically marks the last six seconds of the recording. A dialogue box opens for naming, printing and saving the marking ❷.

→ Mark ECG manually: With the Start marking button ❸ you can determine the length of the marking yourself. The marking runs until you click End marking. A dialogue box opens for naming, printing and saving the marking ❷.

→ Viewing ECG, marking and measuring HR during a pause: Clicking on Pause ❹ stops the screen display. The recording continues and is displayed on one channel. The scroll bar can be used to view the current recording. The "Mouse function" area (top right) contains the Mark, Measure HR and Measure tools. By dragging the red cursor in the ECG (Mark mouse function), you can mark sections. A dialogue box opens for naming, printing and saving the marking. Click on Continue to return to the normal view.

→ Online ECG print (print ECG): With the Print button ❺, a page of ECG is printed out from the point of clicking. The printout contains 4.5 to 9 seconds of ECG depending on the display speed.
Under Examination, Resting ECG, Settings, Print, General you can specify in the area "Online ECG print settings" whether the ECG should be printed as it is displayed on the monitor or whether the online print should be done according to the already specified print settings for analysed ECG.

Fig. 38: Resting ECG recording, editing functions

> **TIP:** *Text modules for specifying marked parts*
>
> *Application: If a marking is made during recording, the "Markings" dialogue box appears. The marked parts will be automatically specified by pressing the corresponding key (e.g., F5) or a previously configured text module button.*
>
> *Configuring text modules: Under Examination, Resting ECG, Settings, Menu/Functions, Markings the text modules can be configured for specifying marked parts.*
>
> *Enter a name for the text module in the "Description" field. This name later appears on the button for calling the text module. In the "Text module" field, enter the text which will later be used to specify the marked parts. Save your input.*

3.4   Resting ECG rhythm strips

During resting ECG recordings, additional rhythm strips can be recorded. These are ECG sections of any duration during which the recording can be manually controlled. The "Rhythm strip" function can be activated under Examination, Resting ECG, Settings, Menu/Functions, Workflow ❶. Specify whether the recording is to be stopped manually ❷ or after a certain duration ❸. Save ❹ your input.

Recording of a rhythm strip is triggered in the ECG interface with the Rhythm button. If the recording duration is not set, the recording of the rhythm strip can be stopped using the Stop button.

In the evaluation, the available rhythm strips can be called up and displayed via the menu at the top left ❺. It is possible to print out the rhythm strips. Under Examination, Resting ECG, Settings, Print, Print pages activate Rhythm ❻. Save your input.

Fig. 39: Rhythm strip settings

Fig. 40: Resting ECG evaluation with rhythm strips

Fig. 41: Rhythm strip printout

3.5   Perform stress ECG recording

> **NOTE** on the procedure
>
> The steps necessary to record and evaluate ECG data in custo diagnostic are shown without a surgery IT system or HIS connection.

→   Apply the ECG device to the patient.
→   Observe the correct sequence of work steps.

Starting the program, calling up stress ECG

→   Start custo diagnostic and log in.
→   Click on Examination, Stress ECG, New Stress ECG.

Selecting a patient

→   Select a patient for the examination. Enter the patient's name into the input fields in the search mask.
→   Select the patient from the list.
→   Confirm the selection with Select Patient. The patient can also be selected by double-clicking on the name.

Creating a new patient

→   If the patient does not yet exist in your database:
      Click on New Patient.
→   Enter the patient data. The fields marked with an asterisk are mandatory.
→   Save the data.
→   The patient is entered into the database.

Tip for entries in the patient menu: Press the tab key to move the cursor to the next input field.

Profile selection

→   The profile selection opens.

→   Select a stress profile ❶. The list contains predefined profiles for ergometer (with watt specifications) and treadmill.

→   Set the training device ❷ for the recording.

→   The predefined load profiles can be changed and adjusted if necessary ❸.

→   With Save ❹, the modified load profile can be saved under a new name.

→   With New ❺ new profiles can be created (types: ergometer, free, treadmill).

→   The values in the Notes area ❻ are freely adjustable and can be activated if required. If you want to use the Notes function, the Notes values must be set correctly during profile selection before clicking Start ❼. The Notes values cannot be activated and changed later.

→   After selecting and configuring the load profile, click the Start ❼ button to access the recording screen.

Additional information: Steady State option for ergometer profiles

With Steady State ❽ the load profile can be controlled manually during recording. If Steady State ❽ is selected, entries can no longer be made for the stage duration, increase and end in the input mask. The profile continues to run unchanged during the recording until a manual change is made. To define the end of a load level during the recording, click on the Measurement button. The last ten seconds will be measured. Then set the load for the new load level.

Fig. 42: Profile selection stress ECG

Selecting ECG device

→   If several ECG devices are connected to the workstation, the "Select ECG Device" dialogue box ❶ is displayed.

→   Select the ECG device ❷ and click on Confirm ❸.

→   If only one ECG device is connected, this step can be omitted.

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Fig. 43: Select ECG device

Monitoring and electrode control

The patient's ECG signal will be shown on the display but not recorded (monitoring). Work steps before the start:

→ Change the type of lead **1** if necessary.
→ If there are red lines on the screen, the contact between the skin and electrode(s) is insufficient. The corresponding electrodes will need to be reattached.
→ For ECG devices with USB connection, you can obtain a graphical representation of the signal quality via the Electrodes button **2**.
→ Set the required Filters **3** (Options menu **4**).

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Recommended settings for stress test ECG with treadmill:

→ Under Options **4** activate: Mains filter **5** , Muscle filter **6** and Ergo filter **7** . The Ergo filter **7** is only required if strong movement artifacts are to be expected, e.g., when using a treadmill.

→ ECG display Precordial **8** , 5 mm/mV **9** and 25 mm/s.

→ Click Start **10** or Enter to start recording.

Fig. 44: Monitoring and electrode control stress ECG

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Options menu

1. Turning on and off the automatic blood pressure measurement
2. Trigger an additional BP measurement or F7
3. Dialogue box for entering an unconfirmed report
4. Dialogue box for entering the blood pressure (with manual measurement) or F9
5. Dialogue box for entering lactate values or F10
6. Dialogue box for entering SPO2 values or F11
7. Input of Borg values to document the subjective feeling of a patient (e.g., strenuous) or F12
8. Restart of ergometry without previous profile selection
9. Extending the current level (only possible after starting)
10. Detection of pacemaker spikes, if the patient has a pacemaker
11. Filter for removing interferences caused by the power supply unit
12. Filter for flattening the ECG signal (e.g., in the event of amyostasia)
13. Ergo filter for compensating strong movement artefacts
14. Signal tone with each heart beat
15. Switching on and off of signals when Notes limits are exceeded
16. In the bar below the ECG the heart rate is displayed instead of RR intervals in milliseconds

Fig. 45: Options stress ECG, during recording

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Display and control elements (view after starting)

1. Setting options for ECG display
2. Buttons for controlling and editing the ECG recording
3. Heart rate and blood pressure, countdown of the current level
4. Change current load and increase for ergometer profiles or speed and slope for treadmill profiles
5. Load profile (orange) with heart rate curve (blue)
6. Blood pressure curve (green)
7. Setting of the ST point
8. Display of summary complexes (selection of the channel with the buttons on the left side in front of the ECG signal)
9. Display of ST trend curve, ST values and event overview (online arrhythmia detection); button in the area 9 flashes red when the limits are exceeded

Fig. 46: Stress ECG recording

Load change settings 4:

You can define by how many watts load and increase should change each time the arrow buttons are pressed. This setting can be found under Examination, Stress ECG, Settings, Menu/Functions, ECG view in the "Manual load change" area.

Manual blood pressure measurement

You are regularly requested to measure blood pressure. Enter the values in custo diagnostic. Click on Blood pressure or the "F9" in the Options menu and enter the values. Confirm to apply your input. Entering lactate ("F10"), SPO2 ("F11") and Borg ("F12") values works in the same way.

Resting phase

The resting phase begins after Start. This phase proceeds according to the settings in the profile selection, it has a minimum duration of ten seconds.

Stress phase

The stress phase then begins. This phase proceeds according to the profile. Manual load changes can be made at any time. The Next Stage button can be used to end the current load level and start the next load level.

Note on treadmill profiles: The treadmill can be stopped using the Stop button, e.g. if a lactate measurement should be conducted. The treadmill will be restarted by clicking on the button again. Always warn the patient before you stop or start the treadmill!

Entering an unconfirmed report during recording

Open the Context menu and select Report. Enter the unconfirmed report in the large text field. To save your input, click on Confirm. By pressing Cancel, the unconfirmed report is closed without any changes being applied.

If you save your information with Confirm, the unconfirmed report becomes a (preliminary) report, depending on the reporting rights of the current user. The evaluation is thus (pre-)confirmed. If the evaluation is not to be classified as (pre-)confirmed at this point, you can reset the report status when selecting End.

If the Unconfirmed report option is active in the Settings, custo diagnostic generates an automatic unconfirmed report which is displayed in the evaluation. This option is enabled by default and can be disabled under Stress ECG, Settings, Diagnostic, Reports.

> **IMPORTANT:** All unconfirmed reports produced by the system should be considered as suggestions only. For diagnosis and therapy purposes it is essential that the results are checked and assessed by a qualified physician.

Recovery phase, ending the recording

The recovery phase can be started using the Recovery phase button, e.g., when the Manual end option was selected in the profile selection or as a result of a premature termination. Define the end of the stress phase (immediately or at the end of the load stage). The dialogue for entering the reason for termination is then opened. The reason for termination can be displayed in the evaluation.

If the end of the stress phase is defined in the profile, the recovery phase starts automatically after the last load level has expired. The recovery phase proceeds according to the profile.

If you would like to end the ECG recording but the ECG signal should still be displayed on the screen, click on Stop. Otherwise, the recording will be automatically saved, measured and displayed as an evaluation by clicking on the End button (bottom right).

TIPP: *Text modules for entering the reason for termination*

Application: The text modules are called using the keyboard (F5 to F12) in the "Reason for termination" dialogue or by clicking on the corresponding button.

Configuring text modules: Select Examination, Stress ECG, Settings, Diagnostic, Reason for End to configure text modules for entering a reason for termination. Enter a name for the text module in the "Description" field. This name will appear on the button for calling the text module in the "Reason for termination" dialogue. In the "Text module" field, enter the text which will later be displayed as the reason for termination. Save your input.

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Editing options during the recording process

→ Mark ECG automatically: Clicking the Mark button ❶ automatically marks the last six seconds of the recording. A dialogue box opens for naming, printing and saving the marking ❷.

→ Viewing and marking ECGs and measuring HR during a Pause: Clicking on Pause will stop the screen display. he recording continues to run and is displayed on one channel ❸. The scroll bar ❹ can be used to view the current recording. In the "Mouse Function" ❺ area, the tools Mark, Measure HR and Measure can be found. By dragging the red cursor ❻ in the ECG (using the Mark function), you can mark sections. A dialogue appears for specifying, printing and saving the marked part. With Continue ❼ you return to the normal view.

→ Online ECG printing (printing ECG): By clicking on the Print button ❽ a screen page of the ECG is printed from the point of clicking. The printout contains 4.5 to 9 seconds of the ECG, depending on the display speed. Select Examination, Stress ECG, Settings, Print, General o define in the "Online ECG print settings" area whether the ECG should be printed as it appears on the monitor or if online printing should be carried out according to previously defined print settings for the analysed ECG.

Fig. 47: Stress ECG recording, editing options

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TIP: *Text modules for specifying marked parts*

Application: If a marking is made during recording, the "Markings" dialogue box appears. The marked parts will be automatically specified by pressing the corresponding key (e.g., F5) or a previously configured text module button.

Configuring text modules: Under Examination, Stress ECG, Settings, Menu/Functions, Markings the text modules can be configured for specifying marked parts.

Enter a name for the text module in the "Description" field. This name later appears on the button for calling the text module. In the "Text module" field, enter the text which will later be used to specify the marked parts. Save your input.

3.6   Opening evaluations

3.6.1   Opening an evaluation via the evaluation search

1) The evaluation search can be configured in the custo diagnostic settings, see Examination, Settings, Database, Eval. search.

→   To open the evaluation search[1] right-click on the Patient button **1**.

→   With factory settings, the search screen **2** is displayed. Here, previously saved search criteria, so-called filter sets, can be used to search for evaluations. Filter sets can be created on the Advanced search screen **3**.

→   Depending on the default setting of the system, a filter set is already active and the search results are displayed here full-screen as a list **4**.

→   If no filter set is active yet, select a set **5**.

→   Open an evaluation by double-clicking on the corresponding line or via the Show button **6**.

Configuring the list of search results

→   Right-click on the screen to open the context menu. There click on Select columns and set the required columns. Click on Confirm to apply your changes.

→   By clicking on a column heading, the list is sorted by this column and the sorting within the column can be reversed.

→   The list can be printed and exported **7**.

Renaming filter sets, deleting filter sets

→   Right-click on the screen to open the context menu. There, click on Rename filter set or Delete filter sets.

→   Follow the instructions.

Fig. 48: Evaluation search, search with filter sets

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Advanced search, creating filter sets

→ The Advanced search **8** is used to create filter sets and to quickly select search criteria (e.g., examination, properties, time period) **9**. By setting certain search criteria, the search is narrowed down.

→ The search results are displayed as a list **10**.

→ An evaluation is opened by double-clicking on the corresponding line or via the Show button **11**.

→ The previously selected search criteria can be saved as a filter set with a corresponding name. Enter the name in the input field **12** and click Save current search as set **13**.

Editing filter sets

→ Select the filter set to be edited, see line "Current filter set".

→ Adjust the search parameters (e.g. examination, time period).

→ Save current search as set **13** overwrites the previous set.

→ If a new name is assigned beforehand, a new set is created.

Configuring the list of search results

→ Right-click on the screen to open the context menu. There click on Select columns and set the required columns. Click on Confirm to apply your changes.

→ By clicking on a column heading **14**, the list is sorted by this column and the sorting within the column can be reversed.

→ With the arrow button **15** at the bottom right of the list, the list can be enlarged or reduced.

→ The list can be printed and exported **16**.

Fig. 49: Evaluation search, extended search

3.6.2 Opening an evaluation via the evaluation main menu

Tip for entries in the patient menu: Press the tab key to move the cursor to the next input field.

→ Open the examination main menu via
  Examination, Resting ECG or Stress ECG.
→ Click on Show evaluation ❶.
→ The patient search screen appears. Select the patient whose evaluation you want to open. Enter the name of the patient in the input fields of the search mask ❷.
→ Select the patient from the list below the input fields ❸ and confirm the selection with the Select patient button ❹ or by double-clicking on the name.
→ A list with all evaluations of the patient is displayed. Select the desired evaluation from the list and open it by double-clicking or using the Show evaluation button.

Fig. 50: Resting ECG main menu

Fig. 51: Select patient

3.7 Resting ECG evaluation

3.7.1 Evaluation structure

ECG evaluation is divided into two main areas: ECG and Measurement. The ECG screen is preset as the start screen, and the Measurement screen can be set as the start screen as an alternative if required. From the sub-screens of the two areas, the main screen of the other area can be reached at any time.

The evaluation start screen can be set under Examination, Resting ECG, Settings, Menu/Functions, Workflow in the "Menu/Functions, Show evaluation" area.

Start screen ECG:			
Complete ECG, e.g., 12-channel display			
ECG overview:	**Zoom:**	**Comparison:**	**Options menu**
Complete ECG minimised as 2-channel strip display	Magnified display of a channel (mouse function: zoom, double click on ECG)	Comparison of two evaluations of a patient. Here: 12-channel display	additional screens:
			Events
			HRV
			Sport ECG

Start screen measurement:			
Summary complexes of all channels			
Measured values:	**Single complex:**	**Comparison:**	**Options menu**
Tabular display of all measured values	Summary complex of a channel and vector loop	Comparison of several evaluations belonging to a patient. Here: Summary complexes of all channels	additional screens:
			Events
			HRV

3.7.2   Navigation in the evaluation

At the bottom of the screen there are buttons for opening other evaluation screens. The labelling of the buttons changes as soon as you switch to another evaluation screen. The clicked button always contains the name of the screen from which you came.

Example: You click on the Measurement button **1** in the evaluation (View: ECG start screen). You arrive at the evaluation screen Measurement and the previously clicked button Measurement **1** changes to ECG **2**. Clicking on ECG **2** takes you back to the ECG view.

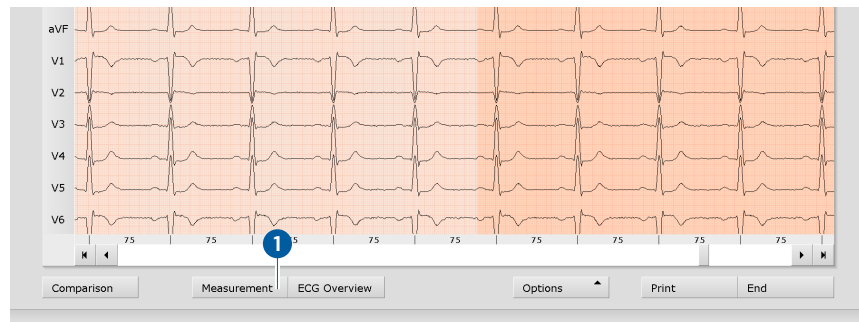*Fig. 52: Evaluation Resting ECG, ECG screen*

Fig. 53: Evaluation Resting ECG, Measurement screen

3.7.3   Resting ECG evaluation screens

ECG start screen

① Setting options for ECG display
② Mouse functions for precise viewing and measuring of the ECG signal
(Zoom, Analysis, Measure HR, Measure, Marking)
③ Further evaluation screens
④ Print evaluation
⑤ Button for closing the evaluation

Fig. 54: Evaluation Resting ECG, ECG start screen

If the Measurement view is set as the start screen, you will find the same operating and navigation elements (1 to 5) there.

The evaluation start screen can be set under Examination, Resting ECG, Settings, Menu/Functions, Workflow in the "Menu/Functions, Show evaluation" area.

Settings for the Print button: On the Examination, Resting ECG, Settings, Menu/Functions, Workflow screen, in the "Workflow, Print" area, you can specify whether the advanced print menu is displayed when the Print button is clicked (default) or whether printing is performed automatically and without further settings, according to the default print settings (= defined printout). The standard print settings for Resting ECG can be found under Examination, Resting ECG, Settings, Print, Print pages. Click on Save to apply your input.

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Options menu

The scope and contents of the options menu change depending on which screen of the evaluation you are on. On the Measurement screen, for example, you can activate the display of ST values in the options menu and set which markers are to be displayed in the summary complexes.

1) For the RR variability to be displayed, at least five minutes of ECG needs to be recorded!

2) Only with recordings including high resolution ECG (custo cardio 300 or 400).

❶ Print menu for temporary changes to the print settings
❷ Export of the evaluation (e.g., as Excel, PDF, DICOM…)
❸ If necessary, assign evaluation to another patient
❹ Manual blood pressure input (F9 key)
❺ HR trend, display of events in ECG (e.g., VES)
❻ Tables and graphics for heart rate variability[1]
❼ New analysis of ECG signal for resetting manual changes in ECG, additions to the report remain available
❽ Automatic creation of a new report after manual changes have been made in the ECG recording
❾ Switching on and off filters in the ECG (options: Display ECG as saved, unfiltered or filtered ECG - mains filter, muscle filter
❿ Showing and hiding of additional contents in the right half of the screen: e.g., enlarged pacemaker spikes[2], HR curve and ST trend, summary complexes and report or table of measured values
⓫ Show or hide pacemaker spikes
⓬ Graphic flattening of ECG signal
⓭ In the bar below the ECG the heart rate is displayed instead of RR intervals in milliseconds
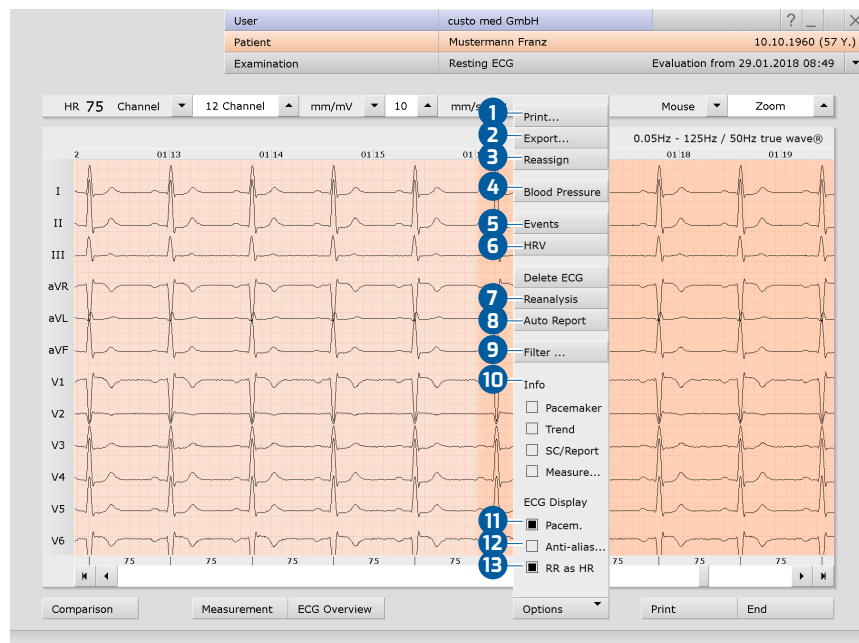

Fig. 55: Resting ECG evaluation, Options menu

3.7.4   Resting ECG with additional function Sport ECG

The Sport ECG function is not part of the standard software and can be purchased optionally.

A resting ECG can be viewed in the context of "Sport ECG" in the case of patients who participate in competitive sports. custo diagnostic takes into account that competitive athletes may have a different anatomy of the heart. In the case of competitive athletes, the results of the automatic analysis are evaluated differently than in patients who do not fall into the category of competitive athletes. The diagnostic approach is based on the following publication: "International recommendations for electrocardiograph interpretation in athletes, ESC 2018".

View resting ECG evaluation in the context of Sport ECG:

→   In the resting ECG evaluation, click on Options, Sport ECG.

→   The "Criteria for competitive athletes" dialogue box opens. Select the applicable items here. Confirm the selection.

→   If the selection meets the criteria for competitive athletes, a new automatic report is generated. For this purpose, Confirm the "Report" dialogue box.

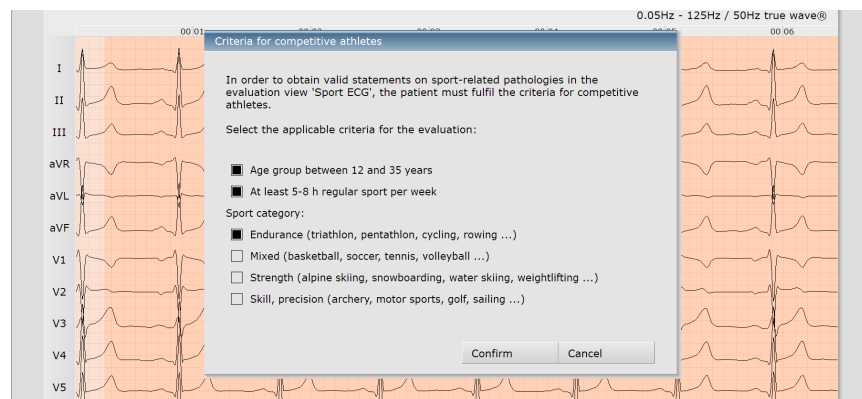→   If the selection does NOT meet the criteria for competitive athletes, the standard view is displayed again.

Fig. 56: "Criteria for competitive athletes" dialogue box

Resting and stress ECG · custo cardio 400 accu

Display and control elements in the Sport ECG

Fig. 57: Sport ECG evaluation view

1. Recorded ECG
2. Sum complex
3. Table of measured values
4. Unconfirmed report
5. Traffic light image with graphical representation of the evaluation
6. Notes on further recommended examinations
7. Reset changes in the unconfirmed report
8. Confirm the unconfirmed report and adopt as report

Meanings of the traffic light states in the unconfirmed report

Red with exclamation mark	Abnormal ECG changes, clarification required
Yellow with question mark	Two or more ECG changes, clarification required
Green and OK	Asymptomatic, no further clarification required

Create Sport ECG report

→ Check the unconfirmed report of the system.
→ If necessary, change or add to the information in the white text field of the unconfirmed report. Click with the mouse in the white text field and make the changes.
→ The Reset button cancels changes in the unconfirmed report.
→ Click the Confirm button to accept the entries. The unconfirmed report becomes a report.
→ In the "Status modification" dialogue box, check whether the traffic light status matches the report.
→ If the traffic light status does not match the report, adjust the traffic light status.
→ After comparing the traffic light status and the report Confirm the "Status modification" dialogue box.
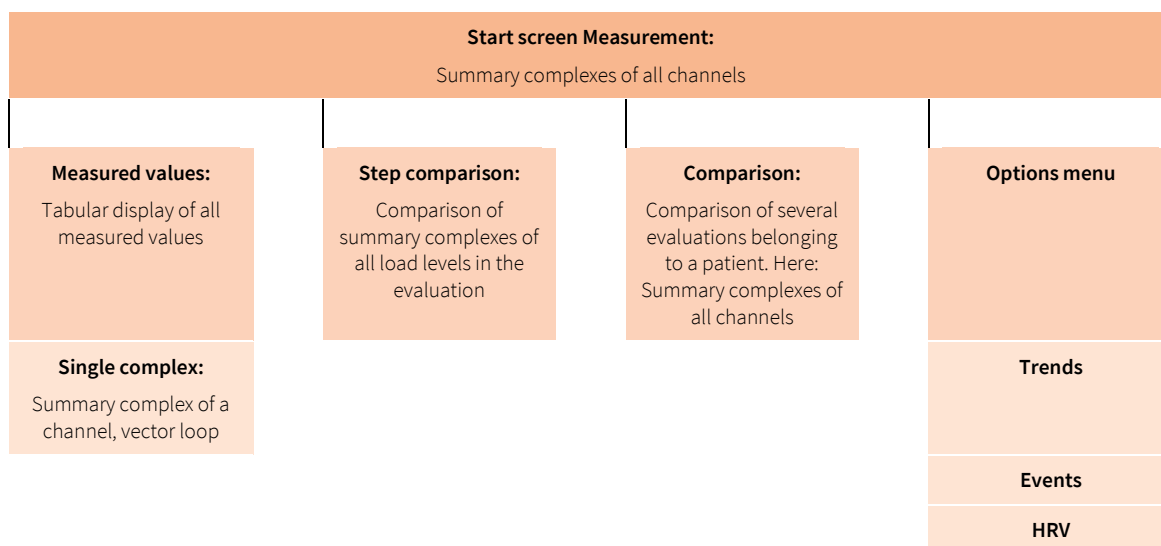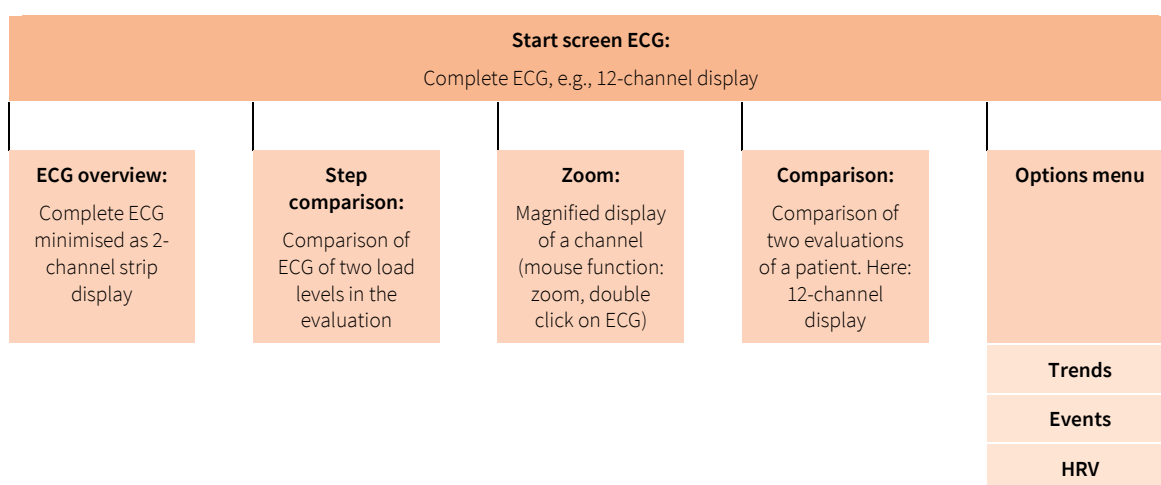
Return to the standard view

→ Click on Options in the Sport ECG evaluation view.
→ Deactivate the Sport ECG option.

3.8 Stress ECG evaluation

3.8.1 Evaluation structure

ECG evaluation is divided into two main areas: ECG and Measurement. The ECG screen is preset as the start screen, and the Measurement screen can be set as the start screen as an alternative if required. From the sub-screens of the two areas, the main screen of the other area can be reached at any time.

The evaluation start screen can be set under Examination, Stress ECG, Settings, Menu/Functions, Workflow in the "Workflow, Show evaluation" area.

Start screen ECG:

Complete ECG, e.g., 12-channel display

ECG overview:	**Step comparison:**	**Zoom:**	**Comparison:**	**Options menu**
Complete ECG minimised as 2-channel strip display	Comparison of ECG of two load levels in the evaluation	Magnified display of a channel (mouse function: zoom, double click on ECG)	Comparison of two evaluations of a patient. Here: 12-channel display	
				Trends
				Events
				HRV

Start screen Measurement:

Summary complexes of all channels

Measured values:	**Step comparison:**	**Comparison:**	**Options menu**
Tabular display of all measured values	Comparison of summary complexes of all load levels in the evaluation	Comparison of several evaluations belonging to a patient. Here: Summary complexes of all channels	
Single complex:			**Trends**
Summary complex of a channel, vector loop			
			Events
			HRV

3.8.2   Navigation in the evaluation

At the bottom of the screen there are buttons for opening other evaluation screens. The labelling of the buttons changes as soon as you switch to another evaluation screen. The clicked button always contains the name of the screen from which you came.

Example: You click on the Measurement button ❶ in the evaluation (View: ECG start screen). You arrive at the evaluation screen Measurement and the previously clicked button Measurement ❶ changes to ECG ❷. Clicking on ECG ❷ takes you back to the ECG view.
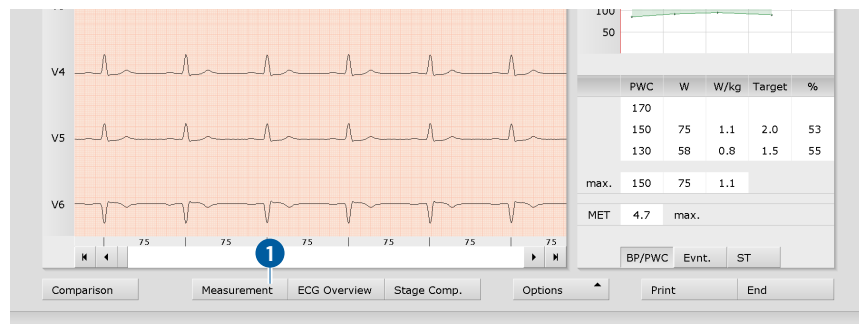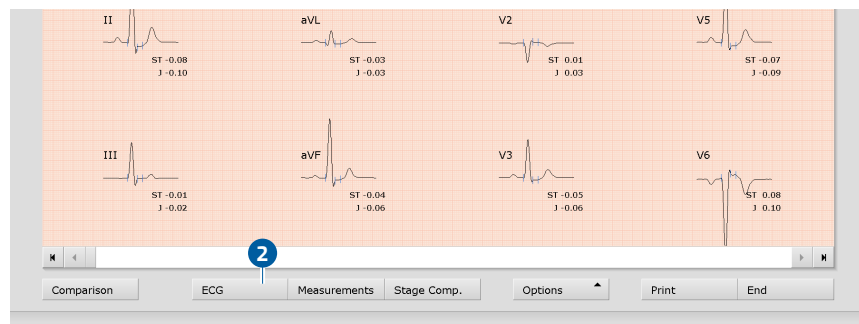

Fig. 58: Evaluation Stress ECG, ECG screen

Fig. 59: Evaluation Stress ECG, Measurement screen

3.8.3   Screens of the stress ECG evaluation

ECG start screen

①   Setting options for ECG display

②   Mouse functions for precise viewing and measuring of the ECG signal (Zoom, Analysis, Measure HR, Measure, Marking)

③   Stress profile with heart rate and blood pressure curve

④   Tabular display of PWC (Physical Working Capacity[1]) and MET (Metabolic Equivalent); further information on PWC and MET can be found in the appendix.

⑤   Further evaluation screens

⑥   Print evaluation

⑦   Button for closing the evaluation

Fig. 60: Evaluation Stress ECG, ECG start screen

If the Measurement view is set as the start screen, you will find the same operating and navigation elements (1 to 7) there.

The evaluation start screen can be set under Examination, Stress ECG, Settings, Menu/Functions, Workflow in the "Workflow, Show evaluation" area.

Settings for the Print button: On the Examination, Stress ECG, Settings, Menu/Functions, Workflow screen, in the "Workflow, Print" area, you can specify whether the advanced print menu is displayed when the Print button is clicked (default) or whether printing is performed automatically and without further settings, according to the default print settings (= defined printout). The standard print settings for Stress ECG can be found under Examination, Stress ECG, Settings, Print, Print pages. Click on Save to apply your input.

Options menu

The scope and contents of the options menu change depending on which screen of the evaluation you are on. On the Measurement screen, for example, you can activate the display of ST values in the options menu and set which markers are to be displayed in the summary complexes.

1) For the RR variability to be displayed, at least five minutes of ECG needs to be recorded!

1 Print menu for temporary changes to the print settings

2 Export of the evaluation (e.g., as Excel, PDF, DICOM…)

3 If necessary, assign evaluation to another patient

4 Display of blood pressure (F9), lactate (F10), SPO2 (F11) and Borg values (F12)

5 Trend graphics, e.g., for load, HR, ST, RPM, blood pressure, lactate, SPO2…

6 HR trend, display of events in ECG (e.g., VES)

7 Tables and graphics for heart rate variability[1]

8 Delete ECG: unmarked ECG will be deleted

9 New analysis of ECG signal for resetting manual changes in ECG, additions to the report remain available

10 Switching on and off filters in ECG (options: Display ECG as saved, unfiltered or filtered ECG - mains filter, muscle filter, ergo filter).

11 Showing and hiding of additional contents in the right half of the screen: summary complexes and report or measured value table (preset: Trend = stress profile with HR and blood pressure curve, PWC and MET).

12 Show or hide pacemaker spikes

13 Graphic flattening of ECG signal

14 In the bar below the ECG the heart rate is displayed instead of RR intervals in milliseconds

Fig. 61: Evaluation of stress ECG, Options menu

3.9   Confirming the evaluation

Unconfirmed report and report

To open the unconfirmed report, right-click on the evaluation interface. In the context menu, select Report. Enter your data in the text field **1**. If the Unconfirmed report or Interpretation option is selected in the system settings, an automatic system unconfirmed report is already present in the text field. If necessary, older reports can be displayed via the report history (collapsible list above the text input field). When you click on Confirm **2** your input is saved and the unconfirmed report becomes a (preliminary) report, depending on the report rights of the current user. If your (unconfirmed) report is not yet complete but you want to save it nevertheless without reaching the "Evaluation (pre)confirmed" status, reset the report status upon ending (End) the evaluation.

Text modules – an aid for writing reports

On the Examination, Resting and stress ECG, Settings, Diagnostic, Reports screen page, text modules can be created for confirming an evaluation **3**. A total of four groups **4** with up to eight text modules **5** can be created. The text modules are called up in the unconfirmed report dialogue via the keyboard (F5 to F12) **6**.

A text module can be composed of normal text and variables. Instead of a variable, the actual value from the evaluation is inserted into the report text when using a text module in the report text. The structure of a variable is {VARIABLE}. Via the button Shortcuts for export values **7** you receive a list with all variables. If the text modules are to be displayed in the unconfirmed report dialogue, make sure that the Enabled **8** option is activated. Otherwise, the text modules can be displayed in the unconfirmed report dialogue via Options **9**, Texts on. It is also possible to write a text that is automatically displayed in each unconfirmed report **10**. The text can be changed later in the unconfirmed report dialogue. Save your entries.
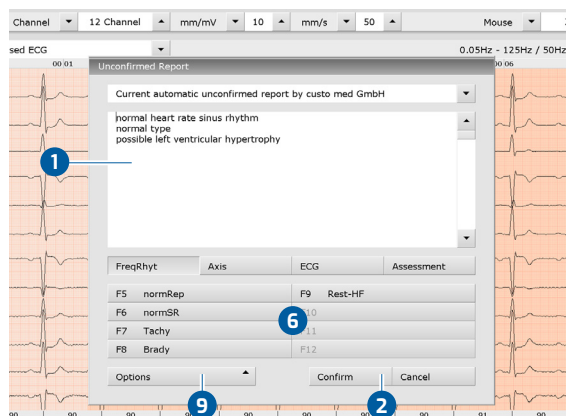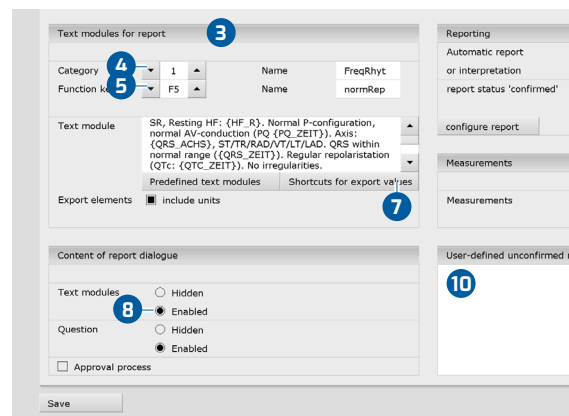

Fig. 62: Unconfirmed report

Fig. 63: Text modules

3.10   Optional: Reporting with approval process

If custo diagnostic is used with approval process, authorised persons with corresponding user rights can save pre-reports of other persons as a report without having to close the evaluation already opened by the previous examiner (shortened workflow) or enter pre-reports/reports directly if the evaluation was created by a person without reporting rights.

The approval process is visible in the unconfirmed report dialogue ❶ of an evaluation. The user or reporter can be changed there: User name ❷, Password ❸, Enter. During the login process, the user rights of the respective user are checked and the software interface is adapted accordingly ❹. The reporting is documented in the evaluation information ❺ (context menu).

The approval process must be activated in the Settings and in the custo service center for each user and project. The user rights must be set to match the workflow. Contact your authorised custo med dealer or custo med.

INFORMATION: Pre-reporting physicians must have the user right Preconfirm evaluations, reporting physicians must have the user rights Confirm evaluations and Change reports of other users.

Fig. 64: Unconfirmed report dialogue with approval process

Fig. 65: Evaluation information

3.11   Ending the evaluation

Click on End (bottom right) in the evaluation. The End dialogue opens.

❶   The status of an evaluation is defined here. Assigning properties (status of the evaluation) in the End dialogue makes it easier to find evaluations in the evaluation search.

❷   Evaluation pre-confirmed: active if a user with the reporting right "Preconfirm evaluations" has confirmed the unconfirmed report of an evaluation.

❸   Confirmed: active if a user with the reporting right "Confirm evaluations" has confirmed the unconfirmed report. The "confirmed" status can be reset if required.

❹   Printed: indicates whether the evaluation has been printed.

❺   Indelible: can be selected after reporting has been completed. The evaluation can now only be viewed and can no longer be changed.

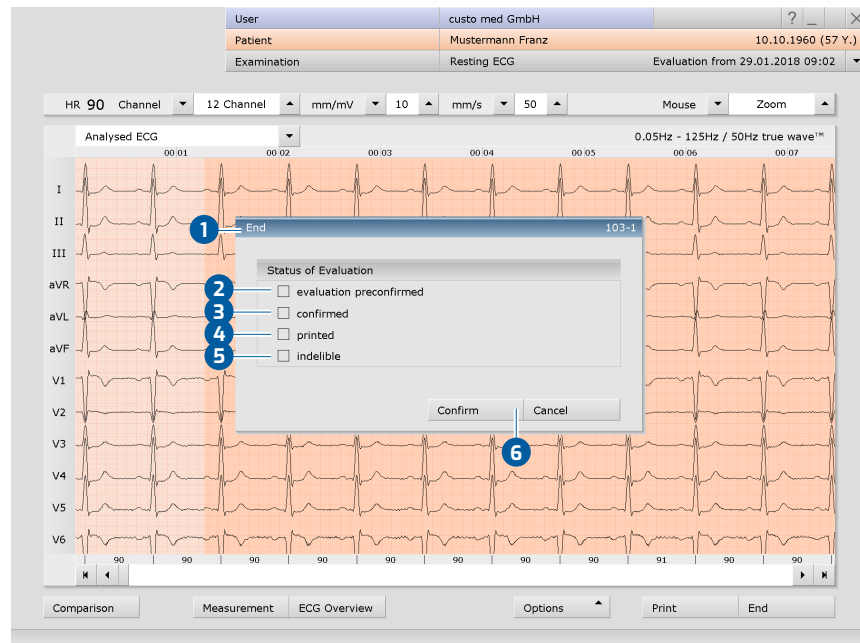**❻**   Click on Confirm to close the evaluation.

Fig. 66: End dialogue

4   Hygiene

4.1   Important notes

Only use cleaning agents and disinfectants recommended by custo med. Unsuitable agents may damage the device.

Under no circumstances should the devices be immersed in liquid or cleaned too wet. Cleaning agents and disinfectants must not be sprayed directly onto or into the device. No moisture must get inside the devices (e.g., via interface contacts).

Contacts must not be soiled or damaged.

Clean and disinfect the devices after each patient. Make sure that the exterior of the devices is always aesthetic and clean.

The device must not be connected to a power source during cleaning and disinfection.

4.2   Hygienic reprocessing

custo cardio 400 accu

→   Reprocessing type: surface cleaning and/or wipe disinfection

> **IMPORTANT:** The cleaning cloth must not be dripping wet. Moisture must not enter the connections of the ECG device under any circumstances. Do not clean the golden contact pins in the connections of the electrode leads. They could be damaged in the process.

Electrodes

> **INFORMATION:** Dark discoloration may occur on the surface of the silver-silver chloride electrode contact surfaces due to use and cleaning. This type of discoloration does not affect the functioning or the quality of the ECG derivation. Do not try to remove the discoloration.

Clean the electrodes after each use. For further hygienic reprocessing, choose one of the two procedures listed, see next sections.

→   Remove the electrodes from the electrode suction tubes:
  →   Place the electrode suction tube in one hand so that the fingertip of the index finger supports the end of the electrode suction tube **1**.
  →   Press the index finger of your other hand onto the electrode **2**.
  →   Move your thumb between the electrode and the electrode suction tube **3**.
  →   Apply a slight upward pressure with your thumb.
  →   The electrode will detach from the electrode suction tube.
→   Clean the electrodes. Use a soft (disposable) brush in combination with water or a mild soap.
→   Disinfect the electrodes, see sections on quick disinfection, disinfectant bath or cleaning and disinfectant bath.
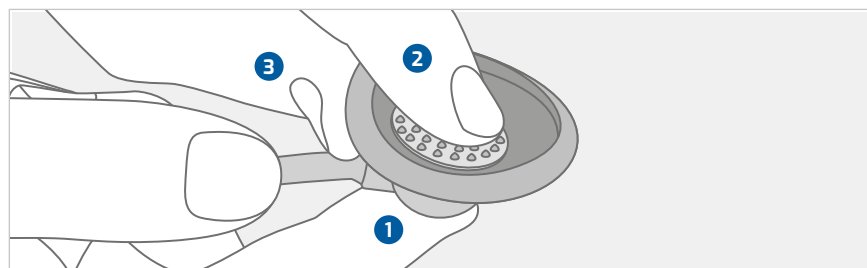

Fig. 67: Removing electrodes from the electrode suction tubes

Non-critical areas: Procedure for quick disinfection (wipe disinfection).

The electrodes can be classified as a non-critical medical device if they only come into contact with intact skin.

→ For a quick disinfection (wipe disinfection), fully wet the electrodes with foam or a disinfection cloth.
→ Observe the manufacturer's instructions regarding exposure times and spectrum of activity!
→ After reprocessing, neutralise (rinse) the electrodes with clear water.
→ Dry electrodes before use – wet electrodes may cause disturbances in the ECG signal.

Critical areas: Procedure according to DGKH certificate (German Society for Hospital Hygiene).

Disinfection bath (disinfection of instruments):

→ Place electrodes in the disinfection bath.
→ Observe manufacturer's instructions for dosage and exposure time!
→ Do not exceed the specified exposure times.
→ After the disinfection bath, neutralise (rinse) with clear water.
→ Dry electrodes before use – wet electrodes may cause disturbances in the ECG signal.

Washing and disinfection unit (laboratory dishwasher):

→ Use a program suitable for temperature-sensitive materials for reprocessing (e.g. MIELE G7883: program "G").
→ Avoid high temperatures and long exposure times.
→ If the unit is not equipped with a rinser (water), neutralise (rinse) the electrodes with clear water.
→ Remove the electrodes from the washing and disinfection unit immediately after reprocessing to avoid damage to the electrodes.
→ Dry electrodes before use – wet electrodes may cause disturbances in the ECG signal.

Cleaning the electrode suction tubes

For hygienic use, for maintenance of the device and for consistent quality of the ECG recordings, the excess moisture must be blown out of the electrode suction tubes regularly. The settings for internal cleaning of the electrode suction tubes are preset in custo diagnostic: Examination, Settings, Resting ECG or Stress ECG, Device, ECG Device.

The detachment time should be at least 30 seconds. After each examination, moisture is blown out of the electrode suction tubes for 30 seconds.

The cleaning time should be at least 30 minutes. Perform a 30-minute internal cleaning once per day, e.g., at the end of a workday (for frequent use) or once per week (for normal use). During the cleaning time, moisture is blown out of the electrode suction tubes for 30 minutes. custo cardio 400 accu switches off automatically after the cleaning time has elapsed.

Procedure

→ Remove the electrodes from the electrode suction tubes ❶.
→ Press the cleaning button ❷ on the front of the device.
→ During the set time interval, the excess moisture is blown out of the electrode suction tubes.
→ The process ends automatically after the set time.
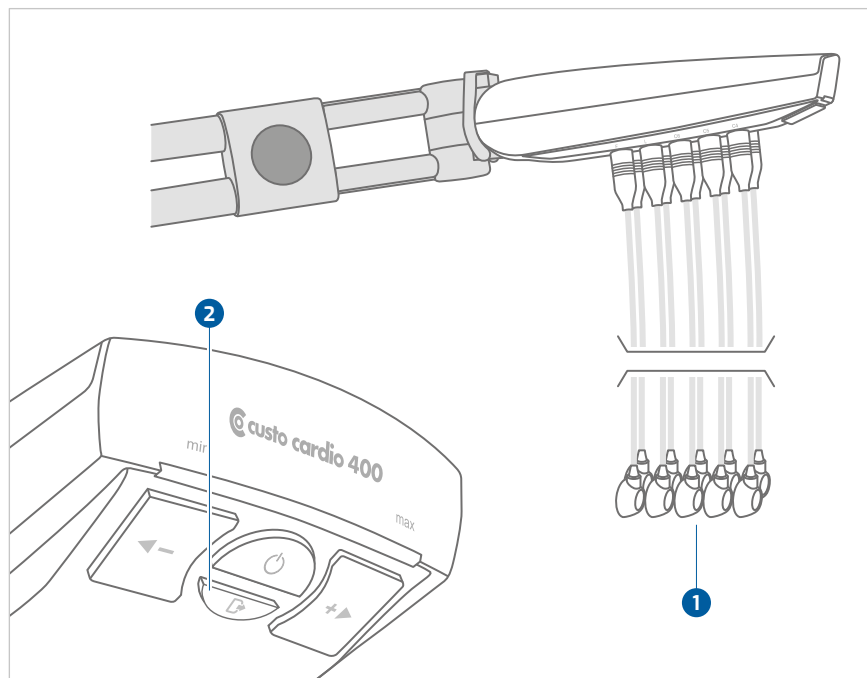→ The process can be interrupted at any time.

Fig. 68: custo cardio 400 accu without electrodes

4.3   Recommended cleaning agents and disinfectants

Wipe disinfection:

→ Meliseptol® Wipes sensitive (B.Braun)
→ Meliseptol® Foam pure (B.Braun), use a soft, lint-free cloth for this purpose.
→ Observe the manufacturer's instructions!

Procedure according to DGKH certificate:

→ gigasept med® (Schülke & Mayr GmbH)
   disinfectant bath: 1 % solution, max. 15 minutes
→ Sekusept Plus® (Ecolab GmbH)
   Disinfectant bath: 1 % solution, max. 15 minutes
→ Observe the manufacturer's instructions!
→ Do not exceed the specified exposure times and concentrations. This will result in excess wear due to reprocessing.

Cleaning agents:

→ Mild soap, neutral cleaning agent

INFORMATION:

The recommended disinfectants can be replaced by products from other manufacturers provided they are equivalent in terms of disinfection and material compatibility. For more information, contact your partner for hygiene and disinfection.

4.4 Disposal of the electrodes

The electrodes can be sent to custo med for disposal.

5   Appendix

5.1   Values and formulas in the ECG evaluation

Isoelectric segments within the QRS complex.

The isoelectric segments within the QRS complex are included in the Q, R, or S waves.

The duration of each spike/wave is the same in all 12 channels and is determined by the channel where the first event (this refers to the beginning or end of a spike/wave) occurs.

PWC (physical working capacity)

The PWC values indicates the physical ability of a patient at a specific heart rate. The PWC value is specified in watt/kg (body weight). In custo diagnostic, the PWC value is determined for a heart rate of 130, 150 and 170. To determine the PWC value, the patient must have a heart rate of +/- 10 to the reference rate (130, 150 and 170). If the heart rate has not been precisely achieved, the PWC value will be calculated using interpolation or extrapolation. Example: If a patient who weighs 100 kg reaches a heart rate of 170 to 200, the PWC value will be calculated as follows:

PWC170 = 200 W : 100 kg = 2 W/kg

The PWC predicted values are preset in custo diagnostic and can be changed under Examination, Stress ECG, Settings, Diagnostic, Reference values. Click on Save to apply your changes.

MET (metabolic equivalent)

The metabolic equivalent is used to determine the expenditure of energy during the maximum load. In custo diagnostic, the metabolic equivalent is calculated as follows:

Treadmill ergometry:

v = max. speed in miles per hour, m = gradient in %.

*MET = 1 + (v * 26.8 * (0.1 + m * 0.018)) : 3.5*

Bicycle ergometry:

L = max. load in watts, G = weight in kg

*MET = 1 + (12 * L) : (3.5 * G)*

Calculation of QTc duration

Formula according to Bazett:

$$QTc\text{-}Duration = QT * \sqrt{\frac{HR}{60}}$$

Formula according to Fridericia:

$$QTc\text{-}Duration = QT * \sqrt[3]{\frac{HR}{60}}$$

Calculation of the target load

custo diagnostic offers two different calculation options for calculating the target load at maximum workload: "standard" and "according to Prof. Froelicher". The settings can be found under Examination, Stress ECG, Settings, Diagnostic, Reference values.

Standard formula

Male, under 30 years of age:

*Target load = 3 * weight*

Female, under 30 years of age:

*Target load = 2.5 * weight*

Male, over 30 years of age:

*Target load = 3 * weight * ((130 - age) : 100)*

Female, over 30 years of age:

*Target load = 2.5 * weight * ((130 - age) : 100)*

Source: Rost, R. & Hollmann, W. (1982): Belastungsuntersuchungen in der Praxis, Georg Thieme Verlag, Stuttgart, New York. 164 p.

Formula according to Prof. Froelicher

female:

*3.933 + (86.641 * body surface) - (0.015 * age) - (0.346 * body surface * age)*

male:

*6.773 + (136.141 * body surface area) - (0.064 * age) - (0.916 * body surface area * age)*

Body surface area according to DuBois & DuBois

*BSA = 0.007184 * height [cm] 0.725 * weight [kg] 0.425*

Source: DuBois, D. & DuBois, E.F. (1916): A formula to estimate the approximate surface area if height and weight be known. Arch Intern Med, 17: 863

BORG values for stress ECG

When performing a stress ECG, it is possible to enter BORG values during recording. BORG values are used to evaluate the subjective perceived exertion and were established by the Swedish physiologist Gunnar Borg in the Borg scale named after him. Classification is carried out either by the physician or by the patients themselves.

Simplified scale of subjective perceived exertion:

06 very very light	13 somewhat hard
07 very very light	14 somewhat hard
08 very very light	15 hard
09 very light	16 hard
10 very light	17 very hard
11 light	18 very hard
12 light	19 very very hard
	20 too hard, no longer possible

Simplified BORG scale: Source: http://www.uni-bielefeld.de (Christian Stallmann)

5.2   Keyboard navigation and shortcuts

Use the quick links in the main navigation, the keyboard navigation and the keyboard shortcuts to enable fast and convenient working.

Quick links in the main navigation

User		custo med GmbH	①			? _ ✕
Patient	④		②	⑤		
Examination			③	⑥		▾

Left click

→ ① Change user password
→ ② Call last patient
→ ③ Examination main menu

Right click

→ ④ Evaluation search
→ ⑤ Call last patient
→ ⑥ Most recently opened evaluation

User	custo med GmbH	⑦		? _ ✕
Patient	Mustermann Franz	⑧	⑩	10.10.1960 (60 Y.)
Examination	Holter	⑨	⑪	▾

Left click

→ ⑦ Change user password
→ ⑧ Patient master data
→ ⑨ Menu of the current examination

Right click

→ ⑩ All evaluations of the patient
→ ⑪ Last opened evaluations of this examination

Keyboard navigation

When you press the Alt key, the initial letter of all the buttons on a screen page is underlined. Pressing an initial letter again triggers the corresponding button.

User	custo med GmbH		? _ ✕
Patient			
Examination			▾
Holter			
ABPM			
Resting ECG			
Stress ECG			
Cardiopulmonary Exercise Testing			

Keyboard shortcuts

General shortcuts

Enter	Confirm
Tabulator	Cursor jumps to next input field (patient menu)
Ctrl I	Program information
Ctrl H	User main menu
Ctrl P	Patient main menu
Ctrl U	Examination main menu
Ctrl A	All examinations of the selected patient
Ctrl G	List of last opened evaluations
	(same as clicking on the arrow button at top right)
Ctrl F	List of last opened evaluations
Ctrl L	Evaluation search
Ctrl W	Work list
Ctrl Q	Device list
Ctrl M	Switch to Metasoft

Generally valid keyboard shortcuts in an open evaluation

Ctrl N	Unconfirmed report input dialogue
Ctrl K	Medication input dialogue
Ctrl T	Call trend
Ctrl D	Call print dialogue
Ctrl O	Call options menu

Resting ECG keyboard shortcuts during the recording

Enter	Start recording
Esc	End the recording
+	Increase amplitude
-	Decrease amplitude
F9	Input dialogue box blood pressure

Stress test ECG keyboard shortcuts during the recording

Enter	Start recording
Esc	End the recording
+	Increase amplitude
-	Decrease amplitude
F7	Starts an additional blood pressure measurement
F8	Creates a new load level for steady state profiles
F9	Input dialogue box blood pressure
F10	Input dialogue box lactate
F11	Input dialogue box SPO2
F12	Input dialogue box BORG
Arrow keys right/left	increase/decrease the load rise (bicycle) or the slope (treadmill)
Arrow keys up/down	increase/decrease the load (bicycle) or the speed (treadmill)

5.3   Manufacturer's declaration regarding EMC

Electromagnetic compatibility according to DIN EN 60601-1-2:2016-05

Lead lengths

Electrode suction tubes:	approx. 1200 mm, approx. 1450 mm, approx. 1650 mm
USB cable:	approx. 3000 mm

Manufacturer's declaration – electromagnetic emissions

Emission measurements	EMC standard / test method	Compliance
RF emissions	CISPR11	Group 1
RF emissions	CISPR11	Class B
Harmonics	IEC 61000-3-2	Class A
Voltage fluctuations/flickers	IEC 61000-3-3	Complies

Manufacturer's declaration – electromagnetic immunity

custo cardio 400 accu meets the test levels specified here.

Phenomenon	EMC standard / test method	IMMUNITY TEST LEVEL
Static electricity discharge (ESD)	IEC 61000-4-2	± 8 kV contact discharge ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV air
Radio-frequency electromagnetic fields	IEC 61000-4-3	10 V/m 80 MHz to 2.7 GHz 80 % AM at 1 kHz
Radiofrequency electromagnetic fields in the in the immediate vicinity of wireless communication devices	IEC 61000-4-3	Conforms to the standard, for the immunity test level refer to the table on the next page
Quick transient electric interference factors / bursts	IEC 61000-4-4	± 2 kV 100 kHz Repetition frequency
Surges line against line	IEC 61000-4-5	± 0.5 kV, ± 1 kV
Surges line against earth	IEC 61000-4-5	± 0.5 kV, ± 1 kV, ± 2 kV
Conducted disturbances, induced by high-frequency fields	IEC 61000-4-6	3 V 0.15 MHz to 80 MHz 6 V in ISM frequency bands between 0.15 MHz and 80 MHz[1] 80 % AM at 1 kHz
Power frequency magnetic fields	IEC 61000-4-8	30 A/m 50 Hz
Voltage drops	IEC 61000-4-11	0% UT; ½ period[2] at 0, 45, 90, 135, 180, 225, 270 and 315 degrees 0% UT; 1 period[2] and 70% UT; 25/30 periods[2] Single-phase: at 0 deg.
Voltage interruptions	IEC 61000-4-11	0% UT; 250/300 periods[2]

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.

2) UT is the alternating supply voltage prior to application of test levels

Recommended protective distances between portable and mobile RF telecommunication devices and custo cardio 400 accu

custo cardio 400 accu 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.

> ⚠ Portable RF communication devices (radios) (including their accessories such as antenna cables and external antennas) should not be used within 12 inches (30 cm) of the manufacturer's designated parts and leads of the custo cardio 400 accu device. Failure to observe this warning can compromise the performance of the device.

> ⚠ 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	17
5100 to 5800	WLAN 802.11 a/n	0.2	0.3	9

a) For some radio services, only the frequencies for the radio link from the mobile communication device to the base station (EN: uplink) have been included in the table.

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

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

P is the maximum output in Watt (W), d the minimum clearance in metres (m) and E the immunity test level in Volts 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.

5.4   EC Declaration of Conformity

Simplified declaration of conformity

custo cardio 400 accu complies with the requirements of the Medical Device Directive 93/42/EEC or Medical Device Regulation (EU) 2017/745 and Directive 2011/65/EU.

Hereby custo med declares that the radio device type(s) custo cardio 300 BT; custo cardio 400 BT; custo cardio 400 accu; custo screen 400; custo watch; custo guard 1/3/LR; custo guard holter; custo com RF; custo com RF LR is/are in compliance with Directive 2014/53/EU.

The full text of the EC declaration of conformity is available at the following internet address: https://www.customed.de/information/zertifizierung/konformitaetserklaerungen

Declarations of Conformity for accessories and supplementary parts, if applicable, can also be found there.

5.5   Product components and accessories

Description	Product name	Part no.	Quantity/pcs.
ECG application system	custo cardio 400 accu	84025	1

Description	Accessories	Part no.	Quantity/pcs.
	Electrode suction tubes, length 1.20 m	85034	1
	Electrode suction tubes, length 1.45 m	85035	1
	Electrode suction tubes, length 1.65 m	85061	1
	electrode "hair"	85027	10 pieces
	Electrode, "standard"	85064	10 pieces
	Electrode, "small"	85064	10 pieces

Description	Complementary parts	Part no.	Quantity/pcs.
	Spacer 2-fold	85032	2
	Spacer 3-fold	85033	2
	Coding set (1 set of 10 stickers)	85036	1
	custo move extension arm incl. USB cable	85082	1
	Cable hook for custo move extension arm	85083	1
	Bracket for custo move extension arm incl. mounting material	12931	1
	Universal bracket for custo cardio 400 BT / accu	85068	1
	Wall mounting set	85079	1
	LM506 Bluetooth 4.0 USB adapter	55050	1
	USB extension cable 1.8 m, A-to-A	16018	1
	Power supply unit BET-0612 for custo cardio 400, 12 V, 5 A	85023	1
	Power cable 1 m for power supply unit BET-0612 and VEC50US15	85044	1
	Clamp adapter socket 4 mm for connection to patient simulator	85056	5 pieces
	Adapter for patient simulator	85057	10 pieces

5.6   List of Figures

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