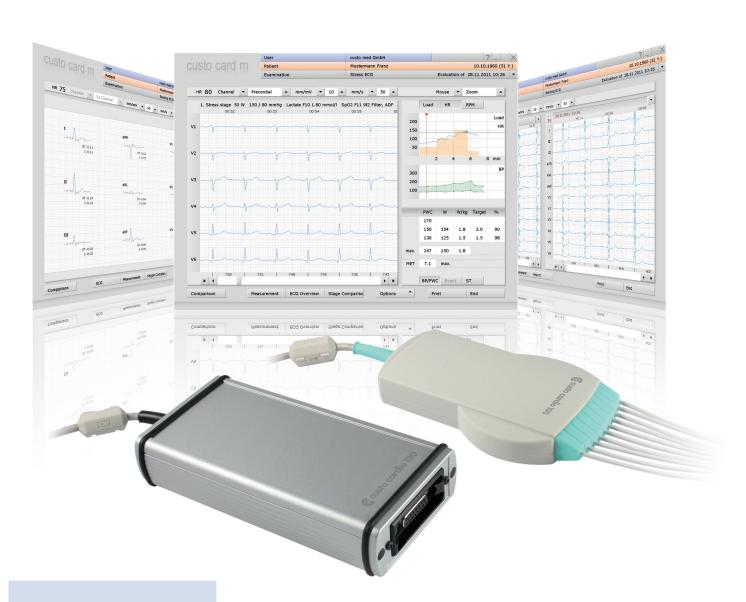
# 

**Operating Manual** 

# Resting and Stress ECG

with custo cardio 100/110/130 and custo diagnostic



#### Operating characteristics:

custo diagnostic V04 and higher for Windows®

GEB 0199 - DK 1643 15.02.2017









# **Operating Manual**

# Resting and Stress ECG

# with custo cardio 100/110/130 and custo diagnostic

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

#### Manufacturer's contact details:

custo med GmbH Maria-Merian-Str. 6 85521 Ottobrunn Germany

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



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# 01.1 Symbols on the device

***	Manufacturer: custo med GmbH, Maria-Merian-Str. 6, 85521 Ottobrunn, Germany
<b>( €</b> 0123	CE mark
(i)	Observe the Operating Manual
	Separate collection of electrical and electronic equipment, do not dispose with domestic waste
-  <b>*</b>	Protection class classification of medical electrical equipment according to IEC 60601-1 (type BF, defibrillation protected)

#### 01.2 Intended use

custo cardio 100/110/130 is a 12-channel PC ECG device which is designed for recording, analysing and evaluating ECG recordings in medical practices and hospitals.

custo cardio 100/110/130 is perfectly safe for patients with a pacemaker. The ECG recording is not affected by pacemaker pulses. custo cardio 100/110/130 is not suitable for intracardiac use.



# 01.3 Symbols used in this Operating Manual

This Operating Manual uses the following symbols to indicate important information, comments and tips:

#### **ACTIONS THAT ARE PROHIBITED**

or not allowed under any circumstances!



#### **WARNING**

used to indicate situations which, if not avoided, may result in personal injury and property damage



#### NOTE

provides important information which must be observed



#### TIP

contains practical information to assist you with your work



Words highlighted in colour indicate buttons or click paths for the corresponding program point, e.g. Examination, Resting ECG

Words highlighted in colour..

#### 02.1 General notes

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 this Operating Manual, in particular the safety instructions.

#### Laws and regulations applicable to the product

- This system is designed in accordance with Medical Device Directive 93/42/EEC, Class IIa, and meets the requirements of protection class I or II (depending on the power supply unit used; custo cardio 100/110 BT is a device with an internal power supply), type BF (defibrillation protected), 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 60950) and 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..

#### 02.2 Safety installations and safe working



custo cardio 100/110/130 must only be used in a technically perfect condition. Regularly carry out a visual inspection of the device and the cables, in particular the patient cable. Only use accessories approved by custo med.

The device is protected against defibrillation only in connection with the manufacturer's patient cable. For custo cardio 130 only patient cables with a defibrillation protection resistance of 10 K $\Omega$  must be used.

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 100/110/130 has a recovery time of less than ten seconds.



#### Installation of the system

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.

#### Ambient conditions, handling

For the installation and operation of the device, please observe the EMC notes (electromagnetic compatibility) in these instructions for use, see chapter *07.3 Manufacturer declaration on EMC...*.



custo cardio 100/110/130 is not suitable for use in rooms or areas with a risk of explosion.

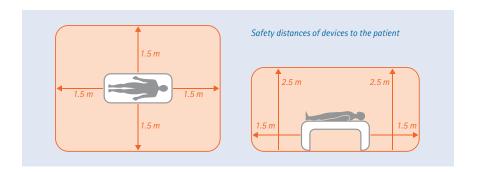
Strong electromagnetic sources in the immediate vicinity of the custo cardio 100/110/130 may result in recording errors (e.g. HF electrosurgical devices, mobile phones, induction furnaces).

The device must not be operated simultaneously with HF surgical equipment.

The device must be protected against the ingress of moisture, dust or dirt and also against mechanical impacts such as damage due to dropping or transit damage.

#### Patient safety





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.

Non-medical devices and the patient may not be touched simultaneously during the examination.

When coupled with other devices, make sure that there is no danger due to the accumulation of leakage currents.

During routine maintenance work to non-medical devices connected to the system the patient must not be touched (risk of electric shock).

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



All results of 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.

#### custo cardio 100/110 BT (Bluetooth), rechargeable lithium-ion battery



Remove the rechargeable battery if the device is not used for a long period.

Only use the supplied charger to charge the rechargeable battery.

Do not expose the rechargeable battery to extreme temperatures, fire and moisture. Do not immerse the rechargeable battery 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.



#### Hygiene

For cleaning and disinfection observe the legal requirements and the current state of technology.



Use only cleaning agents and disinfectants approved by custo med for cleaning and disinfection. Clean and disinfect your device in accordance with the specifications given in *chapter 04 Hygiene*.

#### Safe use of treadmills during stress ECG

Please inform your patient before you stop the treadmill in custo diagnostic using the Stop button and before you restart the treadmill using the Continue button. Otherwise, the patient may become injured due to an unexpected, abrupt stopping or starting of the treadmill.



Always inform you patient before the speed is changed.

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

Observe the manufacturer's safety instructions.

#### Display of the ECG signal in custo diagnostic

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.

The device is not suitable for binding pacemaker checks. In case of doubt, use the device approved by the pacemaker manufacturer (see the patient's pacemaker record).

#### System and data security



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 dealer.

Only change data generated in custo diagnostic within custo diagnostic itself and not in your EPR system (Electronic Patient Record) or your hospital information system (HIS).

custo med does not accept any responsibility for any changes to data in your EPR 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.

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



#### 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. An incorrect allocation can lead to a 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 the 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.

#### 02.3 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.

# 02.4 Maintenance (regular safety checks)

The operator is responsible for maintenance. The operator must ensure that the device is checked for proper condition at the latest every two years. The functionality and the state of accessories must be checked at regular intervals. If damaged and/ or heavily soiled, the complete system must no longer be used.



All interventions in the existing system, changes to system components, enhancements as well as internal cleaning and repairs may only be performed by your authorised custo med dealer or custo med.

#### Technical safety check

After each system or device repair, modification or conversion, a technical safety check must be performed by your authorised custo med dealer.

#### 02.5 Disclaimer

The manufacturer is not responsible for improper operation, failure to comply with the safety instructions and non-observation of specifications due to negligence.

custo med will only assume responsibility for the safety and reliability of the custo cardio 100/110/130 when all changes, enhancements, repairs and other work to the device or system have been performed by an authorised custo med dealer or custo med and the Operating Manual has been observed during device operation.



# 02.6 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 expiration of the warranty period only use original spare parts and accessories from custo med. This is the only way to ensure the safe and trouble-free operation of your device.

#### 03.1 Part names, components for ECG recording



- custo cardio 100 (USB) custo cardio 100 (USB) ERG
- Neoprene case, Carrying belt ECG electrodes



- 2 custo cardio 110 (USB)
- Neoprene case, Carrying belt ECG electrodes



- 3 custo cardio 100 BT ERG custo cardio 110 BT
- Neoprene case, Carrying belt ECG electrodes Rechargeable lithium-ion battery Charger with power supply unit Bluetooth USB stick



#### Note about the electrodes

For optimal results, we recommend using high-quality ECG electrodes, e.g. custo sensive, and custo prep ECG cream to prepare the electrode application points.



#### 5 custo cardio 130

ECG PC module
with 15-pin ECG input connector
(D-Sub screw connection or Siemens plug)
for connection of suction system
or patient cable



#### Notes about on custo cardio 100 ERG

The systems with the "ERG" addition have shortened patient cables. The cable lengths of the patient leads are adjusted /customised to the electrode application points. The excess cable lengths are reduced, leading to improved ECG quality. We recommend this version for stress ECG.

#### **➤** Length of patient cables for ERG systems

#### custo cardio 100 ERG, custo cardio 100 BT ERG

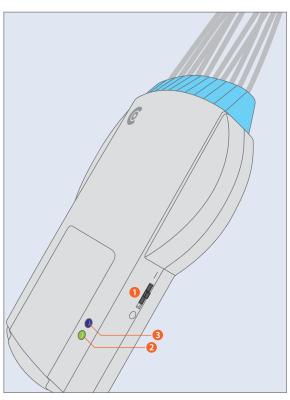
R, L	.approx.	700 mm
C4 – C6	approx.	650 mm
N, F	approx.	600 mm
C1 - C3	approx.	500 mm

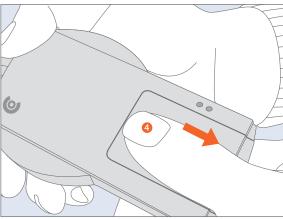
#### **▶** Length of patient cables for standard systems

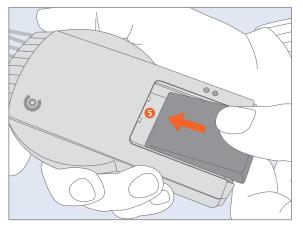
#### custo cardio 100, custo cardio 110, custo cardio 110 BT

R, L, F, N	approx.	1050 mm
C1 - C6	approx	k. 700 mm

#### 03.2 Operation of custo cardio 100/110 BT (Bluetooth)







#### On/off switch

The switch on the right side of the housing ① switches the device on and off. Only switch on the device immediately before the start of recording and switch it off again directly after the recording is completed. The maximum operation duration is 4 hours after which the rechargeable battery will need to be replaced or charged.

#### LED display

When the device is switched on, the lower LED ② indicates the charge status of the battery:

Green:	100% - 65%
Orange:	65% - 35%
Red:	< 35 %

If the lower LED flashes red after switch-on, the rechargeable battery must be immediately removed from the device and charged.

The upper LED ③ indicates whether the Bluetooth connection is active between the device and the PC. At the start of an ECG recording, the Bluetooth connection is established between the device and the PC and the upper LED lights blue. The precondition for this is that the Bluetooth connection has been installed correctly (see 03.4 Connecting ECG devices to the PC). If no connection has been established, the LED will not light.

#### Note on the rechargeable battery

The rechargeable lithium-ion battery does not have memory effect. The battery can be charged at any time, irrespective of the discharging times.

#### Charging the rechargeable battery

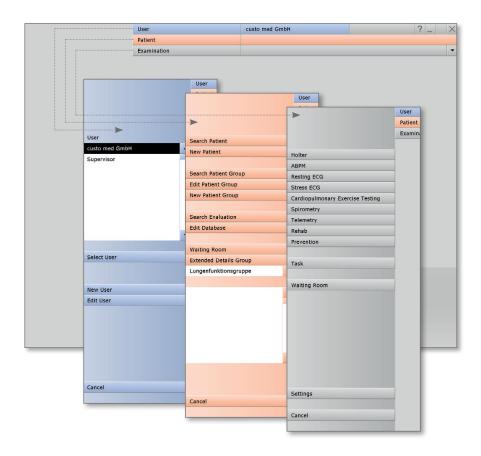
With your thumb, slide the battery cover back ② and take out the battery. Insert the battery into the supplied charger. A description of the charging method can be found in the Operating Manual of the charger. The charging time is 2 to 3 hours.

Reinsert the charged battery so that the contacts of the battery and custo cardio 100/110 BT come into contact **5**. Close the battery cover.



#### 03.3 custo diagnostic – basic program structure

The program is divided into three areas – User, Patient and Examination. This structure ensures that you can always recognize 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, Patient or Examination.



In the User main menu the users of the system can be created and managed. The user administration can be used to allocate user rights and control user-specific settings, e.g. the creation of a separate patient database for each user.

The Patient main menu is used for patient management.

Its most important functions include Search for Patient, New Patient and Search Evaluation.

The Examination main menu lists all of the examination types which are possible with custo diagnostic. The modules which you do not own are deactivated – this can be recognised by the 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.

# 03.4 Connecting ECG devices to the PC

#### Precondition:

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 using the custo diagnostic standard setup or via targeted selection during the custo diagnostic setup.

#### 03.4.1 ECG device with USB port

#### ➤ Connecting the USB cable to the PC

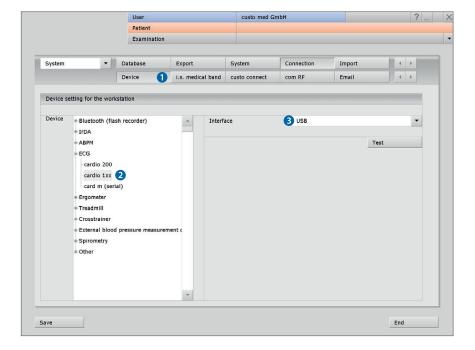
Connect the USB cable of the ECG device to the PC. Power is supplied via the USB cable. The Windows driver installation for the new hardware starts automatically. Select the "Find driver automatically" option. Use the Next and Finish buttons to control the installation process.

#### ➤ Setting up the interface in custo diagnostic

Start custo diagnostic. Select Examination, Settings, Connection, Device ①. Select ECG, cardio 1xx ② in the device selection list; select USB in the interface selection list ③. Click on the Save button (at bottom left).

#### ➤ Selecting ECG device for resting and stress ECG

See section 03.4.3 Selecting ECG device for resting and stress ECG.





#### 03.4.2 ECG device with Bluetooth connection

#### Note on Bluetooth USB stick

The supplied Bluetooth USB stick is supported by Windows XP and Windows 7, but not by Windows 2000 and Windows Vista.



To ensure the smooth installation of the supplied Bluetooth USB sticks in WINDOWS XP, the full installation of the current custo diagnostic version (not the update) must be carried out from the CD, even if another version of custo diagnostic is already installed. Otherwise, the operating system will need to be accessed manually. The custo diagnostic installation must be completed before connecting the Bluetooth USB stick to the PC.

For WINDOWS 7, no subsequent installation of custo diagnostic or additional access is required as the Bluetooth USB stick is already known in the operating system.

#### Overview Bluetooth installation

- 1. Connect the Bluetooth USB stick to the PC
- 2. Driver installation for the Bluetooth USB stick
- 3. Check the driver installation
- 4. Install the Bluetooth interface in custo diagnostic
- 5. Allocate the device for examination (see 03.4.2 Device settings for resting and stress ECG)

A description of work steps 1. to 3. can be found in the "Quick guide for installing Bluetooth devices in custo diagnostic". This Quick Guide is located on your custo diagnostic CD and the custo med website: www.customed.de.

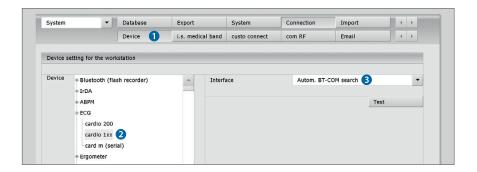
**IMPORTANT:** Before continuing with the configuration of the Bluetooth interface in custo diagnostic, make sure that the Bluetooth USB stick is correctly connected and the power supply to the ECG device is guaranteed.

# Description of device, basic instructions for initial operation

#### ➤ Installing the BT interface in custo diagnostic

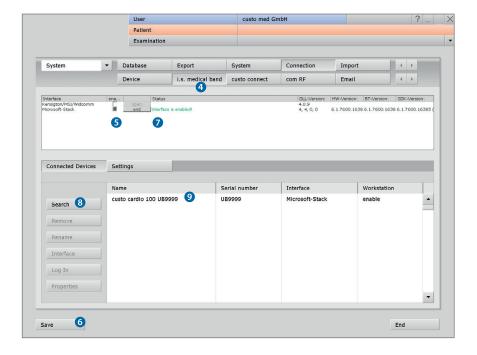
Start custo diagnostic. Select Examination, Settings, Connection, Device ①. Select ECG, cardio 1xx ② in the device selection list and Autom. BT-COM search ③ in the interface selection list.

Click on the Save button (at bottom left).



Then select Examination, Settings, Connection, i.s. medical band 4. Activate the Microsoft Stack 5 option, click on Save 6 and then on Open (to the left of Microsoft Stack). The message "Interface is enabled" appears 7.

Switch on custo cardio 100/110 BT and click on the Search button ③. The "i.s. medical band search" dialogue appears. Restart the search if the device is not found (repeat the process several times if necessary). Select the desired device and click on Confirm. The previously selected device is displayed in the table on the i.s. medical band page ④. Save ⑤ your input.

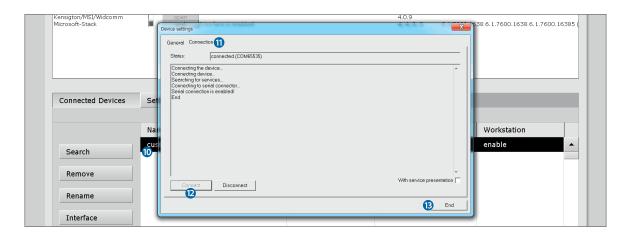




To establish the Bluetooth connection, double-click on the device name in the table ①. In the open dialogue, go to the Connection ① tab and click on Connect ②. After the connection has been established, the message "Serial connection is enabled! End" will appear. End ③ the dialogue.

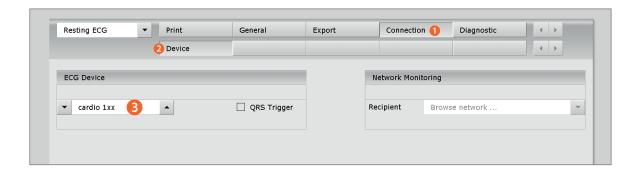
If the Bluetooth connection was successful between the PC and custo cardio 100/110 BT, the LED on the device will light blue.

Save your input and close the i.s. medical band page with End. Restart the program to transfer the changed parameters to the configuration database.



#### 03.4.3 Selecting ECG device for resting and stress ECG

- ➤ In custo diagnostic, select: Examination, Resting ECG or Stress ECG, Settings, Connection ①, Device ②.
- Select cardio 1xx 6 from the list under "ECG Device".
- > Click on the Save button (at bottom left) to apply your input.
- Close the page with End (button at bottom right).
- The device is ready for operation.



#### 03.5 Connecting ergometer/treadmill to the PC

#### 03.5.1 Connecting and configuring devices

#### Connecting devices to the PC

 The number of serial interfaces on the PC can be expanded using USB-to-serial converters or a PCI plug-in card with serial connections. Connect the ergometer or treadmill to the PC using the supplied cable (serial interface) <sup>1)</sup>. Make a note of the number of the serial connection (Windows device manager). The number of the serial connection will be needed later in custo diagnostic.

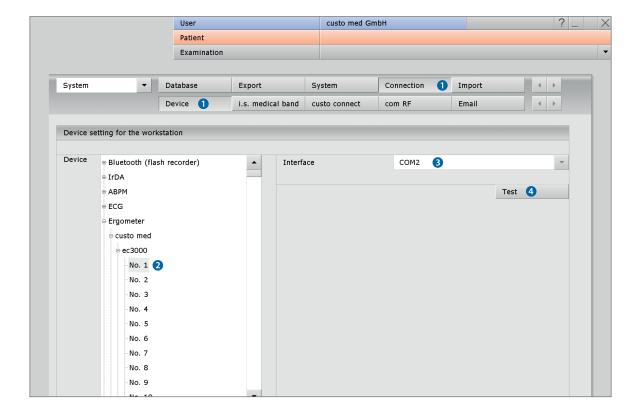
Some devices (e.g. ergometer ec3000 and treadmill er2000) can be connected to the PC using a network cable.

#### > Setting up the interface in custo diagnostic

Select Examination, Settings, Connection, Device ①. Select the connected device (e.g. ergometer, custo med, ec3000, no. 1) ② and its connection ③ (number from the device manager).

You can use the Test 4 button to check if the correct connection was selected and if the connection between the device and custo diagnostic is functioning correctly. If the device was successfully connected, the status "Started OK" will be shown in the test dialogue.

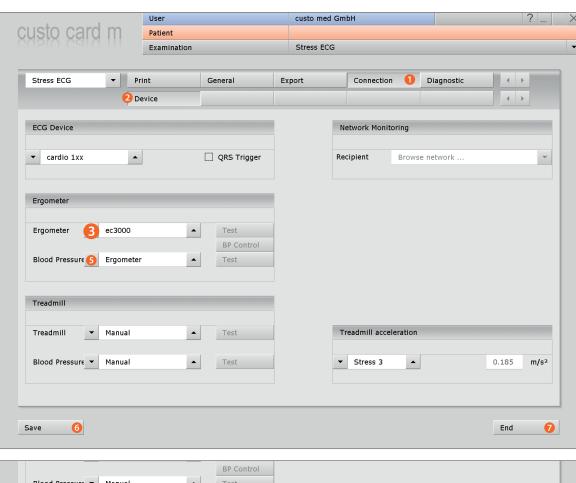
Save your input (button at bottom left).

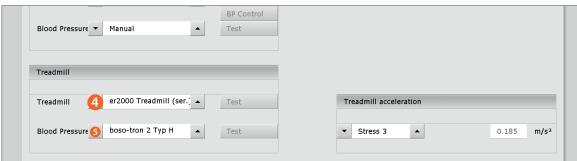




#### 03.5.2 Selecting devices for stress ECG

- In custo diagnostic, select:
  - Examination, Stress ECG, Settings, Connection 1, Device 2
- Select the ergometer 6 or treadmill 4 that was previously set.
- Select the blood pressure module of the ergometer or the previously connected and set sphygmomanometer 5.
- ➤ Click on the Save button 6 (at bottom left) to apply your input.
- Close the page with End (button at bottom right).
- ➤ The device is ready for operation.





#### 04.1 Cleaning and disinfection

#### Important notes



Use only cleaning agents and disinfectants recommended by custo med. Unsuitable agents may damage the device.

Observe the manufacturer's specifications (e.g. regarding dosage and contact times).

The device must never be immersed in liquids or cleaned with too much water.

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

#### Surface cleaning

Make sure that the exterior of the device is always aesthetic and clean. Wipe the device using a damp cleaning cloth and a mild (acid-free!) cleaning agent or a suitable disinfectant.

Cleaning agents and disinfectants must not be sprayed directly on or into the device.

#### Carrying case and belt



Machine wash at 40°



Do not use bleach.



Do not iron.



Do not tumble dry.

The carrying case and belt can be machine washed at up to 40 degrees. In addition, we recommend a quick disinfection with alcohol after each use.



# 04.2 Recommended cleaning agents and disinfectants

#### Disinfectants:

All alcohol-based disinfectants (e.g. propanol, ethanol) approved for medical use.

#### 05.1 Preparing the patient and examination procedure

#### Resting ECG

- Make sure that the ECG device is connected to the PC and the power supply to the device is guaranteed.
- > Check that your patient is lying comfortably and is not cold.
- Shave, clean (e.g. with custo prep ECG cream) and dry the electrode application points thoroughly.
- > Place the electrodes (e.g. custo sensive) on the patient.
- Connect the patient leads to the electrodes.

Start custo diagnostic and click on Examination, Resting ECG, New Resting ECG, select the patient for the examination and start the recording (a precise description of the procedures can be found in *Chapters 05.2 and 05.3*).

The patient should not move or talk during the recording process.

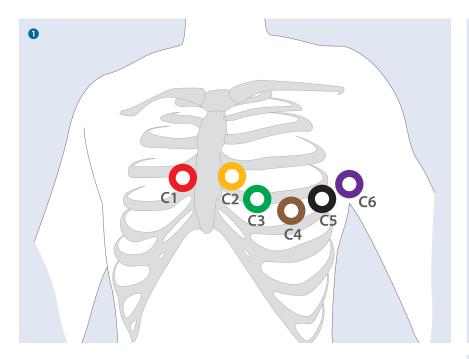
- Stress ECG 

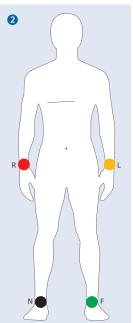
  Make sure that the ECG device is connected to the PC and the power supply to the device is guaranteed.
  - > When using an ergometer, make sure that the patient is in the optimal seating position (the extended leg should be slightly bent).
  - > When using a treadmill, make sure to follow instructions in Chapter "05.1.2 Instructions for stress ECG with treadmill" and observe the instructions "Safe use of treadmills during stress ECG" on page 11.
  - Shave, clean (e.g. with custo prep ECG cream) and dry the electrode application points thoroughly.
  - Place the electrodes (e.g. custo sensive) on the patient.
  - Connect the patient leads to the electrodes.
  - Wait several minutes so that the contact between the skin and the electrodes can develop optimally.
  - Apply the blood pressure cuff.

Start custo diagnostic and click on Examination, Stress ECG, New Stress ECG, select the patient for the examination, set the load profile and start the recording (a precise description of the procedures can be found in Chapters 05.2 and 05.4).



#### 05.1.1 Electrode application for resting and stress ECG





#### • Chest wall resting and stress ECG, standard according to Wilson

#### 2 Extremities resting ECG

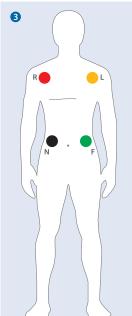
R red Right arm
L yellow Left arm
F green Left leg
N black Right leg

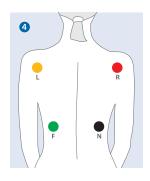
#### 3 Extremities stress ECG (lying or standing)

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

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

R red Attachment deltoid muscle right
L yellow Attachment deltoid muscle left
F green 9. Left rib
N black 9. Right rib





#### 05.1.2 Instructions for stress ECG with treadmill



For stress ECG with treadmill, we recommend using an ECG device with short patient cables, e.g. custo cardio 100 BT ERG combined with custo sensive electrodes.

The patient should ideally be wearing running shoes or trainers.

The patient should not hold onto the handles of the treadmill during the recording process. This will lead to muscle tension which will affect the ECG signal.

Missing skin tension, in interaction with shoulder movement, will increase artefacts in the ECG signal.

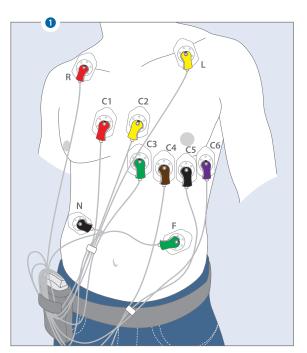
The extremity leads should if possible be applied on taut skin areas in order to avoid excessive movement artefacts and therefore interference in the other derivations.

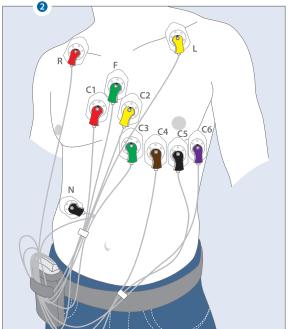
Fix any overlong trailing leads to the carrying case. No tension must be exerted on the electrodes. Make sure that no lead passes over the contact of an electrode.



Tip: To fix electrodes and cables to the patient's body and therefore reduce interference in the ECG signal, the patient should wear a stretchable ECG vest.

• Normal electrode application / ② artefact reduced electrode application With artefact reduced electrode application, the amplitudes are smaller in the extremity derivations.







#### 05.2 First work steps in custo diagnostic

#### 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.

#### Program start, calling the ECG

Start custo diagnostic and log on with your user name and password if required.

#### Click on:

Examination **1**, Resting ECG **2**, New Resting ECG **3** or:

Examination 1, Stress ECG 2, New stress ECG.

#### Selecting the patient

Select a patient for the examination. Enter the patient's name or the first letter of their name into the input fields of the patient search screen **4**.

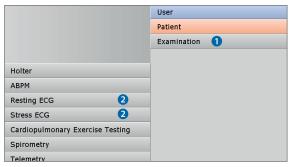
Select the patient from the list below the input fields
and confirm your selection by clicking the Select
Patient 6 button. You can also select the patient by
double clicking on the corresponding name.

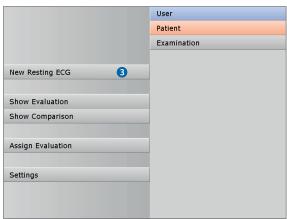
#### New patient

If the patient is not in your database, click on the New patient button. Enter the patient data. The fields marked with an asterisk are mandatory.

Save the details to enter the patient in your database.









#### 05.3 Recording resting ECG

#### 05.3.1 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** (standard, left, right, Nehb, Cabrera) if necessary.
- ➤ Check if all electrodes are attached optimally. If there are red lines ② on the screen, the contact between the skin and electrode(s) is insufficient and the corresponding electrodes need to be reattached. For ECG devices with USB connection, the Electrodes button ③ provides you with a graphic representation of the signal quality of all electrodes.
- Set the required filters (Options menu 4).



The preset standard procedures for automatic ECG and manual recordings are described in this chapter.

These procedures can be changed in the custo diagnostic settings:

and the same of th

#### Print settings for automatic ECG:

The contents for a printout after an automatic ECG recording can be compiled at Examination, Resting ECG, Settings, Print, Automatic in the "Printout Automatic ECG" area.

This setting is only required if the automatic ECG print pages should contain content other than the data already defined in the standard print settings for resting ECG (see Examination, Resting ECG, Settings, Print, Default, "Printout" area).



#### 05.3.2 Starting and ending a resting ECG

# Automatic ECG (Auto Start button 1):

Click on Auto Start 10 to start the automatic recording. The standard 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 1).

#### ➤ Manual recording (Start button ② or Enter key):

If you want to perform a recording without a time limitation (e.g. because of suspected irregularities), you have to activate the recording with Start 2. Click on End 3 to close the recording. Click on Confirm in the End dialogue to ensure that the recording is saved, measured and displayed as an evaluation 2.

# 2) Settings for manual recordings Under Examination, Resting ECG, Settings, General, Workflow in the Workflow area (in the first block "After recording") the procedures after the recording can be set. Click on Save to apply changes.

#### Note on the recording duration: At least 10 seconds of the ECG signal must be recorded. A recording cannot be ended before this time

has elapsed.



#### 05.3.3 Editing options during the recording process

#### Marking ECG sections

Automatic marking: By clicking on the Mark button 1, the last six seconds are automatically marked. A dialogue appears for specifying 3, saving and printing the marked part 3.

Manual marking: By clicking on the Start Mark button 2 you can determine the length of the marking yourself. The marking continues to run until you click on the Stop Mark button. A dialogue appears for specifying 3, printing and saving the marked part 3.

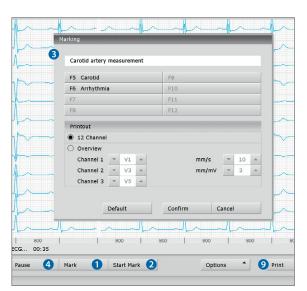


Tip: Keyboard shortcut





Change amplitude (mm/mV)





# 3) TIP: Text modules for specifying marked parts

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

Configuring text modules: Under Examination, Resting ECG, Settings, General, Marking the text modules can be configured for specifying marked parts. A name is assigned to the text module in the "Name" 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.

#### Viewing and marking ECG, measuring HF during a pause

Clicking on Pause 4, will stop the screen display. The recording continues to run and is displayed on one channel 5 (fig. right). The scroll bar 6 can be used to scroll through the current recording.

The tools Mark, Measure HR and Calliper can be found at the top right in the Mouse menu. By dragging the red cursor of in the ECG, you can mark ECG sections (using the Mark mouse function). A dialogue appears for specifying, printing and saving the marked part. With Continue of you return to the normal view of the recording.

#### 05.3.4 Online ECG printing (printing ECG)

Click on Print **9**. A screen page of the ECG signal is printed from the point of clicking. The printout contains 4.5 to 9 sec of the ECG signal, depending on the display speed <sup>4</sup>).

4) Note on online printing:
Under Examination, Resting ECG,
Settings, Print, Default, you can
define in the "Online ECG printout"
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 analysed ECG.

### 05.4 Recording stress ECG

#### 05.4.1 Selection of load profile

Select a load profile in the "Protocol" area **1**. The list includes predefined profiles for ergometers (with watt indications) and the treadmill .

You can modify the predefined profiles. By clicking on Save 3 the predefined profile is overwritten. By clicking on Save as 4 you can save the modified profile under a new name. With the New 5 button you can create new profiles. The values in the alarm area 6 can be set freely and have to be activated if required 1).

After making the profile selection, click on Start 2 to start monitoring.

#### Ergometer profile

"Steady state" option: Activate this option if you want to manually control the load profile during the recording. If Steady state is selected, entries cannot be made for the stage duration, load increase and end in the profile input mask. During the recording, the profile will continue running unchanged, with the defined initial load, until a manual change is made. Click on the Measurement button or the "F8" key to define the end of a load level during the recording. The last 10 seconds will be measured. Then set the load for the new load level.

#### Note on alarm function:

If you want to use the alarm function for the stress ECG, the alarm values must be correctly set in the profile selection before clicking on Start. The alarm values cannot be activated or changed later.

Treadmill profile







#### 05.4.2 Monitoring and electrode control

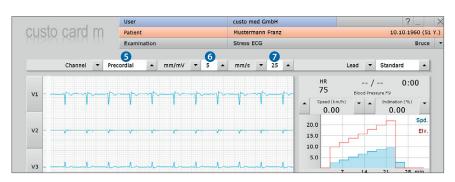
The patient's ECG signal will be shown on the display but not recorded (monitoring). Work steps before the start:

- ➤ Change the type of lead **1** (standard, left, right, Nehb, Cabrera) if necessary.
- ➤ Check if all electrodes are attached optimally. If there are red lines ② on the screen, the contact between the skin and electrode(s) is insufficient and the corresponding electrodes need to be reattached. For ECG devices with USB connection, the Electrodes button ③ provides you with a graphic representation of the signal quality of all electrodes.
- Set the required filters (Options menu 4).



#### Recommended settings for stress ECG with treadmill<sup>2)</sup>:

- ➤ To prevent interferences and movement artefacts, activate power filter, muscle filter and anti-drift filter in the Options menu ④.
- ➤ ECG display: Precordial 5, 5 mm/mV 6 and 25 mm/s 7.





2) Note for the settings: Under Examination, Stress ECG, Settings, General, ECG, the recommended settings for stress ECG with treadmill can be defined as the standard setting for all stress ECG recordings.

Save your input.

#### 05.4.3 Overview of the workspace



Keyboard shortcuts:



Additional blood pressure measurement



Ending and measuring a load level for steady state profile



Blood pressure input



Lactate input



SPO2 input

- Content in Options menu
- Turning the automatic blood pressure measurement on and off
- Activating an additional blood pressure measurement
- Dialogue for entering the report
- **d** Dialogue for entering the blood pressure (with manual measurement)
- Dialogue for entering the lactate values
- **1** Dialogue for entering the SPO2 values (oxygen saturation in the blood)
- New start of ergometry without previous profile selection
- **b** Extending the current stage (only available after the start)
- Recognition of pacemaker spikes for patients with pacemakers
- Filter for removing interferences caused by the power supply
- Anti-drift filter for compensating fluctuations in the zero line
- Signal tone with each heart beat
- Switching alarm signals on and off when the set alarm limits
   (e.g. for ST, HR and blood pressure values and arrhythmias) have been exceeded

Click on Start to start the recording.





#### **▶** Display and control elements (view after Start)

- Setting options for ECG display
- **b** Buttons for controlling and editing the ECG recording
- O Display of heart rate and blood pressure, countdown of the current level
- Changing the current load and load increase for ergometer profiles<sup>3</sup> or speed and slope for treadmill profiles
- Load profile (orange) with heart rate curve (blue)
- Blood pressure curve (green), according to the measured values
- Setting of ST point, display of averaged complex (selection of channel via buttons at left in front of the ECG signal)
- (Online arrhythmia detection), buttons in the area b blink red when the set alarm limits are exceeded:

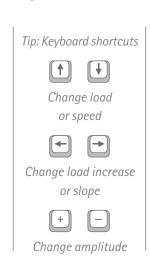
#### 05.4.4 Hint for manual blood pressure measurement

You are regularly requested to measure blood pressure. Enter the measured values in custo diagnostic. To do so, click on Blood pressure in the Options menu or the "F9" key and enter the measured values. Click on Confirm to apply your input. The input of lactate ("F10" key) and SPO2 values ("F11" key) functions in precisely the same way.

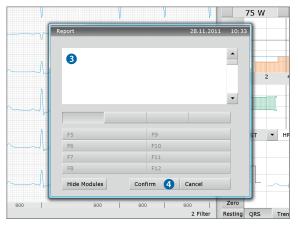
# 3) Note on settings for the load change:

You can define the number of watts by which the load and load increase should change when pressing the

arrow buttons.
This setting can be found under:
Examination, Stress ECG, Settings,
General, ECG in the "Manual load
change" area.







## Note for 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!

#### 5) TIP: Text modules for entering the reason for interruption

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

## Configuring text module:

Select Examination, Stress ECG, Settings, Diagnostic, Reason for End to create text modules for entering a reason for interruption. A name is assigned to the text module in the "Name" field. This name later appears on the button for calling the text module in the "Reason for End" dialogue. In the "Text module" field, enter the text which will later be used to display the reason for interruption. Save your input.

#### 05.4.5 Starting the recording, resting phase

Click on Start 1 or press the Enter key to start the recording. The resting phase begins. It takes ten seconds without blood pressure measurement. The duration is at least one minute with blood pressure measurement (duration can be set freely; see profile selection).

#### 05.4.6 Stress phase 4)

Then the stress phase begins and runs according to the selected load profile. Manual load changes can be made at any time. The Next Stage 2 button can be used to end the current load level and start the next load level

#### Enter report

A report can be entered during the ECG recording. The report dialogue is opened using the Report button in the Options menu. Write your report in the white text field 3. Click on Confirm 4 to save your data.

#### 05.4.7 Recovery phase, ending the recording

The recovery phase can always 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 interruption. Then the dialogue for entering the reason for interruption will open. The reason for interruption can be entered using the text modules, see tip 5). The reason for interruption can be subsequently displayed in the evaluation using the context menu.

If the end of the load phase is already defined in the profile (End at ... watts option or for treadmill profiles), the recovery phase starts automatically after the last load level has expired.

The recovery phase proceeds according to the selected profile. If you would like to end the ECG recording but the ECG signal should still be displayed on the screen, click on the Stop button. Otherwise, the recording will be automatically saved, measured and displayed as an evaluation by clicking on the End button (End is also used to close the evaluation).



#### 05.4.8 Editing options during the recording process

#### Marking ECG sections

Automatic marking: By clicking on the Mark button 1, the last six seconds are automatically marked. A dialogue appears for specifying 6, saving and printing the marked part 3.





# 6) TIP: Text modules for specifying marked parts

Use: If a part is marked during the recording, the "Marking' dialogue appears. The marked parts will be automatically specified by pressing a previously configured text module button or the corresponding key (e.g. F5).

Configuring text modules:
Under Examination, Stress ECG,
Settings, General, Marking the
text modules can be configured for
specifying marked parts. A name is
assigned to the text module in the
"Name" 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.

#### > Viewing and marking ECG, measuring HF during a pause

Clicking on Pause **3**, will stop the screen display. The recording continues to run and is displayed on one channel **2**. The scroll bar **3** can be used to scroll through the current recording.

The tools Mark, Measure HR and Calliper can be found at the top right in the Mouse menu **9**. By dragging the red cursor **10** in the ECG, you can mark ECG sections (using the Mark mouse function). A dialogue appears for specifying, printing and saving the marked part. With Continue **10** you return to the normal view of the recording.

#### 05.4.9 Online ECG printing (printing ECG)

Click on Print ②. A screen page of the ECG signal is printed from the point of clicking. The printout contains 4.5 to 9 sec of the ECG signal, depending on the display speed 7.

7) Note on online printing: Under Examination, Stress ECG, Settings, Print, Default, you can define in the "Online ECG printout" 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 analysed ECG.

## 06.1 Opening the evaluation

custo diagnostic offers different options to open an evaluation, e.g. via the evaluation search or the main menu of the respective examination (resting or stress ECG in this case).

#### Opening an evaluation via the evaluation search

Click with the right mouse button on the Patient **1** button. This opens the evaluation search.

In the Examinations area, enter what type of evaluation you are searching for, e.g. Stress ECG 2. In the Properties area 3 you can define more search criteria.

If you set the confirmed preference to No, you will receive a list of all the evaluations which have not yet been confirmed – a type of to-do list.

To start the search, click on Search Evaluation 4 or activate Search automatically option 5. This option triggers an automatic search in your database whenever the search criteria are changed.



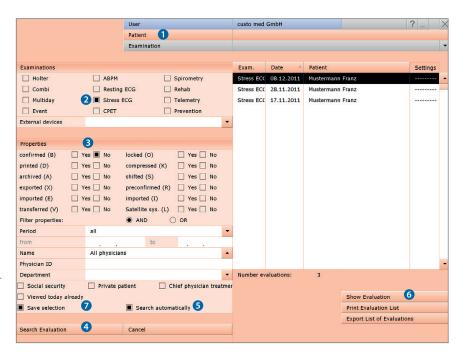
Reference between End dialogue and search screen

In order to make
proper use of the search
screen, the correct
examination status must
be defined in the End
dialogue when closing an
examination.

Example: An
examination can only
be found in the search
screen with the
preference "confirmed:
No" when the evaluation
status "Confirmed" is NOT
selected
in the End dialoque.

The right part of the screen displays a list of all the evaluations which correspond to the activated search criteria. To open the desired evaluation, select it from the list and click on the Show Evaluation button 3 or double-click on the evaluation.

If you want to use the same search criteria for the next search, activate the Save Selection option.





#### Opening an evaluation via the examination main menu

Open the examination main menu via Examination, Resting ECG or Stress ECG, and then click on Show Evaluation 1.





The patient search screen appears. In this screen select the patient whose evaluation you want to open. Enter the patient's name or the first letter of their name into the input fields of the patient search screen ②.

Select the patient from the list below the input fields **3** and confirm your selection by clicking the Select Patient **4** button. You can also select the patient by double-clicking on the corresponding name.

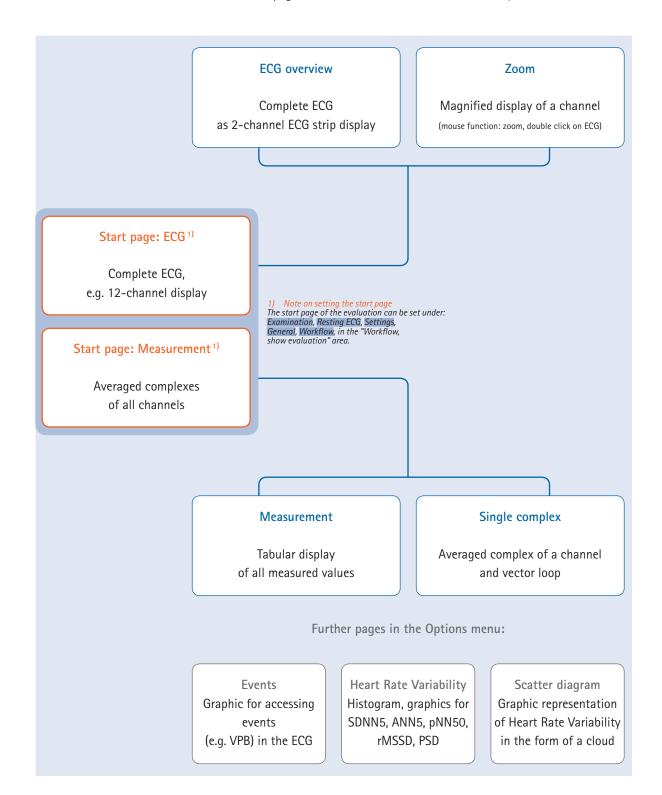
A list containing all the evaluations of the patient is then displayed. Select the desired evaluation from the list and open it by means of a double-click or via the Show Evaluation button.

# Further work steps: 06.2 Resting ECG evaluation p. 42 06.3 Stress ECG evaluation p. 52

# 06.2 Resting ECG evaluation

#### 06.2.1 Screen pages within an evaluation

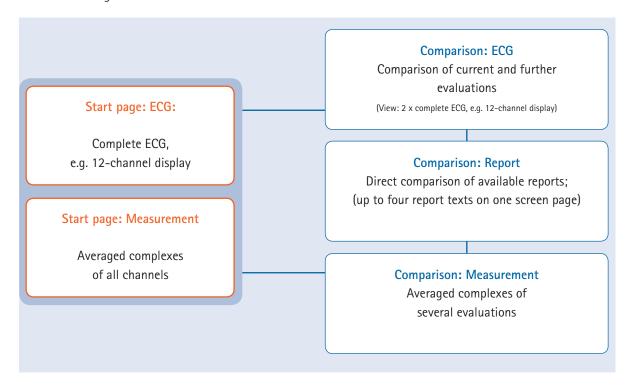
The ECG evaluation is divided into two main areas, ECG and Measurement (the ECG page is preset as the start page of the evaluation). From the subpages of the two areas the main page of the other area can be accessed at any time.





#### 06.2.2 Comparing several evaluations from one patient

The current evaluation can be compared to other evaluations of the patient using the Comparison button. The comparison pages can only be opened if additional ECG evaluations from the patient are available. The Evaluation button will bring you back to the single view.



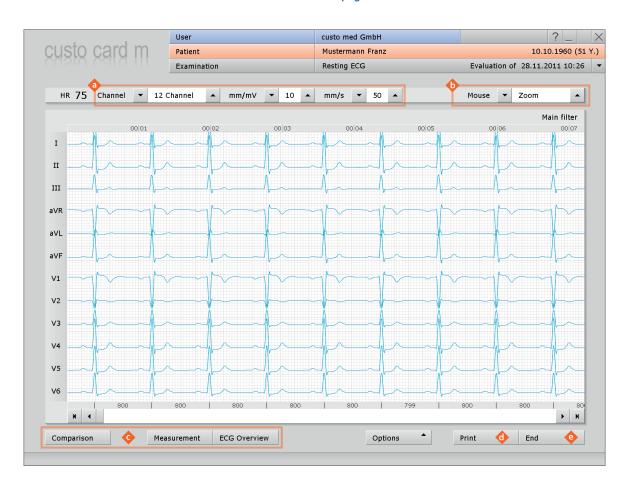
#### 06.2.3 Note on navigation in the evaluation

The buttons for opening further evaluation pages are located on the lower edge of the screen. The labelling of the buttons changes as soon as you switch to a different evaluation page. The button that has been clicked always contains the name of the page you just left.

Example: You click on the Measurement button in the evaluation (view: ECG start page). You go to the Measurement screen and the previously clicked Measurement button changes to ECG. By clicking on ECG, you can return to the previous ECG viewing mode.



#### 06.2.4 Overview of evaluation pages



#### **➤** Elements of the ECG start page

2) Settings for the Print button:

Options for ECG display

Under Examination,
Resting ECG, Settings, General,
Workflow in the "Workflow, Default"
area, you can define whether the
extended print menu should be
displayed when the Print button is
clicked (standard setting) or whether
printing should be conducted automatically according to the standard
print settings (= option Default
printout) without any additional
settings being made.

Mouse functions for detailed viewing and measuring of the ECG signal (Zoom, Analysis, Measure HR, Calliper, Mark)

Further evaluation pages

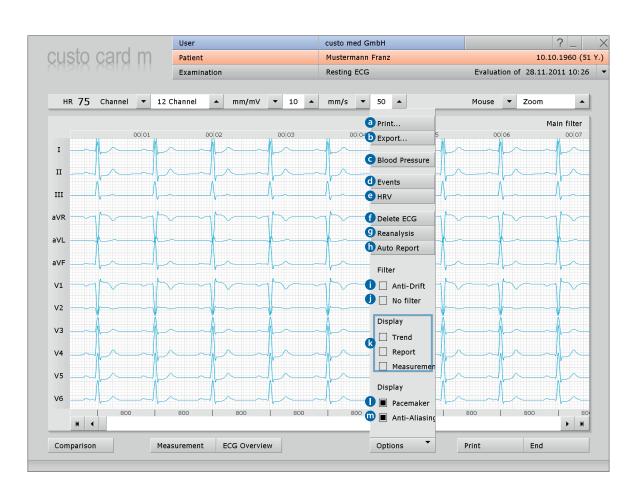
- Button for printing the evaluation<sup>2</sup>
- Button for closing the evaluation

The standard print setting for resting ECG can be found under Examination, Resting ECG, Settings, Print, Default. If the Measurement view is set as the start page, the same operating and navigation elements can be found there ( to .).

Click on Save to apply your changes.

The start page of the evaluation can be set under: Examination, Resting ECG, Settings, General, Workflow in the "Workflow, Show evaluation" area.





#### **➤** Content in the Options menu <sup>3)</sup>

- Print menu for temporary changes to the print settings
- **6** Button for exporting the evaluation (e.g. Excel, PDF, e-mail, DICOM, etc.)
- Manual blood pressure input ("F9" key)
- **d** Trend graphic for displaying events in the ECG (e.g. VPB)
- Tables and graphics for Heart Rate Variability 4) (e.g. SDNN5, ANN5, pNN50, rMSSD, PSD)
- **1** Deletion of ECG outside the marked sections
- New analysis of ECG signal for resetting manual changes in the ECG, additions to the report remain
- Automatic creation of a new report after manual changes have been made in the ECG recording
- 1 Anti-drift filter for compensating fluctuations in the zero line
- Deactivation of all filters (display of raw data)
- Fade in and fade out of additional content in the right half of the screen: e.g. HR curve and ST trend, averaged complexes and report or measurement table
- Fade in and out of pacemaker spikes
- Graphic flattening of ECG signal

#### 3) Note on Options menu The scope and content

The scope and content of the Options menu changes based on which page of the evaluation you are currently on.

e. g. on the Measurement page in the Options menu, you can activate the display of ST values and set which marks should be displayed in the averaged complexes.

4) Note on Heart Rate Variability For the heart rate variability to be displayed, at least five minutes of ECG need to be recorded!

#### > Evaluation pages in the ECG area

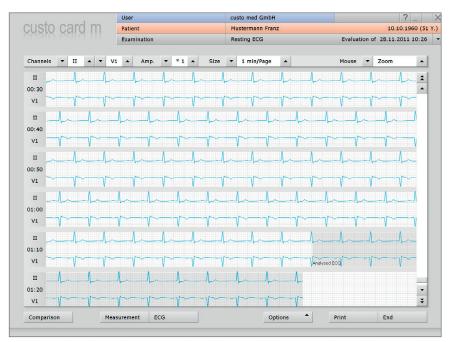
View: ECG start page with additional content



Extended ECG start page with averaged complexes and report.

In the Options menu, select Report to show the additional contents. In the Options menu, measured values (Measurement) or the HR curve and (ST) Trends can also be displayed instead of the report.





Select: ECG Evaluation > ECG Overview

Overview of complete ECG as 2-channel ECG strip display.





View: Zoom

Select: ECG evaluation, mouse function Zoom, double click on ECG Magnified display of a channel. By double clicking on the ECG again, all or the set channels are displayed again.

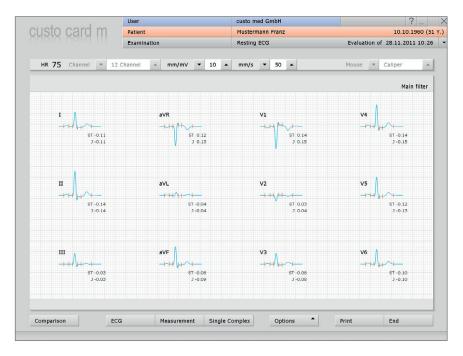


Mouse functions: Measure HR

The selection list "Mouse" (top right, above the ECG) contains, besides Zoom, the Analysis, Measure HR, Calliper and Mark mouse functions.

#### > Evaluation pages in the Measurement area

View: Measurement (averaged complexes)

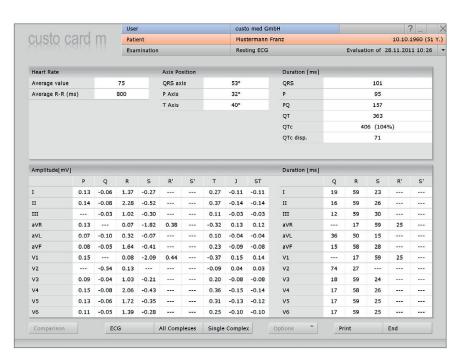


Select: ECG Evaluation > Measurement

Averaged complexes of all channels. In the Options menu, you can display the ST values for the averaged complexes.

View: Measurement (measured values)

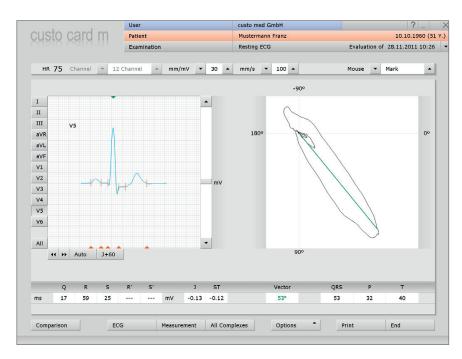
On the page Examination, Resting ECG, Settings, Diagnostic, Calculation can be set if the QTc duration is to be calculated according to Bazett (preset) or Fridericia. Save your input.



Select: ECG Evaluation > Measurement > Measurement

Tabular display of all measured values.





View: Single complex

Using the All button, all averaged complexes will be shown on top of each other, highlighted light grey.

Select: ECG Evaluation > Measurement > Single Complex

Averaged complex of a channel and vector loop.

#### **➤** Further evaluation pages from the Options menu



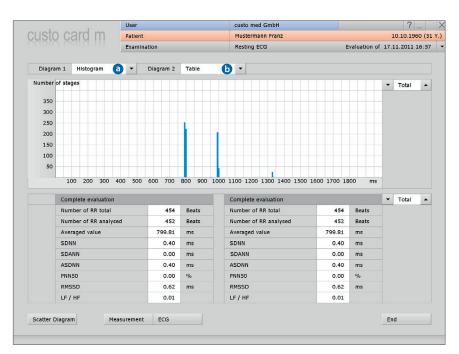
View: Events

Select: ECG evaluation > Options > Events

If the red cursor in the top graphic is moved over an event mark (= orange line), the corresponding ECG section will be displayed.

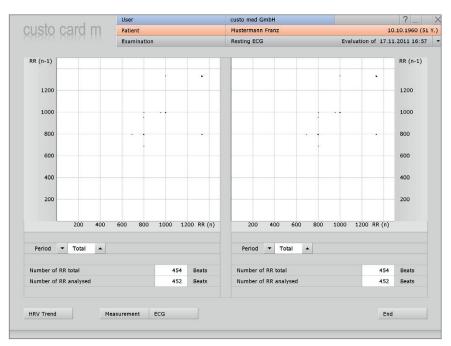
# 06 Working with the evaluation

View: Heart Rate Variability



Select: ECG evaluation > Options > HRV (Heart Rate Variability)
Using the Diagram 1 3 and Diagram 2 5 menus, additional graphics for Heart Rate Variability can be opened.

View: Scatter diagram



Select: ECG evaluation > Options > HRV > Scatter diagram
The more regular the heart rate, the fewer the points which differ from the diagonal of the diagram.



#### **➤** Comparison pages (comparison of different evaluations)



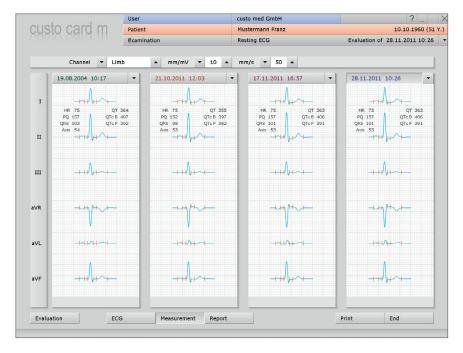
View: ECG comparison

#### Caution

The Comparison button is deactivated (light grey) if no further evaluations of the patient are available.

#### Select: ECG Evaluation > Comparison > ECG

The current evaluation is compared with a further evaluation; the selection lists above the ECG offer further evaluations for comparison. With the Report button, the reports of the evaluations can be directly compared to each other.



View: Measurement comparison

TIP: additional display of measured values

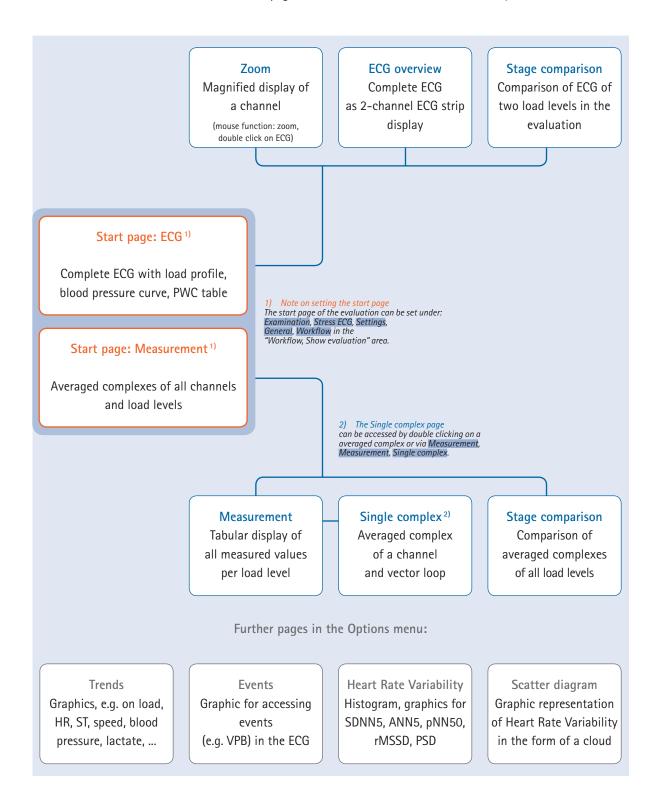
The display of measured values in the averaged complexes can be activated in the settings. This setting is available under Examination, Resting ECG, Settings, General, ECG. In the "Default settings for ECG" area, select the AVG complex comparison with measured values option.

Select: ECG evaluation > Comparison > Measurement
Comparison of averaged complexes of several evaluations

#### 06.3 Stress ECG evaluation

#### 06.3.1 Screen pages within an evaluation

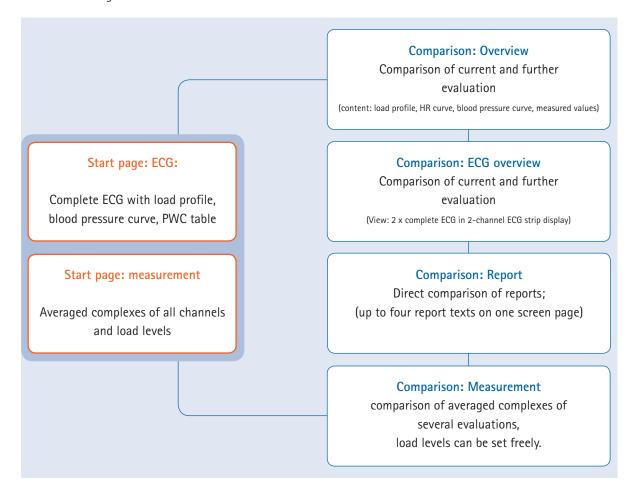
The ECG evaluation is divided into two main areas, ECG and Measurement (the ECG page is preset as the start page of the evaluation). From the subpages of the two areas the main page of the other area can be accessed at any time.





#### 06.3.2 Comparing several evaluations from one patient

The current evaluation can be compared to other evaluations of the patient using the Comparison button. The comparison pages can only be opened if additional ECG evaluations from the patient are available. The Evaluation button will bring you back to the single view.



#### 06.3.3 Note on navigation in the evaluation

The buttons for opening further evaluation pages are located on the lower edge of the screen. The labelling of the buttons changes as soon as you switch to a different evaluation page. The button that has been clicked always contains the name of the page you just left.

Example: You click on the Measurement button in the evaluation (view: ECG start page). You go to the Measurement screen and the previously clicked Measurement button changes to ECG. By clicking on ECG, you can return to the previous ECG viewing mode



#### 06.3.4 Overview of evaluation pages



#### ➤ Elements of the ECG start page

3) Setting the PWC reference values:

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

4) Settings for the Print button:

Under Examination,
Stress ECG, Settings, General,
Workflow in the "Workflow, Default"
area, you can define whether the
extended print menu should be
displayed when the Print button is
clicked (standard setting) or whether
printing should be conducted automatically according to the standard
print settings (= option Default
printout) without any additional

The standard print setting for stress ECG can be found under Examination, Stress ECG, Settings, Print, Default.

settings being made.

Click on Save to apply your changes.

- Options for ECG display
- Mouse functions for detailed viewing and measuring of the ECG signal (Zoom, Analysis, Measure HR, Calliper, Mark)
- Load profile with HR and blood pressure curve
- Tabular display of PWC<sup>3</sup> (physical working capacity) and MET (metabolic equivalent),

further information on PWC and MET available in the appendix

- Further evaluation pages
- Button for printing the evaluation<sup>4</sup>
- Button for closing the evaluation

If the Measurement view is set as the start page, the same operating and navigation elements can be found there ( to .).

The start page of the evaluation can be set under: Examination, Stress ECG, Settings, General, Workflow in the "Workflow, Show evaluation" area.





#### Content in the Options menu 5)

- Print menu for temporary changes to the print settings
- **6** Button for exporting the evaluation (e.g. Excel, PDF, e-mail, DICOM, etc.)
- © Display of blood pressure ("F9"), lactate ("F10") and SPO2 values ("F12")
- d Trend graphics, e.g. on load, HR, ST, speed, blood pressure, lactate, SPO2...
- Trend graphic for displaying events in the ECG (e.g. VPB)
- Tables and graphics for heart rate variability (e.g. SDNN5, ANN5, pNN50, rMSSD, PSD)
- Obligation of ECG outside the marked sections
- New analysis of ECG signal for resetting manual changes in the ECG, additions to the report remain
- Anti-drift filter for compensating fluctuations in the zero line
- Deactivation of all filters (display of raw data)
- Fade in and fade out of additional content in the right half of the screen: Averaged complexes and report or measurement table (preset: trend = load profile with HR curve, blood pressure curve, PWC table and MET table)
- Fade in and out of pacemaker spikes
- Graphic flattening of ECG signal

#### 5) Note on Options menu The scope and content

The scope and content of the Options menu changes based on which page of the evaluation you are currently on.

e. g. on the Measurement page in the Options menu, you can activate the display of ST values and set which marks should be displayed in the averaged complexes.

6) Note on Heart Rate Variability For the Heart Rate Variability to be displayed, at least five minutes of ECG need to be recorded!

#### > Evaluation pages in the ECG area

View: ECG start page



Extended ECG start page with averaged complexes and report. To show additional content, select Report in the Options menu.

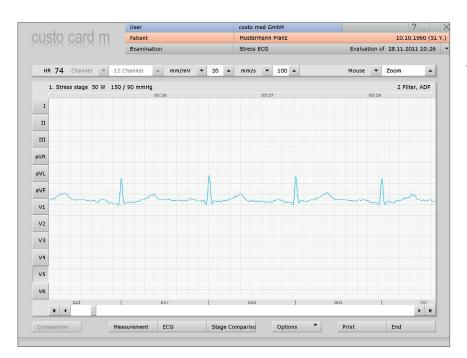
View: ECG start page



Extended ECG start page with measured values.

To show additional content, select Measurement in the Options menu.





View: Zoom

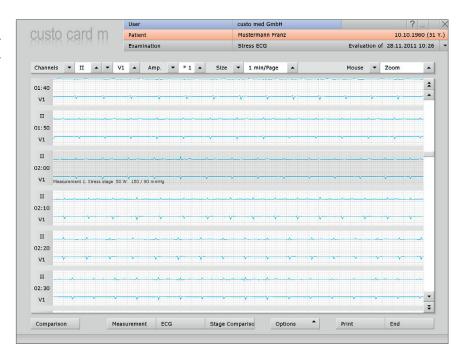
Select: ECG evaluation, mouse function Zoom, double click on ECG Magnified display of a channel. By double clicking on the ECG again, all or the set channels are displayed again.



View: Measure HR

The selection list "Mouse" (top right, above the ECG) contains, besides Zoom, the Analysis, Measure HR, Calliper and Mark mouse functions.

View: ECG overview



Select: ECG Evaluation > ECG Overview

Overview of complete ECG, as 2-channel ECG strip display.

View: Stage comparison



Select: ECG Evaluation > Stage Comparison

ECG of two load levels in comparison. The load levels can be selected using the arrow buttons under the ECG.



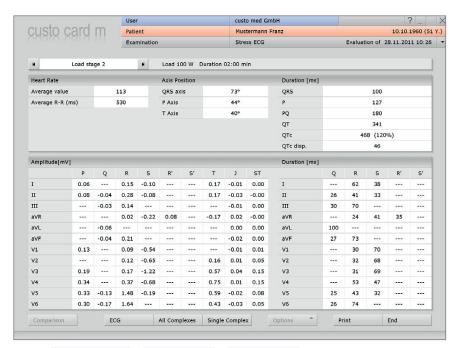
#### > Evaluation pages in the Measurement area



View:
Measurement
(averaged complexes)

Select: ECG Evaluation > Measurement

Averaged complexes of all channels and load levels. In the Options menu, you can display the ST values for the averaged complexes.



View: Measurement (measured values)

On the page Examination, Stress ECG, Settings, Diagnostic, Calculation can be set if the OTc duration is to be calculated according to Bazett (preset) or Fridericia. Save your input.

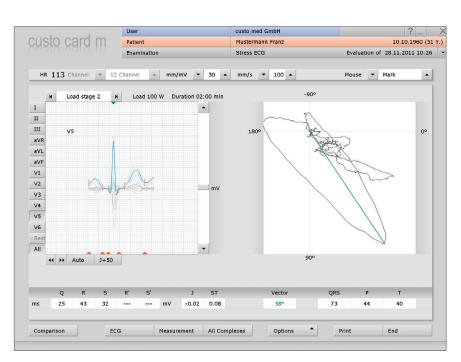
Select: ECG Evaluation > Measurement > Measurement

Tabular display of all measured values per load level (selection at top left).

# 06 Working with the evaluation

View: Single complex

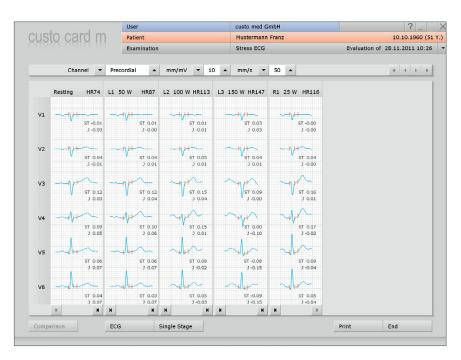
Using the All button, all averaged complexes will be shown on top of each other, highlighted light grey.



Select: ECG evaluation > Measurement > Measurement > Single complex

Averaged complex of a channel and vector loop. The single complex can also
be opened on the Measurement page by double clicking on a averaged complex.

View: Stage comparison



Select: ECG Evaluation > Measurement > Stage Comparison

Comparison of the averaged complexes of all load levels in the current evaluation.



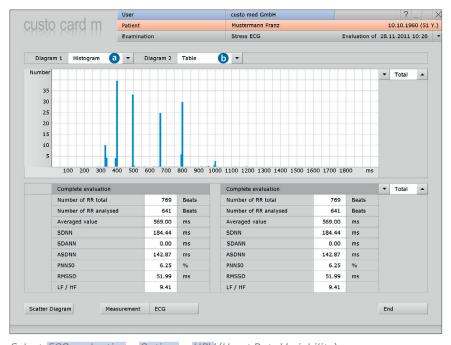
#### > Further evaluation pages from the Options menu



View: Events

Select: ECG evaluation > Options > Events

If the red cursor in the top graphic is moved over an event mark (= orange line), the corresponding ECG section will be displayed.



View: Heart Rate Variability

Select: <u>FCG evaluation</u> > <u>Options</u> > <u>HRV</u> (Heart Rate Variability)

Using the Diagram 1 and Diagram 2 menus, additional graphics for Heart Rate Variability can be opened.

View: Trends

The sequence and content of the graphics can be set under: Examination, Stress ECG, Settings, General, Trends. Save your input.



#### Select: ECG evaluation > Options > Trends

Trend graphics for evaluation, e.g. load profile, HR curve, ST curves, etc.

#### Comparison pages (comparison of different evaluations)



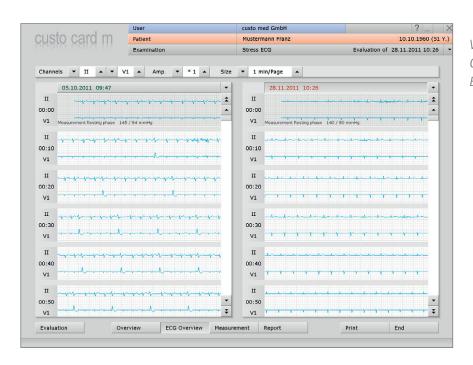


Caution!
The Comparison button
is deactivated (light grey) if no
further evaluations of the
patient are available.

Select: ECG Evaluation > Comparison > Overview

The current evaluation is compared with a further evaluation; the selection lists above the ECG offer further evaluations for comparison.





View: Comparison ECG overview

Select: ECG evaluation > Comparison > ECG Overview

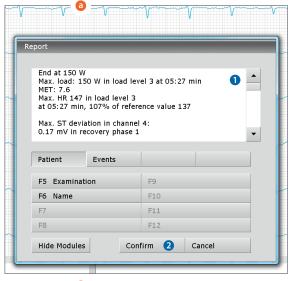
 $\begin{tabular}{ll} \it Minimised\ ECG\ (2-channel\ ECG\ strip\ display)\ of\ two\ evaluations\ in\ comparison. \\ \end{tabular}$ 

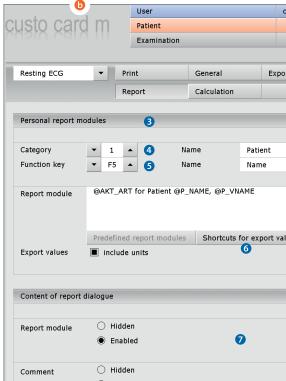
With the Report button, the reports of the evaluations can be directly compared to each other.

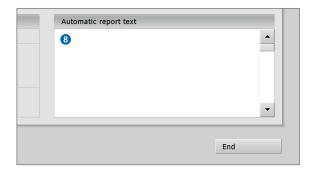


View: Comparison Measurement

Select: ECG evaluation > Comparison > Measurement Comparison of averaged complexes of several evaluations, load levels can be set freely.







## 06.4 Writing the report

The report is opened by right-clicking on the evaluation interface. In the context menu, select Report.

Enter your data in the white text field ①. If the "Add report" option is active in the system settings (on page Examination, Settings, Resting ECG or Stress ECG, Diagnostic, Report), an automatic report is already present in the text field. When you click on Confirm ② your input is saved and the evaluation gets the "Confirmed" status (see "End dialogue").

In the event that your report text is not yet complete but you want to save it nevertheless, without reaching "Confirmed" status, reset the evaluation "Confirmed" status in the "End dialogue".

#### **(b)** Text modules for writing reports

On the page Examination, Resting ECG or Stress ECG, Settings, Diagnostic, Report text modules for writing a report can be created ③. A total of four groups ④ with up to eight text modules ⑤ can be stored. The text modules are called in the "Report dialogue" using keyboard commands (F5 to F12).

A report module can be created from normal text as well as variables. When using a report module in the "Report dialogue", the actual value from the evaluation is used instead of the variable and is automatically inserted in the report text. The structure of a variable is @VARIABLE (e.g. Heart Rate, Resting: @HF\_R). The Shortcuts for export values obutton provides you with a list containing all the available variables.

If the report modules should be shown in the "Report dialogue", make sure that the **Enable** option **?** is activated. Alternatively, the text modules can be shown in the "Report dialogue" via the Show modules button.

There is also the option of entering a text or a user-defined report text (also as normal text and variables), which will be automatically shown in each report ③. The predefined text can be changed later in the "Report dialogue".

Save your input.



## 06.5 Ending the evaluation

The evaluation is closed with the End button. The end dialogue is opened. The status of an examination can be changed here 1.

#### Confirmed 2

A confirmed evaluation can be reset to "Not confirmed" by deselecting the "Confirmed" option (e.g. if reporting has not been completed).

#### ➤ Printed <sup>3</sup>

Indicates if the evaluation has been printed.

#### ➤ Locked 4

After reporting has been completed by an authorised person, set the status of the evaluation to "Locked". After that, the evaluation can still be viewed, but no longer changed.

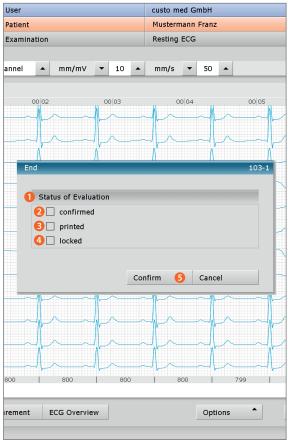
Click on Confirm 5 to close the examination.

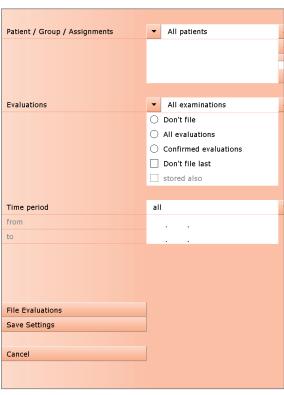
# 06.6 Archiving evaluations (optional)

Archiving is not a data backup (copy), instead your evaluations are just moved to another storage location. Take adequate measures to backup data within your archive at regular intervals in order to avoid data loss.

Archiving is used to save recordings on a long-term basis. During archiving, the evaluations are moved to a directory on your hard disc, which you can then save on a data carrier (CD, DVD, etc.).

The archiving functions can be found under Patient, Edit Database.





# 07.1 Technical data and system requirements

Frequency response	0.05 – 500 Hz		
Accuracy	< 1.5%		
Time constant	3.2 sec		
Sampling rate	1.0ms/1000 Hz for extremities and chest wall		
	0.25ms/4000 Hz for pacemaker		
A/D converter	24 bit		
Input impedance	> 50 MΩ		
Amplitude quantification	0.3 μV/bit		
CMRR	> 70 dB		
Impedance measurement *)	At all electrode leads (not N) with automatic quality indication		
Defibrillation protection	Electrical strength 5000 V		
	Recovery time after defibrillation	on < 10s	
Voltage supply	USB devices	USB cable	
	BT devices	Rechargeable lithium-ion battery	
Energy consumption	Max. 2.5 watt during recording		
IT connection	USB (cable length 2.50 m)		
	or Bluetooth (range up to 80 m, depending on ambient conditions)		
Software, additional functions	Power filter, muscle filter,		
(custo diagnostic)	AD filter (Anti-drift), pacemake	rrecognition	
Operating conditions	Temperature	+10°C +40°C	
	Air humidity	25 95% rH	
	Air pressure	700 1060 hPa	
Transport and storage	Temperature	-20°C +45°C	
conditions	Air humidity	25 95% rH	
	Air pressure	700 1060 hPa	
Dimensions	Size custo cardio 100/110	approx. 160 * 85 * 25 mm (L * W * H)	
	Size custo cardio 130	approx. 160 * 78 * 32 mm (L * W * H)	
	Weight custo cardio 100/110	approx. 300 g	
	Weight custo cardio 130	approx. 430 g	
Patient leads	custo cardio 100/110	approx. 1050 mm (extremities)	
	·	approx. 700 mm (chest)	
	custo cardio 100 ERG	approx. 600 – 700 mm (extremities)	
		approx. 500 – 650 mm (chest)	
	custo cardio 130	15-pin ECG input connector	
		(D-Sub screw connection or Siemens plug	
Classification	custo cardio 100/110/130 USB	Safety class II	
Classification	custo cardio 100/110 BT	Device with internal power supply	
	Class IIa		
	Type BF defibrillation protected (not intracardiac)		
	IEC 60601-1	,	
	IEC 60601-2-25		
	IEC 60601-2-51		

<sup>\*)</sup> Does not apply to Bluetooth devices



System requirements				
Operating system	Windows XP (x64)			
	Windows Vista (x64)			
	Windows 7 (x64)			
	Windows Server 2003 (x64)			
	Windows Serve	Windows Server 2008 (x64)		
	Windows Serve	er 2008 R2		
	older versions	older versions are not supported		
PC	The PC hardwa	The PC hardware must meet the minimum requirements		
	of the operatin	of the operating system used.		
	custo diagnost	custo diagnostic requires additional RAM (256 MB).		
	Ensure that there is enough free hard disk space			
	for the custo d	for the custo diagnostic evaluations.		
File size of the evaluations	Holter ECG	approx. 15 MB (max. 60 MB)		
	ABPM	approx. 128 KB (max. 512 KB)		
	Resting ECG	approx. 200 KB (approx. 10 sec ECG)		
	Stress ECG	approx. 6 MB (approx. 20 min. ECG)		
	CPET	see Stress ECG		
	Spirometry	approx. 50 KB (max. 256 KB)		
	Rehab	approx. 6 MB (approx. 45 min. training session)		
Hardware & ports	DVD or CD-RO	DVD or CD-ROM drive		
	USB port			

# 07.2 Support

If you have any questions or problems which are not dealt with here, please do not hesitate to contact your authorised custo med dealer. A list of the authorised custo med dealers can be found in the Internet under <a href="https://www.customed.de">www.customed.de</a>, in the category <a href="https://contact">Contact</a>, Dealers.

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 dealer or contact your authorised custo med dealer and forward your queries.

# **Product information**

# 07.3 Manufacturer declaration on EMC (Electromagnetic Compatibility) according to IEC 60601–1–2:2007

#### Cable lengths of the patient leads and the USB cables

Patient leads 100/110 approx. 1050 mm & 700 mm

100 ERG approx. 600 – 700 mm and approx. 500 – 650 mm

USB cable 100/110/130 approx. 2500 mm

#### Manufacturer's Declaration - electromagnetic emissions

The custo cardio 100/110/130 ECG device is designed for operation in the electromagnetic environment stated below. The customer or user of custo cardio 100/110/130 should make sure that it is used in such an environment.

Emission Measurements	Compliance	Electromagnetic Environment - Guidelines	
HF emissions according to CISPR11	Group 1	custo cardio 100/110/130 uses HF energy only for its internal function. Its level of HF emission is therefore very low and is unlikely to be sufficient to interfere with other electronic devices.	
HF emissions according to CISPR11	Class B	custo cardio 100/110/130 is suitable for use in all est lishments, including domestic establishments and the directly connected to the public low voltage power sply network that supplies buildings used for domespurposes.	
Harmonics according to IEC61000-3-2	Not applicable		
Voltage fluctuations/flickers according to IEC61000-3-3	Not applicable		

#### Manufacturer's Declaration - electromagnetic immunity

The custo cardio 100/110/130 ECG device is designed for operation in the electromagnetic environment stated below. The customer or user of custo cardio 100/110/130 should make sure that it is used in such an environment.

Immunity Tests	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment - Guidelines
Electrostatic discharge (ESD) according to IEC 61000-4-2	± 6 kV contact discharge ± 8 kV air discharge	± 6 kV contact discharge ± 8 kV air discharge	Floors should be made of wood or concrete or be equipped with ceramic tiles. If the floor is provided with synthetic material, the relative air humidity must be at least 30%.
Fast transient electric interference factors/bursts according to IEC 61000-4-4	± 2 kV for net wires ± 1 kV for input and output wires	Not applicable	The quality of the supply voltage should correspond to the one of a typical business or clinical environment.
Surges according to IEC 61000-4-5	± 1 kV push-pull voltage ± 2 kV push-push voltage	Not applicable	The quality of the supply voltage should correspond to the one of a typical business or clinical environment.
Voltage drops, short-time interruptions and fluctuations in the supply voltage according to IEC 61000-4-11	< 5% U <sub>T</sub> for 0.5 period (> 95% drop) 40% U <sub>T</sub> for 5 periods (60% drop) 70% U <sub>T</sub> for 25 periods (30% drop) < 5% U <sub>T</sub> for 5s (> 95% drop))	Not applicable	The quality of the supply voltage should correspond to the one of a typical business or clinical environment. If the user of custo cardio 100/110/130 requires continued function, even if interruptions in the energy supply occur, it is recommended to supply custo cardio 100/110/130 from an interruption-free power supply.
Magnetic field with supply frequency (50/60 Hz) according to IEC 61000-4-8	3 A/m	3 A/m	Magnetic fields with net frequency should correspond to the typical values, as they can be found in the business and clinical environment.

COMMENT:  $U_T$  is the net AC voltage before applying the test levels



#### Manufacturer's Declaration - electromagnetic immunity

The custo cardio 100/110/130 ECG device is designed for operation in the electromagnetic environment stated below. The customer or user of custo cardio 100/110/130 should make sure that it is used in such an environment.

Immunity Tests	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment - Guidelines
			Portable and mobile radio sets should not be used at a closer distance to the device including the leads than the recommended protective distance which is determined according to the equation of transmitting frequency.  Recommended protective distance:
Conducted HF transients	3 V <sub>effective</sub> value	[U <sub>1</sub> ] V	$d = (3.5/U_1) \sqrt{P}$
according to IEC 61000-4-6	150 KHz to 80 Mhz	10 V <sub>effective</sub> value	d = (3.5/E₁) √P 80 MHz to 800 MHz
Radiated HF transients	3 V/m	10 V/m	$d = (7/E_1) \sqrt{P}$ 800 MHz to 2.5 GHz
according to IEC 61000-4-3	80 MHz to 2.5 GHz		with P as the nominal power of the transmitter in watt (W) according to the indications of the transmitter manufacturer and d as the recommended protective distance in meters (m).  According to an examination on-site a) the field strength of stationary radio transmitters should be inferior to the compliance level b) with regard to all frequencies. In the vicinity of devices carrying the following symbol, interferences are possible:

#### COMMENT 1:

With 80 MHz and 800 MHz the higher frequency range is valid.

#### COMMENT 2:

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

a) The field strength of stationary transmitters, such as e.g. base stations of mobile phones and mobile transmitting stations, amateur radio stations, AM and FM broadcasting as well as television networks cannot be exactly predetermined theoretically. In order to determine the electromagnetic environment regarding the stationary transmitters, a study of the location should be considered. If the measured field strength exceeds the abovementioned compliance levels at the location where the device is used, the device should be watched in order to prove the intended functions. If unusual performance features are observed, it may be necessary to take additional measures, for example reorienting or relocating the device.

b) Over the frequency range from 150 kHz to 80 MHz the field strength should be inferior to 10 V/m.

# **Product information**

# Recommended protective distances between portable and mobile HF telecommunication devices and custo cardio 100/110/130

custo cardio 100/110/130 is designed for the operation in an electromagnetic environment in which the HF transients can be controlled. The user can help avoid electromagnetic interferences by maintaining the minimum distance between portable and mobile HF telecommunication devices (transmitters) and the device – depending on the initial performance of the communication device – as indicated below.

	Protective distance depending on the transmitting frequency in m			
Nominal power of the transmitter W	150 kHz to 80 MHz d= (3.5/U1) √P	80 MHz to 800 MHz d= (3.5/E1) √P	800 MHz to 2.5 GHz d= (7/E1) √P	
0.01	0.04	0.04	0.08	
0.1	0.11	0.11	0.22	
1	0.35	0.35	0.70	
10	1.11	1.11	2.22	
100	3.50	3.50	7.00	

For transmitters whose maximum nominal power is not indicated in the above table, the recommended protective distance d can be determined in meters (m), using the equation affiliated with the corresponding column. P is the maximum nominal power of the transmitter in watt (W) according to the indications of the manufacturer of the transmitter.

#### COMMENT 1:

With 80 MHz and 800 MHz the higher frequency range is valid.

#### COMMENT 2:

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



## 07.4 EC Declaration of Conformity

# 

# **EG-Konformitätserklärung** *EC Declaration of Conformity*

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

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

EKG-Systeme custo diagnostic

ECG Systems custo cardio 100/100 BT

custo cardio 110/110 BT

custo cardio 130

custo cardio 200/200 BT

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

Die Konformitätsbewertung entspricht dem Verfahren von Anhang II (ohne Abschnitt 4), Richtlinie für Medizinprodukte 93/42/ EWG.

The conformity assessment procedure is based on Annex II (excluding section 4), Medical Device Directive 93/42/EEC.

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

Benannte Stelle / Notified Body

Kenn-Nummer | ID number EG Zertifikat Nr. | EC Certificate no. Ausstellungsdatum | Date of issue Ablaufdatum | Expiry date TÜV SÜD Product Service GmbH Ridlerstr. 65, 80339 München, Germany

0123

G1 16 10 12998 007 01.12.2016 30.05.2019

Ort / City

Ottobrunn, den 13.12.2016

© custo-med

Peter Müller

Geschäftsführer / Director

## 07.5 Shutdown, storage and transport

#### Putting out of operation and storage



Clean and disinfect custo cardio 100/110/130 and its components before putting it 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, custo cardio 100/110/130 may only be used again if a technical safety check has been carried out by your authorised custo med dealer.

#### **Transport**



Clean and disinfect custo cardio 100/110/130 and its components before transport.



Use the original packaging for transport. This is a sensitive piece of electronic equipment.



If the original packaging is not available, pack the device in a way that it is protected against collision, humidity and dust.

The device must comply with the operating conditions when it is put into operation again, e.g. operating temperature (see 07.1 Technical Data...).

#### Ambient conditions for storage and transport



-20° ... +45°C Temperature: Air humidity: 25 ... 95% rH 700 ... 1060 hPa Air pressure:

#### 07.6 Disposal



The device and all its components must be disposed of in a proper manner in compliance with applicable regulations (that is, in accordance with the valid laws governing electrical and electronic waste). The device must not be disposed of as normal domestic waste.



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



## 07.7 Keyboard navigation and shortcuts in custo diagnostic

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

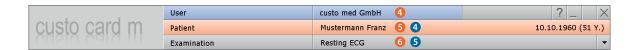


#### LEFT-CLICK

- User master data
- 2 Call last patient
- Examination main menu

#### RIGHT-CLICK

- Evaluation search
- 2 Call last patient
- 3 Evaluation last displayed



#### LEFT-CLICK

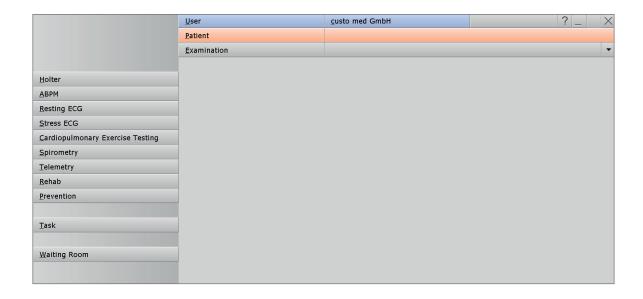
- User master data
- Patient master data
- 6 Examination main menu

#### **RIGHT-CLICK**

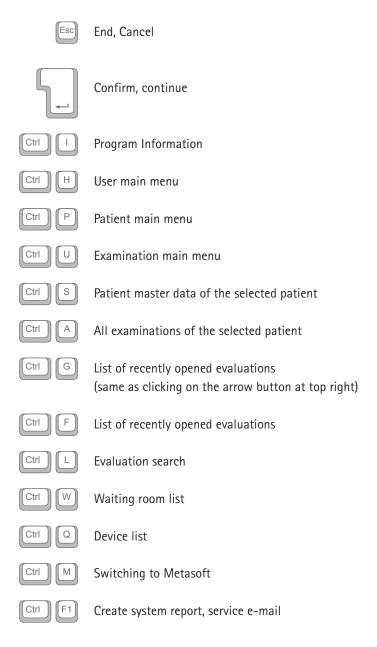
- 4 All the patient's evaluations
- **5** Evaluation last displayed of this examination

#### 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 in combination with the Alt key triggers the corresponding button.



#### Generally accepted keyboard shortcuts



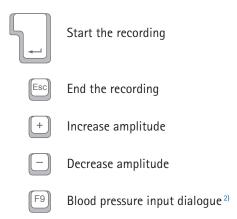


#### Generally accepted keyboard shortcuts for open evaluation



<sup>1)</sup> Keyboard shortcut will only work if the corresponding button is available on the screen page.

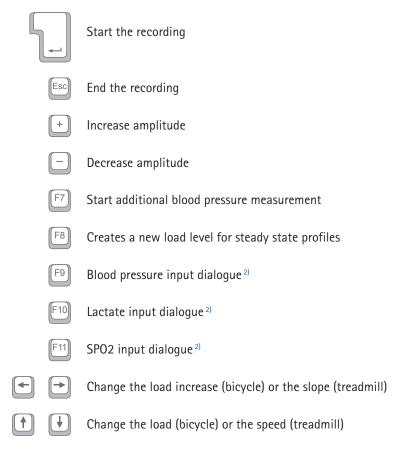
#### Resting ECG keyboard shortcuts during the recording



<sup>2)</sup> This keyboard shortcut is also available in the evaluation display.



#### Stress ECG keyboard shortcuts during the recording



<sup>2)</sup> This keyboard shortcut is also available in the evaluation display.

#### Values and formulas in the ECG evaluation

#### PWC (physical working capacity)

The PWC value 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. 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 at 200 W, the PWC value will be calculated as follows:

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

The PWC reference 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:

- for stress ECG with treadmill:
- v = max. speed in miles per hour

m = slope in %

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

- for stress ECG with ergometer:
- L = max. load in watts

W = weight in kg

$$MET = 1 + (12 * L) : (3.5 * W)$$

#### Calculation of QTc duration

- ► Formula according to Bazett:  $QTc\text{-}Duration = QT * \sqrt{\frac{HR}{60}}$
- Formula according to Fridericia:  $QTc\text{-}Duration = QT * \sqrt[3]{\frac{HR}{60}}$






#### Manufacturer's contact details:

custo med GmbH Maria-Merian-Str. 6 85521 Ottobrunn Germany

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

