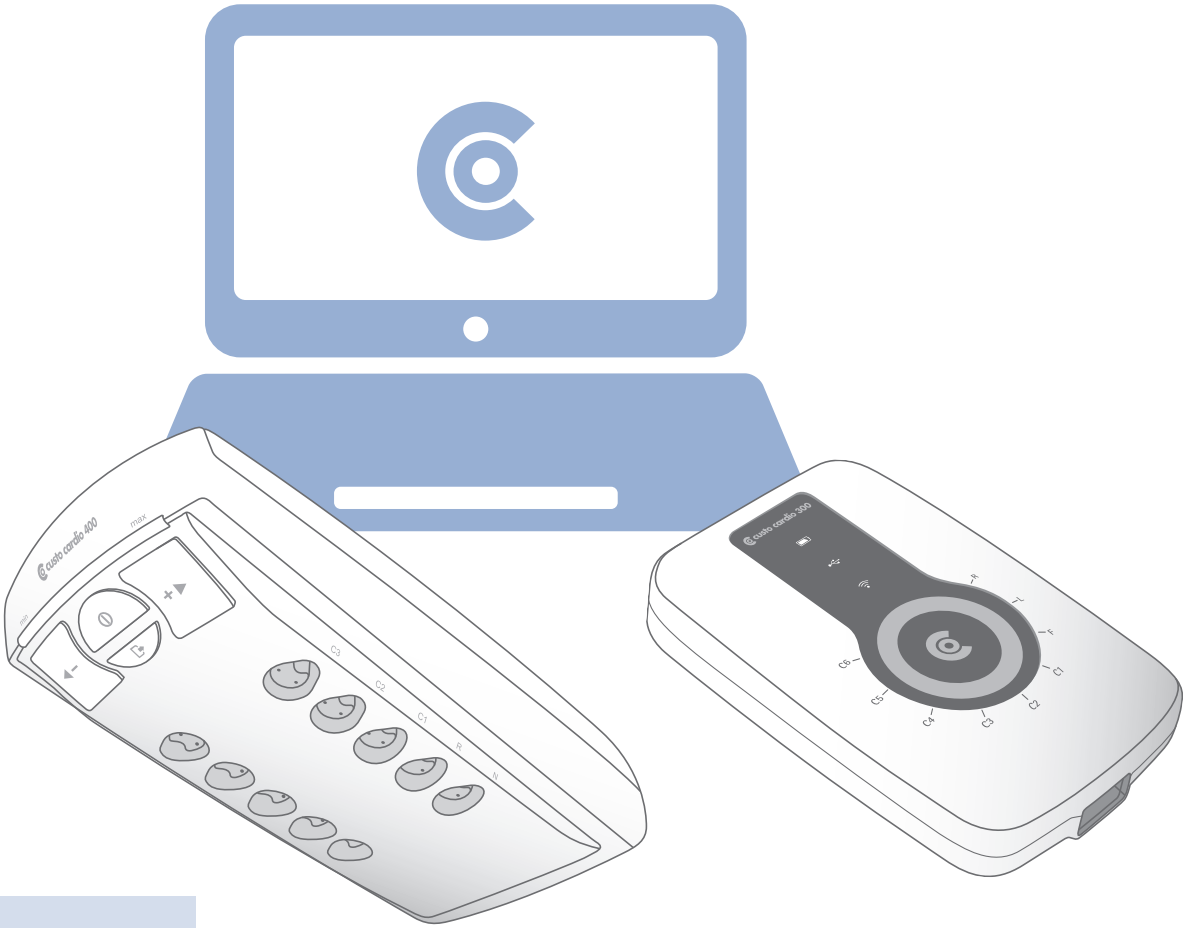
Operating Manual

Resting and Stress ECG

1 Safety | 2 Hardware | **3 Software** | 4 Hygiene

Part 3: custo diagnostic software for custo cardio 300 / 400



Operating characteristics:
custo diagnostic 5.2
and higher
for Windows®

MSW 0030 – DK 1834
Version 001 – 10/01/2020

CE 0123

custo·med
EXCELLENCE IN DIAGNOSTICS

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

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

Operating Manual

Resting and Stress ECG

1 Safety | 2 Hardware | 3 Software | 4 Hygiene

Part 3: custo diagnostic software for custo cardio 300 / 400

Table of contents

3.1 Symbols used in this Operating Manual

ACTIONS THAT ARE PROHIBITED
or not allowed under any circumstances!

WARNING
used to indicate situations which, if not avoided, could result in personal injury or 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 to the corresponding program point, e.g. Examination, Settings, ...

Words highlighted in colour...

3.2 custo diagnostic program structure

The custo diagnostic program is divided into three areas – User, Patient and Examination. This structure ensures that you can always recognise who (which user) is carrying out what type of examination with whom (which patient). The main menus of each area can be reached by clicking on User, Patient or Examination.

In the User ❶ main menu, the user of the system can be selected. The administration of users takes place in the custo diagnostic service centre (creating users, allocating user rights, user-specific settings).

The Patient ❷ main menu is used for patient management. Its most important functions include Search for patient, Add new patient and Search Evaluation.

The Examination ❸ main menu lists all of the examination types which are possible with custo diagnostic. Modules already purchased are active (black font), all other modules are inactive (light grey font).
This menu is also linked to the Settings ❹ area. This area is for making cross-program, examination-related and user-specific settings.

3.3 Connecting custo med devices to the PC

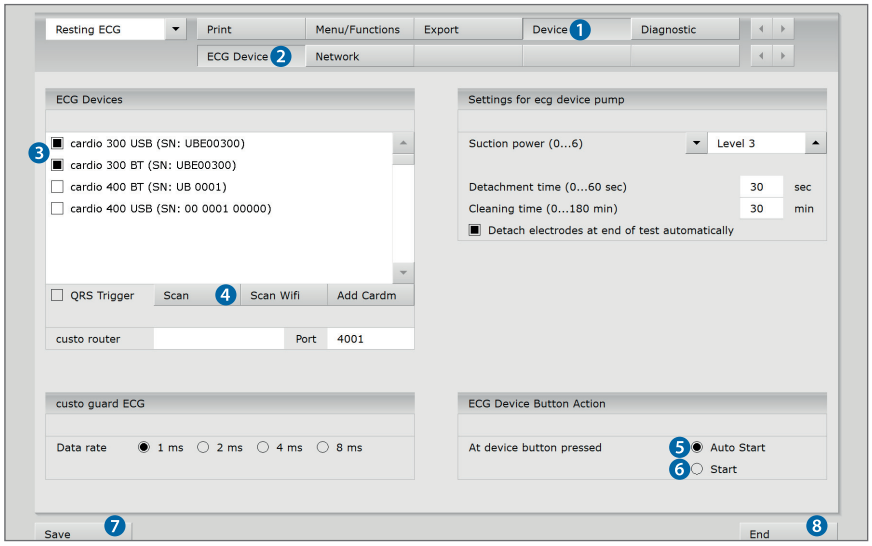
Prerequisite: custo diagnostic is installed on your PC and ready to use. The custo med devices and components may only be connected to the PC after custo diagnostic has been installed. The required device drivers are installed on the PC via the custo diagnostic standard setup or by specific selection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

3.3.1 Connecting and configuring custo cardio 300

custo cardio 300 USB version

Connect the ECG device to the PC using the supplied USB cable. Power is supplied via the USB cable. This charges devices with an integrated battery. The Windows driver installation starts automatically. After the driver installation has been completed, the device is configured in custo diagnostic:

- Start custo diagnostic and select Examination, Resting ECG or Stress ECG, Settings, Device ❶, ECG Device ❷.
- The ECG device is shown in the "ECG devices" section: cardio 300 USB ❸.
- If it does not appear, click Scan ❹.
- Select the ECG device cardio 300 USB ❸.
- Later on, the ECG recording can also be started by pressing the button on the device. Here you can define the recording type: Auto start ❺ (automatic ECG 10 s) or Start ❻ (manual recording, any duration).
- Save ❼ your input and close the screen with End ❽.
  The ECG device is ready for operation.
- For stress ECG: Configure the training device, *see Chapter 3.3.3 and 3.3.4*.



custo cardio 300 Bluetooth & USB version[1] with rechargeable batteries or batteries

1) To use the USB port, follow the instructions on the previous page.

Setting up the Bluetooth connection

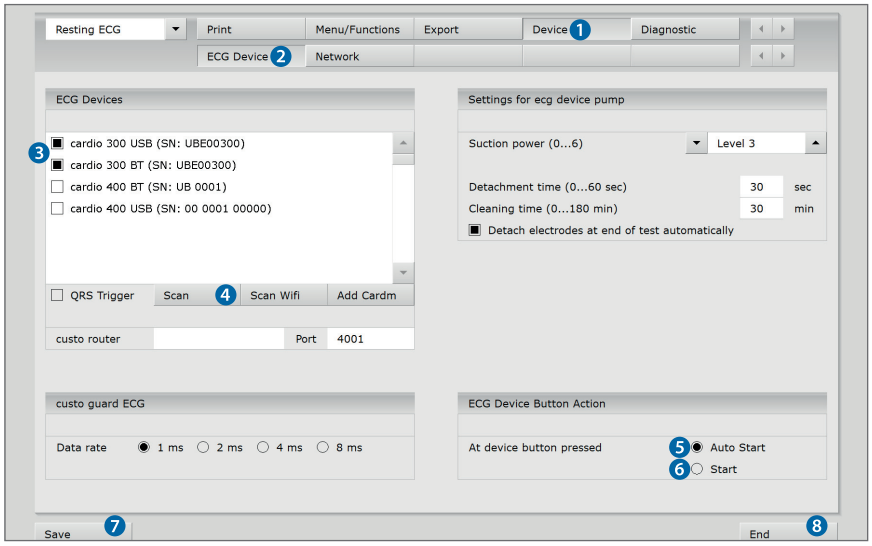
- Plug the Bluetooth USB stick into the PC.
  The driver installation starts automatically.
- Check whether the Bluetooth driver was installed correctly:
- On your Windows desktop right-click on Workspace or Computer.
  Select Manage in the context menu.
- In the left side of the window, click Device Manager.
- In the right side of the window, expand the Bluetooth item.
  The options Broadcom BCM20702 Bluetooth 4.0 USB Device and Microsoft Bluetooth Enumerator should appear.

Connecting custo cardio 300 BT to the PC

- Switch the device on by pressing and holding the custo med logo until the battery symbol, Bluetooth symbol and electrode monitoring field illuminate.
- Open Windows Control Panel.
- Click on Devices and printers, Add device. The ECG device is found.
- Select the custo cardio 300 entry in the "Add device" dialogue box and click on Next. The device is added without pairing code.

Device configuration for resting and stress ECG

- Start custo diagnostic and select Examination, Resting ECG or Stress ECG, Settings, Device ❶, ECG Device ❷.
- The ECG device is shown in the "ECG Devices" section: cardio 300 BT ❸.
- If it does not appear, click Scan ❹.
- Select the ECG device cardio 300 BT ❸.
- Later on, the ECG recording can also be started by pressing the button on the device instead of using the software interface. Define the recording type: Auto start ❺ (automatic ECG 10 s) or Start ❻ (manual recording, any duration).
- Save ❼ your input and close the screen with End ❽.
  The ECG device is ready for operation.
- For stress ECG: Configure the training device, *see Chapter 3.3.3 and 3.3.4*



3.3.2 Connecting and configuring custo cardio 400 BT (with Bluetooth and USB)

Connect the supplied power supply unit to the custo cardio 400 BT ECG device or to the custo cardio 400 BT supply line of the telescopic boom. Connect the power supply unit to the mains.
Either both connections (BT and USB) or only one connection can be configured as necessary. The user can define the configuration sequence.

Setting up the Bluetooth connection

- Plug the Bluetooth USB stick into the PC.
  The driver installation starts automatically.
- Check whether the Bluetooth driver was installed correctly:
- On your Windows desktop right-click on Workspace or Computer.
  Select Manage in the context menu.
- In the left side of the window, click Device Manager.
- In the right side of the window, expand the Bluetooth item.
  The options Broadcom BCM20702 Bluetooth 4.0 USB Device and Microsoft Bluetooth Enumerator should appear.

Connecting custo cardio 400 BT Bluetooth to the PC

- Open Windows Control Panel.
- Click on Devices and printers, Add device.
  The ECG device is found.
- Select the custo cardio 400 BT entry in the "Add device" dialogue box and click on Next. The device is added without pairing code.

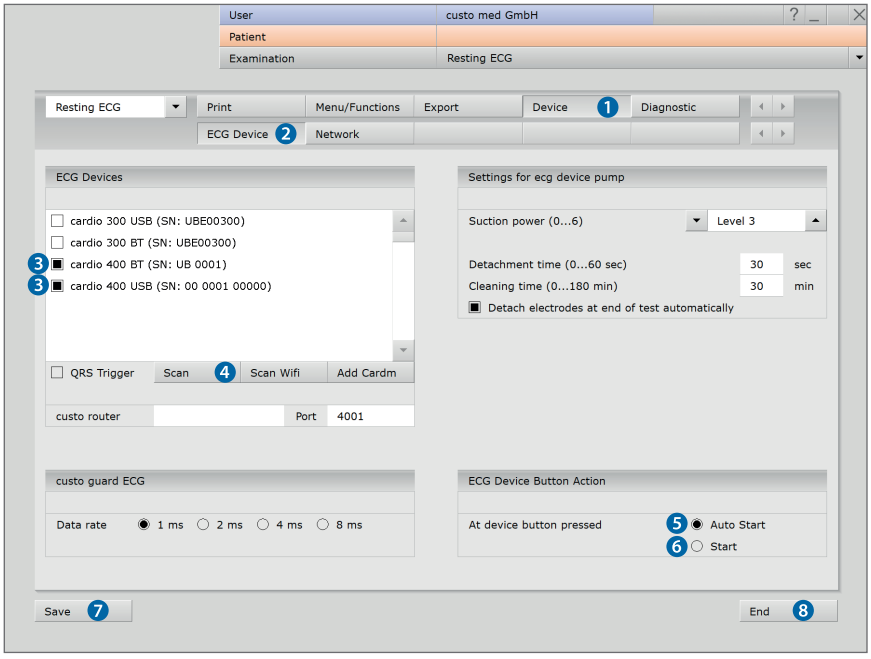
Setting up the custo cardio 400 BT USB connection

Connect the ECG device to the PC using the supplied USB cable. The Windows driver installation for the new hardware starts automatically. Select the "Find driver automatically" option. After the driver installation has been completed, the device is configured in custo diagnostic.

The device configuration for the resting and stress ECG is on the next page.

Device configuration for resting and stress ECG

- Start custo diagnostic and select Examination, Resting ECG or Stress ECG, Settings, Device ❶, ECG device ❷.
- The ECG device is shown in the "ECG devices" section: cardio 400 BT and custo cardio 400 USB ❸.
- If it does not appear, click Scan ❹.
- Select cardio 400 BT and/or custo cardio 400 USB ❸.
- Later on, the ECG recording can also be started by pressing the ⏻ button on the device instead of using the software interface. Define the recording type: Auto start ❺ (automatic ECG 10 s) or Start ❻ (manual recording, any duration).
- Save ❼ your input and close the screen with End ❽. The ECG device is ready for operation.
- For stress ECG: Configure the training device, *see Chapter 3.3.3 and 3.3.4*.



Additional custo cardio 400 BT device settings

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

❸ Suction power

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

❹ Detachment time

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

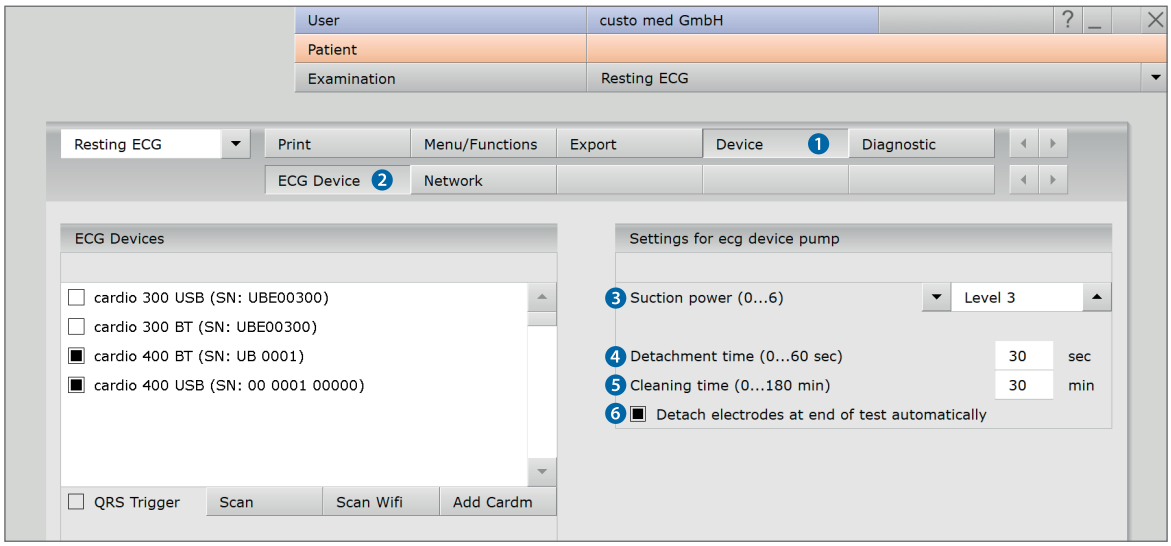
❺ Cleaning time

Extended blowing-out of moisture out of the electrode cables, e.g. at the end of a working day.

❻ Detach electrodes at end of test automatically

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

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



3.3.3 Connecting training devices for stress ECG

Connect the training device to the PC using the supplied cable (serial interface [1]). Make a note of the number of the serial connection, see Windows device manager. The number of the serial connection will be needed later in custo diagnostic.

1) 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.

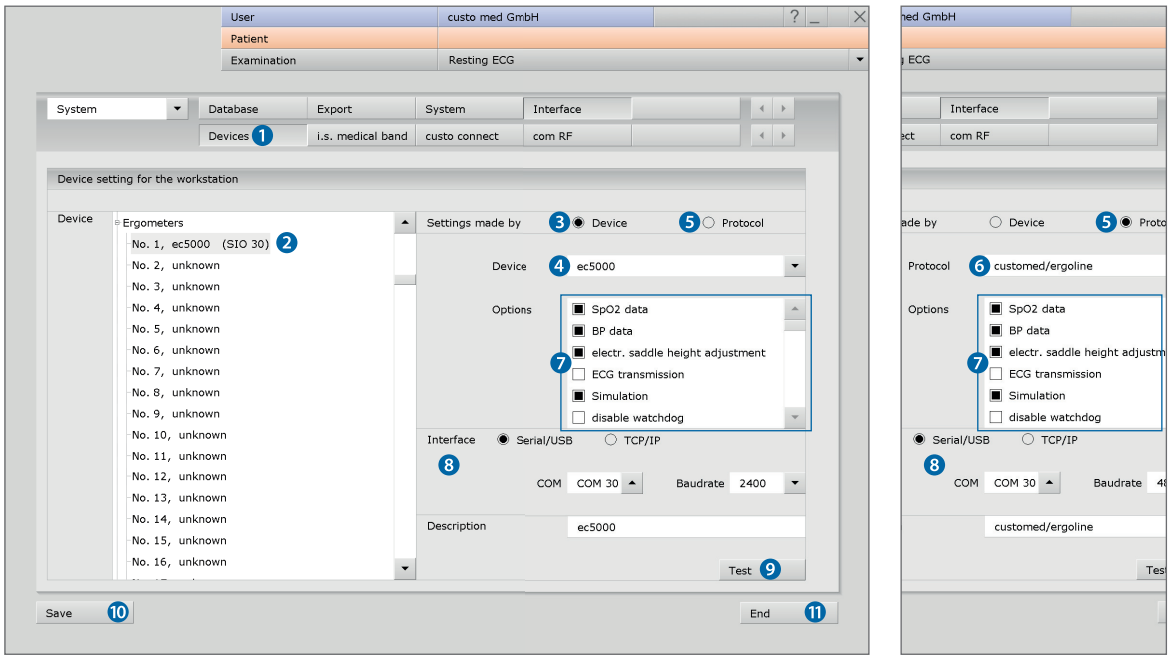
Some devices (e.g. ergometer ec5000 and treadmill er2100) can be connected to the PC using a network cable.

Start custo diagnostic and open the Examination, Settings, Interface, Devices ❶ screen. In the left side of the window, select the device, e.g. Ergometers, No. 1 ❷. In the right side of the window, change any settings as required. If the device type is known, select the Device ❸ option and in the "Device" dropdown list select the device type, e.g. ec5000 ❹. If the device type is not obviously apparent, select the Protocol ❺ option and in the "Protocol" dropdown list select the connected device, e.g. customed/ergoline ❻.

In the "Options" dropdown list, set the device options ❼. Details about the device connection are entered in the "Interface" area ❽.

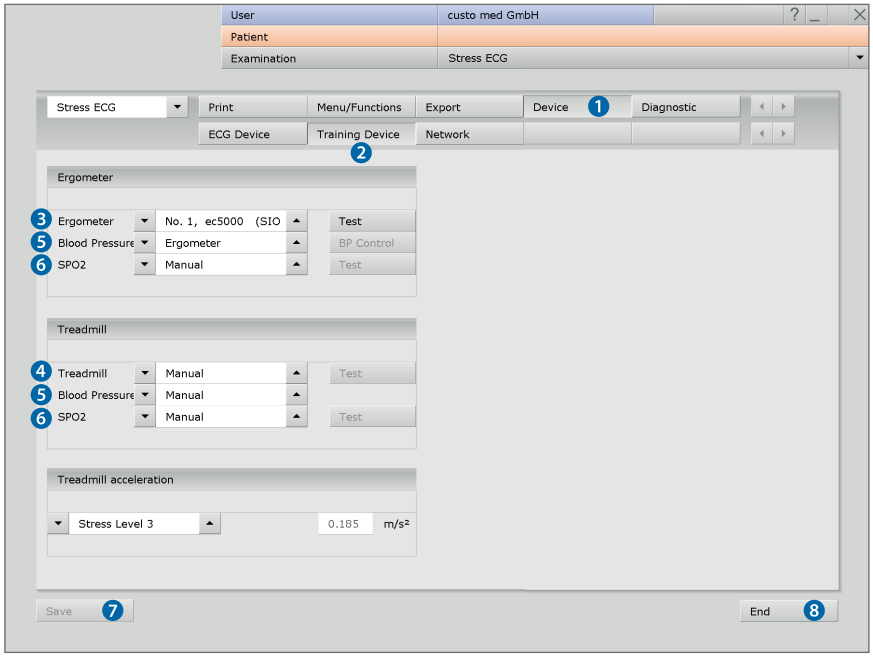
Use the Test ❾ button to check whether the connection between device and PC is working. If the connection is working, the test dialogue box shows "Status: O.K. started".

Save ❿ your input and close the screen with End ⓫.



3.3.4 Configuring a training device for stress ECG

- In custo diagnostic, select Examination, Stress ECG, Settings, Device ❶, Training device ❷.
- Select the Ergometer ❸ or Treadmill ❹ that was previously set.
- Select the blood pressure module of the ergometer or the previously connected and set sphygmomanometer ❺.
- Select the SPO2 module of the ergometer or the previously connected and set SPO2 meter ❻.
- Click on Save ❼ to apply your input.
- Click on End ❽ to close the screen.
- The training device is ready for operation.



3.4 ECG recording with 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 in.
- Click on Examination, Resting ECG ❶, New Resting ECG ❷ or:
  Examination, Stress ECG ❸, New Stress ECG.

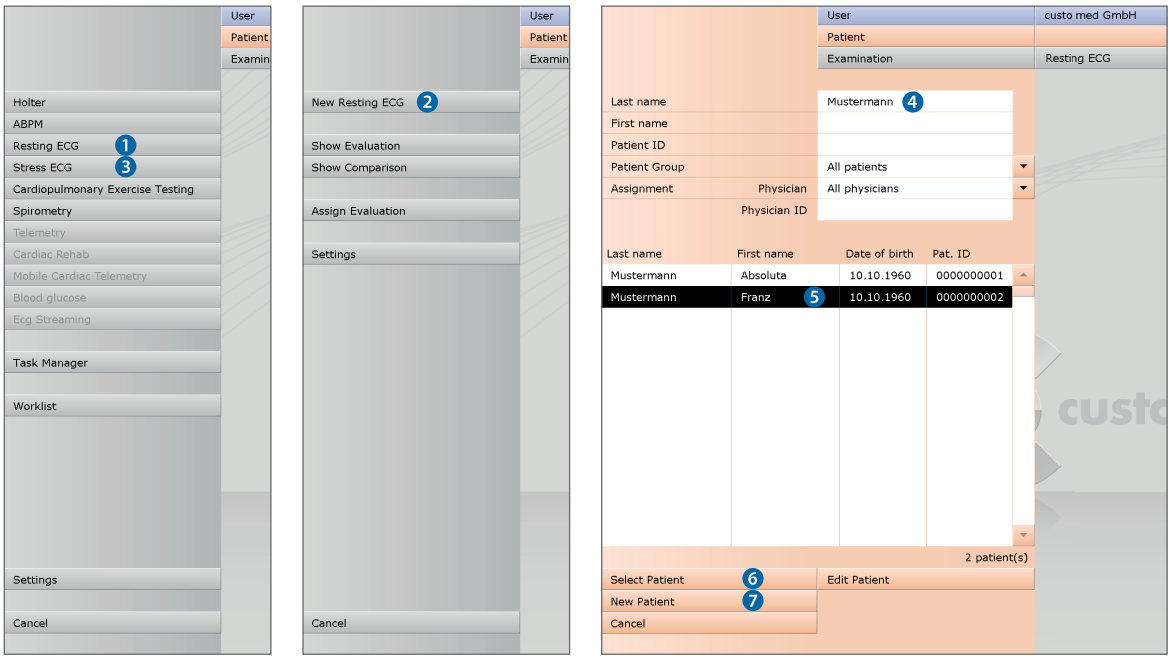
Selecting the patient

- Select a patient for the examination:
  Enter the patient's name into the input fields in the search screen ❹.
- Select the patient from the list ❺.
  Confirm your selection with Select Patient ❻.
  You can also select the patient by double-clicking on the name.

New patient

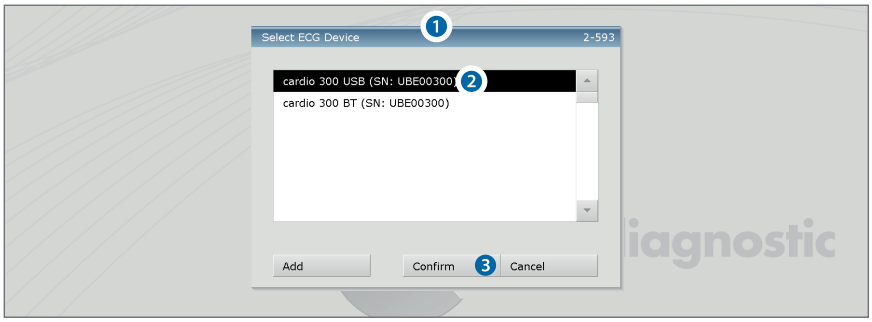
- If the patient does not yet exist in your database:
  Click on New Patient ❼.
- Enter the patient data.
  The fields marked with an asterisk are mandatory.
- Save the data, the patient is entered into the database.

Further work steps



3.4.1 Recording of resting ECG

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



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 if necessary ❹.
- Check if all electrodes are attached optimally.
  If there are red lines on the screen, the contact between the skin and electrode(s) is insufficient. The corresponding electrodes will need to be reattached. For ECG devices with USB connection, selecting Electrodes ❺ provides you with a graphic representation of the signal quality.
- Set the required filter (Options menu ❻).

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

Note on recording with a tablet PC:
The rechargeable battery capacity of the system is queried before a recording is started. If it is less than 15%, no new recording can be performed.

Automatic ECG[1] – Auto Start button ❼

- Click on Auto Start ❼ to start the automatic recording.
  The default setting for the duration of automatic recording is ten seconds.
- At the end of the ten seconds, the recording is automatically ended, saved, measured and printed out.

1) The preset standard procedures for automatic ECG and manual recordings can be changed in custo diagnostic under Examination, Resting ECG, Settings, Menu/Functions, Workflow. Save your input.

Manual recording[1] – Start ❽ button or Enter key:

- If you would like to perform a recording without a time limitation, (e.g. because of suspected irregularities), trigger the recording using the Start ❽ key.
- At least ten seconds of the ECG must be recorded before a recording can be ended.
- Use Stop to end the recording, the ECG interface remains open.
- Use Start ❽ and Stop to record additional sections.
- Use End ❾ to close the recording.
- Click on Confirm ❿ in the End dialogue to ensure that the recording is saved, measured and displayed as an evaluation.

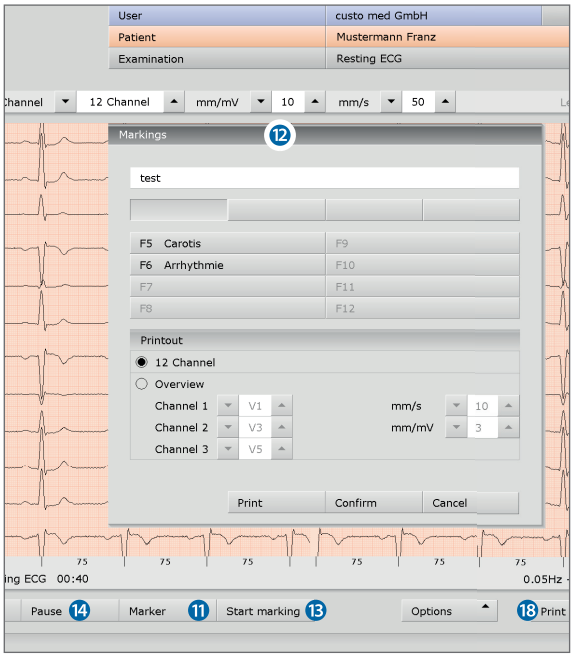
Editing options during the recording process

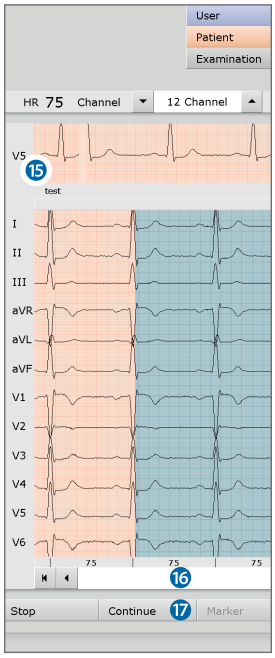
Automatic marking of the ECG

Clicking on the Marker ⓫ button will automatically mark the last six seconds of the recording. A dialogue appears for specifying [2], printing and saving the marked part ⓬.

Manual marking of the ECG

By clicking on the Start marking ⓭ button you can determine the length of the marking yourself. The marking continues to run until you click on the End marking button. A dialogue appears for specifying [2], printing and saving the marked part ⓬.





Viewing and marking ECGs and measuring HR during a pause ⓮

Clicking on Pause ⓮, will stop the screen display. The recording continues to run and is displayed on a channel ⓯. The scroll bar can be used to view the current recording ⓰.

The tools Mark, Measure HR and Measure can be found in the "Mouse Function" area. By dragging the red cursor in the ECG (using the Mark mouse function), you can mark sections. A dialogue appears for specifying, printing and saving the marked part. With Continue ⓱ you return to the normal view.

Online ECG printing (printing ECG)

By clicking on the Print ⓲ button a screen page of the ECG is printed from the point of clicking. The printout contains 4.5 to 9 seconds of the ECG, depending on the display speed [3].

Tip:
Keyboard shortcut

Change amplitude (mm/mV)

2) Text modules for specifying marked parts

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

Configuring text modules: Under Examination, Resting ECG, Setings, Menu/Functions, Markings, the text modules can be configured for specifying marked parts. Enter a name for the text module in the "Description" field. This name later appears on the button for calling the text module. In the "Text module" field, enter the text which will later be used to specify the marked parts. Save your input.

3) Note on online printing: Under Examination,Resting ECG, Settings, Print, General, you can define in the "Online ECG print settings" area whether the ECG should be printed as it appears on the monitor or whether online printing should be carried out according to previously defined print settings for the analysed ECG.

3.4.2 Recording of stress ECG

The profile selection is opened. Select a stress profile ❶. The list contains predefined profiles for ergometers (with watt indications) and the treadmill. Then set the training device for the recording ❷.

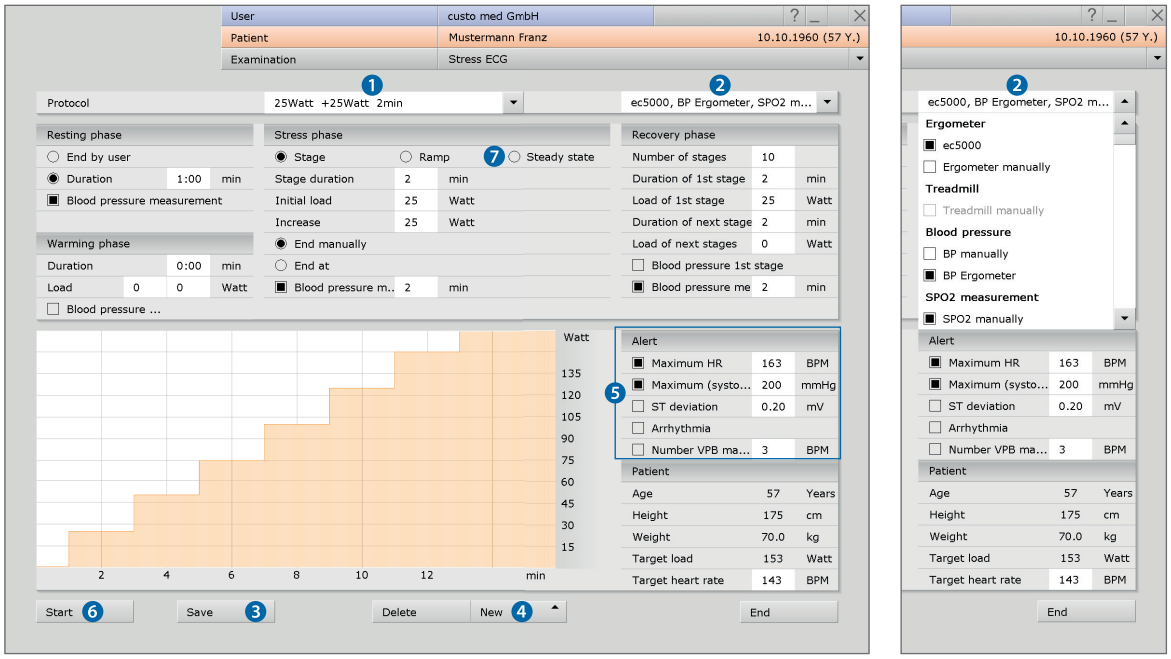
The predefined stress profiles can be modified and adapted as required. By clicking on Save ❸ you can save the modified stress profile under a new name. With the New ❹ button you can create new profiles (types: Ergometer, Free, Treadmill). The values in the Alert area ❺ can be set freely and have to be activated if required.

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

After selecting and configuring the stress profile, click on the Start ❻ button to access the recording screen.

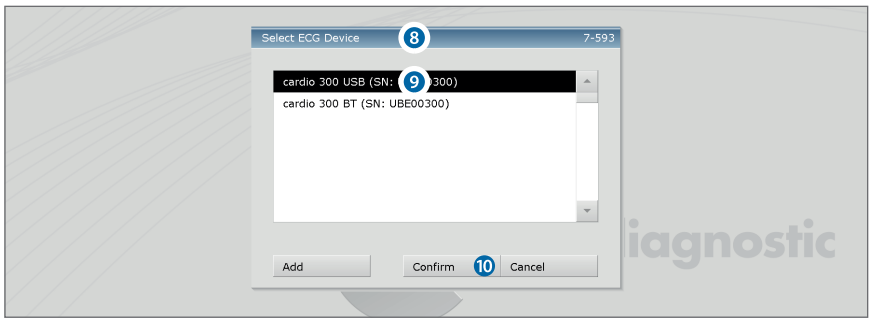
Additional information: Steady state option for ergometer profiles

By using Steady state ❼, the stress profile can be manually controlled during recording. If Steady state ❼ is selected, entries can no longer be made for the stage duration, increase and end in the input mask. During the recording, the profile will continue running unchanged until a manual change is made. Click on the Measurement button to define the end of a load level during the recording. The last ten seconds will be measured. Then set the load for the new load level.



If several ECG devices are connected to the workplace, the "Select ECG Device" ❽ dialogue will be displayed. Select the ECG device ❾ and click on Confirm ❿.

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



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 if necessary ⓫.
- Check if all electrodes are attached optimally.
  If there are red lines on the screen, the contact between the skin and electrode(s) is insufficient. The corresponding electrodes will need to be reattached. For ECG devices with USB connection, selecting Electrodes ⓬ provides you with a graphic representation of the signal quality.
- Set the required filter (Options menu ⓭).
- **Recommended settings for stress ECG with treadmill:**
  Under Options activate: Mains Filter, Muscle Filter and Ergo-Filter[1)].
  ECG display Precordial, 5 mm/mV and 25 mm/s (line above ECG ⓮).
- Click on Start ⓯ or Enter to start the recording.

1) The Ergo-Filter is only needed when strong movement artefacts are to be expected, e.g. when using a treadmill.

Options menu

- a Turn the automatic blood pressure measurement on and off
- b Activates an additional blood pressure measurement or F7 key
- c Dialogue for entering an unconfirmed report
- d Dialogue for entering the blood pressure (with manual measurement) or F9 key
- e Dialogue for entering the lactate values or F10 key
- f Dialogue for entering the SPO2 values (oxygen saturation in the blood) or F11 key
- g Entry of Borg values to document the subjective perception of a patient, e.g. moderate, strenuous... or F12 key
- h New start of ergometry without previous profile selection
- i Extend the current step (only available after the start)
- j Select a different ECG device if several devices are connected
- k Recognition of pacemaker spikes if the patient has a pacemaker
- l Filter for removing interferences caused by the power supply unit
- m Filter for flattening the ECG signal (e.g. in the event of amyostasia)
- n Ergo-Filter for compensating strong movement artefacts
- o Signal tone with each heart beat
- p Switch alarm signals on and off when the alarm limit is exceeded
- q The bar below the ECG shows the heart rate instead of RR intervals in milliseconds

Keyboard shortcuts:

F7
Add. BP measurement

F8
End and measure a load level for steady state profile

F9
Blood pressure input

F10
Lactate input

F11
SPO2 input

F12
Borg input

Display and control elements (view after Start)

- a Setting options for ECG display
- b Buttons for controlling and editing the ECG recording
- c Display of heart rate and blood pressure, countdown of the current level
- d Change the current load and increase for ergometer profiles [2)]
  or speed and slope for treadmill profiles
- e Load profile (orange) with heart rate curve (blue)
- f Blood pressure curve (green)
- g Set the ST point, display the summary complex
  (selection of channel via buttons at left in front of the ECG signal)
- h Show ST trend curve, ST values and overview of results
  (Online arrhythmia detection); button in the area h
  flash red when the alarm limits are exceeded

Tip: Keyboard shortcuts

Change load or speed

Change increase

Change amplitude

Note on manual blood pressure measurement

You are regularly requested to measure blood pressure. Enter the values in custo diagnostic. In the Options menu, click on Blood Pressure or press the F9 key and enter the values. Click on Confirm to apply your input. The method of entering lactate (F10), SPO2 (F11) and Borg values (F12) is the same.

2) Note on the settings for the load change:
You can define by how much watts Load and Increase should change each time the arrow buttons are pressed.
This setting can be found under: Examination, Stress ECG, Settings, Menu/functions, ECG view in the "Manual load change" area.

Resting phase

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

Stress phase

The stress phase then begins[3)]. This phase proceeds according to the profile. Manual load changes can be made at any time. The Next Stage ⑯ button can be used to end the current load level and start the next load level.

Entering an unconfirmed report during recording

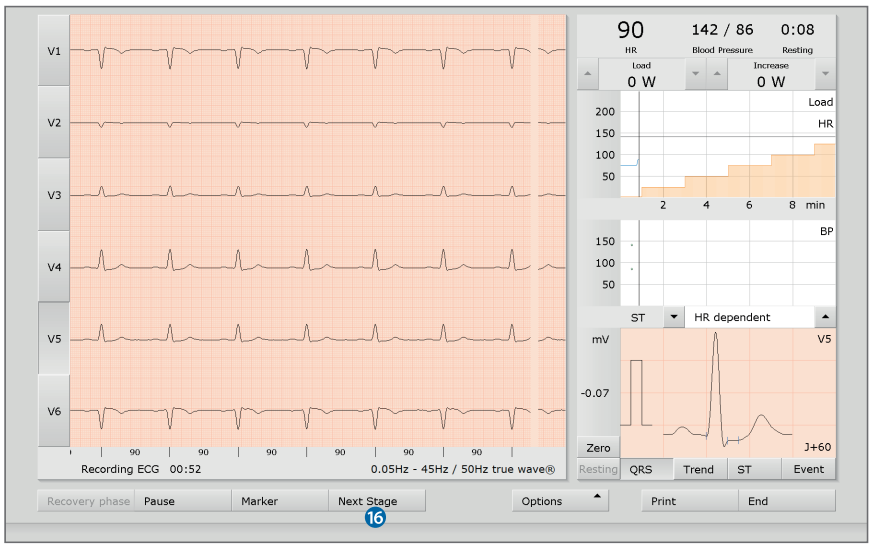
Open the context menu and select Report. Enter the unconfirmed report in the large text field ⑰. To save your input, click on Confirm ⑱. By pressing Cancel ⑲, the unconfirmed report is closed without any changes being applied.

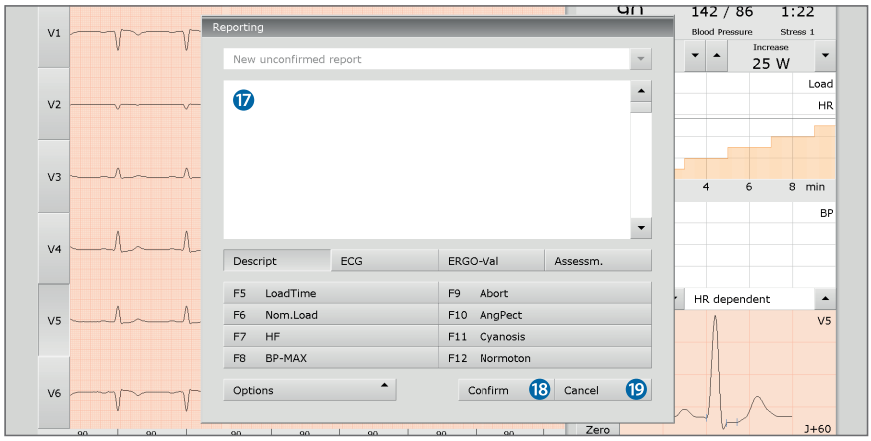
If you save your information with Confirm ⑱, the unconfirmed report becomes a (preliminary) report, depending on the reporting rights of the current user. The evaluation is thus (pre-)confirmed. If the evaluation is not to be classified as (pre-) confirmed at this point, you can reset the report status when selecting End.

3) Note on treadmill profiles:

The treadmill can be stopped using the Stop button, e.g. if a lactate measurement should be conducted. The treadmill will be restarted by clicking on the button again.

Always warn the patient before you stop or start the treadmill!





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

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

Recovery phase, ending the recording

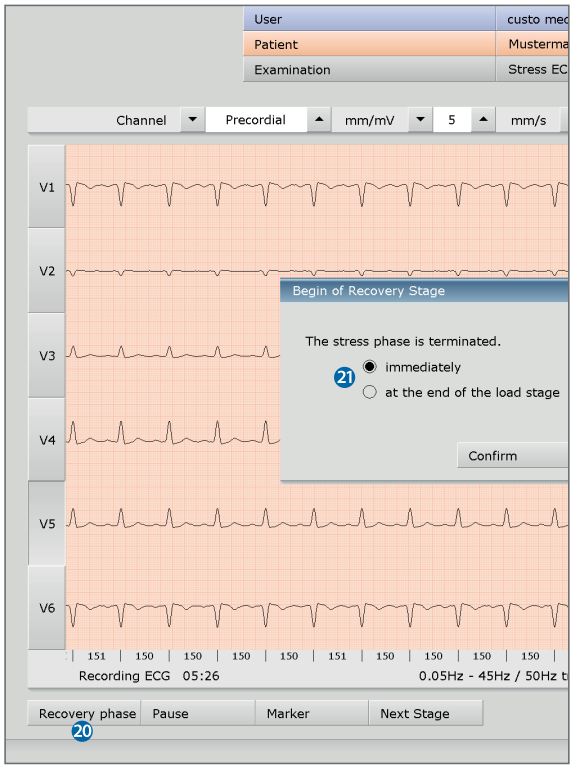
The recovery phase can be started using the Recovery phase ⑳ button, e.g. when the Manual end option was selected in the profile selection or as a result of a premature termination. Define the end of the stress phase (immediately or at the end of the load stage ㉑). The dialogue for entering the reason for termination ㉒ is then opened [4]. The reason for termination can be displayed in the evaluation.
If the end of the stress phase is defined in the profile, the recovery phase starts automatically after the last load level has expired. The recovery phase proceeds according to the profile.

If you would like to end the ECG recording but the ECG signal should still be displayed on the screen, click on Stop ㉓. Otherwise, the recording will be automatically saved, measured and displayed as an evaluation by clicking on the End button (bottom right).

4) Text modules for entering the reason for termination

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

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



Editing options during the recording process

Automatic marking of the ECG

Clicking on the Marker 24 button will automatically mark the last six seconds of the recording. A dialogue appears for specifying [5], printing and saving the marked part.

Viewing and marking ECGs and measuring HR during a pause

Clicking on Pause 25, will stop the screen display. The recording continues to run and is displayed on a channel 26. The scroll bar can be used to view the current recording 27.

The tools Mark, Measure HR and Measure can be found in the "Mouse Function" area 28. By dragging the red cursor in the ECG (using the Mark function), you can mark sections. A dialogue appears for specifying, printing and saving the marked part 29. With Continue 30 you return to the normal view.

Online ECG printing (printing ECG)

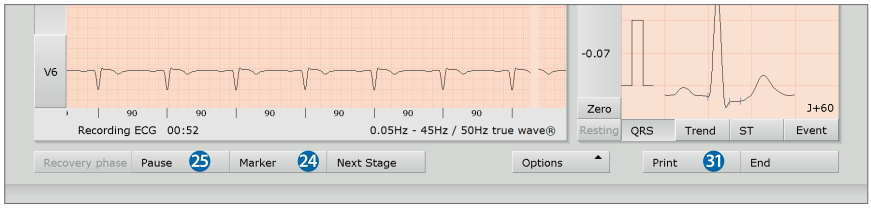
By clicking on the Print 31 button a screen page of the ECG is printed from the point of clicking. The printout contains 4.5 to 9 seconds of the ECG, depending on the display speed [6].

5) Text modules for specifying marked parts

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

Configuring text modules: Select Examination, Stress ECG, Settings, Menu/Functions, Markings to configure text modules for specifying marked parts. Enter a name for the text module in the "Description" field. This name later appears on the button for calling the text module. In the "Text module" field, enter the text which will later be used to specify the marked parts. Save your input.

6) Note on online printing: Select Examination, Stress ECG, Settings, Print, General to define in the "Online ECG print settings" area whether the ECG should be printed as it appears on the monitor or if online printing should be carried out according to previously defined print settings for the analysed ECG.



3.4.3 Extended ECG settings

» **Changing the ECG colour scheme:** The ECG colours are preset in custo diagnostic and can be changed under Examination, Settings, System, ECG colour. Click on Save to apply your changes.The ECG grid in custo diagnostic corresponds to normal ECG paper. The small boxes measure 1 * 1 mm, the large boxes 5 * 5 mm. To ensure the graph paper is correctly displayed on the screen, the screen diagonal of the monitor must be specified in the custo service centre. Contact your authorised custo med dealer.

» **Resting ECG, automatic ECG procedures:** It is possible under Examination, Resting ECG, Settings, Menu/Functions, Workflow to define the procedures for automatic ECG recordings in the "Automatic ECG" area. For example, recording duration and procedures after recording. Click on Save to apply your changes.

» **Procedures for manual resting ECG recordings and stress ECG:** It is possible under Examination, Resting ECG or Stress ECG, Settings, Menu/Functions, Workflow to set the procedures after recording and the display options in the evaluation in the "Workflow" area. Click on Save to apply your changes.

» **Print settings for resting ECG:** It is possible under Examination, Resting ECG, Settings, Print, Print pages to define the contents for different printouts. In the "Type of printout" list, select the desired entry, for example automatic printing (automatic ECG). In the "Printout" area, select the contents for the printout after an automatic ECG.
Important: This setting is only required if the automatic ECG print pages contains content other than the standard printout (see "Type of printout" Standard). Click on Save to apply your changes.

» **Print settings for stress ECG:** It is possible under Examination, Stress ECG, Settings, Print, Print pages to define the contents for different printouts. In the "Type of printout" list, select the desired entry and compile the contents of the printout. Important: This setting is only required if the selected printout (see "Type of printout") contains content other than the standard printout (see "Type of printout" Standard). Click on Save to apply your changes.

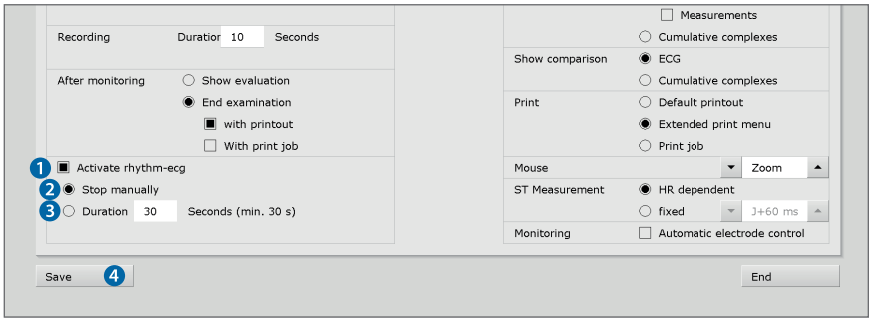
» **Maximum load:** The maximum load is displayed in the evaluation and serves for comparison with the nominal load. The criteria for determination of the maximum load are set on the Examination, Stress ECG, Settings, Diagnostic, Calculation screen. For example, when undercutting a certain duration the corresponding examination stage can be excluded.

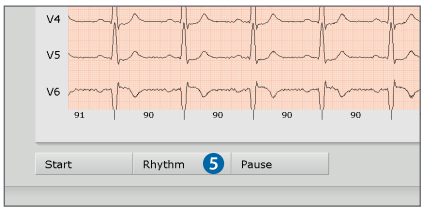
Resting ECG, rhythm strips

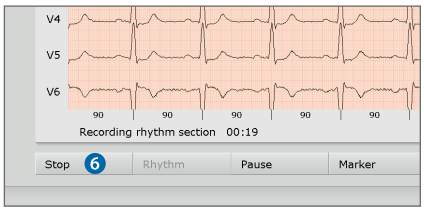
During resting ECG recordings, additional rhythm strips can be recorded. These are ECG sections of any duration during which the recording can be manually controlled. The "Rhythm strip" function can be activated under Examination, Resting ECG, Settings, Menu/Functions, Workflow ❶. Define whether the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

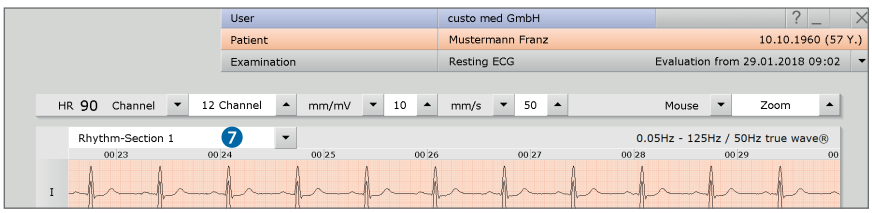
The recording of a rhythm strip is activated on the ECG interface by clicking the Rhythm ❺ button. If the recording duration is not set, the recording of the rhythm strip can be stopped using the Stop ❻ button.
In the evaluation, the available rhythm strips can be called and displayed via the menu on the top left ❼.

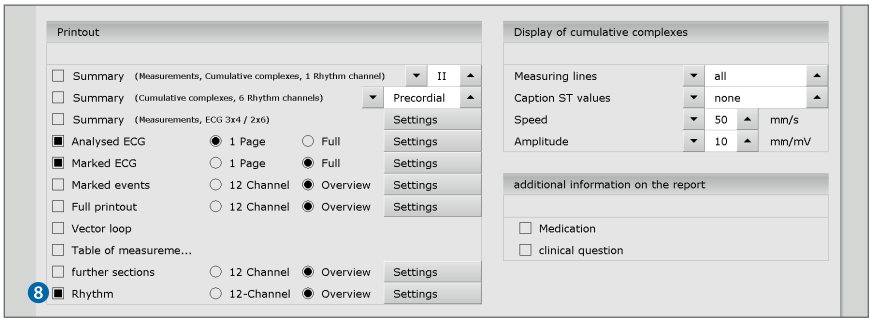
It is possible to print the rhythm strips. Select the Examination, Resting ECG, Settings, Print, Print pages screen and activate Rhythm ❽. Save your input.











3.5 Working with the evaluation

3.5.1 Opening an evaluation via the evaluation search

- To open the evaluation search[1)] right-click on the Patient button ❶.
- With factory settings, the Search screen ❷ is displayed.
  Here you can search for evaluations with previously defined and saved search criteria, so called filter sets. Filter sets can be created on the Advanced search screen ❸.
- Depending on the default setting of the system, a filter set is already active and the search results are displayed here full-screen as a list ❹.
- If no filter set is active, select a set ❺.
- Open an evaluation by double-clicking on the corresponding line or via the Show evaluation button ❻ .

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

Configuring the list of search results

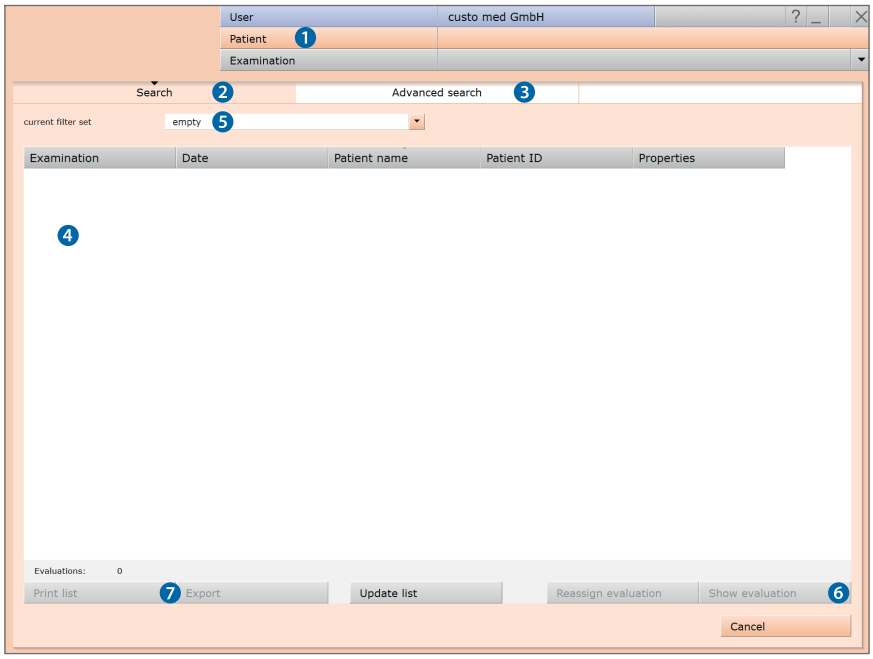
- Right-click on the screen to open the context menu.
  There click on Select columns and set the required columns.
  Click on Confirm to apply your changes.
- Clicking on a column header sorts by this column and sorting within the column can be reversed.
- The list can be printed and exported in various formats ❼.

Renaming filter sets, deleting filter sets

- Right-click on the screen to open the context menu.
  There click on Rename filter set oder Delete filter sets.
- Follow the instructions.

Editing filter sets

- Open the Advanced search screen ❸, *see next page*.



Advanced search, creating filter sets

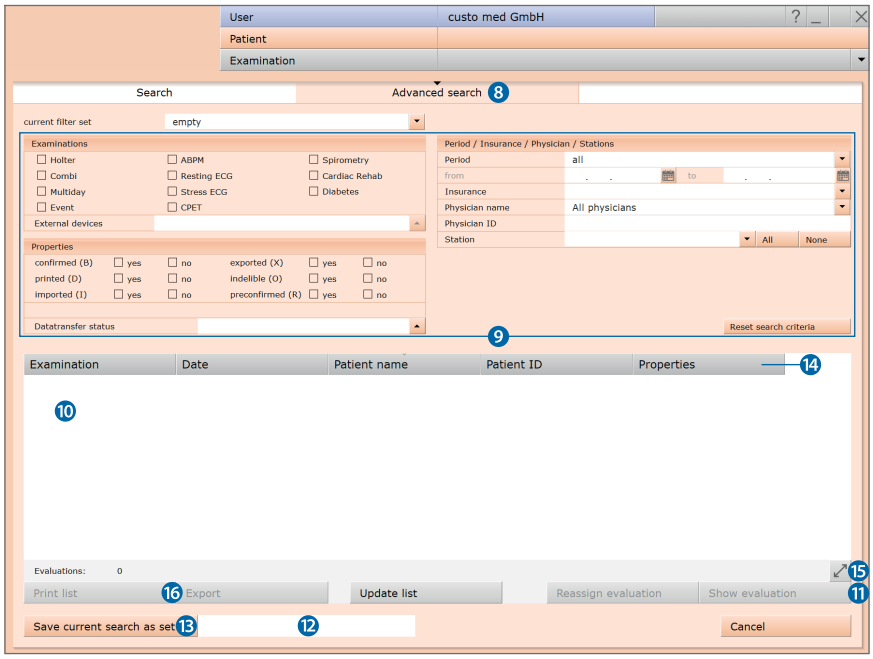
- The Advanced search screen ❽ is used for creating filter sets and for quick selection of search criteria (e.g. examination, properties, period) ❾.
  The search is limited by setting certain search criteria.
- The search results are displayed in the lower half of the screen as a list ❿.
- An evaluation can be opened by double clicking on the corresponding entry in the list of search results or with the Show evaluation ⓫ button.
- The previously selected search criteria can be saved for later use as a filter set with the appropriate name. Enter the name into the input field ⓬ and click on Save current search as set ⓭.

Editing filter sets

- The filter set to be edited must be selected, see line "Current filter set".
- Adapt the search parameters (e.g. examination, properties, period).
- Click on the Save current search as set ⓭ button to overwrite the previous set.
- If a new name is assigned beforehand, a new set will be created.

Configuring the list of search results

- Right-click on the screen to open the context menu.
  There click on Select columns and set the required columns.
  Click on Confirm to apply your changes.
- Clicking on a column header ⓮ sorts by this column and sorting within the column can be reversed.
- Use the arrow button ⓯ at the bottom right of the list to increase or decrease the size of the list.
- The list can be printed and exported in various formats ⓰.



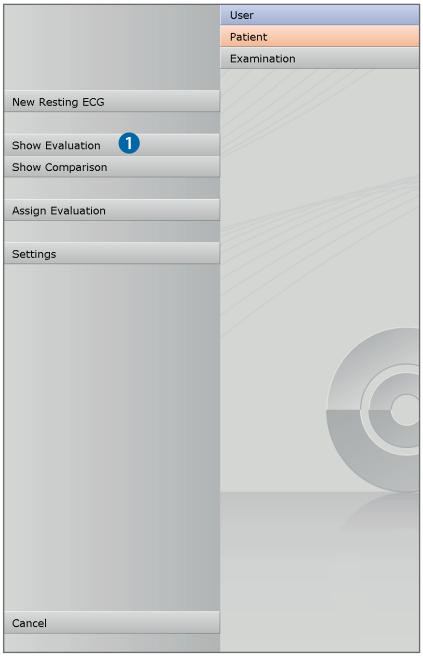
Reference between the end dialogue and the evaluation search

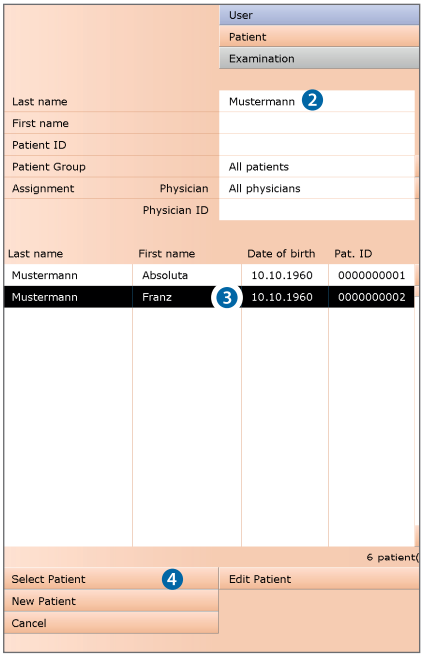
In order to make proper use of the evaluation search, the status of the evaluation must be set correctly in the end dialogue when you exit an evaluation.

Example:
An evaluation can only be found in the evaluation search with the property confirmed "No" if the status "Evaluation confirmed" is NOT selected in the end dialogue.

3.5.2 Opening an evaluation via the evaluation main menu

- Open the examination main menu via Resting ECG or Stress ECG.
- Click there on Show Evaluation ❶.
- The patient search screen appears. In this screen select the patient whose evaluation you want to open. Enter the patient's name into the input fields in the search screen ❷.
- Select the patient from the list below the input fields ❸ and confirm your selection by clicking on the Select Patient ❹ button or by double-clicking on the name.
- A list containing all the patient's evaluations 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.

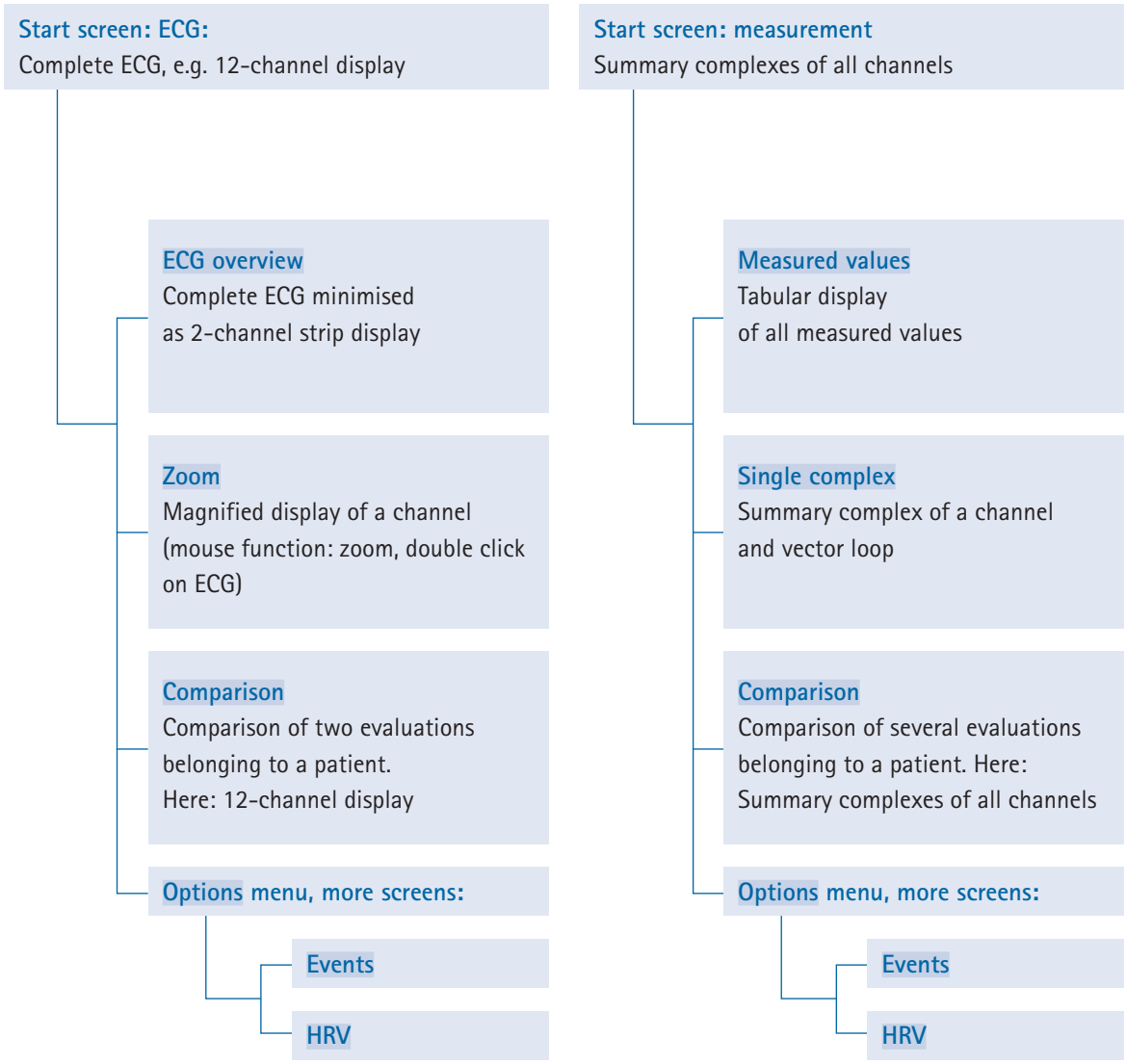




3.5.3 Resting ECG evaluation

The ECG evaluation is divided into two main areas, ECG and Measurement. The ECG screen is preset as the start screen, the Measurement screen can be alternatively set as the start screen if required[1)].
From the sub-screens of the two areas the main screen of the other area can be accessed at any time.

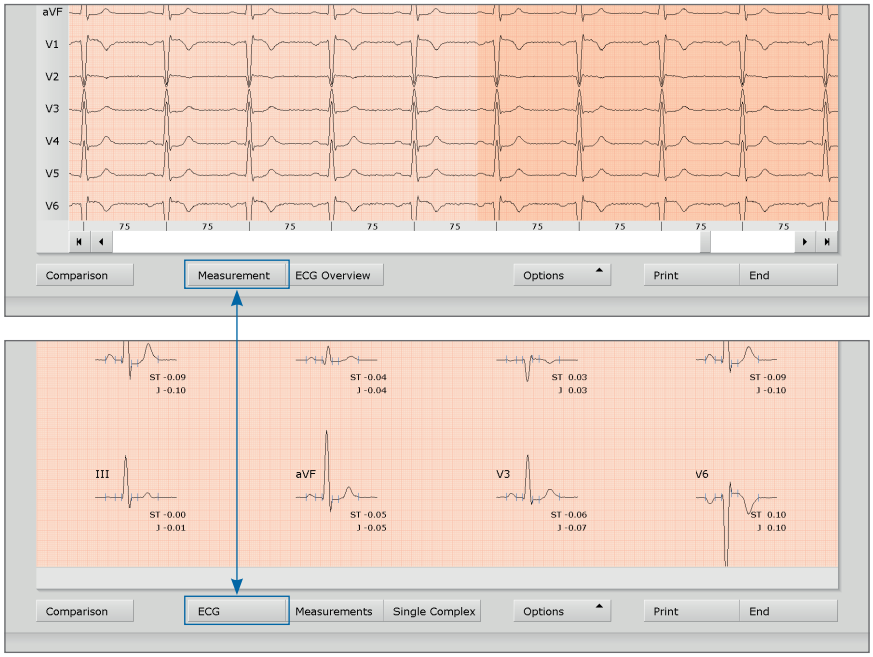
1) Setting the start screen: The start screen of the evaluation can be set under Examination, Resting ECG, Settings, Menu/Functions, Workflow in the "Menu/Functions, Show Evaluation" area.



Navigation in the resting ECG evaluation

The buttons for opening further evaluation screens are located at the bottom of the screen. The labelling of the buttons changes as soon as you switch to a different evaluation screen. The button that has been clicked always contains the name of the screen you just left.

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



"ECG" evaluation screen

"Measurement" evaluation screen

Resting ECG evaluation, start screen ECG

- (a) Setting options for ECG display
- (b) Mouse functions for detailed viewing and measuring of the ECG signal (Zoom, Analysis, Measure HR, Measure, Marking)
- (c) Further evaluation screens
- (d) Button for printing the evaluation [2)]
- (e) Button for closing the evaluation

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

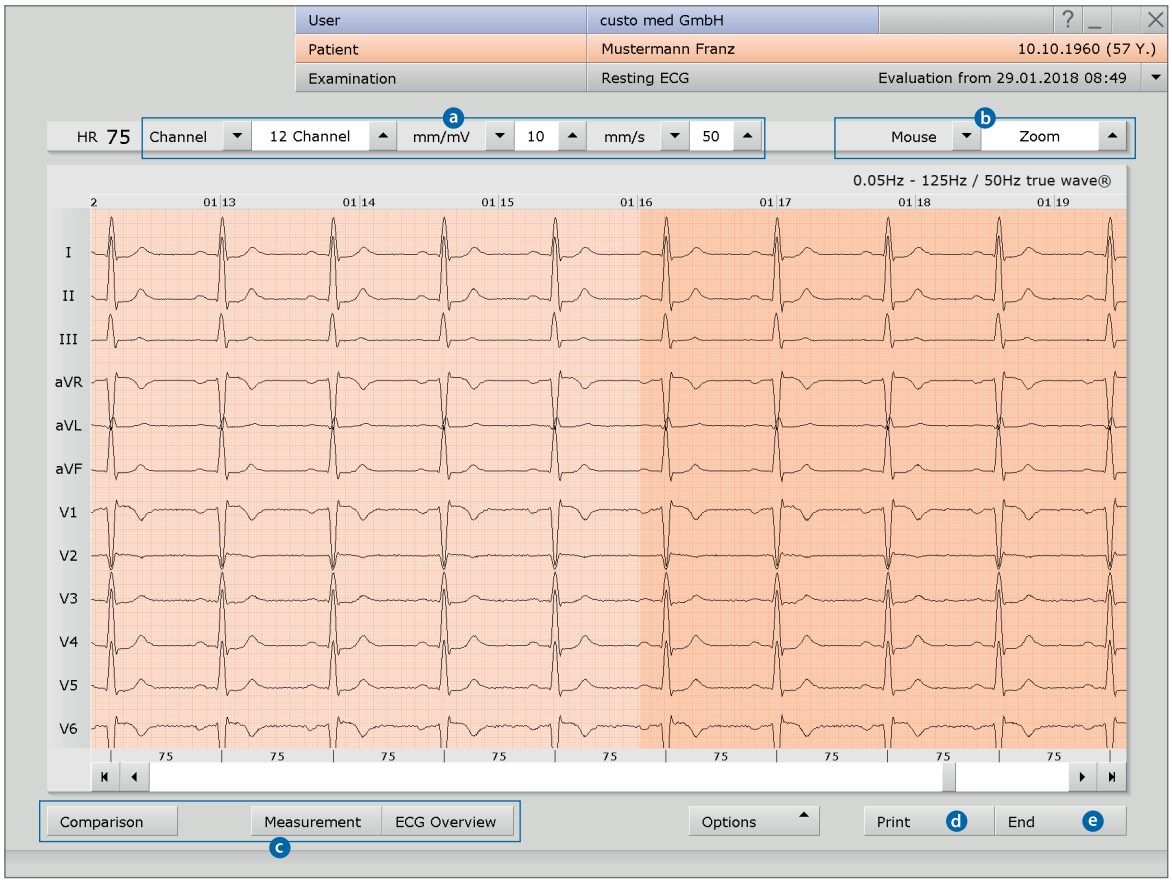
The evaluation start screen can be set under:
Examination, Resting ECG, Settings, Menu/Functions, Workflow
in the "Procedure control, Show Evaluation" area.

2) Settings for the Print button:

Under Examination, Resting ECG, Settings, Menu/Functions, Workflow, in the "Workflow, Print" area, you can display the expanded print menu by clicking on the Print button (standard setting) and define whether printing should be conducted automatically without further settings according to the standard print settings (= defined printout).

The standard print settings for resting ECG can be found under Examination, Resting ECG, Settings, Print, Print pages.

Click on Save to apply your input.



Resting ECG evaluation, Options menu [3)]

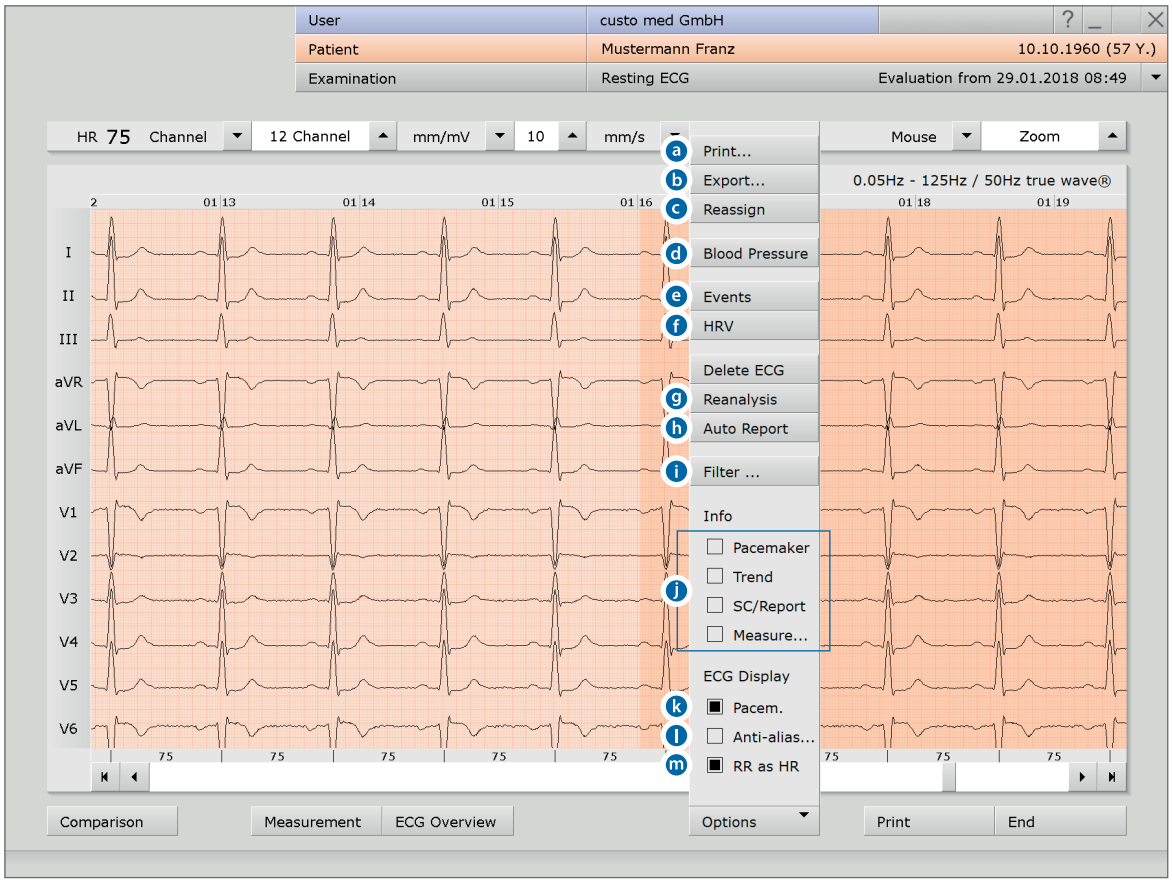
- (a) Print menu for temporary changes to the print settings
- (b) Button for exporting the evaluation (e.g. as Excel, PDF, DICOM...)
- (c) Assign the evaluation to another patient, if necessary
- (d) Manual blood pressure input (F9 key)
- (e) HR trend, display of events in the ECG (e.g. VES)
- (f) Tables and graphics for heart rate variability [4)]
- (g) New analysis of ECG signal for resetting manual changes in the ECG, additions to the report remain available
- (h) Automatic creation of a new report after manual changes have been made in the ECG recording
- (i) Switch filters in the ECG on or off (options: Display ECG as saved, unfiltered or filtered ECG - mains filter, muscle filter)
- (j) Show or hide additional content in the right half of the screen: e.g. enlarged pacemaker spikes, HR curve and ST trend, summary complexes and report or table of measured values
- (k) Show or hide pacemaker spikes
- (l) Graphic flattening of ECG signal
- (m) The bar below the ECG shows the heart rate instead of RR intervals in milliseconds

3) Note on Options menu
The scope and content of the Options menu changes based on which evaluation screen you are currently on.

In the Options menu under Measurement, you can activate the display of ST values and set which marked parts should be displayed in the summary complexes.

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

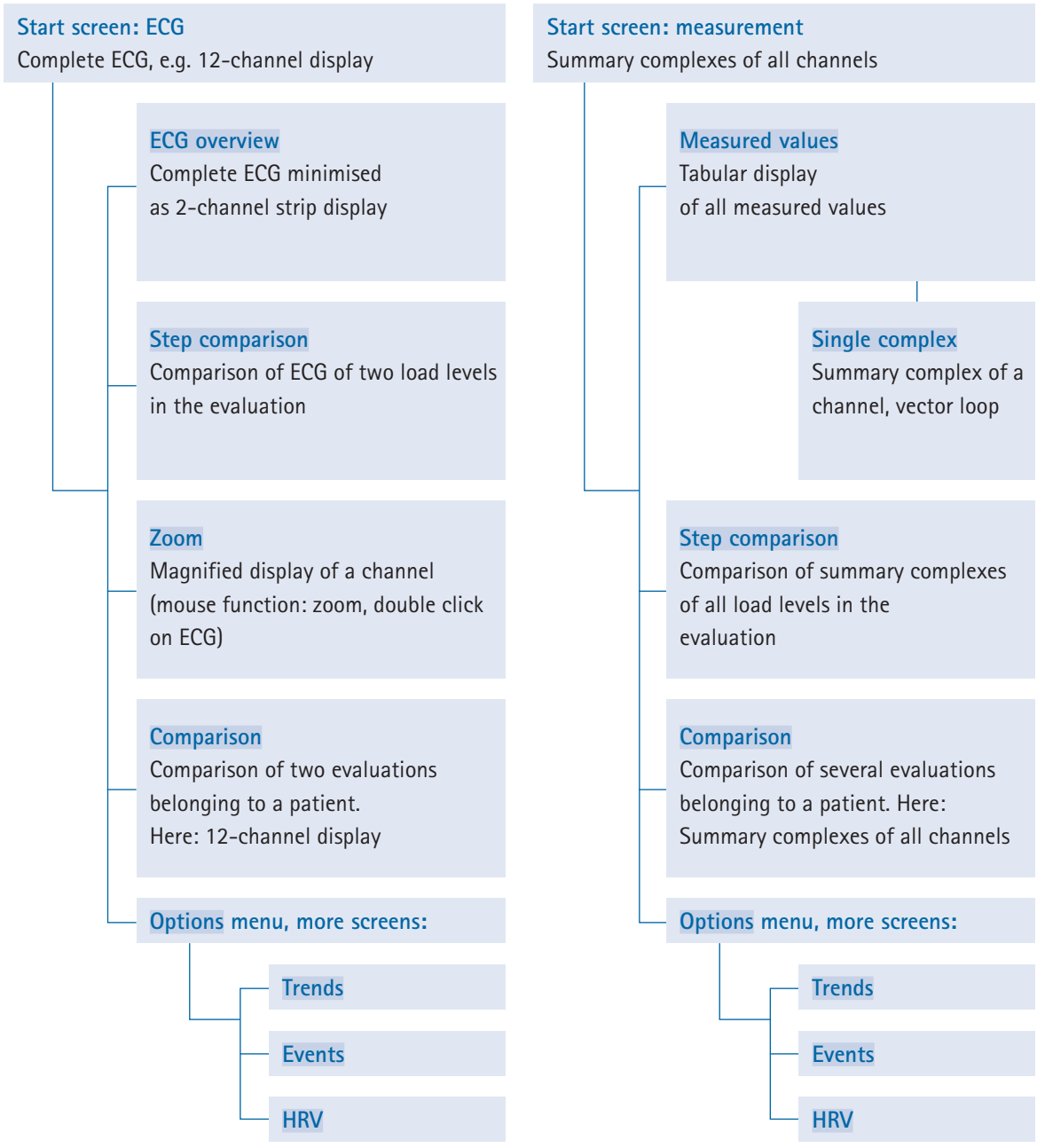
5) Only with recordings including high resolution ECG (custo cardio 300 or 400).



3.5.4 Stress ECG evaluation

The ECG evaluation is divided into two main areas, ECG and Measurement. The ECG screen is preset as the start screen, the Measurement screen can be alternatively set as the start screen if required[1)].
From the sub-screens of the two areas the main screen of the other area can be accessed at any time.

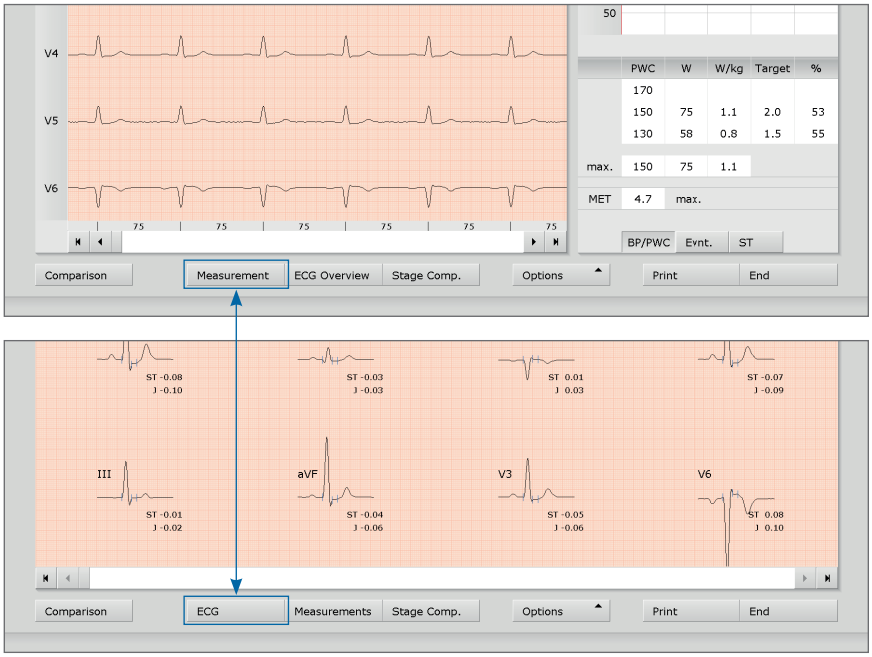
1) Setting the start screen: The evaluation start screen can be set under Examination, Stress ECG, Settings, Menu/Functions, Workflow in the "Workflow, Show Evaluation".



Navigation in the stress ECG evaluation

The buttons for opening further evaluation screens are located at the bottom of the screen. The labelling of the buttons changes as soon as you switch to a different evaluation screen. The button that has been clicked always contains the name of the screen you just left.

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



"ECG" evaluation screen

"Measurement" evaluation screen

Stress ECG, start screen ECG

- (a) Setting options for ECG display
- (b) Mouse functions for detailed viewing and measuring of the ECG signal (Zoom, Analysis, Measure HR, Measure, Marking)
- (c) Load profile with heart rate and blood pressure curve
- (d) Tabular display of PWC[2)] (physical working capacity) and MET (metabolic equivalent), further information on PWC and MET available in the appendix
- (e) Further evaluation screens
- (f) Button for printing the evaluation[3)]
- (g) Button for closing the evaluation

If the Measurement view is set as the start screen, the same operating and navigation elements can be found there (a to g, without c and d).

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

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

3) Settings for the Print button:
Under Examination, Stress ECG, Settings, Menu/Functions, Workflow, in the "Workflow, Print" 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 (= defined printout) without any additional settings being made.

The standard print settings for stress ECG can be found under Examination, Stress ECG, Settings, Print, Printed pages.

Click on Save to apply your input.

Stress ECG, Options menu [4]

- a Print menu for temporary changes to the print settings
- b Button for exporting the evaluation (e.g. as Excel, PDF, DICOM...)
- c Assign the evaluation to another patient, if necessary
- d Display of blood pressure (F9), lactate (F10), SPO2 (F11) + Borg values (F12)
- e Trend graphics, e.g. on load, HR, ST, speed, blood pressure, lactate, SPO2...
- f HR trend, display of events in the ECG (e.g. VES)
- g Tables and graphics for heart rate variability [5]
- h New analysis of ECG signal for resetting manual changes in the ECG, additions to the report remain available
- i Switch filters in the ECG on or off (Options: Display ECG as saved, unfiltered or filtered ECG - mains filter, muscle filter, Ergo-filter)
- j Show or hide content in the right half of the screen: Summary complexes and report or table of measured values (preset: Trend = load profile with HR and blood pressure curve, PWC and MET)
- k Show or hide pacemaker spikes
- l Graphic flattening of ECG signal
- m The bar below the ECG shows the heart rate instead of RR intervals in milliseconds

4) Note on Options menu
The scope and content of the of the Options menu changes based on which screen of the evaluation you are currently on.

In the Options menu under Measurement, you can activate the display of ST values and set which marked parts should be displayed in the summary complexes.

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

3.5.5 Confirming the evaluation

Unconfirmed report and report

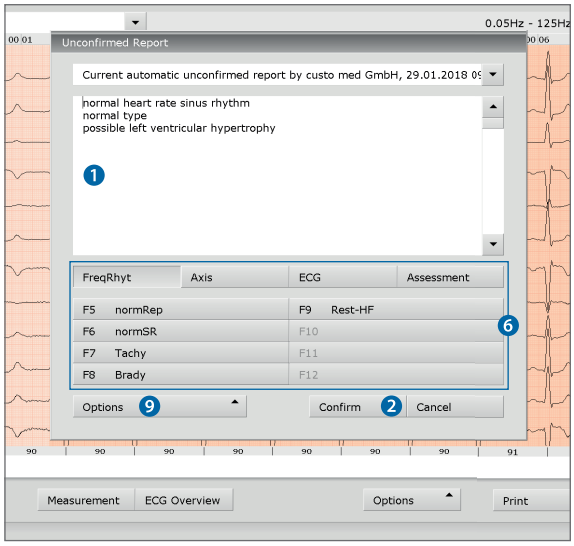
To open the unconfirmed report, right-click on the evaluation interface. In the context menu, select Report. Enter your data in the text field ❶. If the Unconfirmed report or Interpretation option is selected in the system settings, an automatic system unconfirmed report is already present in the text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

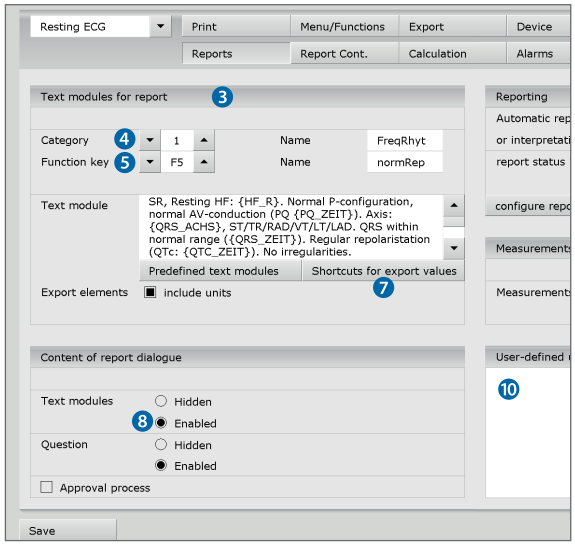
Text modules – an aid for writing reports

Select Examination, Resting ECG or Stress ECG, Settings, Diagnostic, Reports to configure text modules for confirming an evaluation ❸. A total of four groups ❹ can be stored with up to eight text modules ❺. The text modules are called in the unconfirmed report dialogue using the keyboard (F5 to F12) ❻.

A text module can be created from normal text as well as variables. When you use a text module in the unconfirmed report, the actual value from the evaluation is inserted in the report text instead of a variable. The structure of a variable is {VARIABLE} (e.g. heart rate, resting: {HR_R}). The Shortcuts for export values ❼ button provides you with a list containing all the variables. If the text modules should be shown in the unconfirmed report, make sure that the Enabled ❽ option is activated.

Alternatively, the text modules can be shown in the unconfirmed report via Options, Texts on ❾. You also have the option of entering a text, which will be automatically shown in each unconfirmed report ❿. The text can be changed later in the unconfirmed report dialogue. Save your input.





3.5.6 Ending the evaluation

Click on End (bottom right) in the evaluation. The End dialogue opens. This is where the Status of Evaluation ❶ is defined [1].

❷ Evaluation preconfirmed: active if a user with the reporting right "Preconfirm evaluations" has confirmed the unconfirmed report.

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

❹ Printed: indicates if the evaluation has been printed.

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

Click on Confirm ❻ to close the evaluation.

1) The assignment of properties (status of evaluation) in the End dialogue makes it easier to find evaluations in the evaluation search.

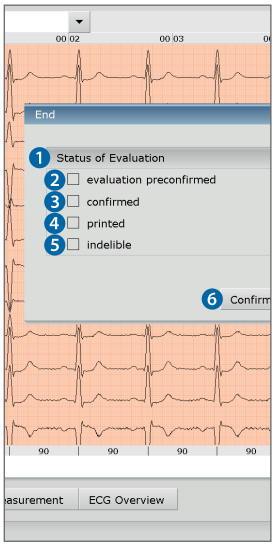
3.5.7 Optional: Reporting with approval process

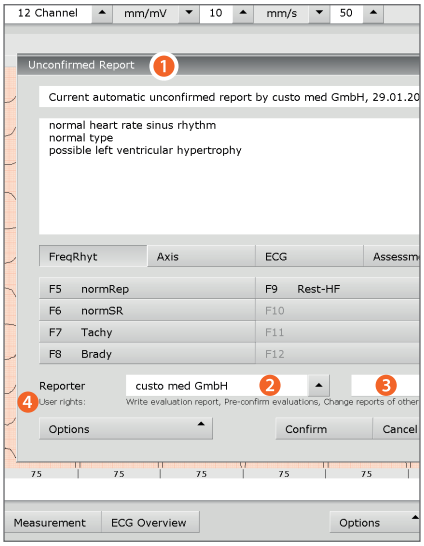
If custo diagnostic is used with approval process, then authorised persons with the corresponding user rights can save pre-reports of other persons as a report, without having to close the evaluation which was opened previously (shortened workflow) or enter pre-reports/reports directly if the evaluation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

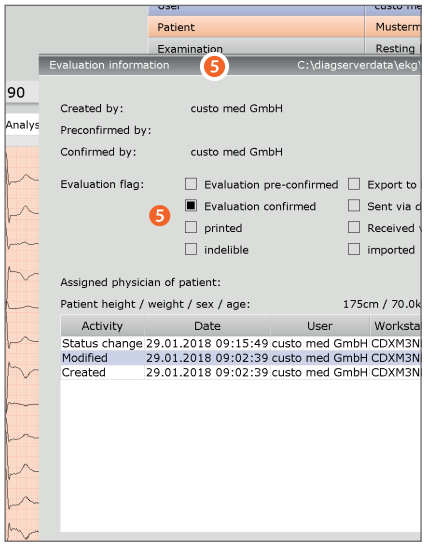
The approval process is visible in the unconfirmed report dialogue ❶ of an evaluation. The user or reporter can be changed there (User name ❷, Password ❸, Enter). During the logon process, the user rights of the respective user are checked and the software interface is adapted accordingly ❹. The reporting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

The approval process must be activated user and project-related in the settings and in the custo service centre. The user rights must be set according to the workflow [2]. Contact your authorised custo med dealer or custo med.

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







3.6 Appendix

3.6.1 Values and formulas in the ECG evaluation

PWC (physical working capacity)

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

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

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

MET (metabolic equivalent)

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

Treadmill ergometry:

v = max. speed in miles per hour
m = slope in %

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

Bicycle ergometry:

L = max. load in watts
W = weight in kg

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

Calculation of QTc duration

Formula according to Bazett:

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

Formula according to Fridericia:

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

Calculation of the target load

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

Standard formula

Male, under 30 years of age	*Target load = 3 * weight*
Female, under 30 years of age:	*Target load = 2.5 * weight*
Male, over 30 years of age:	*Target load = 3 * weight * ((130 - age) : 100)*
Female, over 30 years of age:	*Target load = 2.5 * weight * ((130 - age) : 100)*

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

Formula according to Prof. Froelicher

Female:

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

Male:

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

Comment: The body surface area is calculated according to the formula of DuBois & DuBois:
*BSA = 0.007184 * height [cm]0.725 * weight [kg] 0.425*
Source: DuBois, D. & DuBois, E.F. (1916): A formula to estimate the approximate surface area if height and weight be known. Arch Intern Med, 17: 863

BORG values for stress ECG

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

Simplified scale of subjective perceived exertion:

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

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

3.6.2 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

1. Change user's password
2. Call last patient
3. Examination main menu

RIGHT-CLICK

1. Evaluation search
2. Call last patient
3. Most recently opened evaluation

LEFT-CLICK

4. Change user's password
5. Patient master data
6. Menu for the current examination

RIGHT-CLICK

4. All evaluations for the patient
5. Most recently opened evaluation for this examination

Keyboard navigation

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

Generally valid keyboard shortcuts

Esc	End, cancel
Enter	Confirm, continue
Ctrl I	Program information
Ctrl H	User main menu
Ctrl P	Patient main menu
Ctrl U	Examination main menu
Ctrl S	Patient master data for the selected patient
Ctrl A	All examinations belonging to the selected patient
Ctrl G	List of the most recently opened evaluations (same as clicking on the arrow button at top right)
Ctrl F	List of the most recently opened evaluations
Ctrl L	Evaluation search
Ctrl W	Waiting room list
Ctrl Q	Device list
Ctrl M	Switch to Metasoft
Ctrl F1	Create system report, service e-mail

Resting ECG keyboard shortcuts during the recording

Enter	Start the recording
Esc	End the recording
+	Increase amplitude
-	Decrease amplitude
F9	Blood pressure input dialogue

Stress ECG keyboard shortcuts during the recording

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

Generally valid keyboard shortcuts in an open evaluation

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

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