Operating Manual

Holter ECG

with custo watch and custo diagnostic

Operating characteristics:

custo diagnostic 4.4.3 and higher
for Windows®

GEB 0185 – DK 1393
Version 002 – 05/10/2015

CE 0636

custo·med
EXCELLENCE IN DIAGNOSTICS

Operating Manual

Holter ECG

with custo watch and custo diagnostic

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.

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01.1 Symbols on the devices
(custo watch, custo guard, custo docking station, custo belt)

	Manufacturer: custo med GmbH, Leibnizstr. 7, 85521 Ottobrunn, Germany
CE 0636	CE mark
	Protection class classification of medical electrical equipment according to DIN EN 60601-1 (Type BF)
	Observe the Operating Manual
IP65	Protection class of electrical equipment (protection against the ingress of foreign matter and spray water)
	Non-ionising electromagnetic radiation, Device contains a HF transmitter
	Separate collection of electrical and electronic equipment, do not dispose with domestic waste

01.2 Intended use

The custo watch is a portable Holter ECG recorder with an internal power supply for recording a 3-channel ECG signal during a period of 24 hours. The 3-channel ECG signal is taken via the custo guard 3 ECG transmitter (includes the custo belt 3 electrode belt) in accordance with the Holter ECG standard. The ECG transmitter has an internal power supply and transmits the data to the custo watch via radio. The 3-channel ECG is received in the Holter ECG device via a radio interface.

The custo watch system is perfectly safe for patients with a pacemaker. Pacemaker recognition is not possible with the device. Caution: The ECG recording may be affected by pacemaker pulses.

The system is intended for use by trained specialist staff or physicians in clinics and medical practices. Patients are only allowed to use the recording device after receiving instruction by trained specialist staff. Patients who are not capable of understanding and following the instructions given are not allowed to use the device. This applies in particular to senile patients or patients suffering from dementia.

custo watch and custo guard are not suitable for intracardiac use.

custo watch and custo guard are not suitable for children with a weight below 10 kg.

The system is not suitable for electrocardiographic monitoring of patients in accordance with DIN EN 60601-2-27, e.g. use in intensive care.

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, 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, Holter

Words highlighted in colour...

02 Safety instructions

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 the 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; the recorder and the ECG transmitter are devices with an internal power supply), Type BF according to DIN EN 60601-1.
- Other devices which are part of the system must meet the requirements of the Standard for Information Technology Equipment (DIN EN 60950) or the Standard for Electrical Medical Devices (DIN EN 60601-1).
- The electrical installations in the rooms in which the system is used must meet the requirements of the applicable safety standards (e.g. VDE 0100 Part 710).
- 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 watch must only be used in a technically perfect condition. Regularly carry out a visual inspection of the device and the corresponding components. Only use accessories approved by custo med. The use of accessories other than those specified may result in increased emissions or decreased immunity.

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

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 for the custo watch system (recorder and ECG transmitter)

For the installation and the operation of the devices, the EMC notes (electromagnetic compatibility) included in this Operating Manual must be observed, refer to chapter *07.4 Manufacturer's Declaration regarding EMC...* .

The custo watch system is not suitable for use in rooms or areas with a risk of explosion.

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

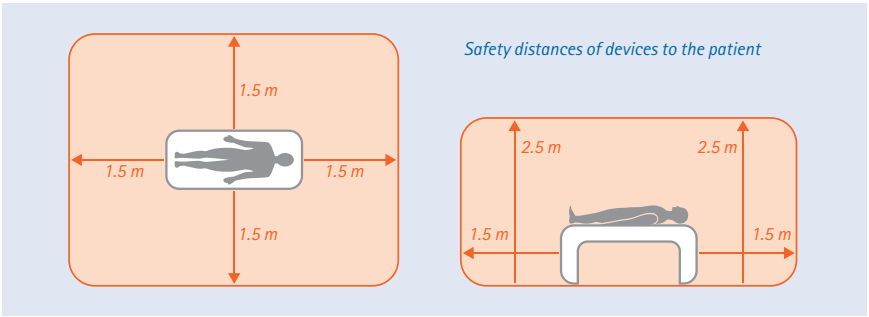
Other devices may interfere with the custo watch system, even if they comply with the applicable emissions requirements according to CISPR.

custo watch and custo guard are protected against the ingress of dust and splash water (IP65). It is not permitted to wear the devices in a swimming pool or in the bath. The devices must not be submerged under water.

The devices each contain a rechargeable lithium polymer battery. Any mechanical stress which is beyond the intended use must be avoided. Do not use force to open the devices.

The custo guard ECG transmitter may only be used in combination with the custo belt electrode belt or adhesive electrodes. Electrode belts from other manufacturers may change the band width and amplitude of the ECG signal which could result in a misdiagnosis.

Patient safety



Safety distances of devices to the patient

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.
Any non-medical devices and the patient must not be touched at the same time during the examination or routine maintenance (risk of electric shock).

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

All results achieved by automatic analysis and the resulting unconfirmed reports produced by the system must be considered as suggestions only.

For diagnosis and therapy purposes it is essential that the results are checked and assessed by a qualified physician.

Notes on pacemaker detection

With custo guard no pacemaker detection is possible.

Any disturbances in the ECG signal may be interpreted as a pacemaker by mistake.

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*.

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 surgery IT system or your hospital information system (HIS).

custo med does not accept any responsibility for any changes to data in your surgery IT system or your HIS which were made after the export from custo diagnostic.

To ensure the safe operation of custo diagnostic, deactivate the screensaver and energy management options on your PC.

Set up your operating system in such a way to prevent the PC from being switched off either accidentally or automatically during the examination (standby mode/idle mode).

custo connect

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

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: allocate new 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.

Allocation of case and job numbers

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

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 may be used.

02.4 Maintenance (regular safety checks)

The operator is responsible for maintenance. The operator must ensure that the device and accessory parts are checked at regular intervals to verify they are in perfect condition and function correctly. 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 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, however at the latest every two years, a technical safety check must be performed by your authorised custo med dealer or custo med.

Service life of the custo watch

The expected service life of the custo watch depends on its use. If used under normal conditions, and maintained and operated according to specifications, a service life of approx. 500 charging cycles can be expected.

➤ Definition of charge cycle:

Using and recharging 100 % of the battery's capacity equals one full charge cycle. A charging operation is therefore not always equivalent to a charge cycle. Example: A device may be used for several hours on a particular day. During this process approximately half the capacity is used. The device is then fully recharged. If the same procedure is repeated on the following day, this is equal to a total of just one charging cycle and not two charging cycles.

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 only assumes responsibility for the safety and reliability of the device if all changes, enhancements, repairs and other work on the device and/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.

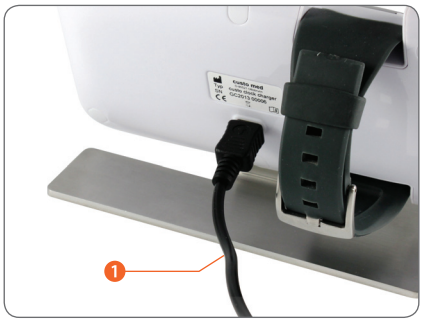
This does not include damage that can be attributed to usual wear and tear, improper use, unauthorised modification of parts and the use of violent force.

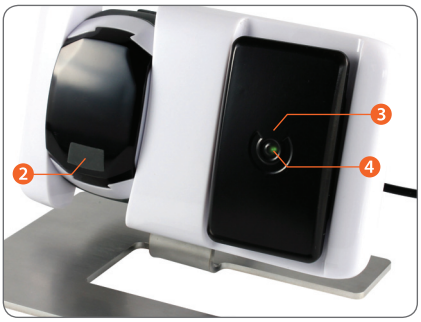
After the warranty period has expired, only use original spare parts and accessories supplied by custo med. Only this will ensure the safe and problem-free operation of your device.

03.1 Part names, components for the Holter ECG recording

- **(Part no. 10320) custo watch Holter set:**
- 1 (Part no. 10305) custo watch incl. strap set grey
- 2 (Part no. 10306) Strap set green
- 3 (Part no. 10302) custo guard 3, 3-channel ECG transmitter
- 4 (Part no. 10301/R) custo belt 3 red, 3-channel electrode belt
- 5 (Part no. 10118) custo belt 1/3 extender, extension piece for the electrode belt
- (Art.-Nr. 10307) Washing net for custo belt
- 6 (Part no. 10304) custo docking station, charger for custo watch and custo guard, connection to the PC
- 7 (Part no. 16021) Micro USB cable 2.0 1.5 m, for connecting the custo docking station to the PC
- (Part no. 10110-T) Plug-in power supply unit for the custo docking station
- 8 **(Part no. 10311) Adapter set for custo guard 3, for fitting without the electrode belt:**
- a (Part no. 23064) Carry case for the custo guard
- b (Part no. 23065) Neck strap for case
- c (Part no. 10106) Cable adapter for adhesive electrodes, length of 300 mm
- d (Part no. 10119) Coding rings for cable adapter and ECG transmitter

03.2 Charging custo watch and custo guard





IMPORTANT:

Charge the devices before first use!

Connect the custo docking station with the micro USB cable ❶ to the PC while it is on. Only use the supplied micro USB cable. Alternatively, the custo docking station can be connected to the power supply with the plug-in power supply unit.
Place the custo watch onto the custo docking station. The custo watch must engage noticeably and be firmly seated on the custo docking station, with the grey button pointing downwards ❷. The custo guard ECG transmitter is also charged in the custo docking station. The direction of insertion is determined by the shape of the housing (the opening of the custo med logo points upwards ❸).

Charging & running times	custo watch	custo guard 3
Max. charging time	approx. 3 h	approx. 2 h
Max. running time [1)]	approx. 4 days	approx. 2 days
Sampling rate	125 Hz	1 kHz
Standby	approx. 30 days	approx. 60 days

1) custo watch and custo guard are supplied with power by a rechargeable lithium polymer battery. This rechargeable battery initially has a capacity of 280 mAh (custo watch) or 105 mAh (custo guard). After approx. 300 charging cycles there is a capacity of 80 % of the initial capacity.

Display of operational readiness[2)], battery capacity

The LED of the custo guard ECG transmitter ❹ indicates the operational readiness of the system when both devices are in the custo docking station:

LED RED.....Battery capacity of at least one device < 24 hours
.....and/or recording not yet downloaded
LED GREEN.....Battery capacity of both devices > 24 hours
.....and recording has been downloaded = ready for recording

*2) Prerequisite:
custo watch and custo guard have already been connected with each other in custo diagnostic and the serial number of the custo guard ECG transmitter is stored in the custo watch. The devices are connected during the start procedure (refer to chapter 05.3 Starting the custo watch Holter ECG recorder).*

It is only possible to display operational readiness if no recording is currently in progress and both devices are in the custo docking station that is connected to the PC.

If the grey button on the custo watch is pressed ❷ while both devices are in the custo docking station, the battery capacity of both devices is shown on the display. If there is sufficient battery capacity for a 24-hour recording period, a checkmark appears for the corresponding device. If the battery capacity is less than 24 hours, the current charge status is displayed. If there is no custo guard ECG transmitter on the custo docking station or an incorrect custo guard (i.e. one which is not connected to the custo watch) is on on the custo docking station, the display shows guard: ---. Place the correct custo guard onto the custo docking station.

Frequency of charging cycles

We recommend charging the devices after each recording. Clean, disinfect and dry the devices before recharging.

03.3 Operating custo watch and custo guard

03.3.1 Display and operating elements on the devices

The custo watch has a display ❶. The display is activated by pressing the grey button ❷. The contents displayed by the custo watch differ depending on its state – standby or record. A description how to operate the custo watch is provided in chapter *03.3.4 Operating the custo watch display*.

The custo guard ECG transmitter has a LED display ❸ which indicates the operational readiness of the system when both devices are in the custo docking station and connected to the PC.

Both devices are charged via the custo docking station.

03.3.2 Changing the custo watch strap set

To change the strap set, hold the custo watch so that the rear side of the housing can be seen (with the type plate and four charging contacts). Press the strap lock ❶ (plastic clip in the centre of the strap attachment) away from the custo watch housing while sliding the strap backwards, away from the housing. Repeat the process for the remaining strap.

To attach the other strap set, hold the custo watch so that the top of the housing can be seen. Place the strap from above on the corresponding parts on the housing ❷ and press the strap down until it clicks into place. Repeat the process for the remaining strap.

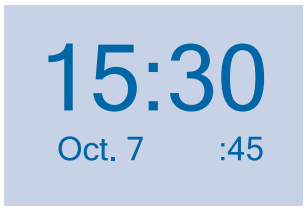
03.3.3 custo watch information elements during recording

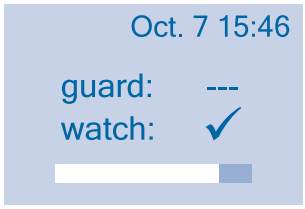
The custo watch shows the following elements during a recording:

- a Radio symbol: appears when the connection to the ECG transmitter is successful
- b ECG symbol: appears when QRS complexes are detected
- c Recording symbol: appears when the ECG recording has been started
- d Duration of current recording
- e Information line: shows contents identifying the custo watch, the contents are specified in custo diagnostic, e.g. patient name
- f Time (1st line hours : minutes, 2nd line seconds)
- g Date

Instead of f and g, an ECG signal, feedback or error messages can also be displayed during the recording.

03.3.4 Operating the custo watch display

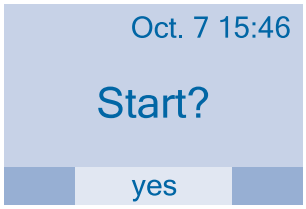




❶ Standby

The custo watch is in idle mode, no recording is in progress. If the custo watch is not connected to the PC, the time and date can be displayed by briefly pressing the grey button.

If the custo watch is connected to the PC via the custo docking station, the battery capacity of the custo watch and the corresponding custo guard ECG transmitter (if it is also on the custo docking station) can be displayed by briefly pressing the grey button. If there is sufficient battery capacity for a 24-hour recording period, a checkmark appears for the corresponding device. The progress bar at the lower edge of the display continues to run until both devices are fully charged (maximum battery capacity).

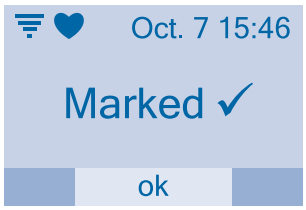


❷ Starting a recording manually

It is only necessary to manually start a recording if the custo watch was prepared in custo diagnostic with the Start later option. As long as both devices are in the custo docking station after the Start later option has been set, the battery capacity of the devices can be displayed on the display (by briefly pressing the grey button). To ensure a full 24 hour recording, both devices must be sufficiently charged.

If the custo watch is outside the custo docking station, the display is switched on by briefly pressing the grey button and the Start? query appears after the date and time have been displayed. The recording is started by briefly pressing the grey button again.

As soon as the recording is in progress, the duration of current recording is shown at the top right of the display. The radio symbol (the first symbol at the top left) appears when a connection to the ECG transmitter could be established. The ECG symbol (the second symbol at the top left) appears when QRS complexes are detected, i.e. the ECG transmitter is fitted on the patient. The display goes out after a few seconds.



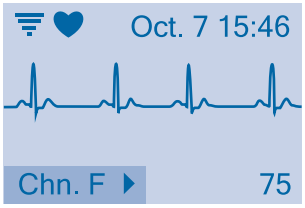
❸ Setting a marker in the recording

The patient is able to set markers during the ECG recording, for example if feeling unwell, in cases of stress or at special events.

The display is switched on by briefly pressing the grey button. The Mark? query appears by briefly pressing the grey button again. The marker is set by briefly pressing the grey button again and the confirmation Marked✓ is displayed. This is acknowledged by briefly pressing the grey button and then closed. The display shows the duration of current recording, time and date again. If no further input is made, the display goes out after a few seconds.

❹ Displaying the ECG signal

The ECG signal can be displayed during the recording. The display is switched on by briefly pressing the grey button. The grey button is then held pressed down (approx. 10 seconds) until the ECG signal is displayed. It is possible to switch between the three ECG channels by briefly pressing the grey button.
To exit the ECG view, the grey button is held pressed until the duration of current recording, time and date are displayed again. If no further input is made, the display goes out after a few seconds.



❹

❺ Ending the recording automatically

The recording ends automatically after 24 hours. The message "Recording finished" appears in the display.

❺

❻ Prematurely ending/cancelling the recording

A recording can be ended manually. For this, the ECG signal is first displayed, see ❹. The grey button is then held pressed (approx. 10 seconds) until the Finish recording? query appears in the display. The recording is ended by briefly pressing the grey button again. The message "Recording finished" appears in the display.

❻

❼ Error messages

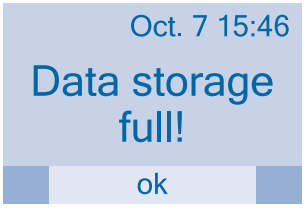
» guard is not available!:

The connection to the custo guard ECG transmitter is interrupted. Make sure that the ECG transmitter is in radio range and sufficiently charged. Establish a line of sight between the custo watch and custo guard, for example, by holding the custo watch in "reading position" in front of your body. The custo guard ECG transmitter must not be covered by body parts, such as crossed arms or the chest. As soon as the connection to the ECG transmitter can be established again, the message Connected to guard✓ appears. The messages can be hidden by briefly pressing the grey button.

❼

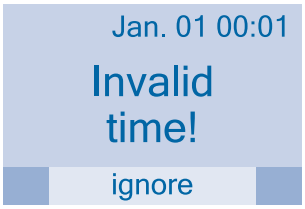
» Attach ECG belt!:

No QRS complexes are detected or the quality of the derivation is not sufficient. Fit the custo belt electrode belt on the patient or check that the electrode belt is fitted correctly. There must not be any textiles between the skin and electrode belt. As soon as QRS complexes are detected, the message ECG signal✓ appears. The messages can be hidden by briefly pressing the grey button.



- Memory full!:

The memory card in the custo watch is full. The custo watch must be downloaded into custo diagnostic before a new recording can be performed. The data are stored in the custo diagnostic evaluation directory.

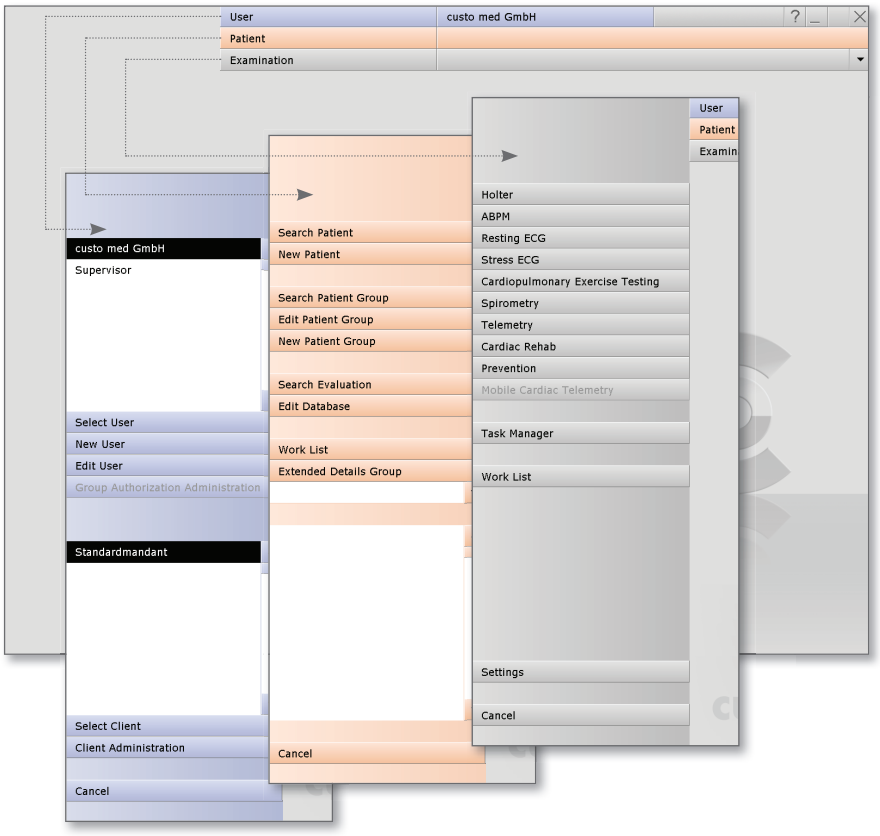


- Invalid time!:

This message appears if the custo watch has not been used for a prolonged period and it is fully discharged. After charging, the display does not respond to a key press. To perform an automatic reset, connect the custo watch via the custo docking station to the PC, start custo diagnostic and open the Examination, Holter, New Holter page. The custo watch is operational again.

03.4 custo diagnostic – basic program structure

The 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 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 Patient, New Patient and Search Evaluation.

The Examination main menu lists all of the examination types which are possible with custo diagnostic. All 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.

03.5 Device connection and configuration

Prerequisite:
custo diagnostic is installed on your PC and ready for operation.

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

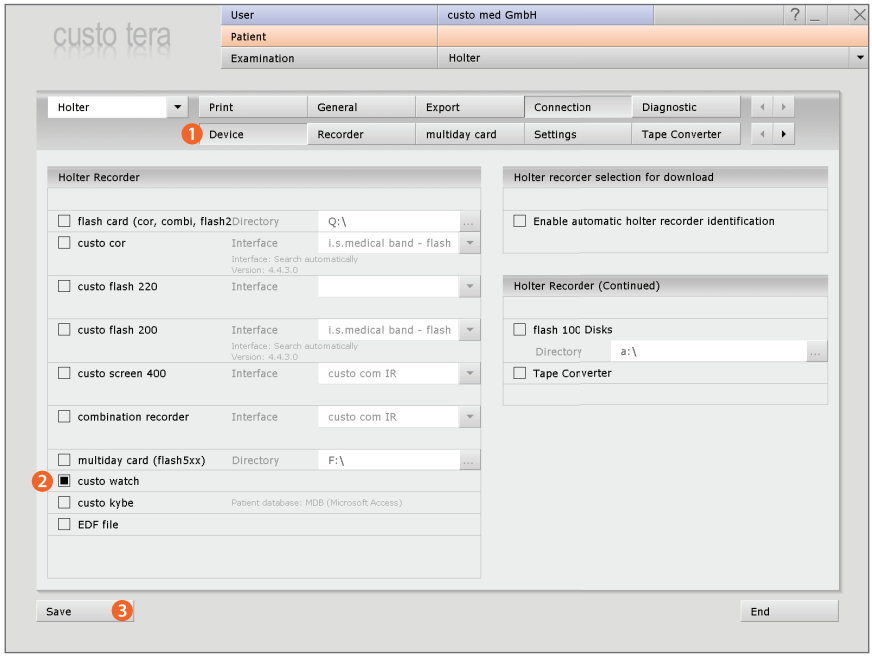
03.5.1 Connecting the custo watch

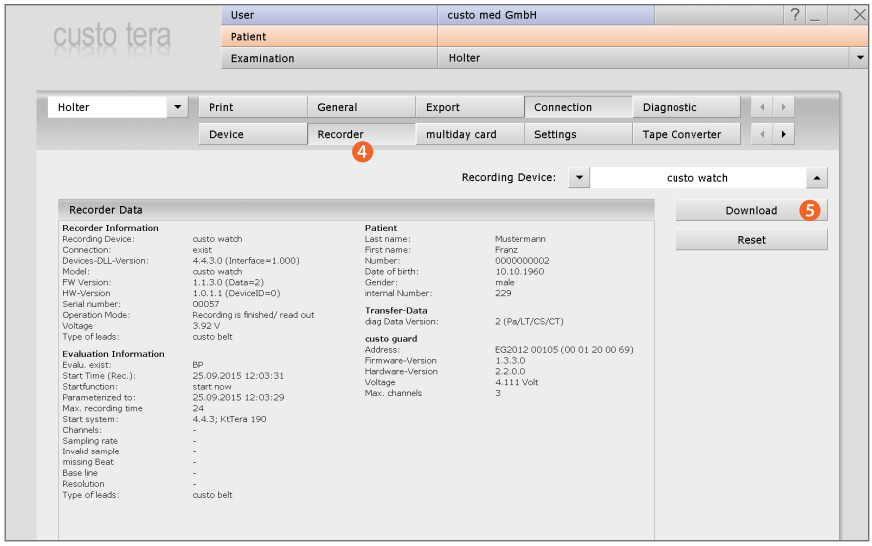
Connect the custo docking station with the USB cable to the PC. If possible, not via a USB hub. Place the custo watch into the custo docking station. Driver installation takes place automatically. Wait until the installation is complete.

03.5.2 Setting the custo watch as a Holter ECG recorder

Start custo diagnostic and open the Examination, Holter, Settings, Connection, Device ❶ page. Select the custo watch ❷ item. Click on Save ❸ to apply your input.

On the Examination, Holter, Settings, Connection, Recorder ❹ page, the recorder data (firmware version, hardware version etc.) of the custo watch can be displayed via the Download ❺ button. This information is needed for service work.





Note on the EDF file option:

If there are Holter ECG recordings from "external" recorders (not from custo med) as EDF files, these can be downloaded to custo diagnostic and displayed as a Holter ECG evaluation.

This procedure requires that the EDF file option on the Examination, Holter, Settings, Connection, Device page is activated. Click on Save to apply your input.

04 Hygiene

04.1 Cleaning and disinfection

Important notes

Use only cleaning agents and disinfectants that have been approved by custo med. Unsuitable agents could damage the device.

The devices must never be immersed in liquid or cleaned with too much liquid.

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

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

custo watch incl. strap, custo guard 3

- Reprocessing type: Wipe disinfection
- Note: Do not store the device when wet in the custo docking station. Ensure that the device is dry before placing it on the custo docking station.

custo docking station

- Reprocessing type: Wipe down the dry device with a soft, lint-free cloth.
- Note: Make sure that no moisture gets inside the device (e.g. via interface contacts). Contacts must not become soiled or damaged (this will impair the charging function).

custo belt 3, custo belt extender

- Reprocessing type: Washing with a disinfectant in a washing net
- Note: Lay flat to dry. Do not hang dry. Allow to dry completely before stretching or using it. Up to 100 washing cycles.

The custo belt and the extender must no longer be used after use on infectious patients.

Adapter set for custo guard 3

custo guard carry case and neck strap

- Reprocessing type: Washing with a disinfectant

Cable adapter for adhesive electrodes

- Reprocessing type: Wipe disinfection

04.2 Approved cleaning agents and disinfectants

Wipe disinfection

Meliseptol® Wipes sensitive
Meliseptol® Foam pure (B.Braun)

- Note: Observe the manufacturer's instructions

Washing with a disinfectant

Eltra 40® (ECOLAB)

- Note: Observe the manufacturer's instructions

Machine wash at 40°C in a washing net, (do not spin)


Do not treat with harsh chemicals or bleach


Do not iron


Do not tumble dry

05.1 Overview of work steps

START

Patient instructions, explain how to operate the device

Start the custo watch Holter ECG recorder in custo diagnostic:
Set the recording parameters, ECG transmitter and information line

Start now:
The recording parameters
and the patient data are stored
in the custo watch,
custo watch and custo guard
are connected, recording starts.

Or Start later:
The recording parameters
are stored in the custo watch,
custo watch und custo guard
are connected.
Recording does not yet
take place.

Manually start the recording
on the custo watch
CAUTION: Keep the previously
selected ECG transmitter together
with the custo watch until
the manual start!

Fit the custo watch Holter ECG recorder and
custo guard ECG transmitter on the patient

DOWNLOAD

Remove the custo watch Holter ECG recorder and
custo guard ECG transmitter from the patient

Download the Holter ECG recording to custo diagnostic

Holter ECG recording is displayed, write report, end evaluation

05.2 Patient instructions, operating the device

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

The devices must also be worn during the night. If the custo watch is taken off, ensure that it is always in radio range of the ECG transmitter. An active connection exists when the radio symbol is shown on the custo watch display.

No x-rays must be taken on the day of recording. Other electrical appliances (e.g mobile phones) may affect the quality of the recording.

The devices must be protected against extreme cold, heat, moisture, dirt and mechanical impact. No showers, no visits to the swimming pool and sauna.

If the ECG transmitter is detached from the electrode belt during recording, it must be ensured that the ECG transmitter is aligned correctly when it is reattached:

- custo guard "R" = custo belt red snap fastener
- custo guard "3" = custo belt green snap fastener
- custo guard "L" = custo belt yellow snap fastener

A custo belt electrode belt stretches after prolonged wear, due to moisture (sweat). The custo belt should be re-tensioned after some time so that it rests firmly against the upper body again and to ensure the ECG is of adequate quality.

The patient is able to set markers during the ECG recording, for example if feeling unwell, in cases of stress or at special events. The reason for a marker can be registered in the patient diary. Instruct the patient how to use the custo watch Marker button. Setting a marker:

- Switch on the custo watch display by briefly pressing the grey button
- Pressing the button again activates the Mark? query
- Pressing the button again sets the marker, message Marked✓
- Pressing the button again confirms the action and hides the message Marked✓

CAUTION:

The custo belt and the neck strap must be kept away from children due to risk of strangulation.

Small parts must be kept away from children due to risk of suffocation.

In the case of known allergies, e.g. against substances in the adhesive electrodes or custo belt, the further procedure must be agreed with a doctor before the recording.

05.3 Starting the custo watch Holter ECG recorder

The steps necessary to carry out and evaluate a Holter ECG recording in custo diagnostic are shown without a surgery IT system or HIS connection. This chapter shows the standard procedure for starting a recording with the custo watch.

05.3.1 Program start, selecting the Holter ECG recorder

Make sure that the custo docking station is connected to the PC. Place the custo watch and custo guard ECG transmitter onto the custo docking station. Start custo diagnostic and log in with your user name and password if required. Click on Examination, Holter, New Holter. The screen for setting the recording parameters is displayed. Select custo watch ❶ as the Holter recorder.

05.3.2 Setting the Holter ECG parameters

Set the Holter ECG parameters for the recording. Select a set of Holter ECG parameters which has already been saved, e.g. Standard ❷, or create a new set. With the Edit ❸ button, the Holter ECG parameters can be re-defined and saved. With the buttons 1 to 4 ❹, more pages with Holter ECG parameters can be opened.

Options in the Holter ECG parameters

❺ Print diary: Prints out the patient diary during the start procedure.

❻ Later start with patient: Allows a patient to be selected when the recorder is started via the Start later button [1].

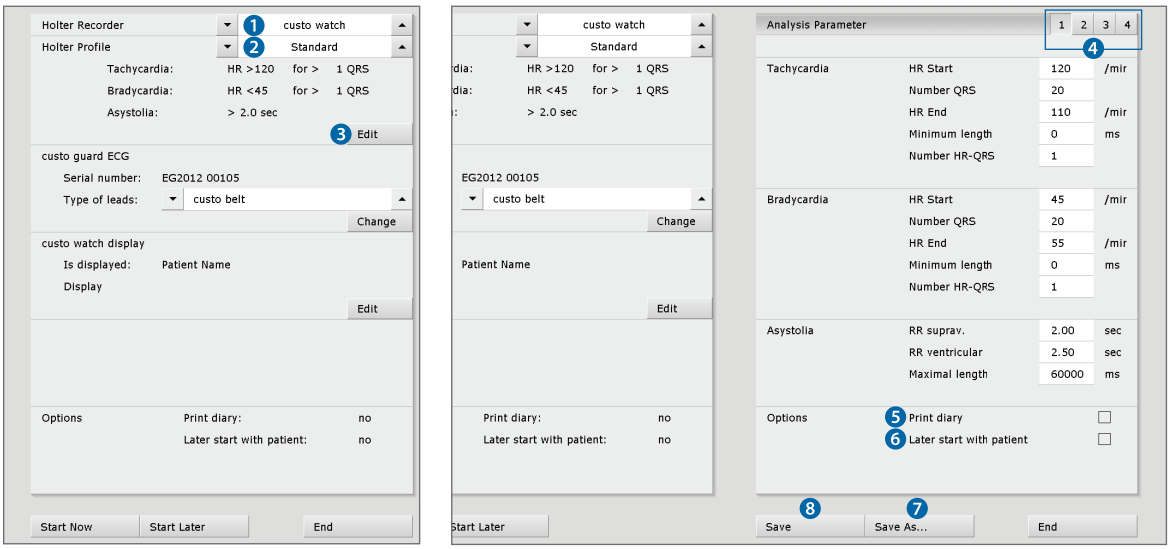
With Save As ❼ the set parameters can be saved under a new name and made available for more recordings. With Save ❽ the original parameters are overwritten.

1) Information on the Start later function:

When the Start later function is used, usually no patient is selected. The Start later function is used for setting up a recorder in advance and anonymously before a patient is present.

The recording parameters are transmitted to the recorder during the start procedure (without any patient data). The recording is started manually on the custo watch at a later point in time.

After the recording, when the custo watch is received, the evaluation must be allocated to a patient immediately or the device must be identified with patient data. Always ensure that the device and the recording data are uniquely allocated to the patient.



2) The serial number of the custo guard ECG transmitter is located on the rear side of housing, on the type plate and consists of two letters, year and five digits (XX2014 00000):

05.3.3 Selecting the custo guard ECG transmitter

To enable a data transmission between the ECG transmitter and the custo watch during recording, the devices must be connected to each other.

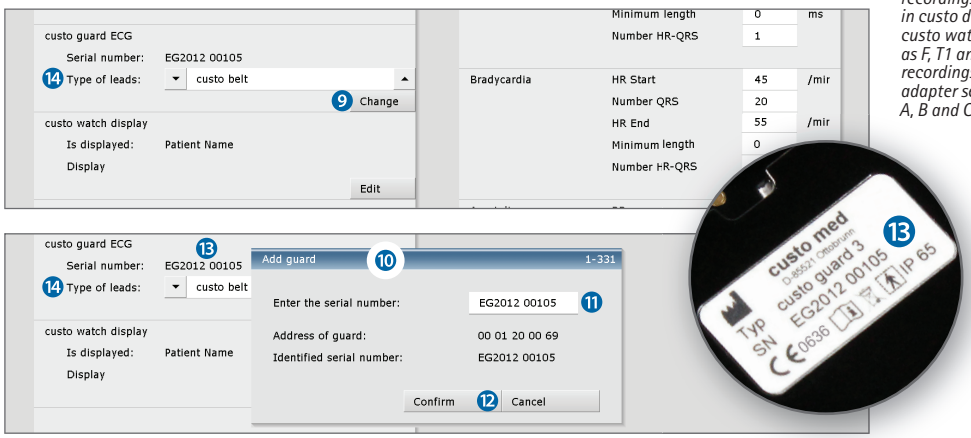
For this, click on Change ❾ in the "custo guard ECG" area. The "Add guard" dialogue ❿ is opened. Enter the serial number of the desired custo guard ECG transmitter[2)] in the input field ⓫ and click on Confirm ⓬. After the serial number has been entered successfully, it is displayed in the "custo guard ECG" area ⓭. The serial numbers on the ECG transmitter and in custo diagnostic, in the "custo guard ECG" area, must be identical ⓭. During the start procedure, the serial number of the ECG transmitter is transmitted to the custo watch[3)].

If you are only working with one custo watch system or there is only one ECG transmitter, skip work steps ❾ to ⓬.

Then select the type of leads[4)] ⓮. For carrying out recordings with the electrode belt, select custo belt; for carrying out recordings with the custo guard adapter set, select cable adapter for adhesive electrodes.

3) Safety information when using the "Start later" function:
If the Start later function is used, the custo watch and the allocated ECG transmitter must be stored together until fitted on the patient. If an "incorrect" ECG transmitter, i.e. one which is allocated to a different custo watch, is fitted on the patient, no ECG will be recorded as there is no connection between the custo watch and the ECG transmitter.

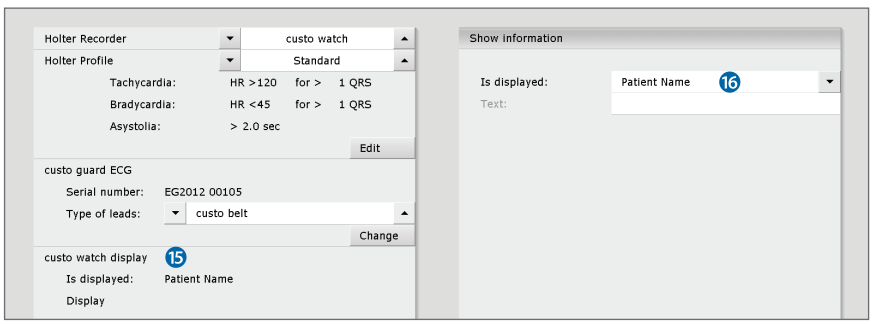
4) Note on the designation of ECG leads: When carrying out recordings with custo belt, the leads in custo diagnostic (and on the custo watch display) are labelled as F, T1 and T2; when carrying out recordings with the custo guard adapter set, they are labelled as A, B and C.



05.3.4 Defining the contents of the custo watch information line

To ensure the custo watch can always be uniquely allocated, the custo watch display has an information line (2nd line from the top, max. 15 letters). The content of the line is specified in custo diagnostic, e.g. patient name.

Click on Change in the "custo watch display" area ⓯ to specify the content of the information line. Select the desired content in the right half of the screen ⓰. The selection is automatically applied and transmitted to the custo watch during the start procedure.



05.3.5 Starting the recording

If it has not already been done, place the custo watch and the custo guard onto the custo docking station. Click on Start now or Start later.

Sequence for "Start now"

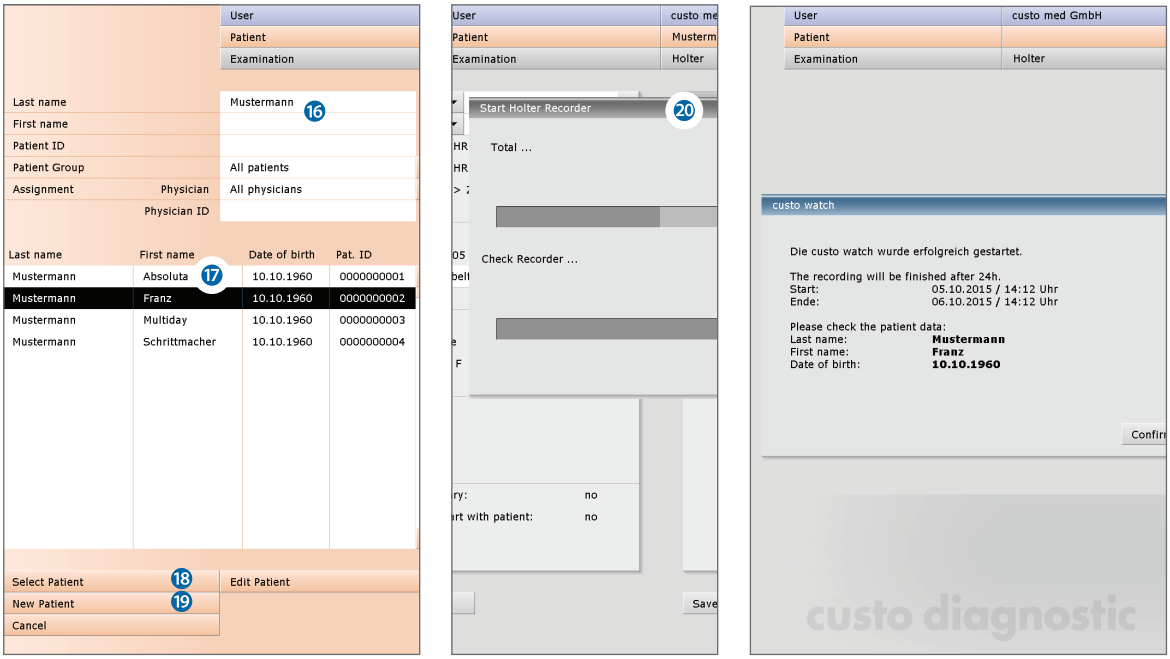
The patient search screen appears. Select a patient for the examination. Enter the patient's name, or the first letter of their name, into the input fields on the search screen ⑯. Select the patient from the list below the input fields ⑰ and confirm your selection by clicking on the Select Patient ⑱ button.

If the patient does not yet exist in your database, click on New Patient ⑲. Enter the patient data. The fields marked with an asterisk are mandatory. Save the entries to enter the patient into your database.

After the patient has been selected, the recording parameters are transmitted to the custo watch ⑳. Fit the custo watch and custo guard on the patient, refer to *chapter 05.4 Fitting the Holter ECG recorder on the patient*.

Sequence for "Start later"

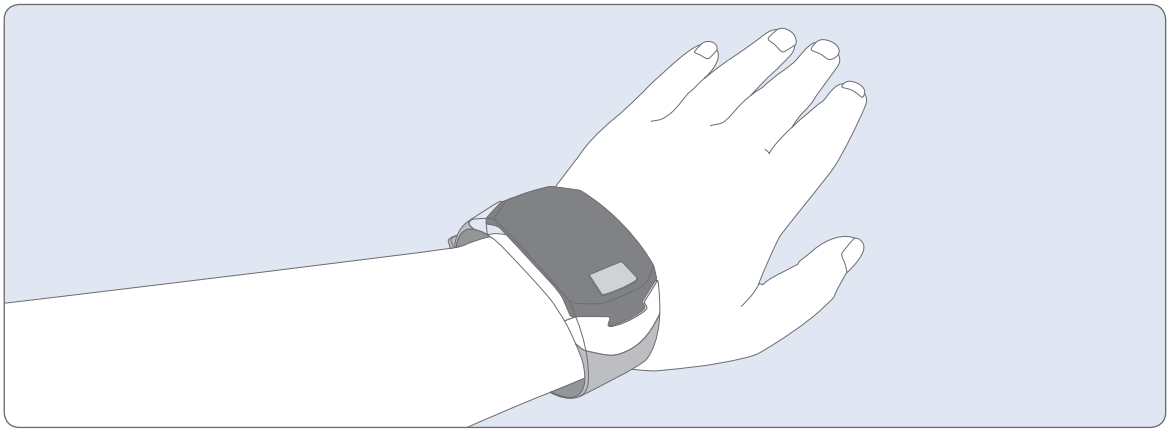
The recording parameters are transmitted to the custo watch. Keep the custo watch and custo guard ECG transmitter together until the devices are fitted on the patient. To start the recording, activate the custo watch display by briefly pressing the grey button. By pressing the button again, the start query appears. Confirm this by pressing the button. Fit the custo watch and custo guard on the patient, refer to *chapter 05.4 Fitting the Holter ECG recorder on the patient*.



05.4 Fitting the Holter ECG recorder on the patient

05.4.1 Fitting the custo watch

The custo watch is worn like a wristwatch, as shown in the figure below. The custo watch saves the ECG signal from the custo guard ECG transmitter.



05.4.2 Fitting the custo guard ECG transmitter with electrode belt

The ECG transmitter is fitted to the upper part of the patient's body with the electrode belt. The skin must be free from grease and personal care products.
The electrode belt must be set up so that it fits tightly and the contact surfaces make good contact, but that the patient is not impaired or hindered in breathing. The contact surfaces on the inside of the electrode belt must not be soiled. Soiling will affect the quality of the ECG [1].

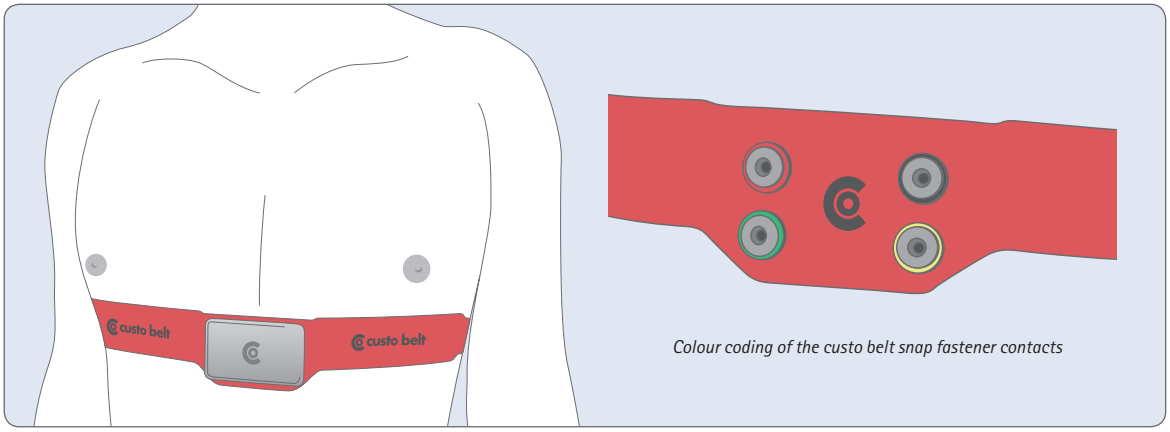
1) Checking the radio connection and the ECG

After the devices have been fitted on the patient, activate the custo watch display by briefly pressing the grey button and check whether the radio symbol (radio connection to the ECG transmitter) and the heart (ECG signal) are shown on the display. If not, check and improve the position of the electrode belt.

CAUTION: The electrode contact surfaces must always be in contact with the skin. Ensure that there are no textiles between the electrode and the skin.

Make sure that the custo guard ECG transmitter is attached properly to the snap fastener contacts of the electrode belt:

- custo guard "R" = custo belt red snap fastener
- custo guard "3" = custo belt green snap fastener
- custo guard "L" = custo belt yellow snap fastener



Colour coding of the custo belt snap fastener contacts

05.4.3 Length adjustment of the custo belt 3

❶ Opening and closing the custo belt

To open the custo belt, pull the material loop off the black plastic hook. To close the custo belt, pull the material loop back over the black plastic hook. Then adjust the belt length with the length adjustment to the circumference of the patient's chest.

❷ Initial minimum length position

The length adjustment slider is located directly next to the point where the material becomes wider on the custo belt. The elastic excess length is completely pulled through the slider so that the slider is directly next to the black plastic hook.

❸ Adjustment from minimum length to medium length

Hold the slider with your right hand. The upper layer of material, next to the slider on the left, is pulled through the slider until there is no more elastic excess length. The black plastic hook is then pulled to the left.

❹ Adjustment from medium length to maximum length

Hold the slider or the upper layer of material next to the slider on the left with your left hand and pull the material next to the slider on the right to the right until the slider is situated next to the black plastic hook.

❺ Adjustment from maximum length to medium length

Hold the slider with your right hand, grasp the lower layer of material to the left of the slider and pull it through the slider up to the wide point.

❻ Adjustment from medium length to minimum length

Hold the slider with your left hand and pull the elastic excess length completely to the right through the slider until the slider is back between the black plastic hook and the wide material point.

❼ Extension with the custo belt extender

If the maximum length is not sufficient, use a custo belt extender (extension piece). The custo belt extender is adjusted to the minimum length when the slider is located next to the material loop. The maximum length is reached when the slider is next to the black plastic hook. There is no limit on the number of custo belt extenders that can be used.

❽ Movable back electrode

For petite patients the back electrode is fitted towards the front electrode (see Figure) so that the back electrode does not rest on the spine. Open the Velcro fastener and turn the electrode module to the desired position. Close the Velcro fastener again. The electrodes must always be in full contact with the patient's skin.

05.4.4 Fitting the custo guard ECG transmitter with cable adapters

If it is not possible to use the electrode belt, the custo guard ECG transmitter can be fitted with cable adapters and adhesive electrodes:

- Attach the cable adapters to the custo guard ECG transmitter ❶.
  For custo guard 3, three cable adapters are attached – R, 3 and L [2)].
  Attach the cable adapters in accordance with the colour coding.
- Attach the electrodes (e.g. custo sensive) to the cable adapters.
- Place the ECG transmitter in the case ❷ and close the case.
- Attach the neck strap to the case.
- Adjust the neck strap to the desired length.
- Clean the electrode contact points,
  the skin must be free from grease and personal care products.
- Remove the protective films from the electrodes.
- Stick the electrodes to the chest, see Figure ❸.

2) The two snap fastener contacts of a cable adapter have different diameters. Only one end of the cable adapter will fit onto the ECG transmitter contacts. For fitting, try both ends, if required. Do not press with force.

To prepare the electrode contact points we recommend the use of custo prep ECG preparation cream. Rub the skin areas to which the electrodes will be attached lightly with custo prep. We also recommend the use of custo sensive ECG electrodes (latex-free, PVC-free, skin-friendly, permeable to air and moisture).

05.5 Removing the recorder, downloading the recording

Work steps after the Holter ECG recording:

- Remove the custo watch from the patient's arm
- Remove the custo guard and custo belt from the patient, remove the electrodes if necessary
- Clean and disinfect the custo watch, custo guard and textiles, refer to chapter *04 Hygiene*
- Dry the custo watch and custo guard thoroughly before placing them onto the custo docking station for downloading and charging.

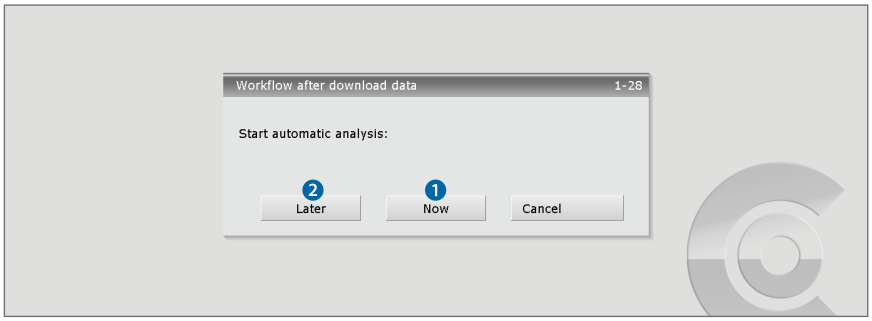
  CAUTION: Make sure that no moisture (sweat, disinfectant) gets onto or into the custo docking station. Recharging wet devices will lead to the oxidation of the electric contacts.
- Place the custo watch onto the custo docking station
- Make sure that the custo docking station is connected to the PC
- Open custo diagnostic...

Downloading process in custo diagnostic

- In custo diagnostic open the Examination, Holter, Download Data page. The "Workflow after download data" dialogue appears. You can decide here whether the recording should be analysed and displayed now ❶ or later ❷.

- Now ❶ button: The recording is analysed during the download process and then displayed.

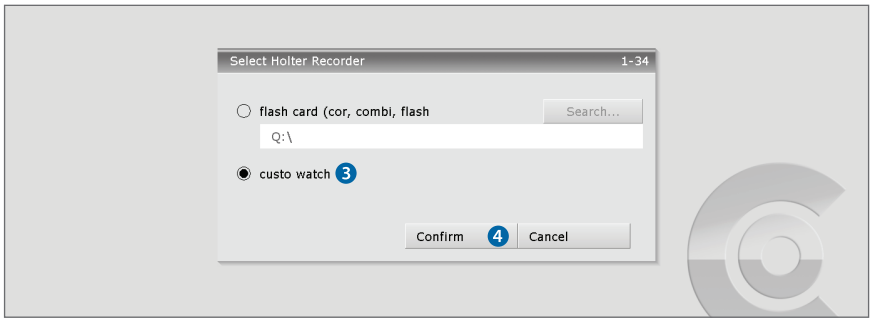
- Later ❷ button: The recording is stored – without analysis – in the Task Manager. The Task Manager is suitable for downloading several devices in a short period of time.



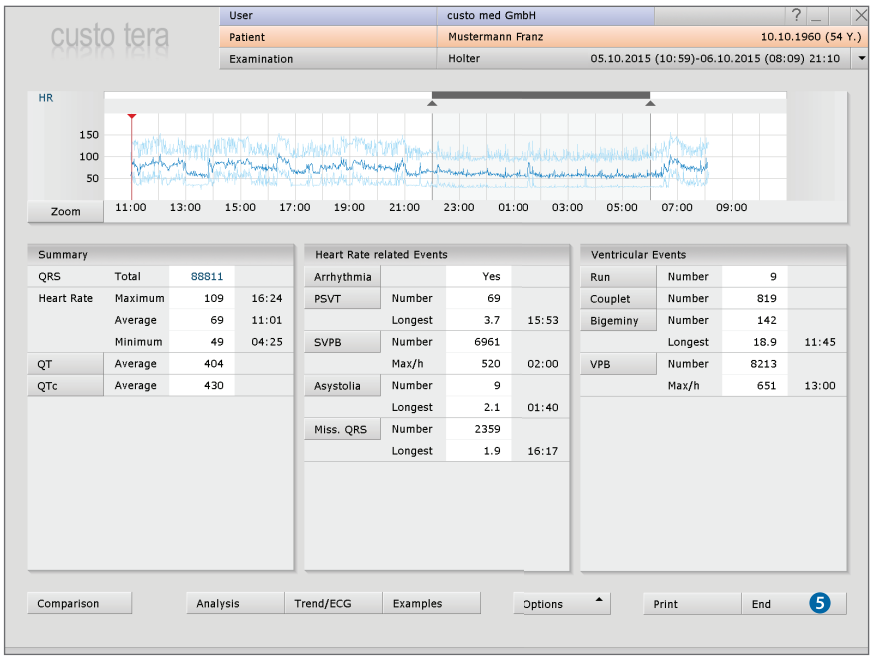
Additional information, workflows after the "Later" downloading process:

To make recordings from the Task Manager available, in the Examination main menu, click on the Task Manager button.
The "shown job types" area is used to set which job types are displayed in the list, e.g. only analysis tasks. Click on Execute all or select a job and click on Execute.
After the job has been executed, the entry disappears from the list and the analysed recording can be opened.

➤ When using multiple recorder types, the "Select Holter Recorder" dialogue appears. Select the custo watch ❸ option. Click on Confirm ❹. The evaluation is displayed (Now button) or stored in the Task Manager (Later button).



To close an evaluation, click on End ❺ and on Confirm in the End dialogue.



Preparation for the next examination

custo watch and custo guard must be sufficiently charged, refer to chapter 03.2.

06.1 Opening the Holter ECG evaluation

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

Opening an evaluation via the evaluation search

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

In the Examinations area, enter what type of evaluation you are searching for, e.g. Holter ❷. In the Properties area ❸ you can define more search criteria.

If you set the confirmed property 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 ❹ or activate Search automatically ❺. This option triggers an automatic search in your database whenever the search criteria are changed.

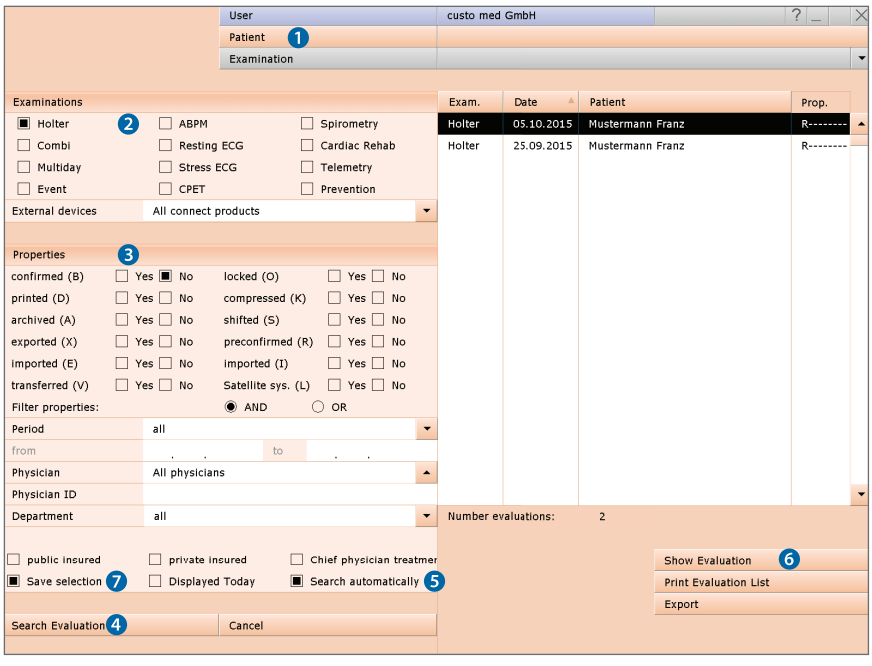
The right part of the screen displays a list of all the evaluations which correspond to the activated search criteria. To open the desired evaluation, select it from the list and click on the Show Evaluation ❻ button or double-click on the evaluation.

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

Reference between End dialogue and search screen

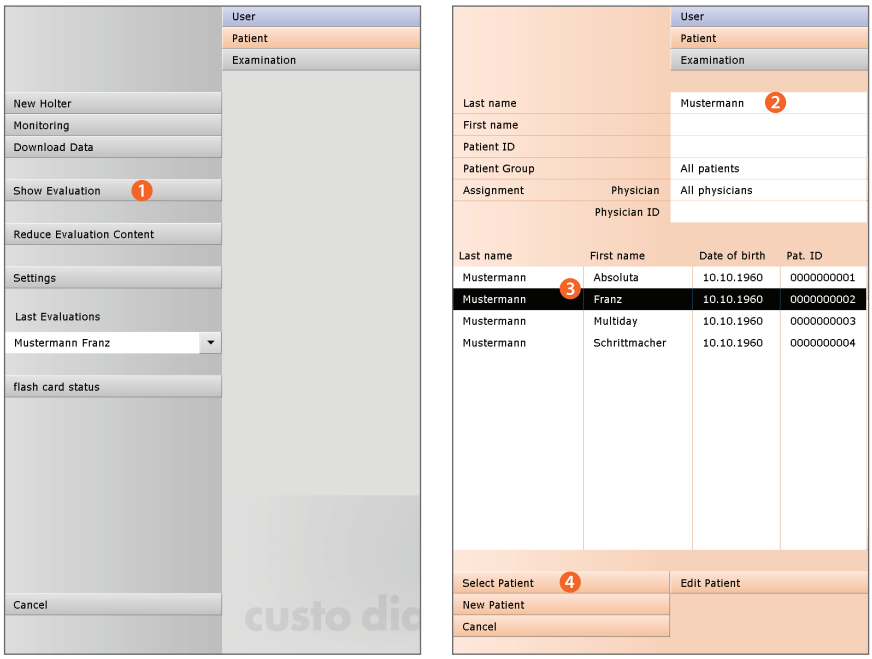
In order to make proper use of the search screen, the status of the evaluation must be set correctly when you end an evaluation in the End dialogue.

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



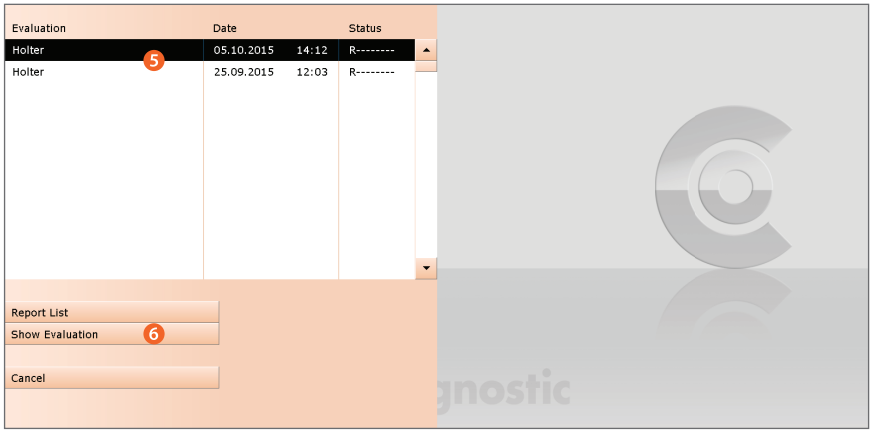
Opening an evaluation via the examination main menu

Open the Holter ECG main menu via Examination, Holter, and click there on Show Evaluation ❶.

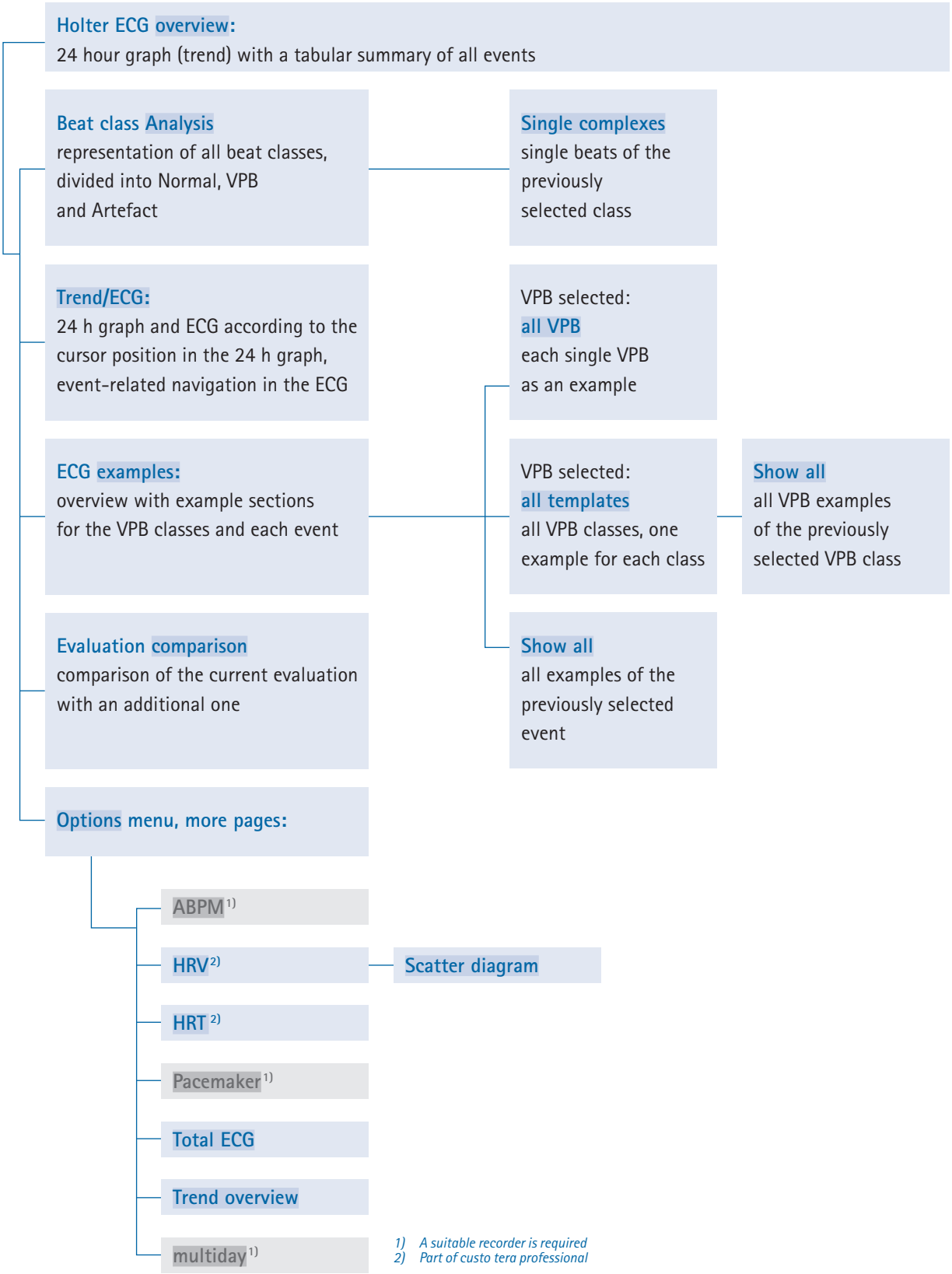


The patient search screen appears. In this screen select the patient whose recording you want to open. Enter the patient's name, or the first letter of their name, into the input fields on the search screen ❷. Select the patient from the list below the input fields ❸ and confirm your selection by clicking on the Select Patient ❹ button. 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 ❺ and open it by means of a double-click or via the Show Evaluation ❻ button.

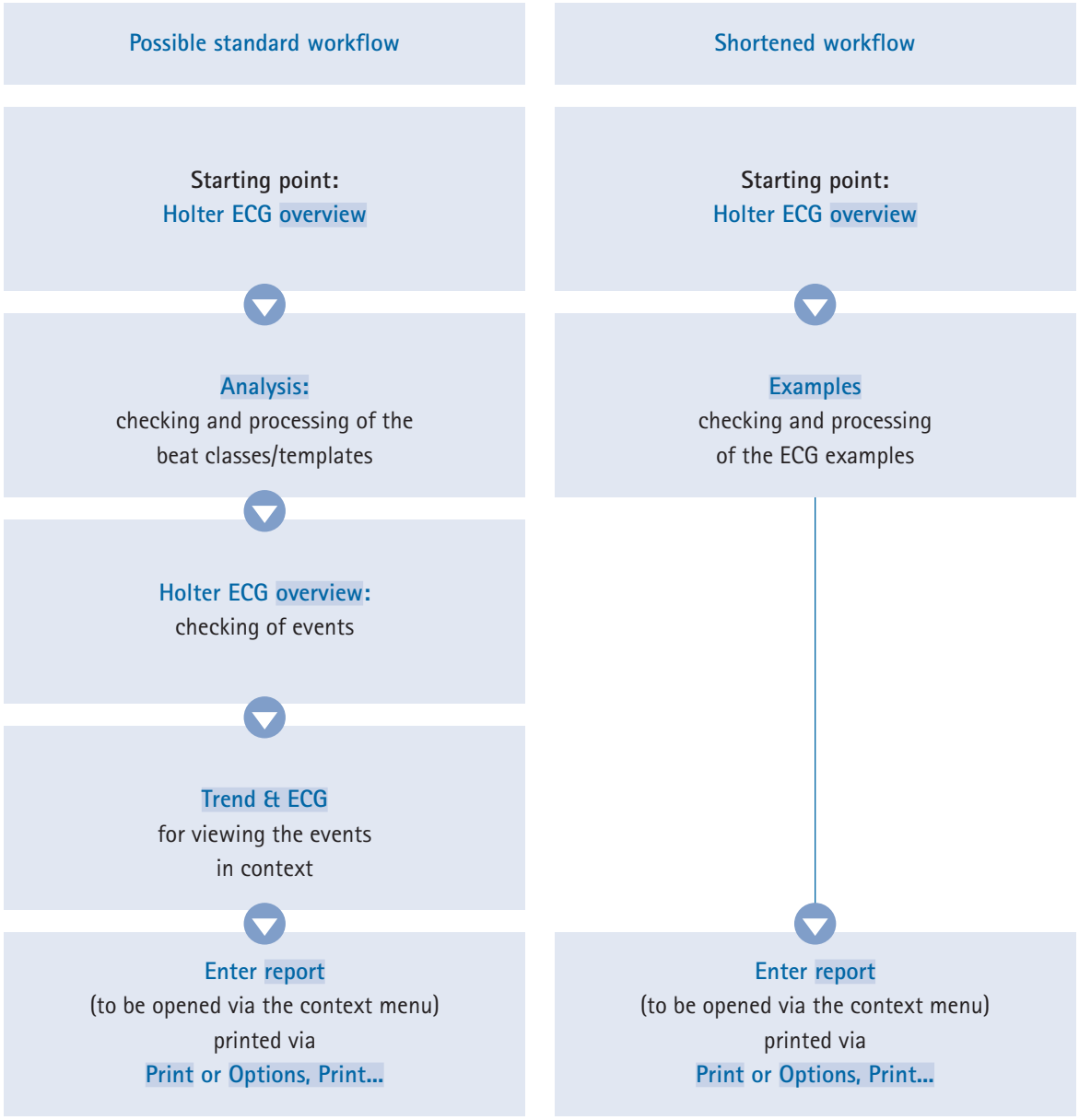


06.2 Structure of the evaluation



1) A suitable recorder is required
2) Part of custo tera professional

Examples for the procedure for evaluation and confirmation

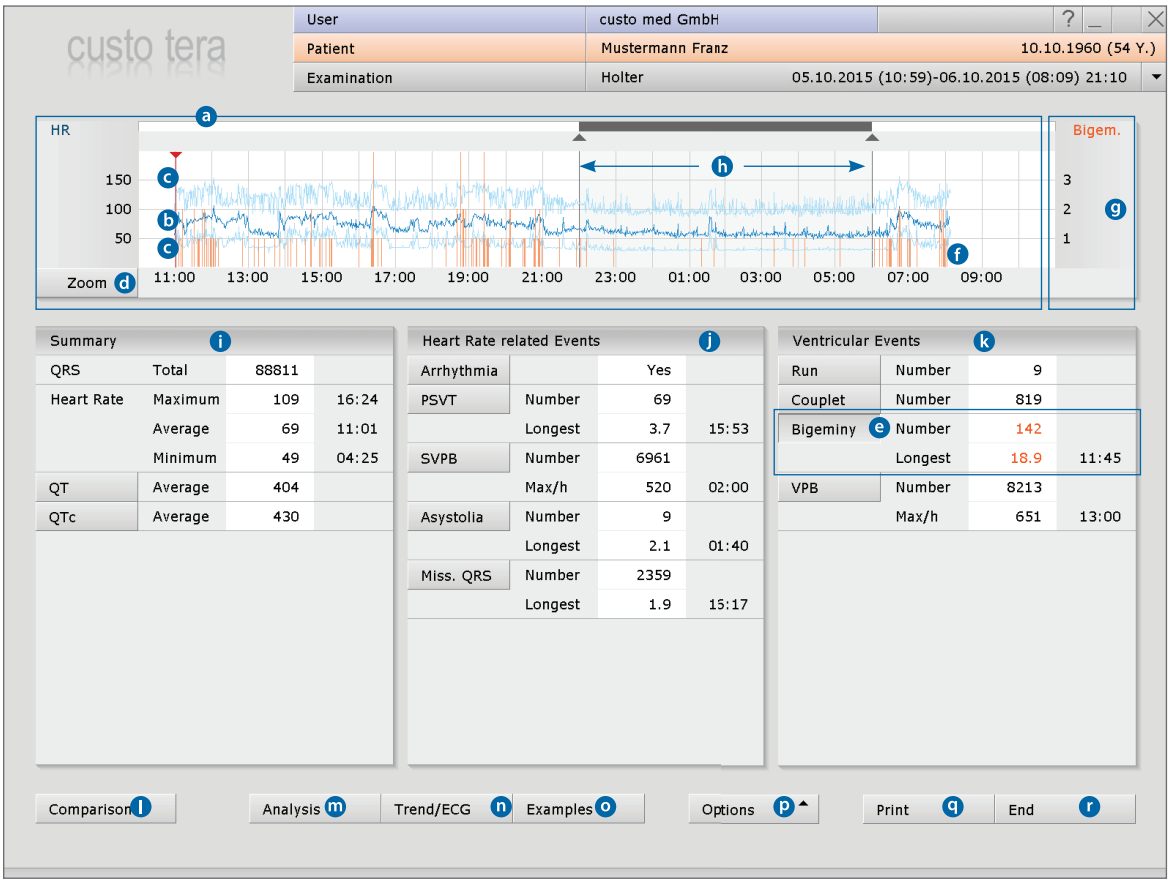


06.3 Holter ECG evaluation pages

The following pages display the individual pages of the evaluation with navigation and editing options:

Advanced options

06.3.1 Holter ECG overview



Graphic representation of the recording

- a 24 hour graph (trend)
- b HR average (dark blue, between HR maximum and minimum) results from the average heart rate per minute
- c HR maximum, HR minimum (light blue above and below the HR average) show the highest and lowest value within a minute
- d With the Zoom button, one hour of the graph is shown enlarged (30 min. before and after the cursor)

Event log

If you click on one of the events, e.g. Bigeminy e, vertical orange lines will appear in the 24 hour graph (trend) f which indicate when the selected event occurred. The selected event is marked in the overview table with orange lettering and the button pressed down e. To display another event, click on the button of the desired event. The height of the orange lines in combination with the scale on the right-hand side of the screen g provides information on the number of occurrences within a minute.

Night phase (h)

The area highlighted in light grey in the graph shows the night phase in the recording. The start and end can be changed using the arrows above the graph.

Navigation in the 24 hour graph

Double-click on any position in the 24 hour graph (trend) to go to the Trend/ECG page. The position that you clicked is shown enlarged under the 24 hour graph. This method is suitable for viewing specific events in the ECG. By clicking on the Overview button you can return to the Holter ECG overview.

Tabular overview, events detected by the analysis:

- (i) Summary with the number of all cardiac activities, overview of HR
- (j) List of the existing heart rate-related events
- (k) List of the existing ventricular events

The existing events are sorted in descending order by severity. Each event is provided with the information how often it occurred during the recording, sometimes including the maximum value and the time of the maximum value.

Navigation options in the tabular overview

By double-clicking on any Event button (see (e)) you can open the Trend/ECG (n) page. By clicking on number/maximum value/time of an event you can open all examples of the event. The examples are ECG sections which contain the corresponding event.

Buttons for opening additional evaluation pages

- (l) Comparison of two evaluations belonging to a patient
- (m) Analysis – graphic representation of all beat classes of the evaluation
- (n) Trend/ECG – 24 hour graph in combination with an enlarged ECG
- (o) Examples – overview of several ECG sections for each event
- (p) Options menu with additional evaluation pages and editing functions
- (q) Prints the evaluation in accordance with the system settings
- (r) End – closes the evaluation

The context menu

The context menu is opened by right-clicking on the evaluation. The report dialogue can be called here. The contents of the context menu vary according to the evaluation page.

06.3.1.1 Context menu

Functions in the context menu	Overview	Analysis	Trend/ECG	Examples	Total ECG
Report	✓	✓	✓	✓	✓
Evaluation Info	✓	✓	✓	✓	✓
Medication Info	✓	✓	✓	✓	✓
Clinical question	✓	✓	✓	✓	✓
Help	✓	✓	✓	✓	✓
Settings	✓	×	✓	✓	×
ECG failure	✓	×	×	×	×
Change (manual event input)	✓	×	×	×	×
Mark	×	✓	✓	×	✓
Change (Edit beat/event)	×	✓	✓	✓	×
Insert beat	×	✓	✓	×	×
Adjust amplitude	×	✓	✓	✓	✓
Select time	×	✓	✓	×	✓
Select templ.	×	✓	×	×	×
Reverse select.	×	×	×	✓	×

Important notes on the functions in the context menu

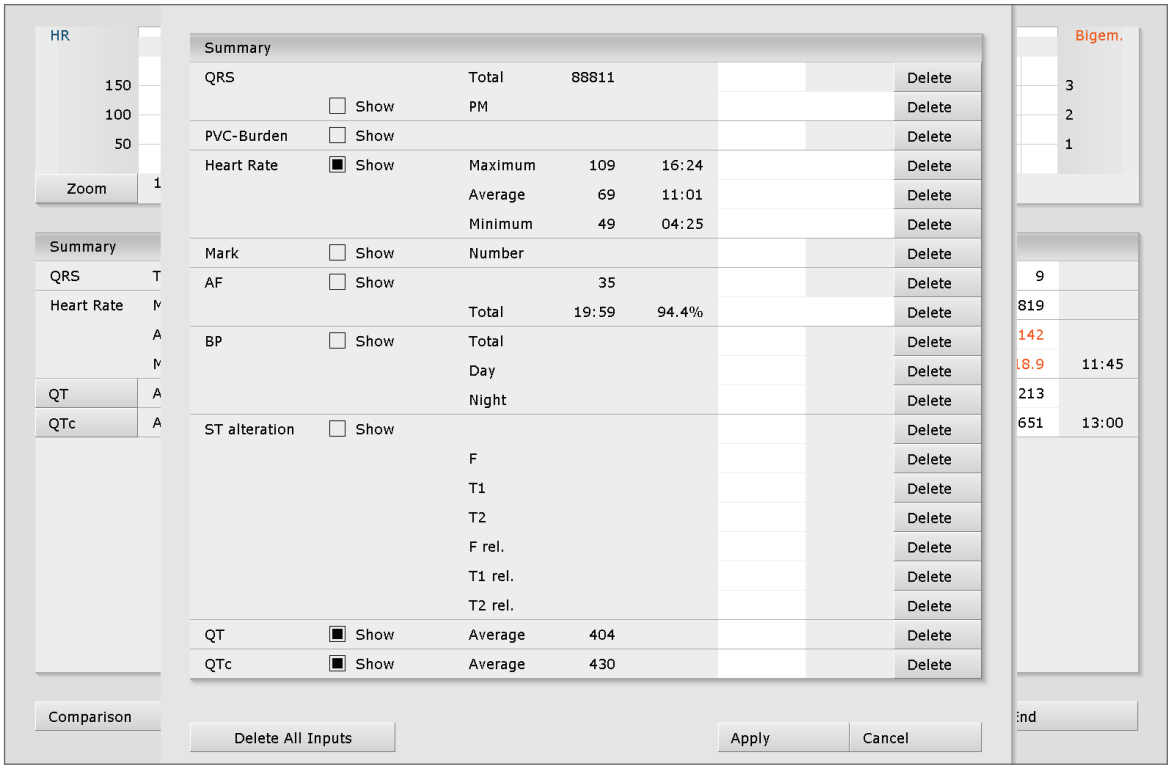
The report dialogue can always be accessed via the context menu.

On the Overview page, you can click on the ECG failure button in the context menu to obtain information on the quality of the ECG recording.

In the Overview you can manually insert events via Change if you should find events which were not detected by the program. Manually inserted events are inserted in the tabular overview with the corresponding designation.

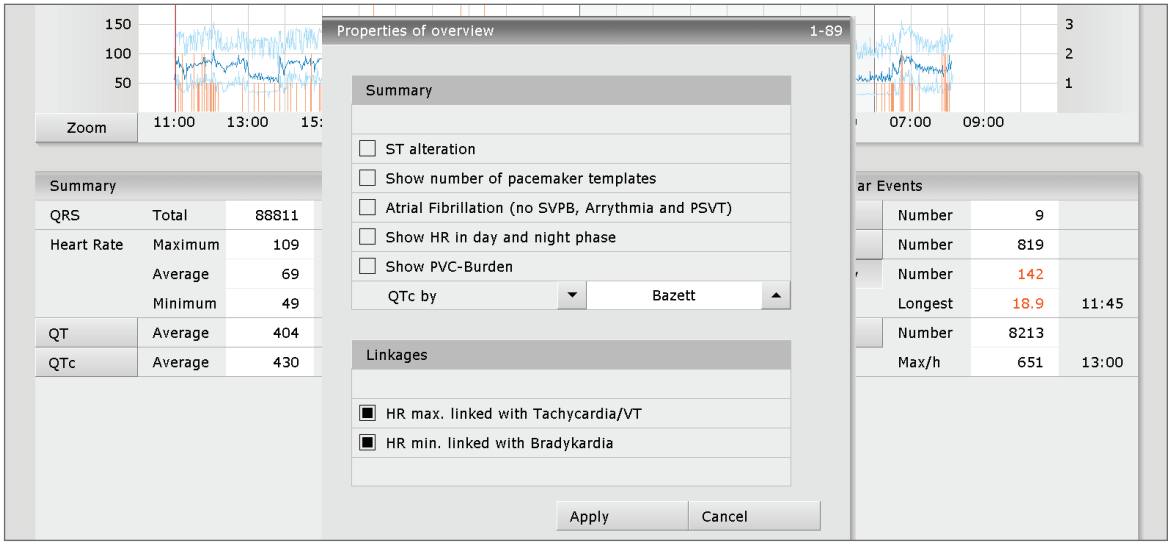
On all evaluation pages on which the ECG is visible you can use the Change function to manually edit beats or events in the ECG (e.g. allocate them to another event).

You can use the Select time function to access specific times on the Analysis, Trend/ECG and Total ECG pages. These are stored in the dialogue with the "Select time" designation and are permanently available.



Overview, *Context menu*, *Change*:

This dialogue is used to manually change the information contained in the overview (and the printout of the summary). To add events, enter the correct number for the corresponding event, activate the Display option and click on Apply. To delete events, enter a zero for the corresponding event, deactivate the Display option and click on Apply.



Overview, *Context menu*, *Settings*:

Menu for selecting additional contents which can be displayed in the summary on the Overview page.

06.3.1.2 Options menu

The contents of the Option menu vary according to the evaluation page. The Print, Export, Reduce, Total ECG, Trend overview and Service functions are available on each evaluation page in the Options menu.

Overview
Print...
Export...
Reduce...
ABPM [1]
HRV [2]
HRT [2]
Pacemaker [2], [3]
Total ECG
Trend overview
multiday [4]
Exclusion
CSV export
Service

Analysis
Print...
Export...
Reduce...
ABPM [1]
HRV [2]
HRT [2]
Pacemaker [2], [3]
Total ECG
Trend overview
multiday [4]
Invert
Channel F
Channel T1
Channel T2
New analysis
ST analysis [2]
Exclusion
Parameters
Service

Trend/ECG & examples
Print...
Export...
Reduce...
ABPM [1]
HRV [2]
HRT [2]
Pacemaker [2], [3]
Total ECG
Trend overview
multiday [4]
Invert
Channel F
Channel T1
Channel T2
Exclusion
CSV export
Service

Explanations of the functions in the Options menu

- Print...

Temporary change of print settings for the current evaluation

- Export...

The evaluation is exported in Excel and PDF format

- Reduce...

Dialogue for reducing the amount of data of an evaluation

- Total ECG

Full-page representation of the ECG, view of the complete recording

- Trend overview

Graphic representation of all events over the entire recording period

- CSV export

ECG and RR values can be exported separately as a .csv file (comma separated value)

1) For combination evaluations with ABPM you need a combination or ABPM recorder.
2) These functions are part of custo tera professional and are not available as standard.
3) Pacemaker recordings are only possible using a suitable recorder, e.g. custo flash 510; the Pacemaker button is only included in the Options menu if the recording is a pacemaker recording.
4) Only possible using a suitable recorder, e.g. custo flash 510. The multiday button is only displayed for multi-day evaluations.

Service

Technical details of the recorder and recording

Invert

The Invert function results in the reversal of the respective ECG channel.

New analysis

Recalculation of the evaluation after manual changes have been made in the beat analysis (e.g. merging or renaming of beat classes)

Exclusion

Exclusion of specific ECG sections, e.g. when the signal is interrupted.

Parameters...

... on the Analysis evaluation page

Setting pages for changing the parameters for beat and event analysis

... on the HRV evaluation page

Setting pages for calculating the FFT display and the histogram

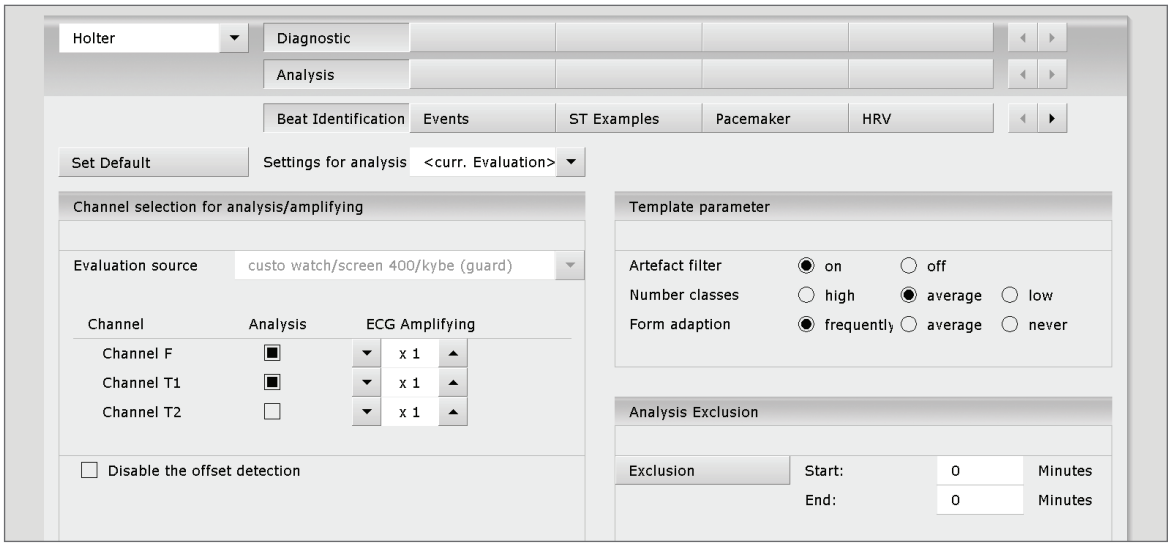
... on the HRT evaluation page

Setting and adjusting filters for calculating the Heart Rate Turbulence

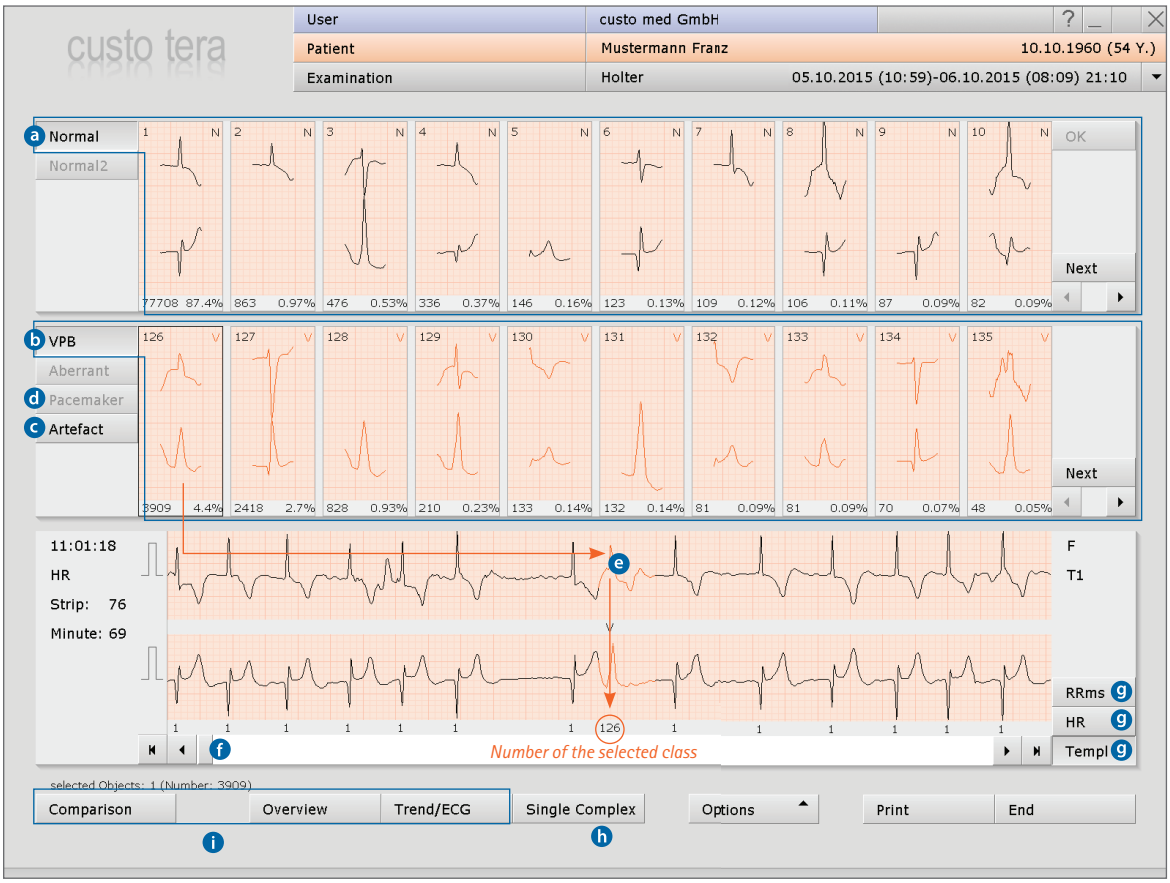
Note on applying or resetting changed parameters

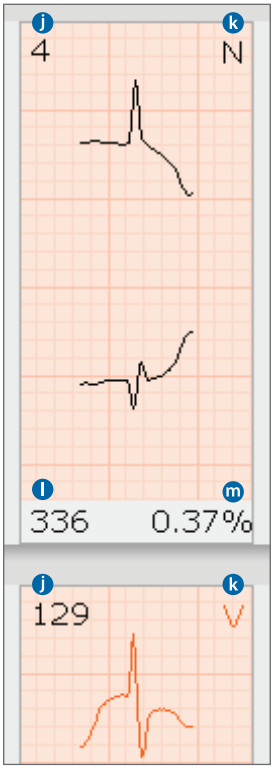
When you click on the Analysis button (at the bottom of the screen), your settings are applied and the ECG is analysed again taking your changes into account.
With the End button you can exit the parameter setting page and your changes are not applied. With the Set Default button you can restore the default settings. This applies to all parameter setting pages in the Holter ECG evaluation.

Screenshot of the parameters for the beat and event analysis:



06.3.2 Analysis (Analysis button in the overview)





- a Beat classes with normal QRS complexes (N);
  navigation in the classes with Next / ◂ ▸ = forward/backward by page
- b Beat classes with changed QRS complexes (V);
  navigation in the classes with Next / ◂ ▸ = forward/backward by page
- c Button for showing the artefact classes (A)
- d Button for showing the pacemaker classes (S)
- e Occurrences of the selected class are marked in colour in the ECG
- f Scrollbar for navigating through the entire recording;
  ⏮ ⏭ = Go to the next occurrence, ◂ ▸ = continuous scrolling
- g Buttons for showing the RR intervals, the heart rate
  or the class numbering below the ECG signal
- h Button for showing single complexes of the selected class
  (e.g. for moving single complexes to other classes)
- i Buttons for opening additional evaluation pages

➤ Labelling of classes

- j Numbering of the class (numbered in ascending order, 1 to max. 256)
- k Annotation: Normal (N), VPB (V), Artefact (A) or Pacemaker (S)
- l Number of single complexes in the class
- m Percentage relative to the number of all the recorded QRS complexes

Editing options on the Analysis page

All the recorded QRS complexes are summarised in beat classes. The classes are sorted by the criteria Normal (N) a, VPB (V) b, Artefact (A) c and Pacemaker (S) d, if applicable. The Analysis page shows all the classes of the recording. At this point you can check, merge and reallocate the classes.

Merging beat classes

Select the beat classes you want to merge with the right mouse button and click with the right mouse button on the numbering (top left) j of one of the selected beat classes. The selected beat classes are merged in the beat class with the lowest numbering. To cancel the merging, click again with the right mouse button on the numbering of one of the selected beat classes.

Keyboard shortcuts:

The allocation of one or several classes can also be changed by pressing the letters N, V, A and S on your keyboard.

Changing the allocation of a beat class

To change the allocation (N/V/A/S) k of a beat class, continue to click in the corresponding beat class with the left mouse button on the letter at the top right k until the correct allocation is shown.
You can also change the allocation of several beat classes at the same time. Select the desired classes with the right mouse button and continue to click in one of the selected classes with the right mouse button on the letter k until the correct allocation is shown.

Moving single complexes of a beat class

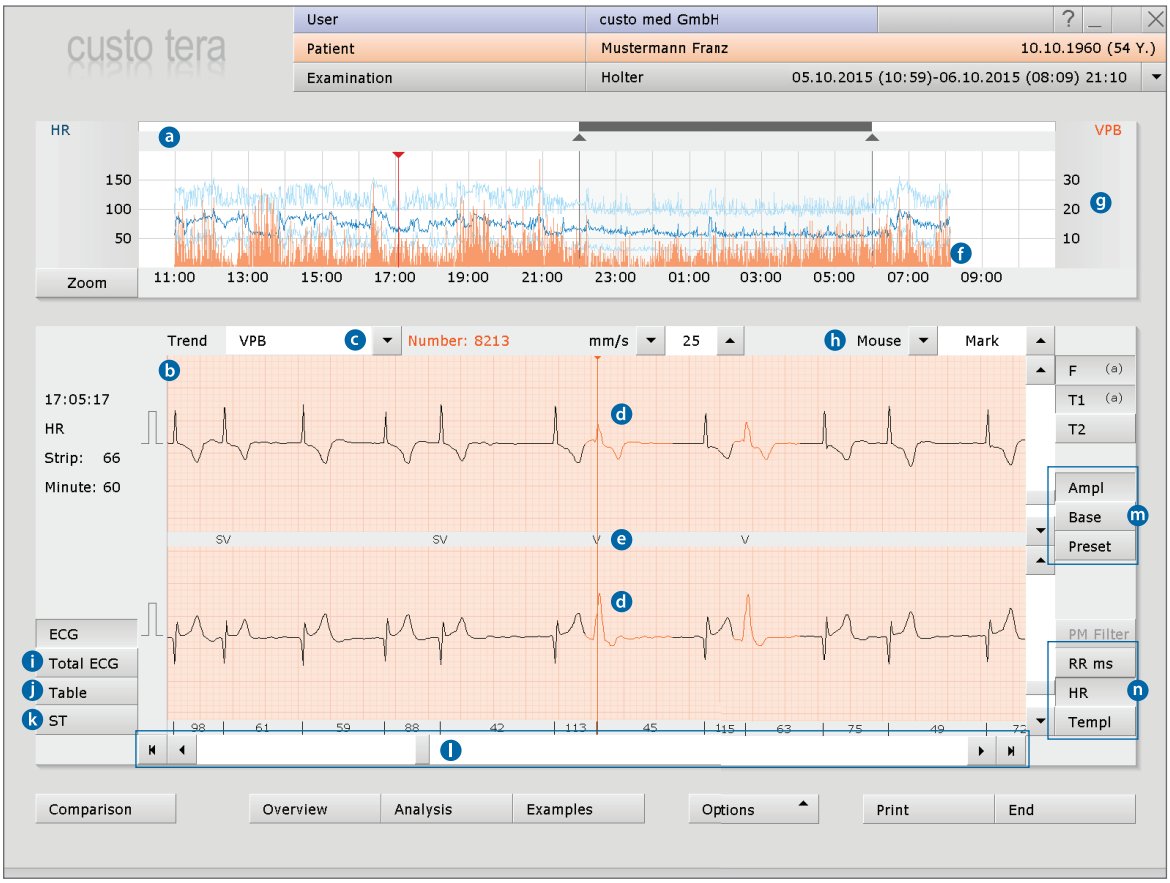
To show the single complexes of a beat class, select a beat class and click on the Single Complex h button. By double-clicking on a single complex you can open the Trend/ECG page – the single complex can be considered in context on this page.

To move single complexes to another beat class, select one or several single complexes (left mouse button and Shift or Ctrl) and click on the Move button. A dialogue appears in which you can select the beat class to which you want to move the selection. Click on the Confirm button to carry out the change.

Applying changes

When you change to another evaluation page, all the changes which you have made on the Analysis page are automatically applied. The ECG is analysed again taking your changes into account.
Alternatively, you can execute the New analysis function on the Analysis page in the Options menu. A dialogue appears informing you that the evaluation is currently being reanalysed. Click on Confirm to start the process. With Cancel the changes are discarded.

06.3.3 Trend/ECG (Trend/ECG button in the overview)



- a Trend (24 hour graph) with Zoom function
- b ECG matching the cursor position in the graph above
- c Menu for selecting an event
  - d The selected event is marked in colour in the ECG
  - e The centrally positioned letters in the ECG show the type of event
  - f In the trend (24 hour graph) the selected event is marked with orange lines
  - g The height of the lines in combination with the scale on the right-hand side of the screen shows the number of occurrences per minute
- h Mouse functions Mark, Change, Time or Measure

- i ECG overview – reduced ECG (e.g. 15 min/page) with identification of the selected event
- j Tabular display of the events with highlighted maximum values
- k ST measurement
- l Scrollbar for navigating in the ECG signal
- m Changing the amplitude size, moving the zero line, resetting the changes
- n Display of the RR intervals, heart rate or beat classes (Templ.) below the ECG signal

Note on opening the Trend/ECG page

When you double-click on an Event button in the overview, the Trend/ECG page is shown with the clicked event marked in colour.

Event-related navigation on the Trend/ECG page

By dragging the scrollbar ⓘ (under the ECG) across the entire length of the recording you can obtain an overview – enabling you to quickly access and check artefacts and ranges without a signal.

When you click on the ⏮ ⏭ buttons, the program automatically goes to the previous or next occurrence of the selected event. The selected event is marked in colour in the ECG. More events can be selected via the ⓒ menu. When you click on the ◀ ▶ buttons, the ECG is shown constantly over the screen.

Instead of clicking on the ⏮ ⏭ buttons under the ECG, you can also use the arrow keys on your keyboard to navigate to specific events in the ECG.

Editing options on the Trend/ECG page

The Mouse Function menu ⓗ contains various tools such as Measure, Mark and Change. Use the two arrow buttons to change between the tools. The tool currently shown in the Mouse Function field is active and can be used in the ECG.

Measuring RR intervals

When you click in the ECG signal, a line appears – the starting point of your measurement. Additional lines appear when you drag the mouse to the left or right. Click again to fix the intervals between the lines. The lines disappear when you click again.

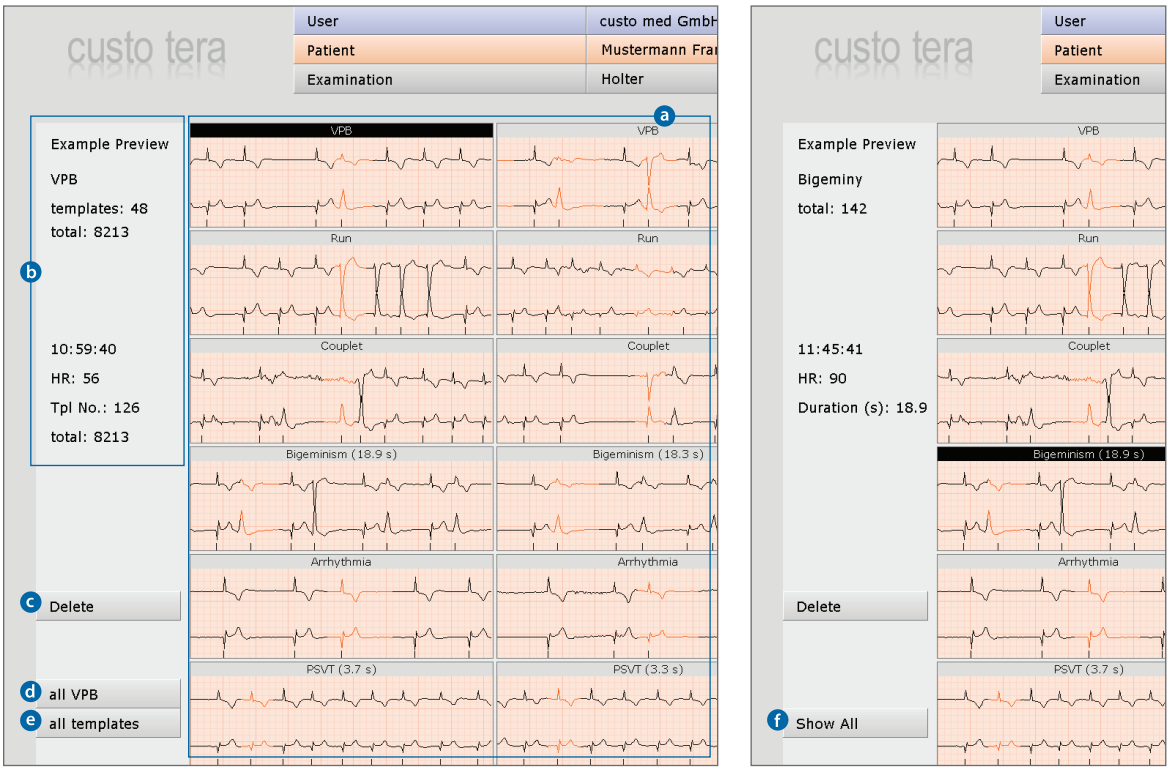
Marking ECG sections (e.g. highlighting events)

To mark an ECG section, drag the cursor in the ECG signal across an ECG section. When you release the cursor, a dialogue appears in which you can name the marking and then print it or save it as an episode in the evaluation. Episodes are stored with the examples.

Changing events

To edit a beat or an event (e.g. changing VPB to Artefact), double-click on the corresponding position in the ECG. A dialogue appears in which you can correct the original allocation. Click on Confirm to apply the change.

06.3.4 Examples (Examples button in the overview)



- a Example preview with several ECG examples for each event
- b Additional information about the selected example. An example is selected with a mouse click. The header of the selected example has a black background.
- c Button for deleting the selected example
- d When VPB example has been selected: Each single VPB as an example
- e When VPB example has been selected: An example for each VPB class
- f Another example has been selected, e.g. Bigeminy: All examples of the event

Considering ECG examples in context

When you double-click on a VPB example in the example preview, all VPB classes (all templates button) are shown with one example each. By double-clicking on one of the VPB classes, all VPB examples for this class are displayed. By double-clicking on a VPB example, the Trend/ECG page is shown with the corresponding position in the ECG[1)].

By double-clicking on another example (e.g. Bigeminy), all examples for the previously selected event are displayed. When you double-click on one of the examples, the Trend/ECG page is shown with the corresponding position in the ECG.

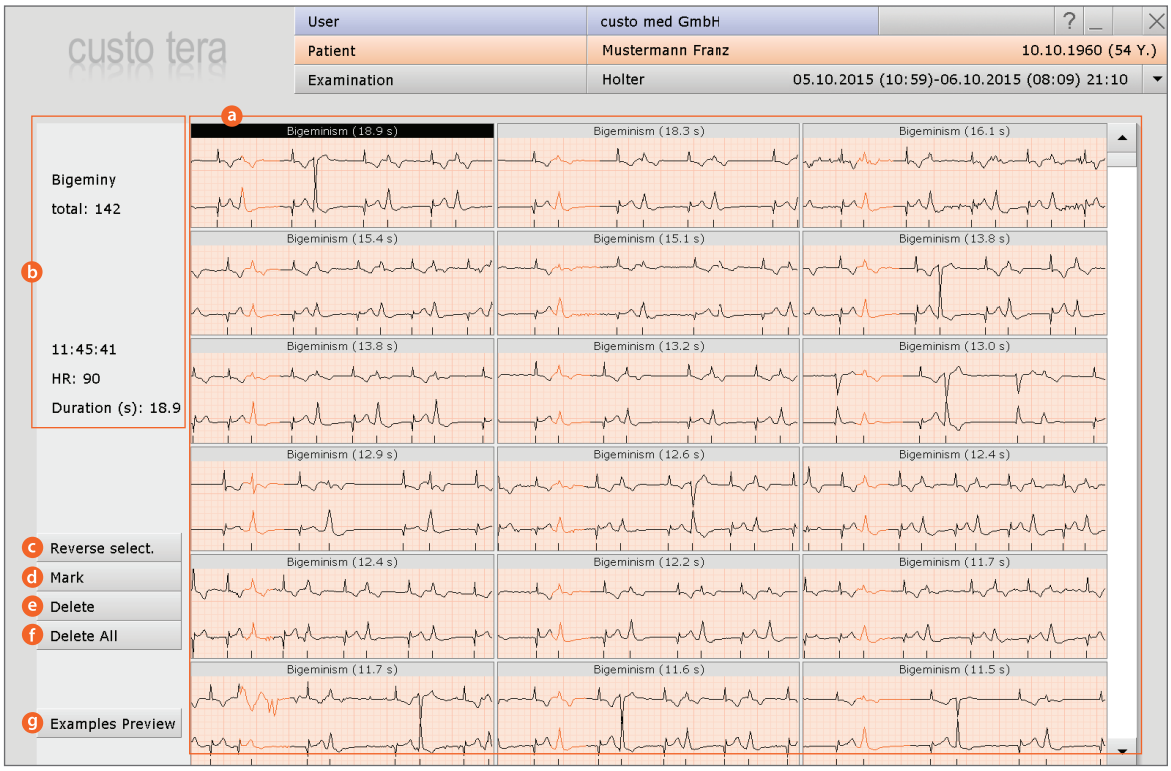
1) custo diagnostic can also be set so that, instead of the Trend/ECG page, the ECG environment dialogue is displayed. The difference with this setting is that the Example Preview page remains open, while the ECG example is considered in context.

To activate the ECG environment dialogue, open the context menu and click there on Settings. Select the "Display selected example in ECG environment" option. Apply the settings.

Changing the allocation of examples

Select an example, open the context menu and click there on Change. In the "Edit beat" dialogue, select the desired event. In this dialogue you can also rename the entire example group or delete the selected example. Click on Confirm to apply the changes.

06.3.5 Examples, show all (Show All button in the example preview)



- a All ECG examples for an event
- b Additional information about the selected example
- c Reverses the current selection,
  selects all examples outside the current selection
- d Marks the selected example
- e Deletes the selected example
- f Deletes all examples for this event
- g Button for opening the example preview (superordinate page)

Considering ECG examples in context

To consider an example in context, double-click on the desired example. The Trend/ECG page is shown with the corresponding position in the ECG or the ECG environment, see marginal note [1] on the previous page. This action is only possible if all examples for an event are displayed.

For VPB: all examples for a VPB class (Example Preview, all templates, Show all) or all VPB examples for the entire recording (Example Preview, all VPB). For all other events: Example Preview, Show all.

Changing the allocation of examples

Select an example, open the context menu and click there on Change. In the "Edit beat" dialogue, select the desired event. In this dialogue you can also rename the entire example group or delete the selected example. Click on Confirm to apply the changes.

Editing several examples:

An example is selected with a click and then marked with the word "selected". The Reverse select. button allows you to reverse the selection (this function can also be found in the context menu). As soon as you make changes, they affect all the selected examples.

06.3.6 Comparison (Comparison button in the overview)

Comparison of two evaluations for a patient each with:

- a Trend (24 hour graph)
- b Overview table with HR summary and events
- c Scrollbar for navigating in the overview table

The overview tables are marked with the date d. The font colour of the date matches the border of the corresponding 24 hour graph.

Navigation options

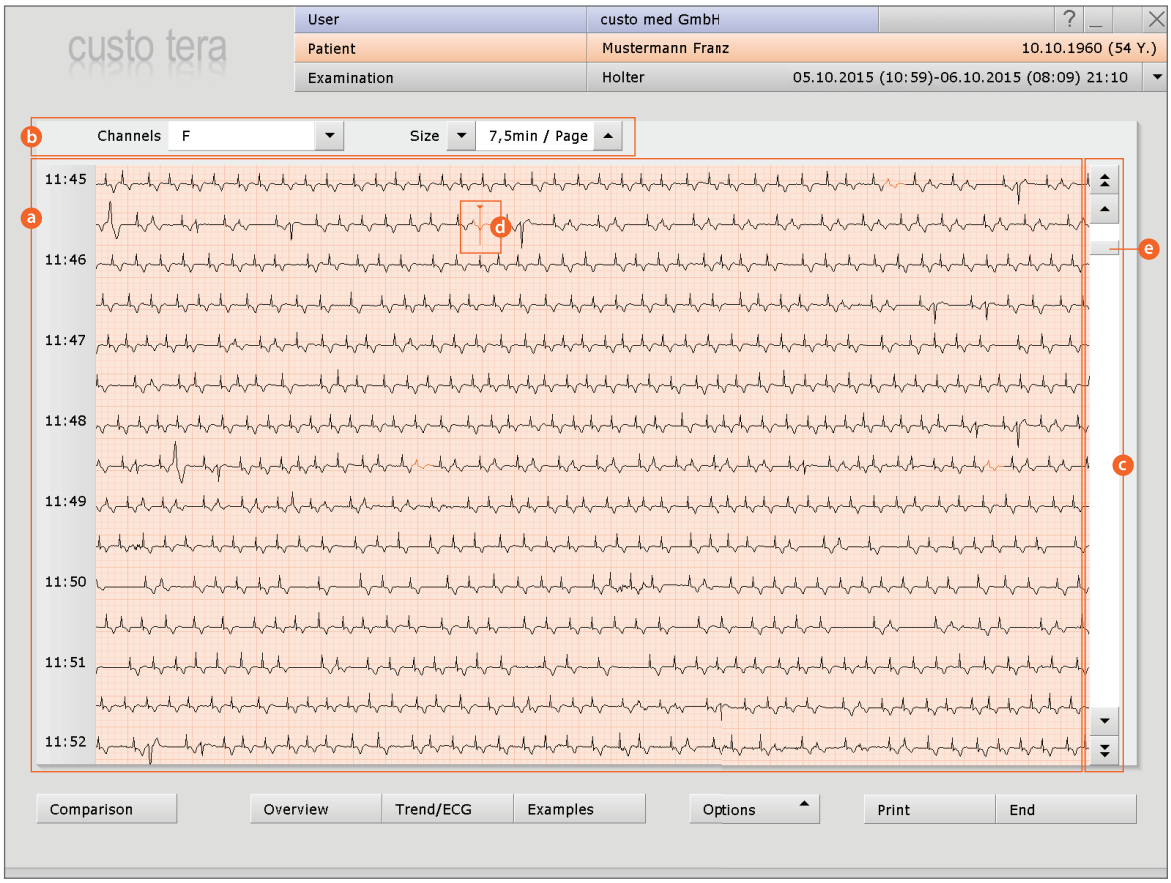
➤ Show additional evaluations for the patient for comparison purposes

The date lines d can be opened by clicking in the line – a selection list appears showing any additional evaluations for the patient (if available). These can be selected for comparison by means of a click.

➤ Showing events in the 24 hour graph

The table contains a list of all the existing events. The designations of the events are created as buttons. When you click on an Event button the corresponding event is shown in the 24 hour graph in the form of e orange lines. The lines show, in combination with the scale on the right-hand edge f, when and how often the event occurred per minute.

06.3.7 Total ECG (Options menu, Total ECG)



- a Minimised representation of the entire recording, e.g. 7.5 min. on one screen page
- b Settings for showing the channels and time periods per page
- c Scrollbar for navigating in the ECG

Editing and navigation options

Marking ECG sections (e.g. highlighting events)

To position the cursor d, click on the desired position in the ECG. To mark, drag the cursor. When you release the cursor, a dialogue appears in which you can name the marking, print it and save it as an episode in the evaluation. Episodes are stored with the examples.

Navigating in the ECG

When you click on the ▼ or ▲ buttons, the ECG automatically moves in the corresponding direction. The throughput speed increases when you click the buttons again. To stop the ECG, click in the ECG. When you click on the ▾ or ▴ buttons, the ECG is scrolled in the corresponding direction for the duration of the click. You can move the ECG at any speed you want by dragging the slider e. When you double-click on the ECG, you go to the Trend/ECG page.

Tip on keyboard control in the Total ECG

Scrolling for the length of time the key is held down

Automatic scrolling, pressing repeatedly increases the speed

Space bar starts/stops scrolling

06.3.8 Trend overview (Options menu, Trend overview)

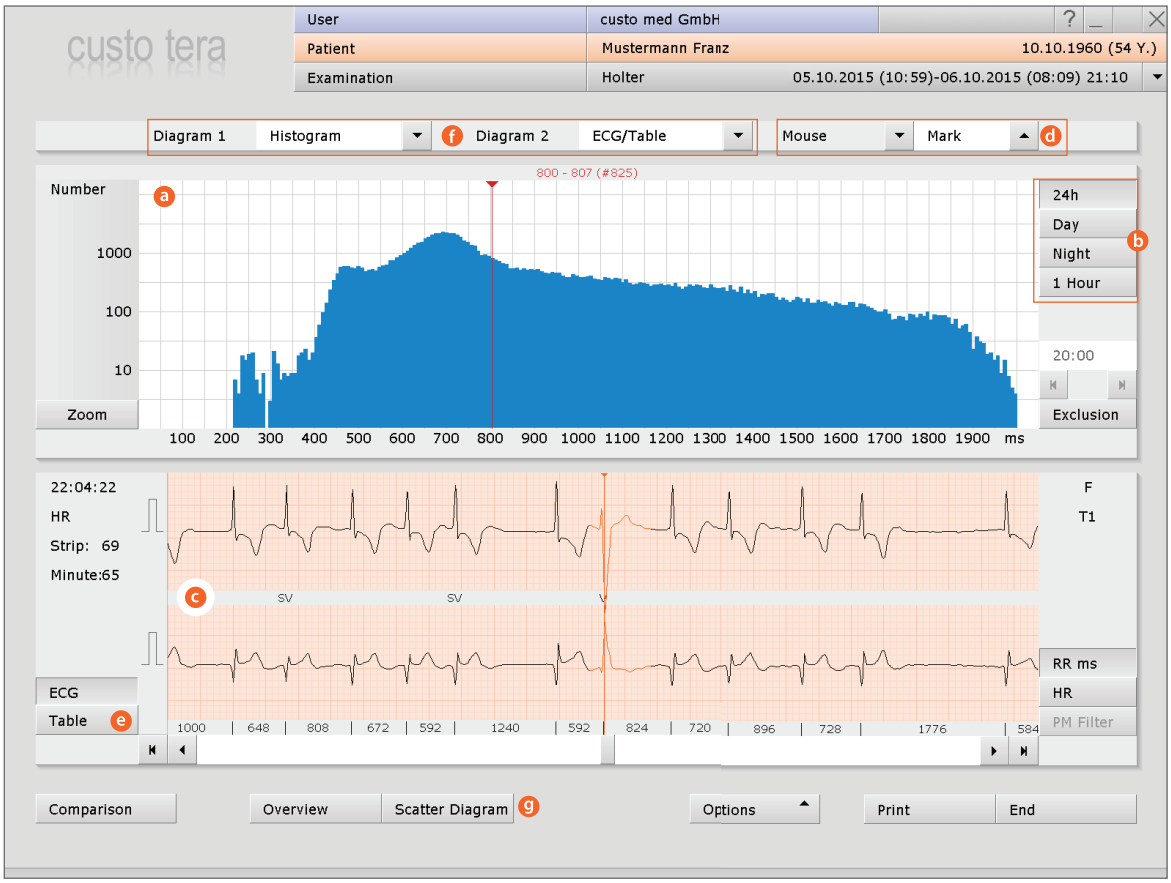
a Interactive table representing all events during the entire recording period

b ECG matching the cursor position in the graph above

Each event is written in the form of a black line in the interactive table c. Simply click on event entries (black lines) to display the corresponding position in the ECG recording. The event is marked in colour in the ECG d.

When you click on an event name (left column in the table a), the Trend/ECG page is opened.

06.3.9 HRV – Heart Rate Variability (Options menu, HRV)



a Graphic representation of heart rate variability (view: 24 hours)
b Buttons for showing the heart rate variability for 24h, day, night, 1 hour
c ECG matching the cursor position in the graph above

The cursor in the histogram and the cursor in the ECG are linked – for the currently selected RR interval in the histogram, the position in the ECG is shown at which this interval occurs. You can use the ⏮ and ⏭ buttons (under the ECG) to go to specific additional occurrences of the RR interval.

d Mouse functions for editing the ECG
e Tabular summary with values for heart rate variability
(e.g. number of RR, SD, SDANN5, SD5, pNN50, RMSSD, Triang. Index)
f Shows additional graphics: SDNN5, ANN5, rMSSD, pNN50, FFT
(Diagram 1 stands for the top graphics, diagram 2 for the bottom graphics)

All graphics have the "Zoom" button; an hour is shown in an enlarged form so that the 5 minute intervals are easy to recognise.

g Opens the scatter diagram (further display of heart rate variability)

NN intervals:
RR intervals between normal beats

SD
Standard deviation

SDNN5
Standard deviation of the NN intervals in the 5 minute intervals within the defined period

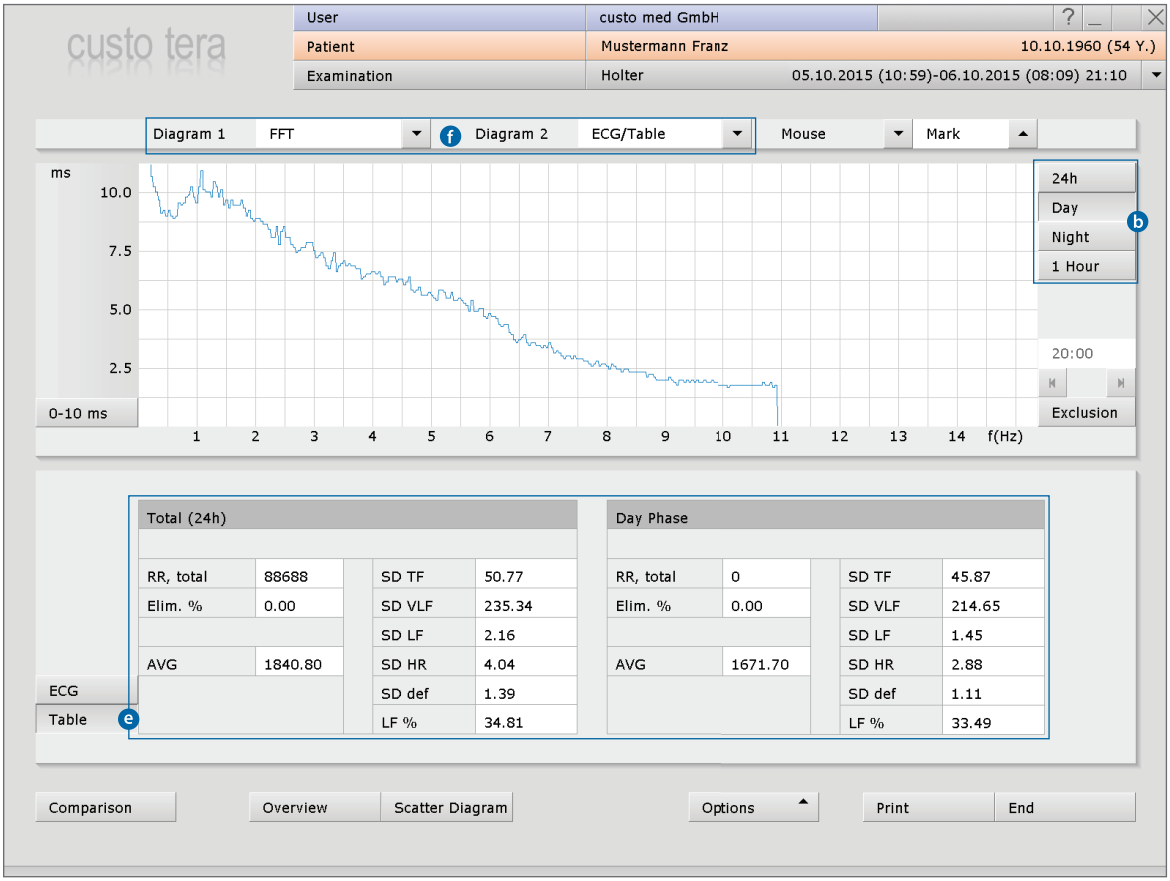
ANN5
Mean value of the NN intervals in the 5 minute intervals within the defined period

SDANN5:
Standard deviation of the mean values of the NN intervals in the 5 minute intervals within the defined period

pNN50:
Percentage of the NN intervals within the defined period that differ from the previous NN interval by more than 50 ms

RMSSD (root mean of squared successive differences):
The root of the average sum of squares of two differences of successive RR intervals within the defined period

06.3.9.1 FFT graph – Fast Fourier Transformation
(can be accessed via the selection list f on the HRV page)



Tabular summary e

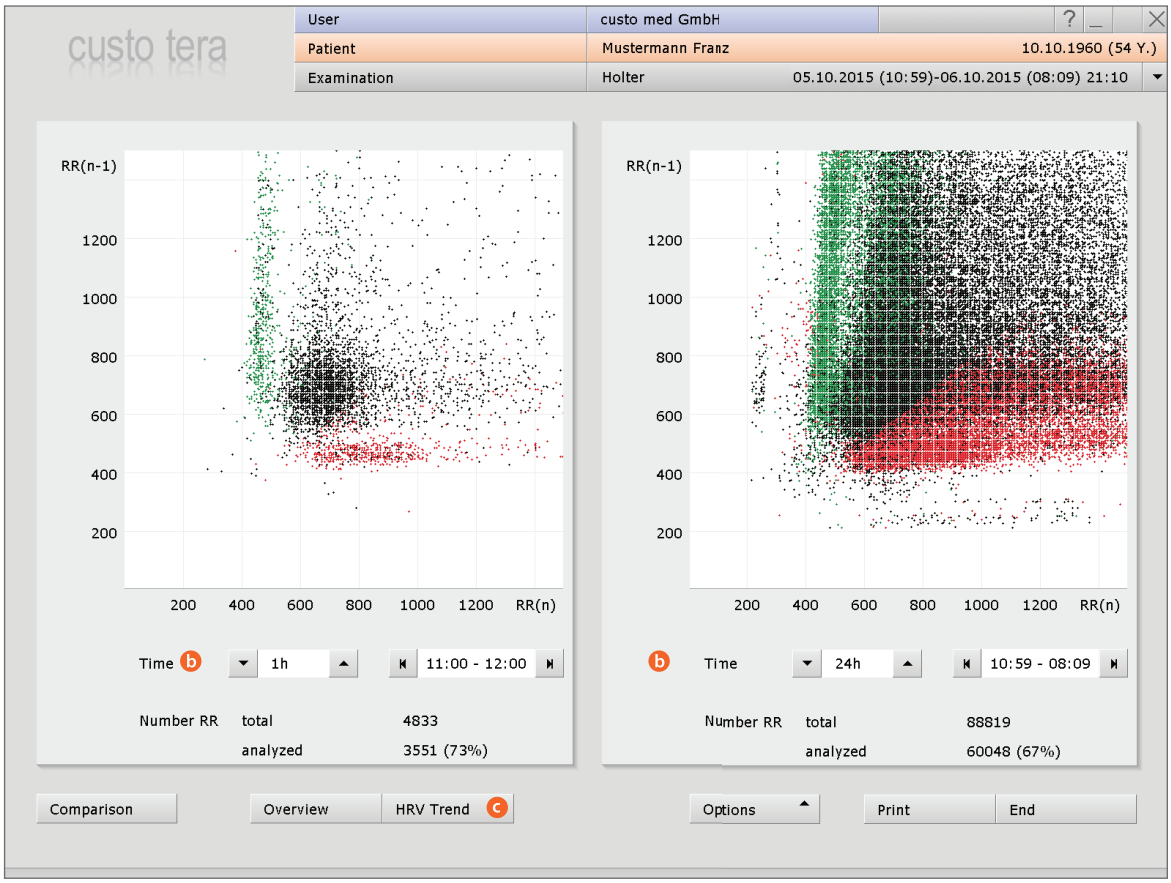
RR, total	Total number of registered RR intervals
Elim.%	Percentage of the excluded beats
AVG	Average value of all RR intervals
TF	Total Frequency
	Power density spectrum in the entire frequency range up to 1.0 Hz
VLF	Very Low Frequency
	Power density spectrum for the frequency range 0.001 and 0.04 Hz
LF	Low Frequency
	Power density spectrum for the frequency range 0.04 and 0.15 Hz
HF	High Frequency
	Power density spectrum for the frequency range 0.15 and 0.4 Hz

In the area b you can select the type of graphic representation: 24h, Day, Night or 1 Hour.

In the lower half of the screen, the values for the selected display (Day, Night etc.) are displayed in the right half of the table.

SDTF	Standard deviation of TF over 24 hours
SDVLF	Standard deviation of VLF over 24 hours
SDLF	Standard deviation of LF over 24 hours
SDHF	Standard deviation of HF over 24 hours
SD def	Standard deviation in the predefined frequency range
LF%	Percentage of LF in TF

06.3.9.2 Scatter diagram (Options menu, HRV, Scatter diagram)

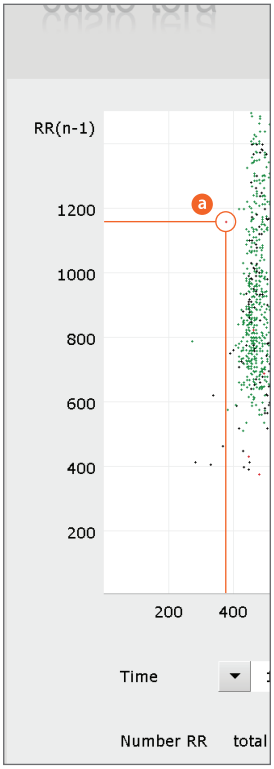


The scatter diagram also provides information on the heart rate variability of a patient. The larger the scatter cloud, the greater the heart rate variability. A highly condensed scatter cloud means that the heart always beats at an even rate.

The RR intervals are represented by the variable n in the coordinate system. A point in the cloud results from a RR interval "n" (x-axis) and the previous RR interval "n-1" (y-axis) a.
The table below the coordinate system shows how many beats were included in the representation of the heart rate variability (number of RR analysed). This quantity is displayed in the form of black dots in the coordinate system. Beats that are not analysed (e.g. VPB, Artefact) are included in the scatter diagram and marked in colour.

In the Time area b you can specify for both graphics which period should be shown as the scatter diagram and compare different recording phases. You can show the graphics for day, night, 24h or an hour. In addition you can select the time for the hour view.

By clicking on the HRV Trend c button you can return to the HRV evaluation page.



06.3.10 HRT – Heart Rate Turbulence (Options menu, HRT)

- **a** Graphic representation of the HRT – Heart Rate Turbulence [1)] (x-axis: number of RR intervals, y-axis: RR intervals in ms)
- **b** Change the number of RR intervals shown on the x-axis
- **c** Summary with Turbulence Onset [2)] and Turbulence Slope [3)]
- **d** Selection list for showing average or single values

On the page Options **e**, Parameters filters and parameters for calculating the HRT can be set.

Information about the Heart Rate Turbulence can be found in the Internet under the following link of the TU Munich: http://www.h-r-t.org/hrt/de/.

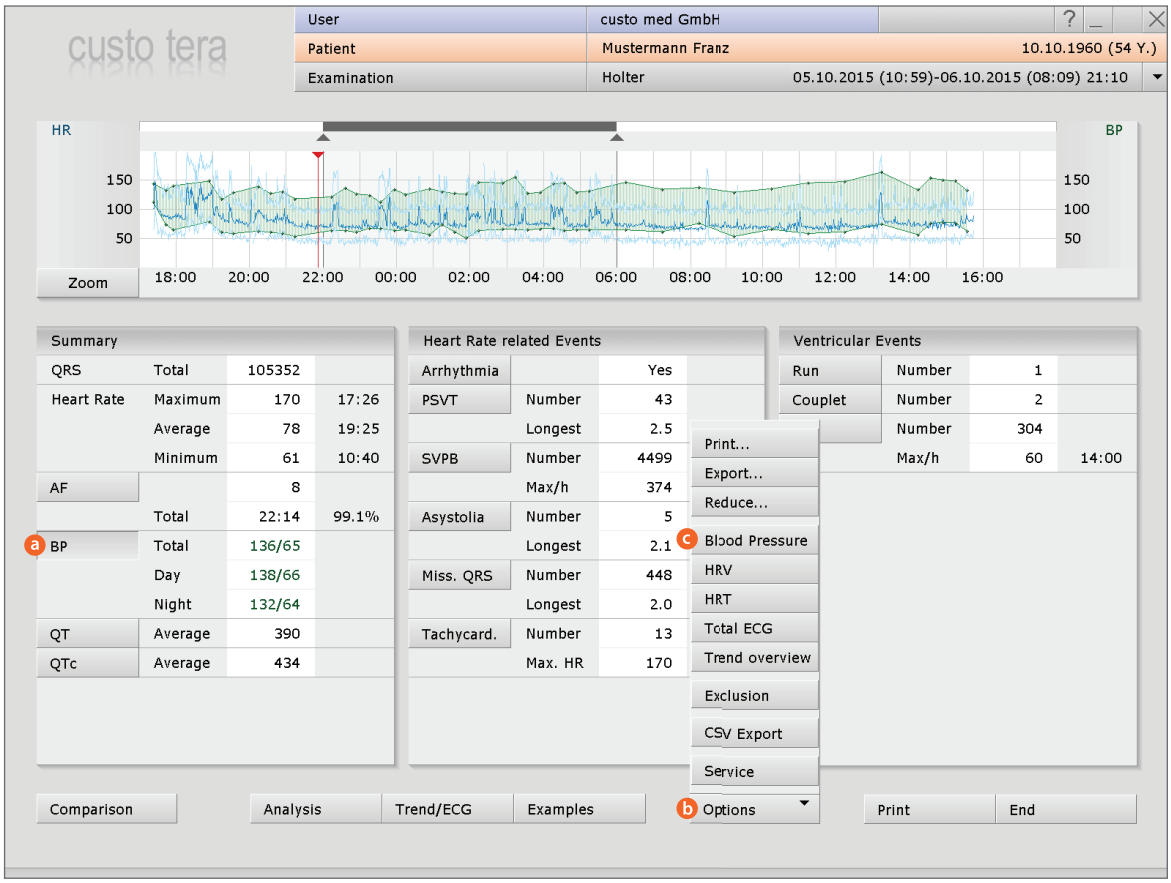
Definitions by the Technical University of Munich on HRT (http://www.h-r-t.org/hrt/de/):

1) Heart Rate Turbulence is the physiological, bi-phasic response of the sinus node to premature ventricular contractions. It consists of a short initial acceleration followed by a deceleration of the heart rate. HRT can be quantified by two numerical parameters, namely the Turbulence Onset and the Turbulence Slope.

2) The Turbulence Onset (TO) is the percentage difference between the heart rate immediately following PVC and the heart rate immediately preceding PVC.

3) The Turbulence Slope (TS) corresponds to the steepest slope of the linear regression line for each sequence of five consecutive normal intervals in the local tachogram. The Turbulence Slope calculations are based on the averaged tachogram and expressed in ms per RR interval.

06.3.11 Combination evaluation with ABPM



If you have carried out an ABPM recording for your patient in addition to the Holter ECG recording, you can open the Holter ECG and ABPM as a combination evaluation in custo tera *(see chapter 06.1 Opening an evaluation)*. For this type of recording you will also need a custo med ABPM recorder or a combination recorder.

To enable a combination evaluation, the maximum time delay between the Holter ECG and ABPM recordings should not be more than 12 hours[1)]. custo diagnostic links both recordings during the download on the basis of the common recording time.

When you click on the BP (a) button in the overview, you can show the blood pressure curve (green) in the 24 hour graph. You can use the Options (b) menu to open the Blood Pressure (c) evaluation.

Except for the blood pressure curve and the link to the ABPM evaluation, the structure of the Holter ECG evaluation remains unchanged and works as described under *06.3 Holter ECG evaluation pages*.

---

1) Only applies when using separate Holter ECG and ABPM recorders. Both recordings are started at the same time with combination recorders.

06.4 Printing the evaluation

Alternative ways to create a printout:

- Printout in accordance with the system settings with the Print button
- Individually compiled print pages for the current printout, via Options, Print... (The settings are not applied permanently)
- Collection of print tasks in the Task Manager for subsequent batch processing (via Options, Print..., Print Task d). To execute the print tasks, open the Task Manager via the Examination Main Menu. Click there on Execute/Execute All.

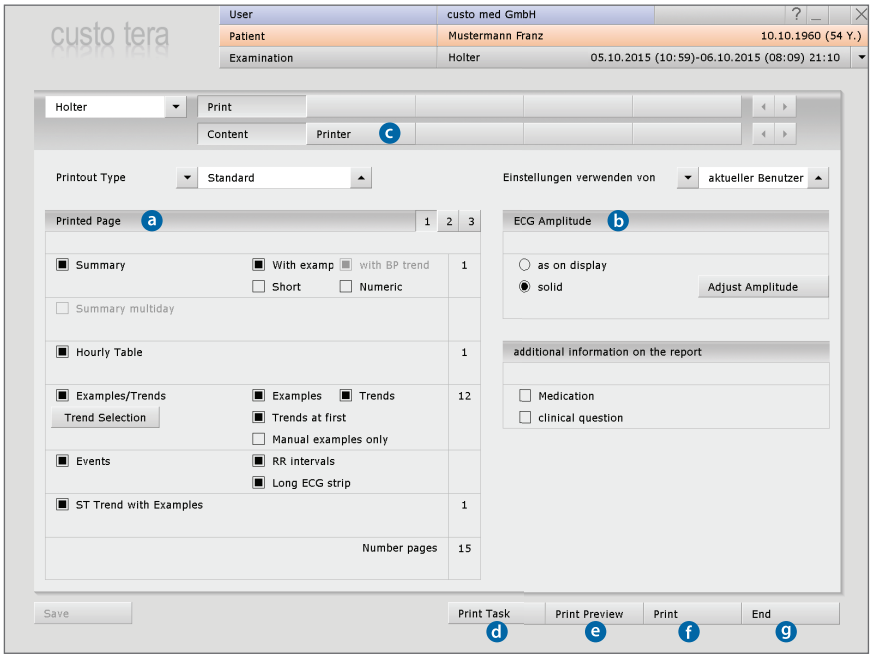


Fig.: Print menu for the individual compilation of a printout; can be called in the evaluation via Options, Print...

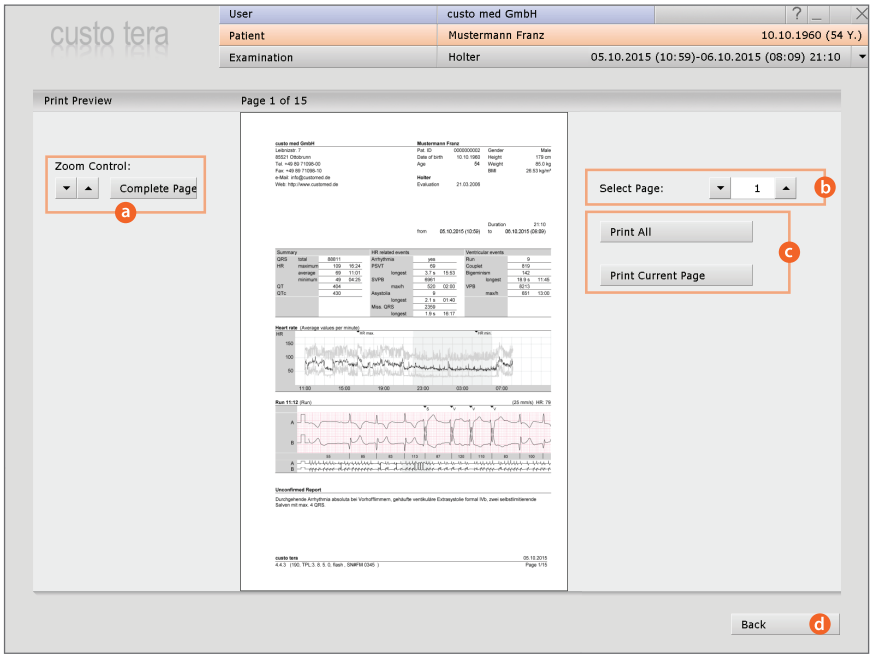
a Compiling the contents
b Amplitude size of the ECG signal in the printout
c Selecting and setting the printer on the Printer page
d Button for saving the print task in the Task Manager
e Preview of the compiled print pages
f Button for starting the printout
g Button for closing the print menu

The system settings for printing out Holter ECG evaluations can be found under Examination, Holter, Settings, Print. To apply changes to the system settings, click on Save.

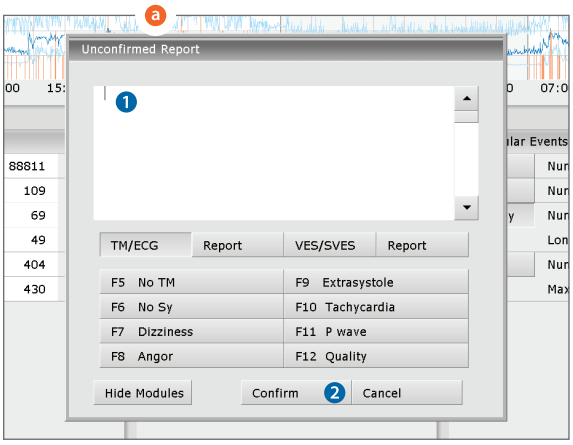
Print preview

By selecting Options, Print..., Print Preview you can view the current print pages before printing.

- a Zoom in and zoom out of the page
- b Page forward/backwards, select page
- c Start printing
- d Close print preview, return to print settings



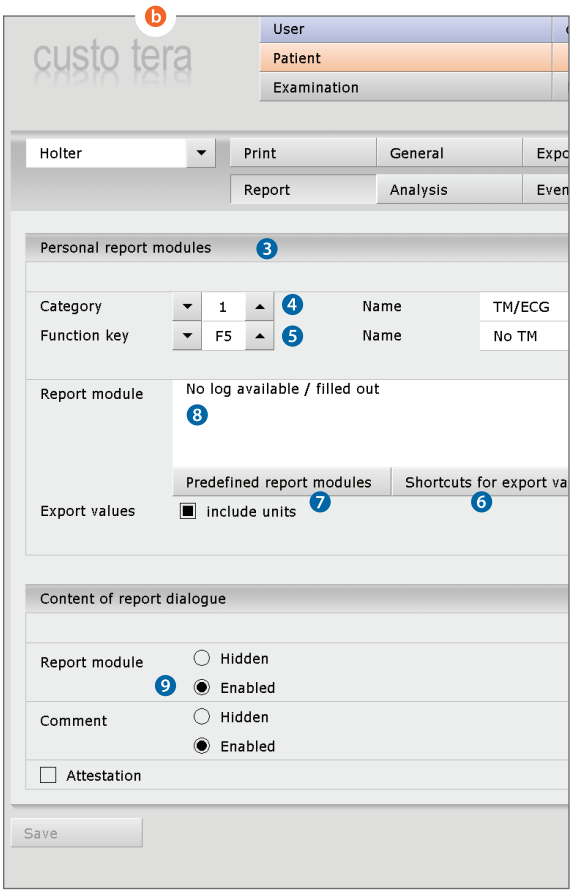
06.5 Writing the report



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

Enter your data in the white text field ❶. When you click on Confirm ❷ your input is saved and the unconfirmed report becomes a report.

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

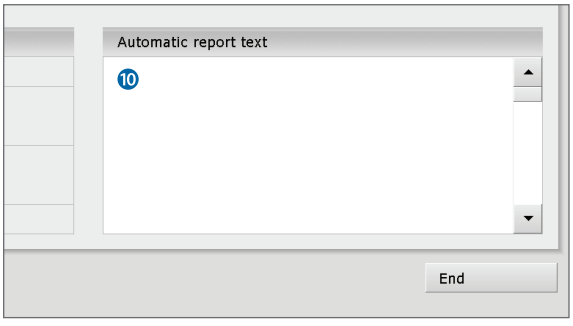


b Text modules for writing reports

On the Examination, Holter, Settings, Diagnostic, Report page you can create 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).

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 used instead of a variable and automatically inserted in the report text. The structure of a variable is {VARIABLE} (e.g. heart rate, maximum: {HF_MAX}). The Shortcuts for export values ❻ button provides you with a list containing all the available variables. The Predefined report modules ❼ button provides you with a completed set of text modules. The text modules can be changed and extended ❽.

If the report modules should be shown in the unconfirmed report dialogue, make sure that the Enabled option ❾ is activated. Alternatively, the text modules can be shown in the unconfirmed report dialogue via the Show Modules button.

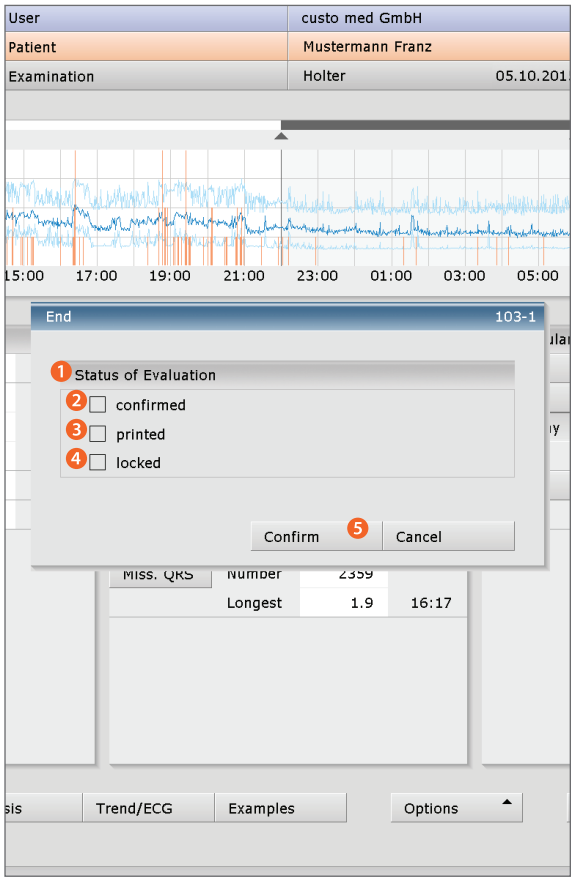


You also have the option of entering a text or a user-defined unconfirmed report (also consisting of normal text and variables), which will be automatically shown in each unconfirmed report ❿. The predefined text can be changed later in the unconfirmed report dialogue.

Save your input.

06.6 Ending the evaluation

The evaluation is closed with the End button (bottom right).
The end dialogue is opened. The status of an evaluation can be changed here ❶.



- Confirmed ❷

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

- Printed ❸

Indicates if the evaluation has been printed.

- Locked ❹

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

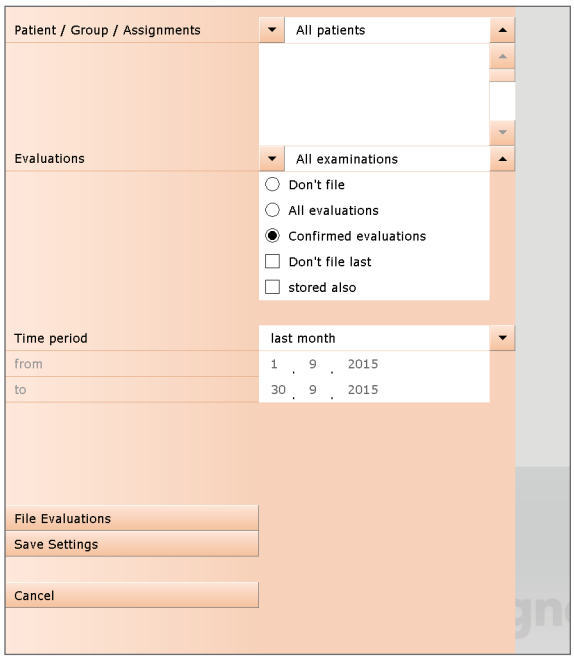
Click on Confirm ❺ to close the evaluation.

06.7 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

Technical data of the custo watch

Number of ECG channels	3	
Sampling rate	125, 250, 500, 1000 Hz	
Radio frequency band	ISM 2.4 GHz	
Radio transmission power	1 mW maximum	
Radio performance	Stationary frequency	
Radio modulation	GFSK	
Radio transmission rate	2 Mbps / 1 Mbps / 250 kbps	
Connection to the PC	USB (docking station)	
Power supply	Rechargeable lithium-polymer battery with 280 mAh	
Battery run time [1)]	Approx. 4 days with an ECG sampling rate of 125 Hz and when recording 3 channels Approx. 30 days on standby (400 µA standby current)	
Charging time of battery	Approx. 3 hours (when fully discharged) Charging current: max. 130 mA	
Display	OLED display (white, 96 * 64 px)	
Dimensions	Basic body without straps	approx. 55 * 38 * 15 mm (L * W * H)
	Basic body with straps	approx. 70 * 38 * 120 mm (L * W * H)
	Strap (circumference)	approx. 160 mm – 215 mm
Weight	40 g	
Ingress protection rating	IP 65 Protection against the ingress of foreign matter and spray water	
Operating conditions	Temperature	+10°C ... +45°C
	Air humidity	10 ... 95 % rH
	Air pressure	700 ... 1060 hPa
Transport and storage conditions	Temperature	-20°C ... +45°C
	Air humidity	10 ... 95 % rH
	Air pressure	700 ... 1060 hPa
Classification	Device with internal power supply Class IIa	
Underlying standards	DIN EN 60601-1, DIN IEC 60601-2-47, DIN EN 60601-1-2, DIN EN 60601-1-11	

1) The battery run time is dependent among other things on the mode of reception of the receiver, the distance and obstacles between the receiver and transmitter (condition of the transmission path) and the age and condition of the battery. After 300 or more charging cycles, the battery has a capacity of 80 % of the initial capacity.

Definition of charge cycle: During a charge cycle the entire battery power is used, however, this does not have to occur in a single charging operation. For example, you can use a device for several hours on a particular day, use approximately half the capacity, and then fully charge it again. If the same procedure is repeated on the following day, this is equal to just one charging cycle and not two charging cycles. It can therefore take a few days for a charge cycle to be fully completed.

Technical data of the custo docking station

Connection to the PC	USB (micro USB cable)
Power supply	5 V via PC USB
Dimensions	Approx. 140 * 92 * 95 mm (L * W * H)
Weight	308 g
Operating conditions	Temperature +10°C ... +45°C Air humidity 10 ... 95 % rH Air pressure 700 ... 1060 hPa
Transport and storage conditions	Temperature -20°C ... +45°C Air humidity 10 ... 95 % rH Air pressure 700 ... 1060 hPa

Technical data of the custo guard 3 ECG transmitter

Number of ECG channels	3	
Sampling rate	125 Hz	
3-dB band width ECG amplifier	0.5 Hz - 150 Hz	
Radio frequency band	ISM 2.4 GHz	
Radio transmission power	1 mW maximum	
Radio performance	Stationary frequency	
Radio modulation	GFSK	
Radio transmission rate	2 Mbps / 1 Mbps / 250 kbps	
Connection to the PC	Via custo com RF (radio receiver unit)	
Power supply	Rechargeable lithium-polymer battery 105 mAh (after 300 charging cycles: approx. 80 % of the initial capacity)	
Battery run time[2)]	Approx. 2 days with an ECG sampling rate of 1 kHz and when recording 3 channels Approx. 60 days on standby (73 µA standby current)	
Charging time of battery	Approx. 2 hours (when fully discharged) Charging current: max. 80 mA	
Status display	LED for charge status	
Dimensions	Approx. 70 * 42 * 12 mm (L * W * H)	
Weight	27 g	
Ingress protection rating	IP 65 Protection against the ingress of foreign matter and spray water	
Operating conditions	Temperature	+10°C ... +45°C
	Air humidity	10 ... 95 % rH
	Air pressure	700 ... 1060 hPa
Transport and storage conditions	Temperature	-20°C ... +45°C
	Air humidity	10 ... 95 % rH
	Air pressure	700 ... 1060 hPa
Classification	Device with internal power supply, Class IIa, Type BF	
Underlying standards	DIN EN 60601-1, DIN EN 60601-2-47, DIN EN 60601-1-2 DIN EN 60601-1-11	

2) The battery run time is dependent among other things on the mode of reception of the receiver, the distance and obstacles between the receiver and transmitter (condition of the transmission path) and the age and condition of the battery. After 300 or more charging cycles, the battery has a capacity of 80 % of the initial capacity.

Definition of charge cycle:
During a charge cycle the entire battery power is used, however, this does not have to occur in a single charging operation.
For example, you can use a device for several hours on a particular day, use approximately half the capacity, and then fully charge it again. If the same procedure is repeated on the following day, this is equal to just one charging cycle and not two charging cycles. It can therefore take a few days for a charge cycle to be fully completed.

Technical data of the custo belt 3 electrode belt

Length	Approx. 650 mm – 850 mm (without stretching) Extension with custo belt extender approx. 250 – 450 mm
Width	approx. 31 mm – 50 mm
Composition	PA, biocompatible in accordance with EN ISO 10993-1, Oeko-Tex® Standard100

General system requirements

Operating system	Windows 7 (32-bit and 64-bit operating system) Windows 8 (32-bit and 64-bit operating system) Windows 8.1 (32-bit and 64-bit operating system) Windows Server 2003 (32-bit and 64-bit operating system) Windows Server 2008 (32-bit and 64-bit operating system) Windows Server 2008 R2 Windows Server 2012 Windows Server 2012 R2 Older versions are not supported	
PC	The PC hardware should meet the minimum requirements of the operating system used. Provide additional RAM (1 GB) for custo diagnostic. Please ensure that there is sufficient free space on the hard disk for the custo diagnostic evaluations. The PC must meet the requirements of the safety standard DIN EN 60950 for information technology equipment.	
File sizes of the evaluations	Holter:	approx. 15 MB (60 MB max.)
	ABPM:	approx. 128 KB (512 KB max.)
	Holter-ABDM:	approx. 20 MB (25 MB max.)
	Resting ECG:	approx. 200 KB (approx. 10 sec. of ECG)
	Stress ECG:	approx. 6 MB (approx. 20 min. of ECG)
	CPET:	refer to Stress ECG
	Spirometry:	approx. 50 KB (256 KB max)
	Rehabilitation:	approx. 6 MB (approx. 45 min. of training)
	custo kybe center:	approx. 10 – 15 MB for a 24h ECG
Hardware & connections	DVD or CD-ROM drive USB port	

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

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 authorised custo med dealers can be found on the Internet at www.customed.de, under Contact, 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.

07.3 Calculation methods in custo diagnostic and custo tera

07.3.1 Method for calculating the heart rate

custo diagnostic or the Holter ECG software module custo tera displays different heart rates, all based on a minute:

HR/minute	Only the disturbance-free time is considered per minute. Sum of the normal beats and the VPB beats divided by the disturbance-free time [in s] * 60 s
HR example	Sum of the normal beats and the VPB beats divided by the length of the example [in s] * 60 s.
HR beat	60 s divided by the interval to the previous beat (RR interval) [in s]
HR max	The highest value of all "HR/minute" during the monitoring time
HR average	The average value of all "HR/minute" during the monitoring time
HR min	The lowest value of all "HR/minute" during the monitoring time
HR day max	The highest value of all "HR/minute" during the day phase of the monitoring time
HR day average	The average value of all "HR/minute" during the day phase of the monitoring time
HR day min	The lowest value of all "HR/minute" during the day phase of the monitoring time
HR night max	The highest value of all "HR/minute" during the night phase of the monitoring time
HR night average	The average value of all "HR/minute" during the night phase of the monitoring time
HR night min	The lowest value of all "HR/minute" during the night phase of the monitoring time
HR event	Sum of the normal beats and the VPB beats divided by the length of the event [in s] * 60 s

Settings (Holter ECG Overview, Context Menu, Settings)

If the "HR max. linked with Tachycardia/VT" option is activated, the HR of the tachycardia/VT is used for the "HR max" calculation if its heart rate is the highest.

If the "HR min. linked with Bradycardia" option is activated, the heart rate of the bradycardia is used for the "HR min" calculation if its heart rate is the lowest.

07.3.2 Method for determining a period of no cardiac activity

The basis is the ECG analysis that automatically detects the beats and disturbances. If there is no disturbance and the break between two normal beats becomes greater than 2.0 s (for VPB 2.5 s), custo tera shows this break as an asystole. The asystole must be shorter than 60 s.

NOTE: All values can be adjusted in custo tera. The values used here correspond to the default settings.

07.3.3 Information for changing the ST segment

ST segment analysis takes place on two analysed derivations. There are no calibration signals.

For the ST segment, the user can select the following from the detection criteria for the ST segment changes:

- Amplitude for the decrease (basic setting 0.3 mV)
- Amplitude for the increase (basic setting 0.3 mV)
- Minimum duration (basic setting 5 minutes)
- Position of the "J+" point (basic setting 60 ms)

These settings are located in the open Holter ECG evaluation on the Analysis, Options menu, Parameters, ST Examples page.

ST segment changes are calculated every minute. It is determined which beat class occurs most frequently in this minute. A sum complex is obtained from all the complexes of this beat class, which is used to determine the value for the increase or decrease.

The following is displayed: The number of incidents, the type of incidents (increase or decrease). The duration of the incidents is not displayed.

In the result report, tera represents the following [1]:

- Overview

ST Chn. yes/no	Indicates whether a ST change exists.
F <number>	Specifies the number of events in the channel.
T1 <number>	Specifies the number of events in the channel.
F rel. <number>	Specifies the number of relative events in the channel.
T1 rel. <number>	Specifies the number of relative events in the channel.

- Trends:

ST Event Trend per Channel
(called "ST Trend F", "ST Trend T1", "ST Change" in the printout),
ST Level Trend per Channel (called "ST Channel F", "ST Channel T1" in the printout)

Heart rate ranges are constantly recorded and are available at all times. Ranges of displacement and slope values are not recorded.

4) Note on the designation of ECG leads: When carrying out recordings with custo belt, the leads in custo diagnostic (and on the custo watch display) are labelled as F, T1 and T2; when carrying out recordings with the custo guard adapter set, they are labelled as A, B and C.

07.4 Manufacturer's declaration regarding EMC (electromagnetic compatibility) according to DIN EN 60601-1-2:2007

Cable lengths of the accessories

Micro USB cable 2.0 (Part no. 16021): 1.5 m

WARNING! The use of longer cable lengths could result in increased emissions or decreased immunity. The use of cables other than those specified above is not permitted.

Manufacturer's declaration – electromagnetic emissions

The custo watch Holter ECG recorder (consisting of the custo watch and ECG transmitter) is intended for use in the electromagnetic environment specified below. The customer or the user of the custo watch Holter ECG recorder should make sure that it is used in such an environment.

Emission Measurements	Compliance	Electromagnetic environment – Guidelines
HF emissions according to CISPR11	Group 2	custo watch must emit electromagnetic energy in order to perform its intended function. Other electronic devices in the vicinity may be affected.
HF emissions according to CISPR11	Class B	custo watch is suitable for use in all establishments, including domestic establishments and those directly connected to the public low voltage power supply network that also supplies buildings used for domestic purposes.
Harmonics according to IEC61000-3-2	Not applicable	
Voltage fluctuations/flickers according to IEC61000-3-3	Not applicable	

Manufacturer's declaration – electromagnetic immunity

The custo watch Holter ECG recorder (consisting of the custo watch and ECG transmitter) is intended for use in the electromagnetic environment specified below. The customer or the user of the custo watch Holter ECG recorder 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 that 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 that 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_T for 0.5 periods (> 95 % drop) 40 % U_T for 5 periods (60 % drop) 70 % U_T for 25 periods (30 % drop) < 5 % U_T for 5 s (> 95 % drop)	Not applicable	The quality of the supply voltage should correspond to that of a typical business or clinical environment. If the user of the custo watch requires continued function, even if interruptions occur in the power supply, it is recommended to supply the custo watch from an interruption-free power supply.
Magnetic field with supply frequency (50/60 Hz) according to IEC 61000-4-8	3 A/m	10 A/m	Magnetic fields with the mains frequency should correspond to the typical values, as they can be found in a business and clinical environment.

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

Manufacturer's declaration – electromagnetic immunity

The custo watch Holter ECG recorder (consisting of the custo watch and ECG transmitter) is intended for use in the electromagnetic environment specified below. The customer or the user of the custo watch Holter ECG recorder 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 custo watch including the leads than the recommended protective distance which is determined according to the equation applicable to the frequency of the transmitter. **Recommended protective distance:**
Conducted RF transients according to IEC 61000-4-6	3 $V_{effective\ value}$ 150 KHz to 80 Mhz	Not applicable	d = (3.5/U1) √P d = (3.5/E_1) √P 80 MHz to 800 MHz
Radiated RF transients according to IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	E_1 = 3 V/m @ 80 MHz to 2.5 GHz	d = (7/E_1) √P 800 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). The field strength of stationary radio transmitters should be less than the compliance level *b)* for all the frequencies in accordance with an on-site test *a)*. In the vicinity of devices carrying the following symbol, disturbances 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 land mobile radios, 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 above-mentioned 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) Within the frequency range of 150 kHz to 80 MHz, the field strength should be less than 10 V/m.

Recommended protective distances between portable and mobile HF telecommunication devices and custo watch

custo watch is intended for use in an electromagnetic environment in which RF transients are controlled. The user of the custo watch can help avoid electromagnetic interference 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 $d= (3.5/U1) \sqrt{P}$	80 MHz to 800 MHz $d= (3.5/E_1) \sqrt{P}$	800 MHz to 2.5 GHz $d= (7/E_1) \sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.37	0.37	0.74
1	1.17	1.17	2.33
10	3.69	3.69	7.38
100	11.67	11.67	23.33

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.

07.5 EC Declaration of Conformity

V001 / DK-1431 / CEK-0200

EC Declaration of Conformity

Manufacturer: custo med GmbH | Leibnizstrasse 7 | 85521 Ottobrunn, Germany

We hereby declare under our sole responsibility that the **CUSTO DIAGNOSTIC SYSTEM** to which this declaration relates is in conformity with the basic requirements according to Annex I of the Medical Device Directive 93/42/EEC. The conformity assessment procedure is based on Annex II (excluding section 4), Medical Device Directive 93/42/EEC.

Notified body:	Testing Institute of Medical Devices Graz (PMG) Technische Universität Graz Kopernikusgasse 24, A-8010 Graz, Austria
ID number:	0636
Certificate registration no.:	EGII-130001-002-1
Date of issue	Graz, 2013-04-30
Certificate expiry date	Graz, 2018-04-29

CUSTO DIAGNOSTIC SYSTEM	
Product Category	Product Name
Medical Software	custo diagnostic
ECG Systems	custo cardio 100/100 BT custo cardio 110/110 BT custo cardio 130 custo cardio 200/200 BT
Holter ECG Systems	custo flash 110/220 custo flash 500/501/510 custo cor 3/12 custo watch custo guard 1/3
ABPM Systems	custo screen 100/200/300/400
Cardiac Rehabilitation Systems	custo care card custo guard 1/3
Telemedical Systems	custo kybe custo guard 1/3
Polysomnography Systems	custo night 300/310
Pulmonary Function Systems	custo vit m R custo spiro mobile custo spiro protect
Ergometry Systems	custo ec3000

Ottobrunn, 06 February 2015

Peter Müller

custo·med
EXCELLENCE IN DIAGNOSTICS

07.6 Putting out of operation, storage and transport

Putting out of operation and storage

Clean and disinfect the custo watch and its components before putting it out of operation.

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

Transport

Clean and disinfect the custo watch 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 such a way that it is protected against impact, moisture 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 transportation (custo watch system)

Temperature:	-20°C ... +45°C
Air humidity:	10 ... 95% rH
Air pressure:	700 ... 1060 hPa

07.7 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 waste electrical and electronic equipment). The device must not be disposed of as normal domestic waste.

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

07.8 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. User master data
2. Call last patient
3. Examination main menu

RIGHT-CLICK

1. Evaluation search
2. Call last patient
3. Evaluation last displayed

LEFT-CLICK

4. User master data
5. Patient master data
6. Menu for the current examination

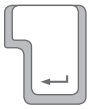
RIGHT-CLICK

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 will be underlined. Pressing an initial letter in combination with the Alt key triggers the corresponding button.

Generally valid keyboard shortcuts

Esc	End, Cancel
	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	Switching to Metasoft
Ctrl + F1	Create system report, service email

Generally valid keyboard shortcuts in an open evaluation

Ctrl + N	Unconfirmed report input dialogue
Ctrl + K	Medication input dialogue
Ctrl + Alt + 1	Service dialogue
Ctrl + ← / Ctrl + →	Calls the previous/next screen

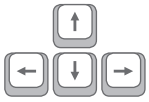
Keyboard shortcuts for Holter ECG: Analysis

W	Skip normal beats forward
⇧ + W	Skip normal beats backwards
⇧ + D	Skip normal beats forward in increments of 10
⇧ + A	Skip normal beats backwards in increments of 10
⇧ + C	Skip VPB/Artefact/Pacemaker forward in increments of 10
⇧ + Y	Skip VPB/Artefact/Pacemaker backwards in increments of 10
N	Selected beat classes are converted to (N) Normal Beat
2	Selected beat classes are converted to (2) Normal-2
V	Selected beat classes are converted to (V) VPB
E	Selected beat classes are converted to (E) Abberant
A	Selected beat classes are converted to (A) Artefact
S	Selected beat classes are converted to (S) Pacemaker
Space	After pressing the space bar, the selected beat classes are changed to N/A/V/S
Esc	Current selection is cancelled
↵	Changes are applied, a new analysis of the ECG is started
← + →	Scroll ECG forwards/backward
F2	Marking dialogue

Keyboard shortcuts for Holter ECG: Trend/ECG

← →	Go to the next or previous occurrence of the selected event
F2	Marking dialogue
N	If the "Change" mouse function is selected: The next beat besides the cursor is changed to normal beat
V	If the "Change" mouse function is selected: The next beat besides the cursor is changed to VPB

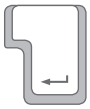
Keyboard shortcuts for Holter ECG: Example overview



Move inside the examples

Selector cursor moves to the first/last example

Scroll up/down one page



Opens all examples from the selected event

Set marking, pressing again will remove the marking

Delete all examples of the selected event

Deletes the top (currently displayed) example of the event.
If there is no example of the event left, the event is deleted.

Keyboard shortcuts for Holter ECG: Total ECG

Scroll ECG up/down by lines

Scroll ECG up/down by pages

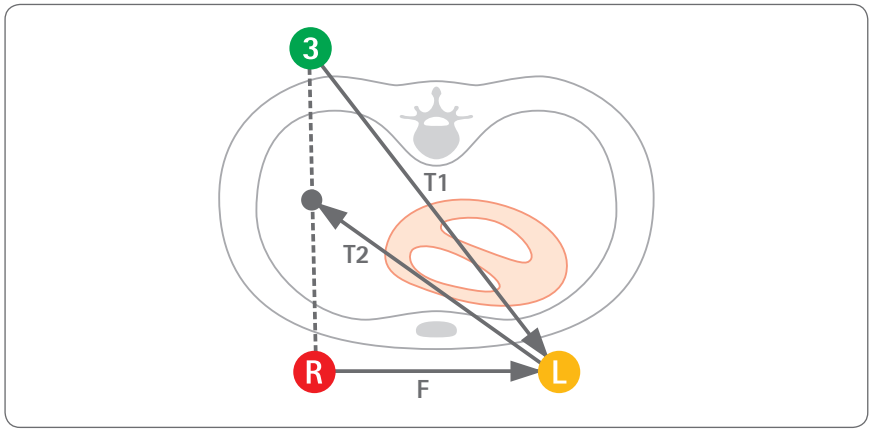
Scroll ECG up/down for the duration of the key press

Scroll ECG automatically up/down
Repeated pressing of the key increases the speed,
pressing the "opposite direction" reduces the speed

Space bar starts/stops the automatic scrolling

Marking dialogue

Schematic representation of the leads of custo belt 3



The custo belt 3 has three electrodes of which two (R and L) are located in frontal position and the third (3) can be positioned in either a lateral or dorsal direction. This allows the custo belt 3 to be adapted to the anatomical conditions of the patient. We recommend that the third electrode is used as standard in the lateral position (towards the R electrode).

The electrode arrangement in the custo belt 3 results in the following leads:

F	(frontal)	=	L – R	(corresponds to I)
T1	(transthoracic 1)	=	L – 3	(corresponds to V5)
T2	(transthoracic 2)	=	(3 – R) : 2 – L	(additional analysis channel)

Lead F is preferably used to represent the excitation propagation over the side wall of the left ventricle of the heart. It correlates with lead I in the resting ECG. Lead F is the primary analysis channel in the Holter ECG.

Lead T1 is preferably used to represent the excitation propagation over the left lateral surface of the heart. Due to the angle it correlates with lead V5 in the resting ECG. Lead T1 is the secondary analysis channel in the Holter ECG.

Lead T2 provides an additional channel for analysis. This lead is displayed inversely.

Patient Diary for 24-Hour Recordings

Type of recording	**Patient data**
☐ Holter ECG	First name .....
☐ ABPM (long term blood pressure)	Name .....
☐ Combination recording (Holter ECG & ABPM)	Sex .....
Recording period	Date of birth .....
from ..... to	Patient Number .....

IMPORTANT: Please complete the activity log during the 24-hour recording period.
Use the numbers 1 to 10. Each number represents a certain activity.
Avoid heavy physical activity and do not use a mobile phone.

1 Driving	**6** Exercise (walking)
2 Workplace	**7** Taking medication – specify?
3 Eating	**8** Watching television
4 Housework – specify?	**9** Resting
5 Physical activity – specify?	**10** Sleeping

00.00 – 00.30	12.00 – 12.30 .....
00.30 – 01.00	12.30 – 13.00 .....
01.00 – 01.30	13.00 – 13.30 .....
01.30 – 02.00	13.30 – 14.00 .....
02.00 – 02.30	14.00 – 14.30 .....
02.30 – 03.00	14.30 – 15.00 .....
03.00 – 03.30	15.00 – 15.30 .....
03.30 – 04.00	15.30 – 16.00 .....
04.00 – 04.30	16.00 – 16.30 .....
04.30 – 05.00	16.30 – 17.00 .....
05.00 – 05.30	17.00 – 17.30 .....
05.30 – 06.00	17.30 – 18.00 .....
06.00 – 06.30	18.00 – 18.30 .....
06.30 – 07.00	18.30 – 19.00 .....
07.00 – 07.30	19.00 – 19.30 .....
07.30 – 08.00	19.30 – 20.00 .....
08.00 – 08.30	20.00 – 20.30 .....
08.30 – 09.00	20.30 – 21.00 .....
09.00 – 09.30	21.00 – 21.30 .....
09.30 – 10.00	21.30 – 22.00 .....
10.00 – 10.30	22.00 – 22.30 .....
10.30 – 11.00	22.30 – 23.00 .....
11.00 – 11.30	23.00 – 23.30 .....
11.30 – 12.00	23.30 – 00.00 .....

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