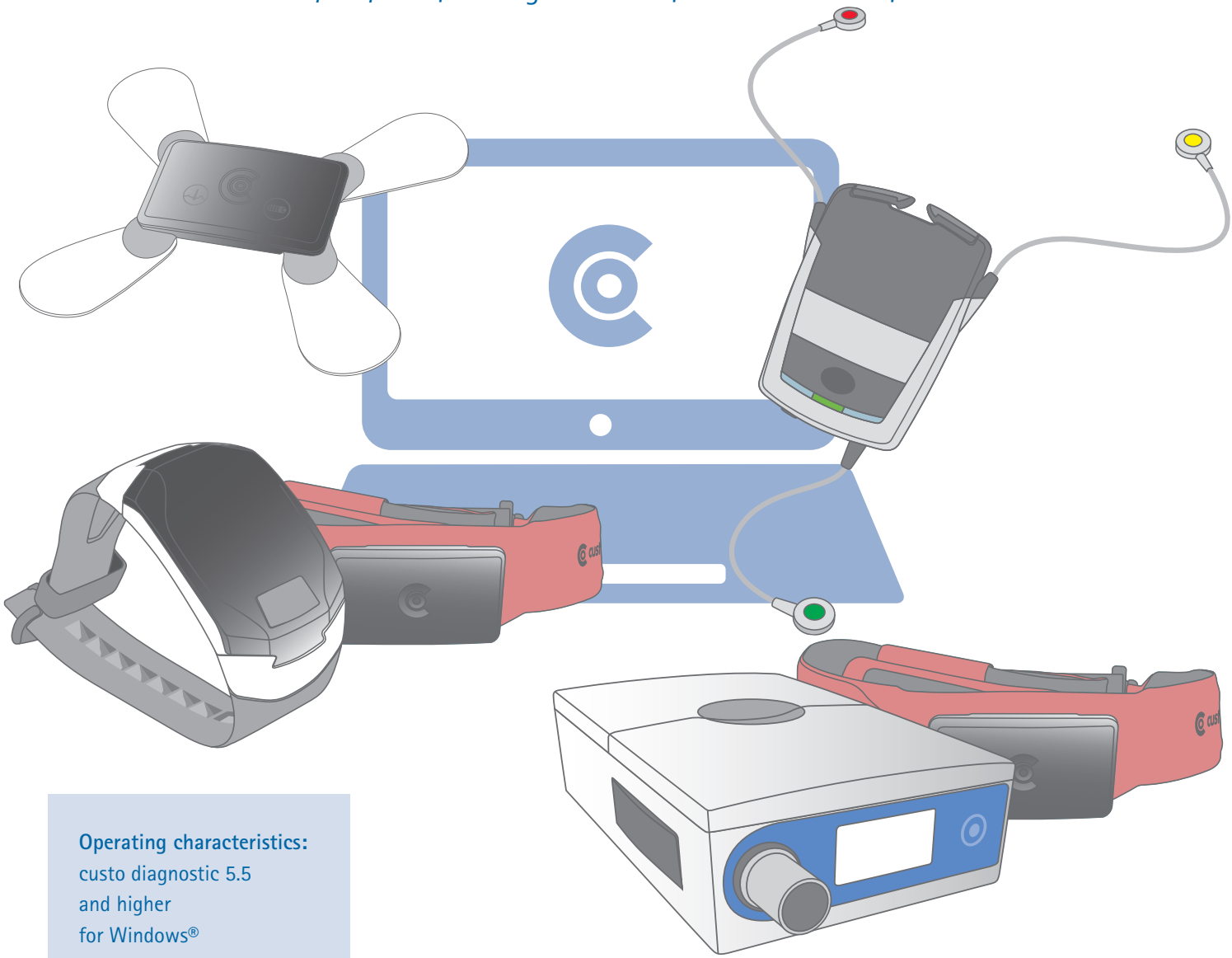
Operating Manual

Holter

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

Part 3: custo diagnostic software for
custo flash 500/510/510V, custo guard holter, custo screen 400, custo watch



Operating characteristics:
custo diagnostic 5.5
and higher
for Windows®

MSW 0055 – DK 1902
Version 002 – 05/03/2021

CE 0123

custo·med
EXCELLENCE IN DIAGNOSTICS

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

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

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1 Safety | 2 Hardware | 3 Software | 4 Hygiene

Part 3: custo diagnostic software for custo flash 500/510/510V, custo guard holter, custo screen 400, custo watch

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3.1 Symbols used in this Operating Manual

ACTIONS THAT ARE PROHIBITED
or not allowed under any circumstances!

WARNING
used to indicate situations which, if not avoided, could result in personal injury or damage to property

NOTE
provides important information which must be observed

TIP
contains practical information to assist you with your work

Words highlighted in colour indicate buttons or click paths to the corresponding program point, e.g. Examination, Settings, ...

Words highlighted in colour...

3.2 Overview of the Holter software and recorders

Software function	Holter software versions & recorders		
	Software light[1] custo flash 501/L recorder	Software standard all recorders[2]	Software professional all recorders[2]
Comparison of evaluations	✓	✓	✓
Analysis (editing of templates)	✓	✓	✓
Trend/ECG	✓	✓	✓
Examples	✓	✓	✓
Trend overview	×	✓	✓
Total ECG	×	✓	✓
Export as a PDF file	×	✓	✓
Reduction of data volume	×	✓	✓
Movement data	×	guard holter, watch ✓	guard holter, watch ✓
Combination recording with ABPM[3]	screen 300/310/400[4] ✓	screen 300/310/400[4] ✓	screen 300/310/400[4] ✓
multiday evaluation[3] up to 7 days or 3 days	×	flash 500/510/510V, guard holter, watch ✓	flash 500/510/510V, guard holter, watch ✓
Pacemaker analysis[3]	×	×	flash 510/510V, guard holter ✓
Event system	×	×	✓
ST measurement	×	×	✓
QT measurement	×	×	✓
HRV	×	×	✓
AF diagnostics	×	×	✓
HRT	×	×	✓
ANS diagnostics[5]	×	flash 510V, guard holter, screen 400, watch ✓	flash 510V, guard holter, screen 400, watch ✓
12 channel recording[5]	×	EDAN SE-2012 ✓	EDAN SE-2012 ✓
CSV export RR interv.[5]	×	✓	✓

1) *The custo tera light with custo flash 501/L product version is described in another Operating Manual.*
2) *For the standard and professional software versions, all custo med Holter recorders can be used, with the exception of custo flash 501 and custo flash 501/L.*
3) *Only possible with the specified recorder type.*
4) *custo screen 300 is an ABPM recorder only. If it is attached to the patient simultaneously with a custo med Holter recorder, the two recordings will be displayed as a combination evaluation due to their common recording period.*
5) *Optional, independent of the software version – but possibly with restrictions due to the recorder type.*

3.2 custo diagnostic program structure

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

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

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

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

3.4 Connecting custo med devices to the PC

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 set-up or via targeted selection during the custo diagnostic set-up.

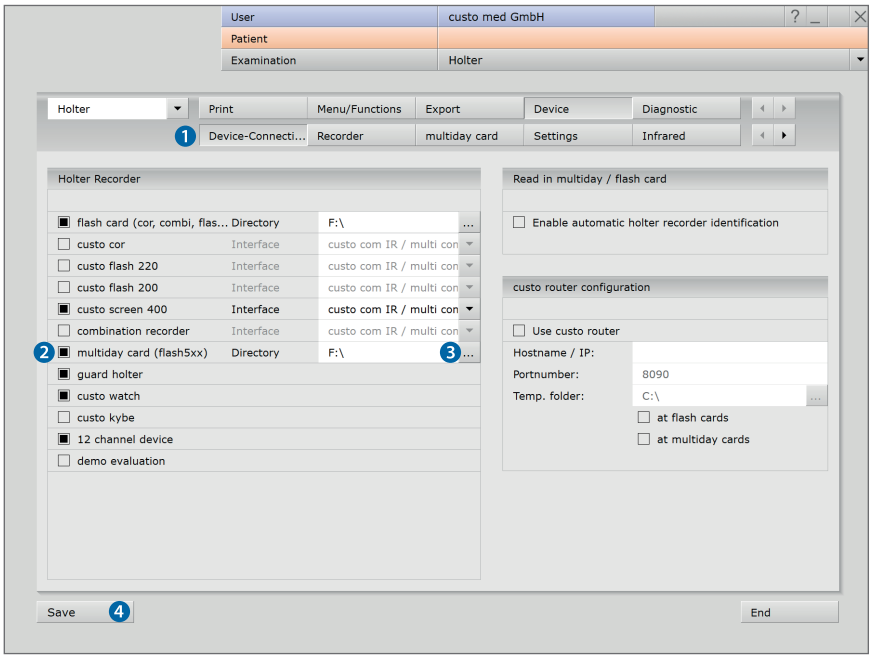
Note on custo med EDAN SE-2012, 12-channel holter recorder

Initial operation of custo med EDAN SE-2012 is described in another document (Quick Guide). The screens and evaluation procedures are shown in this document.

3.4.1 custo flash 5xx

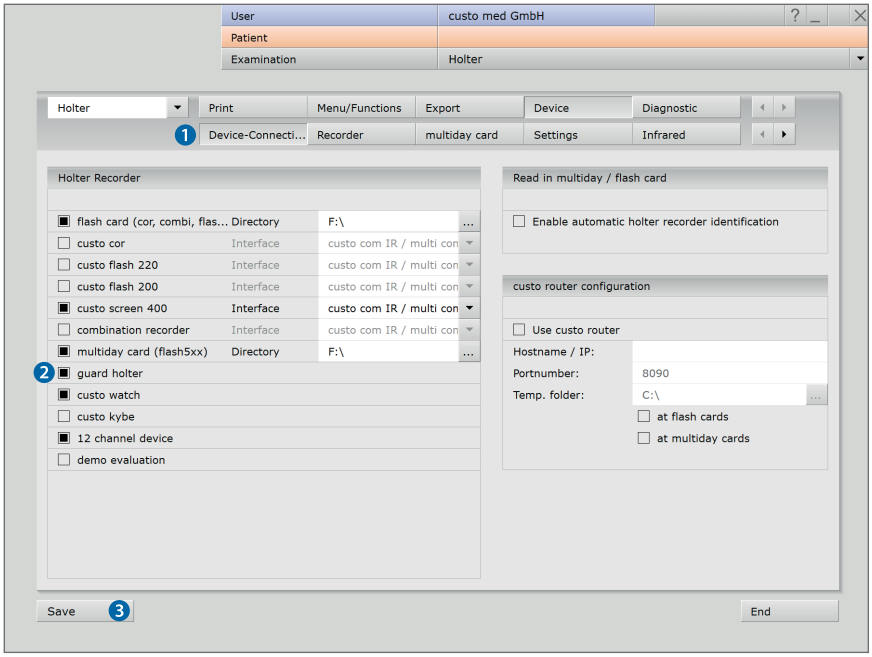
Connecting and configuring the USB card reader

- Connect the USB card reader to the PC.
  The device driver is installed automatically.
- Start custo diagnostic and select:
  Examination, Holter, Settings, Device, Device-Connection. ❶
- Activate the multiday card (flash5xx) option. ❷
- Select the drive of the USB card reader. To do this, click on the ... button ❸ at the end of the line. Select the appropriate drive in the directory structure, confirm with OK.
- Click on Save ❹ to apply your input.
- The USB card reader is ready for operation.



3.4.2 custo guard holter

- Connect the custo guard base charging and programming unit to the PC with the USB cable. If possible, not via a USB hub. The LED on the housing of the custo guard base charging and programming unit lights up in orange.
- Place the custo guard holter ECG device in the custo guard base charging and programming unit. The driver is installed automatically.
- Start custo diagnostic and select:
  Examination, Holter, Settings, Device, Device connection ❶.
- Select custo guard holter ❷.
- Save your input ❸.
- The device is ready for operation.



Preparing the Bluetooth connection (for monitoring)

A Bluetooth connection between the custo guard holter ECG device and the custo diagnostic workstation is required for the ECG monitoring in custo diagnostic (e.g. to check ECG quality before recording). Requirements: Windows 10 and Bluetooth Low Energy. Ensure that Bluetooth is activated.

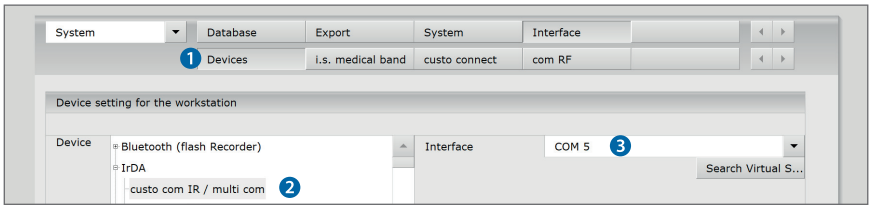
If the PC has no Bluetooth functionality, the supplied Bluetooth USB stick can be connected to the PC. The driver is installed automatically. No further steps are required.

3.4.3 custo screen 400

Setting up the infrared interface

- Connect the custo com IR/multi com infrared interface to the PC [1].
  The device drivers are installed automatically.
- Find out which COM port was assigned to the interface:
  to do so, on your Windows interface, right-click on
  My Computer or Computer, in the context menu on Manage,
  and then on Device Manager. In the right half of the window, open
  Ports (COM and LTP) and note the port of custo com IR/multi com, e.g. (COM5).
- In custo diagnostic, open the
  Examination, Settings, Interface, Devices ❶ page.
- In the "Device" area, select IrDa, custo com IR/multi com ❷ and
  in the "Interface" area the corresponding COM Port ❸ from
  the Device Manager.
- Click on Save (bottom left) to apply your input.

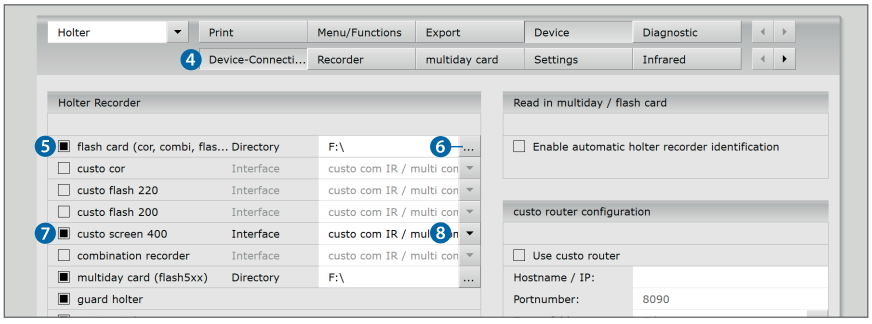
1) Using other infrared interfaces: custo screen 300/400/pediatric can also be connected to your PC via older infrared interfaces, such as custo com USB or JetEye. The method of connecting and configuring is exactly the same as for custo com IR/multi com.



Setting the Holter ABPM recorder[2]

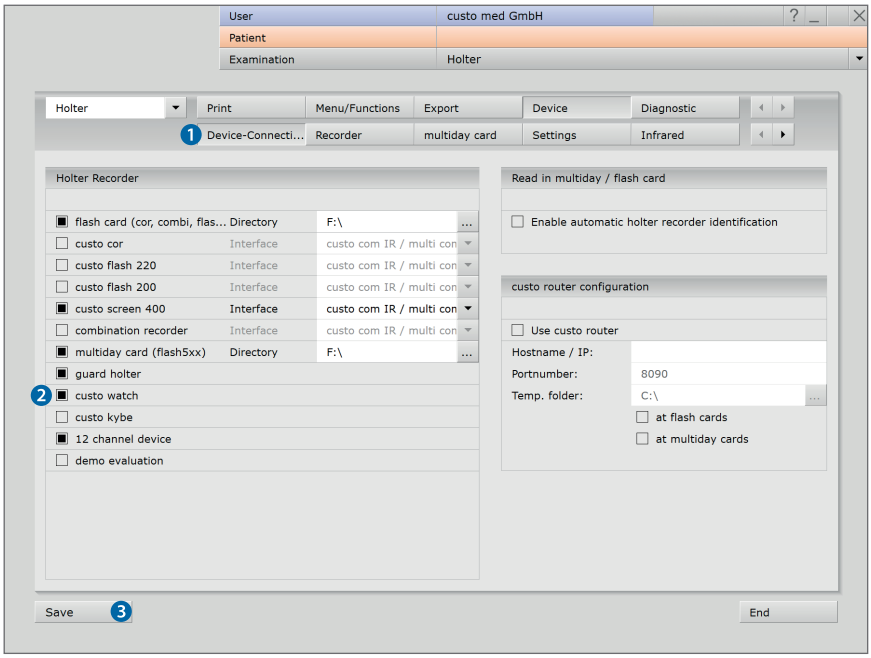
- Connect the USB card reader to the PC, unless you are working with
  custo multi com. The device driver is installed automatically.
- Start custo diagnostic and select:
  Examination, Holter, Settings, Device, Device Connection ❹.
- Activate the flash card ❺ option.
- Select the drive of the USB card reader.
  To do so, click on the ... button ❻ at the end of the line.
  Select the appropriate drive in the directory structure, confirm with OK.
- Activate the custo screen 400 ❼ option and in the
  "Interface" area select the custo com IR/custo multi com ❽ infrared interface.
- Save your input (bottom left). The device is ready for operation.

2) Holter ABPM recordings are started via infrared interface and downloaded into custo diagnostic via the SD card/card reader. It is therefore necessary that both devices are set and saved at this point.



3.4.4 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.
  The driver is installed automatically.
- Start custo diagnostic and select:
  Examination, Holter, Settings, Device, Device-Connection ❶.
- Select the custo watch ❷ item.
- Save ❸ your input. The device is ready for operation.

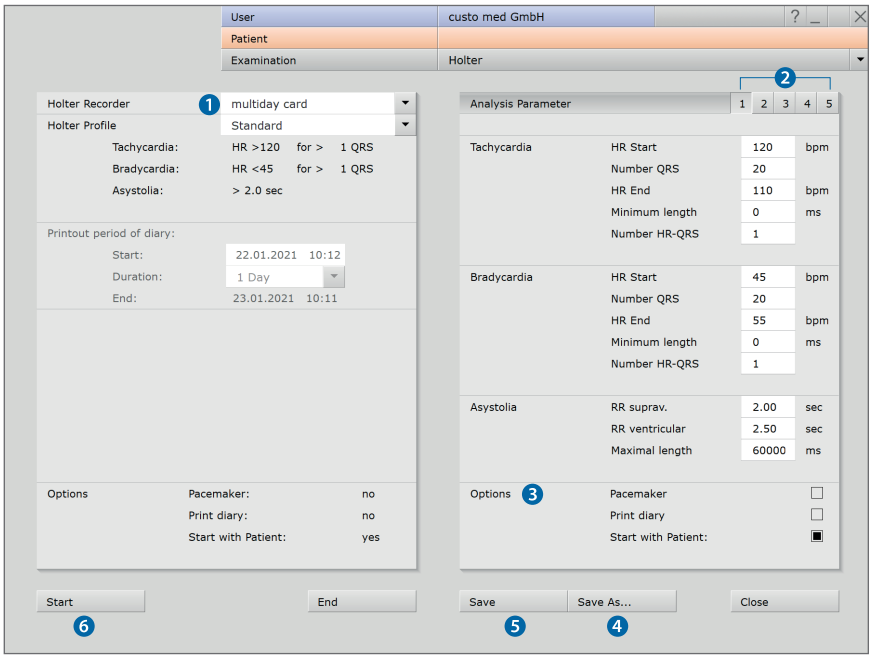


3.5 Performing a holter recording

3.5.1 Starting a holter recording with custo flash 5xx

- Make sure that the USB card reader is ready for operation.
- Insert the custo multiday card into the USB card reader.
- Start custo diagnostic and select:
  Examination, Holter, New Holter.
- Select multiday card ❶ as the Holter recorder.
- The pre-set recording parameters can be changed by selecting Edit.
- The 1 – 5 ❷ buttons contain additional screens with analysis parameters.
- The options ❸ have to be set as required:
  Pacemaker detection (custo flash 510/510V)
  Print diary: Printout of the patient diary during the start procedure
  (to document events during recording).
  Start with patient: in the next step select a patient
  for recording. The custo multiday card will be personalised.
  If you deactivate this option, a patient must be allocated
  when downloading the recording.

- With Save as ❹, new start parameter settings
  can be saved under a different name and made available
  for additional recordings.
- With Save ❺, the originally selected start parameters
  will be overwritten.
- After you have completed the settings, click on Start ❻.
- The patient selection mask appears.



Select patient

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

New patient

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

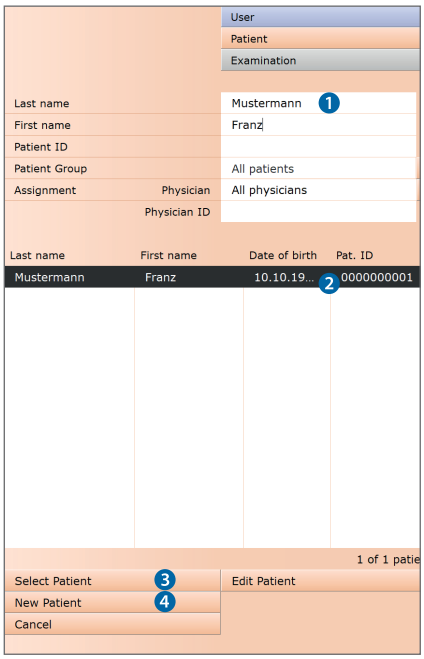
Tip for entries in the patient menu:

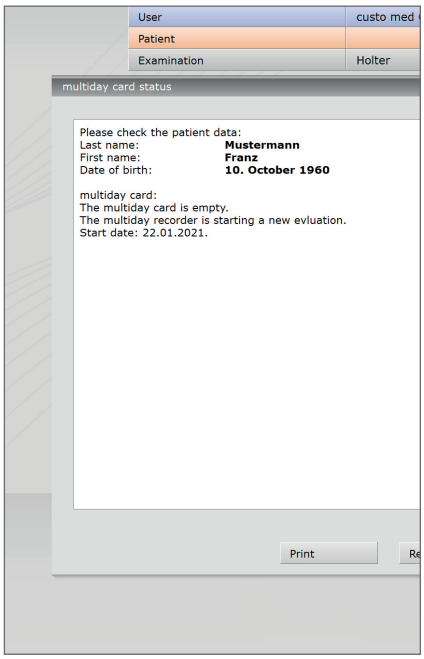
Press the tab key to move the cursor to the next input field.

- After the patient has been selected, the recording parameters are written to the custo multiday card. A dialogue will then appear in which the card status is displayed for checking purposes.
  To close the dialogue, select Confirm (bottom right).

Starting a recording

- Remove the custo multiday card from the USB card reader.
- Insert the custo multiday card into the recorder and assemble the recorder, refer to the hardware description.
- The recorder is started, see the LED display





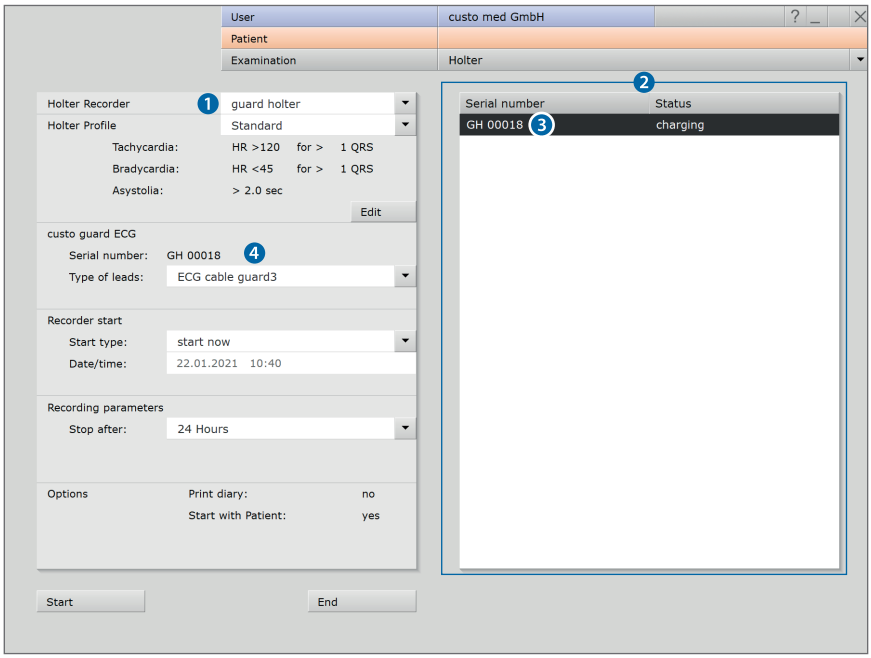
3.5.2 Starting a holter recording with custo guard holter

Selecting the custo guard holter device

- Ensure that the custo guard base is connected to the PC.
- Start custo diagnostic and select:
  Examination, Holter, New holter.
- Select custo guard holter ❶ as the Holter recording device.
- Place the custo guard holter device on the custo guard base.
- All available custo guard holter devices connected to the PC are displayed in a list on the right side of the screen ❷.

Tip: This list can be configured. The context menu is opened by right-clicking in the list. Click on Column selection there and select the desired columns for the list view. The Charge status (whether the device is sufficiently charged for a 24 h or 72 h recording) and Charge time (how long the device must charge until the required battery capacity for the recording is achieved) columns are suitable for checking for proper function for a recording. Confirm this selection to adjust the list view.

- Select the custo guard holter to use for the recording on the right side of the screen ❸. When a list entry is clicked ❸, the corresponding device in the custo guard base flashes briefly (for approx. 30 seconds). The serial number of the selected device is display on the left side of the screen ❹. A custo guard holter device can also be identified by the serial number on the type plate (on the bottom of the housing) – compare the type plate with the software ❹.



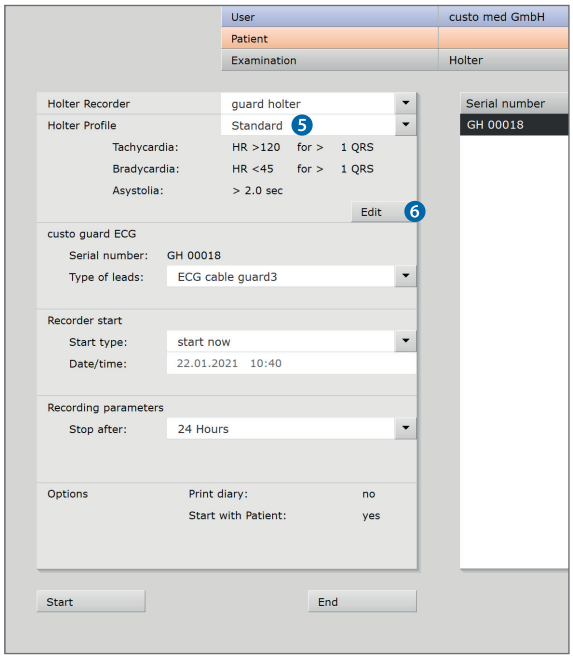
Selecting and configuring analysis parameters

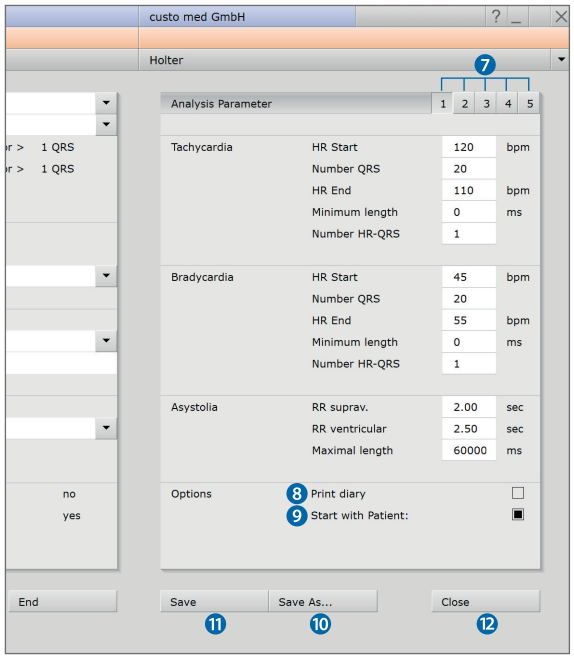
- Select a Holter Profile, e.g. Standard ❺,
  or create a new profile (Edit) ❻.
- Edit ❻: Buttons 1 – 5 ❼ open more windows
  with analysis parameters.
- The options have to be set as required:
  Print patient diary ❽: Printout of the patient diary during the start procedure
  (to document events during recording).
  Start with patient ❾: Allows selection of a patient when starting the recording.
  This option is activated by default.

Attention, when working without selecting a patient:

The medical staff must provide a clear and secure assignment of device and patient to ensure that a recording can be assigned to the correct patient when it is later read into custo diagnostic (e.g. labelling, keeping a daily updated list of device numbers and patients).

- The edited parameters can be saved under a new name via Save As ❿,
  Save ⓫ overwrites the current set.
- Close ⓬ ends the parameter configuration.





Information on lead type, recording start and recording duration

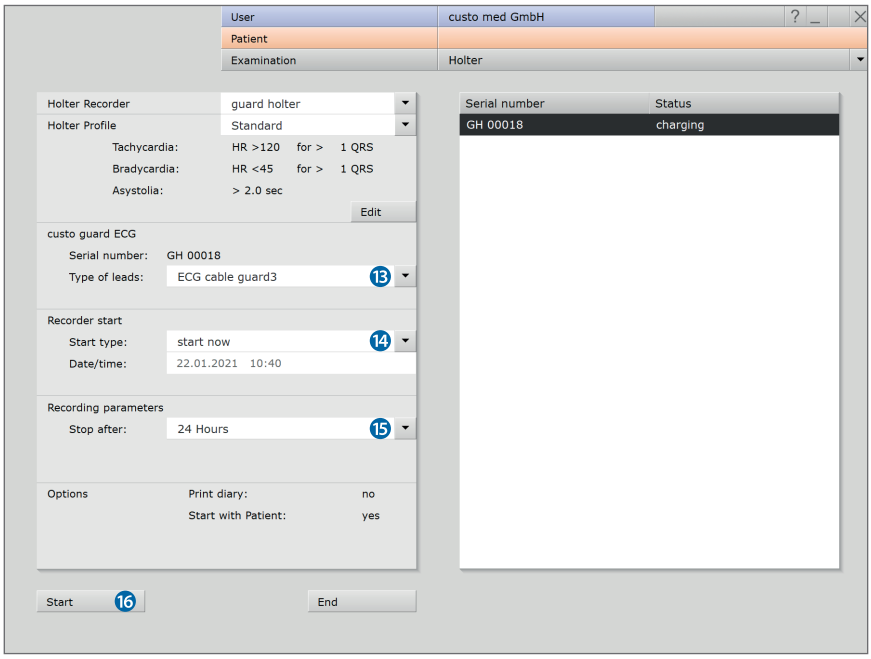
- Select how the custo guard holter device is attached to the patient ⓭:
  ... via custo belt (electrode belt)
  ... via ECG cable guard 3 (adapter for adhesive electrodes)
  ... via custo wing (four single-use adhesive electrodes)
  Depending on the method, the ECG derivations [1] are calculated differently.
- Set when to start the recording device ⓮:
  ... Start now
  ... Start later (manual device start at any time)
  ... Start at (date/time)
  (automatic start at a specified time)
- Set the recording duration[2]: 24 h / 72 h / up to 120 h[3] / unlimited[4] ⓯.
- Click the Start button ⓰.
- The patient selection screen appears[5].

Selecting a patient

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

Creating a new patient

- If the patient does not exist in the database,
  click New Patient.
- Enter the patient data.
  The fields marked with an asterisk are mandatory.
- Save the information, the patient is then entered in the database.



1) ECG derivations for custo guard holter:
with custo belt.....F, T1, T2
with ECG cable guard 3.....I, II, III
with custo wing.....A, B, C
with ECG cable guard 4.....A, B, C

2) The selection of the recording parameters (recording duration) can be configured individually. It can be set in the Examination, Holter, Setting, Menu/Functions, Device start screen. Save your input.

3) The custo guard holter records until the battery charge is depleted, usually four days, maximum five days.

4) IMPORTANT: For recordings with unlimited duration, provide the patient with a custo guard base charging and communication unit to take home. The custo guard holter needs to be recharged at regular intervals (e.g., daily, while the patient is attending to personal hygiene – pauses in the recording are shown in custo diagnostic with red lines). As soon as the battery charge is only sufficient for eight more hours of recording, the custo guard holter emits an acoustic warning signal (beep) every 15 minutes. The custo guard holter needs to be recharged within these 8 hours. If the custo guard holter is not recharged within these eight hours, the device will switch off – however, the device can still be recharged within the next 24 hours and the recording can be continued.
If more than 24 hours elapse after switching off, it is no longer possible to recharge the device and continue recording (due to loss of the real-time clock in the device). In this case, the custo guard holter must be read in and restarted at the medical practice.

5) If the Start with Patient option has been deactivated, patient selection is omitted here. The custo guard holter device is prepared for recording without patient data.
The medical staff must provide a clear and secure assignment of device and patient to ensure that a recording can be assigned to the correct patient when it is later read into custo diagnostic (e.g. labelling, keeping a daily updated list of device numbers and patients).

Data transmission and start

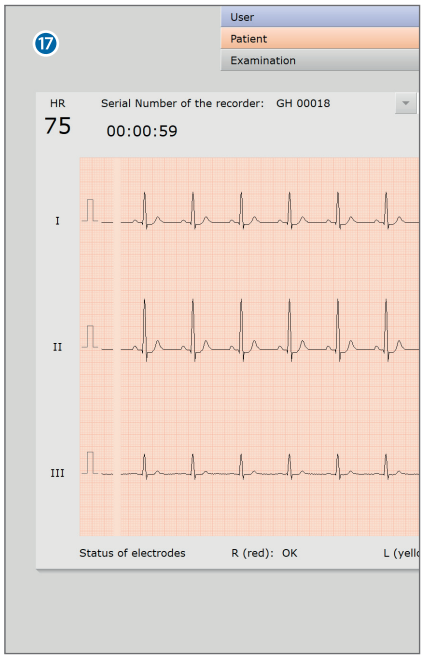
- The recording parameters and patient data are then transmitted to the custo guard holter device. Depending on the type of recorder start, the custo guard holter device then provides various visual and acoustic feedback signals:

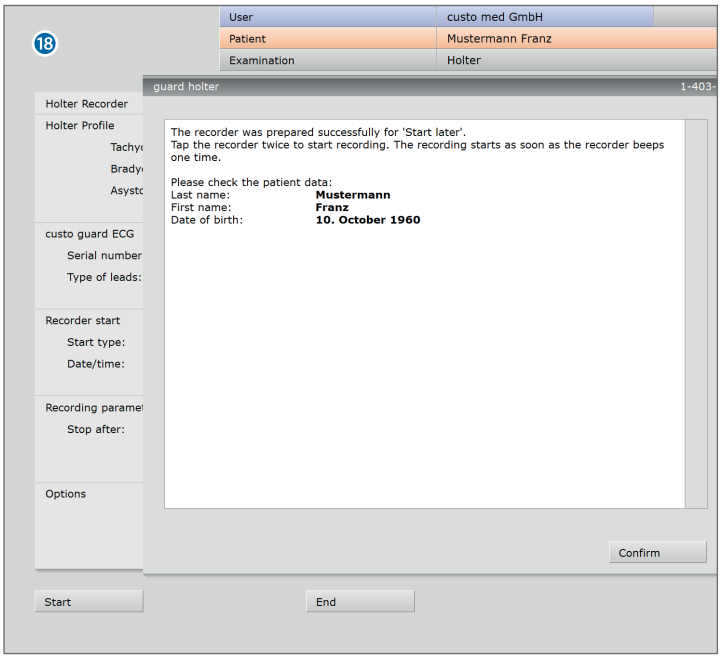
  ... after Start Now: A beep is issued, both LEDs flash rapidly, the recording starts and monitoring is displayed in custo diagnostic ⑰.
  Additional monitoring information can be found on the following page.

  ... after Start Later or Start at (date/time): The LED above the battery symbol flashes rapidly, a dialogue window with recording start information is displayed in custo diagnostic ⑱. Confirm this dialogue.

custo diagnostic charge status warning

If a warning that the battery capacity is too low appears during the start procedure (Charge status insufficient for selected recording duration), custo guard holter can still be started (Start Anyway button), for example if a shorter duration will suffice. Otherwise, cancel the start procedure (Cancel button) and charge the custo guard holter.





Monitoring – Checking the ECG signal, correcting electrode positions

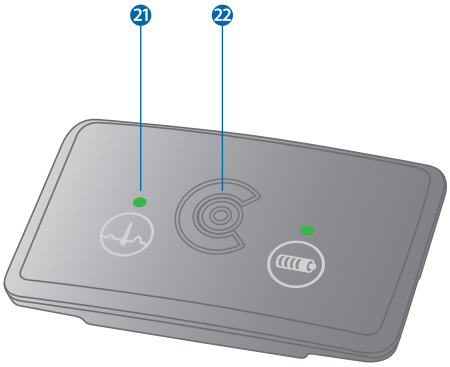
- The Monitoring screen either opens automatically after starting (Start Now with Patient option) or it can be opened in all other cases via Examination, Holter, Monitoring ⑲.
- Put the custo guard holter device on the patient, s*ee part 2: Hardware and device description for the custo guard holter*.

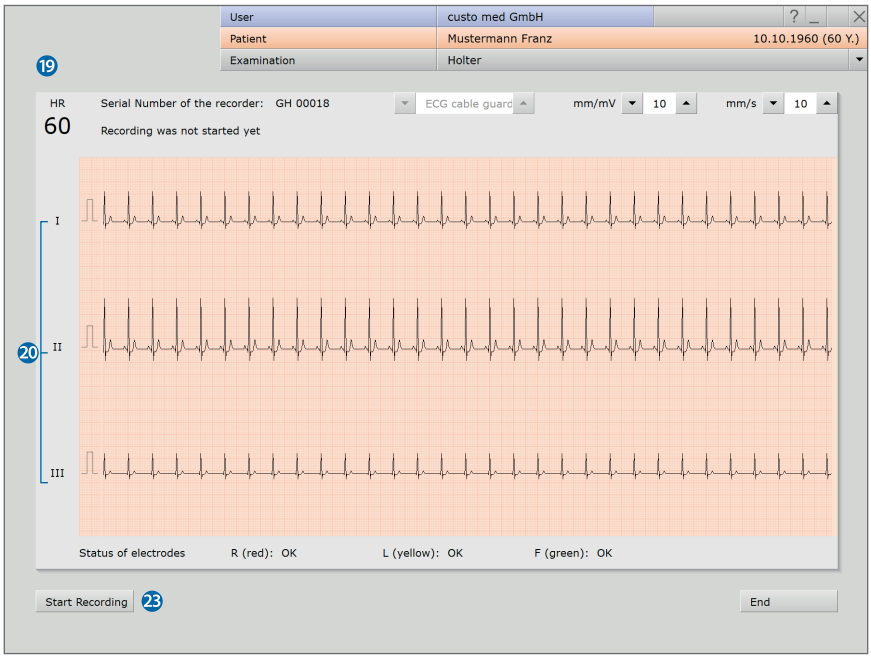
IMPORTANT: When putting the device on the patient, the lead type previously selected must be realised (custo belt/ECG cable guard/custo wing). Otherwise the analysis can contain errors.

custo diagnostic derivations ⑳:

via custo belt (electrode belt) ..... F, T1, T2
via ECG cable guard 3 (adapter for adhesive electrodes) ..... I, II, III
via custo wing (four single-use adhesive electrodes) ..... A, B, C
via ECG cable guard 4 (adapter for adhesive electrodes) ..... A, B, C

- Check the ECG signal on the screen. Correct the electrode positions, if necessary. If QRS complexes are detected, the ECG LED of the custo guard holter device lights up in green at regular intervals ㉑.
- If the Start later option has been selected, start recording at the desired time by double-tapping in the middle of the front side of the device ㉒, or start recording already during Monitoring via the Start Recording button ㉓. Recording begins after a short beep. Checking the quality of the ECG signal is also possible without monitoring. If the ECG quality is insufficient, the ECG LED lights up in red at regular intervals ㉑. Correct the electrode positions until the ECG LED lights up in green ㉑.
- If the Start at a Specified Time option has been selected, recording starts automatically at the specified time. Recording begins after a short beep.





Notes on the monitoring duration:

The maximum possible monitoring duration depends on the type of recorder start and the selected recording duration.

Start now & 24 h / 72 h:
1 h of monitoring after starting.

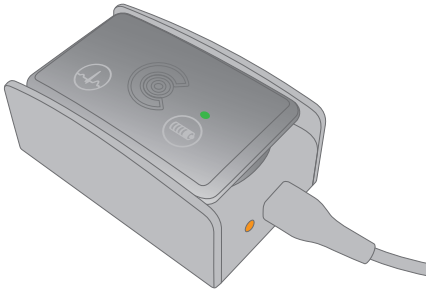
Start later / Start at a specific time & 24 h / 72 h:
1 h of monitoring before starting (e.g., to check the electrodes) and 1 h of monitoring after starting.

Start now & 120 h / unlimited:
15 min of monitoring after starting.

Start later / Start at a specific time & 120 h / unlimited:
15 min of monitoring before starting (e.g., to check the electrodes) and 15 minutes of monitoring after starting.

The shortened duration of monitoring for recordings with 120 h or unlimited duration serves to extend the battery life of the custo guard holter and/or to conserve the battery charge in advance.

"custo guard holter status viewer" work aid, device-specific information and status display for the custo guard holter ECG device



Notes on using the "custo guard holter status viewer"

- To receive information from a custo guard holter device, this must be connected to the PC via the custo guard base charging and communication unit.
- If several custo guard holter devices are connected to the PC (via the custo guard base 6), devices are identified by clicking the list entry in the custo guard holter status viewer. The battery LED of the corresponding custo guard holter flashes rapidly (for approx. 30 seconds).
- The columns in the „custo guard holter status viewer" are freely configurable. To display additional or different columns:
  Right-click in the custo guard holter status viewer, select Column Selection in the context menu, select the desired columns and confirm the selection.
- The "custo guard holter status viewer" runs in parallel with custo diagnostic as a standalone program. The "custo guard holter status viewer" can be displayed at all times on a second screen, for example.

The "custo guard holter status viewer" is opened via Examination, Holter, custo guard holter status viewer. In the "custo guard holter status viewer", the following information on the custo guard holter devices present can be displayed:

- Serial number
- Status
- Power
- Charge status
- Charging time
- Number of leads
- Types of leads
- Recording available
- Description
- Recording start
- Start date
- Stop date
- Recording duration
- Order number
- Assigned patient
- Patient's date of birth

Applications:

- Checking the battery capacity and the outstanding charging times.
- Management and monitoring of multiple custo guard holter devices, for example during sequential batch processing in larger medical practices or hospitals. Possible questions on working with multiple custo guard holter devices: Which custo guard holter device is assigned to which patient? Which lead type has been set for a custo guard holter device? How and when does recording start?

3.5.3 Starting a holter recording with custo screen 400

- Make sure that the infrared interface is ready for operation and that the SD card and fresh batteries/rechargeable batteries are in the recorder.
- Start custo diagnostic and select: Examination, Holter, New Holter.
- Select custo screen 400 ❶ as the Holter recorder.

Holter parameters

- Select a set of Holter parameters, e.g. Standard ❷, or create a new set (Edit).
- The options ❸ have to be set as required:
  Print diary: Printout of the patient diary during the start procedure (to document events during recording).
  Rechargeable battery: Activate if custo screen 400 is operated with rechargeable batteries.
  Start later with patient: Allows a patient to be selected when the recorder is started via the Start later button [1].
- With Save as ❹, the set parameters can be saved under a new name, with Save ❺ they are overwritten.

Connecting custo screen 400 and custo guard to each other

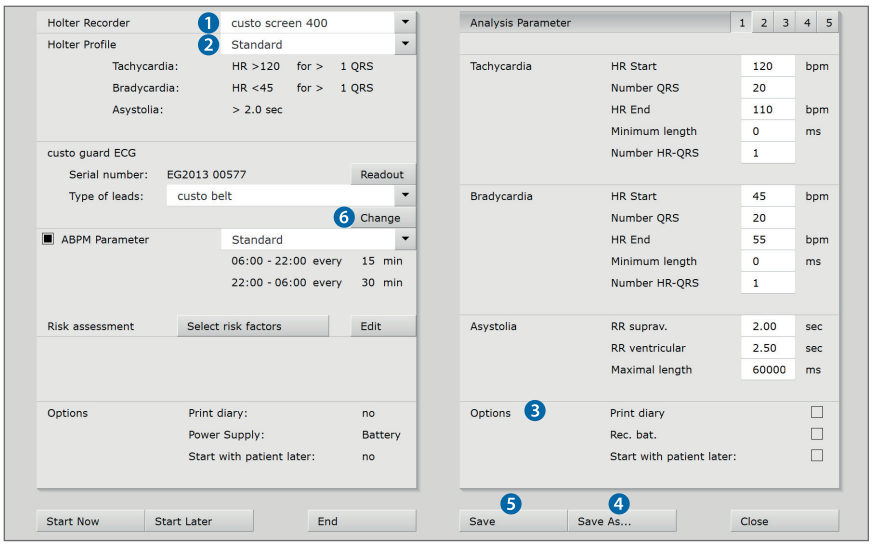
- Place the switched-on recorder in front of the custo com IR/multi com interface so that the two infrared interfaces are opposite each other (at a distance of approx. 10 – 20 cm). If the connection was successful, "PC" will appear on the recorder display [2].
- In the "custo guard ECG" area, click on Change ❻.
  Click on Search guards below the ECG transmitter list.
- Read the serial number of the ECG transmitter from the housing and select this serial number in the ECG transmitter list.
- If the required ECG transmitter is not included in the list, enter the ECG transmitter manually into the system (Show all, Add).

1) Information on the Start later function without the selection of a patient:

If the Start later function is used without additionally selecting the Start later with patient option, no patient will be selected for recording. In this case, 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 a patient). Switch off the recorder after the data have been transmitted. The recording does not start until the recorder is switched on again.

After the recording, when the recorder is received, the evaluation must be allocated to a patient immediately (download to custo diagnostic) or the device must be identified with patient data. Always ensure that patients are clearly allocated!

2) If the message "Please activate the blood pressure monitoring device!" appears, press the round function key next to the display on the custo screen 400 recorder to activate the recorder and to establish a connection to the PC.



If working with only one custo screen 400 system or there is only one ECG transmitter, the devices only have to be connected during initial operation. The allocation still has to be checked each time the recorder is started:

- Click on Readout and compare the serial numbers.
  The serial numbers on the ECG transmitter and in custo diagnostic in the "custo guard ECG" area must match ❼.
  During the start, the serial number of the ECG transmitter ❼ is transferred to the recorder [3)].
- Select the type of leads ❽.
  For recordings with an electrode belt: custo belt,
  for recordings with an ECG cable: ECG cable guard 3.

3) Safety information for ECG recording:
If the Start later function is used, the recorder 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 recorder, is fitted on the patient, no ECG will be recorded as there is no connection between the recorder and the ECG transmitter.

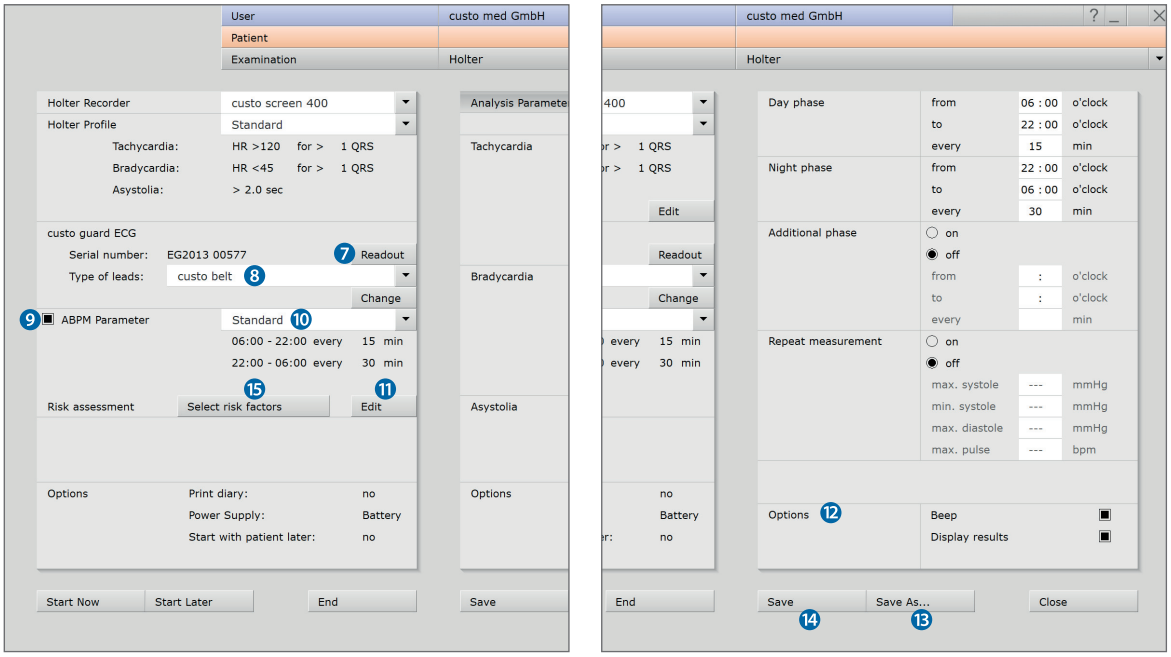
ABPM parameters for Holter ABPM

- Select the ABPM Parameter ❾ option [4)]
- Select a saved set of start parameters, e.g. Standard ❿ or create a new set (Edit ⓫).
- The options ⓬ have to be set as required:
  Beep: A signal is emitted before each measurement.
  Display results: The measured values are shown on the recorder display after each measurement.
- With Save as ⓭, the set parameters can be saved under a new name, with Save ⓮ they are overwritten.

4) If only a Holter is recorded, the ABPM parameters option must be deactivated (no further settings required).

If risk stratification[8)] is used, set the patient's risk factors here. Click on Select Risk Factors ⓯ and select the patient for whom you want to set the risk factors. The dialogue for entering risk factors opens. Click on Confirm to save your entry and close the dialogue.

5) Risk stratification is used to determine the 10-year risk of severe cardiovascular disease for the patient.



Starting a recording

- The switched-on recorder is located in front of the infrared interface.
- Click on Start now or Start later.

Workflow for "Start now"

Select patient

- Select a patient for the examination:
  Enter the patient's name into the input fields in the search mask ⑯.
- Select the patient from the list ⑰.
  Confirm your selection with Select Patient ⑱.
  You can also select the patient by double-clicking on the name.

New patient

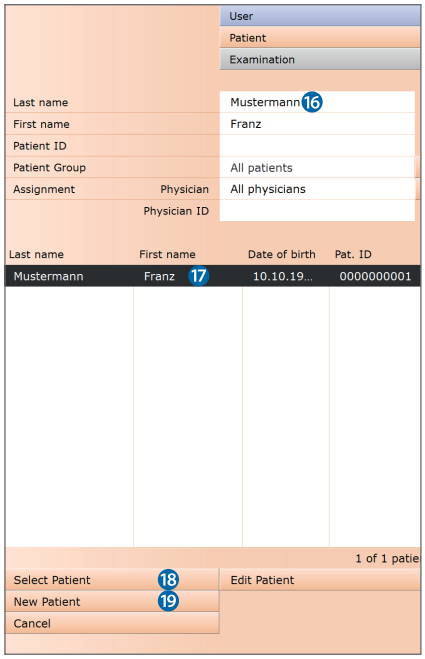
- If the patient does not yet exist in your database:
  Click on New Patient ⑲.
- Enter the patient data.
  The fields marked with an asterisk are mandatory.
- Save the data, the patient is entered into the database.

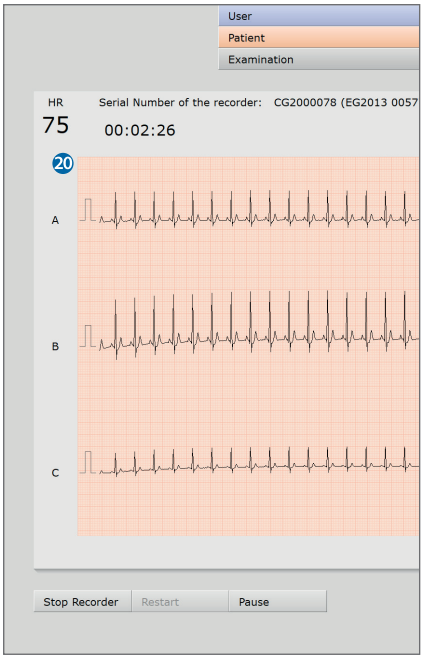
Data transmission and monitoring

- After the patient has been selected, the parameters and patient data are transmitted to the recorder. The Monitoring screen is opened ⑳.
- Fit the custo guard ECG transmitter on the patient and check the ECG signal on the Monitoring [6] screen.

Workflow for "Start later"

- Depending on the configuration, there is no need to select a patient.
  Switch off the recorder after the data have been transmitted.
  The devices must be stored together until they are fitted on the patient.
- To create a recording, fit the devices on the patient and switch on the recorder.





Tip for entries in the patient menu:

Press the tab key to move the cursor to the next input field.

6) For transmitting the ECG signal, the custo screen 400 recorder must be switched on and located in front of the infrared interface and the patient must not be more than 3 meters away from the recorder. Ensure that the line of sight between the ECG transmitter and the recorder is clear of obstructions.

A sample blood pressure measurement is only possible if the Monitoring screen is closed, there is no connection between the recorder and the PC and the SD card is ready prepared. If the SD card is still in preparation, the display will show a flashing "C" and it is incremented from 0 to 100 (process takes max. 2 minutes).

3.5.4 Starting a holter recording with custo watch

- Make sure that the custo docking station is connected to the PC.
- Place the custo watch and custo guard onto the custo docking station.
- Start custo diagnostic and select:
  Examination, Holter, New Holter.
- Select custo watch ❶ as the Holter recorder.

Holter parameters

- Select a set of Holter parameters, e.g. Standard ❷,
  or create a new set (Edit).
- The options ❸ have to be set as required:
  Print diary: Printout of the patient diary during the start procedure
  (to document events during recording).
  Start later with patient: Allows a patient to be selected
  when the recorder is started via the Start later button [1)].
- With Save as ❹, the set parameters can be saved under a
  new name, with Save ❺ they are overwritten.

1) Information on the Start later function without the selection of a patient:

If the Start later function is used without additionally selecting the Start later with patient option, no patient will be selected for recording. In this case, 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 a patient). Then remove the devices from the custo docking station. The recording does not start until the recorder is switched on again (briefly press the grey button to switch on the display and briefly press the grey button again to confirm the start request).

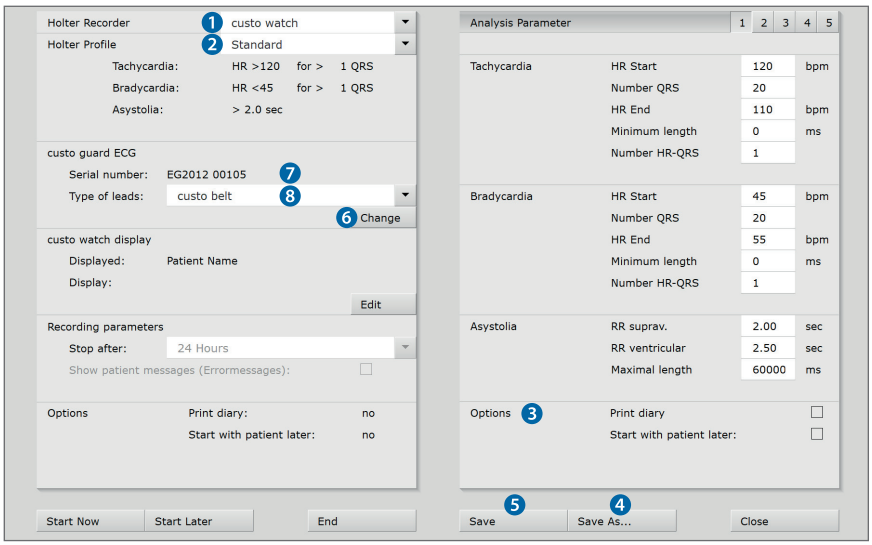
After the recording, when the recorder is received, the evaluation must be allocated to a patient immediately (download to custo diagnostic) or the device must be identified with patient data. Always ensure that patients are clearly allocated!

Connecting custo watch and custo guard to each other

If working with only one custo watch system or there is only one ECG transmitter, the devices only have to be connected during initial operation.

- In the "custo guard ECG" area, click on Change ❻.
- Enter the serial number of the custo guard ECG transmitter in the
  dialogue input field and click on Confirm.
- The serial numbers on the ECG transmitter and in custo diagnostic
  in the "custo guard ECG" area must match. During the start,
  the serial number of the ECG transmitter ❼ is transmitted to the custo watch [2)].
- Select the type of leads ❽:
  For recordings with an electrode belt: custo belt,
  for recordings with an ECG cable: ECG cable guard 3.

2) 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.



Defining the contents of the custo watch information line

- In the "custo watch display" area, click on Edit
- Select the content for the information line in the right half of the screen.
  The selection is transmitted to the custo watch during the start.

Starting a recording

- custo watch and custo guard are on the custo docking station.
- Click on Start now or Start later (both bottom left).

Workflow for "Start now"

Select patient

- Select a patient for the examination:
  Enter the patient's name into the input fields in the search mask 9.
- Select the patient from the list.
  Confirm your selection with Select Patient (below the list).
  You can also select the patient by double-clicking on the name.

New patient

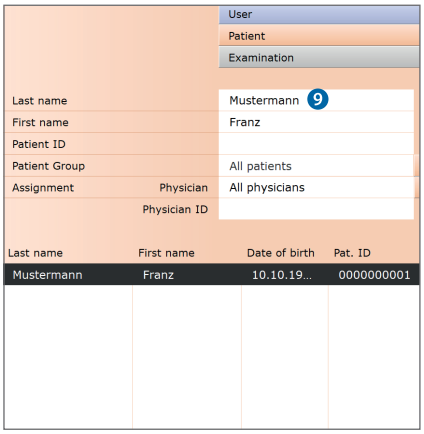
- If the patient does not yet exist in your database:
  Click on New Patient (below the list).
- Enter the patient data.
  The fields marked with an asterisk are mandatory.
- Save the data, the patient is entered into the database.

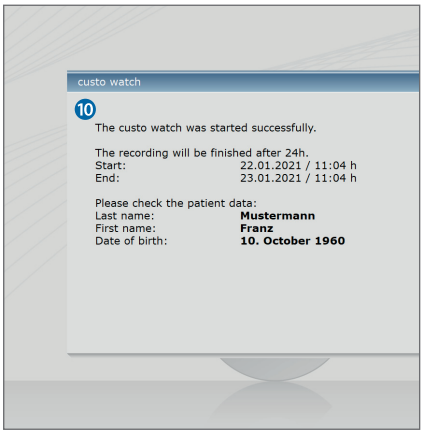
Data transmission

- After the patient has been selected, the parameters and patient data are transmitted to the custo watch. Confirm the message issued by the system 10.
- Follow the instructions on the custo watch display.
  Attach the devices to the patient.

Workflow for "Start later"

- Depending on the configuration, there is no need to select a patient.
  The devices must be stored together until they are fitted on the patient.
- Attach the devices to the patient.
- To start the recording, activate the custo watch display by briefly pressing the grey button. By pressing the button again, the start prompt appears. Follow the instructions.





Tip for entries in the patient menu:

Press the tab key to move the cursor to the next input field.

3.6 Downloading a Holter, showing the evaluation

Work steps after the Holter recording

- Remove the Holter recorder and all accessories (e.g. protective bags, carrying belt, electrodes, ...) from the patient.

- Connect the Holter recorder to the PC so that the recording can be downloaded:

  custo flash 5xx:

  Detach the rechargeable battery from the recorder using the release key.
  Remove the custo multiday card from the recorder [1)].
  Insert the custo multiday card into the USB card reader.

  custo guard holter:

  Clean and dry the custo guard holter.
  Place the custo guard holter device on the custo guard base [2)].

  custo screen 400:

  Switch off the recorder.
  Remove the custo flash card (SD card) [1)].
  Insert the custo flash card (SD card) into the USB card reader.

  custo watch:

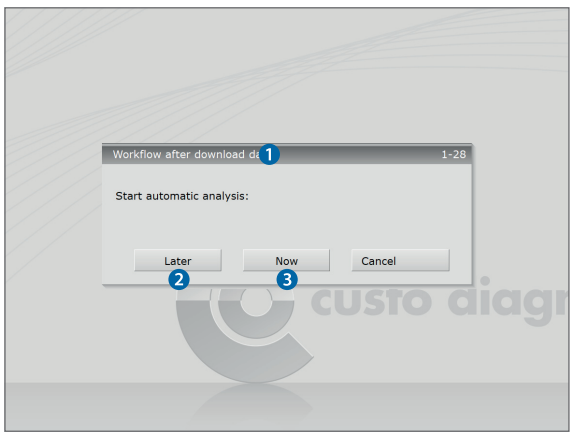
  Clean and dry the custo watch,
  place the custo watch onto the custo docking station [2)].

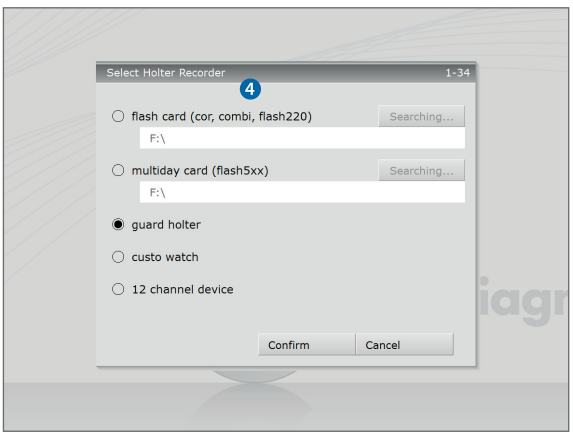
- Start custo diagnostic and select:
  Examination, Holter, Read in recorder.
- The "Workflow after download data" dialogue appears ❶.
  You can analyse and display the recording now or later.
  Later ❷ button:
  The recording is stored without analysis in the Job Manager [3)].
  Now ❸ button:
  The recording is evaluated during the download and then displayed.
- When using different holter devices, the "Select Holter Recorder" dialogue ❹ appears. Select the appropriate device type.

1) custo flash 5xx and custo screen 400:
To remove SD cards, press lightly on the edge of the card. Do NOT apply force to pull out the card!

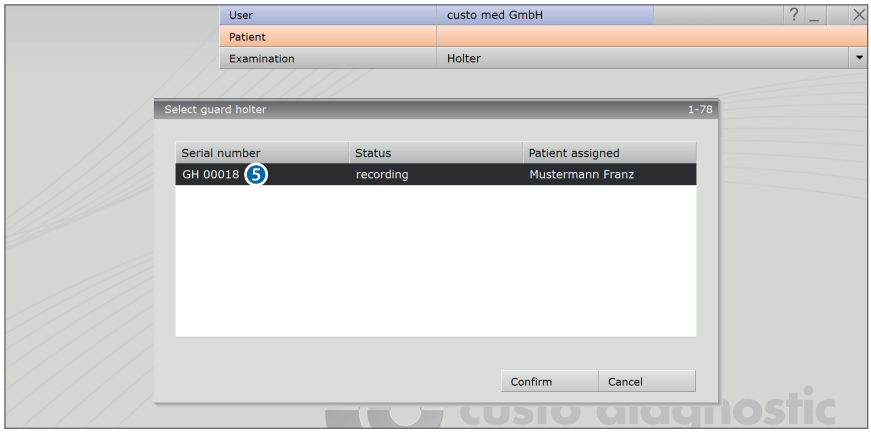
2) custo guard holter and custo watch:
No moisture (perspiration, disinfectants) must not get on/into the charging and communication units (custo guard base/custo docking station). Charging damp devices leads to oxidation of the electrical contacts.

3) The Job Manager is suitable for downloading several recorders in a short period of time.
To make available recordings from the Job Manager, open the Job Manager via the Examination main menu. Activate the Analysis option and start the process (Start). After the analysis, the recordings can be opened.





- custo guard holter:
  If the custo guard holter is selected as the device type, a dialogue for the selection of the custo guard holter device appears.
  The custo guard holter devices connected to the PC (USB via the custo guard base) are displayed in a list ❺. Select the custo guard holter device to read in via mouse click on the corresponding list entry. When the list entry is clicked, the battery LED of the custo guard holter device will flash for approx. 30 seconds (to check and identify the correct custo guard holter device). Confirm the selection.



- Recording without patient data:
  If the Holter device has been started without patient data, the recording must be assigned to a patient at this point.

- Additional optional dialogue:
  Other dialogue windows may follow depending on the device type/software version, for example "Evaluation Start Time" to check and correct the time period of the recording, or "Evaluation Start" to determine whether a recording is read in as a Holter ECG or as an event recorder[4)].

4) With the Event Recorder option, only the events in the recording are downloaded and analysed.

- The data is read in in custo diagnostic.
- If the recording is opened after it has been read in, it can be closed via End (bottom right). Click on Confirm in the End dialogue.

- For the next examination:
  Clean, disinfect and charge the devices.
  Observe "Part 4: Hygiene and Disinfection" of the operating manual.

3.7 Working with the evaluation

3.7.1 Opening an evaluation via the evaluation search

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

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

Configuring the list of search results

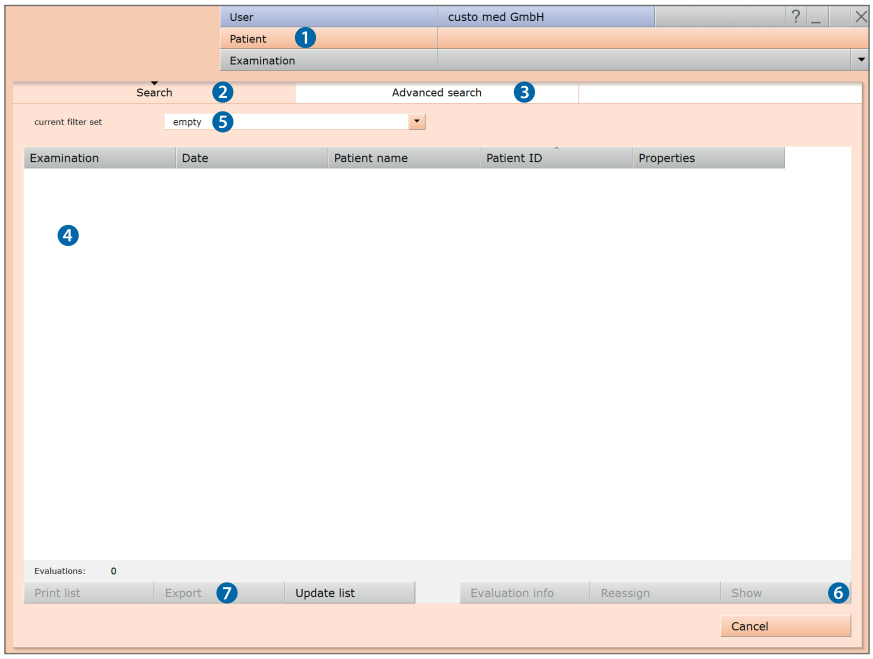
- Right-click on the screen to open the context menu.
  There click on Select columns and set the required columns.
  Click on Confirm to apply your changes.
- Clicking on a column header sorts by this column and sorting within the column can be reversed.
- The list can be printed and exported in various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

Renaming filter sets, deleting filter sets

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

Editing filter sets

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



Advanced search, creating filter sets

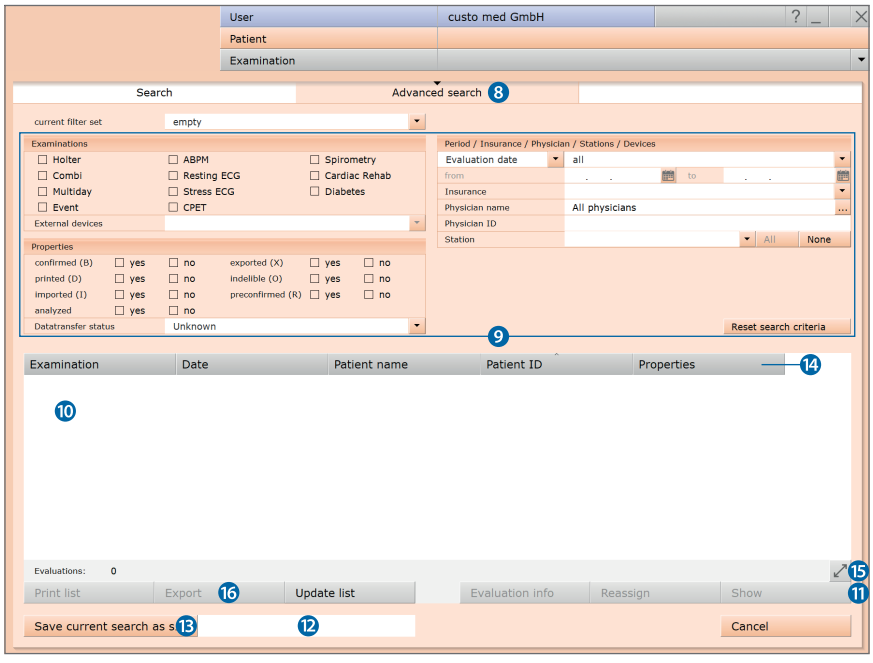
- The Advanced search screen ❽ is used for creating filter sets and for quick selection of search criteria (e.g. examination, properties, period) ❾.
  The search is limited by setting certain search criteria.
- The search results are displayed in the lower half of the screen as a list ❿.
- An evaluation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

Editing filter sets

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

Configuring the list of search results

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



Reference between the end dialogue and the evaluation search

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

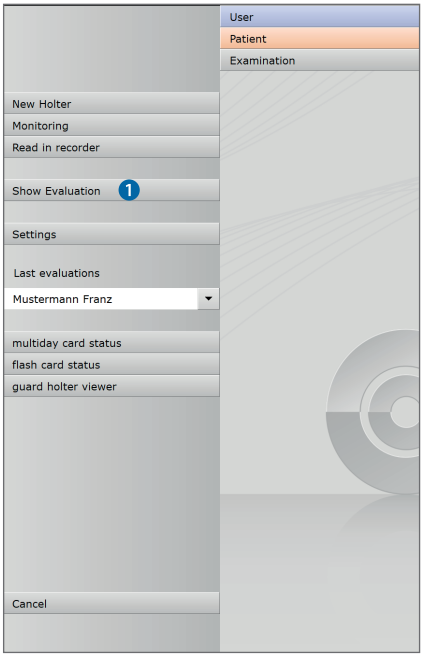
Example:
An evaluation can only be found in the evaluation search with the property confirmed "No" if the status "Evaluation confirmed" is NOT selected in the end dialogue.

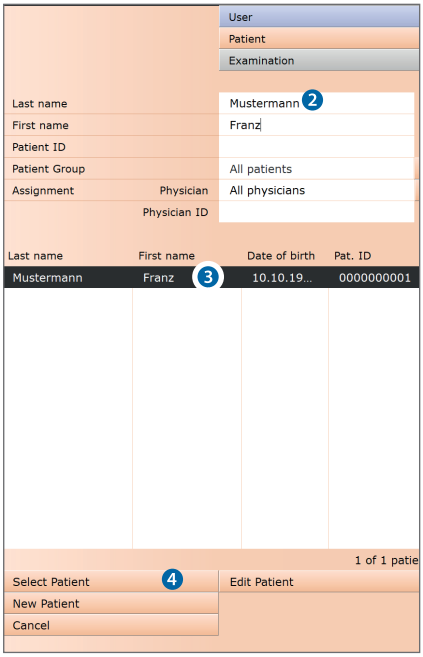
3.7.2 Opening an evaluation via the examination main menu

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

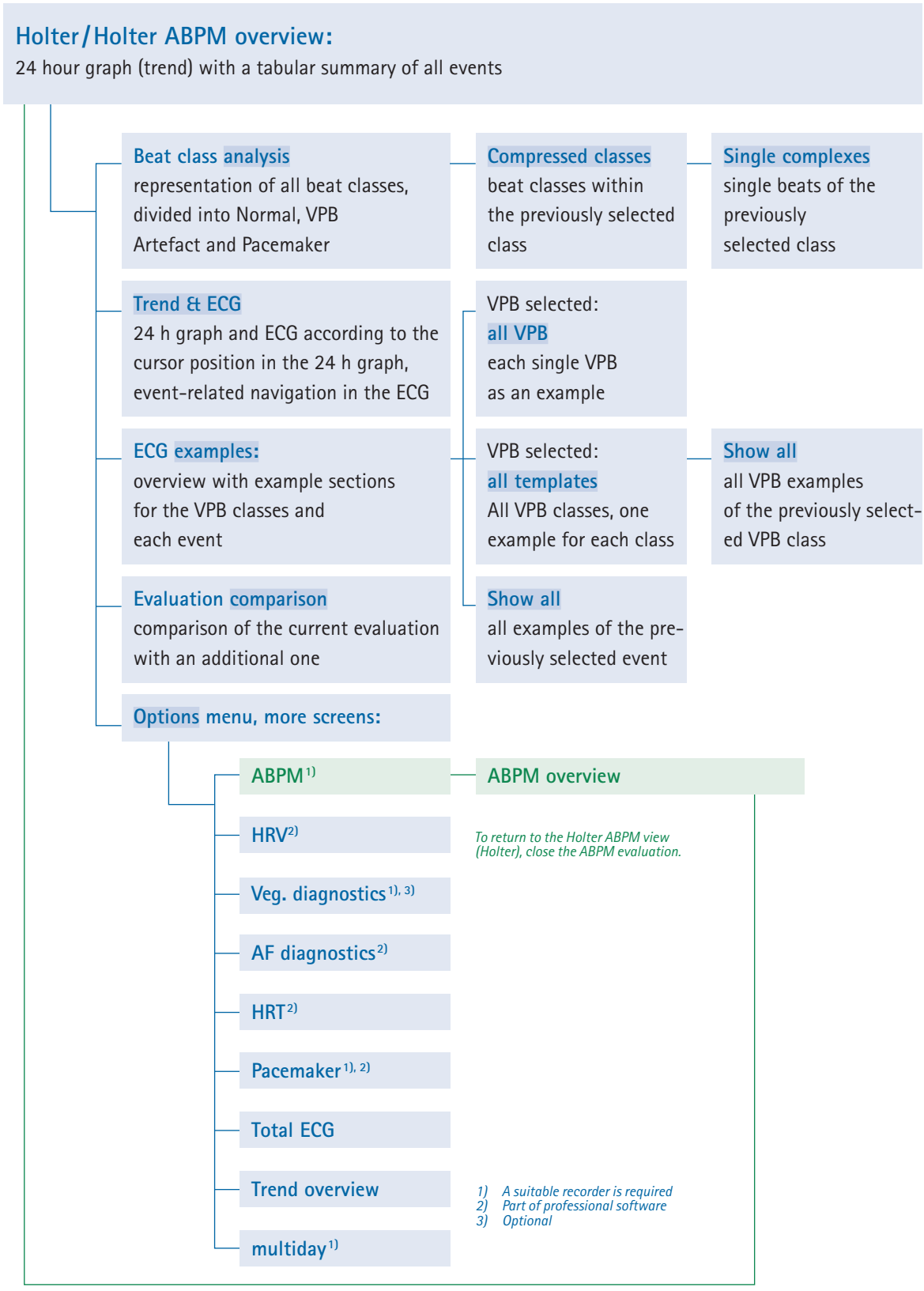
Tip for entries in the patient menu:

Press the tab key to move the cursor to the next input field.





3.7.3 Structure of the evaluation



Possible workflow for writing the report for an evaluation: Getting to the report in five steps

1

Holter overview screen:
Check quality and rhythm,
exclude ECG (Options, Exclusion)

2

Analysis screen:
Check, rename, summarise
templates/beat classes (N/V/A) ...

3

Examples screen:
Check, rename, summarise events ...

4

Context menu, Report:
Input using text modules
(one-time configuration under
Holter, Settings, Diagnostics, Report)

5

Printout:
via Print or Options, Print...
(one-time configuration under
Holter, Settings, Print, Print pages)

3.7.4 Holter evaluation screens and functions

Some functions or elements in the custo diagnostic Holter are dependent on certain conditions such as the recording device or software version. The corresponding functions are marked in the text at the beginning of the line with the applicable abbreviation.

- f5xx Only applies for the custo flash 5xx series (500/510/510V)
- f500 Only applies for custo flash 500 devices
- f510 Only applies for custo flash 510 devices
- f510V Only applies for custo flash 510V devices
- gh Only applies for custo guard holter devices
- s Only applies for custo screen 400 devices
- w Only applies for custo watch
- EDAN Only applies for custo EDAN SE-2012 devices (12-channel holter recorders)
- p Only included in the "Professional" software version
- o Additional optional function

Or see *chapter 3.2, Overview of Holter software and recorders*.

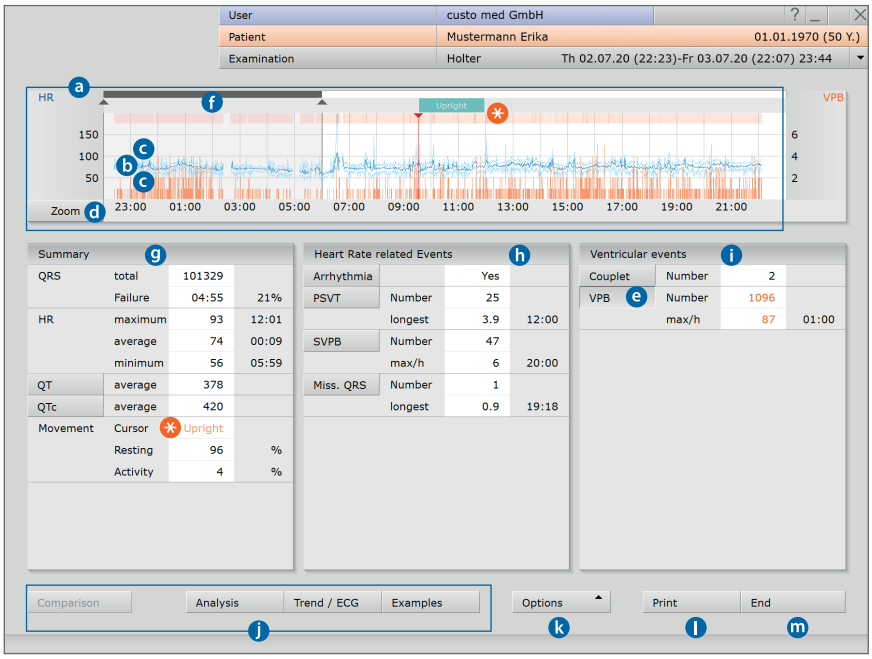
3.7.4.1 Holter overview

- a 24 hour graph (trend)
- gh w * Movement data (e.g. upright, rest (right), rest (back), walking, ...)
- 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 values within a minute
- d Zoom: one hour of the graph enlarged (30 min. before and after the cursor)
- e Selected event – button is pressed, orange font.
  A selected event is displayed in the form of vertical orange lines, at the top, in the trend a. The height of the lines in combination with the scale on the right-hand side of the screen provides information on the number of occurrences within a minute.
- f Night phase – can be adapted by clicking and dragging the grey arrows
- g Summary with the number of all cardiac activities, overview of HR
- h List of the existing heart rate-related events[1)]
- i List of the existing ventricular events[1)]
- j Buttons for opening additional evaluation pages

f500 f510 f510V gh w If the recording is over multiple days (longer than 24 hours and up to a maximum of 3 or 7 days), two arrows for scrolling through the recorded days are displayed to the left of the Analysis button.

- k Options menu with additional evaluation pages and editing functions
- l Printout as per system settings
- m Button for closing the evaluation

1) 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.



Tips on navigation

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

In the tables:
By double-clicking on any Event button you can open the Trend/ECG 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.

3.7.4.2 Context menu

The context menu is opened by right-clicking on the evaluation. The contents of the context menu vary according to the evaluation page.

The report dialogue is always accessible via the context menu.

In the Overview you can manually insert events via Change if you should find events which were not detected by the program. 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.

The Select Time function allows you to select specific time points in the Analysis, Trend/ECG and Total ECG screens. These are stored in the dialogue with the "Select Time" designation and are always available..

3.7.4.3 Options Menu

The contents of the Options menu can vary depending on the evaluation screen. The Print, Export, Total ECG, Trend Overview and Service functions are available on every evaluation screen. Other functions or evaluation screens are available depending on the recording device and software version:

- Print...
  Temporary change of print settings for the current evaluation
- Export...
  The evaluation is exported in Excel and PDF format

s
- ABPM (Ambulatory Blood Pressure Measurement)
  Combined Holter ECG and ABPM recording,
  either via custo screen 400 or via simultaneous use of a
  custo med holter ECG device and an ABPM recorder.

p
- RR variability (heart rate variability/HRV)
  Graphic display of the heart rate variability.

o
- ANS diagnostics (autonomous nervous system)

f510V gh s w
  Overview of the autonomous nervous system balance with graphic display of stress and regeneration phases.

p
- AF diagnostics (atrial fibrillation)
  Detection of atrial fibrillation and atrial flutters.

p
- HRT (Heart Rate Turbulence)
  Graphic display of the Heart Rate Turbulence (physiological, biphasic response of the sinus node to ventricular extrasystoles).

p
- Pacemaker

f510 f510V gh
  Holter ECG recordings with pacemaker impulse detection for patients with pacemakers.

f500 f510 f510V
- Multiday (summary of multi-day recordings)

gh w
Multi-day recordings with custo flash 500/510/510V (up to 7 day) or custo guard holter or custo watch (up to 3 days).

p
- ST-Analysis
- Total ECG

  Fullscreen ECG display, view of the complete recording.
- Trend overview

  Graphic display of all heart-rate-related and ventricular events over the entire recording period.
- 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
- Exclusion

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

  Setting pages for changing the analysis parameters of the respective area
- CSV export

  ECG and RR values can be exported separately as a .csv file
- Assign new

  The evaluation can be assigned to another patient
- Service

  Technical details relating to the recorder and recording

Note on applying or resetting changed parameters

Clicking on the Analysis button (at the bottom of the screen) applies the settings and the ECG is analysed again, taking your changes into account.
With the End button you leave the parameter setting page and changes are not taken into account. The Set factory settings button can be used to restore the default settings. This applies to all parameter setting pages in the Holter evaluation.

3.7.4.4 Analysis

On the Analysis page, you can check, summarise and reassign the beat classes of the recording. All the recorded QRS complexes are summarised in beat classes. The method for calculating the beat classes or their accuracy is defined in the settings[1].

- 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)
- If applicable, button for showing the pacemaker classes (P)
- d Occurrences of the selected class are marked in colour in the ECG
- e Marking/saving of changes for analysis
- f Display of all classes or beats of the selected class
- g Scroll forward in steps
- h Scrollbar for navigating through the entire recording;
  ⏮ ⏭ = go to the next single complex, ◂ ▸ = continuous scrolling

Labelling of classes

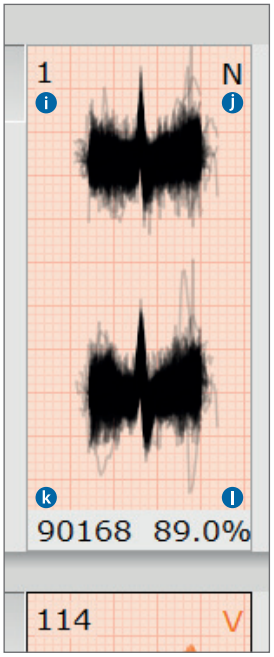
- i Numbering of the class (numbered in ascending order)
- j Annotation: Normal (N), VPB (V), Artefact (A) or Pacemaker (P)
- k Number of single complexes in the class
- l Percentage relative to the number of all the recorded QRS complexes

1) custo diagnostic settings for beat classes in the holter:
To define the number of beat classes in an evaluation, open the following page: Examination, Holter, Settings, Diagnostics, Analysis, Beat Identification. In the "Compress templates for analysis" area, the following options are available:

Disabled: no compression.
Compress: The beat classes are compressed according to the set sensitivity (default "4").
Autocompress: With this option, the beat classes are reduced until either a sensitivity has been reached for which there is no change compared to the previous value or until fewer than 30 classes has been reached.

Tip on checking the beat classes:
The QRS complexes of a beat class can be displayed as an overlaid image. This means that all QRS complexes belonging to a class are superimposed and deviations within a class can be quickly identified.
If the central complex is clearly mapped and without deviations, the QRS complexes of the class match.

If many deviations can be identified, the sensitivity of the beat class analysis may have to be adjusted.
Superimpose function on/off: Examination, Holter, Settings, Menu/Functions, Workflow, Option Show template superimposition.



Editing options on the Analysis page

Display and editing levels:

- Analysis screen: all beat classes of the evaluation
- Compressed class: selected class with assigned classes
- Single complexes: single beats of the previously selected class

The individual levels are opened by double-clicking on a class or using the Show all button. Use Back to return to the previous level.

Selection of several beat classes for further processing:

- Keep the left mouse button pressed and drag it or
  Shift + left-click =
  selection of several classes next to each other (area)
- Ctrl + left-click = specific selection of several classes

Summarising or moving several classes

If several classes are selected, a...

- ... left-click on the numbering (number at the top left) of any class in the selection summarises all selected classes in the class with the lowest numbering.
- ... left-click on the annotation (N/V/A/P) moves all selected classes to the corresponding category.

Summarising or moving individual classes

- A left-click on the numbering (number at the top left) opens the dialogue for "Merging templates". Here you can define a new target for the previously selected class.
- A left-click on the annotation (N/V/A/P) changes the assignment, alternatively enter the letter using the keyboard.

Moving single complexes of a beat class

For this step, the lowest navigation level of a beat class must be open (double-click on a class and its subclasses or use the Show all button repeatedly).
By double-clicking on the beat numbering of an single beat, e.g. #1, you can open the dialogue for moving single complexes. The selected beat (source) can be assigned to another class (target).

Applying changes

The OK button (top right in the Analysis overview) is used to mark the changes made so far. By selecting Options, New analysis, the ECG will be recalculated taking into account the changes. If the new analysis is not triggered manually, it is triggered automatically when another screen page is called. Click on Confirm to start the process. With Cancel the changes are discarded.

3.7.4.5 Trend/ECG

- a Trend (24 hour graph) with Zoom function
- gh w * Movement data (e.g. upright, rest (right), rest (back), walking, ...)
- 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 the selected event is marked with 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; the selected tool can be used in the ECG[1)].
- 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

By dragging the scrollbar across the entire length of the recording, you can quickly detect 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. When you click on the ◀ ▶ buttons, the ECG is shown constantly over the screen.

1) *Explanations of the mouse functions*

Measuring RR intervals
When you click in the ECG signal, a line appears, the starting point of the 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
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.

3.7.4.6 Examples

- **a** Sample preview with an ECG example for every event
- **b** Additional information about the selected example. Selected by mouse click. The header of the selected example has a black background.
- **c** Deletes the selected example [1)]

To view and edit the examples in detail:

- **d** all VPB: display of all VPB examples of the evaluation
- **e** all templates: Examples of all VPB classes
  or Show all: All examples of an event class

1) Editing, deleting and restoring examples
After you Delete examples, the undo function is available for restoring deleted examples.
By selecting Options, Edited examples, you can display all the previously deleted examples and restore them from this page (undo). You can delete all the examples of an event at once (Delete all) in the lower navigation levels in the example preview.

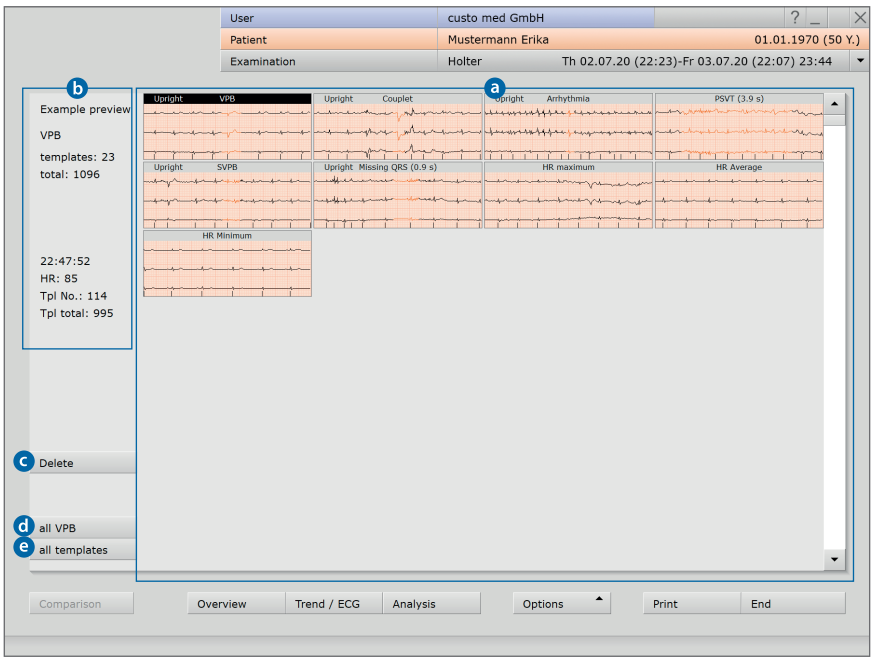
Considering ECG examples in context

The examples can be viewed either on the Trend/ECG page or in the ECG environment in context, i.e. in the ECG recording [2)]. This is done by double-clicking on an example. Additionally opening the ECG recording is only possible on the lowest navigation level in the example area – which can be reached by selecting Example Preview, Select Example and clicking on all VPB or Show all, depending on whether a VPB or another event was selected (alternatively, double-click on an example to navigate in depth). The Example preview button opens the higher-level screen page again.

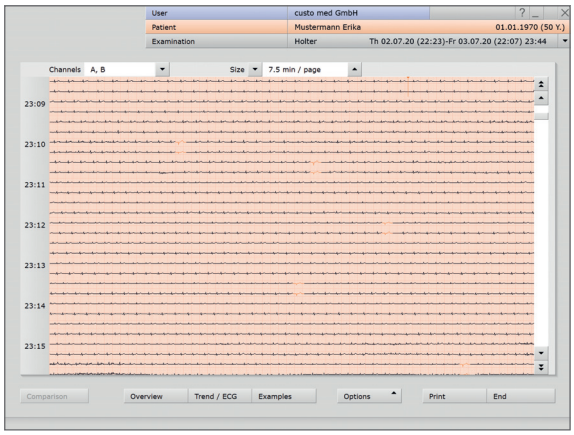
2) custo diagnostic can be set so that instead of the Trend/ECG page, the ECG environment dialogue is displayed when double-clicking on an example. The difference with this setting is that the Example Preview page remains open, while the ECG example is considered in context. To activate the ECG environment dialogue, open the context menu and click there on Properties. 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. Click on Confirm to apply the changes.

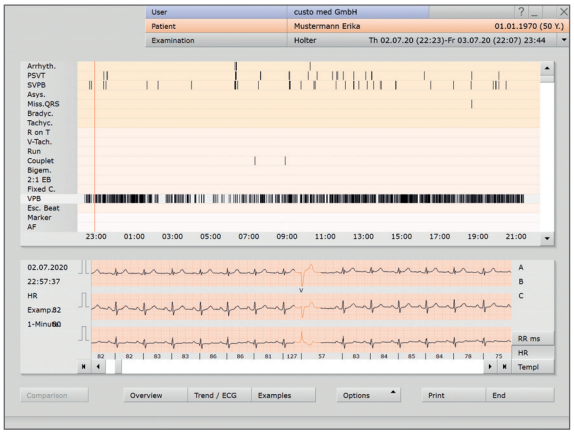


3.7.4.7 Additional standard functions: Comparison, Total ECG, Trend Overview, multiday, Holter ABPM

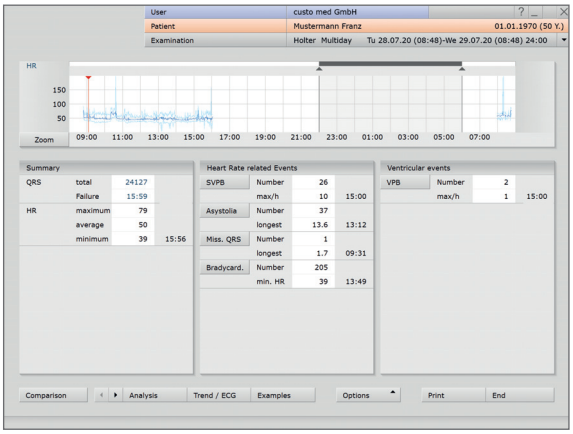


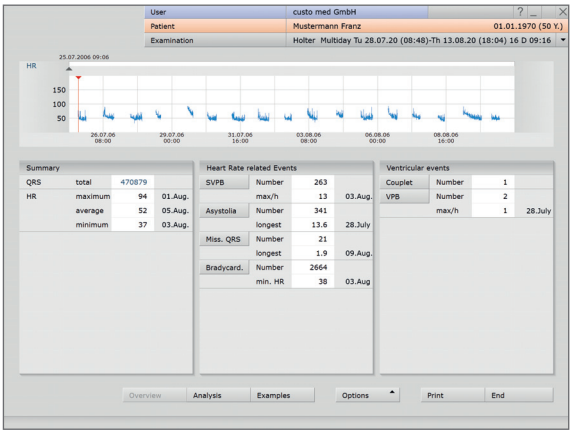
Comparison (button always bottom left) of two patient evaluations each with trend, HR summary and events.
By clicking on an Event button, the event is displayed in the graphic.
The Date lines above the tables can be opened with a mouse click to display other evaluations of the patient.

Total ECG (Options menu, Total ECG):
Minimised representation of the entire recording.
To mark ECG sections, drag the cursor over the ECG.
When you release the mouse button, a dialogue opens for further editing of the selection.
By clicking on the double arrow buttons, the ECG automatically runs in the corresponding direction, clicking again = increased speed.



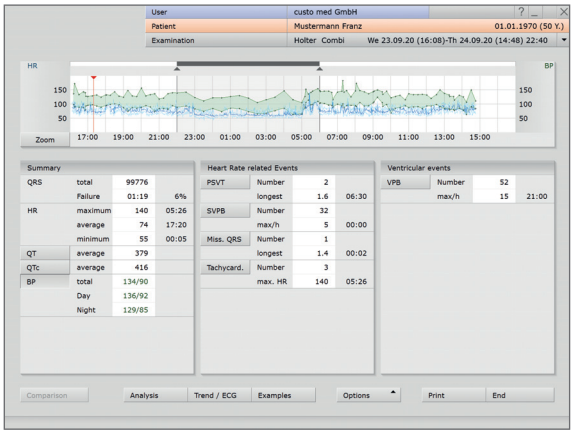
Trend Overview (Options menu, Trend Overview):
An interactive table detailing all events over the entire recording period and ECG in relation to the cursor position in the table.
Each event is represented in the form of a black line in the table. Click on the black lines to display the corresponding position in the ECG.

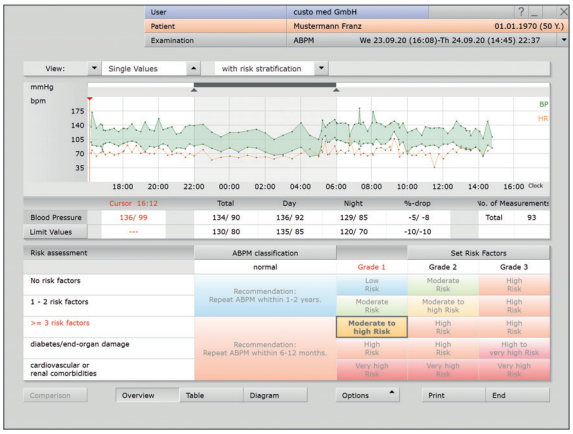




f500 f510 f510V gh w *A multiday evaluation is an evaluation over several days. When you open a multiday evaluation, the previously selected recording day is displayed.*
The multiday summary (overview of all recording days) is opened via Option, multiday. The arrow buttons to the left of the Analysis button can be used to scroll within the recorded days.

multiday summary with a graphical overview of all recording days and tabular summary of all values and events for the entire recording period.
In the graphic above, individual days can be selected with the cursor. Double-click to display the corresponding day as an evaluation.





s *Holter ABPM evaluation [1] with custo screen 400.*
The Blood Pressure (BP) button in the summary displays the blood pressure curve in green in the trend.
The ABPM evaluation is opened via Options, ABPM.

ABPM evaluation
(with risk stratification – professional version):
To open the unconfirmed report, right-click on the evaluation interface. In the context menu, select Report. The ABPM unconfirmed report is automatically transferred to the Holter ABPM view when you exit the ABPM evaluation.

1) A Holter ABPM recording can also be performed with a separate Holter recorder and a AMPM recorder. If you perform a ABPM recording in addition to the Holter recording, you can open both recordings as a combination evaluation in custo diagnostic (time offset < 12 h).

3.7.4.8 Professional functions: HRV, AF Diagnostics, Pacemaker

P HRV – Heart Rate Variability (Options, HRV)

- ⓐ Graphic representation of HRV (view: 24 hours)
- ⓑ Buttons for showing the HRV for 24h, day, night, 1 hour
- ⓒ ECG matching the cursor position in the graph above, the currently selected RR interval from the histogram is displayed
- ⓓ Mouse functions for editing the ECG
- ⓔ Tabular summary with values for HRV[1)], e.g. number of RR, SD, SDANN5, SD5, pNN50, RMSSD, Triang. Index
- ⓕ Shows additional graphics: SDNN5, ANN5, rMSSD, pNN50, FFT (Diagram 1 stands for the top graphics; diagram 2 for the bottom graphics)
- ⓖ Opens the scatter diagram[2)] (Lorenz plot)

FFT graphic (select FFT in the area ⓕ and Table ⓔ):

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
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

1) Values for HRV:

NN intervals:
Time between heartbeats (normal to normal)

SD
Standard deviation

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

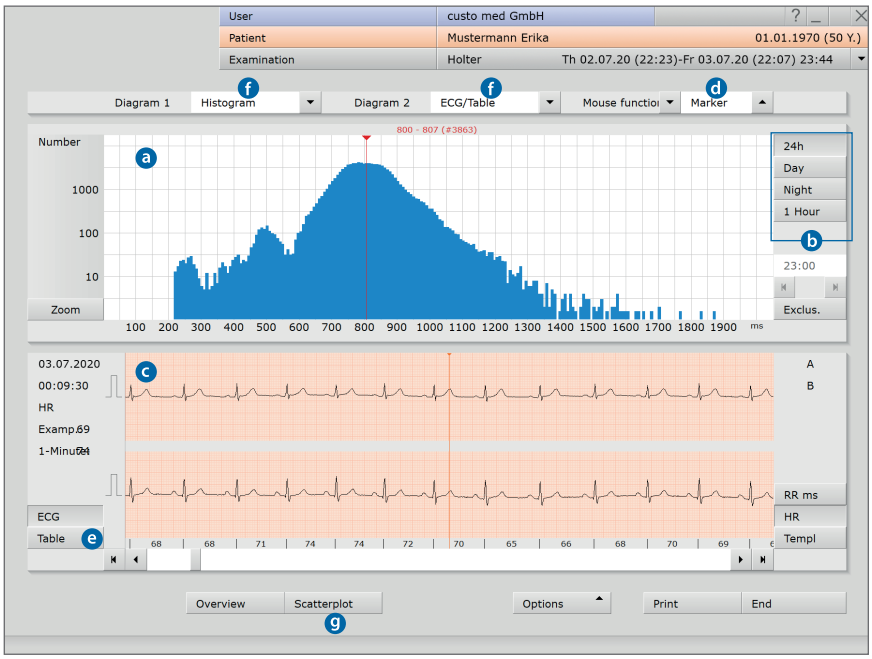
ANN5
Mean value of the NN intervals in the 5 minute intervals within the defined period

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

2) The scatter diagram provides information on the HRV of a patient. If the scatter diagram has a club shape, it indicates a sinus rhythm. Other shapes indicate arrhythmias.



AF Diagnostics (Options, AF Diagnostics)

AF diagnostics is used for conclusive and reliable detection of atrial fibrillation and atrial flutter. Detection is based on P wave diagnostics and rhythm analysis. The path to obtaining conclusive AF diagnostics consists of five steps, the first three of which are for identification and the last two for verification.

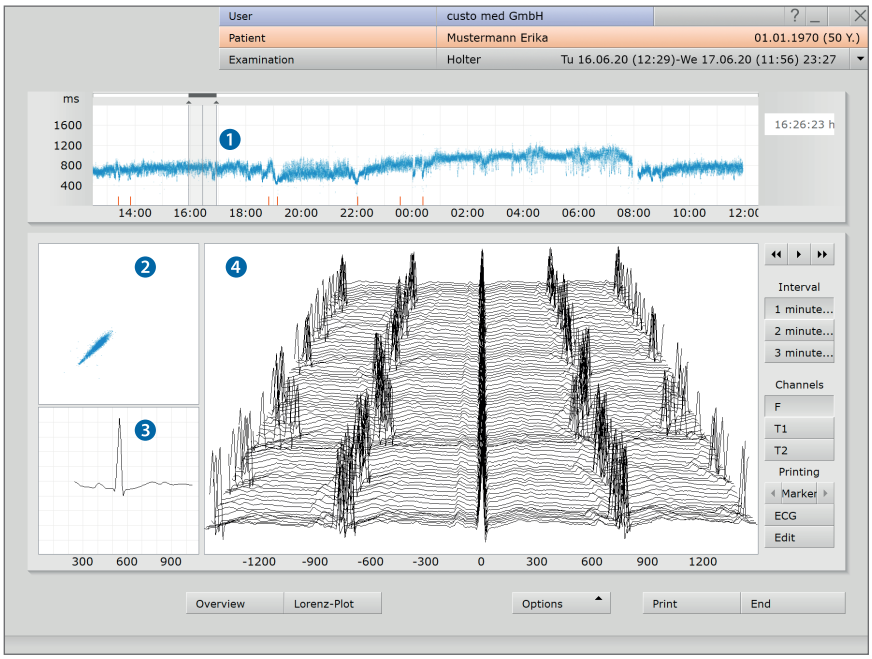
Identification

1. In the RR trend, high-frequency areas that may deviate from the sinus rhythm are clearly identifiable. They can be selected by mouse click.
2. A glance at the Lorenz plot shows whether sinus rhythm ("cigar shape"), rhythm disturbance (e.g. VPB, then "butterfly shape") or atrial fibrillation (diffuse "point cloud") may be present.
3. The cumulative complex shows whether a P wave is present or not.

Verification

4. In the relief ECG, the onset of a paroxysmal fibrillation episode, for example, can be detected easily and quickly.
   Double-clicking on the ECG curve opens the original ECG.

➤ The original ECG allows conclusive assessment.
Use the arrow keys to move forwards or backwards in the ECG.
Use the F2 key to open the marking dialogue.

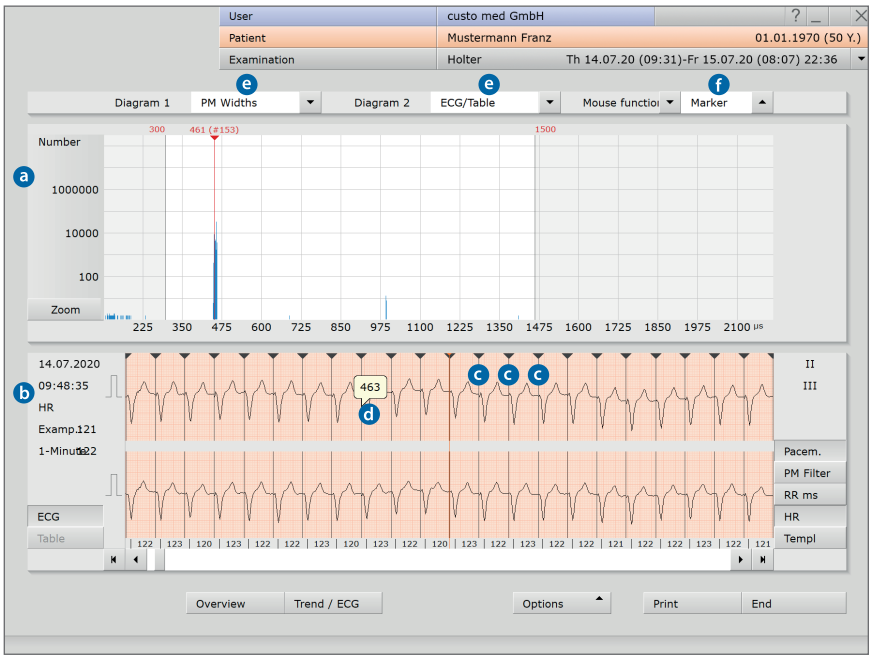


p Pacemaker analysis (Options, Pacemaker)

f510 f510V gh You can open the Pacemaker analysis page via the Options menu with the Pacemaker button or by clicking on the number of pacemaker beats on the evaluation overview page.

- a Graphic representation of the pulse widths during the recording
- b ECG section (matching the cursor position in the graphic)
- c Pacemaker pulses (black lines)
- d Display of the pulse width with the mouse positioned over the pacemaker pulse line
- e Selection of further pacemaker graphics
- f Mouse functions for use in the ECG (Mark, Change, Measure, Time)
- ➤ Change the pacemaker parameters via Options, Parameters

Tip: To reduce the display of interfering pulses, set the pacemaker width according to the specifications in the patient's pacemaker record.



3.7.4.9 Optional functions: ANS diagnostics, 12-channel evaluation

o **ANS diagnostics (Options menu, ANS diagnostics)**

f510V gh s w ANS diagnostics provides an overview of the balance of the autonomic nervous system. Stress and regeneration phases are displayed graphically. The trend (graph above) also shows the movement data.

a Chronocardiogram with spectral analysis of HRV, based on 24 h
horizontal: time axis (h), vertical: frequency axis in Hertz (Hz)

The frequency ranges show the dynamics of various vegetative-mediated activities, such as blood flow rhythm, blood pressure variability, respiration and others. The colours indicate the intensity of the degree of the respective vegetative activities: red = very high, white/yellow = weak and blue = virtually no effect.

b Distribution of the stress and regeneration phases during the recording, shows stress and regeneration phases[1)]

c Drop-down menu for opening the variability/vagal activity diagram
Standard deviation from the average heartbeat (purple band)
and a representation of the decadic logarithm of the respiratory sinus arrhythmia (light blue band).

d Measured value table[2)]

1) The relationship between the two areas of influence during the night can be interpreted as a measure of sleep quality.

*2) Values for the heart rate, the standard deviation from normal beats, the logarithm of the respiratory sinus arrhythmia, the natural logarithm of the "very low/low/high frequency" and the autonomic quotient of LF/HF.
For these areas, the average values and the normal range are indicated – once within 24 hours – and also as a wake and sleep phase.*

EDAN o 12-channel evaluation

A 12-channel Holter recording is only possible with a suitable Holter recording device (custo med EDAN SE-2012).

The 12-channel Holter is opened either via the Evaluation search or the Holter main menu (Examination, Holter, Show Evaluation, ...).

Trend/ECG screen with 12-channel ECG:

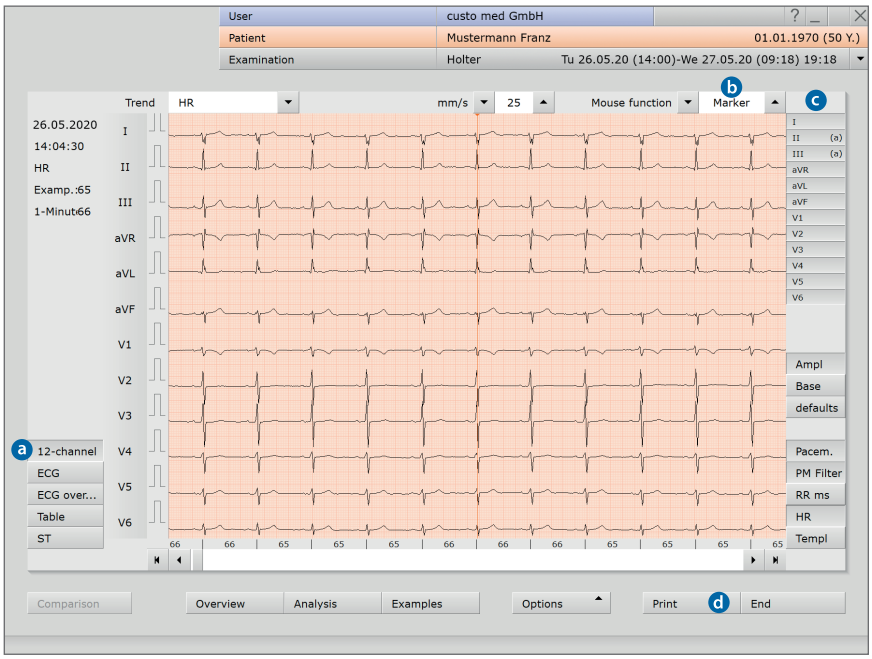
- a Display of the 12-channel ECG
- b Mouse functions Mark, Change, Time or Measure; the selected tool can be used in the ECG[1)].
- c Use the buttons for the different channels to view all the channels of the 12-channel evaluation individually.
- d Select Options, Print (print settings) to individually configure the printout of a 12-channel Holter evaluation.

1) Explanations of the mouse functions

Measuring RR intervals
When you click in the ECG signal, a line appears, the starting point of the 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
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.



3.7.5 Printing the evaluation

Alternative ways to create a printout:

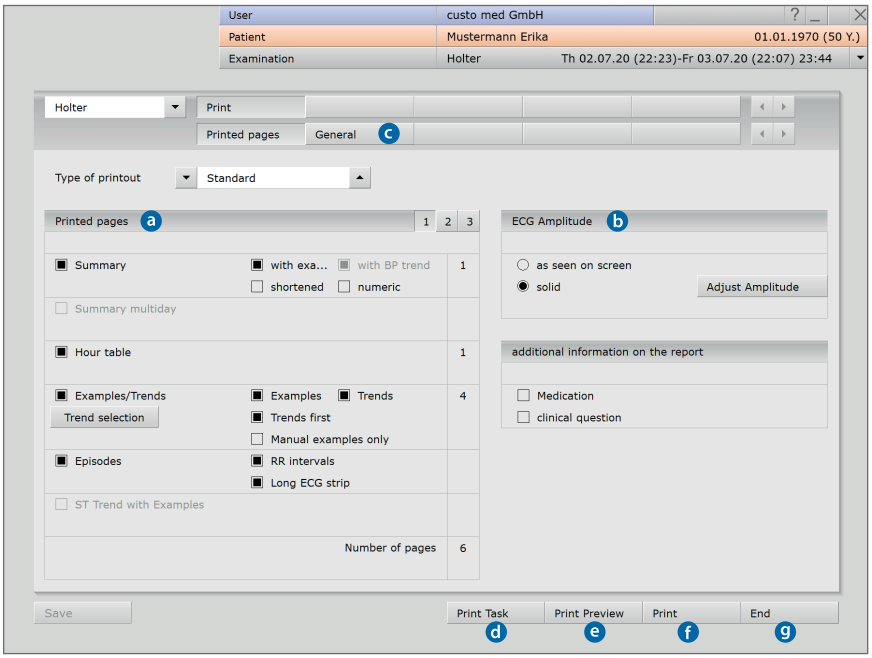
- Printout in accordance with the system settings with the Print button
- Individually compiled print pages for the current printout, via Options, Print... (the settings are not applied permanently)
- Collection of print tasks in the Job Manager for subsequent batch processing [1)]

1) To execute print tasks saved in the Job Manager, click on Examination, Job Manager, Execute or Execute All.

Options menu, Print... screen

- a Compiling the contents
- b Amplitude size of the ECG signal in the printout
- c Selecting and setting the printer on the General page
- d Button for saving the print task in the Job 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 evaluations can be found under Examination, Holter, Settings, Print.
To apply changes to the system settings, click on Save.



3.7.6 Confirming the evaluation

Unconfirmed report and report

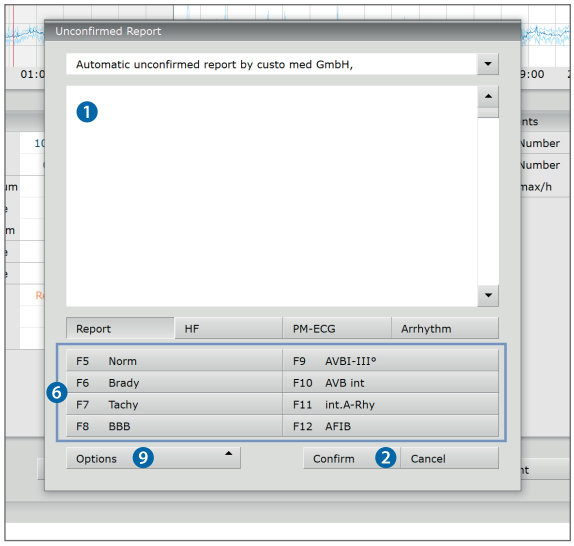
To open the unconfirmed report, right-click on the evaluation interface. In the context menu, select Report. Enter your data in the text field ❶. If the Unconfirmed report or Interpretation option is selected in the system settings, an automatic system unconfirmed report is already present in the text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

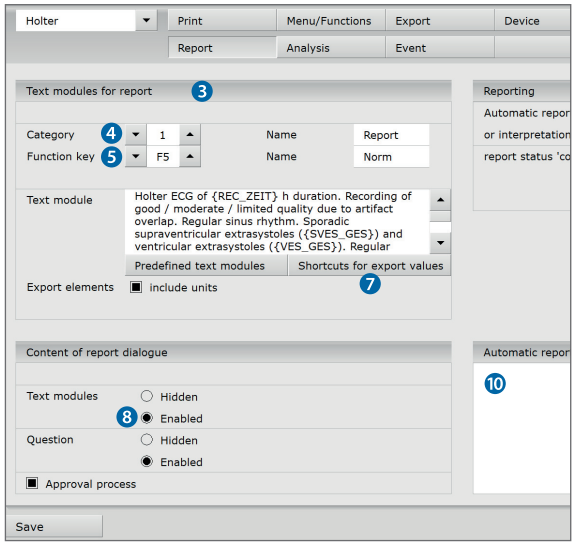
Text modules – an aid for writing reports

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) ❻.

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

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





3.7.7 Ending the evaluation

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

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

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

❹ Printed: indicates if the evaluation has been printed.

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

Click on Confirm ❻ to close the evaluation.

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

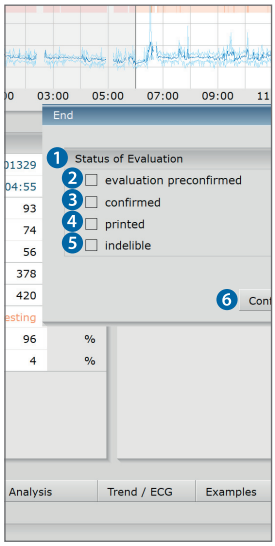
3.7.8 Optional: Reporting with approval process

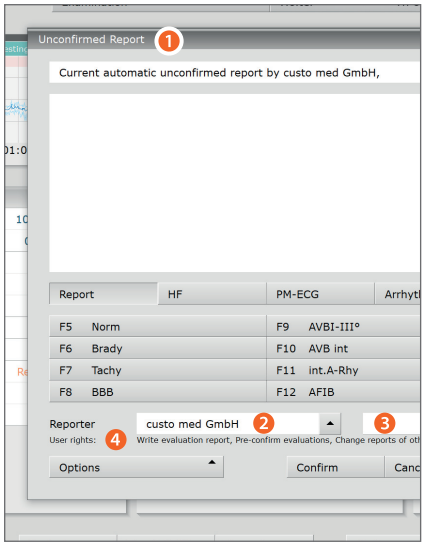
If custo diagnostic is used with approval process, then authorised persons with the corresponding user rights can save pre-reports of other persons as a report, without having to close the evaluation which was opened previously (shortened workflow) or enter pre-reports/reports directly if the evaluation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

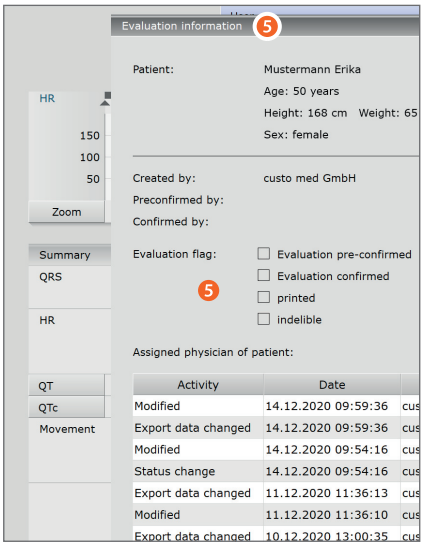
The approval process is visible in the unconfirmed report dialogue ❶ of an evaluation. The user or reporter can be changed there (User name ❷, Password ❸, Enter). During the logon process, the user rights of the respective user are checked and the software interface is adapted accordingly ❹. The reporting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

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

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



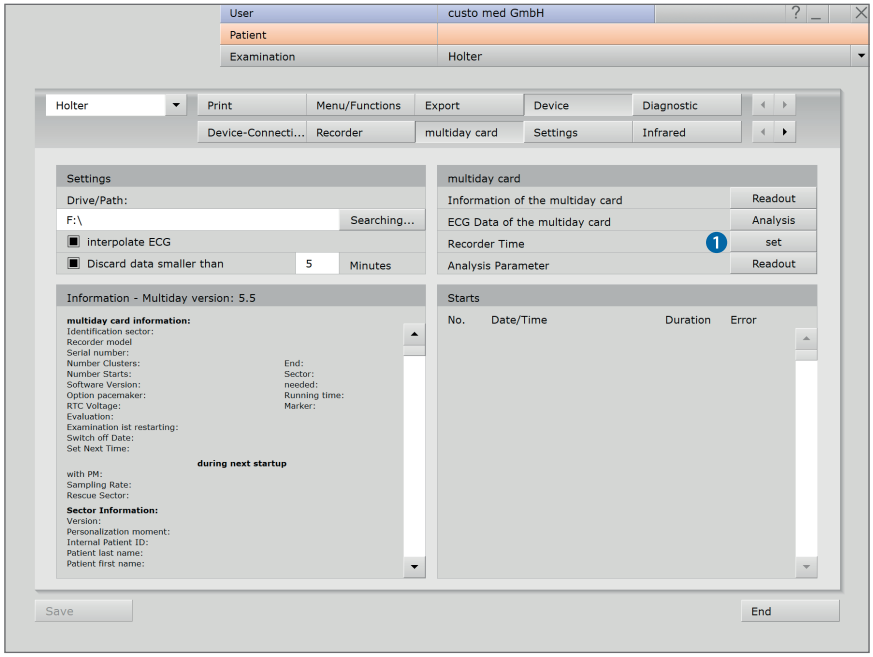




3.8 Appendix

3.8.1 Setting the custo flash 5xx recorder time

custo flash 5xx has a pre-set real time clock. custo diagnostic informs you by a message when the time needs to be readjusted (approx. every six months).
Ensure that the system time of your computer is properly set as this is used for custo flash 5xx.
To adjust the time, in custo diagnostic, open the Examination, Holter, Settings, Device, multiday card page. In the multiday card area, click on the set ❶ recorder time button. The time is set in four steps. The program provides you with specific instructions.



3.8.2 Calculation methods in the Holter

Method for calculating the heart rate

custo diagnostic 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

If the "HR max. linked with Tachycardia/VT" option is activated (context menu, Properties), 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 (context menu, Properties), the heart rate of the bradycardia is used for the "HR min" calculation if its heart rate is the lowest.

Method for determining a heart action break

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), the custo Holter software shows this break as an asystole. The asystole must be shorter than 60 s.

All values can be adjusted in the custo Holter software. The values used here correspond to the factory settings.

Information for changing the ST segment

ST segment analysis takes place on two analysed leads. 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 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, the custo Holter software 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 zones are constantly recorded and are available at all times. Areas of displacement and slope values are not recorded.

1) Note on the designation of the ECG derivations: Depending on the recording device and electrode application system, the derivations are named differently in custo diagnostic

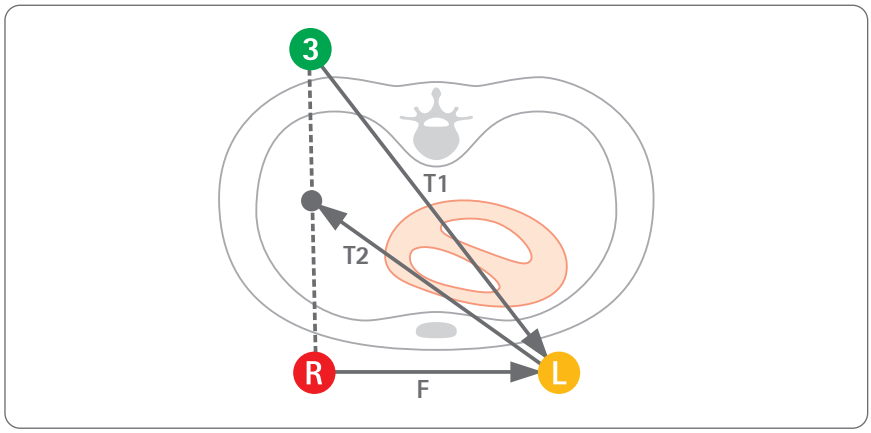
custo flash 5xx ..... I, II, III

custo guard holter...
with custo wing .....A, B, C
with ECG cable guard 4 .....A, B, C
with ECG cable guard 3 ..... I, II, III
with custo belt ..... F, T1, T2

custo screen 400...
with custo belt..... F, T1, T2
with ECG cable guard 3 .....A, B, C

custo watch...
with custo belt ..... F, T1, T2
with ECG cable guard 3 .....A, B, C

3.8.3 ECG derivations for custo belt 3



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 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 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)

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

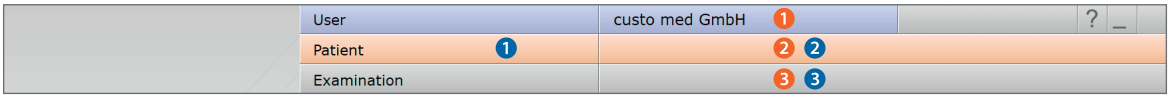
Derivation T1 is preferably used to represent the excitation propagation over the left lateral surface of the heart. Due to the angle it correlates with lead V5 in the resting ECG. Derivation T1 is the secondary analysis channel in the Holter.

Derivation T2 provides an additional channel for analysis. This derivation is displayed inversely.

3.8.4 Keyboard navigation and shortcuts in custo diagnostic

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

Quick links in the main navigation

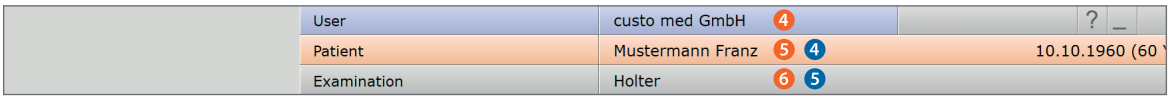


LEFT-CLICK

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

RIGHT-CLICK

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



LEFT-CLICK

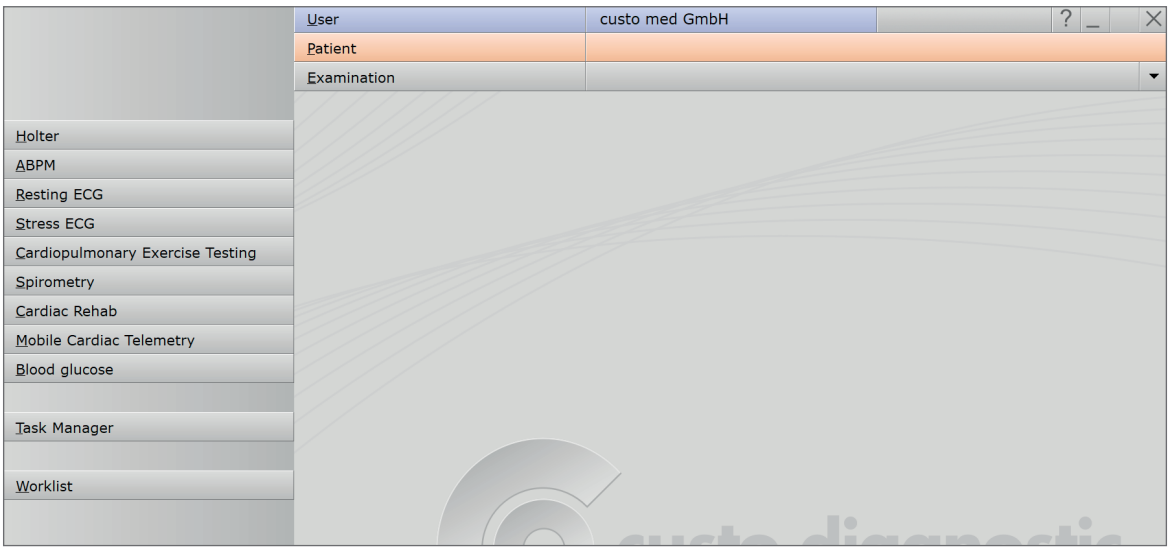
4. Change user's password
5. Patient master data
6. Menu for the current examination

RIGHT-CLICK

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

Keyboard navigation

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



Generally valid keyboard shortcuts

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

Generally valid keyboard shortcuts in an open evaluation

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

Keyboard shortcuts Holter, analysis

W	Skip normal beats forwards
Shift W	Skip normal beats backwards
Shift D	Skip normal beats forwards in increments of 10
Shift A	Skip normal beats backwards in increments of 10
Shift C	Skip VPB/Artefact/Pacemaker forward in increments of 10
Shift Y	Skip VPB/Artefact/Pacemaker backwards in increments of 10
N	Selected beat classes are converted to (N) Normal Beats
V	Selected beat classes are converted to (V) VPB
A	Selected beat classes are converted to (A) Artefact
P	Selected beat classes are converted to (P) Pacemaker
Space bar	After pressing the space bar, the selected beat classes are changed to N/A/V/P
Esc	Current selection is cancelled
Enter	Changes are applied, new analysis of the ECG is started
Arrow right	Scroll ECG forwards
Arrow left	Scroll ECG backwards
F2	Marking dialogue

Keyboard shortcuts Holter, trend ECG

left/right	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 Holter, example preview

Arrow keys	Move inside the examples
Pos1	Selector cursor moves to the first example
End	Selector cursor moves to the last example
Page up	Scroll up one page
Page down	Scroll down one page
Enter	Opens all examples from the selected event
F2	Set marking, pressing again will remove the marking
F3	Delete all examples of the selected event
Del	Deletes the top (currently displayed) example of the event. If there is no example of the event left, the event is deleted.

Keyboard shortcuts Holter, total ECG

Shift arrow up	Scroll ECG up/down by lines
Shift arrow down	Scroll ECG up/down by lines
Ctrl arrow up	Scroll ECG up/down by pages
Ctrl arrow down	Scroll ECG up/down by pages
Arrow up	Scroll ECG up/down for the duration of the key press
Arrow down	Scroll ECG up/down for the duration of the key press
Page up	Scroll ECG automatically up/down
Page down	Repeated pressing of the key increases the speed Pressing the "opposite direction" reduces the speed
Space bar	Starts/stops the automatic scrolling
F2	Marking dialogue

Manufacturer's contact details:
custo med GmbH
Maria-Merian-Straße 6
85521 Ottobrunn
Germany

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

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