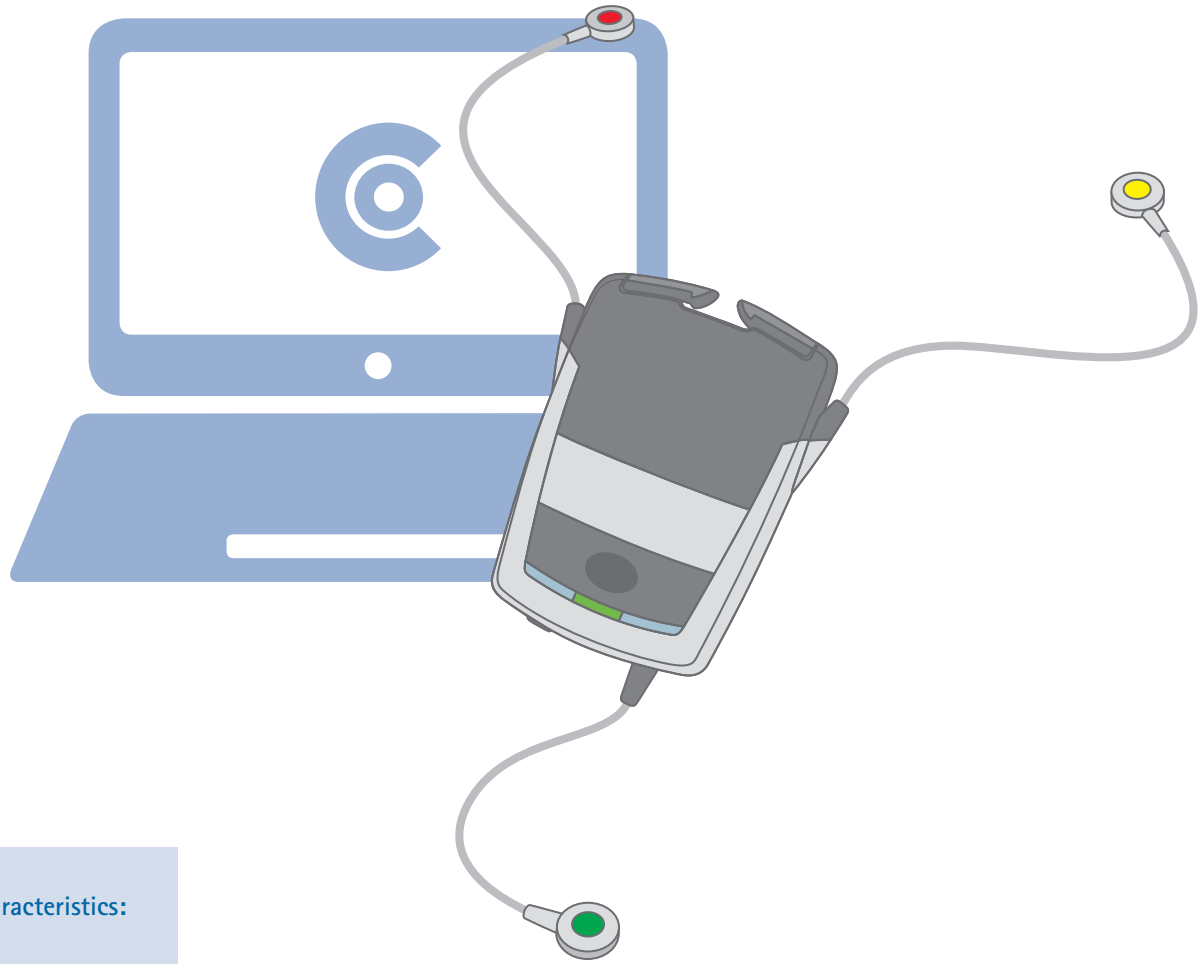
Operating Manual

Holter light

1 Safety | 2 Hardware | 3 Software | 4 Hygiene

Part 3: custo diagnostic software for custo flash 501/L



Operating characteristics:

custo diagnostic 4.6 and higher for Windows®

MSW 0011 – DK 1742
Version 001 – 03/05/2018

CE 0123

custo·med
EXCELLENCE IN DIAGNOSTICS

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

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

Operating Manual

Holter light

1 Safety | 2 Hardware | 3 Software | 4 Hygiene

Part 3: custo diagnostic software for custo flash 501/L

Table of contents

3.1 Symbols used in this Operating Manual

ACTIONS THAT ARE PROHIBITED
or not allowed under any circumstances!

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

NOTE
provides important information which must be observed

TIP
contains practical information to assist you with your work

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

Words highlighted in colour...

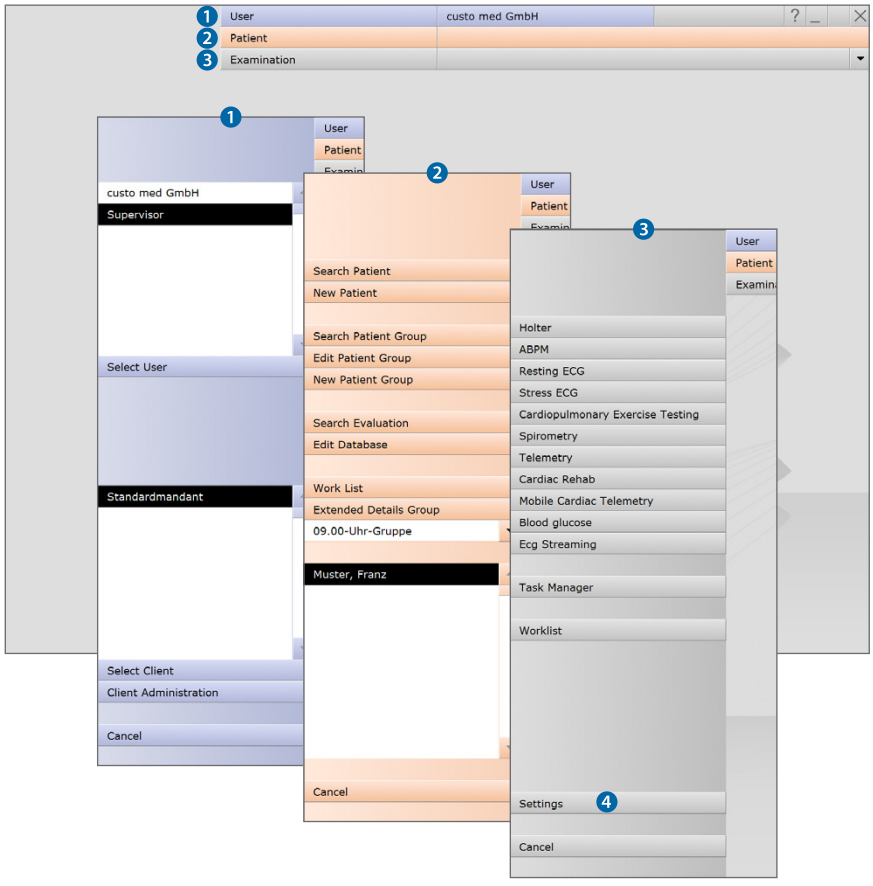
3.2 custo diagnostic program structure

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

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

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

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



3.3 custo flash 501/L

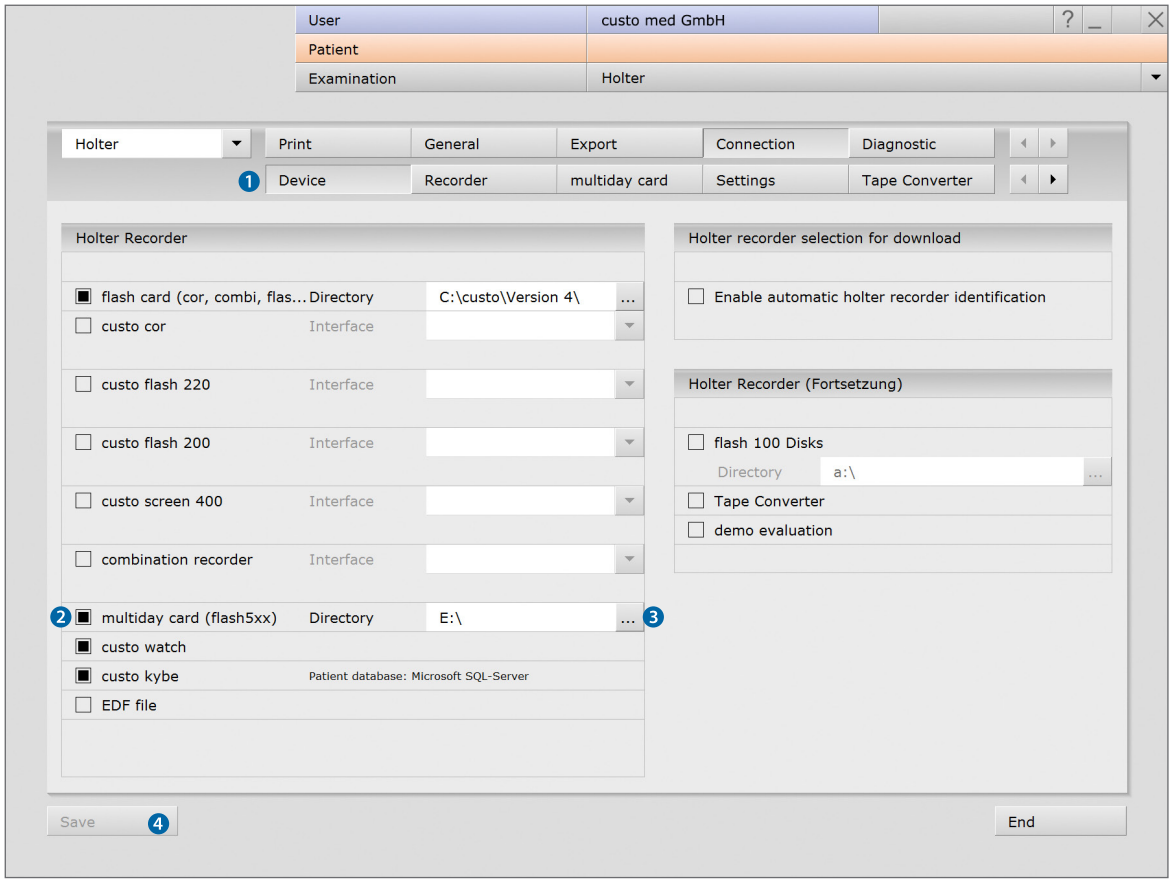
3.3.1 Setting up the custo flash 501/L (card reader)

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

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 option ❷[1)]
- Select the drive of the USB card reader. To do so, click on the ... ❸ button at the end of the line. Select the corresponding drive in the directory structure and confirm by clicking on OK.
- Click on Save ❹ to apply your input.
- The USB card reader is ready for operation.

1) Only multiday cards from custo med may be used as they are certified components of the complete medical-technical system. When using cards not issued by custo med, errors (such as the mix-up of patients) may occur.



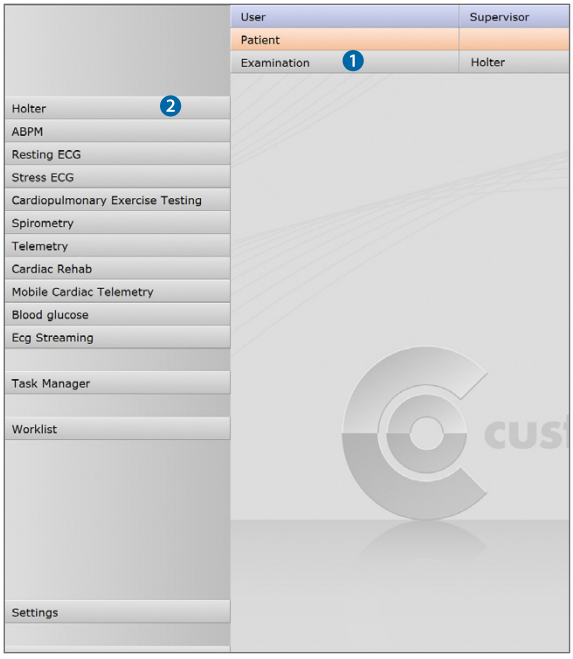
3.3.2 Configuring the custo flash 501/L (multiday card)

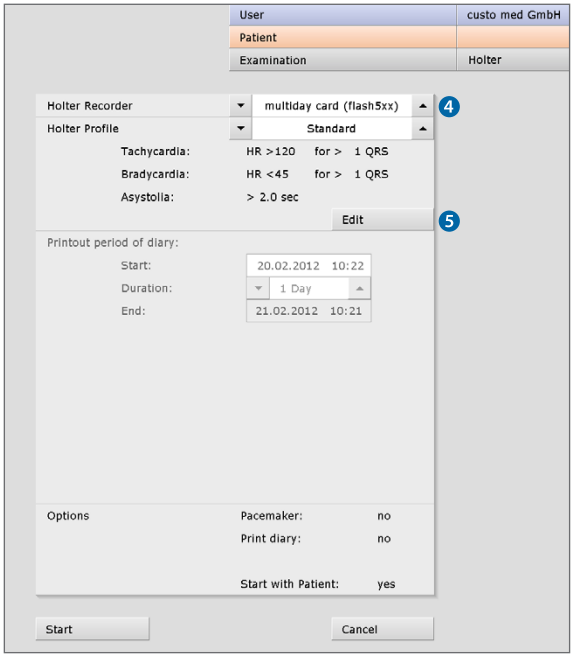
Program start, calling the Holter

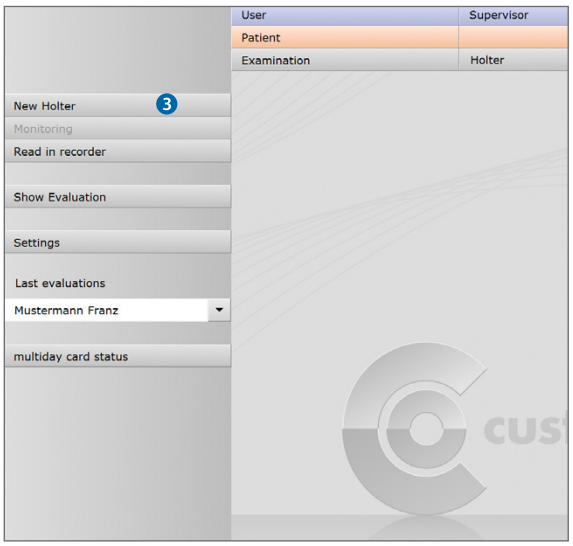
- Make sure that the USB card reader is connected to the PC and ready for operation.
- Insert the custo multiday card into the USB card reader.
- Start custo diagnostic and log in.
- Click on Examination ❶, Holter ❷, New Holter ❸.
- The screen for setting the recording parameters is displayed.
- Make sure that multiday card ❹ is selected as the Holter recorder.

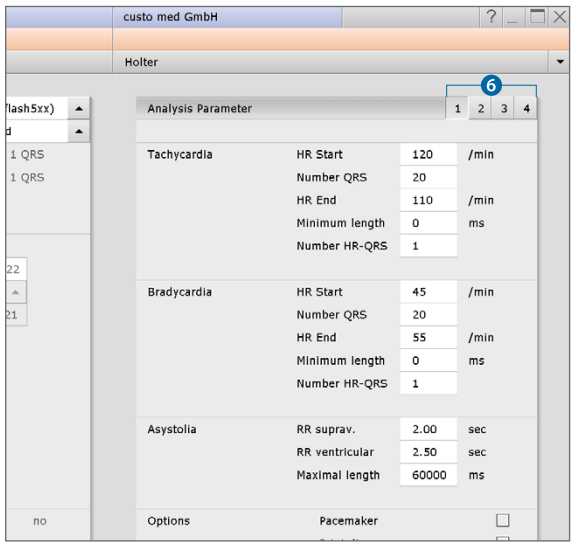
Setting the recording parameters

- The Change ❺ button can be used to change the preset recording parameters.
- The buttons 1 to 4 ❻ can be used to open additional screens with analysis parameters.









- The options have to be set as required:

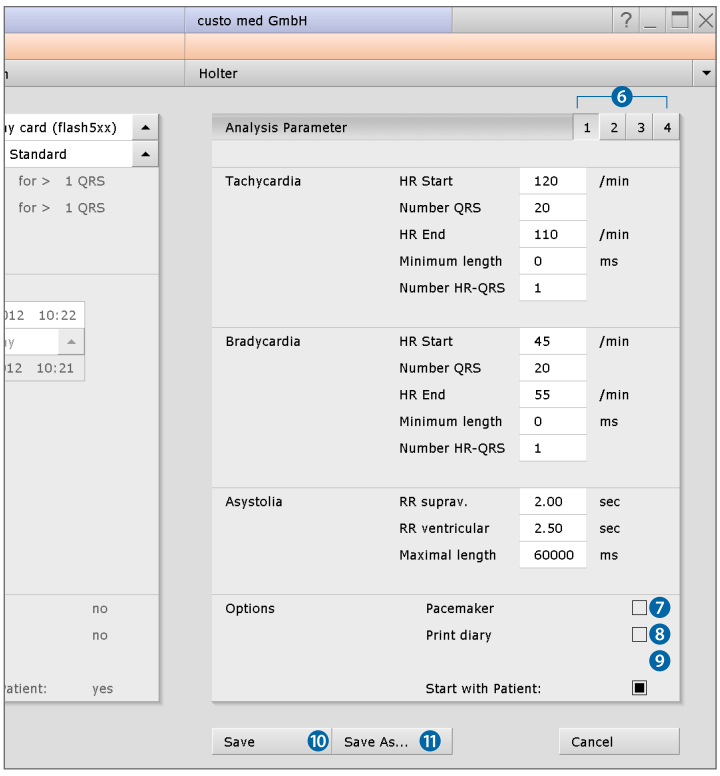
7. Pacemaker (only possible as of standard software with custo flash 510)
8. Trigger Print diary.
9. Start with Patient: Start with Patient means that you will select a patient for the recording in the next step and thus personalise the custo multiday card. If you deactivate this option, a patient must be allocated when downloading the recording.

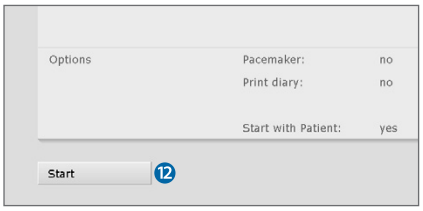
Tip for personalising the card:
To avoid any confusion between patients or incorrectly allocating recording data, it is recommended that you always personalise the custo multiday card prior to the recording and do not deactivate the Start with Patient option.

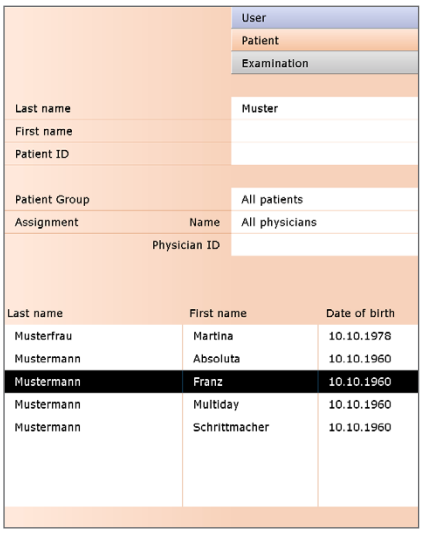
- With Save As ⑩, start parameters with changed settings can be saved under a new name and made available for further recordings.
- With Save ⑪, the originally selected start parameters will be overwritten.

Writing data to the custo multiday card

After you have completed the settings, click on Start ⑫.
The patient selection screen appears.







Selecting the patient

- Enter the patient's name into the input fields in the search screen.
- Select the patient from the list.
  Confirm your selection with Select Patient ⓭.
  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 ❻.
- Enter the data. The fields marked with an asterisk are mandatory.
- Save the data, the patient is entered into the database.

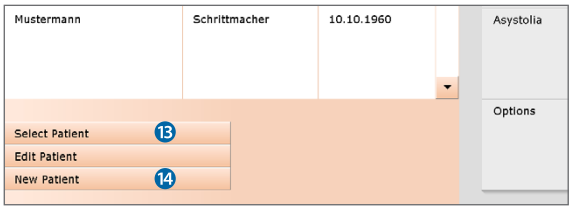
- After you have selected a patient, the recording parameters are written to the custo multiday card. A dialogue then appears in which the patient's data and the card's status are shown for checking purposes. To close the dialogue, select Confirm.

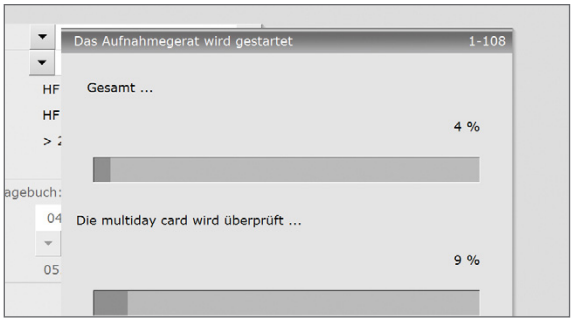
Please note: Different process for start without patient

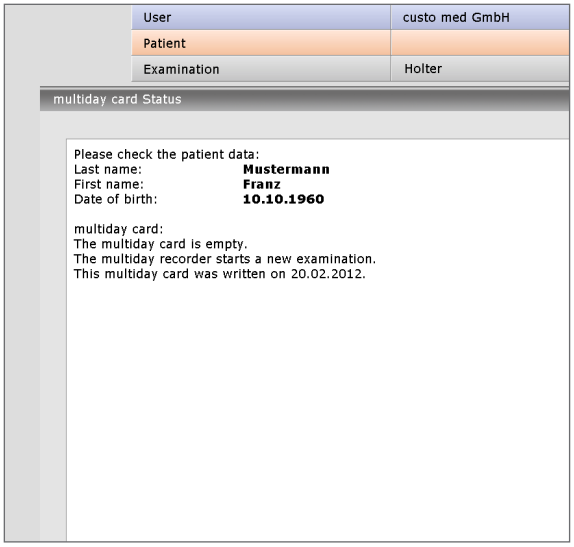
If you deactivated the Start with Patient ❾ option when setting the recording parameters, the data will be written to the custo multiday card without a patient being selected in advance. In this case, you are informed by message that the custo multiday card does not contain any patient data and to ensure that the correct patient is allocated when downloading the data. To close the dialogue, select Confirm.

3.3.3 Starting the custo flash 501/L

- Take the custo multiday card out of the USB card reader.
- Assemble the recorder for the recording *(see part 2 (Hardware) in this modular Manual.)*
- The recording starts automatically.







3.3.4 Removing the custo flash 501/L, downloading the recording

Take the recorder off the patient after the recording:

- Detach the ECG leads from the electrodes – taking care not to pull on the leads!
- Remove the neck strap together with the device over the head
- Remove the electrodes and any adhesive residue from the patient
- Detach the rechargeable battery from the recorder using the release key
- Remove the custo multiday card from the recorder
  To do so, gently push the edge of the card,
  do NOT use force to remove the card.
- Insert the custo multiday card into the USB card reader
- Open custo diagnostic...

After opening custo diagnostic, click on Examination, Holter, Download Holter Recorder. The "Workflow after download data" dialogue appears. You can define here whether the recording should be analysed now or later and displayed for editing.

- Later button:

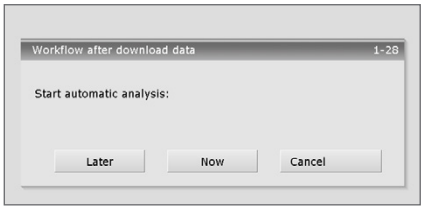
The recording is stored – without analysis – in the Task Manager.

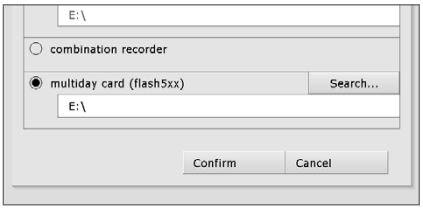
The Task Manager is suitable for downloading several recorders in a short period of time. To make available recordings from the Job Manager, open the Job Manager via the Examination Main Menu. Activate the Analysis Option and start the process (Start). After the analysis the recordings can be opened.

- Now button:

The recording is evaluated during the download and then displayed.

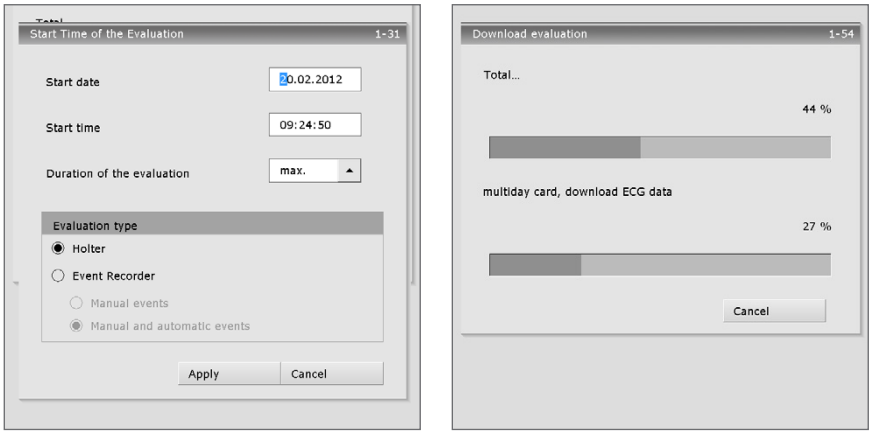
When using different Holter recorders, the "Select Holter Recorder" dialogue appears. Select custo multiday card. Click on Confirm to start the download.



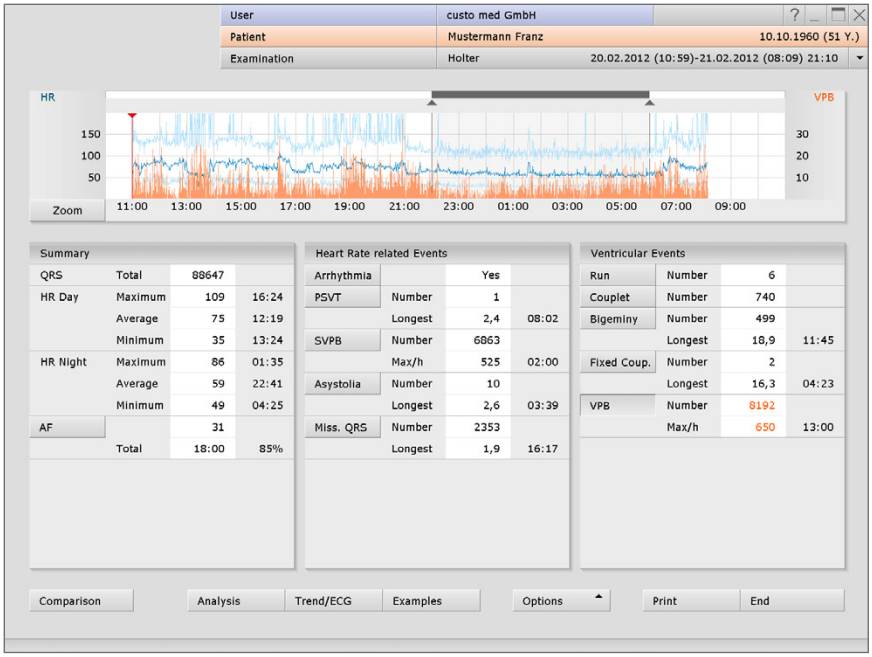


During the custo multiday card download process, the "Start Time of the Evaluation" dialogue appears. You can check the start date and start time of the recording here and make corrections if necessary.
In addition, under "Duration of the evaluation" you can define how many days of recording should be downloaded (e.g. in the case of multiday recordings).

Click on Apply to continue with the download.



The evaluation is displayed (Now button) or stored in the Task Manager (Later button). To close an opened recording, click on End and then on Confirn in the end dialogue.



3.4 Opening the Holter evaluation

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

Opening an evaluation via the evaluation search

Right-click on the Patient ❶ button. This opens the evaluation search.

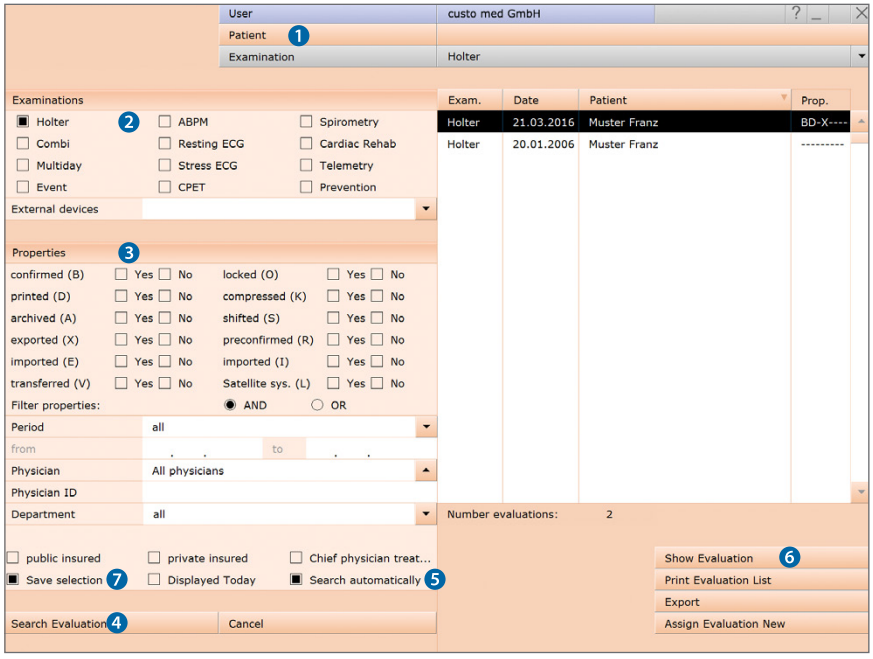
In the Examinations area, enter what type of evaluation you are searching for, e.g. Holter ❷. In the Properties area ❸ you can define more search criteria.

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

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

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

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



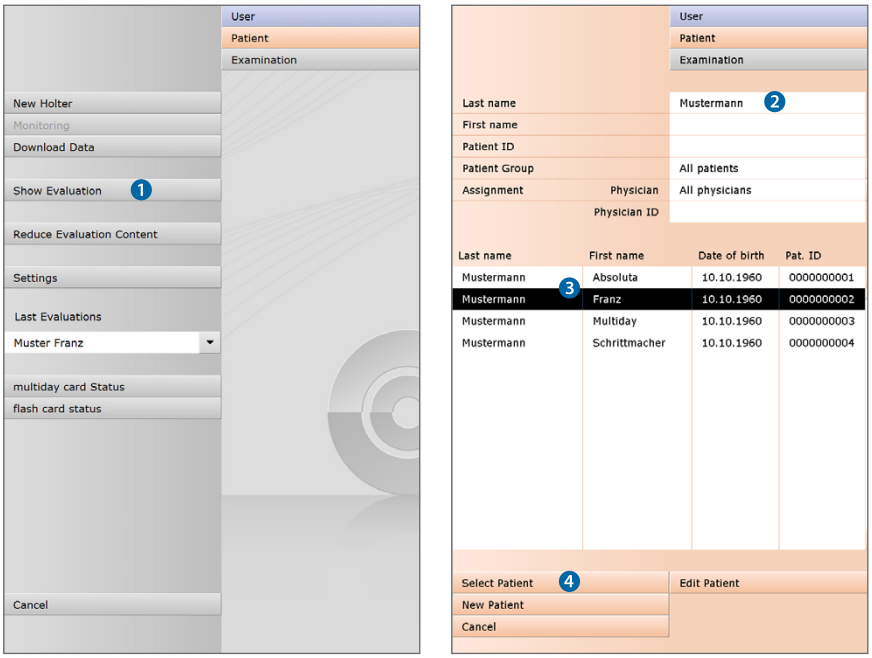
Reference between End dialogue and search screen

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

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

Opening an evaluation via the examination main menu

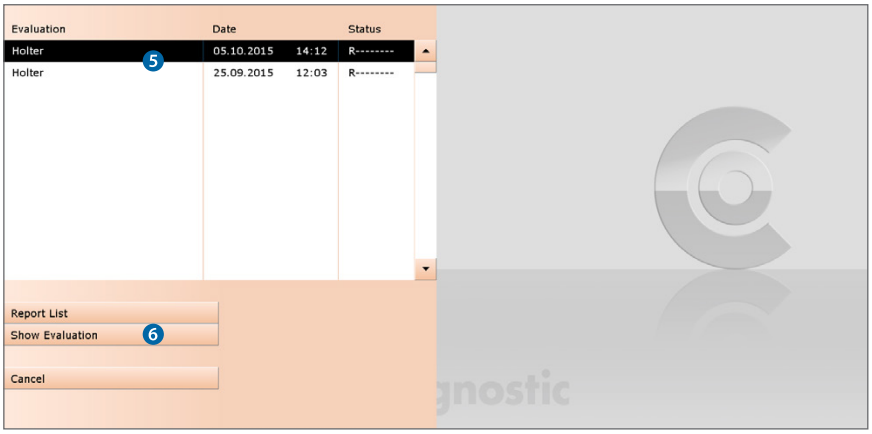
Open the Holter main menu via Examination, Holter, and click there on Show Evaluation ❶.



The patient search screen appears. On this screen, select the patient whose recording you want to open. Enter the patient's name, or the first letter of their name, into the input fields on the search screen ❷.

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

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



3.5 Structure of the evaluation

Holter/Holter ABPM overview:
24 hour graph (trend) with a tabular summary of all events

- **Beat class analysis**
  representation of all beat classes, divided into Normal, VPB and Artefact
  - **Single complexes**
    single beats of the previously selected class
- **Trend & ECG**
  24 h graph and ECG according to the cursor position in the 24 h graph, event-related navigation in the ECG
- **EKC examples:**
  overview with example sections for the VPB classes and each event
  - VPB selected:
    all VPB
    each single VPB as an example
  - VPB selected:
    all templates
    all VES classes, one example for each class
    - **Show all**
      all VPB examples of the previously selected VPB class
  - **Show all**
    all examples of the previously selected event
- **Evaluation comparison**
  comparison of the current evaluation with an additional one
- **Options menu, more screens:**
  - **Print menu**
  - **Exclusion**
  - **Service**

Note on navigation in the evaluation

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

Example: You click in the Holter overview (start screen) on the Analysis button. You go to the screen with the beat class analysis and the previously clicked Analysis button changes to Overview. By clicking on Overview you can return to the Holter overview.

3.6 Holter evaluation screens

3.6.1 Holter overview

A Holter overview screen displays a maximum recording of 24 hours (a).

Zoom function (d)

Click on this button to enlarge the display of an hour of the recording in the 24 h graph (half an hour before and after the cursor).

The zoom function appears on each screen with the 24 h graph.

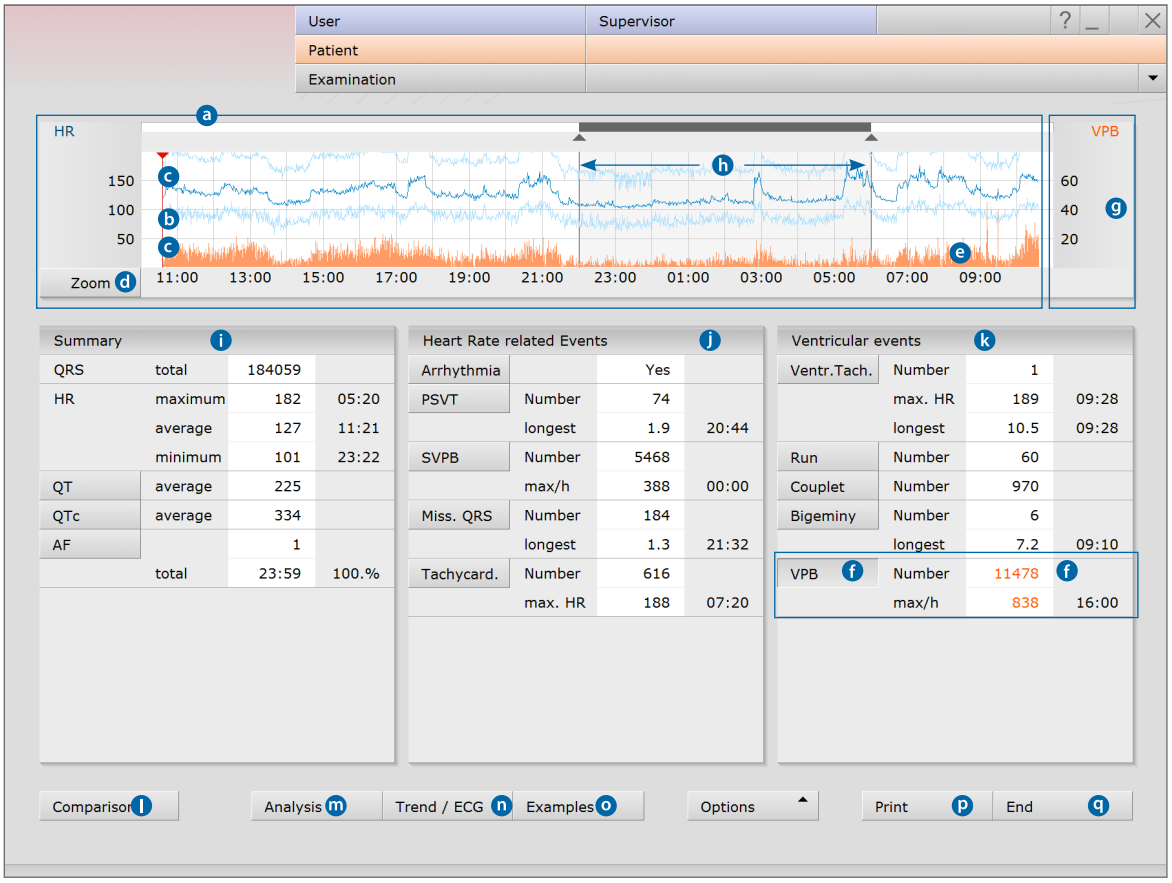
24 h graph (trend) – heart rate curve

- (b) HR average (dark blue, between HR maximum and minimum) results from the average heart rate per minute
- (c) HR maximum, HR minimum (light blue, above and below the HR average) show the highest and lowest value within a minute

Event log

The vertical orange lines (e) in the 24 h graph (trend) show the times at which the selected event occurred. The selected event is marked in the overview table with orange lettering and the button pressed down (f).

To display another event, click on the button of the desired event. The height of the orange lines in combination with the scale on the right-hand side of the screen (g) provides information on the number of occurrences within a minute.



Night phase (h)

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

Navigation in the 24 h graph

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

Tabular overview:

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

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

Navigation options in the tabular overview

By double-clicking on any Event button (see (f)) you can open the Trend/ECG (n) screen.

By clicking on number/maximum value/time of an event in the overview you can open all the examples of the event. The examples are ECG sections which contain the corresponding event.

Buttons for opening additional evaluation screens

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

The context menu

The context menu is opened by right-clicking on the evaluation. The report dialogue can be called here. The contents of the context menu vary according to the evaluation screen – for the range of functions see the next screen.

3.6.2 Context menu

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

Important notes on the functions in the context menu

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

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

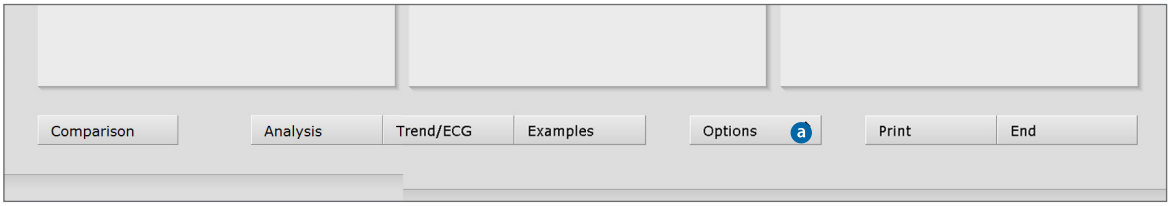
In the Overview you can manually insert events via Change if you should find events which were not detected by the program. Manually inserted events are inserted in the tabular overview with the corresponding designation.

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

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

3.6.3 Options menu

The contents of the Option menu (a) vary according to the evaluation screen. The Print, Export, Reduce, Total ECG, Trend Overview and Service functions are available on each evaluation screen in the Options menu.



Explanations of the functions in the Options menu

- Print...

Temporary change of print settings for the current evaluation

- Export...

The evaluation is exported in Excel and PDF format

- Reduce...

Dialogue for reducing the amount of data of an evaluation

Explanations of the functions in the Options menu

- Print...

Temporary change of print settings for the current evaluation

- Export...

The evaluation is exported in Excel and PDF format

- Reduce...

Dialogue for reducing the amount of data of an evaluation

- Total ECG

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

- Trend overview

Graphic representation of all events over the entire recording period

- CSV export

ECG and RR values can be exported separately from each other as a .csv file

- Assign New

The evaluation can be assigned to another patient

- Service

Technical details of the recorder and recording

- Invert

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

- New analysis

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

- Exclusion

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

- Parameters...

Setting screens for changing the parameters for beat and event analysis.

Note on applying or resetting changed parameters

When you click on the Analysis button (at the bottom of the screen), your settings are applied and the ECG is analysed again taking your changes into account.

With the End button you can exit the parameter setting screen and your changes are not applied. With the Set Default button you can restore the default settings. This applies to all parameter setting screens in the Holter evaluation.

3.8.4 Analysis (Analysis button in the overview)

- a Beat classes with normal QRS complexes (N);
  navigation in the classes with Next / ◂ ▸ = forward/backward by page
- b Beat classes with changed QRS complexes (V);
  navigation in the classes with Next / ◂ ▸ = forward/backward by page
- c Button for showing the artefact classes (A)
- d Button for showing the pacemaker classes (S)
- e Occurrences of the selected class are marked in colour in the ECG
- f Scrollbar for navigating through the entire recording;
  ⏮ ⏭ = Go to the next occurrence, ◂ ▸ = continuous scrolling
- g Buttons for showing the RR intervals, the heart rate
  or the class numbering below the ECG signal
- h Buttons for showing the examples *(see 3.9.6, 3.9.7, 3.9.8)*
- i Buttons for opening additional evaluation screens

➤ Labelling of classes

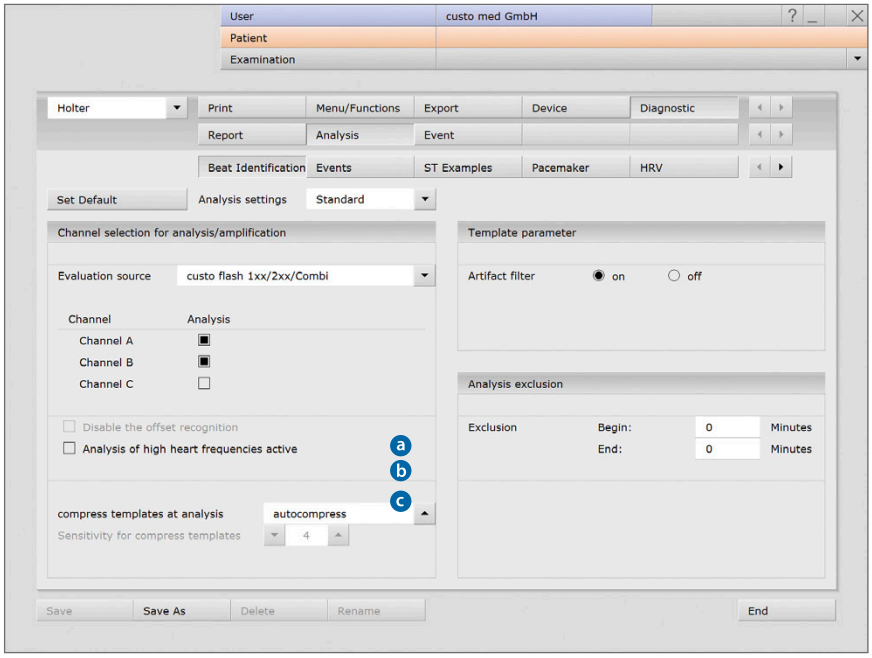
- j Numbering of the class (numbered in ascending order)
- k Annotation: Normal (N), VPB (V), Artefact (A) or Pacemaker (S)
- l Number of single complexes in the class
- m Percentage relative to the number of all the recorded QRS complexes

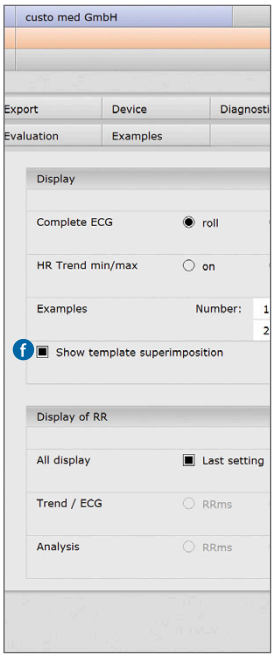
Editing options on the Analysis screen

All the recorded QRS complexes are summarised in beat classes. The classes are sorted by the criteria Normal (N), VES (V), Artefact (A) and possibly Pacemaker (S). The Analysis screen shows all the classes of the recording. At this point you can check, summarise and reallocate the template classes.

Compressing beat classes

To limit the number of template classes, they can be compressed in different ways under Examination, Holter, Settings, Diagnostic, Analysis, Beat Identification:





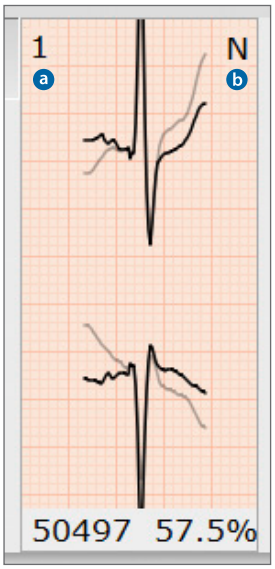
- Disable a: The template classes are not compressed
- Compress b: The template classes are compressed manually. The amount of compression can be adjusted by sensitivity.
- Autocompress c: With this option, the template classes are reduced until either a sensitivity has been reached for which there is no change compared to the previous value or ideally until fewer than 30 template classes has been reached.

Compressed template classes are always the same in the central beat (QRS complex). There are four levels: Overview screen, compressed templates, templates, single complexes. Double-clicking always takes you to the next level down. In the lower levels the Back button is displayed which takes you back to a higher level.

Under Examination, Holter, Settings, Menu/Functions, Workflow you can f show or hide the view of compressed templates if the superimposed view (all templates over each other) g is confusing.

Summarising beat classes

Click with the left mouse button on the numbering (at the top left) ⓐ of the selected beat class that you want to summarise with another beat class. The Edit context menu opens where you can summarise the beat classes/templates via source and target. New templates can also be created there.



Changing the allocation of a beat class

To change the allocation (N/V/A/S) ⓑ of a beat class, continue to click in the corresponding beat class with the left mouse button on the letter at the top right ⓑ until the correct allocation is shown. Or you can press the corresponding letters on the keyboard: (N/V/A/S)

You can also change the allocation of several beat classes at the same time. Select the desired classes with the right mouse button and continue to click in one of the selected classes with the right mouse button on the letter ⓑ until the correct allocation is shown.

Moving single complexes of a beat class

To display the single complexes of a beat class, you have to click through the different levels of the beat classes.

- If the "Compressed templates" option is selected, there are four levels: Overview screen, compressed templates, templates, single complexes. Double-clicking always takes you to the next level down. In the lower levels the Back button is displayed which takes you back to a higher level.
- If the "Compressed templates" option is not selected, there are only 3 levels that work according to the same principle.

Keyboard shortcuts:

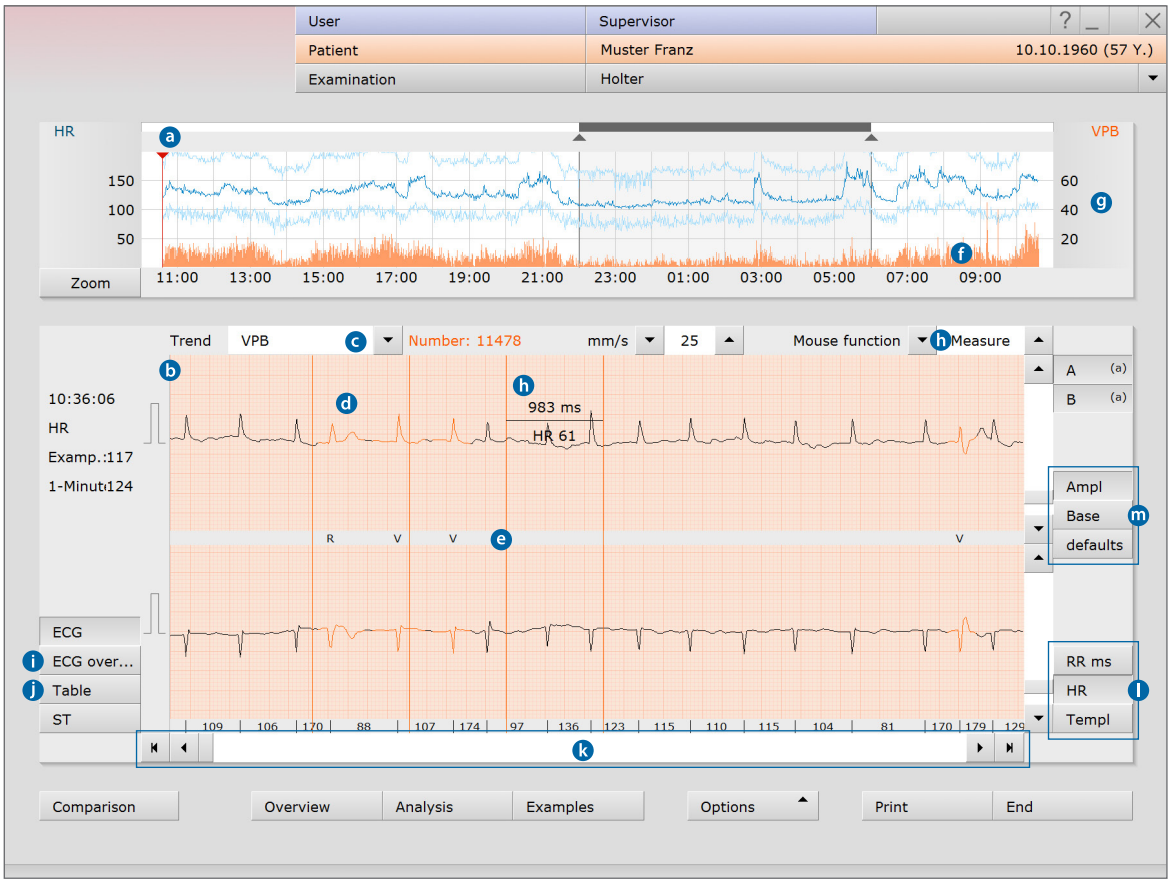
The allocation of one or several classes can also be changed by pressing the letters N, V, A and S on your keyboard.

Applying changes

If you change to another evaluation screen, all the changes which you made on the Analysis screen are applied after a prompt. You can also agree to the changes by clicking on OK at the top right of the analysis screen. The ECG is analysed again taking your changes into account.

Alternatively, you can execute the New analysis function on the Analysis screen in the Options menu. A dialogue appears informing you that the evaluation is being completely re-analysed. Click on Confirm to start the process. Use Cancel to discard the changes.

3.6.5 Trend/ECG – (Trend/ECG button in the overview)



- a Trend (24 h graph) with zoom function
- b Enlarged ECG display
- c Pull-down menu for selecting an event
  - d The selected event is marked red in the enlarged ECG
  - e The centrally positioned letters in the ECG show the type of event
  - f In the trend (24 h graph) the selected event is marked with orange lines
  - g The height of the lines in combination with the scale on the right-hand side of the screen shows the number of occurrences per minute
- h Mouse functions Mark, Change, Time or Measure

- i Reduced ECG (e.g. 15 min./screen) with identification of the selected event
- j Tabular display of the events with highlighted maximum values

- k Scrollbar for navigating in the ECG signal
- l Display of the RR intervals, heart rate or beat classes under the ECG
- m Changing the amplitude size, moving the zero line, resetting the changes

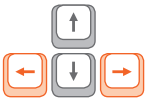
Note on opening the Trend/ECG screen

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

Event-related navigation on the Trend/ECG screen

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

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



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

Editing options on the Trend/ECG screen

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

Keyboard shortcuts:

An ECG can also be marked independently of the tool by pressing the "F2" key.

If the "Change" tool is active, you can also change V and N by pressing the corresponding keys.

➤ Measuring RR intervals (see representation of Trend/ECG ⓗ)

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

➤ Marking ECG sections (e.g. highlighting events)

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

➤ Changing events

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

3.6.6 Examples (Examples button in the overview)

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

Considering ECG examples in context

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

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

Changing the allocation of examples

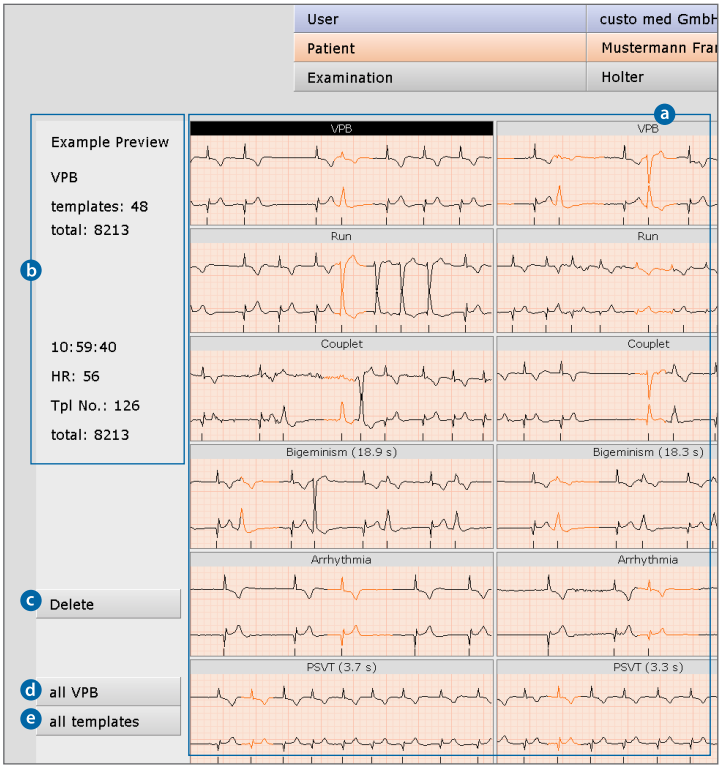
Select an example, open the context menu and click there on Change. In the "Edit beat" dialogue, select the desired event. In this dialogue you can also rename the entire example group or delete the selected example. Click on Confirm to apply the changes.

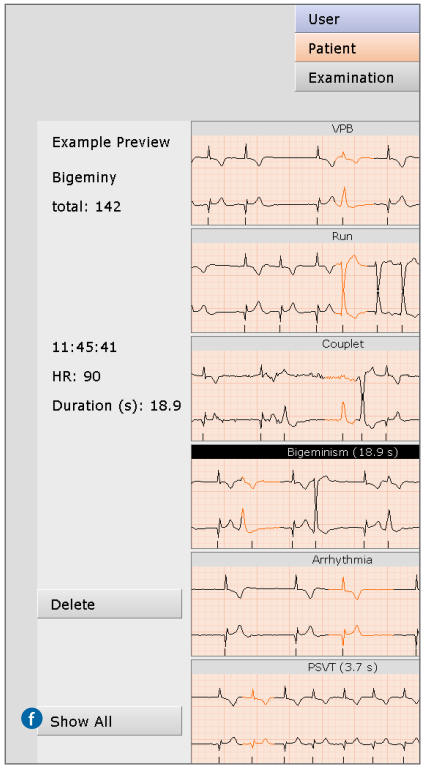
Example properties

The Properties dialogue can be opened by right-clicking on an example (or several). This dialogue allows the way in which examples are edited and printed to be adapted.

1) custo diagnostic can also be set so that, instead of the Trend/ECG screen, the ECG environment dialogue is displayed. The difference with this setting is that the Example Preview screen 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 the ECG environment" option. Apply the settings.





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

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

Editing several examples:

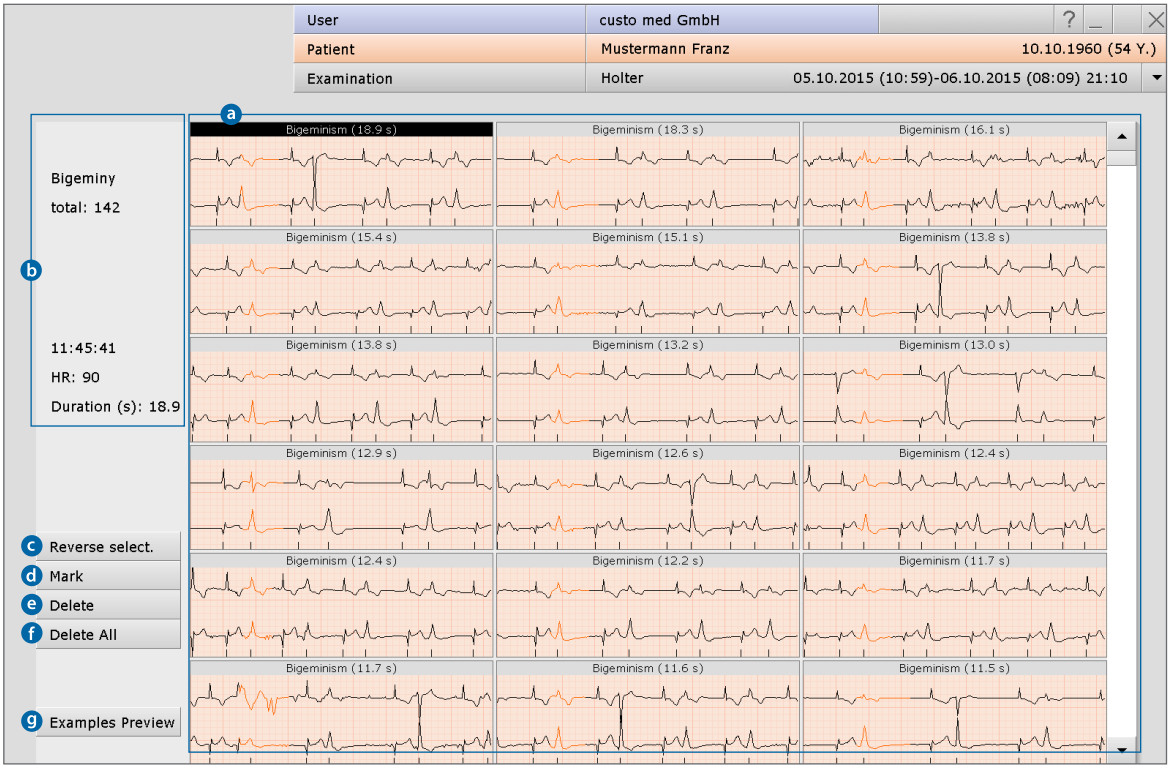
An example is selected with a click and then marked with the word "selected". The Reverse select. button allows you to reverse the selection (this function can also be found in the context menu). As soon as you make changes, they affect all the selected examples.

Considering ECG examples in context

To consider an example in context, double-click on the desired example. The Trend/ECG screen is shown with the corresponding position in the ECG or the ECG environment, see marginal note 1) on the previous screen. This action is only possible if all examples for an event are displayed. For VPB: all examples for a VPB class (Example Preview, all templates, Show all) or all VPB examples for the entire recording (Example Preview, all VPB). For all other events: Example Preview, Show all.

Changing the allocation of examples

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



3.6.8 Examples, delete, restore (undo button) and setting options

- (a) Restore function for the event that was last deleted
- (b) List of and restore function for all deleted events
- Setting options for the example view via the context menu

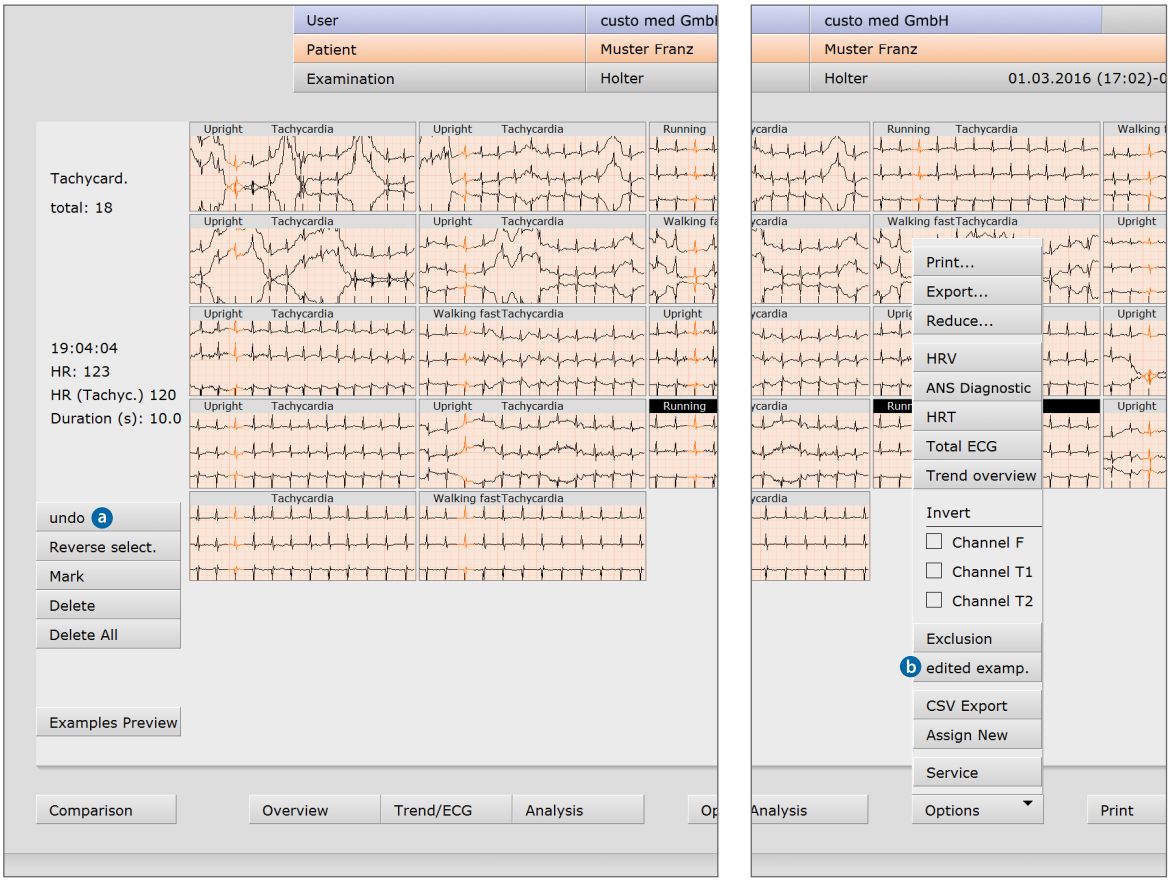
Deleting and restoring events

The Display and Delete all buttons can be used to remove examples from the view. To undo this step, the undo button must be pressed.

To view all the deleted events again, the edited examp. button can be selected in the Options menu. To restore selected examples, they first have to be selected and then the undo selection button must be pressed. The edited/deleted events are retained.

Setting options for the example view

The context menu (right mouse click in the example view), Properties button, can be used to individually set various display options for the examples (e.g. ECG amplitude, channel selection, etc).



3.6.9 Comparison (Comparison button in the overview)

Comparison of two evaluations for a patient each with:

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

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

Navigation options

Show additional evaluations for the patient for comparison purposes

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

Showing events in the 24 hour graph

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

3.7 Writing the report

Unconfirmed report and report

The unconfirmed report is opened by right-clicking on the evaluation interface. Select Report via the context menu. Enter your data in the text field ❶. If the Unconfirmed report or Interpretation option is selected in the system settings, an automatic system unconfirmed report is already present in the text field. If necessary, older reports can be displayed via the report history (collapsible list above the text input field).

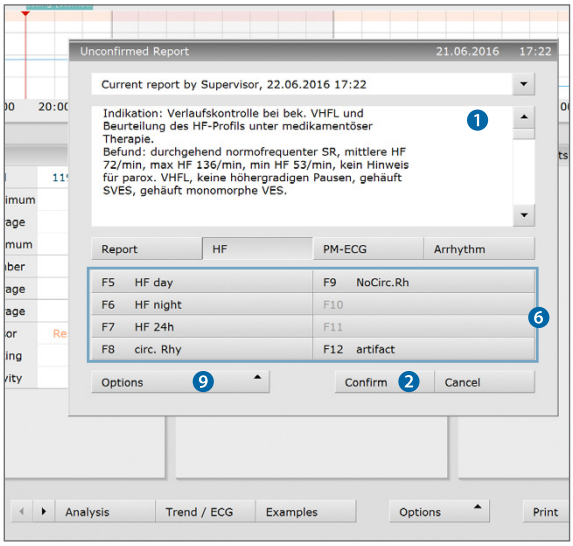
When you click on Confirm ❷ your input is saved and the unconfirmed report becomes a (preliminary) report, depending on the report rights of the current user. If your (unconfirmed) report is not yet complete but you want to save it nevertheless without reaching the "Evaluation (pre)confirmed" status, the report status is reset upon ending (End)the evaluation.

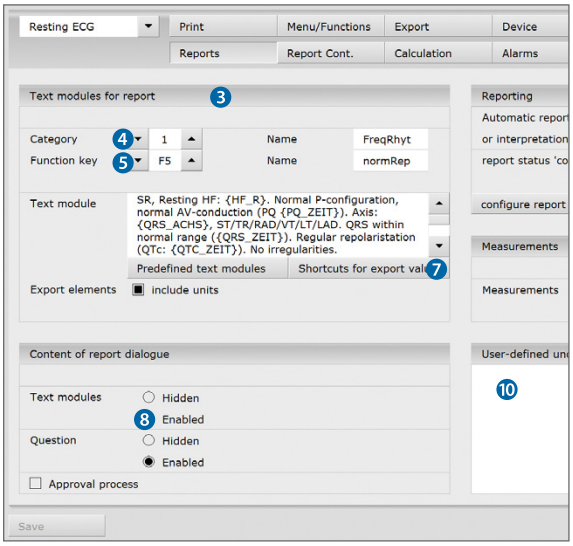
Text modules – an aid for writing reports

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

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

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





3.8 Printing the evaluation

Alternative ways to create a printout:

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

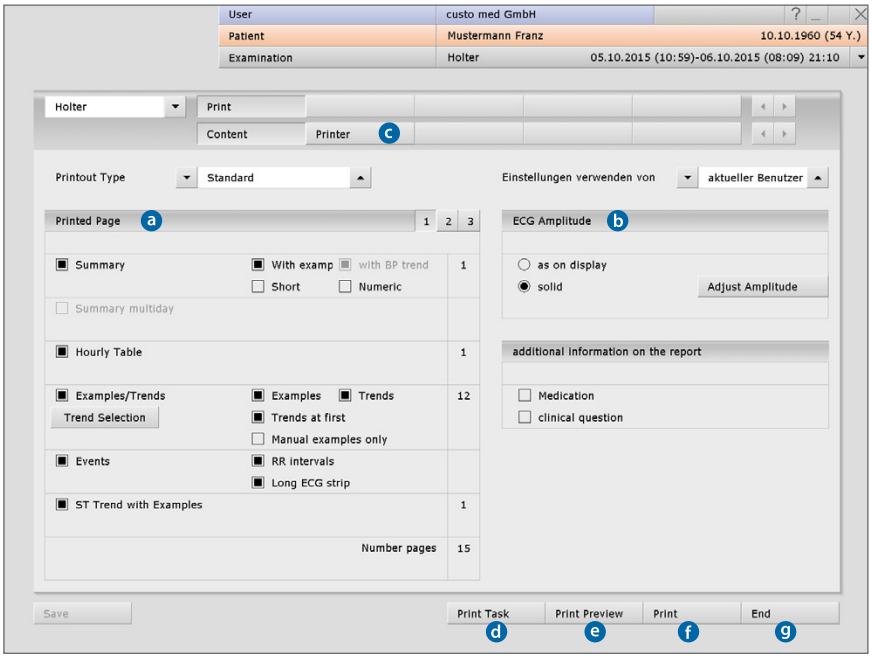


Fig.: Print menu for the individual compilation of a printout; can be called in the evaluation via Options, Print...

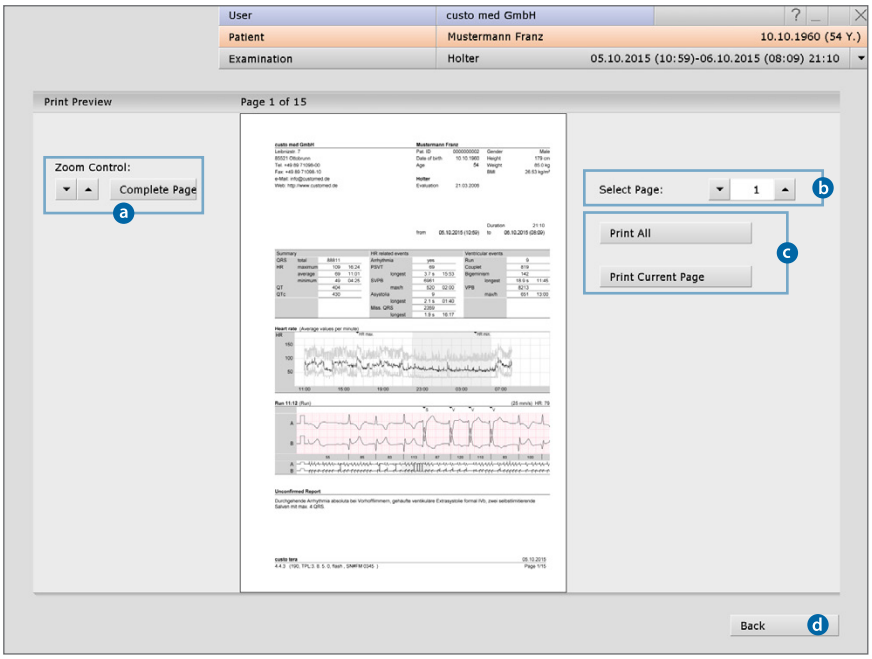
- a Compiling the contents
- b Amplitude size of the ECG signal in the printout
- c Selecting and setting the printer on the General screen
- d Button for saving the print task in the Task Manager
- e Preview of the complied print pages
- f Button for starting the printout
- g Button for closing the 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.

Print preview

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

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



3.9 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)].

- unconfirmed ❷ – active if a user with the reporting right "Preconfirm evaluations" has confirmed the unconfirmed report of an evaluation.
- confirmed ❸ – active if a user with the reporting right "Confirm evaluations" has confirmed the unconfirmed report. The "confirmed" status can be reset if required.
- printed ❹ – indicates if the evaluation has been printed.
- indelible ❺ – 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.

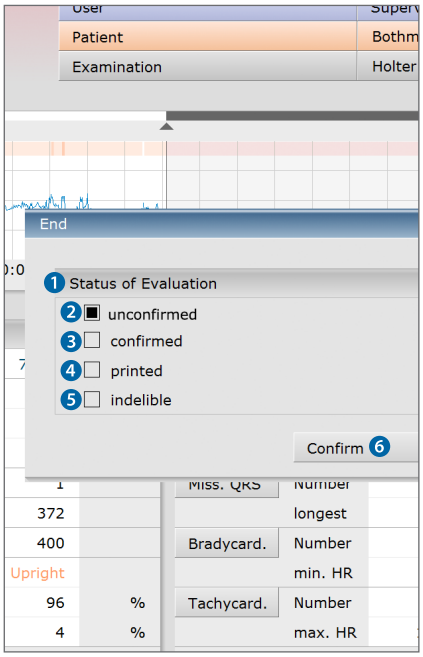
3.10 Optional: Reporting with approval process

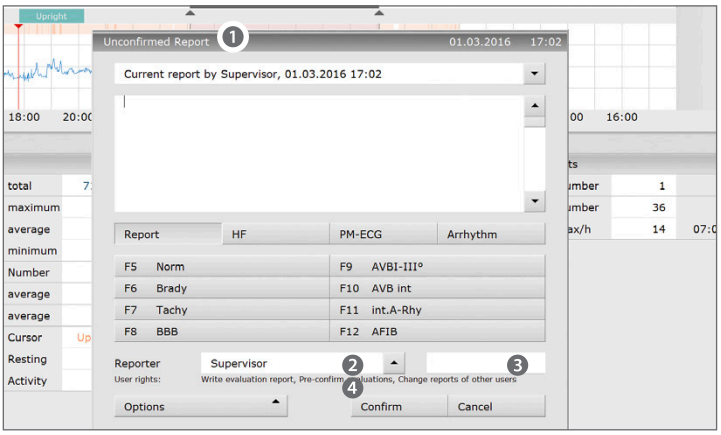
If approval process is used, then persons with the corresponding user rights can save pre-reports of other persons as a report, without having to close the evaluation which was opened previously or enter pre-reports/reports directly if the evaluation was created by a person without reporting rights.

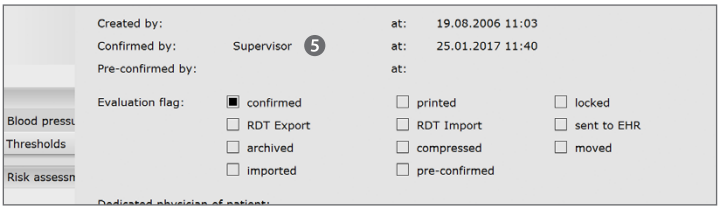
The approval process is visible in the unconfirmed report dialogue ❶ of an evaluation. The user or reporter can be changed there (User name ❷, Password ❸, Enter). During the logon process, the user rights of the respective user are checked and the software interface is adapted accordingly ❹. The reporting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

The approval process must be activated user and project-related in the settings. 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.







3.11 Appendix

3.11.1 Setting the recorder time for custo flash 5xx

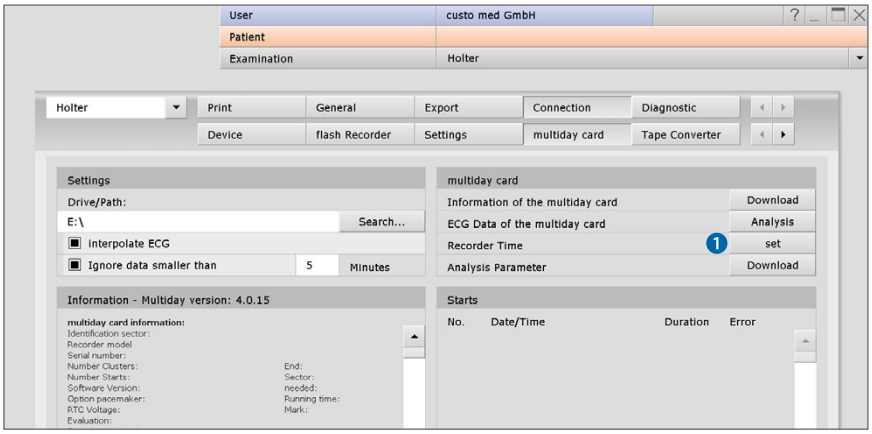
custo flash 500/510 has a preset real time clock. custo diagnostic informs you by a message when the time needs to be readjusted (approx. every six months).

Ensure that the system time of your computer is set properly as it is used for custo flash 500/510.

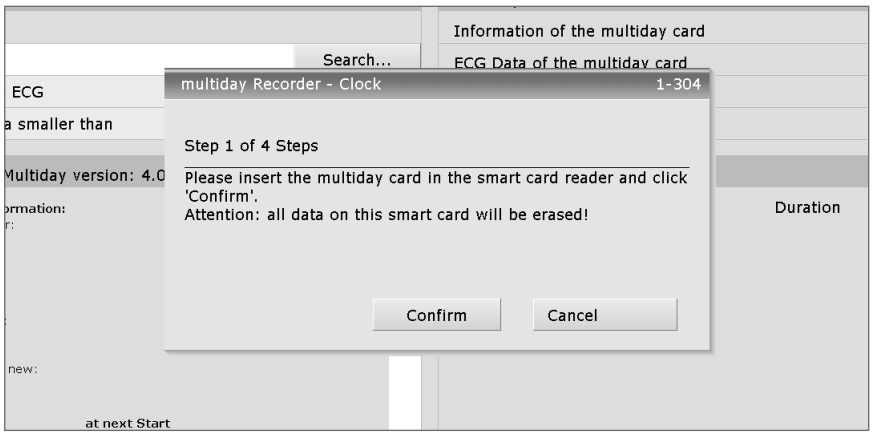
To adjust the time, open the page Examination, Holter, Settings, Connection, multi-day card. In the multiday card area click on the set recorder time button ❶.

The time can be adjusted in four steps. The program provides you with specific instructions...

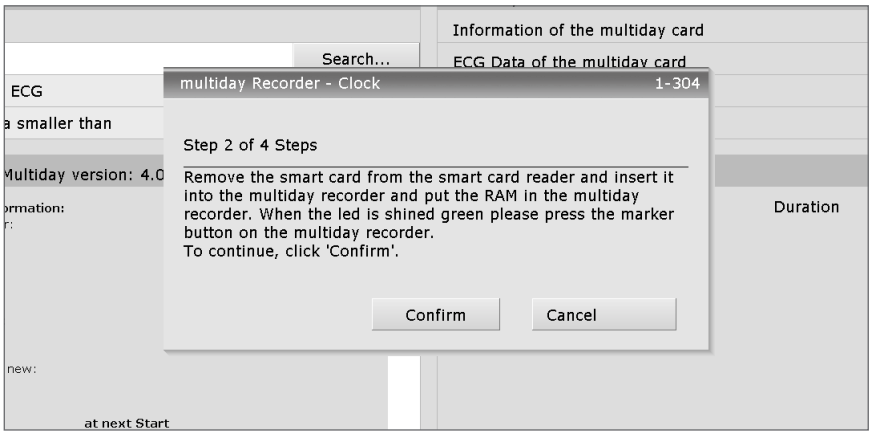
Set recorder time button ❶



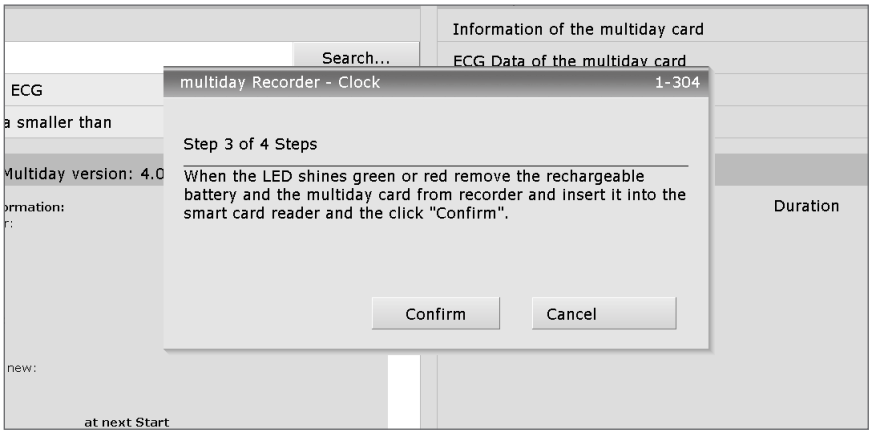
Insert the custo multiday card into the card reader...



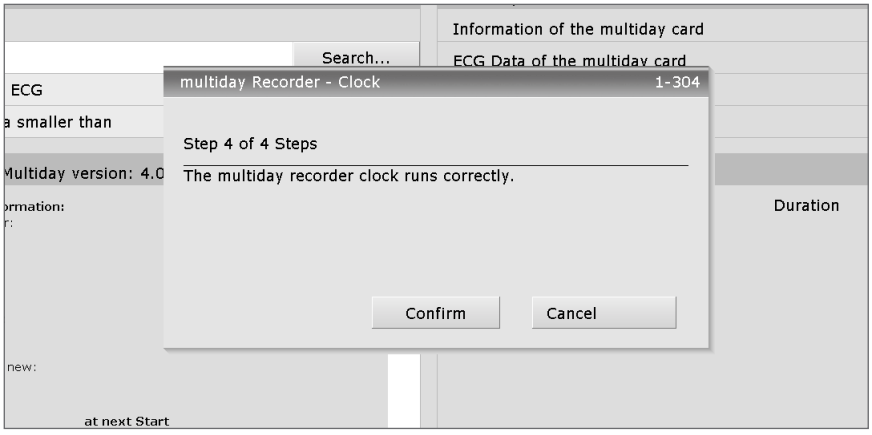
Insert the custo multiday card in the recorder, insert the rechargeable battery,
Press the event key...



Reinsert the custo multiday card in the card reader...



The time has been adjusted.
If errors occur during these steps, repeat the entire process.



3.11.2 Method for calculating the heart rate

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

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

Settings (Holter Overview, Context Menu, Settings)

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

3.11.3 Method for determining a period of no cardiac activity

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

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

3.11.4 Information for changing the ST segment

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

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

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

These settings are located in the open Holter 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 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.

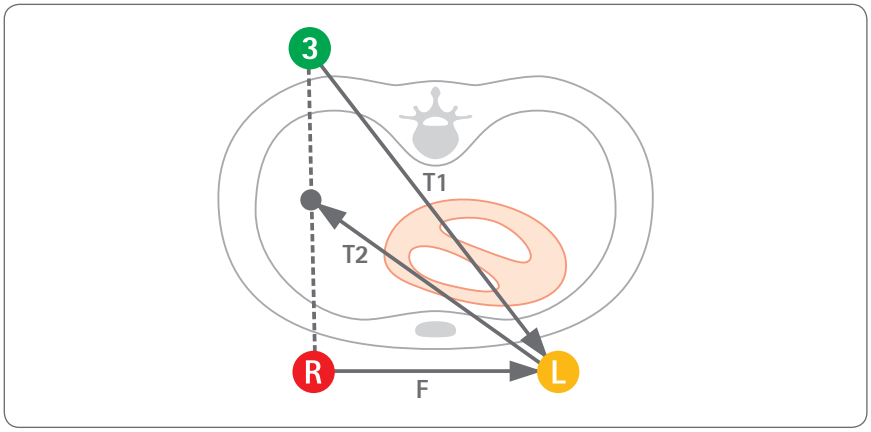
- Trends:

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

1) Note on the designation of ECG leads: When carrying out recordings with custo belt, the leads in custo diagnostic (and on the custo watch display) are labelled as F, T1 and T2; when carrying out recordings with the custo cable guard 3, they are labelled as A, B and C.

3.11.5 Schematic representation of the leads of custo belt 3



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

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

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

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

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

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

3.11.6 Keyboard navigation and shortcuts in custo diagnostic

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

Quick links in the main navigation

LEFT-CLICK

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

RIGHT-CLICK

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

LEFT-CLICK

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

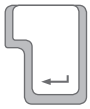
RIGHT-CLICK

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

Keyboard navigation

When you press the Alt key, the initial letter of all the buttons on a screen page will be underlined. Pressing an initial letter in combination with the Alt key triggers the corresponding button.

Generally valid keyboard shortcuts

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

Generally valid keyboard shortcuts in an open evaluation

Ctrl + N	Unconfirmed report input dialogue
Ctrl + K	Medication input dialogue
Ctrl + R	Open comparison [1)]
Ctrl + T	Open trend [1)]
Ctrl + D	Open Print dialogue [1)]
Ctrl + E	Open settings [1)]
Ctrl + O	Open Options menu [1)]

1) Keyboard shortcuts will only work if the corresponding button is available on the screen page.

Keyboard shortcuts for Holter: Analysis

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

Keyboard shortcuts for Holter: Trend/ECG

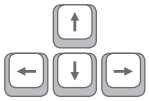
Go to the next or previous occurrence of the selected event

Marking dialogue

If the "Change" mouse function is selected:
The next beat besides the cursor is changed to normal beat

If the "Change" mouse function is selected:
The next beat besides the cursor is changed to VPB

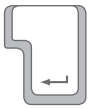
Keyboard shortcuts for Holter: Example overview



Move inside the examples

Selector cursor moves to the first/last example

Scroll up/down one page



Opens all examples from the selected event

Set marking, pressing again will remove the marking

Delete all examples of the selected event

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

Keyboard shortcuts for Holter: Total ECG

Scroll ECG up/down by lines

Scroll ECG up/down by pages

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

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

Space bar starts/stops the automatic scrolling

Marking dialogue

Patient Diary for 24-Hour Recordings

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

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

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

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

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