



Operating Manual

Holter light

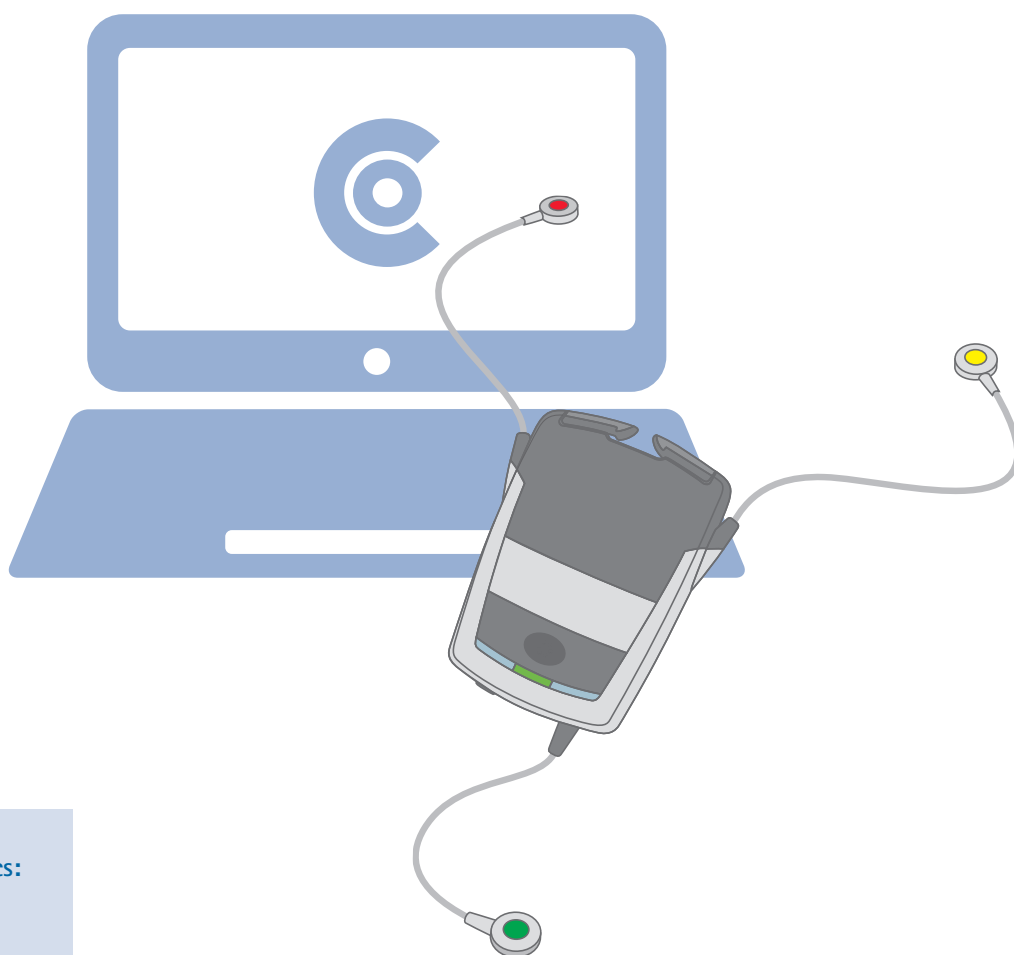
1 Safety

2 Hardware

3 Software

4 Hygiene

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



Operating characteristics:
custo diagnostic 5.5
and higher
for Windows®

MSW 0056 – DK 1903
Version 001 – 11/01/2021

CE 0123

 **custo-med**
EXCELLENCE IN DIAGNOSTICS



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

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 501/L

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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	x	✓	✓
Total ECG	x	✓	✓
Export as a PDF file	x	✓	✓
Reduction of data volume	x	✓	✓
Movement data	x	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	x	flash 500/510/510V, guard holter, watch ✓	flash 500/510/510V, guard holter, watch ✓
Pacemaker analysis ³⁾	x	x	flash 510/510V, guard holter ✓
Event system	x	x	✓
ST measurement	x	x	✓
QT measurement	x	x	✓
HRV	x	x	✓
AF diagnostics	x	x	✓
HRT	x	x	✓
ANS diagnostics ⁵⁾	x	flash 510V, guard holter, screen 400, watch ✓	flash 510V, guard holter, screen 400, watch ✓
12 channel recording ⁵⁾	x	EDAN SE-2012 ✓	EDAN SE-2012 ✓
CSV export RR interv. ⁵⁾	x	✓	✓

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** ① 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** ② main menu is used for patient management. Its most important functions include **Search for patient**, **Add new patient** and **Search Evaluation**.

The **Examination** ③ 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

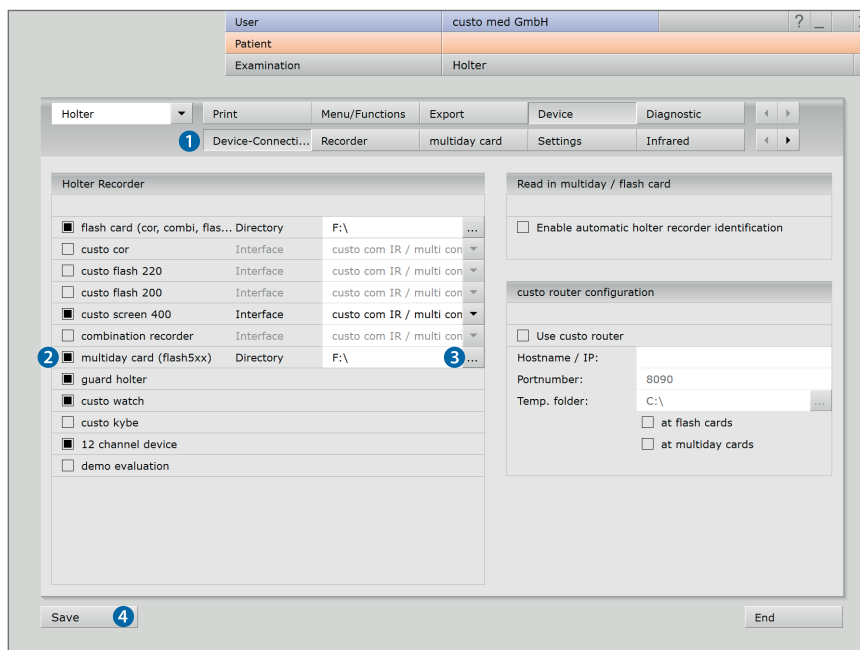
Prerequisite

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.



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 ①.
- Activate the **multiday card** option. ②
- Select the drive of the USB card reader.
To do this, click on the **...** button ③ at the end of the line.
Select the appropriate drive in the directory structure,
confirm with **OK**.
- Click on **Save ④** to apply your input.
- The USB card reader is ready for operation.



3.5 Performing a holter recording

- 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 ① as the Holter recorder.
- The preset recording parameters can be changed by selecting Edit.
- The ① – ⑤ ② buttons contain additional screens with analysis parameters.
- The options ③ 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 ④, new start parameter settings can be saved under a different name and made available for additional recordings.
- With Save ⑤, the originally selected start parameters will be overwritten.
- After you have completed the settings, click on Start ⑥.
- The patient selection mask appears.

User: custo med GmbH

Patient:

Examination: Holter

Holter Recorder ①: multiday card

Holter Profile

Tachycardia: HR >120 for > 1 QRS

Bradycardia: HR <45 for > 1 QRS

Asystolia: > 2.0 sec

Printout period of diary:

Start: 22.01.2021 10:12

Duration: 1 Day

End: 23.01.2021 10:11

Options

Pacemaker: no

Print diary: no

Start with Patient: yes

Analysis Parameter ②

		1	2	3	4	5
Tachycardia	HR Start	120	bpm			
	Number QRS	20				
	HR End	110	bpm			
	Minimum length	0	ms			
	Number HR-QRS	1				
Bradycardia	HR Start	45	bpm			
	Number QRS	20				
	HR End	55	bpm			
	Minimum length	0	ms			
	Number HR-QRS	1				
Asystolia	RR suprav.	2.00	sec			
	RR ventricular	2.50	sec			
	Maximal length	60000	ms			

Options ③

Pacemaker: ☐

Print diary: ☐

Start with Patient: ☒

Start ⑥ End Save ⑤ Save As... ④ Close

Select patient

- Select a patient for the examination:
Enter the patient's name into the input fields in the search mask ①.
- Select the patient from the list ②.
Confirm your selection with **Select Patient** ③.
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** ④.
- Enter the patient data.
The fields marked with an asterisk are mandatory.
- **Save** the data, the patient is entered into the database.
- 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).



*Tip for entries
in the patient menu:*

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

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

User			
Patient			
Examination			
Last name: Mustermann ①			
First name: Franz			
Patient ID			
Patient Group: All patients			
Assignment: All physicians			
Physician ID			
Last name	First name	Date of birth	Pat. ID
Mustermann	Franz	10.10.19...	0000000001
1 of 1 patient			
Select Patient ③		Edit Patient	
New Patient ④			
Cancel			

User	
custo med	
Patient	
Examination: Holter	
multiday card status	
Please check the patient data: Last name: Mustermann First name: Franz Date of birth: 10. October 1960 multiday card: The multiday card is empty. The multiday recorder is starting a new evaluation. Start date: 22.01.2021.	
Print Re	

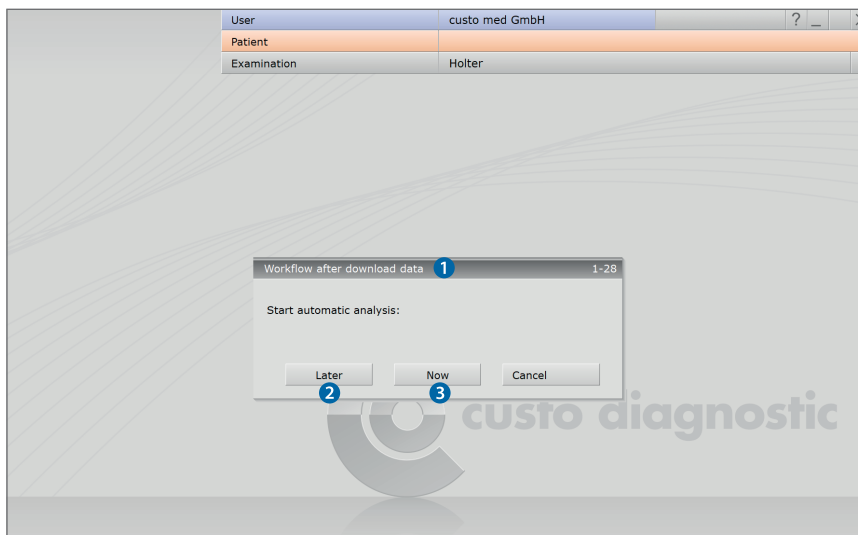
3.6 Downloading a Holter, showing the evaluation

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 501/L:
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.
- Start custo diagnostic and select:
Examination, Holter, Read in recorder.
- The "Workflow after download data" dialogue appears ¹. You can decide whether the recording should be displayed **now** or **later** for evaluation.
Later ² button:
The recording is stored without analysis in the Job Manager³.
Now ³ button:
The recording is evaluated during the download and then displayed.
- When you exclusively work with custo flash 501/L the download process starts automatically.
When using different Holter systems, the "Select data source" dialogue ⁴ appears. Select the appropriate device type.
- Further dialogues depending on the device type/software version, for example:
Start time of the evaluation: Check/correction of the recording period.
- If the recording was opened after it was downloaded, you can close it by clicking on **End** (bottom right).
In the End dialogue, click on **Confirm**.
- For the next examination: Clean, disinfect and charge the devices.

1) To remove SD cards, press lightly on the edge of the card. Do NOT apply force to pull out the card!

2) 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.



3.7 Working with the evaluation

3.7.1 Opening an evaluation via the evaluation search

- To open the evaluation search¹⁾ right-click on the **Patient** button ①.
- With factory settings, the **Search** screen ② 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 ③.
- 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 ④.
- If no filter set is active, select a set ⑤.
- Open an evaluation by double-clicking on the corresponding line or via the **Show** button ⑥.

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

Configuring the list of search results

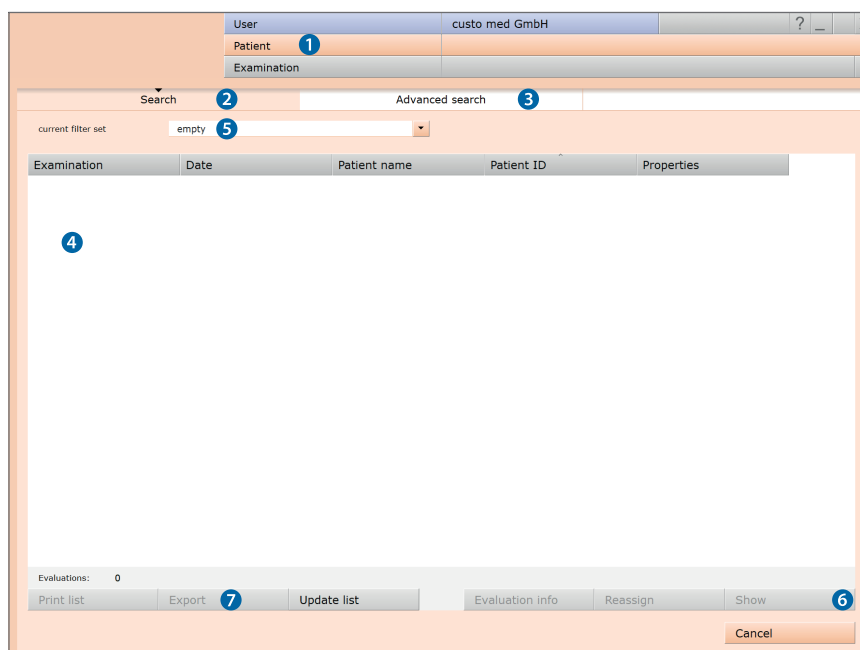
- Right-click on the screen to open the **context menu**.
There click on **Select columns** and set the required columns.
Click on **Confirm** to apply your changes.
- Clicking on a **column header** sorts by this column and sorting within the column can be reversed.
- The list can be printed and exported in various formats ⑦.

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 ③, *see next page*.



Advanced search, creating filter sets

- The **Advanced search** screen **8** is used for creating filter sets and for quick selection of search criteria (e.g. examination, properties, period) **9**.
The search is limited by setting certain search criteria.
- The search results are displayed in the lower half of the screen as a list **10**.
- An evaluation can be opened by double clicking on the corresponding entry in the list of search results or with the **Show** **11** button.
- The previously selected search criteria can be saved for later use as a filter set with the appropriate name. Enter the name into the input field **12** and click on **Save current search as set** **13**.

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** **13** 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** **14** sorts by this column and sorting within the column can be reversed.
- Use the **arrow button** **15** 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 **16**.



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** ①.
- 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 ②.
- Select the patient from the list below the input fields ③ and confirm your selection with the **Select Patient** button ④ 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.*

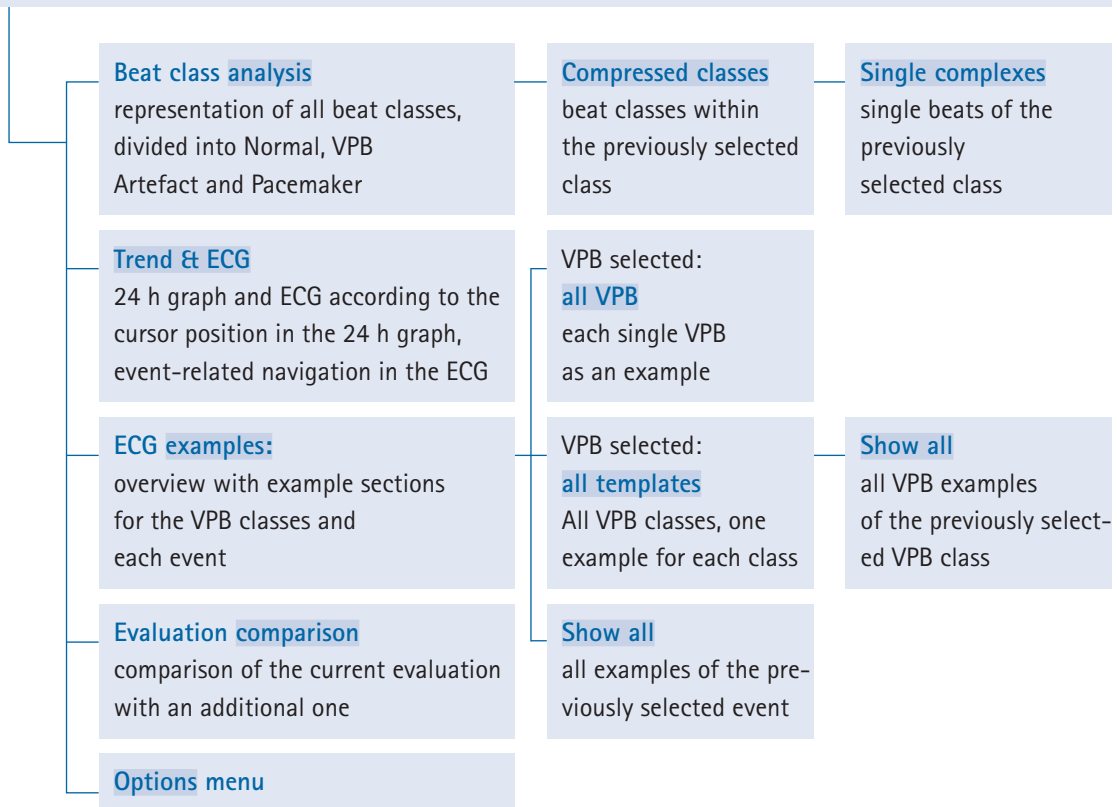
The screenshot shows the 'Examination' menu. The 'Show Evaluation' option is highlighted with a blue circle labeled 1. Other options include 'New Holter', 'Monitoring', 'Read in recorder', 'Settings', 'Last evaluations', 'multiday card status', 'flash card status', 'guard holter viewer', and 'Cancel'.

The screenshot shows the patient search mask. It has input fields for 'Last name' (Mustermann ②), 'First name' (Franz), 'Patient ID', 'Patient Group' (All patients), and 'Assignment' (All physicians). Below these is a table with columns 'Last name', 'First name', 'Date of birth', and 'Pat. ID'. The first row shows 'Mustermann', 'Franz' (③), '10.10.19...', and '0000000001'. At the bottom, there are buttons 'Select Patient' (④), 'New Patient', and 'Cancel'.

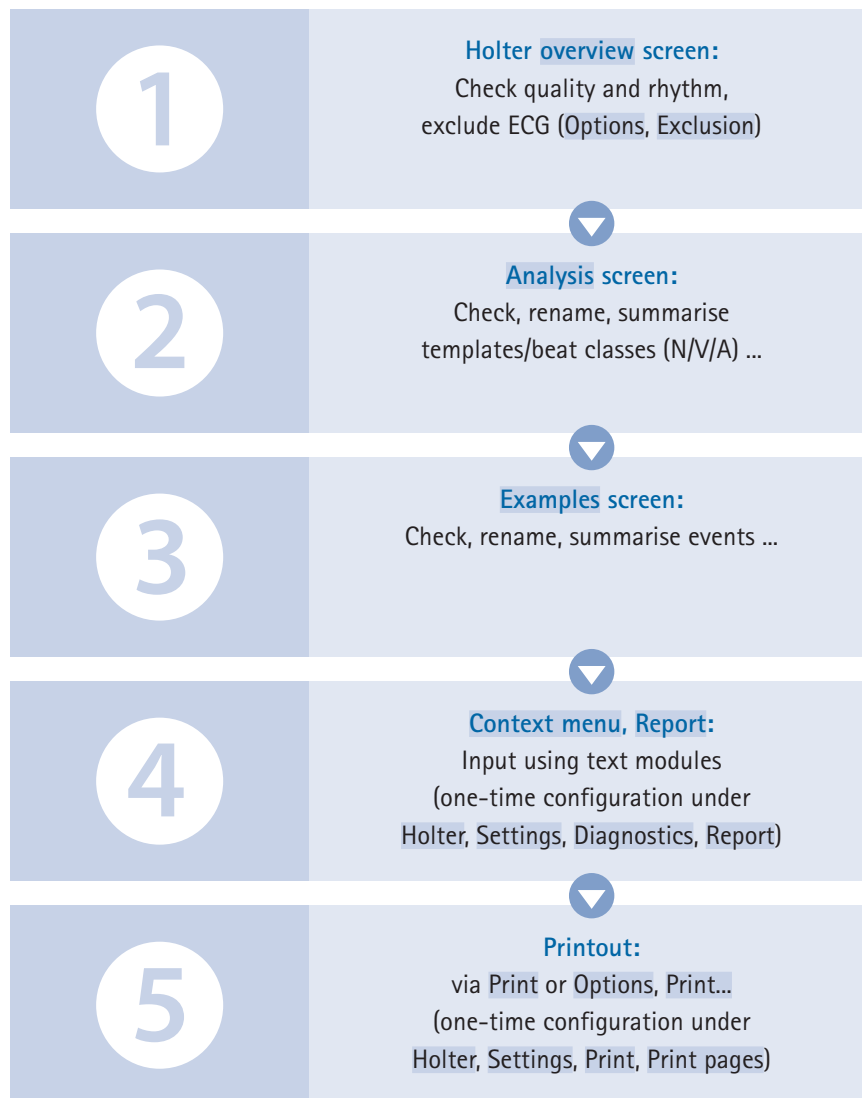
3.7.3 Structure of the evaluation

Holter/Holter ABPM overview:

24 hour graph (trend) with a tabular summary of all events



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

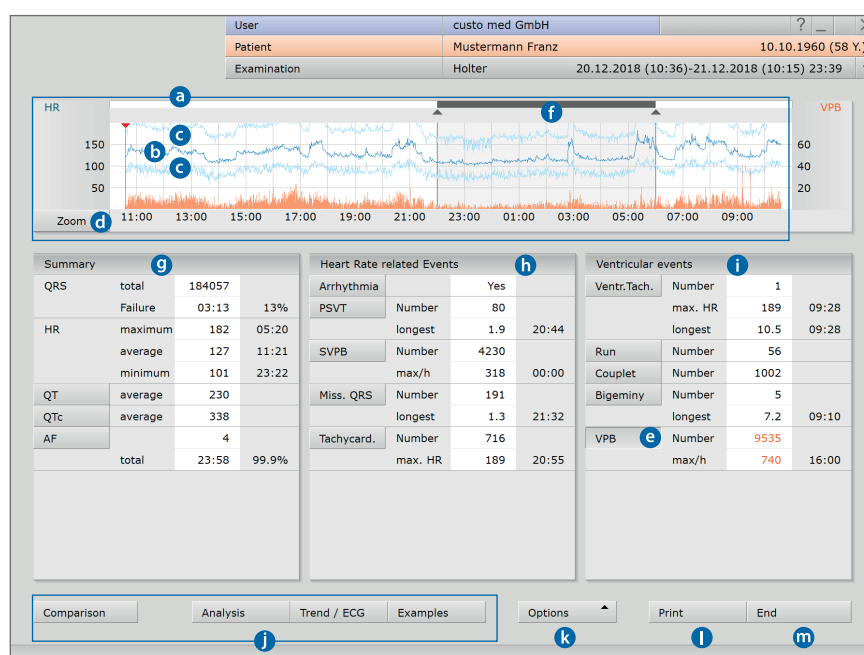


3.7.4 Holter evaluation pages

3.7.4.1 Holter overview

- a 24 hour graph (trend)
- b HR average (dark blue, between HR maximum and minimum)
results from the average heart rate per minute
- c HR maximum, HR minimum (light blue above and below the HR average)
show the highest and lowest 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 events¹⁾
- i List of the existing ventricular events¹⁾
- j Buttons for opening additional evaluation pages
- 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.

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 on the **Analysis** and **Trend/ ECG** pages. These are saved in the dialogue with the designation "Select time" and are permanently available.



Options menu

The contents of the Option menu vary according to the evaluation page.
The most important functions are:

➤ Print...

Temporary change of print settings for the current evaluation

➤ Assign new

The evaluation can be assigned to another patient

➤ Service

Technical details relating to 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

➤ 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

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 analyzed 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.

3.7.4.2 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 settings¹⁾.

- 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.

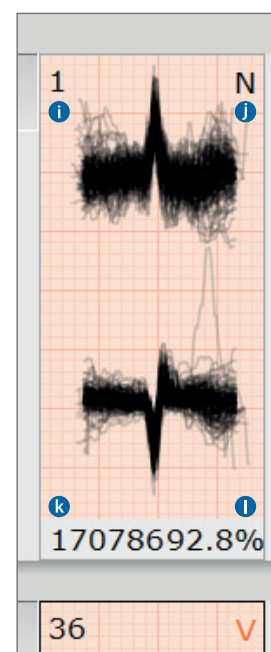
Compress: The beat classes are compressed according to the set sensitivity (default "4").

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.

3.7.4.3 Trend/ECG

- a Trend (24 hour graph) with Zoom function
- b ECG matching the cursor position in the graph above
- c Menu for selecting an event
 - d The selected event is marked in colour in the ECG
 - e The centrally positioned letters in the ECG show the type of event
 - f In the trend 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 ECG¹⁾.
- 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

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

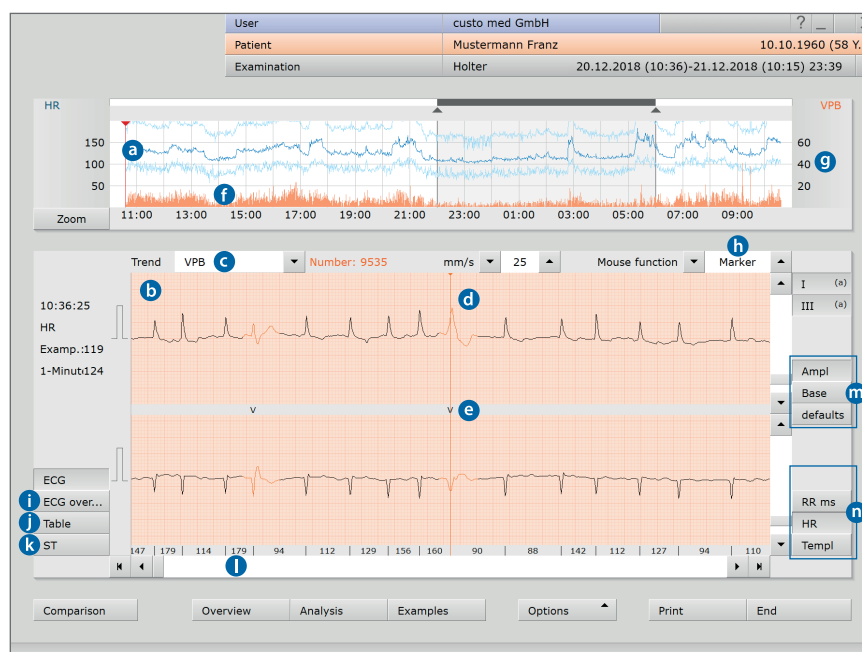
To mark an ECG section, drag the cursor in the ECG signal across an ECG section. When you release the cursor, a dialogue appears in which you can name the marking and then print it or save it as an episode in the evaluation. Episodes are stored with the examples.

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.

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.



3.7.4.6 Examples

- a Example preview with one ECG example for each 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 example¹⁾

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

Considering ECG examples in context

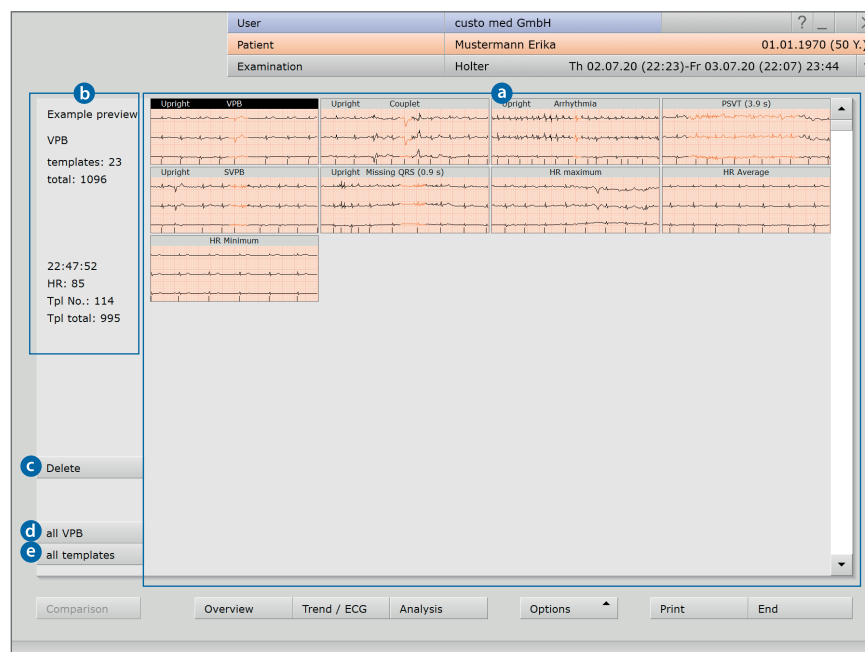
The examples can be viewed either on the **Trend/ECG** page or in the **ECG environment** in context, i.e. in the ECG recording²⁾. This is done by double-clicking on an example. Additionally opening the ECG recording is only possible on the lowest navigation level in the example area – which can be reached 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.

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.

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.

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.*



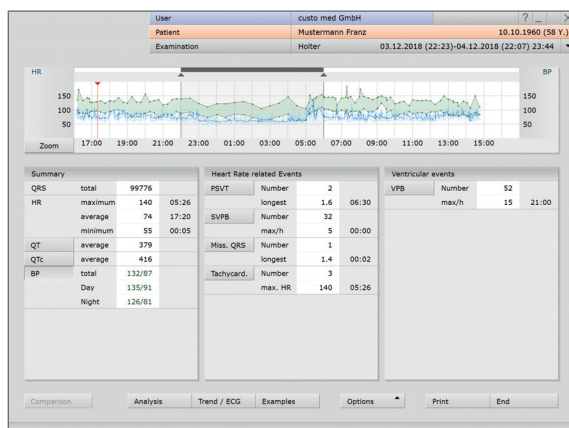
3.7.4.5 Additional standard functions: Comparison, Total ECG, Trend Overview, multiday, Holter ABPM



Comparison (button always bottom left) of two patient evaluations each with trend, HR summary and events.

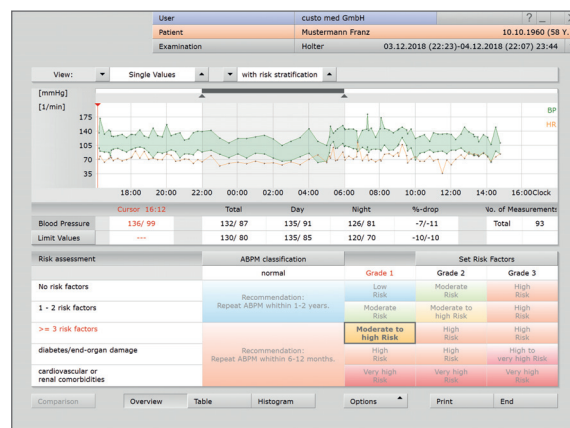
By clicking on an **Event** button, the event is displayed in the graphic.

The **Date lines** above the tables can be opened with a mouse click to display other evaluations of the patient.



Holter ABPM evaluation¹⁾ with custo screen 400: The blood pressure curve (green) is displayed in the graphic via the **Blood Pressure** button in the summary. The ABPM evaluation is opened via **Options, ABPM**.

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).



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.

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 processing¹⁾

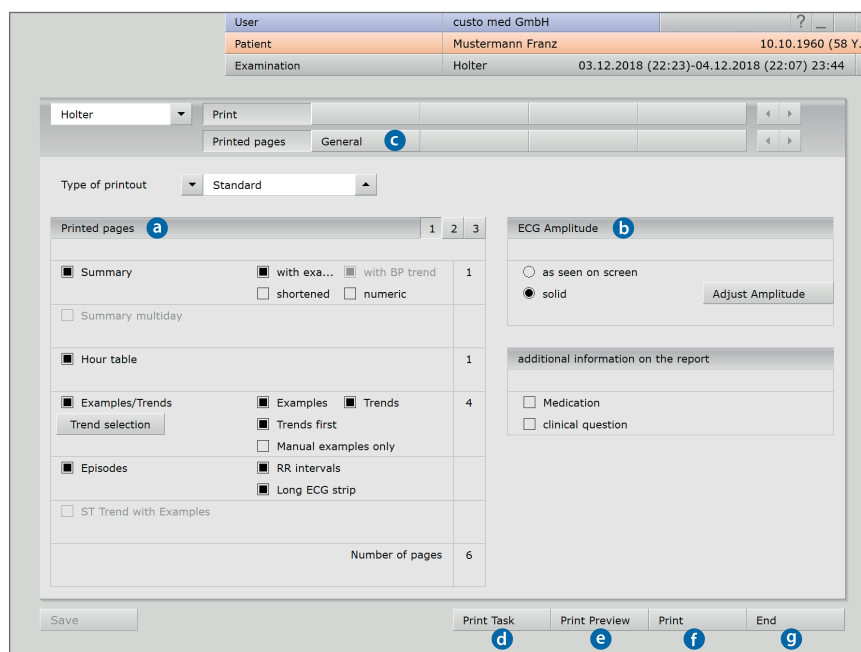
1) To execute print tasks saved in the Job Manager, click on **Examination**, **Job Manager**, **Execute** or **Execute All**.

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

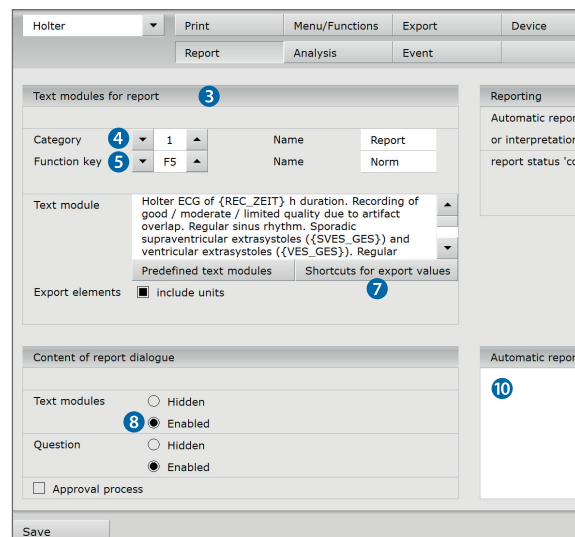
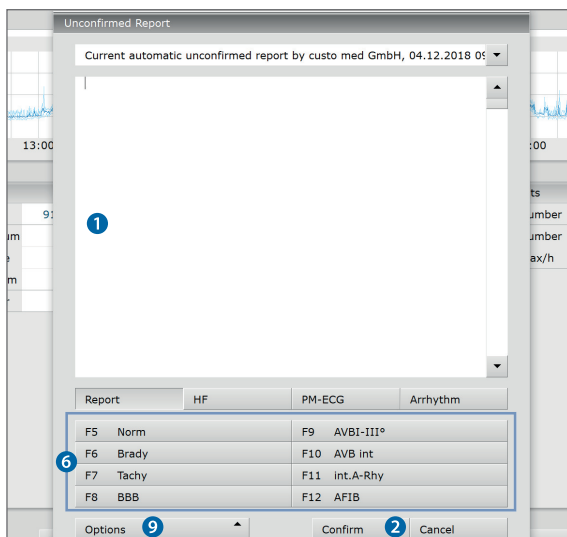
To open the unconfirmed report, right-click on the **evaluation interface**. In the context menu, select **Report**. Enter your data in the text field **1**. If the **Unconfirmed report or Interpretation** option is selected in the system settings, an automatic system unconfirmed report is already present 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** **2** 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 **3**. A total of four groups **4** can be stored with up to eight text modules **5**. The text modules are called in the unconfirmed report dialogue using the keyboard (F5 to F12) **6**.

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** **7** 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** **8** option is activated.

Alternatively, the text modules can be shown in the unconfirmed report dialogue via **Options**, **Texts on** **9**. You also have the option of entering a text, which will be automatically shown in each unconfirmed report **10**. 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 ① is defined ¹⁾.

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

- ② **Evaluation preconfirmed**: active if a user with the reporting right "Preconfirm evaluations" has confirmed the unconfirmed report.
- ③ **Confirmed**: active if a user with the reporting right "Confirm evaluations" has confirmed the unconfirmed report. The "confirmed" status can be reset if required.
- ④ **Printed**: indicates if the evaluation has been printed.
- ⑤ **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** ⑥ to close the evaluation.

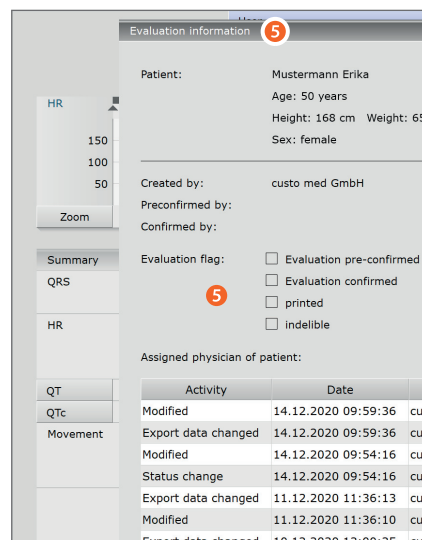
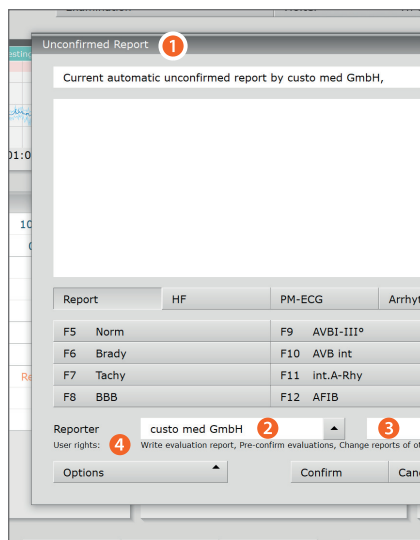
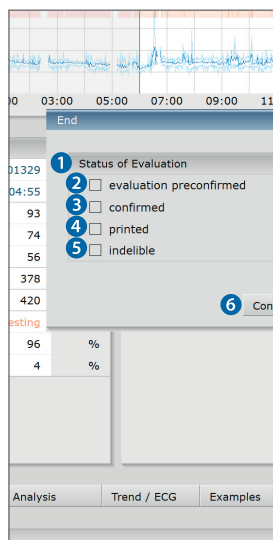
3.7.8 Optional: Reporting with validation

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 ① of an evaluation. The user or reporter can be changed there (**User name** ②, **Password** ③, **Enter**). During the logon process, the user rights of the respective user are checked and the software interface is adapted accordingly ④. The reporting is documented in the **evaluation information** ⑤ (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**.

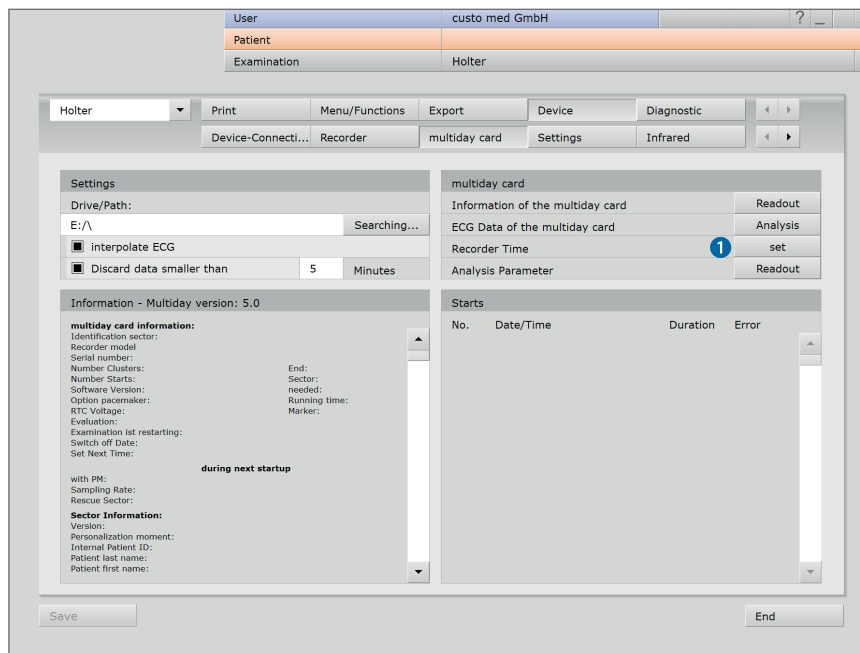


3.8 Appendix

3.8.1 Setting the custo flash 5xx recorder time

custo flash 5xx has a 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 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 1** 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)

1) *Note on the designation of the ECG derivations:
Depending on the recording device and application of electrodes, the derivations are designated differently in custo diagnostic.*

custo flash 5xx I, II, III

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

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

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

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

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

User	custo med GmbH	1	?
Patient		2 2	
Examination		3 3	

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

User	custo med GmbH	4	?
Patient	Mustermann Franz	5 4	10.10.1960 (60)
Examination	Holter	6 5	

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.

User	custo med GmbH	?	_	×
Patient				
Examination				▼
Holter				
ABPM				
Resting ECG				
Stress ECG				
Cardiopulmonary Exercise Testing				
Spirometry				
Cardiac Rehab				
Mobile Cardiac Telemetry				
Blood glucose				
Task Manager				
Worklist				

Generally valid keyboard shortcuts

Enter	Confirm, continue
Tabulator	Tabulator Cursor jumps to next input 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.



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