Operating Manual

ABPM

with custo screen 300/400 and custo diagnostic

Features:

custo diagnostic 4.1 and higher
for Windows®

GEB 0172 – DK 1280
Version 002 – 05.06.2013

CE 0636

custo·med
EXCELLENCE IN DIAGNOSTICS

Operating Manual

ABPM

with custo screen 300/400 and custo diagnostic

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

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MASTER COPY: Patient Diary for 24-Hour Recordings....59

01.1 Symbols on the devices

	Manufacturer: custo med GmbH, Leibnizstr. 7, 85521 Ottobrunn, Germany
CE 0636	CE mark
	Protection class classification of medical electrical equipment according to IEC 60601-1 (Type BF)
	The device is not suitable for newborn babies and infants.
	Non-ionizing electromagnetic radiation, device has a HF transmitter (radio unit not active for custo screen 300)
	Observe the Operating Manual
	Separate collection of electrical and electronic equipment, do not dispose with domestic waste
	Illustration on the custo screen 400 recorder to indicate the direction of insertion for the SD card (custo flash card mini)

01.2 Intended use

01.2.1 Use as ABPM recorder

custo screen 300/400 is an ABPM recorder with an internal power supply and is used for recording and evaluating a patient's blood pressure characteristics. Recording time can be up to 72 hours. custo screen 300/400 is perfectly safe for patients with pacemakers.

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

The device is not suitable for unsupervised operation with unconscious patients (applies to recordings with long-term blood pressure measuring).

01.2.2 Use as Holter-ABPM recorder (custo screen 400)

custo screen 400 can also be used as a Holter-ABPM recorder, for the synchronous recording of ABPM and holter ECG. For the Holter-ABPM functionality the custo guard ECG transmitter and the custo diagnostic module, custo tera (for holter ECG), will be required. The handling of the Holter-ABPM system is described in the operating manual *"Holter-ABPM, Synchronous recording of ABPM and holter ECG with custo screen 400 and custo diagnostic".*

01.3 Symbols used in this Operating Manual

This Operating Manual uses the following symbols to indicate important information, comments and tips:

ACTIONS THAT ARE PROHIBITED
or not allowed under any circumstances!

WARNING
used to indicate situations which, if not avoided, may result in personal injury and 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..

02.1 General notes

Strict compliance with the safety instructions protects against personal injury and property damage during device operation. This Operating Manual is designed to accompany the product and should be kept ready to hand close to the device.
As either the operator or user of this device you should have read and understood this Operating Manual, in particular the safety instructions.

Laws and regulations applicable to the product

- This system is designed in accordance with Medical Device Directive 93/42/EEC, Class IIa, and meets the requirements of protection class I or II (depending on the power supply unit used, the recorder is a device with an internal power supply), type BF in accordance with IEC 60601-1.

- Other devices which are part of the system must meet the requirements of the Standard for Information Technology Equipment (IEC 60950) or the Standard for Electrical Medical Devices (IEC 60601-1).

- The electrical installations in the rooms in which the system is used must meet the requirements of the applicable safety standards (e.g. VDE 0100 Part 710).

- For users outside the Federal Republic of Germany, the respective national accident prevention measures, regulations and requirements apply.

02.2 Safety installations and safe working

custo screen 300/400 must only be used in a technically perfect condition. Regularly carry out a visual inspection of the device. Only use accessories approved by custo med.

Installation of the system

Portable socket outlets must not be placed on the ground.

Portable multiple socket outlets which are supplied with the system are to be used only for supplying devices which are part of the system. Additional portable multiple socket outlets, lines and other equipment which are not part of the system, must not be connected to the system.

When using a multiple socket outlet, the maximum permitted load is 3200 VA.

Slots which are not used in the delivered system (portable multiple socket outlets) must be provided with covers.

Ambient conditions

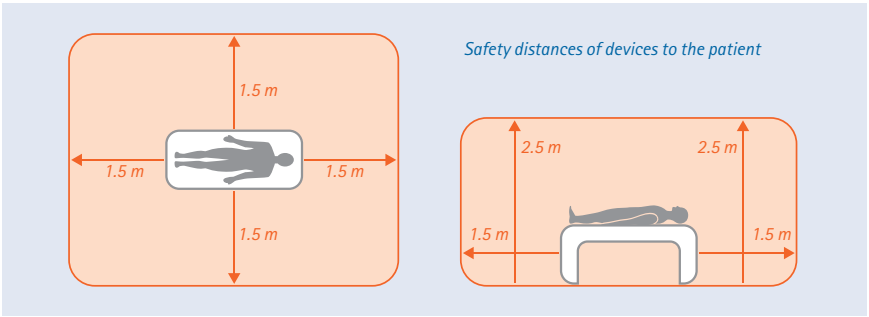
For the installation and the operation of the device the EMC notes (electromagnetic compatibility) in this operating manual must be observed, refer to chapter *08.7 Manufacturer's Declaration regarding EMC...* .

The custo screen 300/400 is not suitable for use in rooms and/or areas with a risk of explosion.

Strong electromagnetic sources in the immediate vicinity of the custo screen 300/400 may result in recording errors. custo screen 300/400 must not be stored or used in the vicinity of X-ray equipment, diathermy units and magnetic resonance devices (MRT). Other electrical devices such as mobile phones or radio transceivers may impair the quality of the recording.

The custo screen 300/400 recorder is not protected against the ingress of dust and spray water. custo screen 300/400 must be protected from moisture, dust, dirt and mechanical impact such as dropping or transport damage.

Patient safety



Without medical protective devices, for example medical protector, the PC and all the non-medical devices connected to the system (e.g. the monitor and printer) must be set up and used at a distance of at least 1.5 m to the patient unit (see the orange area in the figure) as leakage currents may occur.
Any non-medical devices and the patient must not be touched at the same time during the examination.

During routine maintenance work on non-medical devices connected to the system the patient must not be touched (risk of electric shock).

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

Important notes on handling the custo screen 300/400

A permanent cuff pressure, e.g. from a bent cuff tube can cause injury to the patient. If the cuff pressure continues, the patient should open the Velcro fastening on the cuff or switch off the recorder.

Compressing or reducing the cross section of the cuff tubes should be avoided.

The cuff must not be placed on wounds, open areas or areas where surgery has been carried out recently.

Blood pressure measurements may impair the function of other medical devices which are attached to the patient near the blood pressure cuff.

Ensure that the brief interruption of the blood circulation due to the measurement method does not affect the patient permanently. Ensure that the intervals between the blodd pressure measurements are sufficient.

The results of blood pressure measurements may be influenced by:
the patient's position (lying down, standing, sitting), movement, the general health of the patient, heart rate-related or ventricular events as well extreme temperatures and relative humidity. Observe the operating conditions and the patient instructions.

The device is not protected against the potential impact of high-frequency (HF) surgery devices.

Never use damaged batteries or rechargeable batteries. If the custo screen 300/400 will not be used for an extended period, remove the batteries.

If any liquid has been spilled onto the device, remove the batteries or rechargeable batteries immediately and send the device to your authorised custo med dealer or custo med.

custo flash card mini memory card (mini SD card in custo screen 400)

The mini SD card is only required for Holter-ABPM recordings with custo screen 400. If only the blood pressure is recorded with custo screen 400 (ABPM), no data is saved to the mini SD card.

custo med recommend to leave the mini SD card supplied in the recorder so that it does not get lost and no dirt can get in the opening.

Hygiene

For cleaning and disinfection observe the legal requirements and the current state of technology.
Use only cleaning agents and disinfectants approved by custo med for cleaning and disinfection. Clean and disinfect your device in accordance with the specifications given in *Chapter 04 Hygiene*.

System and data security

The device must only be used with the supplied custo med software (custo diagnostic).

As the operator you are responsible for ensuring regular data backups (patient databases, evaluations etc.) and system backups. We recommend that you backup the data at the latest before new installations, updates and far-reaching system configurations.

custo diagnostic new installations, updates and system configurations may only be performed by your authorised custo med dealer.

Only change data generated in custo diagnostic within custo diagnostic itself and not in your EPR system (Electronic Patient Record) or your hospital information system (HIS).

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

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

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

custo connect

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

When you use custo connect to integrate additional medical devices in the custo med system, on starting the connected medical device check whether the patient name was taken over correctly.

Data management in custo diagnostic: Assign evaluation (allocate evaluation)

If an examination was conducted with incorrect patient data, the evaluation can be subsequently allocated to the correct patient. Make sure that the evaluation is definitely allocated to the correct patient. An incorrect allocation can lead to a misdiagnosis. Please note that data which has already been exported to an external system (e.g. surgery IT system) cannot be changed.

custo diagnostic is preset with the Assign evaluation function deactivated; however it can be reactivated via user rights if necessary. Only the Supervisor can configure the user rights. If the Assign evaluation function is activated, it can be found in the evaluation search or in open evaluations in the Options menu.

We recommend configuring user rights in custo diagnostic so that only authorised persons can execute the Assign evaluation function.

02.3 Maintenance (regular safety checks)

The operator is responsible for maintenance. The operator must ensure that the device is checked for proper condition at the latest every two years. The functionality and the state of accessories must be checked at regular intervals. If damaged and/or heavily soiled, the complete system must no longer be used.

Any interventions in the existing system, changes to system components, enhancements as well as internal cleaning and repairs may only be performed by your authorised custo med dealer or custo med.

Technical safety check

After each system or device repair, modification or conversion, a technical safety check must be performed by your authorised custo med dealer.

Technical measurement check

For custo screen 300/400 a technical measurement check must be carried out every two years. Please contact your authorised custo med dealer.

02.4 Disclaimer

The manufacturer is not responsible for improper operation, failure to comply with the safety instructions and non-observation of specifications due to negligence.

custo med only assumes responsibility for the safety and reliability of the device if all changes, enhancements, repairs and any other work on the device and/or system have been performed by an authorised custo med dealer or custo med and the Operating Manual has been observed during device operation.

02.5 Warranty

Our product philosophy is committed to providing you with faultless products which meet your expectations. Should you have reason to complain we aim to rectify any defects immediately or provide a replacement delivery.

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

Only use original spare parts and accessories from custo med even after the end of the warranty period. This is the only way to ensure the safe and problem-free operation of your device.

03.1 Part names, components for recording

1. custo screen 300/400 recorder,
   (custo screen 400 including mini SD card)
2. Standard blood pressure cuff

Other cuff sizes are available as accessories:
Small 20 – 24 cm, XL 32 – 40 cm, XXL 38 – 50 cm,
Standard without retainer, XXL without retainer

3. Carrying case for custo screen 300/400
4. Carrying belt
5. Batteries (set of 3) type AA Mignon, 1.5 Volt

Starter kit

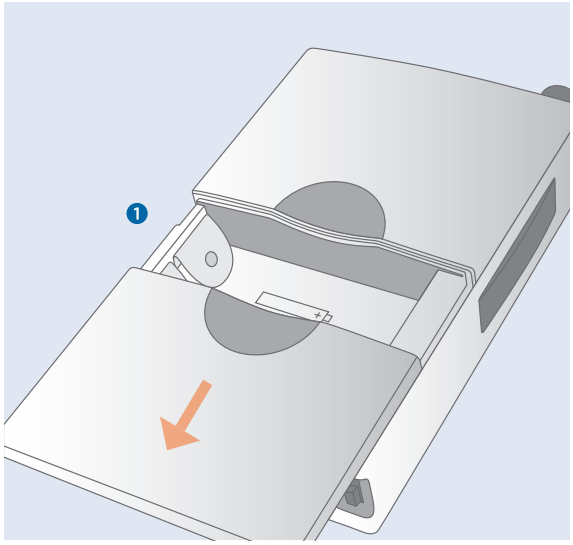
6. custo com IR infrared interface
   incl. USB connection cable, type B mini
   (for data transfer between PC and recorder)
   - USB card reader (not shown)

7. *Tip: custo screen protect hygiene set*

For increased hygiene and comfort when wearing the blood pressure cuff we recommend the use of custo screen protect non-woven pads. The non-woven pad is worn underneath the blood pressure cuff with the fluffy side on the skin and the protective layer facing away from the skin. A custo screen protect hygiene set contains six washable non-woven pads.

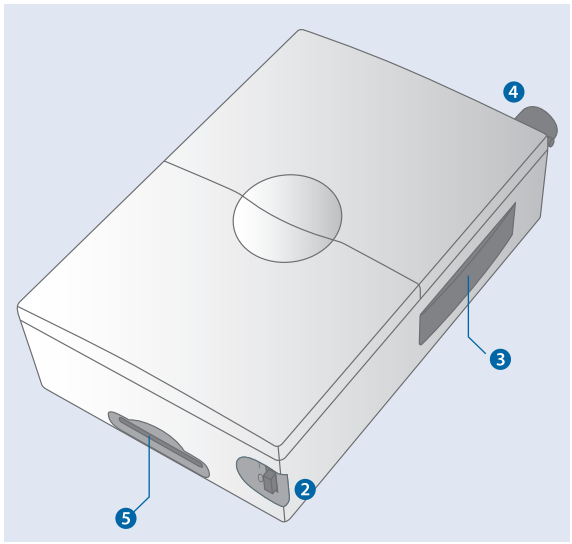
custo screen protect hygiene set

03.2 Device operation



Inserting the batteries or rechargeable batteries

Open the battery compartment as shown on the left ❶ and insert three standard batteries. The direction of insertion is shown on the drawings inside the battery compartment.



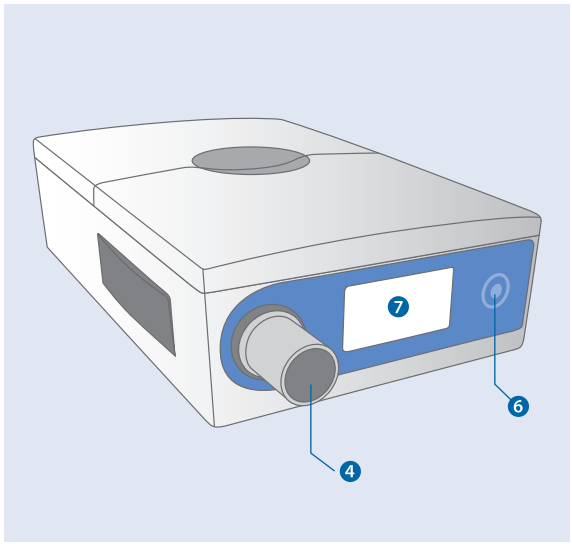
Functional elements on the device

❷ On-Off switch:
for switching the recorder on and off
I = on
0 = off

❸ Infrared interface
for data transfer between
custo screen 300/400 and a PC

❹ Connection for blood pressure cuff

❺ Card slot for mini SD card
(for custo screen 400 only)

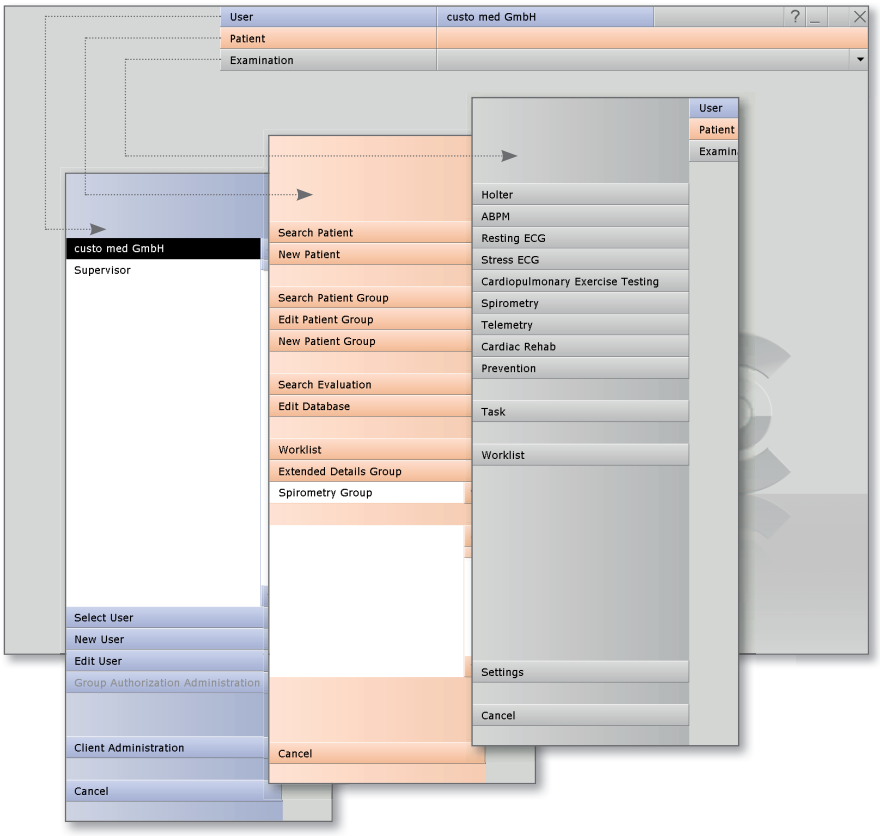


❻ Function key
for starting and stopping measurements

❼ Display
to show results and error messages
(refer to chapters 08.1 and 08.2)

03.3 custo diagnostic – basic program structure

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



In the User main menu, the system users can be created and managed. The user administration can be used to allocate user rights and control user-specific settings, e.g. the creation of a separate patient database for each user.

The Patient main menu is used for patient administration. Its most important functions include Search for Patient, New Patient and Search Evaluation.

The Examinationmain menu lists all the examination types which can be carried with custo diagnostic. The modules you do not own are deactivated – this can be recognised by the light grey font.
This menu is also linked to the Settings area. This area is for making cross-program, examination-related and user-specific settings.

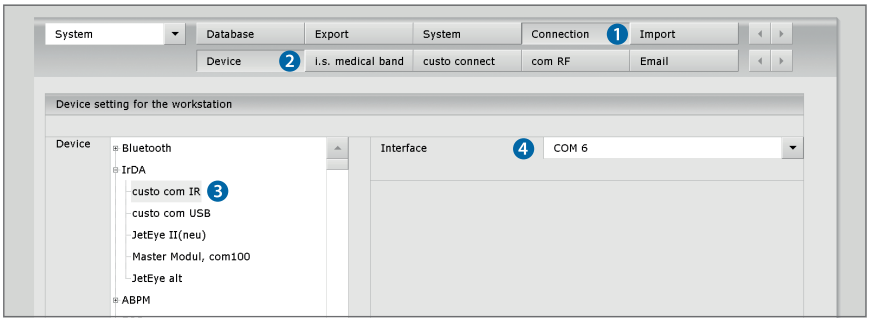
03.4 Device connection and configuration

Requirement:
custo diagnostic is installed on your PC and ready for operation[1)].

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

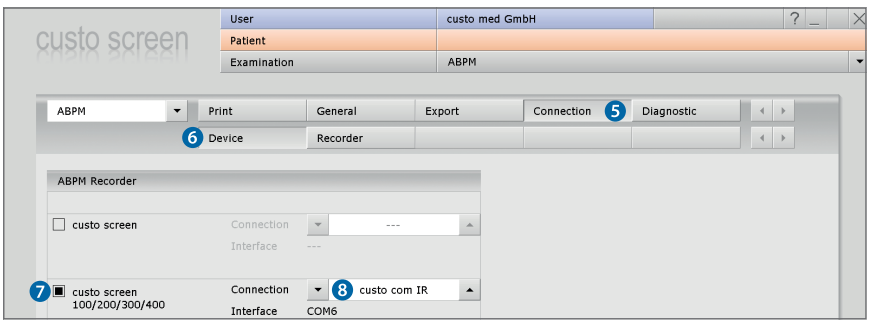
Connection and set-up for infrared interface custo com IR

Connect the infrared interface custo com IR to your PC[2)]. The device drivers are installed automatically.
Check in the Windows device manager which COM connection is allocated to custo com IR so that you can enter it in custo diagnostic. To do this, right-click the Workplace icon or the Computer icon from your Windows user interface, then Manage in the context menu, there click on Device Manager (left-hand side of the window). On the right-hand side of the window, open the menu point Connections (COM and LTP) and write down the connection for custo com IR, e.g. (COM6).
In custo diagnostic, open the page Examination, Settings, Connection ❶, Device ❷. In the device area, select IrDa, custo com IR ❸ and, in the Connection area select the corresponding COM port ❹ from the device manager. By clicking on Save (bottom left) your data will be applied.



custo screen 300/400, device selection

Open the page Examination, ABPM, Settings, Connection ❺, Device ❻. Select custo screen 100/200/300/400 ❼ as the recording device and. Under Connection, select custo com IR ❽. By clicking on Save (bottom left) your data will be applied. The device is ready for operation.



1) custo screen 300/400 and custo com IR in combination with existing custo diagnostic software (Versions below 3.8.4)

custo screen 300/400 is downward compatible and can also be started as an ABPM-recorder in older custo diagnostic versions.
The driver for the infrared interface custo com IR is included in the custo diagnostic set-up from version 3.8.4 onwards. If you have an older version of custo diagnostic and you don't want to carry out a custo diagnostic set-up a manual driver installation must be carried out for the custo com IR infrared interface.
Please contact your authorised custo med dealer.

2) Using other infrared interfaces

custo screen 300/400 can also be connected to your PC via older infrared interfaces such as custo com USB or JetEye.
The connection and configuration procedure for custo com USB is identical to the one described for the custo com IR.

04.1 Cleaning and disinfection

Important notes

Use only cleaning agents and disinfectants recommended by custo med.
Unsuitable agents may damage the device.

Observe the manufacturer's specifications
(e.g. regarding dosage and contact times).

The recorder must never be immersed in liquids or cleaned
with too much water.

custo screen 300/400

Make sure that the exterior of the device is always aesthetic and clean. Wipe the device using a damp cleaning cloth and a mild (acid-free!) cleaning agent or a suitable disinfectant.

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

Carrying case and belt

Machine washable at 40°

Do not use bleach.

Do not iron.

Do not tumble dry.

The carrying case and belt can be machine washed at up to 40 degrees. In addition, we recommend a quick disinfection with alcohol after each use.

Blood pressure cuff

The blood pressure cuff should be cleaned from dirt and sweat after every use. Please observe the information on the package insert of the blood pressure cuff.

- Cleaning and disinfection: Clean the cuff with a damp cloth. If required, remove the bladder and wash the cuff cover with soapy water or a disinfectant solution. The cuff can be disinfected with the following disinfectants: Cidex, Sporicidin, Mikrozid, 70% isopropyl alcohol, ethanol 70%, Buraton fluid. After disinfecting the cuff, rinse under clear water and air dry.

- Sterilisation: The cuff can be sterilised with ethylene oxide (EtO) gas. After sterilisation the parts that were exposed to EtO must be aired; all relevant regulations and safety precautions must be complied with.

Do not autoclave.

The cuff tube, especially the BNC plug must not be immersed in liquids under any circumstances.

04.2 Recommended cleaning agents and disinfectants

Disinfectants (custo screen 300/400, carrying case, belt):

All alcohol-based disinfectants approved for medical use (e.g. propanol, ethanol).

05.1 Patient instructions

For optimum results, inform your patient about the recording procedure and how to handle the recorder correctly.

Operating the recorder

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

The recorder (switched on) and the cuff must also be worn during the night.

On the day of the recording no x-rays must be taken. Sources of interference such as electrical stimulation devices must be avoided.

Each measurement is announced with a beep (unless this function is deactivated in custo diagnostic). Using default settings, the measurements are performed every 15 minutes during the day and every 30 minutes during the night.

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

Preventing incorrect measurements

The arm to which the cuff is fitted must be kept still during measuring. Any physical activity must be stopped.

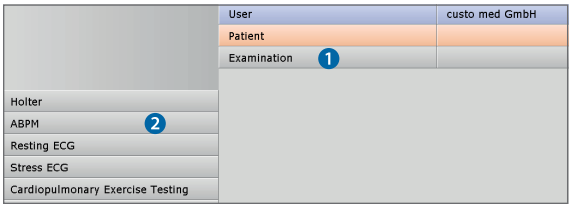
When measurement has failed, a new measurement is automatically performed after two minutes. If several measurements fail during recording (in particular, E6, E21-24 and E25-28) it must be checked if the cuff is still positioned correctly. The marker should be located on the brachial artery and the cuff should be positioned on the arm in such a way that approximately two fingers fit between the cuff and the arm.

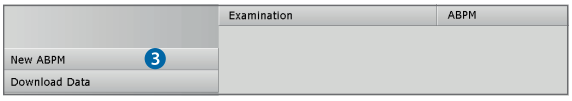
If any problems occur during recording

If any problems occur during recording, e.g. if the cuff pressure is too high, the patient must contact the physician. The patient can stop the measurement at any time by pressing the function key or by opening the Velcro fastening of the cuff.

05.2 Starting the recorder in custo diagnostic

The steps required to record and evaluate an ABPM recording in custo diagnostic are shown without a surgery IT system or HIS connection.

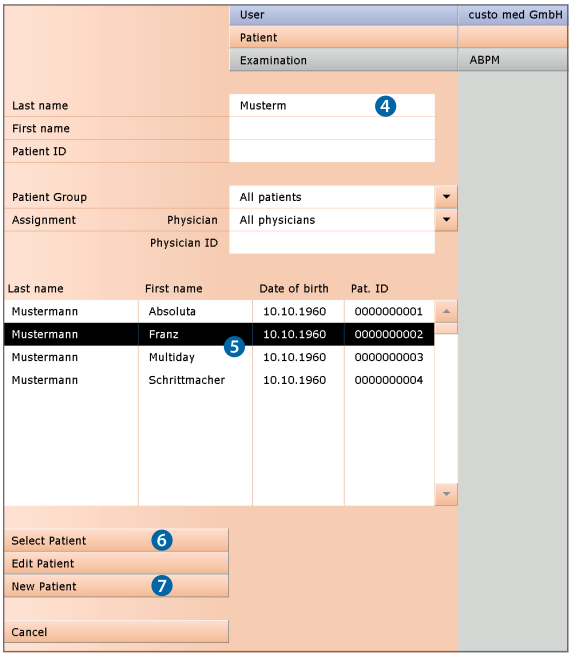




Program start, calling the ABPM

Make sure that the infrared interface custo com IR is connected to the PC and ready for operation. Start custo diagnostic and log in with your user name and password, if required.

Click on: Examination ❶, ABPM ❷, New ABPM ❸.



Selecting the patient

The patient search screen appears. Select a patient for the examination. Enter the patient's name or the first letter of their name into the input fields of the patient search screen ❹.

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

New patient

If the patient does not yet exist in your database, click on the New Patient ❼ button. Enter the patient data. The fields marked with an asterisk are mandatory.

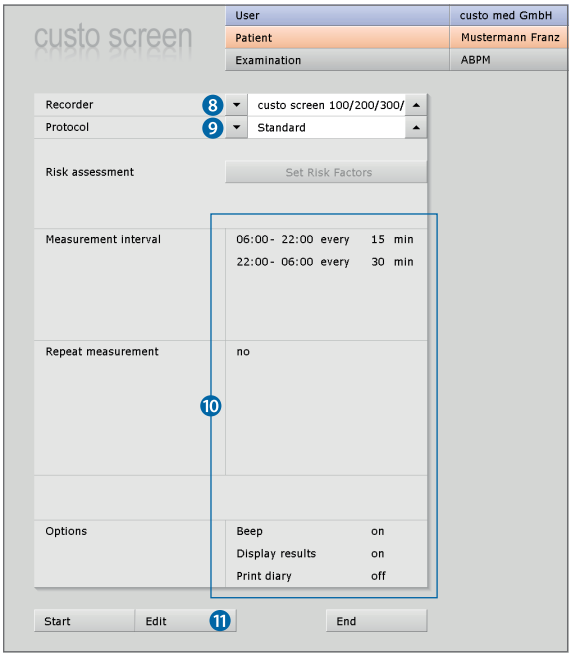
Save the details to enter the patient in your database.

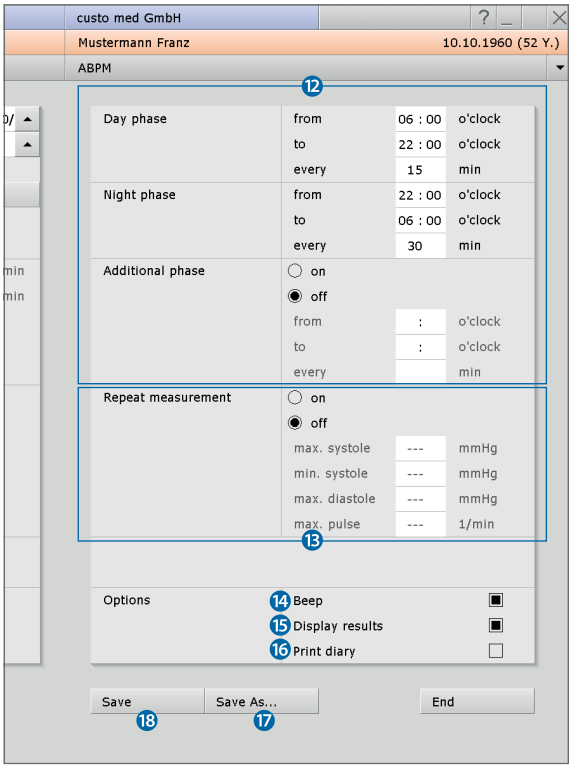
Setting the recording parameters

The screen for setting the recording parameters is displayed. Select custo screen 100/200/300... as the recorder ❽.

Set the start parameters for the blood pressure measurements: select a set of parameters that has already been saved, e.g. Standard ❾ or create a new set. The day and night phases and the measuring intervals of the selected set are displayed below the selection field ❿.

With the Change ⓫ button, the start parameters can be re-defined and saved.





On the right-hand side of the screen day, night and additional phases can be set ⓬. In the repeat measurements area ⓭ you can set whether another measurement is to be carried out if the limit values are exceeded or not achieved.

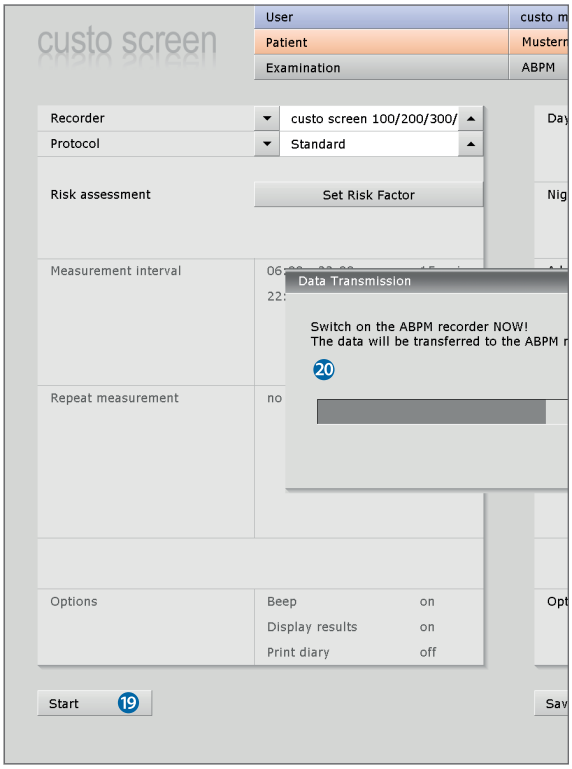
Set the options as required:

⓮ Signal before measurement (Beep): Emits a signal tone before each measurement, so that the patient can get ready.

⓯ Display results: Systolic and diastolic blood pressure and heart rate are shown on the recorder display after each measurement.

⓰ Print Diary: After you click on Start a form for the patient is printed which can be used to document events during the recording.

With Save as ⓱ the set start parameters can be saved with a new name and made available for other recordings. Clicking on Save ⓲ will overwrite the original parameters.



BEFORE YOU START: insert new batteries or fully charged batteries into the recorder. Always use complete rechargeable battery sets (do not mix low batteries with fully charged/new batteries).

Data transfer, starting the recording

Once it has been switched on, place the recorder in front of the infrared interface (at a distance of approx. 10 – 20 cm). Click on Start ⓳ to transfer the recording parameters to the recorder. The data transfer dialogue is displayed ⓴.

If more than 55 seconds pass between switching on the recorder and clicking on Start ⓳, the data cannot be transferred as the recorder is in idle mode. To active the recorder, press the function key ◉. When "PC" is shown on the recorder display, the device is in data transfer mode.

The start parameters and the patient data are transferred. The recorder is ready for the recording and can fitted to the patient.

05.3 Fitting the recorder to the patient

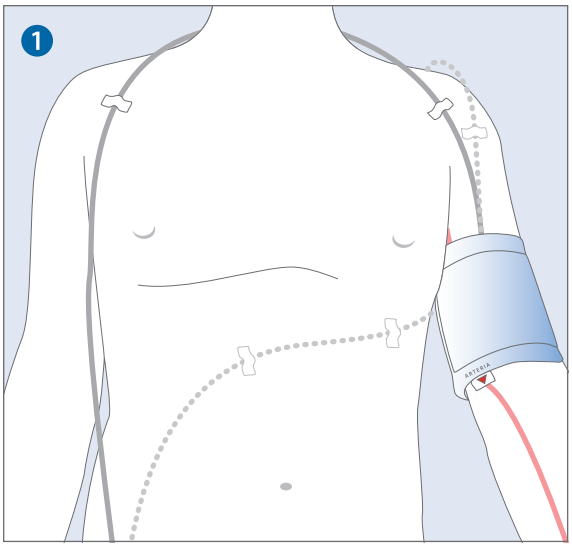
❶ Fitting the blood pressure cuff

Fit the cuff to the left upper arm, two to three cm below the armpit. Fit the cuff in such a way that the marking is on the brachial artery. The cuff must not be too tight. You should be able to fit approximately two fingers between the arm and the cuff.

Please ensure that you select the correct cuff size for the patient. The cuffs are marked with the arm circumference for which they are suitable, e.g. standard 24 – 32 cm.

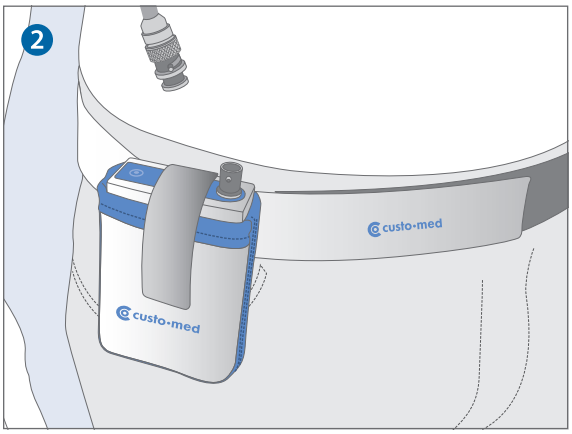
Route the cuff tube from the left shoulder over the right shoulder to the right hip. This is were the recorder will be attached later.

Fix the cuff and the tube to the patient. This will prevent failed measurements due to the incorrect position of the cuff or the tube. Use professional fixing aids with little adhesive residue.

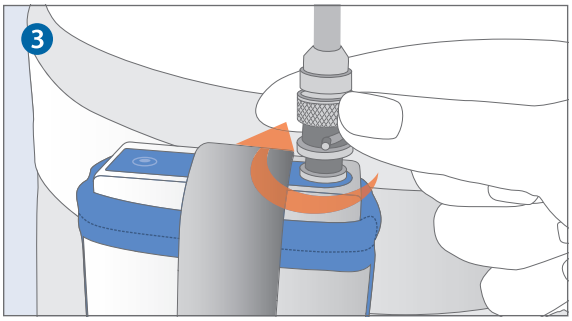


❷ Fitting belt and carrying case

Attach the carrying case to the carrying belt. Place the carrying belt on the patient. The bag should be on the patient's right hip. Place the recorder which needs to be switched on in the carrying bag and close it with the Velcro fastening.

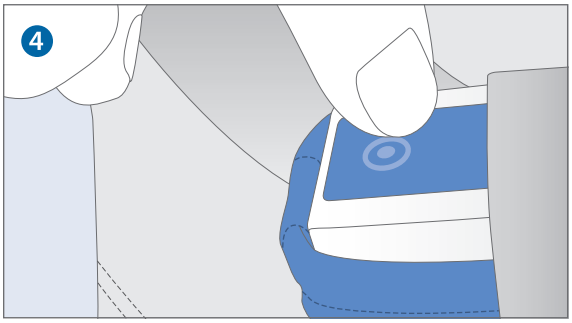


❸ Connect the cuff tube to the recorder as shown.

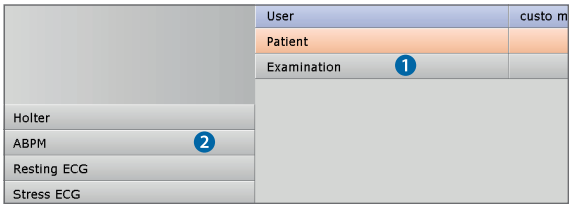


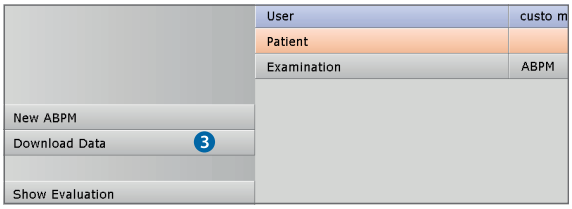
❹ Test measurement

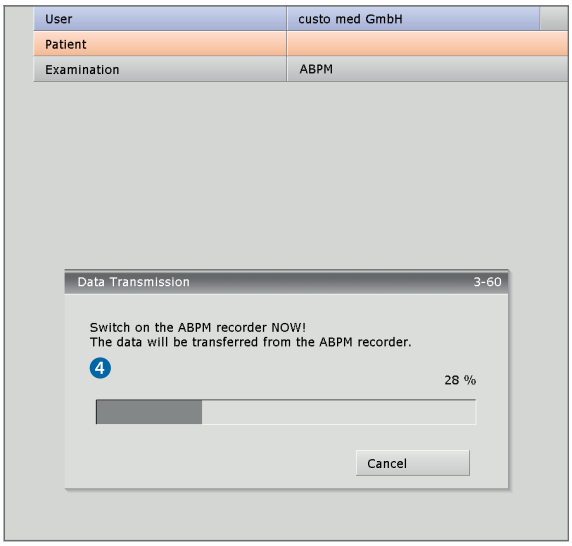
Press the function key to carry out a test measurement. Please ensure that the patient keeps still during the measurement. In case of a failed measurement improve the fit of cuff and tube. If the test measurement was successful, the patient and the recorder will be ready for recording.

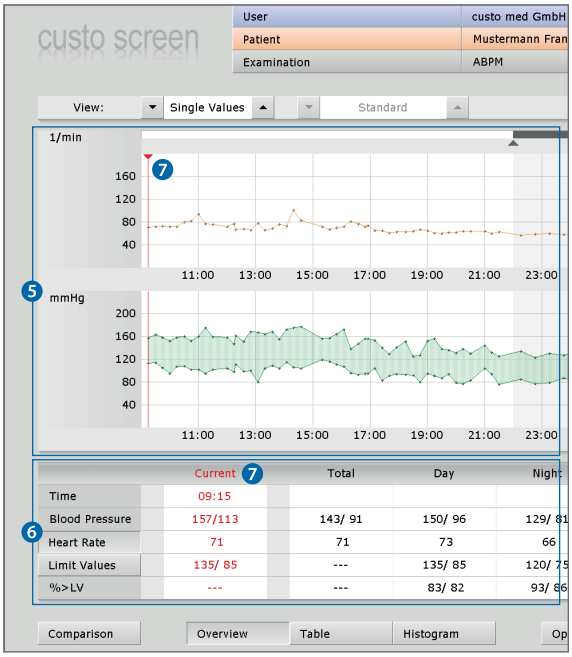


05.4 Downloading the recording









Remove the recorder from the patient:

- Remove the cuff tube from the recorder
- Take the recorder out of the bag and switch it off
- Remove the carrying belt, cuff, fixing aids

Starting the program and downloading the recording

Start custo diagnostic and log in with your user name and password if required. Click on Examination ❶, ABPM ❷.

Once it has been switched on, place the recorder in front of the infrared interface (at a distance of approx. 10 – 20 cm). Click on Download Data ❸. The data transfer dialogue is displayed ❹.

If more than 55 seconds pass between switching on the recorder and clicking on Download Data ❸, the data cannot be transferred as the recorder is in idle mode. To active the recorder, press the function key ◉. When "PC" is shown on the recorder display, the device is in data transfer mode. The recording is downloaded and displayed as an evaluation.

Evaluation overview

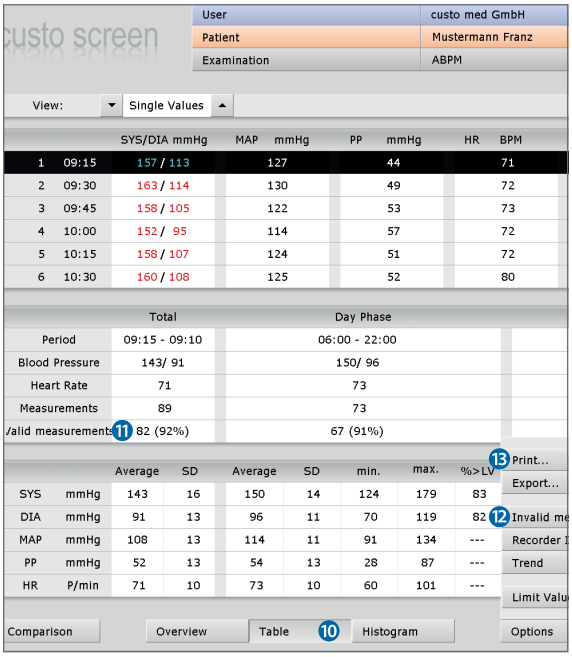
After downloading the evaluation overview is displayed automatically. The overview includes the blood pressure and heart rate trends ❺ (26 hours or a max. of 3 days) and a table with the most important measured values ❻.

With the red cursor ❼ you can select specific points on the trend curves. The measured values for the position are displayed in the table, in the "Current" area ❼.

Checking the quality of the recording

Open the large measured value table by clicking on the Table button ⑩. In the table, the share of measurements which were carried out successfully and which are, therefore, valid is shown ⑪.

To check the causes of failed measurements, click on Options, Invalid meas. ⑫. On this page, the error codes for the invalid measurements are displayed, refer to *08.2 Error codes and their causes*.

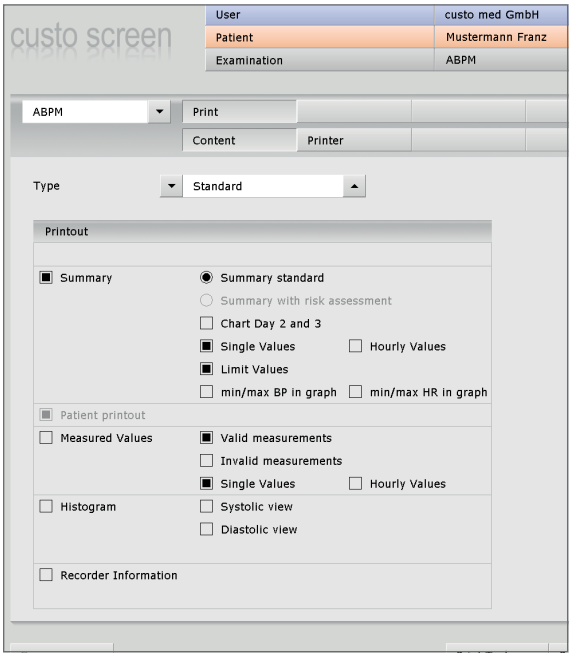


Printing the evaluation

By clicking on the Print button, the evaluation can be printed in accordance with the system settings. The print pages of an ABPM evaluation are defined on the page Examination, ABPM, Settings, Print, Content.

If the opened evaluation is not to be printed as per the system settings, the content of the printed pages can be changed for the current print. To do this, open the print menu in the evaluation via Options, Print... ⑬.

Any changes in the print menu of the evaluation are not transferred to the system settings and only apply to the current print.

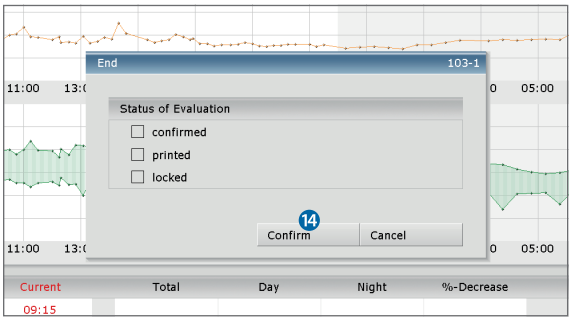


Ending evaluation

Click on End (bottom right) to close the measurement. Confirm ⑭ the end dialogue to exit the evaluation.

Preparation for the next examination

Clean and disinfect the recorder and the accessories as described in *chapter 04 Hygiene*. Remove the batteries from the recorder. Charge the batteries.



06.1 Opening an evaluation

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

Opening an evaluation via the evaluation search

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

In the Examination area, enter what type of examination you are searching for, e.g. ABPM ❷. In the Properties area ❸ you can define more search criteria.

If you set the property Confirmed to No, you will receive a list of all evaluations which are not yet confirmed – a kind of To-Do list.

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

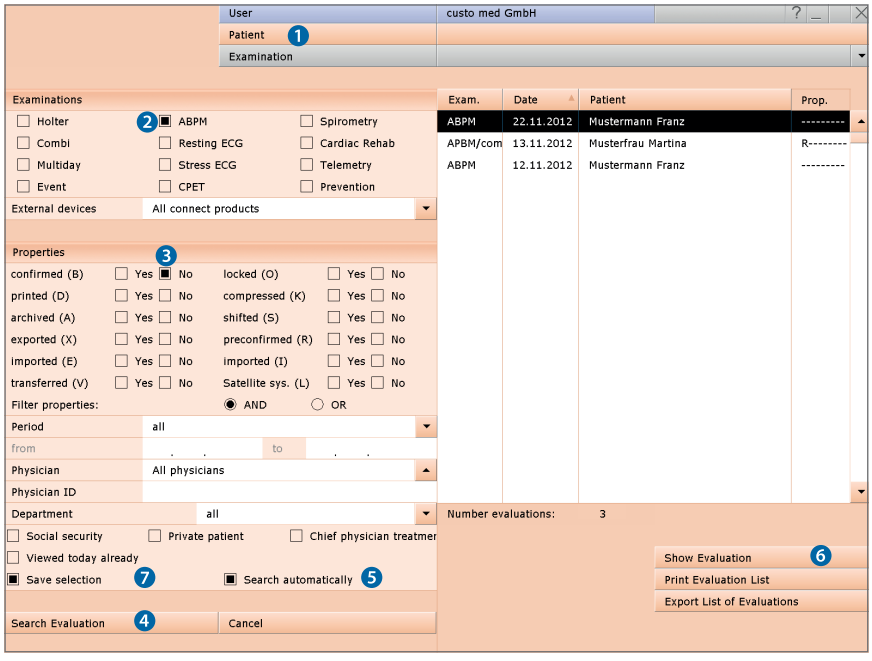
The right part of the screen displays a list of all the evaluations which correspond to the activated search criteria. To open the required evaluation, select it from the list and click on the Show Evaluation button ❻ or double-click on the evaluation.

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

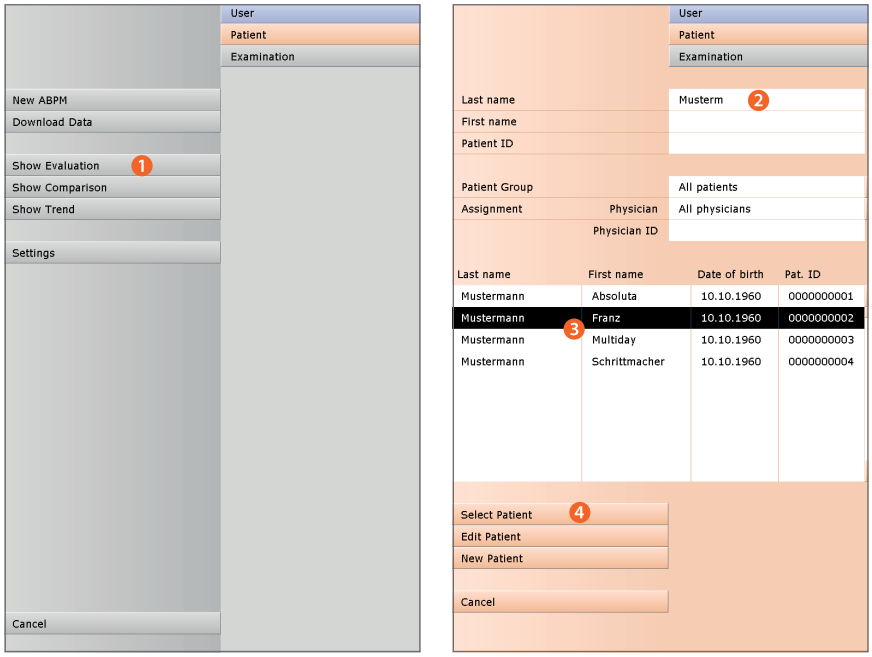
In order to make proper use of the search screen, the correct examination status must be defined in the End dialogue when closing an examination.

Example:
An examination can only be found in the search screen with the property „confirmed" set to „No" if the status "Evaluation confirmed" is NOT selected in the End dialogue.



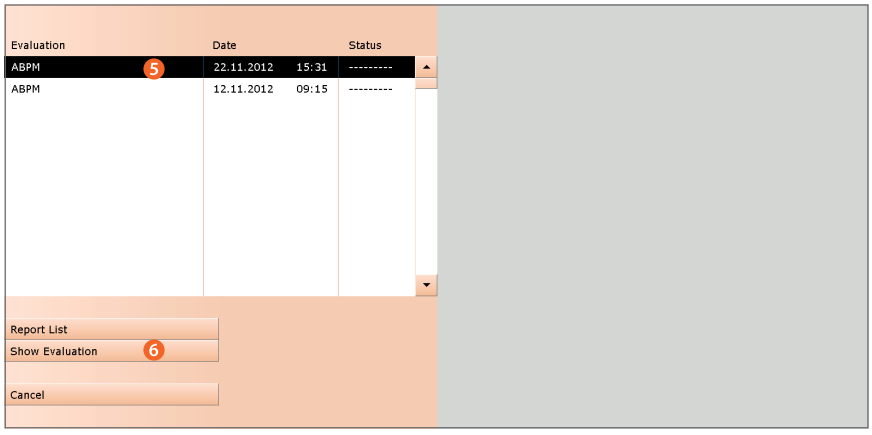
Opening an evaluation via the examination main menu

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

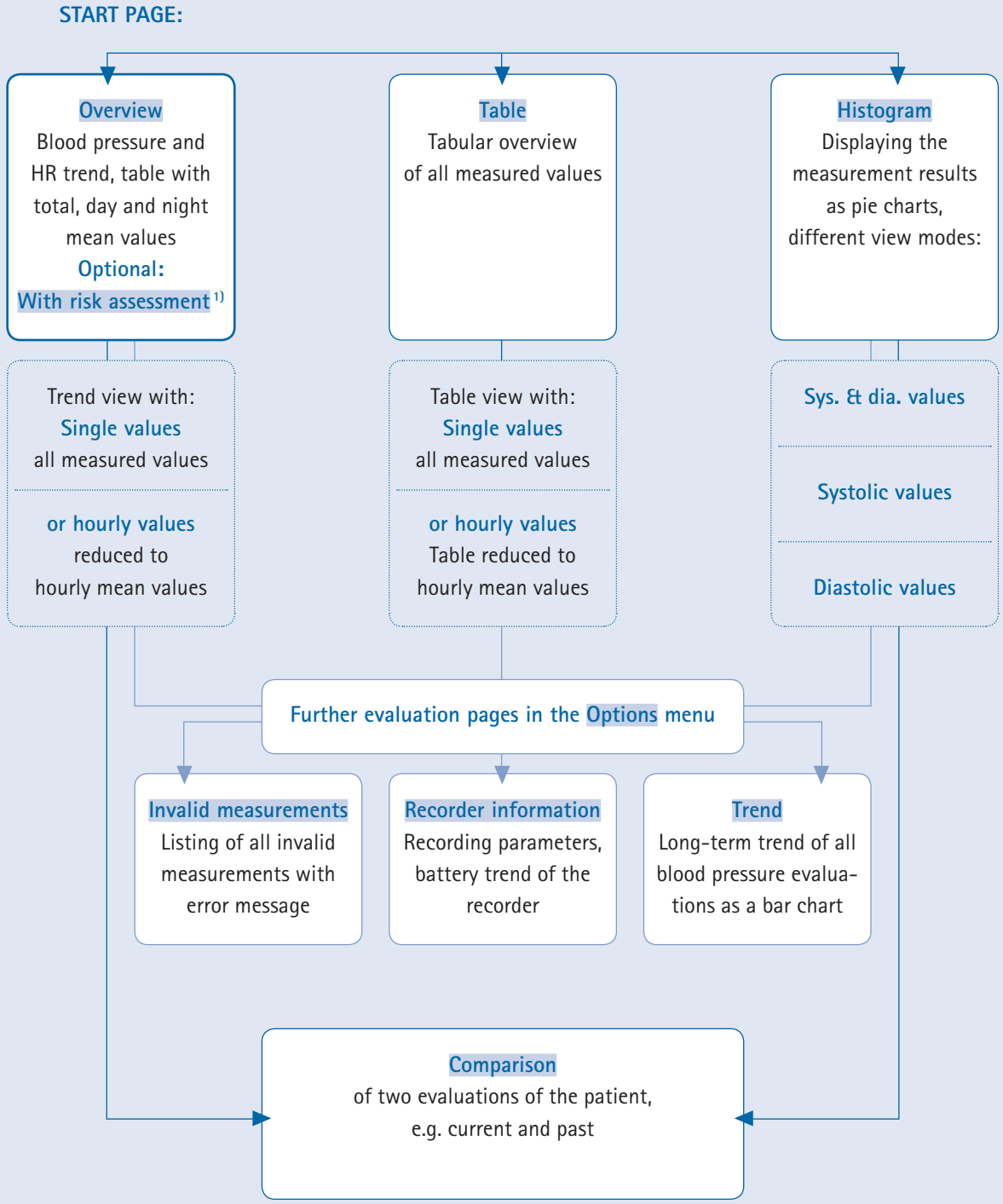


The patient search screen appears. In this screen select the patient whose evaluation you want to open. Enter the patient's name or the first letter of their name into the input fields of the patient search screen ❷. Select the patient from the list below the input fields ❸ and confirm your selection by clicking on the Select Patient button ❹. You can also select the patient by double clicking on the corresponding name.

A list containing all the evaluations of the patient is then displayed. Select the required evaluation from the list ❺ and open it by double-clicking or via the Show Evaluation button ❻.

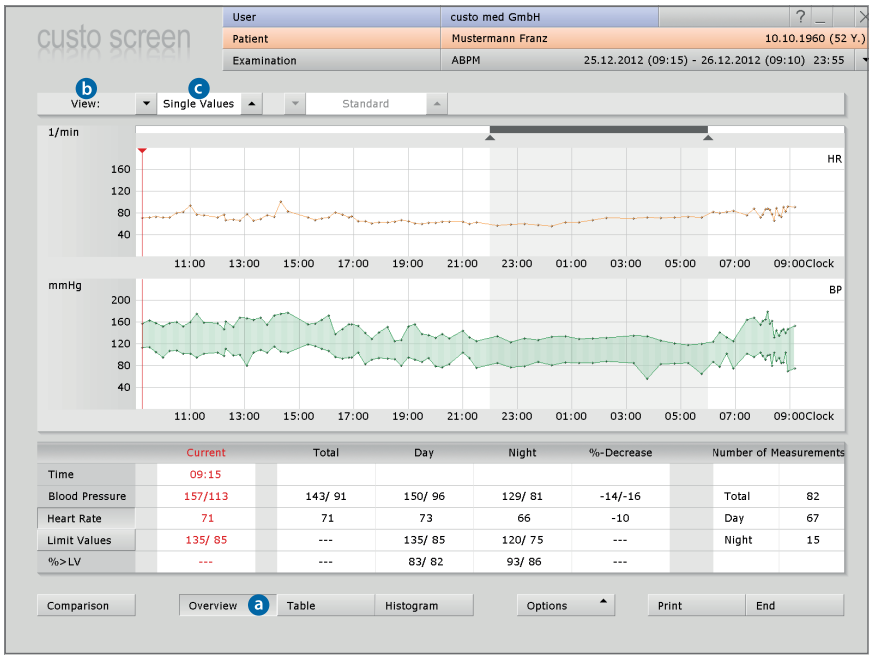


06.2 Structure of the evaluation



1) The custo diagnostic software function"risk stratification" is part of screen professional and is not included as standard. Risk stratification is used to determine the 10-year risk of severe cardiovascular disease for the patient The risk is calculated from the severity of the blood pressure and the cardiovascular risk factors of the patient.

06.3 Navigating the evaluation pages



Opening further pages, orientation

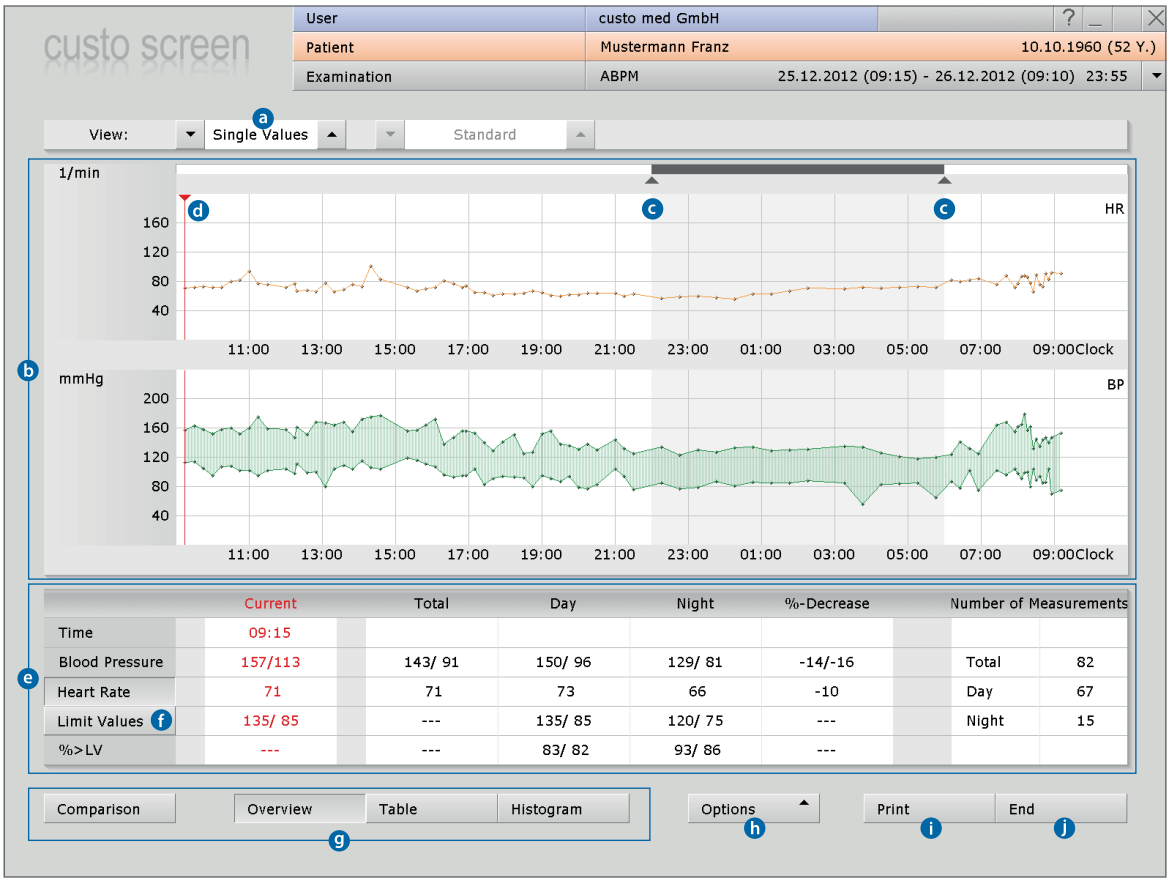
The buttons for opening further evaluation pages are located at the bottom of the screen. The button of the page that is currently open is pressed. In this way you can always see on which page your are **a**.

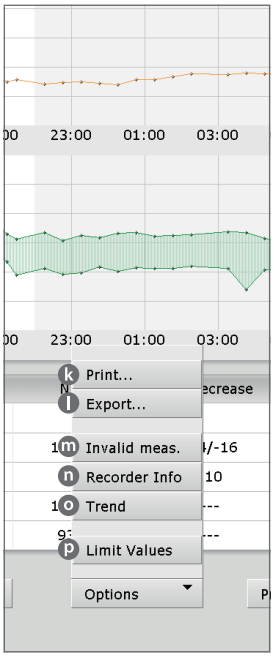
Changing the way in which page content is displayed

At the top of the screen, in the View **b** area, the way in which the content of the page is displayed can be changed. On the Overview page, you can switch, for instance, between Hourly Values and Single Values. Single Values **c** means that the results of all measurements are displayed in the blood pressure and HR trends. If the Hourly Values option is selected, only the hourly mean value is displayed for each hour (advantage: better overview due to a more even measurement curve).

06.4 ABPM evaluation pages

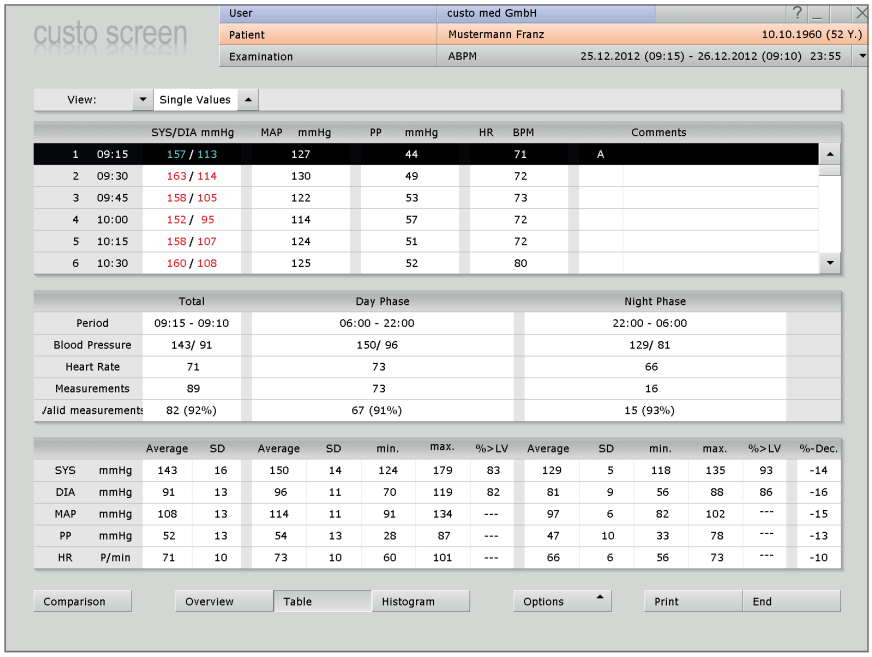
06.4.1 Overview "Standard"





- a Setting page contents: single/hourly values
- b Heart rate curve (orange) and blood pressure curve (green)
- c Controller for changing the night phase (grey area)
- d Cursor for the targeted selection of points in the blood pressure curve, output of the values in the "Current" section of the table e
- e Table with mean blood pressure values and the number of measurements
- f Fading in and out of the limit value line in the blood pressure curve
- g Buttons for opening additional evaluation pages
- h Options menu with further evaluation pages
- i Print with system settings
- j Closing the ABPM evaluation
- k Changing the print settings for current printing
- l Export of the evaluation, e.g. to.Excel, PDF or e-mail
- m Invalid measurements with error codes (check if there are gaps in the recording)
- n Recording parameters and battery voltage of the recorder
- o To assess the blood pressure characteristics over a longer period
- p Dialogue for changing the limit values for the current evaluation

06.4.2 Table, histogram, comparison and trend

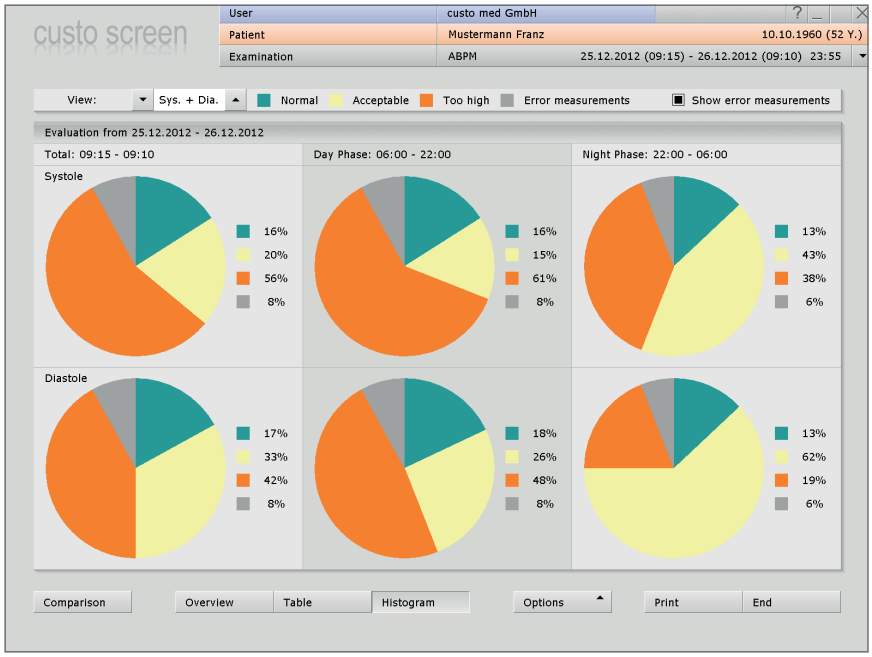


Evaluation page Table

Listing of all single measurements (or hourly mean values) and table with average, minimum and maximum values for the whole recording. In the "valid measurements" row the percentage of successful measurements is shown.

Evaluation page Histogram

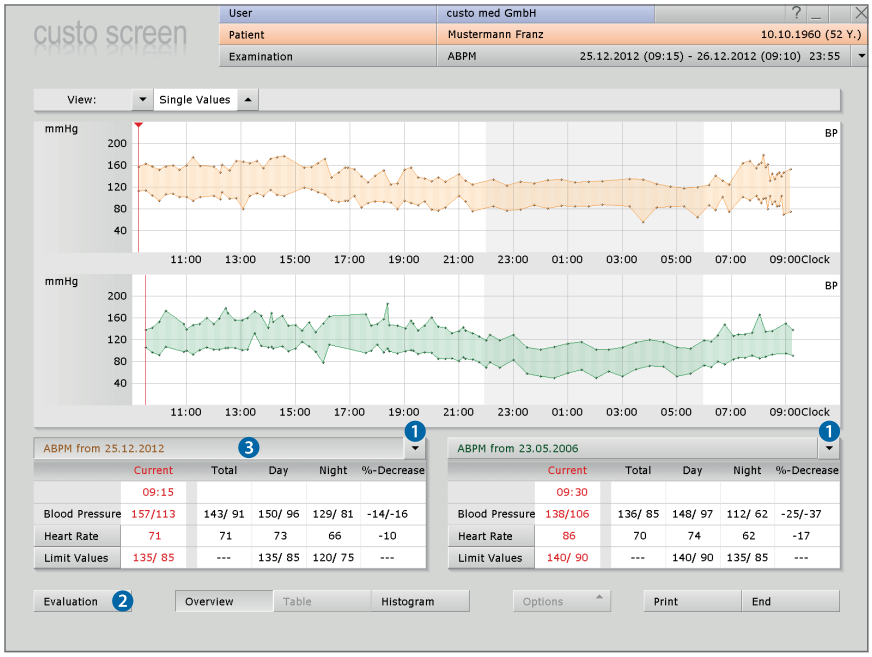
Here you can see at a glance what the percentage of the measured values within and outside of the limits is. As an option, the percentage of invalid measurements can be faded it.



Tips for working in table view

- Transfer patient diary to the software: Click on the required row in the Comments column. You can enter text there.

- Deleting measurements: Click on the measurement to be deleted in the upper table. Right-click to open the context menu and then select Delete meas..

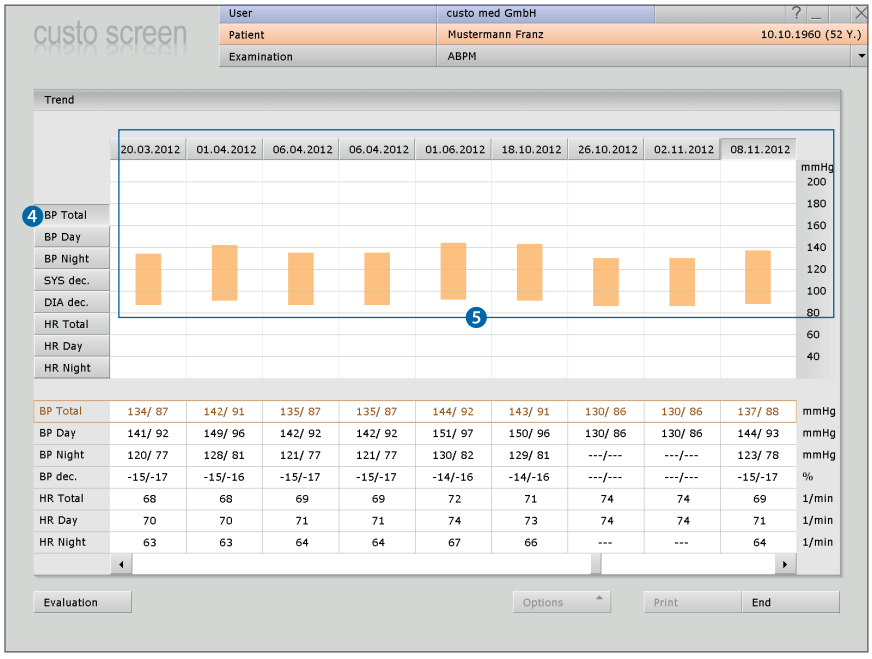


Evaluation page Comparison, Overview

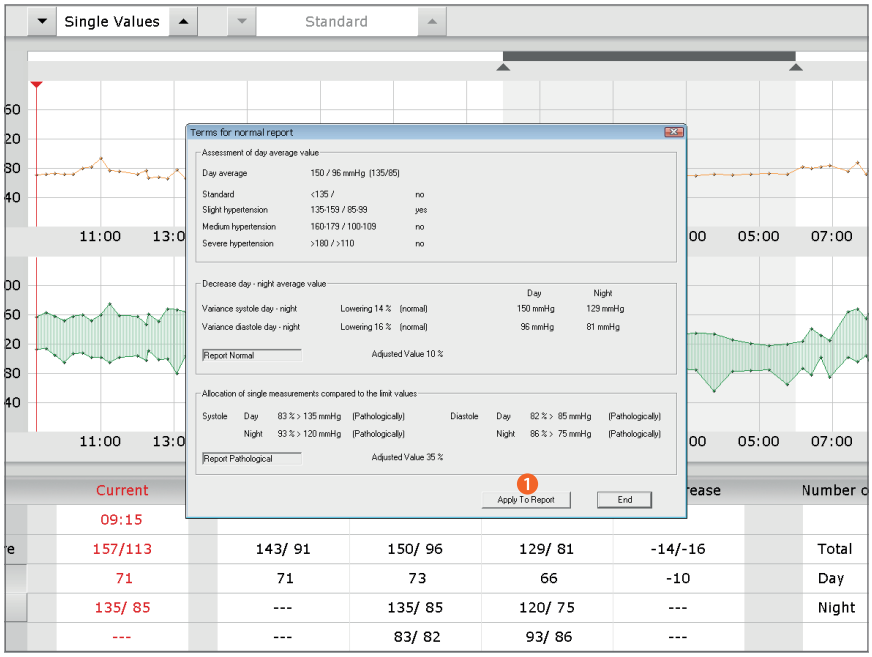
Comparison of two evaluations of a patient. Via the Arrow Keys ❶ more evaluations can be displayed. The Evaluation button ❷ takes you to the individual view of the selected evaluation ❸.

Evaluation page Trend, to be opened via Options

Long-term trend showing all the blood pressure evaluations of a patient. The selected value, e.g. BP Total ❹ is shown as a bar in the coordinate system for all evaluations ❺. In this way, the development can be captured quickly.



06.4.3 Automatic report and printing

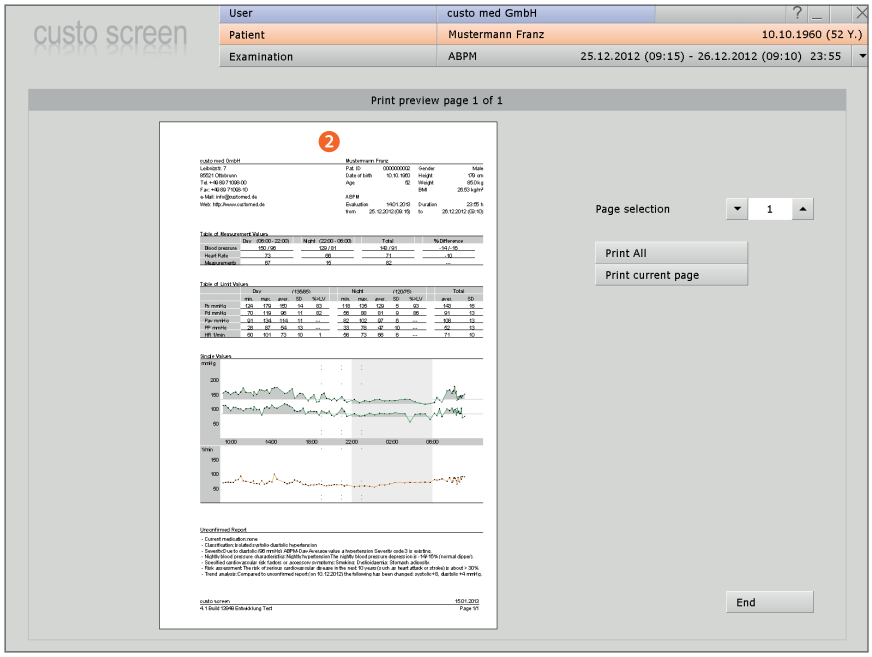


Automatic Report, to open via Context menu, Auto. report

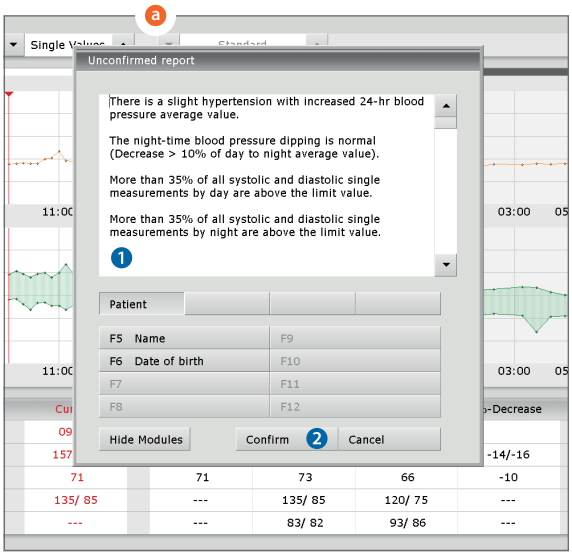
The automatic report is created from the mean values, day-night drop and the portion of the measurements which exceed the limit values. Click on Apply To Report ❶ to apply the results to the unconfirmed report.

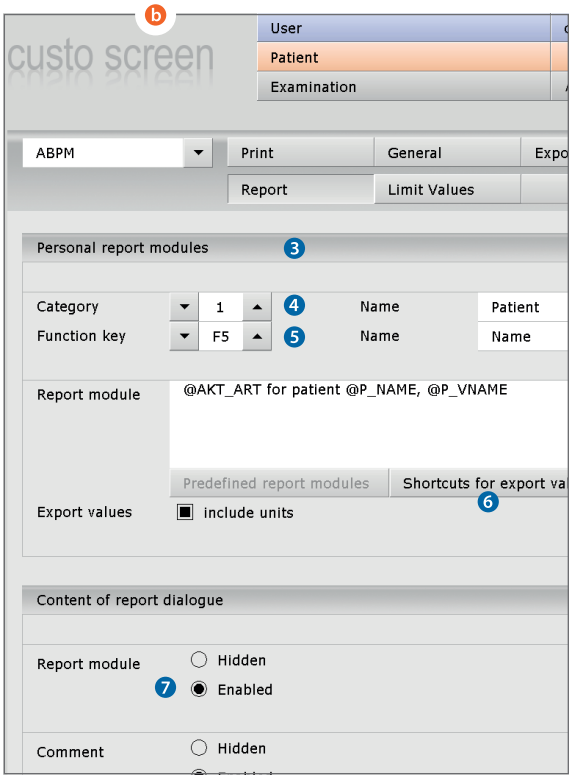
Printing the evaluation

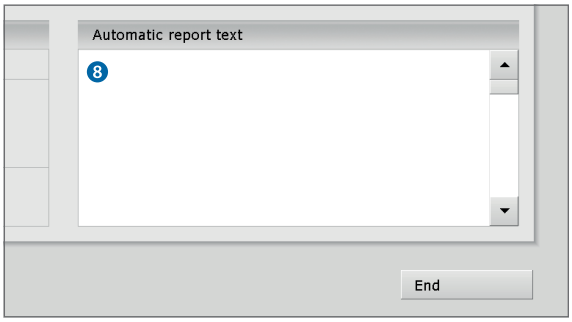
It is printed via the Print button or via Options, Print... (Print menu of the evaluation, to change the contents for the current print). Via the print menu (Print...), a Print Preview ❷ can be opened.



06.5 Writing the report







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

Enter your data in the white text field 1. When you click on Confirm 2 your input is saved and the evaluation gets the "Confirmed" status (see "End dialogue").

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

b Text modules for writing reports

On the page Examination, ABPM, Settings, Diagnostic, Report text modules for writing a report can be created 3. A total of four groups 4 with up to eight text modules 5 can be stored. The text modules are called in the "Report dialogue" using keyboard commands (F5 to F12).

A text module can be created from normal text as well as variables. When using a text module in the "Report dialogue", the actual value from the evaluation is used instead of the variable and is automatically inserted in the report text. The structure of a variable is @VARIABLE (e.g. average systole day: @SYS_T_MT). The Shortcuts for export values button 6 provides you with a list containing all the available variables.

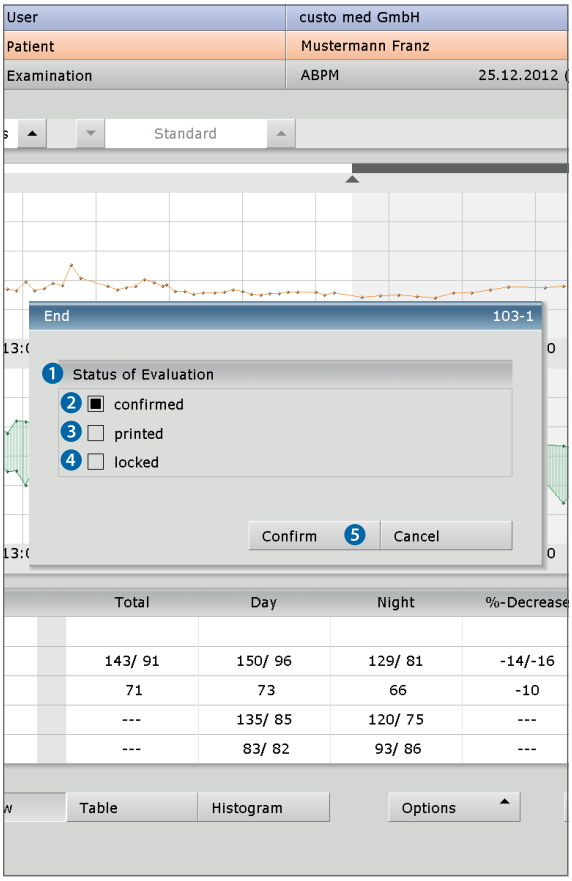
If the text modules should be shown in the "Report dialogue", make sure that the Enable option 7 is activated. Alternatively, the text modules can be shown in the "Report dialogue" via the Show modules button.

There is also the option of entering a text or a user-defined report text (also as normal text and variables), which will be automatically shown in each report 8. The predefined text can be changed later in the "Report dialogue".

Save your inpu

06.6 Ending the evaluation

On the Evaluation page, click on the End button (bottom right of the screen). The end dialogue is opened. Here the status of an evaluation is defined ❶. Assigning properties (e.g. confirmed/not confirmed) makes it easier to find evaluations in the evaluation search.



➤ Confirmed evaluation ❷

A confirmed evaluation can be reset to "not confirmed" by deselecting the option "Evaluation confirmed", e.g. if the report text has not been completed yet.

➤ Printed ❸

Indicates if the evaluation has been printed.

➤ Locked ❹

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

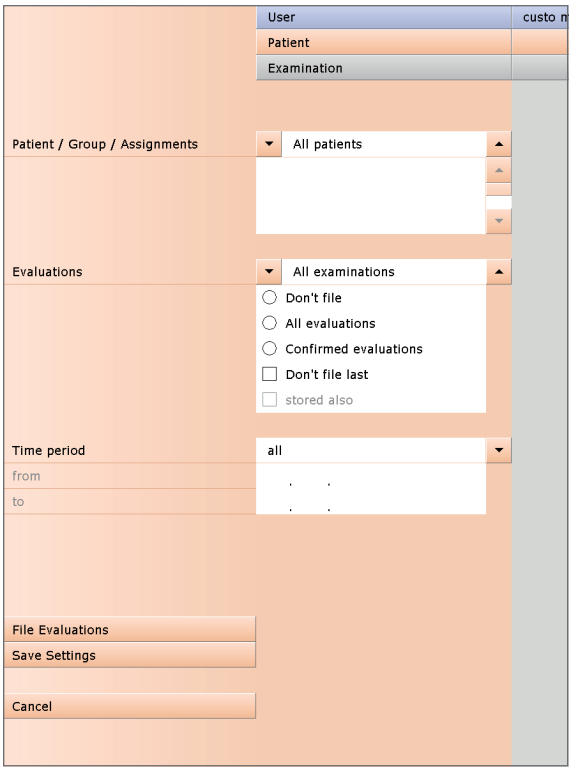
Click on Confirm ❺ to close the evaluation.

06.7 Archiving evaluations (optional)

Archiving is not a data backup (copy), instead your evaluations are just moved to another storage location. Take adequate measures to backup data within your archive at regular intervals in order to avoid data loss.

Archiving is used to save recordings on a long-term basis. During archiving, the evaluations are moved to a directory on your hard disc, which you can then save on a data carrier (CD, DVD, etc.).

The archiving functions can be found under Patient, Edit Database.



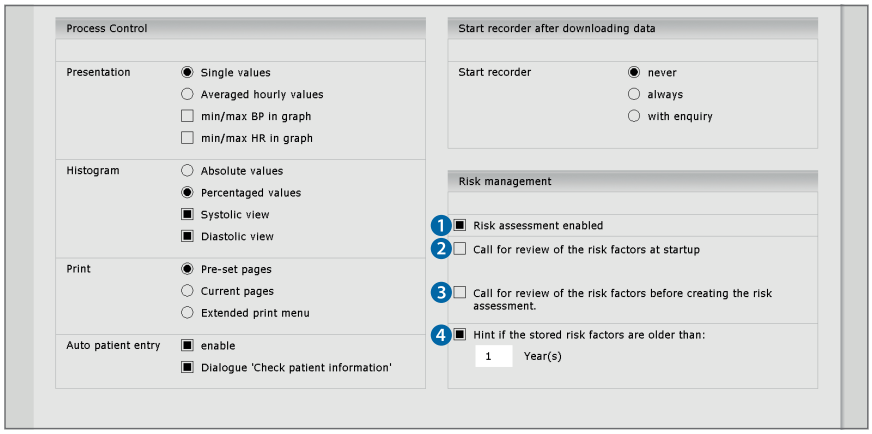
07.1 Configuring risk stratification[1)] in custo diagnostic

1) The software module "Risk stratification" is part of screen professional and is not included as standard.

The custo diagnostic software function "risk stratification" is used to determine the 10-year risk of severe cardiovascular disease for the patient. The result is shown in the form of a graph in the evaluation.
The risk is calculated from the severity of the blood pressure and the cardiovascular risk factors of the patient. The blood pressure severity results from the ABPM recording. The risk factors must be entered in custo diagnostic at the start of the recording or during the evaluation.

07.1.1 Defining workflows and security queries

Start custo diagnostic and open the page Examination, ABPM, Settings, General, Workflow.



❶ The software function risk stratification is switched on and off in the Risk Management area. If the Risk assessment enabled option is not selected, no risk assessment for ABPM recordings will be carried out in custo diagnostic.
❷ If this option is selected, the dialogue for entering the risk factors will be opened automatically when the recorder is started. (Examination, ABPM, New ABPM, Start). If the option is not selected, the input dialogue can be opened manually via the Set Risk Factors button.
❸ If this option is selected a prompt will appear in the evaluation, to check the risk factors that were set previously before the risk assessment is created. If the option is not selected, the risk assessment is created automatically, without any further prompts to check the risk factors.
❹ If this option is selected, a prompt will appear to check the existing risk factors if these are older than the period set (e.g. 1 year). This is to ensure that the set risk factors are consistent with the patient's current condition, for follow-up examinations. The prompt appears when the Set Risk Factors dialogue is opened on the New ABPM page. If there is no check when the recorder starts, the prompt will appear in the evaluation, before the risk assessment is created.

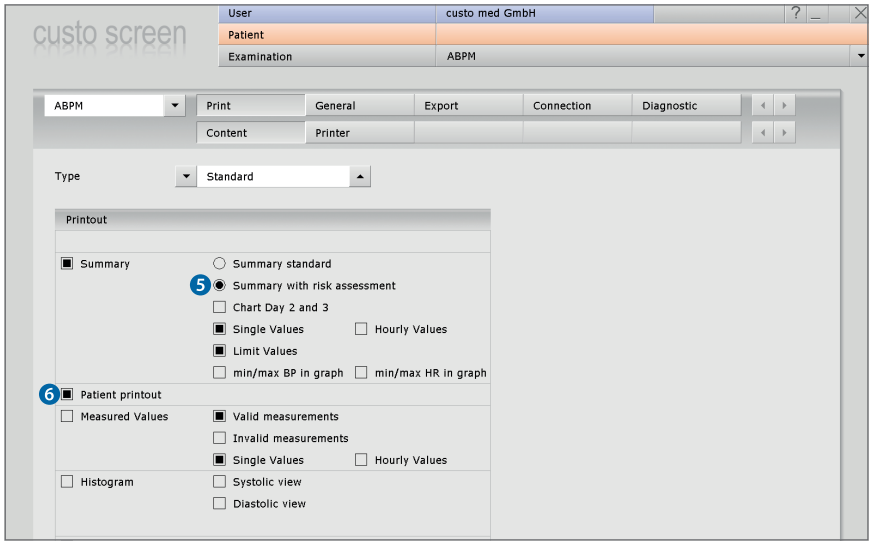
If you click on Save (bottom left) your input will be applied.

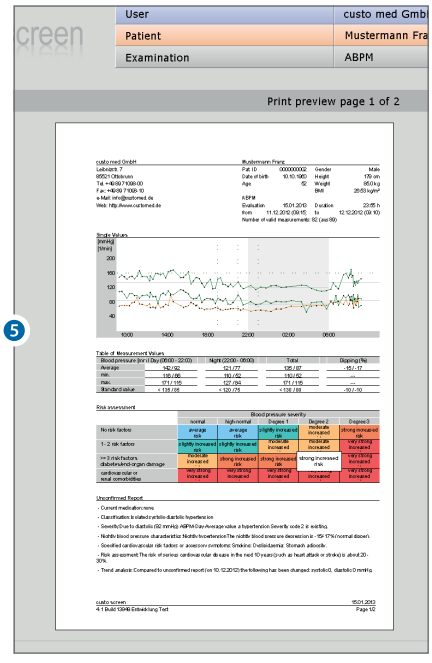
07.1.2 Print risk stratification

The contents of ABPM print pages are defined in custo diagnostic under Examination, ABPM, Settings, Print, Content.

To print the results of the risk stratification, select the option Summary with risk assessment ❺ (printout for physician). With the Patient Printout option ❻ the results are summarised in a simplified form for the patient on an A4 page.

If you click on Save (bottom left) your input will be applied.





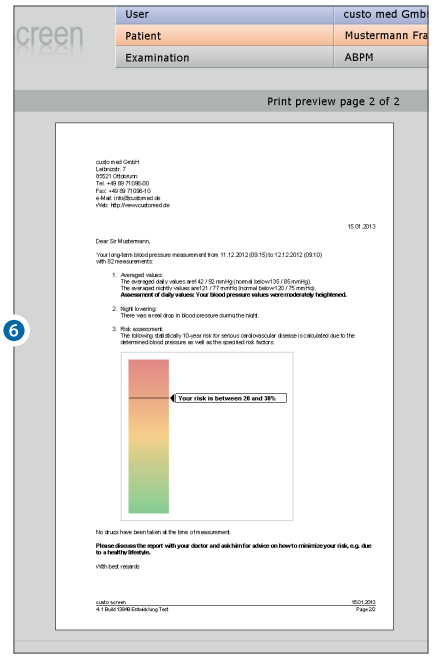


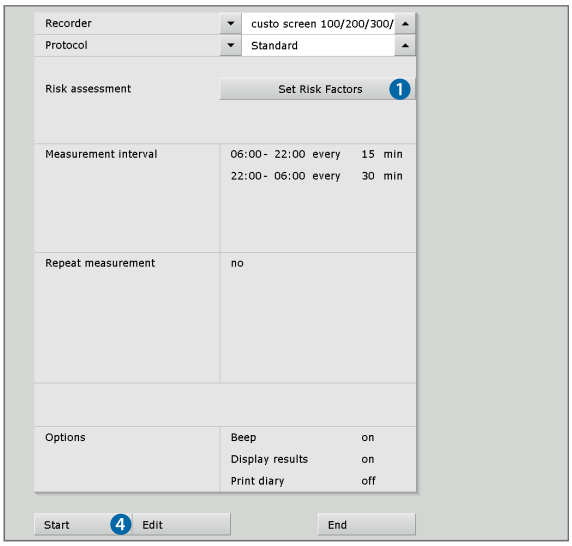
Fig. bottom left:
Print preview of physician printout with risk assessment

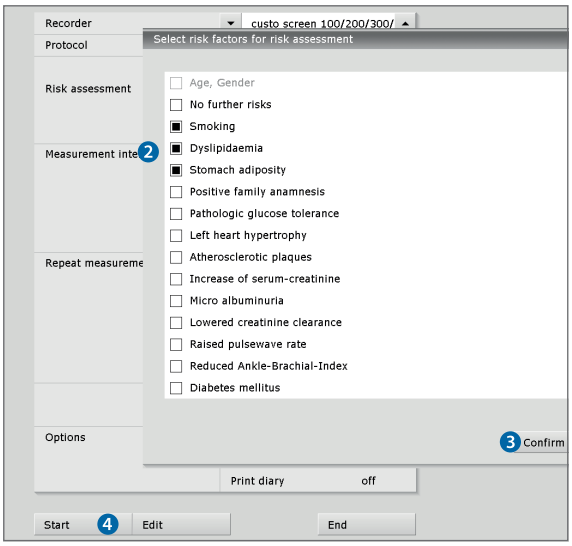
Fig. bottom right:
Print preview of patient printout with risk assessment

07.2 Recorder start with risk stratification

The start procedure for a recording with risk stratification is identical to the standard procedure as described in *Chapter 05.2 Starting the recorder in custo diagnostic*. In addition, the cardiovascular risk factors of the patient must be entered (required for the risk assessment). To enter the factors, click on the page Examination, ABPM, New ABPM, Set risk factors ❶. The dialogue for the entry of the risk factors is displayed. Selected the risks that apply ❷. If none of the risks apply to the patient, the point No further risks must be selected. By clicking on Confirm ❸ the entry is saved and the dialogue is closed. If the risk factors are not entered or checked at this point, this work step must be carried out at a later stage.

Then the recorder can be started via the Start ❹ button.





07.3 Downloading evaluations with risk stratification

The download procedure is identical to the standard procedure, as described in *Chapter 05.4 Downloading the recording*. After downloading the evaluation overview is displayed. In addition to the standard content it includes a risk assessment indicating the 10-year risk of severe cardiovascular disease. The risk assessment is only displayed if the risk factors were set when the recorder was started. Otherwise, you will be prompted to make an entry.

	normal	high-normal	Degree 1	Degree 2	Degree 3
No risk factors	average risk	average risk	slightly increased risk	moderate increased risk	strong increased risk
1 - 2 risk factors	slightly increased risk	slightly increased risk	moderate increased risk	moderate increased risk	very strong increased risk
>= 3 risk factors diabetes/end-organ damage	moderate increased risk	strong increased risk	strong increased risk	**strong increased risk**	very strong increased risk
cardiovascular or renal comorbidities	very strong increased risk	very strong increased risk	very strong increased risk	very strong increased risk	very strong increased risk

07.4 Evaluation overview with risk stratification

Opening a ABPM recording with risk stratification works as described in *Chapter 06.1 Opening an evaluation*. The evaluation Overview contains the following display and control elements:

- a Setting page contents: Single/hourly values with/without risk assessment
- b Heart rate curve (orange) and blood pressure curve (green)
- c Controller for changing the night phase (grey area)
- d Cursor for the targeted selection of points in the blood pressure curve, output of the values in the "Cursor" section of the table e
- e Table with mean blood pressure values and the number of measurements
- f Fading in and out of the limit value lines in the blood pressure curve
- g **Risk assessment including the 10-year risk of severe cardiovascular disease for the patient** [1)]
  The field with the applicable risk is enlarged and has a stronger colour. The existing number of risk factors (left column of the table) and the degree of severity of the patient's blood pressure (second row in the table) are shown in a red font.
- h Buttons for opening additional evaluation pages
- i Menu Options with more evaluation pages, refer to *06.4.1, k to p*
- j Print with system settings
- k Closing the ABPM evaluation

1) The risk is calculated from the severity level of the blood pressure and the cardiovascular risk factors of the patient. The blood pressure severity results from the ABPM recording. The risk factors must be entered in custo diagnostic at the start of the recording or during the evaluation.
This is done via the Set Risk Factors button. The risk for the patient will only be displayed if risk factors have already been set.

Via the ABPM standard values button a tabular overview with the definition and classification of blood pressure severity can be opened. The applicable severity level is marked.

07.4.1 Setting the risk factors in the evaluation

If the evaluation does not yet include a risk assessment, this may be due to the following reasons...

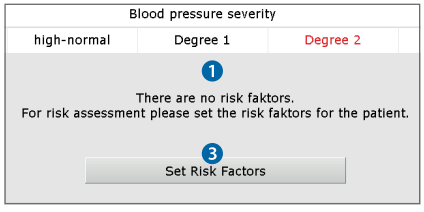
... there are not enough valid blood pressure measurements. In this case, a risk assessment cannot be carried out.

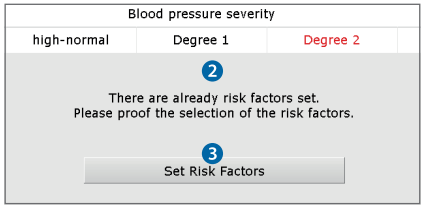
... the cardiovascular risk factors of the patient were not entered when the recorder was started. You will be prompted to make an entry, refer to ❶.

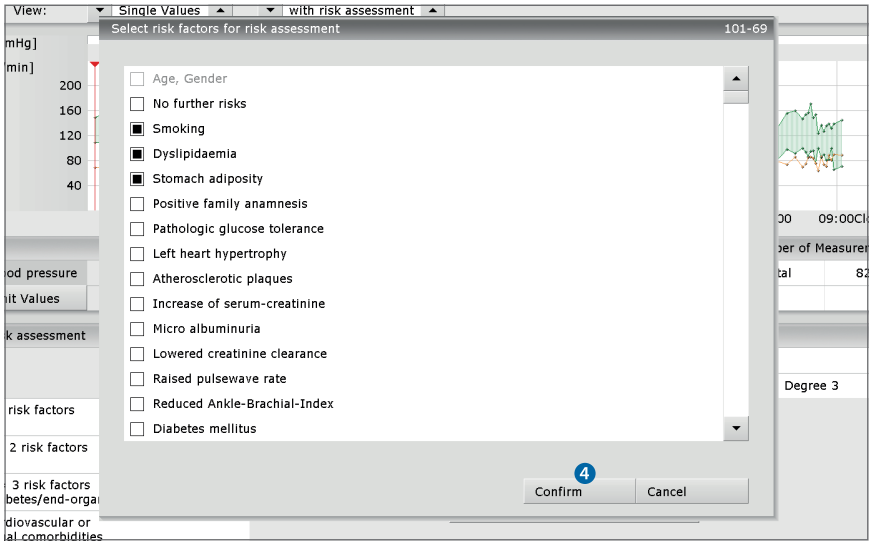
... custo diagnostic is configured in such a way that the saved risk factors always need to be checked before the risk assessment is created. You will be prompted to check, refer to ❷.

... custo diagnostic is configured in such a way that it must be checked that the risk factors which were entered more than a year ago are correct. You will be prompted to check.

To enter or check the risk factors, click on Set Risk Factors ❸. The dialogue for the entry of the risk factors is displayed. Selected the risks that apply. If none of the risks apply to the patient, the point No further risks must be selected.
By clicking on Confirm ❹ the entry is saved and the dialogue is closed. The risk assessment is displayed.

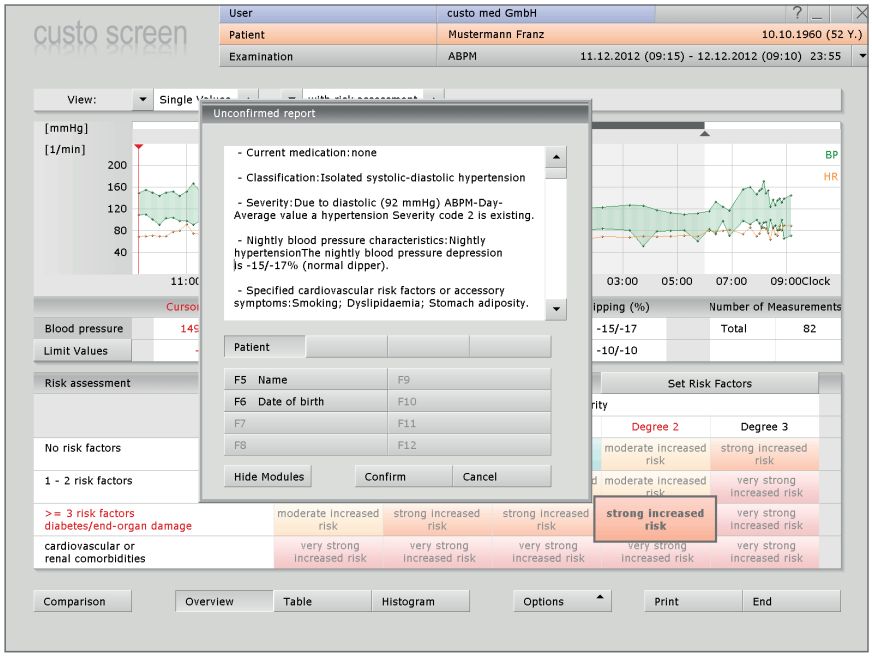






07.4.2 Reports with risk stratification

The report is opened by right-clicking on the evaluation interface. In the context menu, select Report.
The report includes a summary of the blood pressure characteristics, the results of the risk assessment an a trend analysis, for which the current results are compared to the previous report (if applicable). The text can be amended and changed. By clicking on Confirm the changes are applied and the dialogue is closed.
The procedures in connection with the report are identical to the standard procedure, refer to *Chapter 06.5 Writing the report*.



07.4.3 Definition of the severity levels for blood pressure

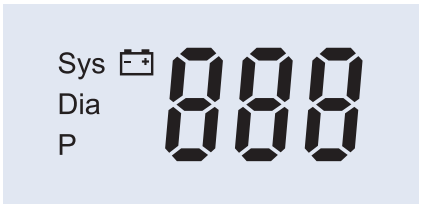
The risk assessment is made on the basis of the patient's risk factors and the severity level of the blood pressure resulting from the recording. A table with the values for the severity levels of the blood pressure can be opened via the ABPM standard values button. The severity levels are defined as follows:

	Daily mean value Sys. [mmHg]	Daily mean value Dia. [mmHg]
Optimum[2)]	< 115	<75
Normal	115 – 124	75 – 79
High-normal	125 – 134	80 – 84
Level 1	135 – 146	85 – 89
Level 2	147 – 156	90 – 95
Level 3	≥ 157	≥ 96
isolated syst. hypertension[2)]	≥ 135	≤ 85

2) The "Optimum" and "isolated systolic hypertension" ranges represent additional information which is not included in the risk assessment table in this form.

Example:
If a patient has daily mean values in the optimum range (< 115/75 mmHg), the severity level of the blood pressure is classified as "Normal" (a better evaluation is not possible). In the definition and classification table (ABPM standard values button) both the "Optimum" row and the "Normal" row are highlighted.

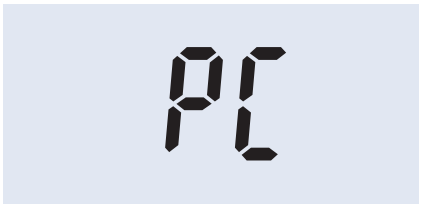
08.1 Measurement and status indication on the display



Display elements on the display

Sys:	Systolic blood pressure
Dia:	Diastolic blood pressure
P:	Pulse
Battery:	Lights up when battery power is low

If blood pressure measuring is successful...
systolic value, diastolic value and pulse are displayed three times in succession



During the data transfer between the recorder and the PC ...
"PC" is shown on the display (the light-emitting diode of the infrared interface custo com IR flashes)

If a measurement fails...
an error code is shown on the display, e.g. "E06"

08.2 Error codes and their causes

E04	**Blood pressure values exceed limit values** Sys: < 70 mmHg > 270 mmHg, Dia: < 40 mmHg > 155 mmHg, Sys - Dia: < 15 mmHg, HF: < 35/min > 220/min ➤ Measurement is repeated automatically
E05	**Pressure release rate outside of the defined limits** Cause: Valve leaking and/or defective ➤ Customer Service
E06	**Measurement interrupted/disturbed** Cause: too many movement artefacts ➤ Fit the cuff carefully, keep the arm steady during measurement
E08	**Battery voltage too low** ➤ Insert new or fully charged batteries into the recorder
E17	**Pressure rises too slowly** Cause: Cuff leaking (defective), valve leaking ➤ Check the cuff (sealing ring in the connection in good condition/present?) ➤ Customer Service
E18	**Pressure rises too quickly** Cause: Cuff tube bent, valve system blocked ➤ Align the cuff tube ➤ otherwise, contact Customer Service
E19	**Release period too long** Cause: Cuff tube bent, valve defective ➤ Customer service, if multiple occurrences during a recording
E21 - E24	**Error during determination of diastolic value** Cause: Cuff incorrectly fitted or oscillations too weak, marking on the cuff is not on the artery ➤ Fit the cuff carefully, keep the arm steady during measurement
E25 - E28	**Error during determination of systolic value** Cause: Systolic value is above the pumping pressure, movement artefacts ➤ Fit the cuff carefully, keep the arm steady during measurement

If a measurement fails, it will be repeated after two minutes. If an error occurs which is not listed here, switch the device off and back on again. Repeat the required work step. If the error persists, please contact your authorised custo med dealer.

08.3 Limit values for blood pressure measurement

The limit values have been defined as follows in custo diagnostic:

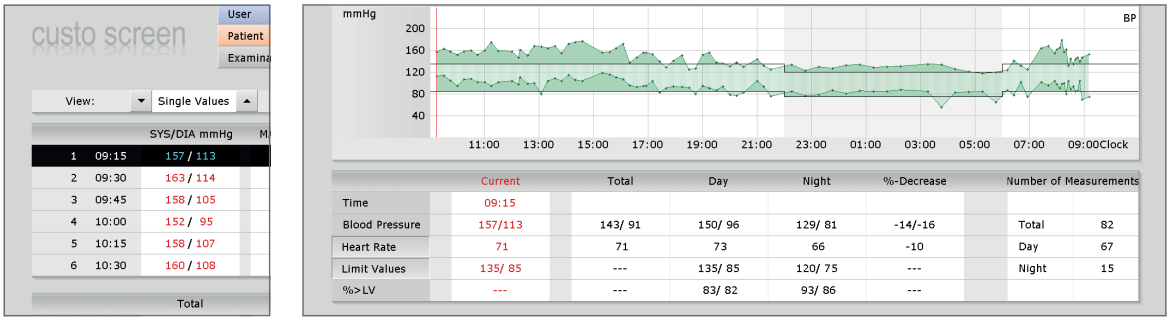
Adults

Day phase		Night phase	
Systolic value	135 mmHg	Systolic value	120 mmHg
Diastolic value	85 mmHg	Diastolic value	75 mmHg

Measurements for which these values are exceeded are displayed in red font in the evaluation.

If required, the limit values can be modified for the current evaluation via the menu Options in the Limit Values dialogue. To change the limit values permanently, enter the required values on the page Examination, ABPM, Settings, Diagnostic, Limit Values.

In the ABPM graph (start page of the evaluation) you can display auxiliary lines around the defined limit values by clicking the Limit Values button. Values outside of the defined limit values will therefore be visible immediately.



Limit values for children and adolescents up to 16 years

Boys	Day		Night	
Height	Sys	Dia	Sys	Dia
120 cm	123	85	104	63
130 cm	125	85	107	65
140 cm	127	85	110	67
150 cm	129	85	113	67
160 cm	132	85	116	67
170 cm	135	85	119	67
180 cm	137	85	122	67

Girls	Day		Night	
Height	Sys	Dia	Sys	Dia
120 cm	120	84	107	66
130 cm	124	84	109	66
140 cm	127	84	111	66
150 cm	129	84	112	66
160 cm	131	84	113	66
170 cm	131	84	113	66
180 cm	131	84	114	66

08.4 Abbreviations used in the evaluation

Ps	Systolic blood pressure
Pd	Diastolic blood pressure
Pm	Mean arterial blood pressure $P_m = \frac{P_{sys} - P_{dia}}{3} + P_{dia}$
PP	Pulse pressure $PP = P_{sys} - P_{dia}$
HR	Heart Rate
Average	Average of the measured value over the complete measuring period, taking into account the intervals between measurements; this is calculated as a weighted arithmetic mean: $Weighted\ arithmetic\ mean = \sum \left(\frac{Measured\ value * Time\ interval\ to\ next\ value}{Total\ measuring\ time} \right)$
SD	Standard deviation $SD = \sqrt{\frac{\sum (Single\ value - Mean\ value)^2}{Number\ of\ measured\ values}}$
Min	Lowest measured value
Max	Highest measured value
%>LV	Percentage of measurements where the limit value has been exceeded
%-dec.	Decrease: Drop from day mean value to night mean value as a percentage; (Mean value day - mean value night = 10 to 15 %)
A	Additional measurement: denotes measurements which were triggered manually with the function key.
R	Repeat measurement: denotes measurements which were triggered when the set values for repeat measurements were exceeded during the previous measurement or if the previous was an invalid measurement.

08.5 Technical data and system requirements

Technical data for the custo screen 300/400

Measuring method	Oscillometric measuring procedure, automatic zero balancing	
Measuring range	Heart rate	35 – 220 beats/min
	Systolic blood pressure	70 – 270 mmHg
	Diastolic blood pressure	40 – 155 mmHg
Max. number of measurements	512	
Max. recording time	72 hours for ABPM recordings 24 hours for Holter-ABPM recordings[1)]	
Duration of a measurement	approx. 30 seconds	
Measuring intervals	can be set in the software, between 5 and 90 minutes. Default: during the day every 15 minutes, during the night every 30 minutes	
Cuff pressure	300 mmHg max.	
Cuff sizes	Small (children)	20 – 24 cm
	Standard (scope of delivery)	24 – 32 cm
	XL	32 – 40 cm
	XXL	38 – 50 cm
Data transfer	custo com IR infrared interface with USB connection (IrDA standard) mini SD card for Holter-ABPM recordings[1)]	
Power supply	3 x 1.5 Volt, type AA batteries, 3 rechargeable Ni-MH batteries, 1.2 Volt, 1500 mAh min.	
Operating conditions	Temperature	+10°C ... +40°C
	Atmospheric humidity	30 ... 85 % rH
	Air pressure	700 ... 1060 hPa
Transport and storage conditions	Temperature	-20°C... +45°C
	Atmospheric humidity	30 ... 85 % rH
	Air pressure	700 ... 1060 hPa
Dimensions	Size	approx. 100 * 66 * 26 mm (L * W * H)
	Weight	approx. 112 g (incl. batteries)
Classification	Device with internal power supply Class IIa Type BF IEC 60601-1, IEC 1060-1 to 1060-4, IEC 80601-2-30	

1) Holter-ABPM recordings (simultaneous recording of blood pressure and ECG) can only be made with custo screen 400.

System requirements

Operating system	Windows XP (x64) Windows Vista (x64) Windows 7 (x64) Windows Server 2003 (x64) Windows Server 2008 (x64) Windows Server 2008 R2 older versions are not supported	
PC	The PC hardware should meet the minimum requirements of the operating system used. Provide additional RAM (256 MB) for custo diagnostic. Please ensure that there is sufficient space on the hard disk for the custo diagnostic evaluations.	
File sizes for evaluations	Holter:	approx. 15 MB (max. 60 MB)
	ABPM:	approx. 1 MB (max. 2 MB)
	Holter-ABPM:	approx. 20 MB (max. 25 MB)
	Resting ECG:	approx. 200 KB (approx. 10 seconds ECG)
	Stress ECG:	approx. 6 MB (approx. 20 minutes ECG)
	CPET:	refer to stress test ECG
	Spirometry:	approx. 50 KB (max. 256 KB)
	Rehab:	approx. 6 MB (approx. 45 min. of training)
Hardware & connections	DVD or CD-ROM drive USB port	

08.6 Support

If you have any questions or problems which are not dealt with here, please do not hesitate to contact your authorised custo med dealer. A list of the authorised custo med dealers can be found in the Internet under www.customed.de, in the category CONTACT, Dealers.

You can also contact custo med GmbH directly at any time. We will be pleased to provide you with information about your authorised custo med dealer or contact your authorised custo med dealer and forward your queries.

08.7 Manufacturer's Declaration regarding EMC (electromagnetic compatibility) according to IEC 60601-1-2:2007

Manufacturer's Declaration – electromagnetic emissions

The custo screen 300/400 ABPM recorder is designed for operation in the electromagnetic environment stated below. The customer or user of custo screen 300/400 should ensure that it is used in such an environment.

Emission Measurements	Compliance	Electromagnetic Environment – Guidelines
HF emissions according to CISPR11 custo screen 300	Group 1 custo screen 300	custo screen 300 uses HF-energy only for its internal function. Its level of HF emission is therefore very low and is unlikely to be sufficient to interfere with other electronic devices.
HF emissions according to CISPR11 custo screen 400 (during ABPM recordings no electromagnetic energy is emitted, only during Holter-ABDM recordings with radio contact to the ECG transmitter)	Group 2 custo screen 400 for Holter-ABDM recordings	custo screen 400 must emit electromagnetic energy to ensure its intended function. Electronic devices nearby may be affected.
HF emissions according to CISPR11	Class B	custo screen 300/400 is suitable for use in all establishments, including domestic establishments and those directly connected to the public low voltage power supply network that supplies buildings used for domestic purposes.
Harmonics according to IEC61000-3-2	Not applicable	
Voltage fluctuations/flickers according to IEC61000-3-3	Not applicable	

Manufacturer's Declaration – electromagnetic immunity

The custo screen 300/400 ABPM recorder is designed for operation in the electromagnetic environment stated below. The customer or user of custo screen 300/400 should ensure that it is used in such an environment.

Immunity Tests	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment – Guidelines
Electrostatic discharge (ESD) according to IEC 61000-4-2	± 6 kV contact discharge ± 8 kV air discharge	± 6 kV contact discharge ± 8 kV air discharge	Floors should be made of wood or concrete or be equipped with ceramic tiles. If the floor is provided with synthetic material, the relative air humidity must be at least 30 %.
Fast transient electric interference factors/bursts according to IEC 61000-4-4	± 2 kV for net wires ± 1 kV for input and output wires	Not applicable	The quality of the supply voltage should correspond to the one of a typical business or clinical environment.
Surges according to IEC 61000-4-5	± 1 kV push-pull voltage ± 2 kV push-push voltage	Not applicable	The quality of the supply voltage should correspond to the one of a typical business or clinical environment.
Voltage drops, short-time interruptions and fluctuations in the supply voltage according to IEC 61000-4-11	< 5 % U_T for 0.5 period (> 95 % drop) 40 % U_T for 5 periods (60 % drop) 70 % U_T for 25 periods (30 % drop) < 5 % U_T for 5 s (> 95 % drop)	Not applicable	The quality of the supply voltage should correspond to the one of a typical business or clinical environment. If the user of custo screen 300/400 requires continued function, even if interruptions to the energy supply occur, it is recommended to supply custo screen 300/400 from an interruption-free power supply.
Magnetic field with supply frequency (50/60 Hz) according to IEC 61000-4-8	3 A/m	3 A/m	Magnetic fields with net frequency should correspond to the typical values, as can be found in business and clinical environments.

NOTE: U_T is the net AC voltage before applying the test levels

Manufacturer's Declaration – electromagnetic immunity

The custo screen 300/400 ABPM recorder is designed for operation in the electromagnetic environment stated below. The customer or user of custo screen 300/400 should ensure that it is used in such an environment.

Immunity Tests	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment – Guidelines
Conducted HF transients according to IEC 61000-4-6	3 $V_{Effective\ value}$ 150 KHz to 80 MHz	$[U_1]$ V Not applicable	Portable and mobile radio sets should not be used at a closer distance to the device including the leads than the recommended protective distance which is determined according to the equation of transmitting frequency. **Recommended protective distance:** d = (3,5/U1) √P d = (3,5/E_1) √P 80 MHz to 800 MHz d = (7/E_1) √P 800 MHz to 2.5 GHz with P as the nominal power of the transmitter in watt (W) according to the indications of the transmitter manufacturer and d as the recommended protective distance in meters (m). According to an examination on-site *a)* the field strength of stationary radio transmitters should be inferior to the compliance level with regard to all frequencies. In the vicinity of devices carrying the following symbol, interferences are possible:
Radiated HF transients according to IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	

COMMENT 1:
With 80 MHz and 800 MHz the higher frequency range is valid.

COMMENT 2:
These guidelines may not apply in every case. The propagation of electromagnetic variables is influenced by absorptions and reflections of buildings, objects and people.

a) The field strength of stationary transmitters, such as e.g. base stations of mobile phones and mobile transmitting stations, amateur radio stations, AM and FM broadcasting as well as television networks cannot be exactly predetermined theoretically. In order to determine the electromagnetic environment regarding the stationary transmitters, a study of the location should be considered. If the measured field strength exceeds the above-mentioned compliance levels at the location where the device is used, the device should be watched in order to prove the intended functions. If unusual performance features are observed, it may be necessary to take additional measures, for example reorienting or relocating the device.

Recommended protective distances between portable and mobile HF telecommunication devices and custo screen 300/400

custo screen 300/400 has been designed for operation in an electromagnetic environment in which the HF transients can be controlled. The user can help avoid electromagnetic interference by maintaining the minimum distance between portable and mobile HF telecommunication devices (transmitters) and the device – depending on the output rating of the communication device, as indicated below.

	Protective distance depending on the transmitting frequency in m		
Nominal power of the transmitter W	150 kHz to 80 MHz d= (3.5/U1) √P	80 MHz to 800 MHz d= (3,5/E_1) √P	800 MHz to 2.5 GHz d= (7/E_1) √P
0.01	Not applicable	0.12	0.23
0.1	Not applicable	0.38	0.73
1	Not applicable	1.20	2.30
10	Not applicable	3.79	7.27
100	Not applicable	12.00	23.00

For transmitters whose maximum nominal power is not indicated in the above table, the recommended protective distance d can be determined in meters (m), using the equation affiliated with the corresponding column. P is the maximum nominal power of the transmitter in watt (W) according to the indications of the manufacturer of the transmitter.

COMMENT 1:
With 80 MHz and 800 MHz the higher frequency range is valid.

COMMENT 2:
These guidelines may not apply in every case. The propagation of electromagnetic variables is influenced by absorptions and reflections of buildings, objects and people.

08.8 EC Declaration of Conformity

V001 / DK-1315 / CEK-0197

EC Declaration of Conformity

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

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

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

CUSTO DIAGNOSTIC SYSTEM	
Product Category	Product Name
Medical Software	custo diagnostic
ECG Systems	custo cardio 100/100 BT custo cardio 110/110 BT custo cardio 130 custo cardio 200/200 BT
Holter ECG Systems	custo flash 110/220 custo flash 500/501/510 custo cor 3/12 custo guard 1/3
ABPM Systems	custo screen 100/200/300/400
Cardiac Rehabilitation Systems	custo care card custo guard 1/3
Telemedical Systems	custo kybe custo guard 1/3
Polysomnography Systems	custo night 300/310
Pulmonary Function Systems	custo vit m R custo spiro mobile custo spiro protect
Ergometry Systems	custo ec3000 custo er2100

Ottobrunn, 04 June 2013

Peter Müller

custo·med
EXCELLENCE IN DIAGNOSTICS

08.9 Putting out of operation, storage and transport

Putting out of operation and storage

Clean and disinfect custo screen 300/400 and its components before putting it out of operation.

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

Transport

Clean and disinfect custo screen 300/400 and its components before transport.

Use the original packaging for transport. This is a sensitive piece of electronic equipment.
If the original packaging is unavailable, pack the device such that it is protected against impact, moisture and dust.

The device must comply with the operating conditions when it is put into operation again, e.g. operating temperature *(refer to 08.5 Technical Data...)*.

Ambient conditions for storage and transport

Temperature:	-20° ... +45°C
Air humidity:	30 ... 85% rH
Air pressure:	700 ... 1060 hPa

08.10 Disposal

The device and all its components must be disposed of in a proper manner in compliance with applicable regulations (that is, in accordance with the valid laws governing electrical and electronic waste). The device must not be disposed of as normal domestic waste.

The original packaging can be recycled.
(cardboard/paper).

08.11 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.

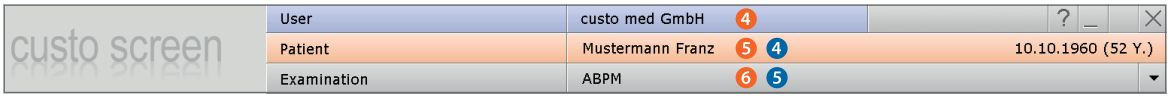
Quick links in the main navigation

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

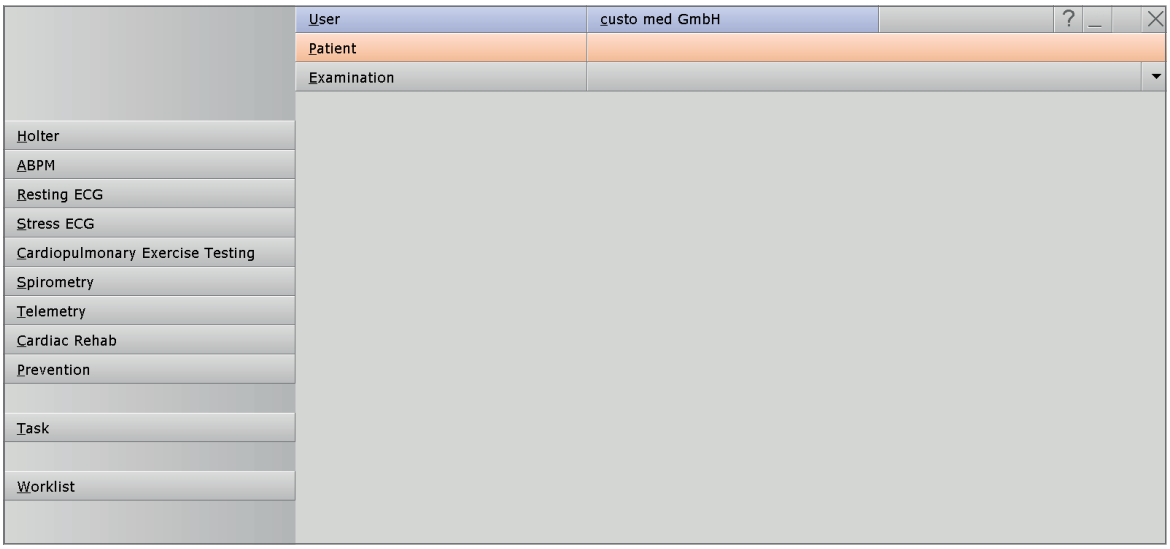
5. User master data
4. Patient master data
6. Examination main menu

RIGHT-CLICK

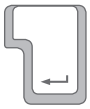
4. All the patient's evaluations
5. Evaluation last displayed of this examination

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 accepted 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 of the selected patient
Ctrl + G	List of most recently opened evaluations (same as clicking on the arrow button at top right)
Ctrl + F	List of 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 e-mail

Generally accepted keyboard shortcuts for open evaluation

Ctrl + N	Report dialogue
Ctrl + K	Medication input dialogue
Ctrl + R	Call comparison [1)]
Ctrl + T	Call trend [1)]
Ctrl + D	Call print [1)]
Ctrl + E	Call settings [1)]
Ctrl + O	Call Options menu [1)]

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

Notes

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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