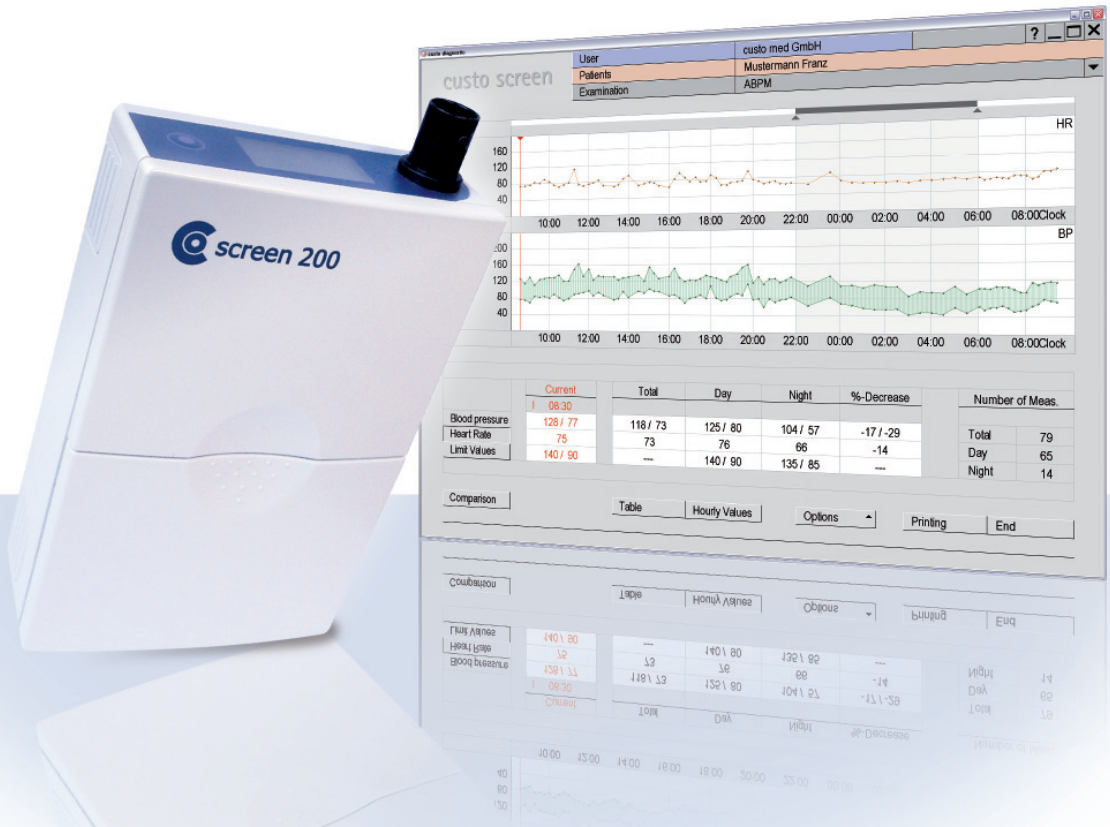
Operating Manual

ABPM

with custo screen 200 and custo diagnostic



Operating Features:

> custo diagnostic version 3.7.x
> Windows version (2000, XP, Vista)

GEB 0123 – DK 0907
Version 002 – 09/04/2009

CE 0297

custo·med
EXCELLENCE IN DIAGNOSTICS

Operating Manual

ABPM

with custo screen 200 and custo diagnostic

The manufacturer reserves the right to modify the indications in this manual without prior notice. The current version can be downloaded from our Internet site: www.customed.de, under Support, Downloads, Manuals.

Contact data of the manufacturer:
custo med GmbH
Leibnizstr. 7
85521 Ottobrunn
Germany

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

custo•med
EXCELLENCE IN DIAGNOSTICS

Contents

07 Product Information

01.1 Symbols on the Device

CE 0297	CE mark
	Safety class designation of a medical electrical device according to DIN EN 60601-1 (type BF)
XXL	Suitable for application with XXL blood pressure cuff
	Take note of the accompanying documents
	Follow the operating manual
	Recyclable material
	Separate collection of electric and electronic equipment, do not dispose with domestic waste

01.2 Intended Use

custo screen 200 is an ABPM recorder and serves for recording, analysing and evaluating the blood pressure behaviour of a patient. The recording period is 24 hours. custo screen 200 can be applied with pacemaker patients without any risk.

	The device is not suited for small children or newborns as well as for the unsupervised use with unconscious patients.

01.3 Symbols in the Operating Manual

In this operating manual the following symbols are used for marking important information, comments and hints:

INTERDICTIONS
and undue behaviour, what you must not do in any case!

BEWARE
of situations which could result in personal or property damage

NOTE
important information and comments which you must absolutely observe

HINT
practical tips for facilitating work for you

Highlighted words in colour mark buttons or click paths to the described program part, e. g. Examination, ABPM

Highlighted items

02.1 General Notes

The observation of the safety instructions prevents from personal and property damages while using the device. This operating manual is an integral part of the product and must be kept close to the device. As operator/user of this device you should have read and understood this operating manual, particularly the safety instructions.

Product Relevant Laws and Regulations

- This system is designed according to MDD 93/42/EWG (Medical Device Directive) class II a, and complies with safety class I or II (depending on the power supply unit), type BF, according to DIN EN 60601-1
- Further devices which are part of the system must comply with the Standard for Safety of Information Technology Equipment (DIN EN 60950) and the Standard for Electro-Medical Devices (DIN EN 60601-1).
- The electrical installation of the rooms in which the system is operated must comply with the requirements of current safety norms.

02.2 Operator Instructions and User Qualifications

As operator you are responsible for:

- Making sure that the operating staff get a technical briefing on the device and take note of the operating manual
- The intended application through trained, qualified staff
- The compliance with safety regulations, safety instructions, precautions for occupational medicine and accident prevention
- The observation of maintenance instructions

The users must:

- Be briefed on the correct operation of the device,
- master required processes for handling,
- know the valid safety regulations for the operation of such devices
- and be informed about potential dangers.

Only medically qualified staff are permitted to operate the device, e.g. medical secretaries, nurses, assistant medical technicians, physicians, etc.
For users outside the Federal Republic of Germany, those measures for accident prevention, regulations and requirements apply which are valid in the respective country.

02.3 Safety Installations and Safe Working

custo screen 200 is allowed to be operated in technically flawless condition only. Carry out a visual inspection of the device regularly. Only use accessories approved by custo med.

Assembly of the System

Power bars must not be put on the floor.

Power bars delivered with the system, only serve for supplying devices which are part of the system.
Additional power bars, wires and resources which are not parts of the system, must not be connected to the system.

When using a power bar, the maximum permissible load is 3200 VA.

Slots within the supplied system which are not used (power bars) must be closed with device cover plates.

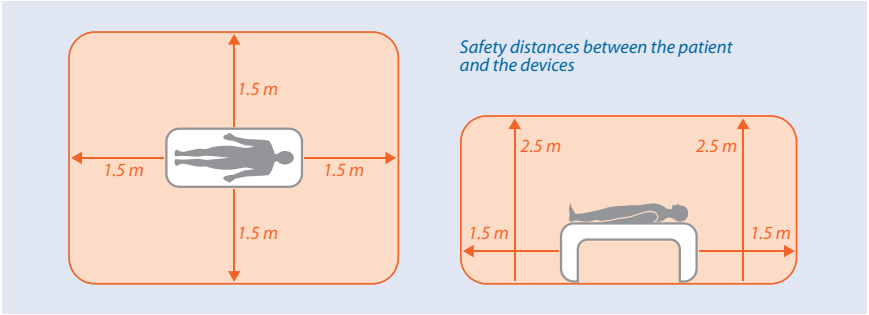
Environmental Conditions, Handling

custo screen 200 is not suited for the operation in explosive rooms and/or areas.

Strong electromagnetic sources in the near vicinity of custo screen 200 may lead to faulty measurements (e. g. HF electrosurgical instruments, mobile phones, inductions cookers).

The device must be protected against the intrusion of humidity, dust or dirt and against mechanical impacts such as fall or transport damages.

Patient Safety



Without medical safety devices, e.g. medical protector, the PC and all non-medical connected instruments (e.g. monitor and printer) of the system must be installed and operated in a distance of at least 1.5 m to the patient seat (see orange area in the illustration) because leakage current might occur.

During routine maintenance works on non-medical devices of the system, the patient must not be touched (danger of electric shock).

All reports of the system must be considered as suggestions only. For diagnosis and therapy the control and evaluation of the results through a qualified physician is indispensable.

Important hints regarding the handling of custo screen 200

See to it that the patient is not permanently impaired due to the short interruption of blood circulation caused by the measuring method.

Any compression or reduction in cross-sectional area of the air tube must be avoided.

The device does not have any protection against potential impacts by high frequency (HF) surgical devices.

Risks arising from defibrillator discharge according to the Standard EN 60601-2-30 are not known.

In no case use damaged batteries or accumulators. If custo screen 200 stands idle for a longer time, remove the batteries from the device.

If liquid is spilled on the device, the batteries or accumulators must be removed immediately and the device must be sent to your authorised custo med dealer or to custo med for inspection.

Hygiene

When cleaning and disinfecting, the legal prescriptions and the current state of the art of technology must be considered.

Use only cleaning and disinfecting agents approved by custo med. Clean and disinfect your device according to the instructions in *chapter 04 Hygiene*.

System and Data Security

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

As operator of the system you are responsible for data backups (e.g. patient databases, evaluations, etc.) and system backups. We recommend carrying out a data and system backup before effecting new installations, updates and fundamental system configurations at the latest.

custo diagnostic new installations, updates and system configurations must only be effected through your authorised custo med dealer.

Modify data generated in custo diagnostic only in custo diagnostic and not in your EPR system (Electronic Patient Record) or your HIS (Hospital Information System).

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

In order to assure a safe operation of custo diagnostic, disable the screen saver and the energy management in your Windows operating system.

Install your Windows operating system in a way that neither accidental nor automatic switching off of the PC or notebook during the examination is possible. (Standby mode / sleep mode).

02.4 Information on EMC (Electromagnetic Compatibility)

The use of other accessories, other converters and wires than the ones indicated, except for the converters and wires sold by custo med as spare parts for inner components, can lead to increased electromagnetic emissions or to a reduced electromagnetic immunity of the system. For connecting the device to other equipment, only specially screened cables supplied by custo med must be used.
You will find further information on this subject under *07.7 Manufacturer's Declaration on EMC (Electromagnetic Compatibility)*.

02.5 Maintenance (Regular Safety Checks)

The operator is responsible for maintenance. The operator has to make sure that the device is checked for proper condition every two years at the latest. The functionality and the condition of the accessories must be controlled at regular intervals. In the event of damages and/or coarse pollution the complete system is no longer allowed to be operated.

All interventions into the existing system, changes to system components, extensions as well as interior cleaning and repairs must only be carried out by your authorised custo med dealer or by custo med.

Technical Safety Controls

After each repair, modification or conversion of the system or device a technical safety control through your authorised custo med dealer must be carried out.

Metrological Controls

For the ABPM recorder custo screen 200 metrological controls are prescribed every two years. Please contact your authorised custo med dealer.

02.6 Exclusion of Liability

The manufacturer is not liable for improper use, failure to observe the safety instructions and negligent disregard of guidelines. custo med will only assume responsibility for the safety and reliability of the custo screen 200 if all changes, extensions, repairs and other works on the device and/or system are effected by authorised custo med dealers or by custo med and if the operating manual is being followed.

02.7 Warranty

It is our product philosophy to supply faultless products only, matching your expectations. However, if you have legitimate complaints, we will be anxious to remove the defects immediately or to provide a compensation delivery. Excluded are damages due to usual wear and tear, usage for purposes other than intended, unauthorised modification of parts and severe force effects.

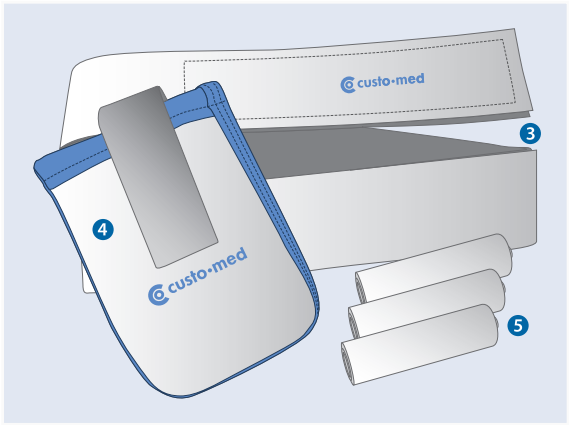
Even after the guarantee expires, use original spare parts and accessories by custo med exclusively. Solely in this case a safe and faultless operation of your device will be assured.

Warranty periods

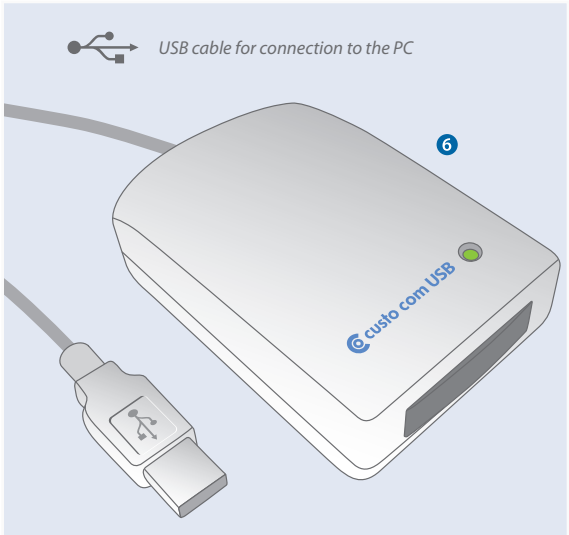
12 months	custo screen 200 custo com USB
6 months	Blood presssure cuff
without warranty	Carrying bag and belt

03.1 Scope of Delivery and Accessories

1. custo screen 200 ABPM recorder
2. Blood pressure cuff (standard)

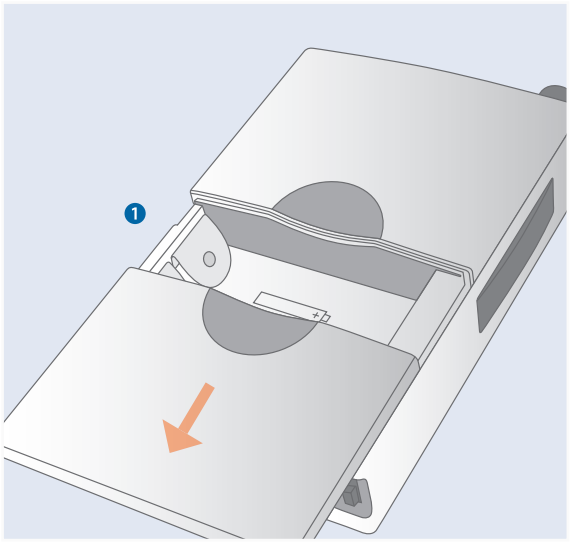


3. Carrying belt
4. Carrying bag
5. Batteries (3 pieces)
   Mignon 1.5 Volt, Type AA



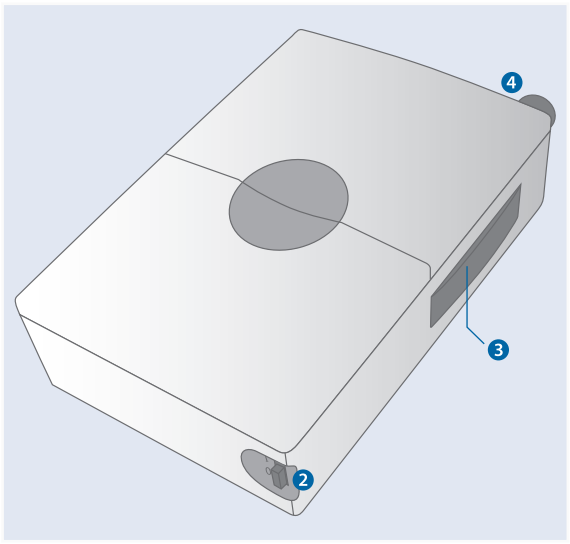
6. custo com USB
   Infrared interface for connection of custo screen 200 to the PC (included in delivery when purchasing a system)

03.2 Operating the Device



Insert batteries or accumulators

Open the battery case as illustrated on the left ❶ and insert three customary batteries or accumulators. The direction of insertion is shown on the illustrations in the battery case.

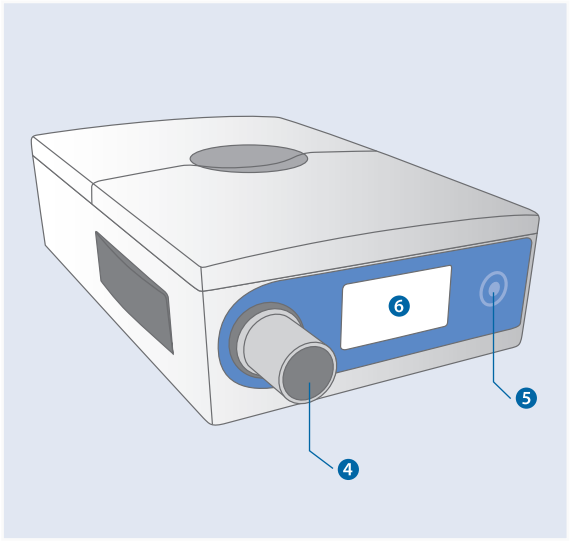


Functional elements on the device

❷ Turn-on-off button:
for turning on and off the recorder

❸ Infrared interface:
for transferring data between
custo screen 200 and PC

❹ Port for blood pressure cuff



❺ Functional key
for starting and stopping measurements

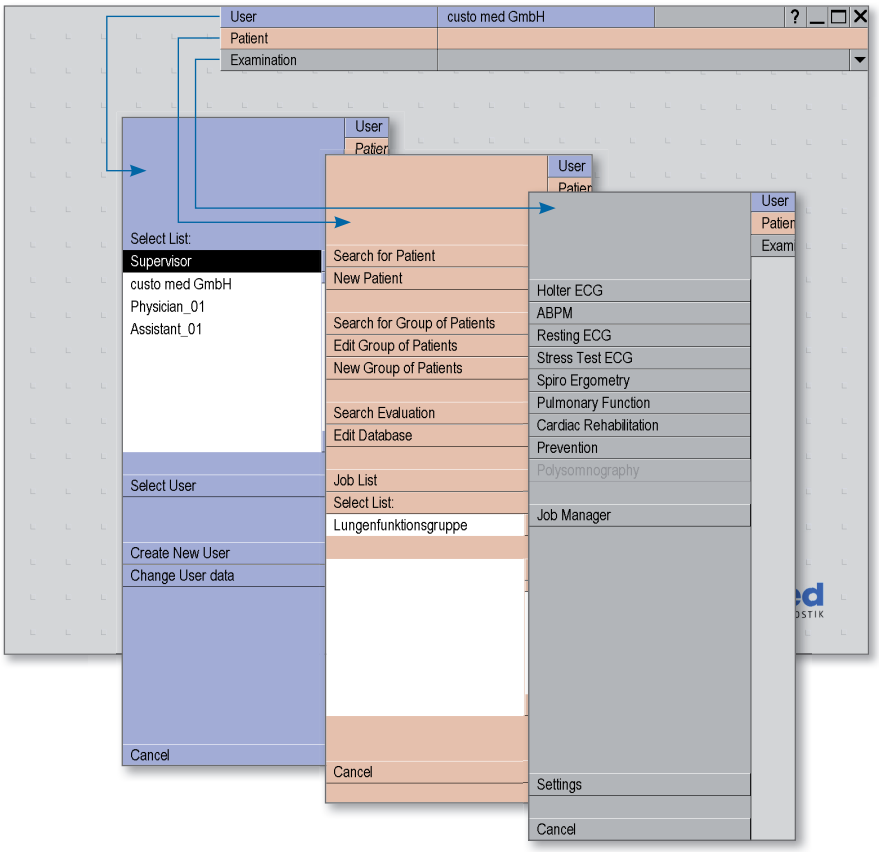
❻ Display
for showing results and error messages
(Errors see chapter 07.2 Error Codes and their Causes)

❹ Port for blood pressure cuff

03.3 custo diagnostic – Basic Program Structure

The program is divided into three areas – User, Patient and Examination. This structure always allows to recognise who (which user) with whom (which patient) is carrying out which kind of examination.

The main menus of the corresponding areas can be accessed by clicking on User, Patient or Examination.



In the main menu of the screen area User, the users of the system can be created and administrated. The user administration allows to grant user rights and to control user-specific settings, e. g. the implementation of a proper patient database for each user.

In the main menu of the area Patient, the patient administration takes place. Among the most important functions are Search Patient, New Patient and Search Evaluation.

In the main menu of the area Examination, all types of examinations which are possible with custo diagnostic are listed. All modules which you do not possess are inactive – this can be distinguished due to the light grey font. In this menu you can also access the area Settings. There program-wide, examination-related and user-specific settings can be established.

03.4 Connection and Selection of Device

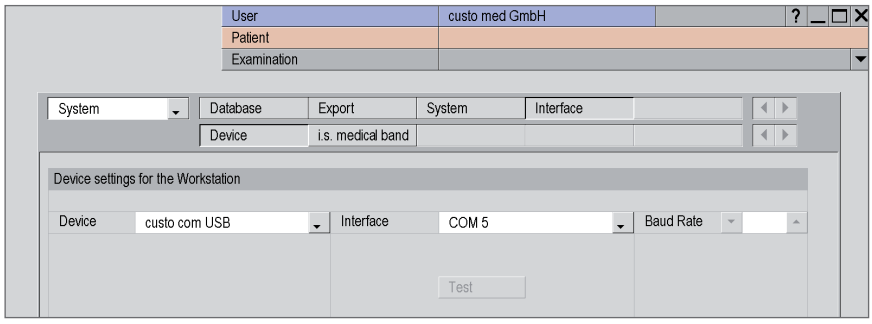
For the following steps custo diagnostic must be installed on your PC. Data transfer between recorder and PC is made via the infrared interfaces on custo screen 200 und custo com USB.

Installing custo com USB (infrared interface)

For data exchange between the recorder and your PC the driver for custo com USB must be installed on your PC (the driver is installed automatically during a custo diagnostic standard installation) and custo com USB must be connected to the PC.

Check in the Device Manager which COM connection is assigned to custo com USB so that you can enter the COM connection in custo diagnostic afterwards. Make a right click on the icon My Computer in your Windows surface, on Administer in the context menu, there on Device Manager (left window half), open the item Connections (COM and LTP) in the right window half and make a note of the custo com USB connection, e. g. (COM5).

Open the page Examination, Settings, Interface, Device in custo diagnostic. Select custo com USB under Device and the corresponding COM connection from the Device Manager under Interface. Your inputs will be taken over with Save.



Installing custo screen 200

Open the page Examination, ABPM, Settings, Device, Device Connection. Activate custo screen 100/200. In the field Connection, custo com USB must be specified. Your inputs will be taken over with Save. Your device is ready for operation.

04.1 Cleaning and Disinfection

Important specifications

Use only cleaning and disinfecting agents approved by custo med. The use of unsuitable agents may damage the device. Consider the manufacturer's instructions (e. g. regarding dosage and residence times)

Under no circumstances must the device or the cuff be immersed in liquids or be washed with too much water.

custo screen 200

- Cleaning: custo screen 200 should always be clean and aesthetic from outside. If there is dirt, rub off the surfaces slightly with a damp cloth and an acid-free cleaning agent.
- Disinfection: The authorised disinfectants area allowed to be sprayed on slightly.

Carrying bag and belt

- Cleaning: Bag and belt can be washed in the washing machine at 30°C with a mild detergent, however must not be put into a dryer.

Blood pressure cuff

- Cleaning: After use, the blood pressure cuff should be cleaned from dirt and sweat. Rub off the surfaces slightly with a damp cloth and an acid-free cleaning agent.
- Disinfection: The authorised disinfectants can be sprayed on slightly.

04.2 Approved Cleaning Agents and Disinfectants

Cleaning Agents
for custo screen 200 and blood pressure cuff

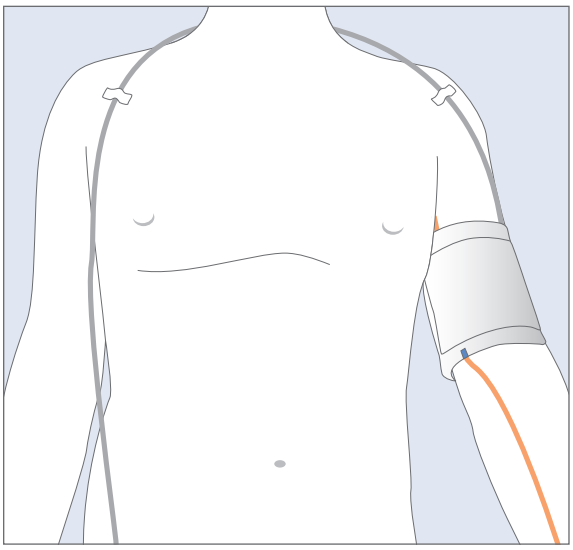
- mild soap, neutral cleaning agent
- usual dishwashing agents

Disinfectants
for custo screen 200 and blood pressure cuff

- Fugaten Spray (Lysoform)
- Esemfix (Schülke & Mayr)

Discuss the application of other cleaning agents and disinfectants with your authorised custo med dealer.

05.1 Preparing the Patient for the Examination



Applying the blood pressure cuff

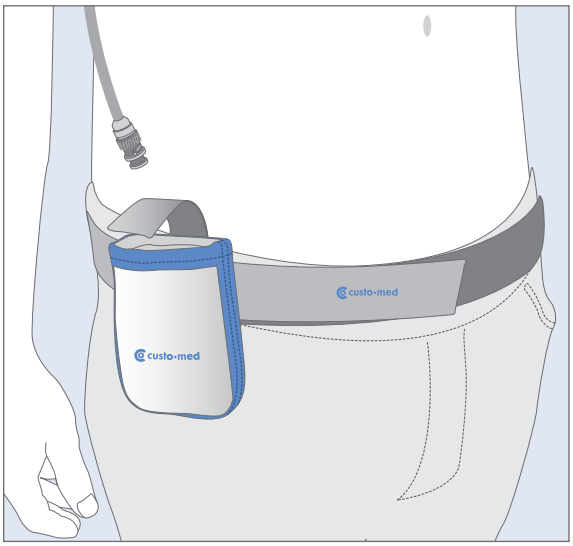
In order to attach cuff and tube optimally, the patient should undress to the waist.

Tip for applying the blood pressure cuff:
Slip the patient a tube bandage over the left upper arm – take a sufficiently sized piece so that you can put the bandage bottom-up over the cuff later. Thus you increase the level of hygiene and the wearing comfort.

Attach the cuff to the left upper arm, two to three centimetres above the crook of the arm. Apply the cuff in a way that the marking is situated on the arteria brachialis. The cuff must not be attached too firmly. It should still be possible to put approximately two fingers between arm and cuff.

Lay the tube from the left shoulder over the right shoulder to the right hip. There, the recorder will be placed later.

Fix the cuff and the tube at the patient's body. Thus faulty measurements due to incorrect cuff or tube position are excluded.



Attaching the carrying belt

Attach the carrying bag to the carrying belt. Apply the carrying belt with the patient. The bag should be positioned on the patient's right hip.

Patient Information

In order to receive optimum results, inform your patients on the recording procedure and about the correct handling of the recorder.

Handling of the recorder

The day on which the recording is made should be planned as normally as possible (no day off, no exceptional events).

The switched-on recorder and the cuff must also be carried during the night.

On the day of recording no X-ray recordings are allowed to be made, interference sources such as stimulation current devices are to be avoided.

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

The recorder must be protected against extreme cold, heat, humidity, dirt and mechanical impacts (e. g. no shower, no use of swimming-pool and sauna).

Avoiding faulty measurements

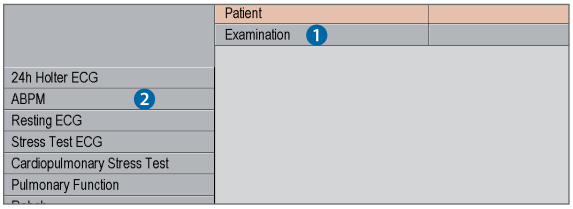
In order to avoid faulty measurements, the patient must keep his/her arm steady during a measurement – physical activities must be stopped.

In case of a faulty measurement the measurement will be repeated automatically after three minutes. When errors occur frequently during the recording process (particularly E6, E21-24 and E25-E28), check if the cuff is still attached correctly. The marking has to be situated on the arteria brachialis and it should be possible to put approximately two fingers between arm and cuff.

In case of disorders during the recording

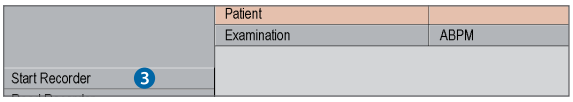
If during the recording process disorders occur, e. g. caused by a too high cuff pressure, the patient has to contact the doctor. The patient is able to stop the measurements at any time by pressing the function key or by opening the cuff's hook and loop fastener.

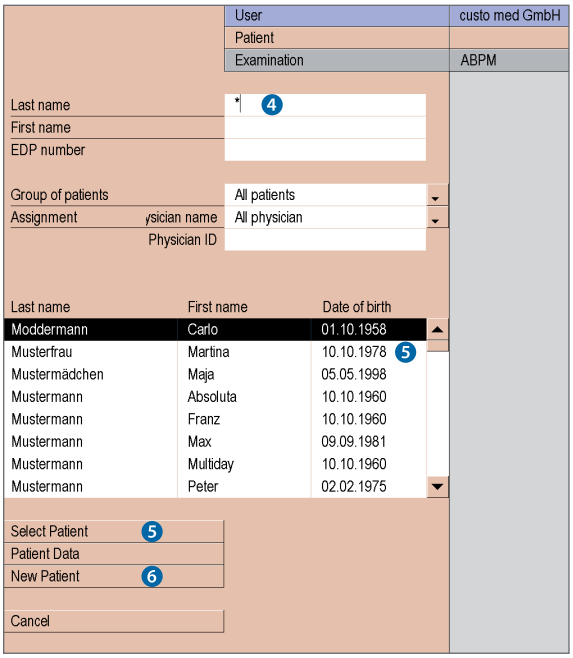
05.2 Preparing the Recorder for Recording



Start Program and Select Examination

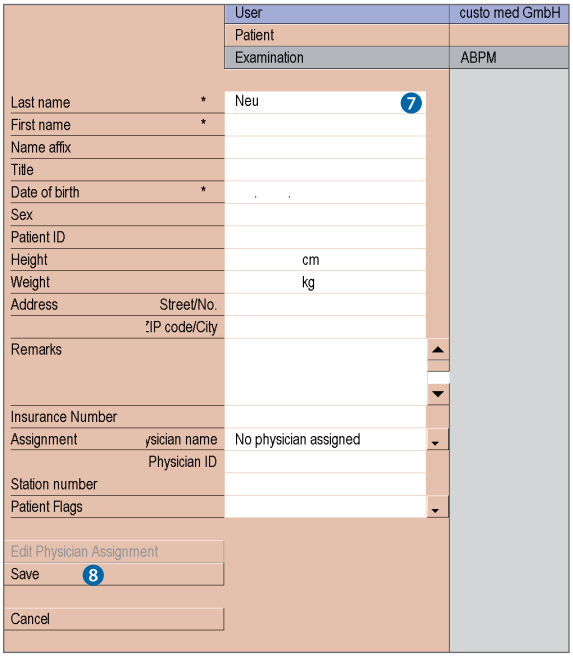
Start custo diagnostic and und log in if required, click on Examination ❶, ABPM ❷, Start Recorder ❸.





Select Patient for the Examination

The patient search form is opened. There, select a patient for the examination. Enter the patient's name or parts of it into the form ❹. The patient can be chosen from the list under the input fields. Confirm your selection with the button Select Patient ❺. You can also select a patient by double-clicking on the patient's name in the list.



If the patient is not in your database, click on New Patient ❻. Enter the patient data ❼ and click on Save ❽.

Define Recording Preferences

You are accessing the settings for recording. By clicking on Edit you can change and complement the standard profile.

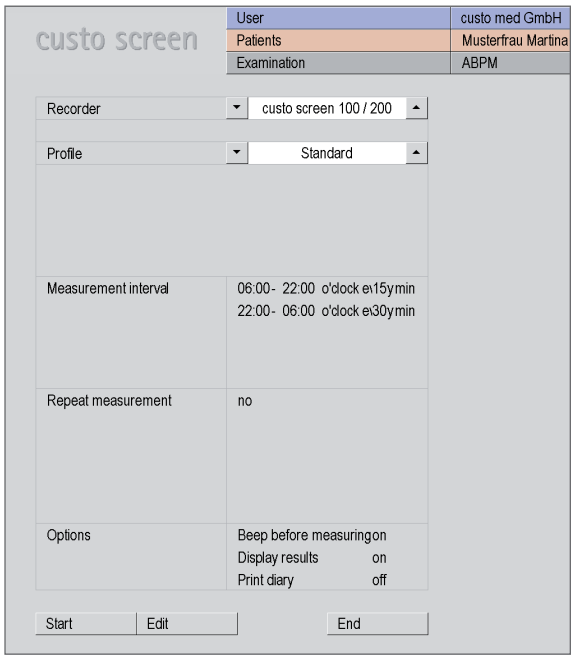
Changing the Standard Profile

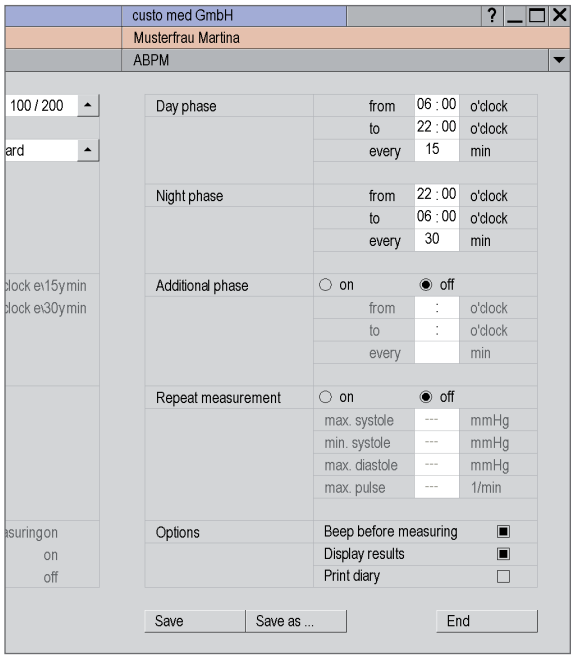
You can change the periods of day and night phase, define an additional phase and release repeat measurements when reaching predetermined limit values.

The Following Options have to be set if required: Beep before measurement: Gives a signal before each measurement so that the patient can prepare him-/herself accordingly. Display results: The measurement results are shown after each measurement. Print diary: After having clicked on Start a form for the patient is being printed in which results as to the measurements can be documented.

You can save the modified standard profile under a new name with Save as... and thus make it available for further recordings. By clicking on Save you overwrite the standard profile or the selected profile.

Hint:
Insert new batteries into the recorder before starting the data transfer.



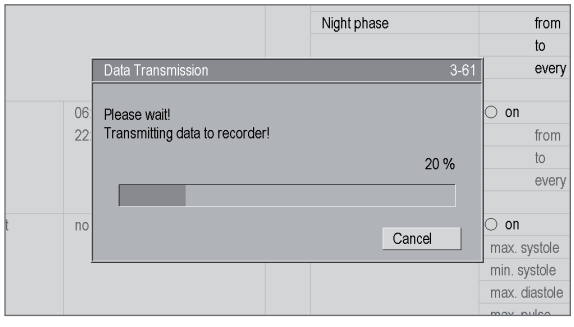


Data Transfer, Starting the Recorder

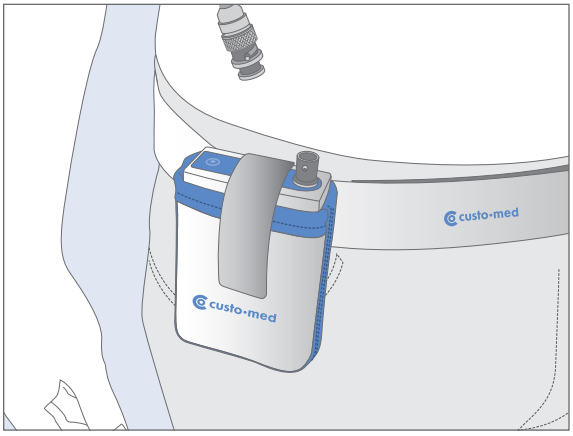
Put the switched-off recorder in front of the infrared interface custo com USB. Click on Start. Switch the recorder on as soon as the dialogue for data transfer is displayed.

If the recorder does not respond, press the function key. If "PC" appears in the display, the recorder is in data transfer mode.

The settings and patient data are being transferred to the recorder. The recorder is ready for recording.



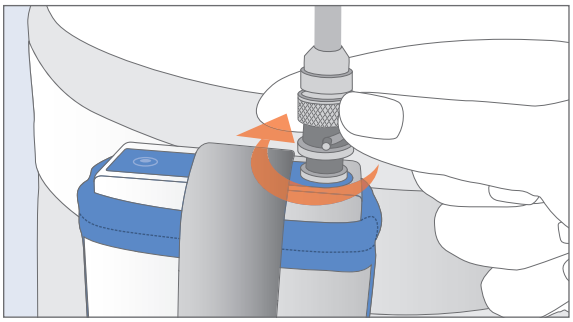
05.3 Attaching the Recorder to the Patient's Body



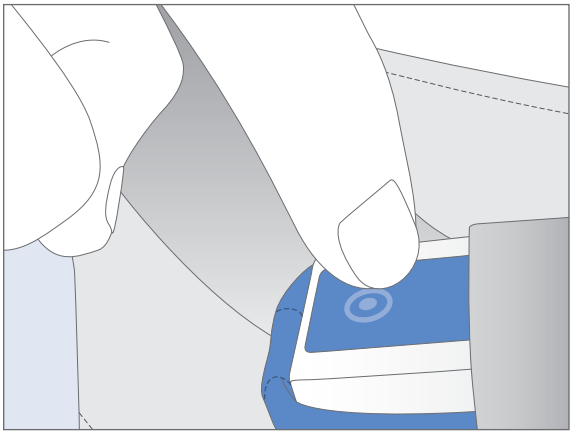
The final steps

If it has not yet happened, attach the carrying belt with the carrying bag to the patient

Put the switched-on recorder into the carrying bag and close it with the hook and loop fastener.



Connect the cuff tube to the recorder as illustrated.

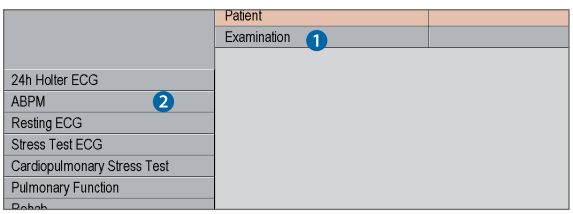


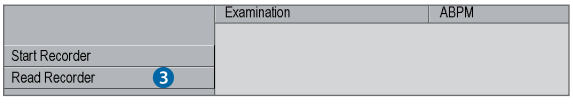
05.4 Start Recording

Press the function key in order to carry out a sample measurement. Take care that the patient keeps steady during the measurement. In the event of a faulty measurement, improve the fitting of cuff and tube.

If the sample measurement has been carried out successfully, patient and recorder are ready for recording.

05.5 Download Recording





Take the recorder from the patient after the recording. Remove the tube (turn the fastener to the left) from the recorder and pull the recorder out of the carrying bag. Switch off the device.

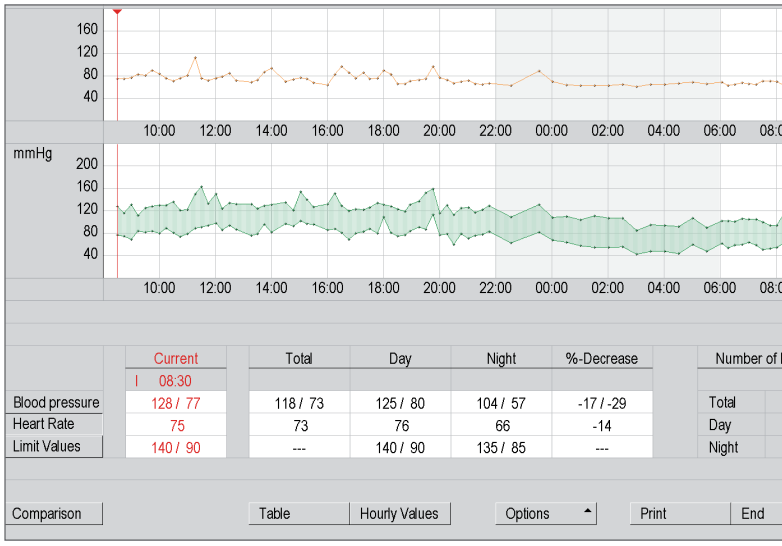
Start Program and Download Recorder Data

Start custo diagnostic and log in if required, click on Examination ❶, ABPM ❷, Download Recorder Data ❸.

Put the switched-off recorder in front of the infra-red interface custo com USB. Switch the recorder on as soon as the dialogue for data transfer is being displayed. After the download, the evaluation will be displayed automatically.

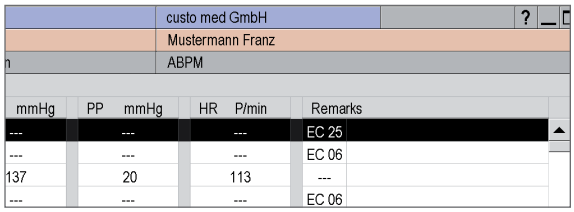
If the recorder does not respond, press the function key. If "PC" appears in the display, the recorder is in data transfer mode.

After the download the evaluation will be displayed automatically.

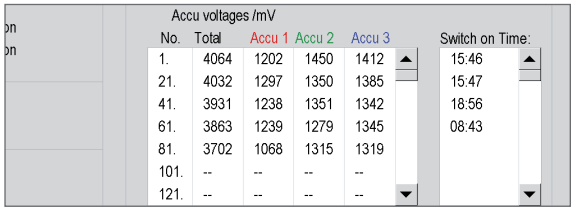


05.6 Control and Close the Evaluation

Check if and how many faulty measurements have occurred – click on Options, Faulty Measure...

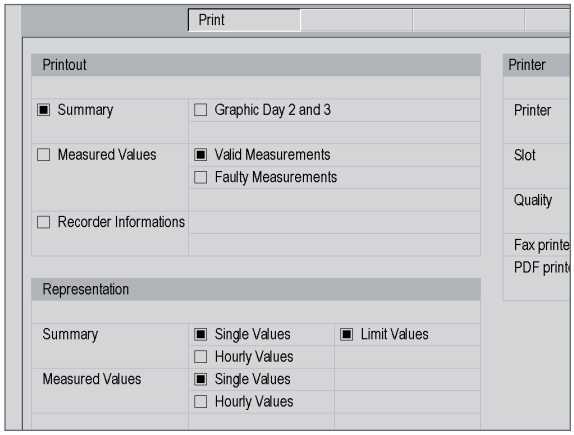


You can see from the error codes which kind of disorder has occurred. In the menu Options, under Recorder Info you can check the accumulator voltage during the recording process. By clicking on the button Graphic you can get back to Evaluation from both pages.



Print Evaluation

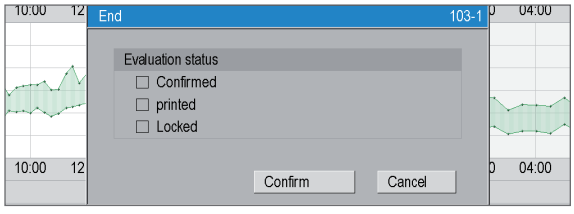
By clicking on the button Print you can print the evaluation according to the system settings. Via Options, Print... you can access the printing menu. There, you can arrange the contents for a printout individually. The printout is started with Print.



End Evaluation

Click on End in order to close the evaluation. The End Dialogue will be opened.

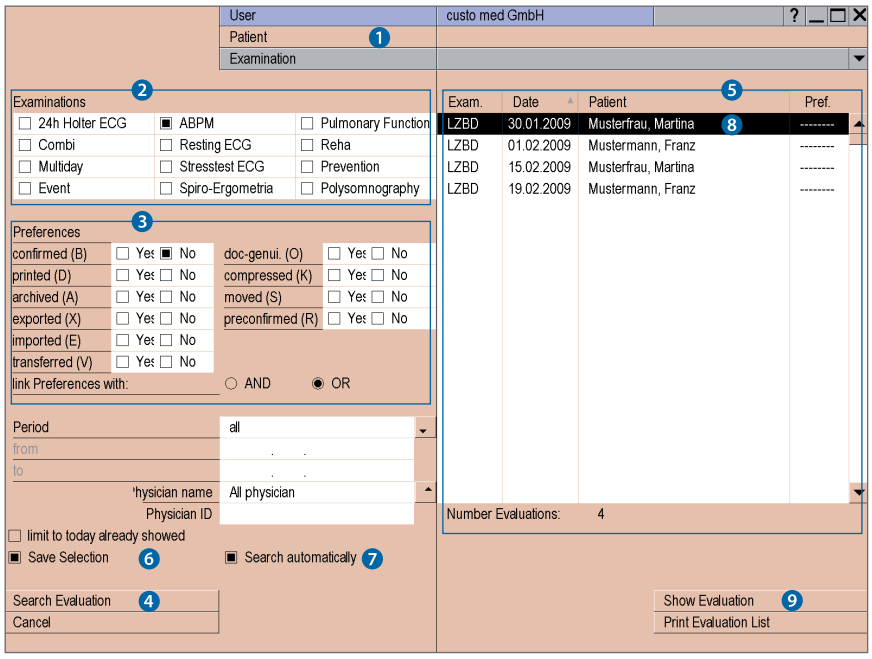
You close the evaluation with Confirm.



Final Work Steps

Remove carrying belt, tube, cuff and fixing aids from the patient.

06.1 Display Evaluation



➤ Open the Evaluation Search with a right click on Patient ❶.

➤ Activate the desired search criteria in the form for evaluation search: select the examination ❷ and additional properties (Preferences) ❸, for example ABPM, confirmed: No. Click on Search Evaluation ❹. Evaluations which comply with your search criteria will be shown in the list on the right screen half ❺.

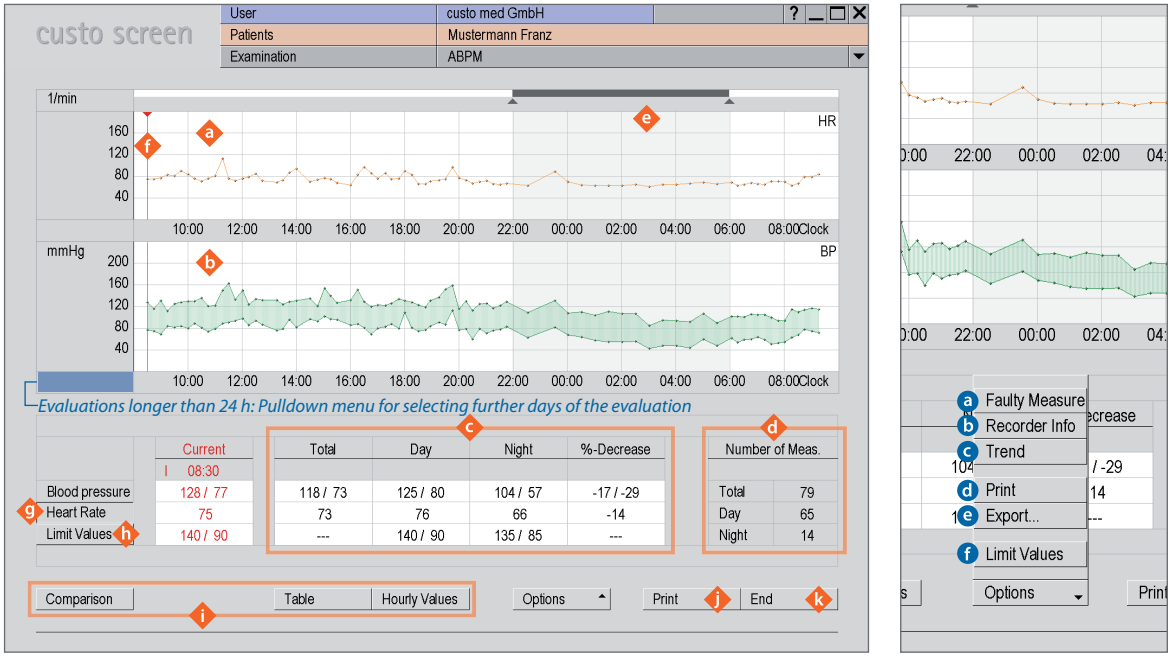
➤ *Example:*
Searching non confirmed evaluations in order to get a job list:
In the screen area Preferences, set the option "confirmed" on "No" and click on Search Evaluation. All non confirmed evaluations will be shown.

➤ Option Save Selection ❸
Activate this option if you always want to search with the set preferences.

➤ Option Search Automatically ❹
With this function the evaluations are searched automatically, without a further click on Search Evaluation. When changing the search criteria the list on the right screen half will be refreshed automatically.

➤ Select and Open Evaluation
Choose the desired examination from the list ❺ and open it by double-clicking or clicking on Show Evaluation ❻

06.2 The Workspace at a Glance



Display and Control Elements

- a Heart rate curve
- b Blood pressure curve
- c Overview table with average values
- d Number of measurements
- e Controller for modifying the night phase;
  in the event of changes, the average values adapt in the overview table
- f Event curser for piloting specific points;
  the corresponding values are presented under "Current" in the overview table
- g Fade in and out of the heart rate curve
- h Fade in and out of limit values for the blood pressure curve
- i Buttons for opening various viewing modes
- j Button for printing the evaluation
- k Button for closing the evaluation

The Menu Options

- a Display of faulty messages with error codes

Hint: We suggest to check the error codes, if there are parts without values in the graphic or gaps in the measured curves (a and b). Error codes see chapter 07 Product Information.

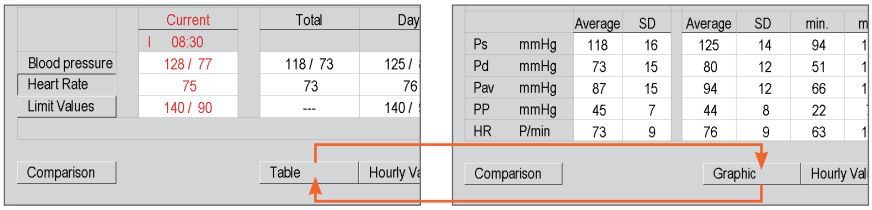
- b Display of recorder information with accumulator voltage during the recording process
- c Opening of trend display for evaluating the blood pressure behaviour over a longer period of time
- d Print menu for temporary modification of the print settings
- e Excel export of the evaluation
- f Dialogue for modifying the limit values

06.3 Navigation and Structure in the Evaluation

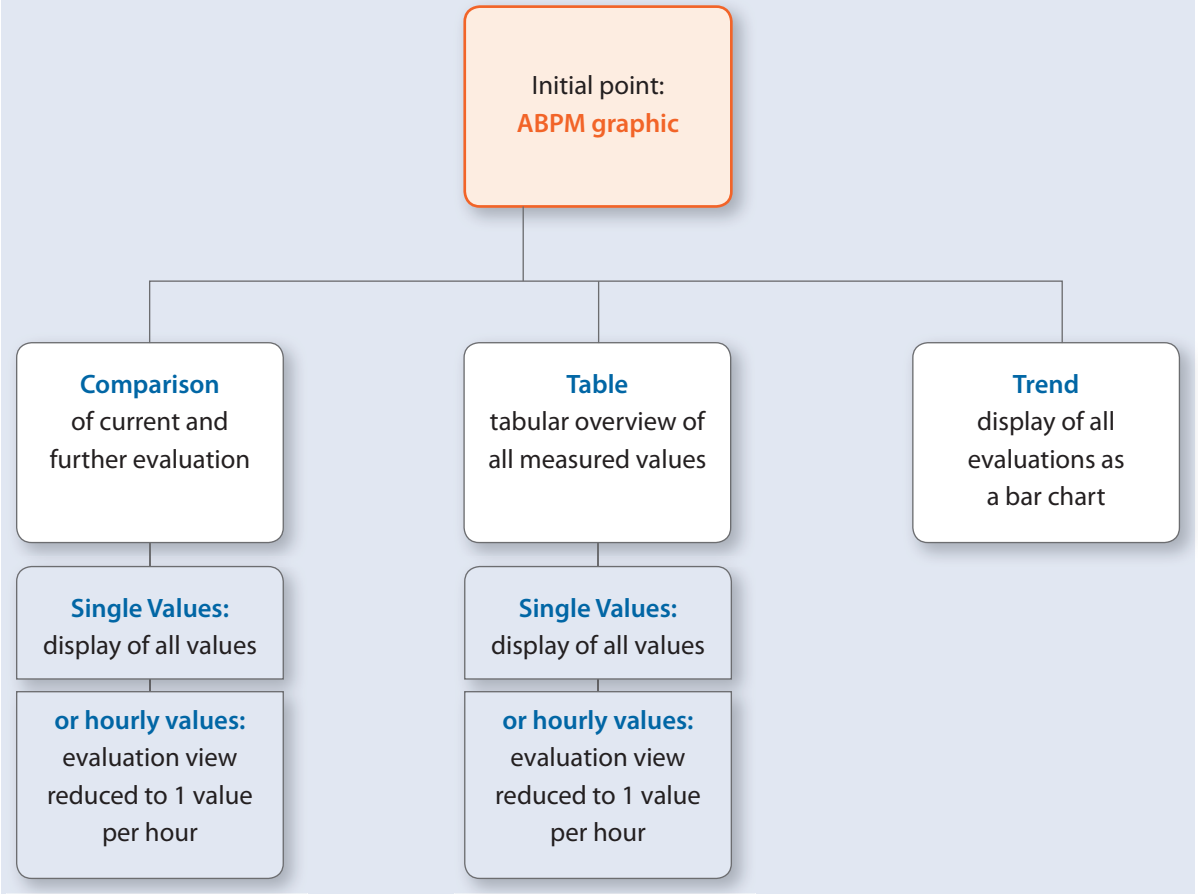
Navigation in the Evaluation

If you change from your start screen to another viewing mode, you get back to the original viewing mode by clicking on the same button.

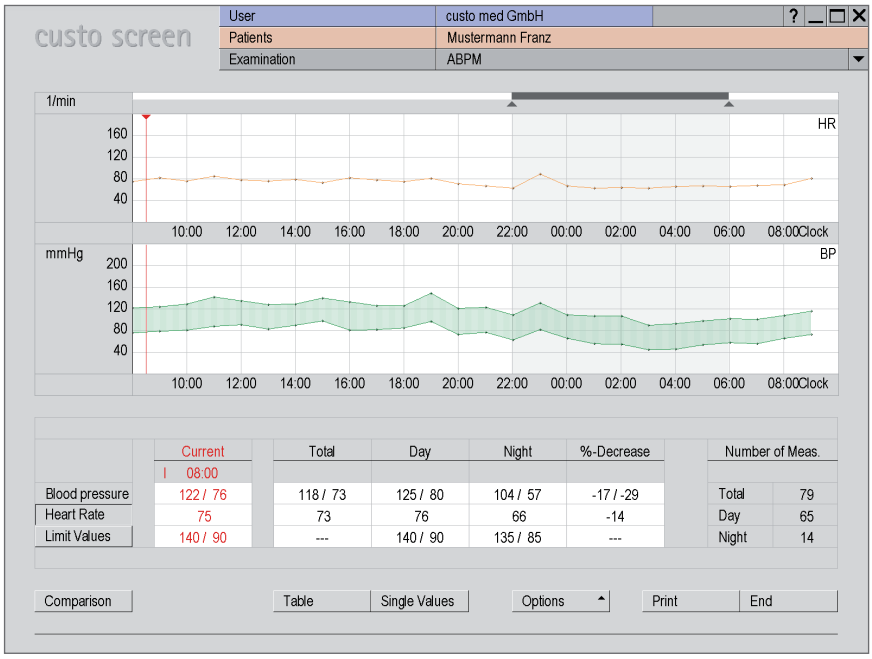
Example: You click on Table in the evaluation. You access the tabular overview of all measured values and the button Table changes to Graphic. By clicking the button Graphic you get back to the original viewing mode.



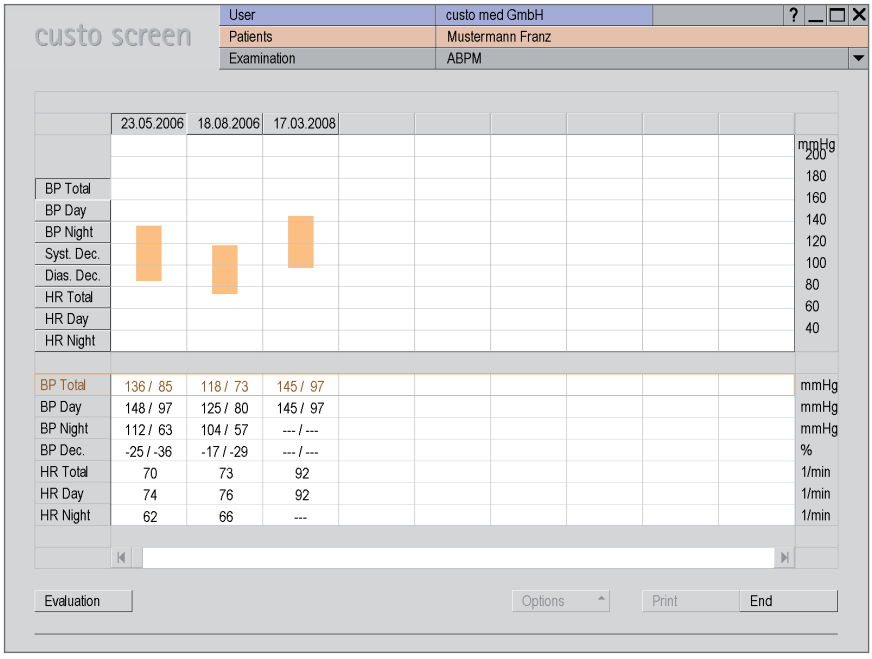
Structure and Connection of the viewing modes



06.4 Viewing Modes in the Evaluation



View: Hourly values (Evaluation > Hourly Values)
Reduction of parameter display to 1 value per hour in the evaluation view
Advantage: better overview through flatter measurement curve without fluctuations in the measured values

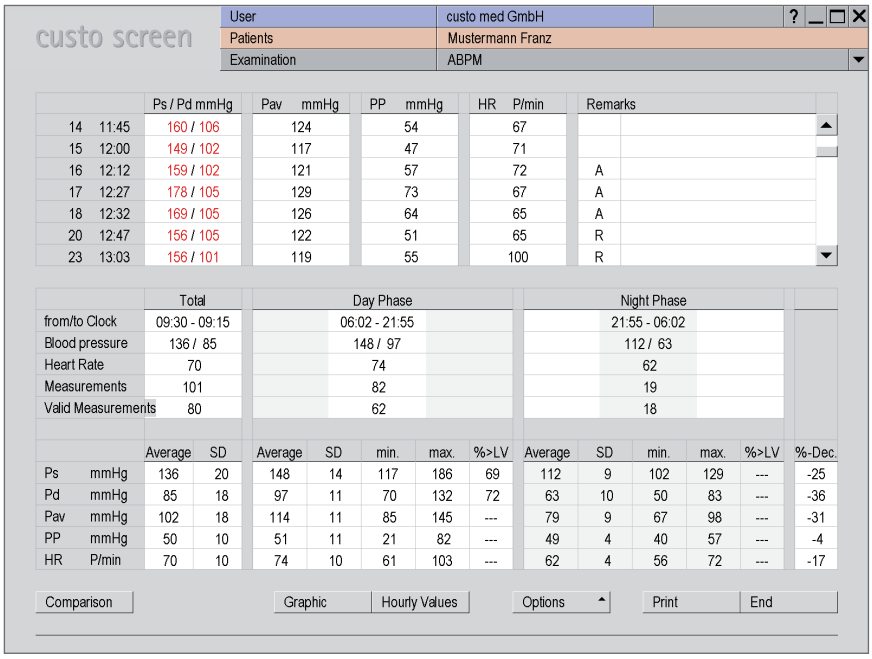


View: Trend (Options > Trend)
Display of all present evaluations as bar charts

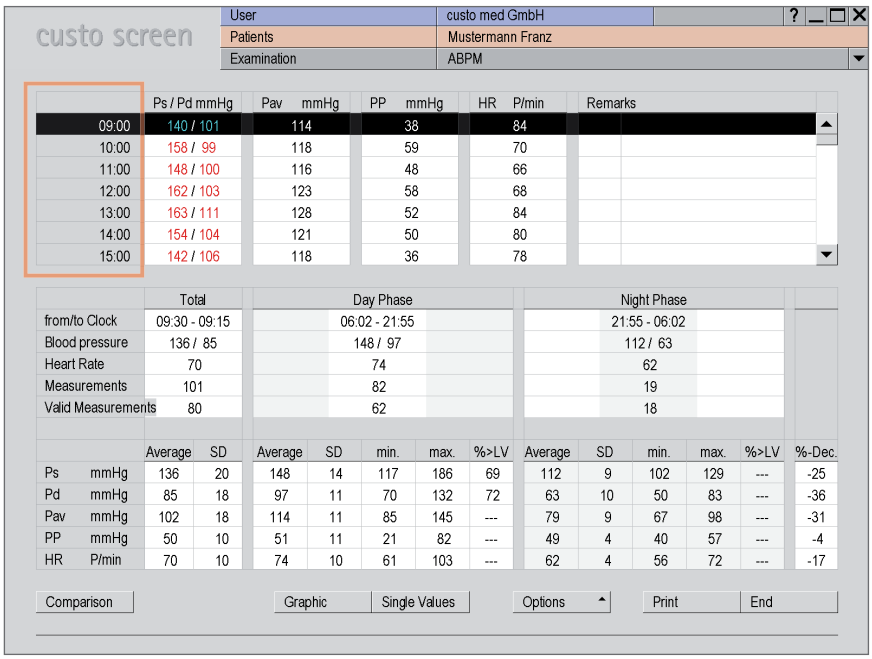
Tips for working in the tabular view

> In order to transfer diary notes into the software, click on the desired line in the column Remarks. There you can enter the text.

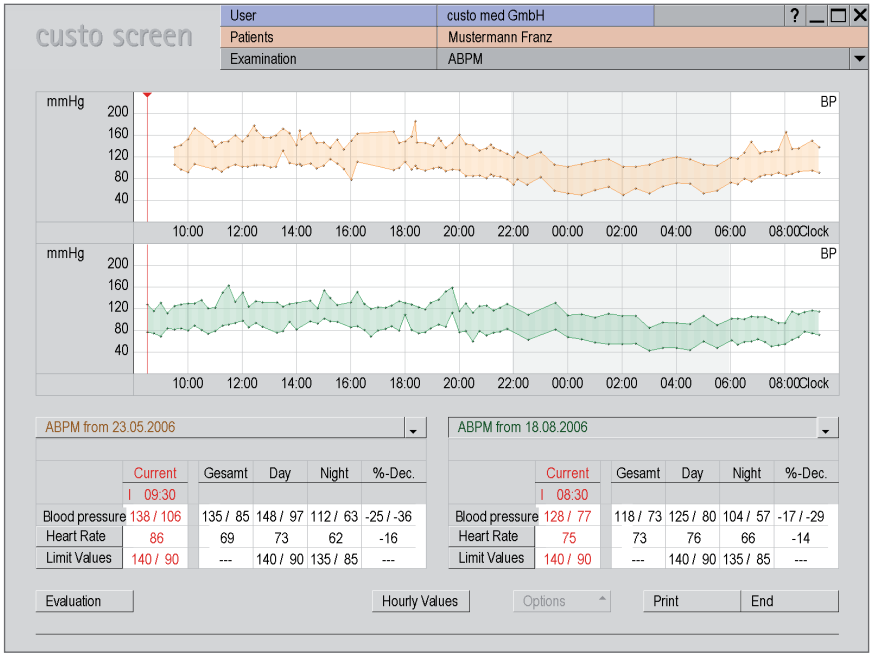
> In order to delete measurements choose the measurement to be deleted in the top table with a mouse click. Open the context menu with a right click and select Delete Measurem. there.



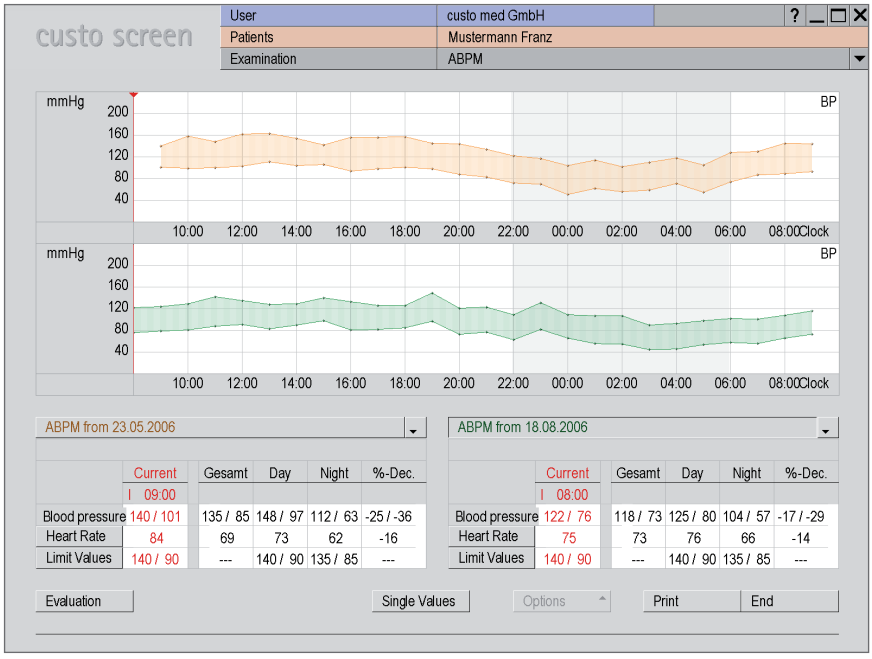
View: Table (Evaluation > Table)
Tabular overview of all parameters including a summary of the complete recording and summary of day and night phase



View: Table with hourly values (Evaluation > Hourly Values > Table)
Tabular overview of all measured values, reduced to 1 value per hour

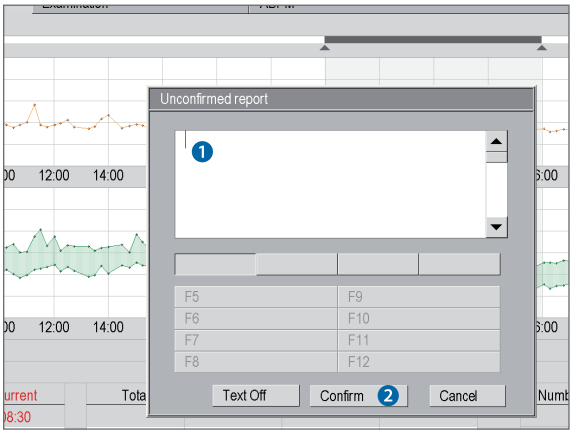


View: Comparison (Evaluation > Comparison)
The current evaluation is compared to another one



View: Comparison to hourly values (Evaluation > Comparison > Hourly Values)
Comparison of two evaluations with only 1 value per hour, for better overview

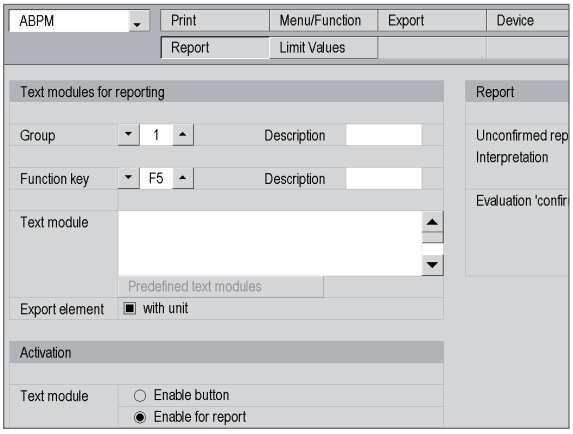
06.5 Confirm Evaluation



The unconfirmed report is opened with a right mouse click on the evaluation screen. Select Report in the context menu.

Enter your data in the white text field ❶. They are saved with Confirm ❷ and the unconfirmed report becomes a report.

If your report text is not yet ready and is to be saved nevertheless without reaching the status of a report, set back the status “Confirmed” when closing the evaluation.



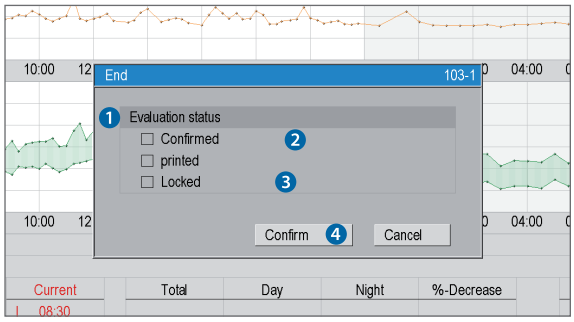
06.6 Auxiliary Tools for Writing Reports

Under Examination, ABPM, Settings, Diagnostic, Report, text modules for a report can be created. The modules are recalled via key commands when writing a report.

The basic structure of a text module is @VARIABLE. Your inputs will be taken over with Save.

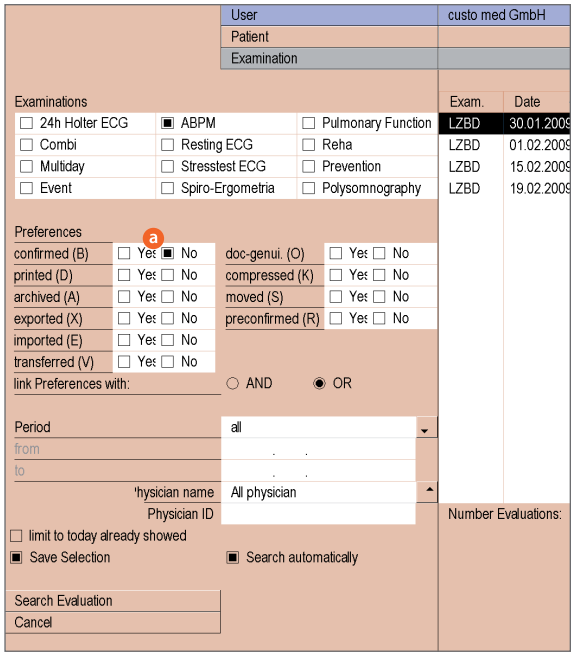
06.7 Close Evaluation

The evaluation is closed with End. The End Dialogue is opened. Here, the status of an examination can be modified ❶.



➤ Confirmed ❷
A confirmed evaluation can be set back to "not confirmed" by deselecting the option "Confirmed".

Hint for the status of the report and evaluation:
The status "not confirmed" serves as a search criterion when searching evaluations for which the physician has not yet given his/her final confirmation. Set the property "confirmed" on "No" when searching an evaluation ⓐ. The list of all not confirmed evaluations will show you what still has to be done.

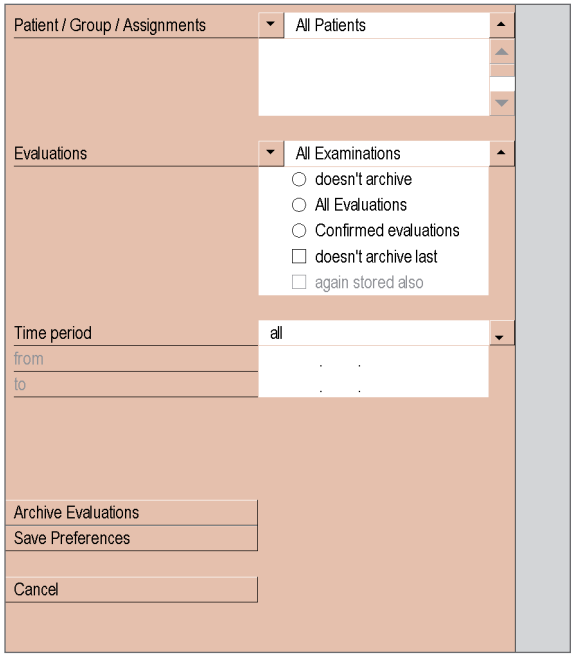


➤ Locked (finalized document) ❸
Signalises that the works on an evaluation have been terminated and has the effect of a write-protection when reopening the evaluation.

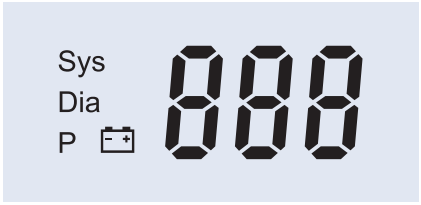
Close the examination with Confirm ❹.

06.8 Archive Evaluations

Archiving evaluations serves for obtaining memory capacity on your hard disk. You find the archiving functions under Patient, Edit Database.



07.1 Presentation of Measured Values and Status in the Display



Display elements

Sys:	Systolic blood pressure
Dia:	Diastolic blood pressure
P:	Pulse
Battery:	will light up if batteries are weak

If the blood pressure measurement has been carried out successfully...
systole, diastole and pulse will be displayed three times one after the other

---

During data transfer between recorder and PC...
"PC" is shown in the display
(the LED of custo com USB is flashing)

In the event of faulty measurements...
an error code is shown in the display, e. g. "E4"

07.2 Error Codes and their Causes *)

E4	**Exceeding the limit values of the blood pressure values** Sys: < 70 mmHg > 270 mmHg Dia: < 40 mmHg > 155 mm Hg Sys - Dia: < 15 mmHg, HR: < 35/min > 220/min ➤ Measurement will be repeated automatically
E5	**Pressure discharge rate outside the given limits** Cause: valve is leaky or defective ➤ Please contact your authorized custo med dealer
E6	**Disturbed measurement** Cause: too many movement artefacts ➤ Attach the cuff correctly ➤ Keep the arm steady during the measurement
E17	**Pressure increase is too slow** Cause: Cuff is not tight (defective), valve is leaky ➤ Check the cuff (o-ring in the connector) ➤ Please contact your authorized custo med dealer
E19	**Discharge period is too long** Cause: cuff tube is snapped off or valve is defective ➤ If error occurs frequently during the recording process: Please contact your authorized custo med dealer
E21 - E24	**Error when determining diastole** Cause: Cuff has been attached incorrectly / insufficient oscillation (marking on the cuff is not situated on the artery) ➤ Attach the cuff correctly ➤ Keep the arm steady during the measurement
E25 - E28	**Error when determining systole** Cause: Systole lies above the pump up pressure, movement artefacts ➤ Attach the cuff correctly ➤ Keep the arm steady during the measurement
E50 - E52	**Zero point balancing is not possible** Cause: System is not at zero pressure when being switched on ➤ If error occurs after connecting the cuff: wait until the display expires, repeat measurement after 10 sec ➤ If error occurs frequently during the recording process: Please contact your authorized custo med dealer

**) When an error occurs during a measurement a new measurement will be started automatically after aprrox. 3 minutes.*
For error codes which are not listed in this manual customer service has to be contacted.

07.3 Limit Values for Blood Pressure Measurement

The limit values are defined as follows in custo diagnostic:

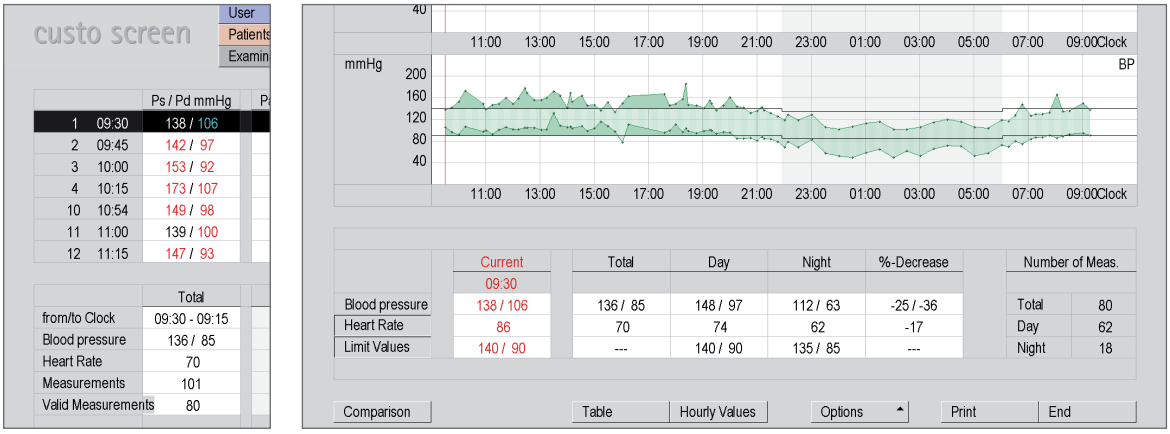
- Adults

Day phase	
Systole	135 mmHg
Diastole	85 mmHg

Night phase	
Systole	120 mmHg
Diastole	75 mmHg

Measurements exceeding these values are marked with red colour in the evaluation. If required, the limit values can be modified via the menu Options, in the dialogue Limit Values.

In the ABPM graphic (initial screen), you can fade in auxiliary lines at the level of the fixed limit values by clicking on the button Limit Values (bottom left, next to the summary table). Consequently, values outside the fixed limit values can be seen immediately and be piloted easily.



- Limit values for children 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

07.4 Abbreviations in the Evaluation

Ps	Systolic blood pressure
Pd	Diastolic blood pressure
Pav	Mean (average) arterial pressure Pav = (Ps - Pd) : 3 + Pd
PP	Pulse pressure PP = Ps - Pd
HR	Heart rate
A	Additional measurement, measurement which has been released with the function key
R	Repeat measurement, e. g. if the limit values have been exceeded before (they can be set individually at the start)
Average	Average value of the corresponding measured value over the total measurement period, taking into consideration the intervals between the measurements
SD	Standard deviation
Min	lowest measured value
Max	highest measured value
%>LV	Percentage of measurements exceeding the limit value
%-Dec.	Decrease in terms of percentage between day and night average values (daily average value - night average value = 10 – 15 %)

07.5 Technical Data and System Requirements

Technical Data custo screen 200		
Measurement method	Oscillometric measurement procedure automatic zero balancing	
Measurement range	Heart rate Systolic blood pressure Diastolic blood pressure	35 – 220 beats / min 70 – 270 mmHg 40 – 155 mmHg
Max. number of measurements	512	
Max. time of recording	72 hours	
Duration of a measurement	approx. 30 seconds	
Measurement intervals	Defined by the examination settings in custo diagnostic Standard setting: every 15 min during the day, every 30 min during the night Intervals can be set between 5 and 90 min Individual adaptation of all phases (day, night, additional) possible	
Cuff pressure	max. 300 mmHg	
Cuff sizes	Standard (within the scope of delivery), children, XL, XXL (with or without retainer)	
Data transfer	Infrared (IrDA standard) via custo com USB (Infrared interface with USB port)	
Voltage supply	3 Mignon, 1.5 Volt, Type AA 3 accumulators, Ni-MH, 1.2 Volt, at least 1500 mAh	
Operating conditions	Temperature Air humidity Air pressure	+10°C ... +40°C 30 ... 80% rH 700 ... 1060 hPa
Transport and storage conditions	Temperature Air humidity Air pressure	-20°C ... +45°C 30 ... 80% rH 700 ... 1060 hPa
Dimensions	Size Weight	approx. 100 * 66 * 26 mm (L * W * H) approx. 190 g (without batteries)
Classification	Safety class III Class II a Type BF DIN EN 60601-1	

System Requirements	
CPU	Pentium 4
Main memory	1 GB RAM
Hard disk	20 GB
Operating system	Windows 2000, XP, Vista older versions are not supported (e. g. Windows 95, 98, NT, ME)
Hardware & ports	DVD or CD ROM drive USB port
Software	custo diagnostic, version 3.7.1 or higher Software module ABPM (custo screen)

07.6 Support

If you have any questions and problems which are not discussed here, please contact your authorised custo med dealer. You will find a list of authorised custo med dealers in the Internet under www.customed.de, under the rubric Contact, Dealers.

You can also contact custo med GmbH directly at any time. We are pleased to inform you about who your authorised custo med dealer is, or even to establish the contact to your authorised custo med dealer and forward your query.

07.7 Manufacturer's Declaration on EMC (Electromagnetic Compatibility)

Manufacturer's Declaration – Electromagnetic Emissions

The custo screen 200 ABPM Recorder is designed for operation in the electromagnetic environment stated below. The customer or user of custo screen 200 should make sure that it is used in such an environment.

Emission Measurements	Compliance	Electromagnetic Environment - Guidelines
HF emissions according to CISPR11	Group 1	custo screen 200 uses HF energy exclusively for its internal function. For this reason its HF emission is very low and it is unlikely that surrounding electronic devices are being disturbed..
HF emissions according to CISPR11	Class B	custo screen 200 is designed for the use in all facilities including living areas and those directly connected to public power supply providing also buildings used for living purposes.
Harmonics according to IEC61000-3-2	non-applicable	
Voltage fluctuations/flickers according to IEC61000-3-3	non-applicable	

Table 201 according to DIN EN 60601-1-2, 6.8.3.201

Manufacturer's Declaration – Electromagnetic Immunity

The custo screen 200 ABPM Recorder is designed for operation in the electromagnetic environment stated below. The customer or user of custo screen 200 should make sure that it is used in such an environment.

Immunity Tests	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment - Guidelines
Discharge of static electricity 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 61000-4-2	± 2 kV for net wires ± 1 kV for input and output wires	non-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	non-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 5s (> 95% drop)	non-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 200 requests continued function, also if interruptions in the energy supply occur, it is recommended to supply custo screen 200 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 they can be found in the business and clinical environment.

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

Table 202 according to DIN EN 60601-1-2, 6.8.3.201

Manufacturer's Declaration – Electromagnetic Immunity

The custo screen 200 ABPM Recorder is designed for operation in the electromagnetic environment stated below. The customer or user of custo screen 200 should make sure that it is used in such an environment.

Immunity Tests	IEC 60601- Test Level	Compliance Level	Electromagnetic Environment - Guidelines
			Portable and mobile radio sets should not be used in a shorter 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:**
Conducted HF transients according to IEC 61000-4-6	3 $V_{effective\ value}$ 150 KHz to 80 Mhz	non-applicable	d = (3,5/V1) √P d = 1,2 √P 80 MHz to 800 MHz
Radiated HF transients according to IEC 61000-4-3	3 V/m 80 MHz to 2,5 GHz	3 V/m	d = 2,3 √P 800 MHz to 2,5 GHz with P as nominal power of the transmitter in Watt (W), according to the indications of the transmitter manufacturer and d as 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: 

COMMENT 1:
With 80 Hz 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 radio transmitters such as e. g. base stations of radio 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 being observed, it may be necessary to take additional measures, for example reorienting or relocating the device.

Table 204 according to DIN EN 60601-1-2, 6.8.3.201

Recommended protective distances between portable and mobile HF telecommunication devices and custo screen 200

custo screen 200 is designed for the operation in an electromagnetic environment in which the HF transients can be controlled. The user can help avoid electromagnetic interferences by keeping to the minimum distance between portable and mobile HF telecommunication devices (transmitters) and the device – depending on the initial performance of the communication device, as indicated below.

	Protective distance depending on the transmitting frequency in m		
Nominal power of the transmitter W	**150 kHz to 80 MHz** $d= (3,5/V1)\sqrt{P}$	**80 MHz to 800 MHz** $d= 1,2\sqrt{P}$	**800 MHz to 2,5 GHz** $d= 1,2\sqrt{P}$
0,01	non-applicable	0,12	0,23
0,1	non-applicable	0,38	0,73
1	non-applicable	1,20	2,30
10	non-applicable	3,79	7,27
100	non-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 factors is influenced by absorptions and reflections of buildings, objects and people.

Table 206 according to DIN EN 60601-1-2, 6.8.3.201

07.8 EC Declarations of Conformity

custo·med
EXCELLENCE IN DIAGNOSTICS

EC CERTIFICATE OF CONFORMITY

Manufacturer:

custo med GmbH
Leibnizstraße 7
85521 Ottobrunn

Product: **Diagnostic Software, Medical Operating System**

Model number: **custo diagnostic**

We declare in sole responsibility that this medical product class IIa is in compliance with **93/42/EWG** and fulfills the requirements of the Medical Product Standards.

Number of registration of the certificate:	69940 MR2
EC identification number of the DQS as notified body:	**DQS** **0297**

Ottobrunn, 07\03\2008

Peter Müller

(Peter Müller)

 V00 DK-0736 / CEK-0086 1

custo·med
EXCELLENCE IN DIAGNOSTICS

EC CERTIFICATE OF CONFORMITY

Manufacturer:

custo med GmbH
Leibnizstraße 7
85521 Ottobrunn

Product: **Ambulatory Blood Pressure Monitor and ECG**

Model number: **custo screen 200**

We declare in sole responsibility that this medical product class IIa is in compliance with **93/42/EWG** and fulfills the requirements of the Medical Product Standards.

Number of registration of the certificate:	69940 MR2
EC identification number of the DQS as notified body:	**DQS 0297**

Ottobrunn, 07\03\2008

Peter Müller

(Peter Müller)

 V00 DK-0762 / CEK-0112 1

07.9 Shutdown, Storage and Transport

Shutdown and Storage

Clean and disinfect custo screen 200 and the associated components before shutdown.

See to it that the storage area is free of dust, dry and not directly exposed to the sun.

Transport

Clean and disinfect custo screen 200 and the associated components before transport.

Use the original packaging for transport. custo screen 200 is a sensitive electronic device.
If the original packaging is not available, pack custo screen 200 in a way that it is protected against collision, humidity and dust.

The device must comply with the operating conditions when being put into operation again, e. g. operating temperature *(see 07.1 Technical Data...)*.

Environmental Conditions for Storage and Transport

Temperature:	-20° ... +45°C
Air humidity:	30 ... 80% rH
Air pressure:	700 ... 1060 hPa

07.10 Disposal

Take care of an appropriate and environmentally sound disposal of the device and the associated components.

Carrying bag, belt and cuff can be disposed with regular (non-recyclable) waste.

The batteries must not be disposed with domestic waste.

custo screen 200 has to be disposed with electronic waste.

The original packaging of custo screen 200 and the associated components is recyclable (paperboard / recovered paper).

Notes

custo•med
EXCELLENCE IN DIAGNOSTICS

Leibnizstr. 7
85521 Ottobrunn
Germany

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