

ABPM

with custo screen 300 and custo diagnostic



Operating characteristics:

- > custo diagnostic 3.8 and higher
- > for Windows®

GEB 0154 – DK 1055

Version 002 – 05.06.2013



custo·med
EXCELLENCE IN DIAGNOSTICS

Operating Manual

ABPM

with custo screen 300 and custo diagnostic

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01	Introduction	
01.1	Symbols on the devices.....	6
01.2	Intended use.....	6
01.3	Symbols used in this Operating Manual.....	7
02	Safety instructions	
02.1	General.....	8
02.2	Safety installations and safe working	9
02.3	Maintenance (regular safety checks)	12
02.4	Disclaimer	13
02.5	Warranty	13
03	Device description, basics of putting into operation	
03.1	Scope of delivery and accessories	14
03.2	Device operation	15
03.3	custo diagnostic – basic program structure	16
03.4	Device connection and configuration	17
04	Hygiene	
04.1	Cleaning and disinfection	18
04.2	Approved cleaning agents and disinfectants.....	19
05	Carrying out an examination	
05.1	Preparing the patient for the examination.....	20
05.2	Preparing the recorder for the recording	22
05.3	Attach the recorder to the patient.....	24
05.4	Start the recording	24
05.5	Download the recording.....	24
05.6	Check the evaluation.....	25

06

Working with the evaluation








06.1	Opening an evaluation.....	26
06.2	The workspace at a glance.....	28
06.3	Navigation and structure in the evaluation.....	29
06.4	Viewing modes in the evaluation	
06.4.1	Chart, hourly values.....	30
06.4.2	Trend.....	30
06.4.3	Comparison.....	31
06.4.4	Comparison with hourly values.....	31
06.4.5	Table.....	32
06.4.6	Table with hourly values.....	32
06.4.7	Automatic report.....	33
06.4.8	Unconfirmed report.....	34
06.5	Confirm the evaluation.....	34
06.6	End the evaluation.....	35
06.7	Archive evaluations (optional).....	35

07

Product information

07.1	Measurement and status indication on the display.....	36
07.2	Error codes and their causes.....	37
07.3	Limit values for blood pressure measurement.....	38
07.4	Abbreviations in the evaluation.....	39
07.5	Technical data and system requirements.....	40
07.6	Support.....	41
07.7	Manufacturer's declaration on EMC (electromagnetic compatibility) according to DIN EN 60601-1-2:2007.....	42
07.8	EC Declaration of Conformity.....	45
07.9	Shutdown, storage and transport.....	46
07.10	Disposal.....	46
07.11	Keyboard navigation and shortcuts in custo diagnostic.....	47

01.1 Symbols on the devices

	Manufacturer: custo med GmbH, Leibnizstr. 7, 85521 Ottobrunn, Germany
	CE mark
	Protection class classification of medical electrical equipment according to IEC 60601-1 (Type BF)
	The device is not suited for small children or newborns
	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

01.2 Intended use

custo screen 300 is an ABPM recorder with an internal power supply which is used to record and evaluate the blood pressure behaviour of a patient. The recording period can last for up to 72 hours. custo screen 300 is perfectly safe for use by patients with a pacemaker.

The system is intended for use by trained specialists or physicians in clinics and medical practices. Patients are only allowed to use the recording device after receiving instruction by trained specialists. 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 suited for unsupervised use with unconscious patients.

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 described program part, e.g. Examination, ABPM

Words highlighted
in colour..

02.1 General

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 according to DIN EN 60601-1.
- Other devices which are part of the system must meet the requirements of the Standard for Information Technology Equipment (DIN EN 60950) and the Standard for Electrical Medical Devices (DIN EN 60601-1).
- The electrical installations in the rooms in which the system is used must meet the requirements of the applicable safety standards.
- 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 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 laid 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 operation of the device, please observe the EMC notes (electromagnetic compatibility) in these instructions for use, see chapter [07.7 Manufacturer's declaration on EMC...](#)



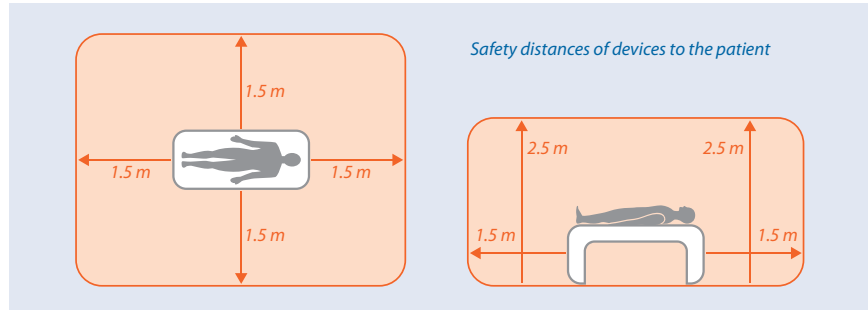
custo screen 300 is not suitable for use in rooms and/or areas with a risk of explosion.

Strong electromagnetic sources in the immediate vicinity of the custo screen 300 may result in recording errors (e.g. HF electrosurgical devices, mobile phones, induction furnaces).

Other electrical devices such as mobile phones or radio transceivers may impair the quality of the recording.

The device must be protected against the penetration of moisture, dust or dirt and also against mechanical influences such as damage due to dropping or damage while in transit.

Patient safety



Without medical safety devices, e.g. medical protector, the PC and all the non-medical devices connected to the system (e.g. 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 can occur.

Non-medical devices and the patient may not be touched simultaneously during the examination.

During routine maintenance work to 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 when handling custo screen 300



Continuous cuff pressure, e.g. exerted by a kinked cuff tube, can cause patient injuries. If the cuff pressure is continuous, the patient should open the cuff's hook and loop fastener or switch off the recorder.

Make sure that the cuff tube does not become crushed or that the cross-section of the cuff tube is not reduced.

The cuff must not be applied to wounds, open or newly operated areas.

When conducting blood pressure measurements, the function of additional medical devices, which are used in the vicinity of the blood pressure cuff on the patient, may be effected.

Make sure that the patient does not suffer any long-term adverse effects as a result of the short-term interruption of the blood circulation as required by the measurement method. Ensure that the intervals between such measurements are sufficient.



The following factors can have an effect on the results of a blood pressure measurement: the patient's posture (whether the patient is lying down, standing or sitting), movement, the patient's physical condition, heart rate-related or ventricular events, as well as extreme temperatures and air humidity.

Observe the operating conditions and the patient instructions.

The device is not protected against the potential effects of high frequency (HF) surgical equipment.

Never use damaged batteries or accumulators. If custo screen 300 is not to be used for a prolonged period of time, remove the batteries.

If liquid has been spilled on the device, remove the batteries or the accumulators immediately and send the device for inspection to your authorised custo med dealer or custo med.

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 (Electronic Patient Record) 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.

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.



All 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 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 will only assume responsibility for the safety and reliability of the custo screen 300 when all changes, enhancements, repairs and other work to 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.

After the expiration of the warranty period only use original spare parts and accessories from custo med. This is the only way to ensure the safe and trouble-free operation of your device.

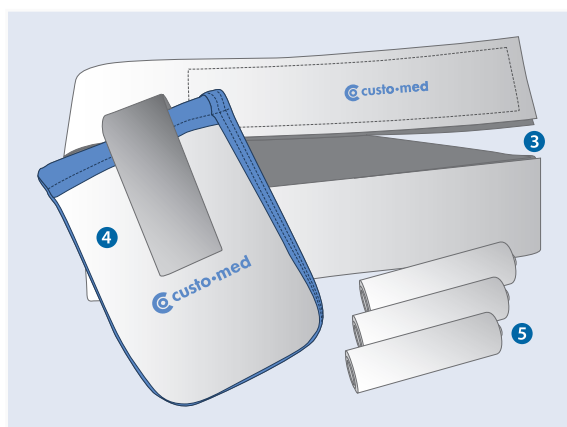
03

Device description, basics of putting into operation

03.1 Scope of delivery and accessories



- ① custo screen 300
ABPM recorder
- ② Blood pressure cuff (standard)



- ③ Carrying belt
- ④ Carrying case
- ⑤ Batteries (set of 3)
Mignon 1.5 Volt, type AA

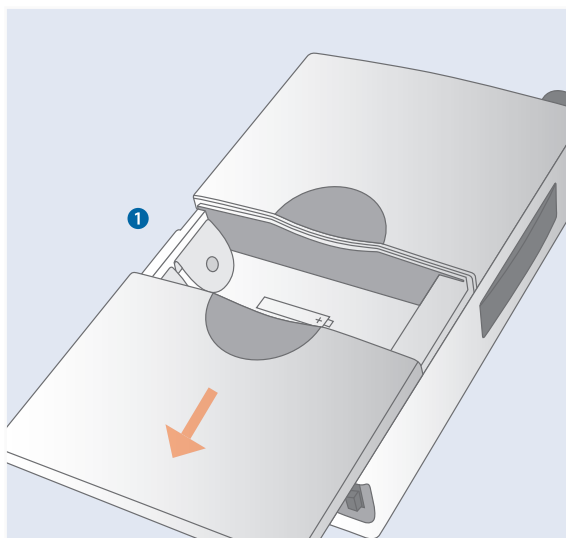


Starter kit

- ⑥ custo com IR
including USB connection cable (type B mini)

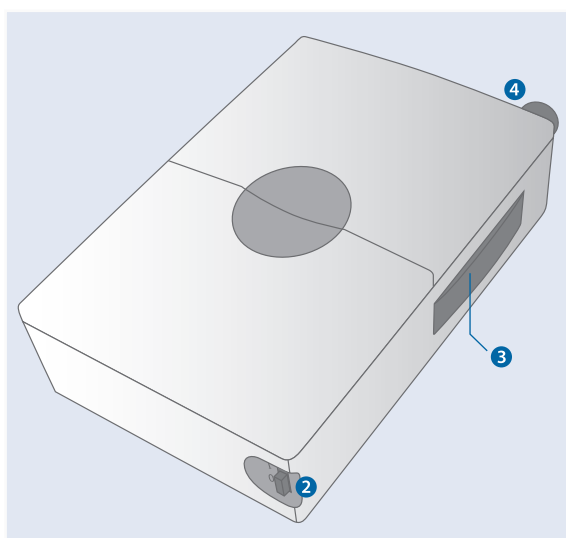
Infrared interface for connecting
custo screen 300 and PC
(only included in the scope of delivery
when purchasing a system)

03.2 Device operation



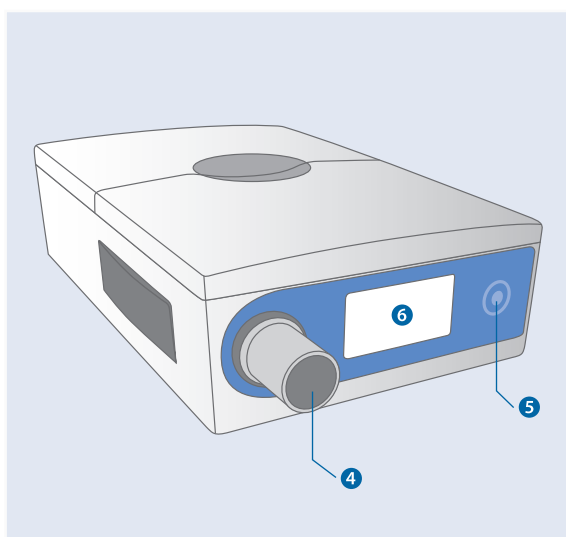
Insert the batteries or the accumulators

Open the battery compartment as depicted on the left ① and insert three standard batteries. The direction of insertion is shown on the illustrations in the battery compartment.



Functional elements of the device

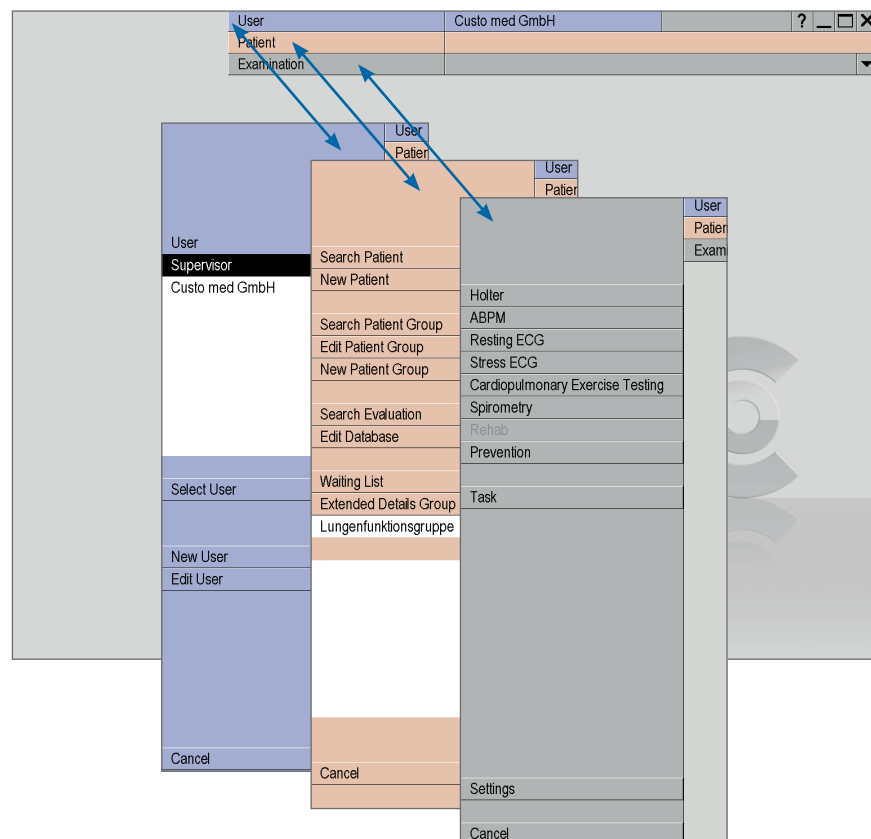
- ② On/off switch
for switching the recorder on and off
- ③ Infrared interface
for transferring data between
custo screen 300 and PC
- ④ Blood pressure cuff port



- ⑤ Function key
for starting and stopping measurements
- ⑥ Display
for displaying results and error messages
(For a list of errors see chapter
07 Product information)
- ④ Blood pressure cuff port

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). The main menus of each area can be reached by clicking on **User**, **Patient** or **Examination**.



In the **User** main menu the users of the system 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 management.

Its most important functions include **Search for Patient**, **New Patient** and **Search Evaluation**.

The **Examination** main menu lists all of the examination types which are possible with custo diagnostic. The modules which 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

Precondition: custo diagnostic must be installed on your PC.

The infrared interface custo com IR must only be connected to the PC after custo diagnostic has been installed. The device drivers for custo com IR are integrated in the custo diagnostic standard setup.

Connecting and configuring the infrared interface custo com IR

Connect custo com IR to the PC. The device drivers are installed automatically.

Find out which COM port is assigned to custo com IR in the device manager and then enter it in custo diagnostic.

To do so, on your Windows interface right-click on **My Computer**, then in the context menu click on **Manage**, and select **Device Manager** (left side of the window). In the right side of the window open **Ports (COM and LTP)** and make a note of the port assigned to custo com IR, e.g. (COM2).

In custo diagnostic, click on **Examination**, **Settings**, **Connection**, **Device**. Select **custo com USB** as the device and the corresponding **COM port** as the port from the Device Manager. Click on **Save** to save your input.

custo screen 300 used in combination with existing software and hardware

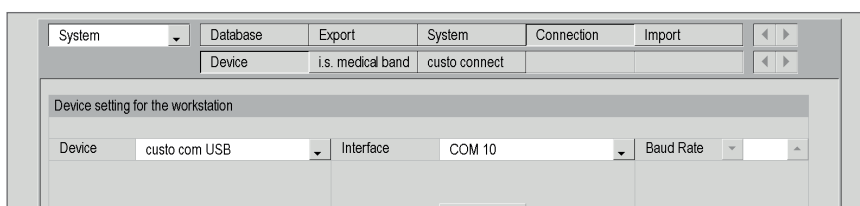
New recorder with legacy software (Version 3.8.4 and older)

If you do not want to carry out a custo diagnostic setup, manual driver installation must be carried out for the infrared interface custo com IR. Contact your authorised custo med dealer.

Use of other infrared interfaces

custo screen 300 can also be connected to your PC via older infrared interfaces such as custo com USB or JetEye.

The method of connecting and configuring custo com USB is exactly the same as for custo com IR.

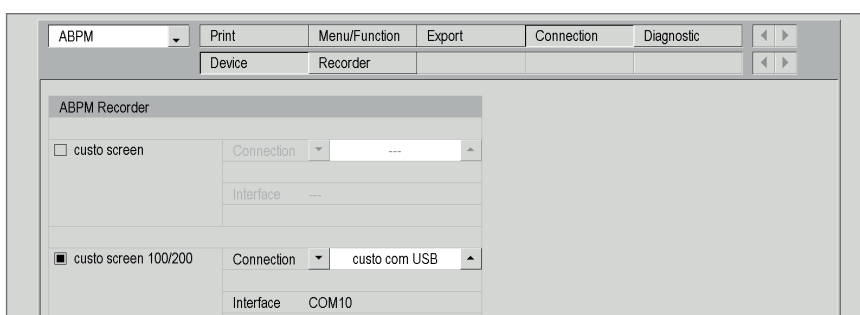


Checking the connection of custo screen 300

Click on **Examination**, **ABPM**, **Settings**, **Connection**, **Device**.

custo screen 100/200 is enabled and **custo com USB** is entered as the port.

Your device is ready for operation.



04.1 Cleaning and disinfection

Important notes



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

Follow the manufacturer's instructions (e.g. regarding dosage and contact times).

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

custo screen 300

The exterior of custo screen 300 should always be aesthetic and clean. If there is any dirt, gently wipe down the surfaces with a damp cleaning cloth and an acid-free cleaning agent.

Light spray application of suitable disinfectants is allowed.

Carrying case and belt

Both case and belt can be machine washed with a mild detergent at 40°C, but must not be dried in a dryer.

Light spray application of suitable disinfectants is allowed.

Blood pressure cuff

After each use, the blood pressure cuff should be cleaned to remove dirt and sweat. Observe the instructions on the instruction leaflet provided with the blood pressure cuff.

► **Cleaning and disinfection:** Sponge cuff with a damp cloth. If necessary, remove bladder and wash cover with soap or detergent disinfectant.

The cuffs have been tested to withstand the following recommended disinfectants: Cidex, Sporidicin, Microzid, Isopropyl-alcohol 70%, Ethanol 70%, Buraton liquid. After disinfection the cuff cover should be rinsed and allowed to air dry.

► **Sterilisation:** The cuff has been tested to withstand Ethylene Oxide (EtO) gas sterilization. Be sure that all safety precautions regarding aeration after EtO exposure are followed. Never autoclave.

04.2 Recommended cleaning agents and disinfectants

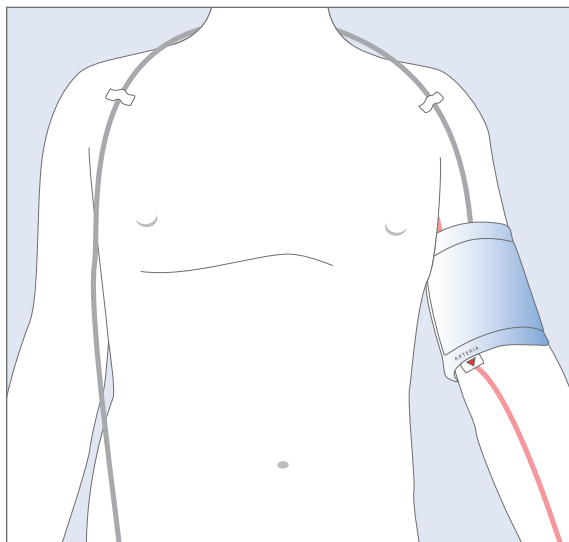
Disinfectants (custo screen 300, carrying case, belt):

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

05

Carrying out an examination

05.1 Preparing the patient for the examination



Applying the blood pressure cuff

In order to attach the cuff and the 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. Use a sufficiently sized piece so that you can put the bandage bottom-up over the cuff later. This increases the level of hygiene and the wearing comfort.

Make sure to select the correct cuff size for the patient. Each cuff contains information for which arm circumference it is suited, e.g. standard 24 – 32 cm.

Attach the cuff to the left upper arm, two to three centimetres above the crook of the arm. Apply the cuff in such a way that the marking is situated on the brachial artery. The cuff must not be attached too firmly. It should still be possible to fit approximately two fingers between the arm and the 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 to the patient's body. This serves to avoid faulty measurements due to the incorrect positioning of the cuff or the tube.

Use professional fixing aids with a low level of adhesive residues.



Attaching the carrying belt

Attach the carrying case to the carrying belt. Put the carrying belt on the patient. The case should be positioned on the patient's right hip.

Patient instructions

In order to receive optimum results, inform your patient of 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 worn during the night.

On the day of recording no X-ray recordings are allowed to be made. Sources of interference, such as stimulation current devices, are to 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, humidity, dirt and mechanical impacts (e.g. no shower, no use of swimming pool or sauna).



Avoiding faulty measurements

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



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

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 must 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 Carrying out an examination

05.2 Preparing the recorder for the recording

	User	Custo med GmbH
	Patient	
	Examination	1
Holter		
ABPM		2
Resting ECG		
Stress ECG		
Cardiopulmonary Exercise Testing		

	Examination	ABPM
New ABPM		3
Download Data		

	User	Custo med GmbH
	Patient	
	Examination	ABPM
Last name	Mus	4
First name		
Patient ID		
Patient Group	All patients	
Assignment	Name	All physicians
	Physician ID	
Last name	First name	Date of birth
Musterfrau	Martina	01.01.1978
Mustermann	Absoluta	10.10.1960
Mustermann	Franz	23.08.1959
Mustermann	Franz	10.10.1960
Mustermann	Multiday	10.10.1960
Mustermann	Schrittmacher	10.10.1960
Select Patient		6
Edit Patient		
New Patient		7
Cancel		

	User	Custo med GmbH
	Patient	
	Examination	ABPM
Last name *		
First name *		
Name suffix		
Title		
Date of birth (dd/mm/yyyy) *		
Sex		
Patient ID		
Height	cm	
Weight	kg	
Ethnic origin	none	
Address	Street/No.	
	Post code/Town	
Comment		
Insurance Number		
Assignment	Name	No physician assigned
	Physician ID	
Department		
Patient status		
Assign physician		
Save		8
Cancel		

The steps necessary to record and evaluate a ABPM recording in custo diagnostic are shown without EPR 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 on with your user name and password if required. Click on Examination 1, ABPM 2, New ABPM 3.

Select Patient

Select a patient for the recording. Enter the patient's name, or the first letters of the name, into the input fields of the search screen 4. Select the patient from the list below the input fields 5 and confirm your selection by clicking on the Select Patient 6 button. You can also select the patient by double-clicking on the corresponding name.

If the patient does not yet exist in your database, click on the New Patient 7 button. Enter the patient's data and click on Save 8.

Setting the recording parameters

The settings for the recording are displayed. The **Edit 9** button can be used to change the preset parameters.

Changing the standard profile

You can change the periods for the day and night phases **10**, define an additional phase **11** and trigger repeat measurements when predetermined **12** limits have been reached.

The options **13** have to be set if required:

Beep: A signal is emitted before each measurement so that the patient can prepare himself/herself accordingly. **Display results:** The measurement results are displayed after each measurement. **Print diary:** After you click on **Start** a form for the patient is printed which can be used to document events during measurements.

You can save the modified profile under a new name with **Save as 14** and thus make it available for further recordings. Click on **Save 15** to overwrite the selected profile.

Note:

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

Data transfer, starting the recorder

Place the switched-on recorder in front of the infra-red interface (at a distance of approx. 10 – 20 cm). Then click on **Start 16** to transfer the data. The data transmission dialogue appears.

If more than 30 seconds elapse between switching on the recorder and clicking on **Start 16**, it will no longer be possible to transfer the data as the recorder switches to idle mode after 30 seconds. To reactivate the recorder, press the **PC** function key. If "PC" appears in the display, the recorder is in data transfer mode.

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

User		Custo med GmbH
Patient		Mustermann Franz
Examination		ABPM
ABPM Recorder	custo screen 100 / 200	
ABPM Profile	Standard	
Measurement intervals	06:00- 22:00 every 15 min 22:00- 06:00 every 30 min	
Repeat measurement	no	
Options	Beep on Display results on Print diary off	
<div> <div>16</div> <div>9</div> <div>End</div> </div>		

Custo med GmbH		Mustermann Franz		23.08.1959 (50 Y.)	
ABPM					
100 / 200	10	Day phase	from	06 : 00	o'clock
			to	22 : 00	o'clock
			every	15	min
	10	Night phase	from	22 : 00	o'clock
			to	06 : 00	o'clock
			every	30	min
	11	Additional phase	<input type="radio"/> on <input checked="" type="radio"/> off		
			from	:	o'clock
			to	:	o'clock
			every	:	min
	12	Repeat measurement	<input type="radio"/> on <input checked="" type="radio"/> off		
			max. systole	---	mmHg
			min. systole	---	mmHg
			max. diastole	---	mmHg
			max. pulse	---	1/min
	13	Options	Beep <input checked="" type="checkbox"/> Display results <input checked="" type="checkbox"/> Print diary <input type="checkbox"/>		
			<div> <div>15</div> <div>14</div> <div>End</div> </div>		

3-61

Data Transmission

Switch on the ABPM recorder NOW!
The data will be transferred to the ABPM recorder.

15 %

Cancel

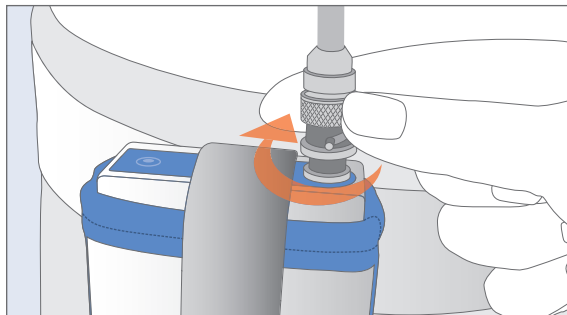
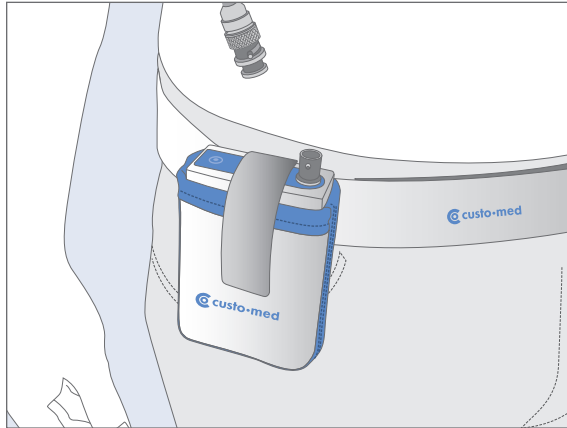
05 Carrying out an examination

05.3 Attach the recorder to the patient

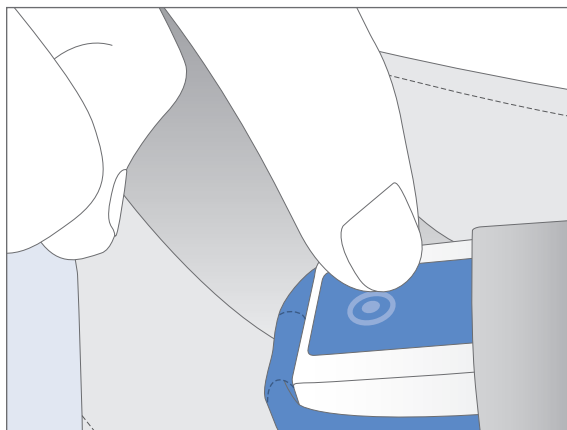
The final steps

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

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



Connect the cuff tube to the recorder as illustrated.



05.4 Start the recording

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

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

05.5 Download the recording

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


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

Start the program and download the recording

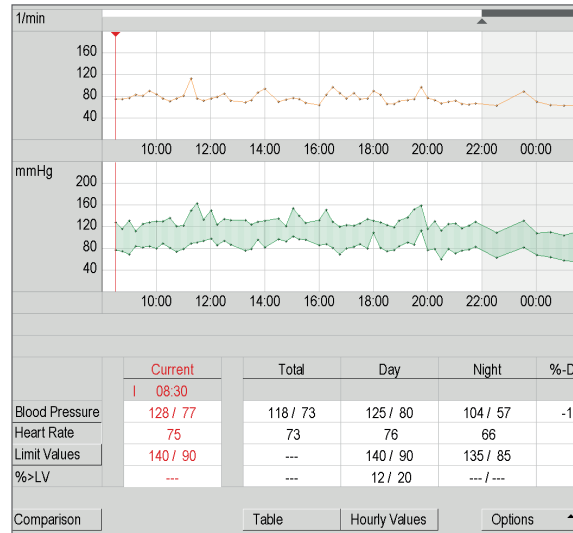
Start custo diagnostic and log in with your user name and password if required. Click on **Examination 1**, **ABPM 2**.

	User	Custo med GmbH
	Patient	
	Examination 1	
Holter		
ABPM 2		
Resting ECG		
Stress ECG		
Cardiopulmonary Exercise Testing		
	Examination	ABPM
New ABPM		
Download Data 3		

Place the switched-on recorder in front of the infrared interface (at a distance of approx. 10 – 20 cm). Then click on **Download Data** ③ to transfer the data. The data transmission dialogue appears.

If more than 30 seconds elapse between switching on the recorder and clicking on **Download Data** ③ it will no longer be possible to transfer the data as the recorder switches to idle mode after 30 seconds. To reactivate the recorder, press the  function key. If "PC" appears in the display, the recorder is in data transfer mode.

After the download the evaluation is displayed automatically.



User	Custo med GmbH
Patient	Mustermann Franz
Examination	ABPM 18.08.2006 (C)

	sys/dia mmHg	MAP mmHg	PP mmHg	HR BPM	Comments
11:15	---	---	---	---	EC 25
12:00	---	---	---	---	EC 06 ①
13:00	151 / 131	137	20	113	---
13:15	---	---	---	---	EC 06

05.6 Check the evaluation

Check if and how many faulty measurements have occurred. In the **Options** menu click on **Faulty Measurements...**. You can see from the error codes ① which kind of disorder has occurred. In the **Options** menu, under **Recorder Info** you can check the accumulator voltage ② during the recording process. By clicking on the **Chart** button you can get back to the evaluation.

on on		2 RAM voltages /mV					Switch on Times:
		No.	Total	RAM 1	RAM 2	RAM 3	
3		1.	4736	1202	1450	1412	15:46
		21.	4562	1297	1350	1385	15:47
		41.	4453	1238	1351	1342	18:56
		61.	4384	1239	1279	1345	08:43
		81.	4365	1068	1315	1319	
		101.	--	--	--	--	
		121.	--	--	--	--	

Printing the evaluation

By clicking on the **Print** button you can print the evaluation according to the system settings.

Via **Options, Print...** you can access the printing menu ③. There, you can compile the contents for a printout individually. The printout is started with **Print**.

ABPM [v] [Print] [Print]

③ Printout

☒ Summary ☐ Chart Day 2 and 3

☐ Measured Values ☒ Valid Measurements ☐ Erroneous measurements

☐ Recorder Information

Measured value - present

Summary ☒ Single Values ☒ Limit Values

Measured Values ☐ Hourly Values ☒ Single Values ☐ Hourly Values

Printer: [Printer] [Slot] [Fax printer] [PDF printer]

Ending the evaluation

Click on **End** in order to close the evaluation. The end dialogue ④ appears. Click on **Confirm** ⑤ to close the evaluation.

10:00 12 End 103-1 04:00

④ Evaluation status

☐ confirmed ☐ printed ☐ locked

Confirm ⑤ Cancel

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 (ABPM in this case).

Opening an evaluation via the evaluation search

Click with the **right mouse button** on the **Patient 1** button. This opens the evaluation search.

In the Examinations area, enter what type of evaluation you are searching for, e.g. **ABPM 2**. In the Properties area **3** you can define more search criteria.

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

To start the search, click on **Search Evaluation 4** or activate **Search automatically 5**. 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 desired evaluation, select it from the list and click on the **Show Evaluation 6** button or double-click on the evaluation.



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 preference "confirmed: No" when the evaluation status "Confirmed" is NOT selected in the End dialogue.

If you want to use the same search criteria for the next search, activate the **Save selection 7** option.

The screenshot shows the 'Evaluation Search' window. At the top, the 'Patient' button is labeled with a circled 1. In the 'Examinations' section, 'ABPM' is selected with a circled 2. In the 'Properties' section, the 'confirmed (B)' property is set to 'No' with a circled 3. At the bottom left, the 'Search Evaluation' button is labeled with a circled 4, and the 'Save selection' checkbox is labeled with a circled 7. Next to it, the 'Search automatically' checkbox is labeled with a circled 5. On the right side, a table lists search results with columns for Exam, Date, and Patient. At the bottom right, the 'Show Evaluation' button is labeled with a circled 6.

Exam.	Date	Patient	Settings
ABPM	05.03.1999	Mustermann, Franz	R-X-----
Holter /co	14.11.2003	Mustermann, Franz	-----
ABPM	23.05.2006	Mustermann, Franz	-----
ABPM	18.08.2006	Mustermann, Franz	-----
ABPM	02.04.2009	Musterfrau, Martina	-----
ABPM	17.09.2009	Musterfrau, Martina	-----
Holter /co	26.02.2010	Musterfrau, Martina	R-----

Opening an evaluation via the examination main menu

Open the ABPM main menu via **Examination**, **ABPM**, and click there on **Show Evaluation** ①.

The left screenshot shows the 'Examination' menu with the following options: New ABPM, Download Data, Show Evaluation ①, Show Comparison, Show Trend, Settings, and Cancel. The right screenshot shows the patient selection screen with the following fields: Last name (Mus ②), First name, Patient ID, Patient Group (All patients), Assignment (All physicians), and Physician ID. Below these fields is a table of patients:

Last name	First name	Date of birth
Musterfrau	Martina	01.01.1978
Mustermann	Absoluta	10.10.1960
Mustermann ③	Franz	23.08.1959
Mustermann	Franz	10.10.1960
Mustermann	Multiday	10.10.1960
Mustermann	Schrittmacher	10.10.1960

Below the table are buttons: Select Patient ④, Edit Patient, New Patient, and Cancel.

The patient search screen appears. In this screen select the patient whose recording you want to open. Enter the patient's name, or the first letters of the name, into the input fields of the search screen ②. Select the patient from the list below the input fields ③ and confirm your selection by clicking on the **Select Patient** ④ button. You can also select the patient by double-clicking on the corresponding name.

A list containing all the patient's evaluations is then displayed. Select the desired evaluation from the list ⑤ and open it by means of a double-click or via the **Show Evaluation** ⑥ button.

The screenshot shows a table with the following data:

Evaluation	Date	Time	Archived
ABPM ⑤	18.08.2006	08:30	no
ABPM	23.05.2006	09:30	no
Holter /combi	14.11.2003	17:23	no

Below the table are buttons: Report List, Show Evaluation ⑥, and Cancel.

06.2 The workspace at a glance



Display and control elements

- a** Heart rate curve
- b** Blood pressure curve
- c** Overview table with mean values
- d** Number of measurements
- e** Cursor for modifying the night phase;
in the event of changes, the average values are adapted in the overview table
- f** Event cursor for piloting specific points;
the corresponding values are displayed 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 additional view modes
- j** Button for printing the evaluation
- k** Button for closing the evaluation

The options menu

- a** Display of faulty messages with error codes

*Note: It can be helpful to display the error codes when the measurement curves (**a** and **b**) show blank spaces. Error codes refer to [chapter 07 Product information](#)*

- b** Display of recorder information, e.g. 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** Export of the evaluation, e.g. in Excel, PDF or e-mail format
- f** Dialogue for changing the limit values

06.3 Navigation and structure in the evaluation

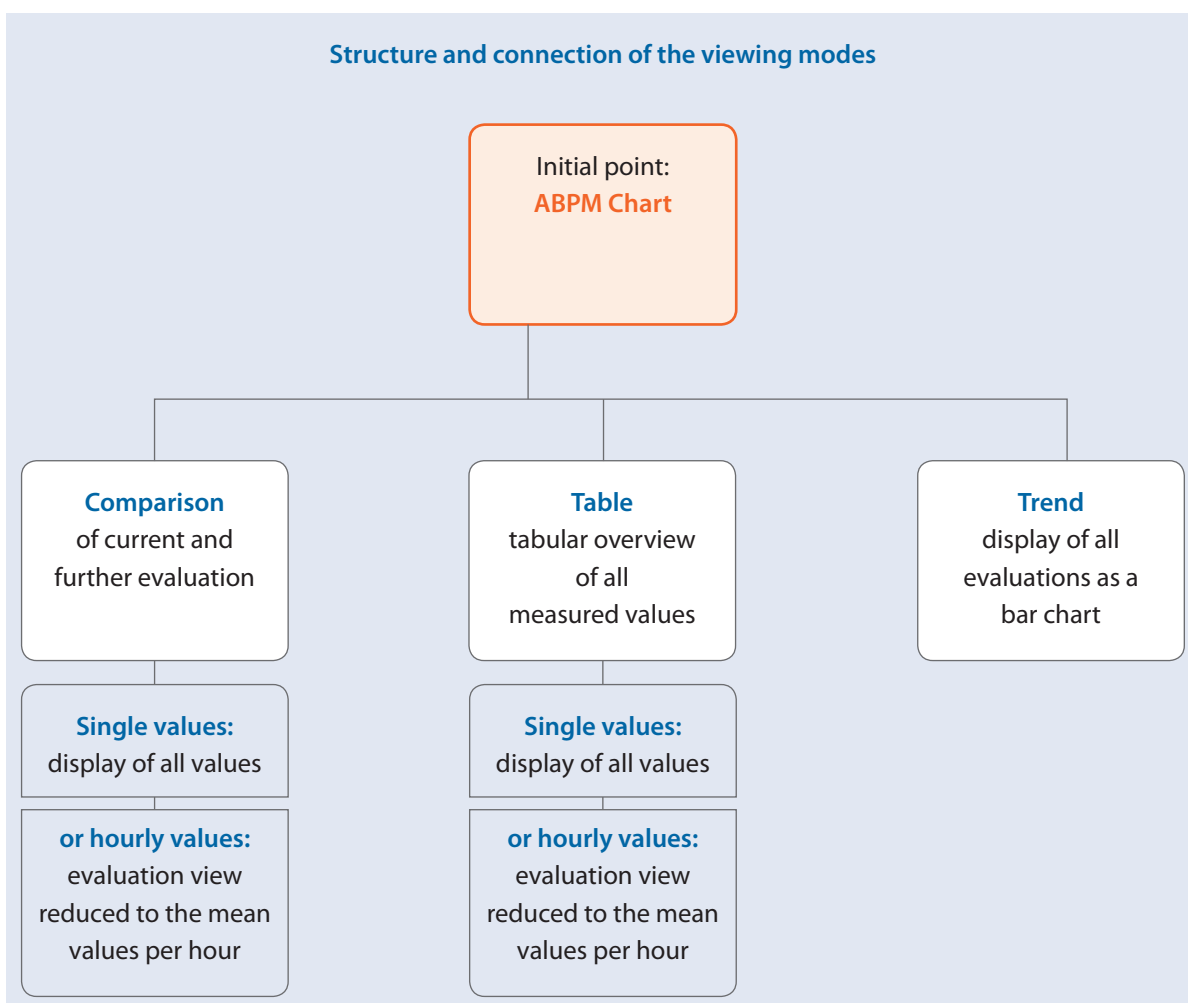
Navigation in the evaluation

When you change from your initial screen to another view mode, you can return to the original view mode by clicking on the same button.

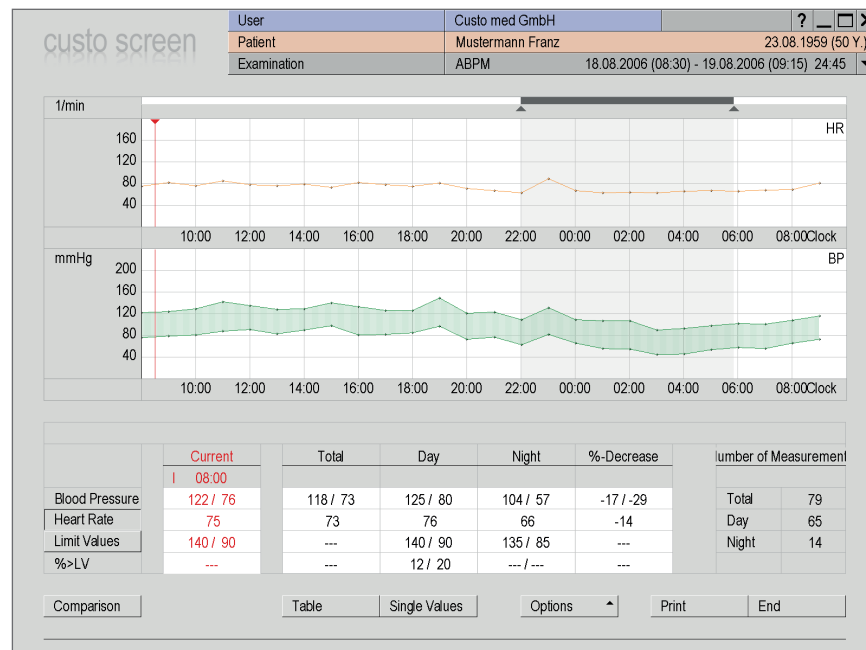
Example: You click on **Table** in the evaluation. You access the tabular overview of all measured values and the **Table** button changes to **Chart**. By clicking on the **Chart** you can get back to the original screen.

	Current	Total	Day
Blood Pressure	I 08:30 128 / 77	118 / 73	125 / 8
Heart Rate	75	73	76
Limit Values	140 / 90	---	140 / 9
%>LV	---	---	12 / 2
Comparison	Table	Hourly Val	

		Average	SD	Average	SD	min.	m
SYS	mmHg	136	20	148	14	117	1
DIA	mmHg	85	18	97	11	70	1
MAP	mmHg	102	18	114	11	85	1
PP	mmHg	50	10	51	11	21	1
HR	P/min	70	10	74	10	61	1
Comparison	Chart	Hourly Val					



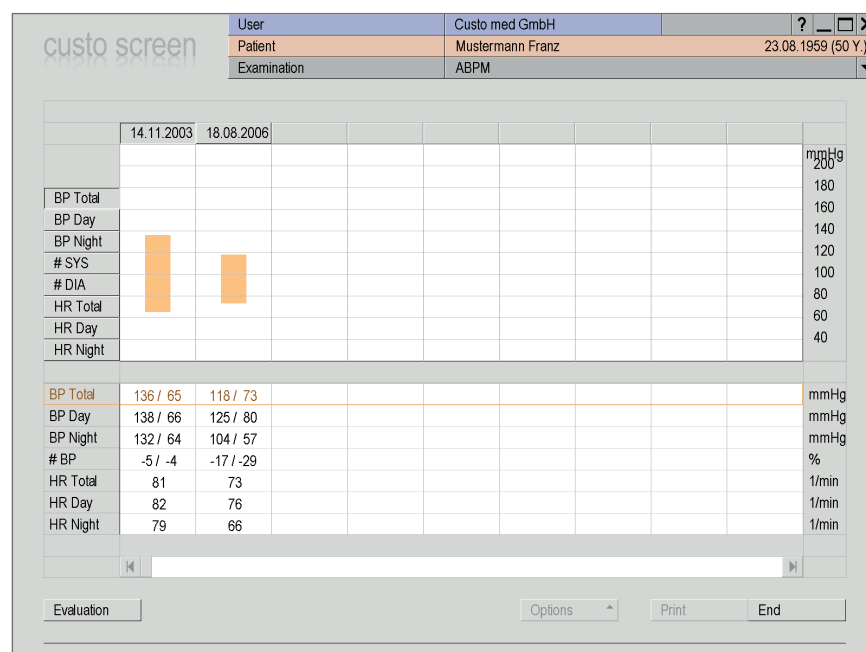
06.4 Viewing modes in the evaluation



06.4.1 Chart, hourly values (Hourly Values)

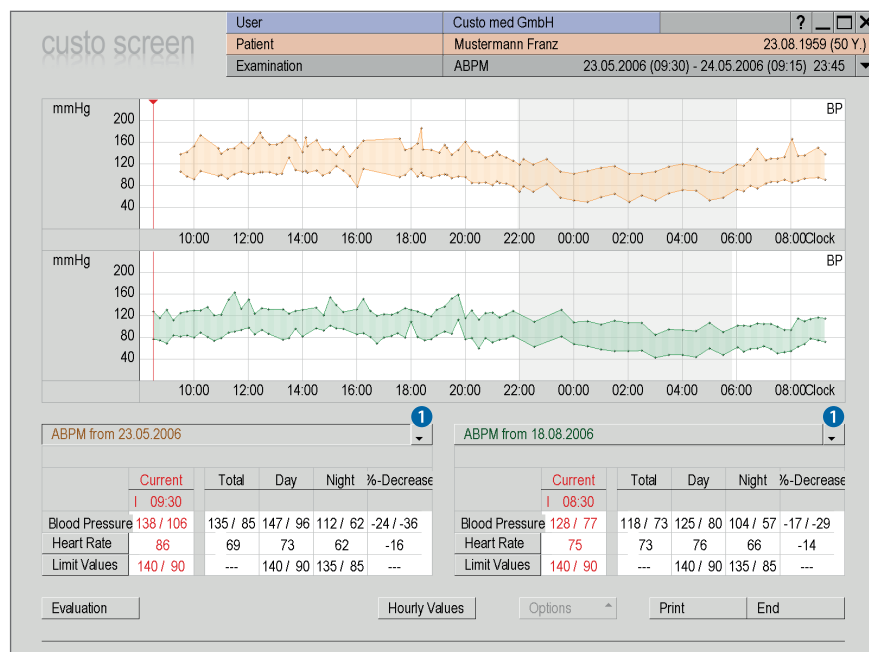
Simplified HR and blood pressure curve with hourly mean values

Benefit: improved overview thanks to a more smooth measurement curve without measurement deviations



06.4.2 Trend (Options > Trend)

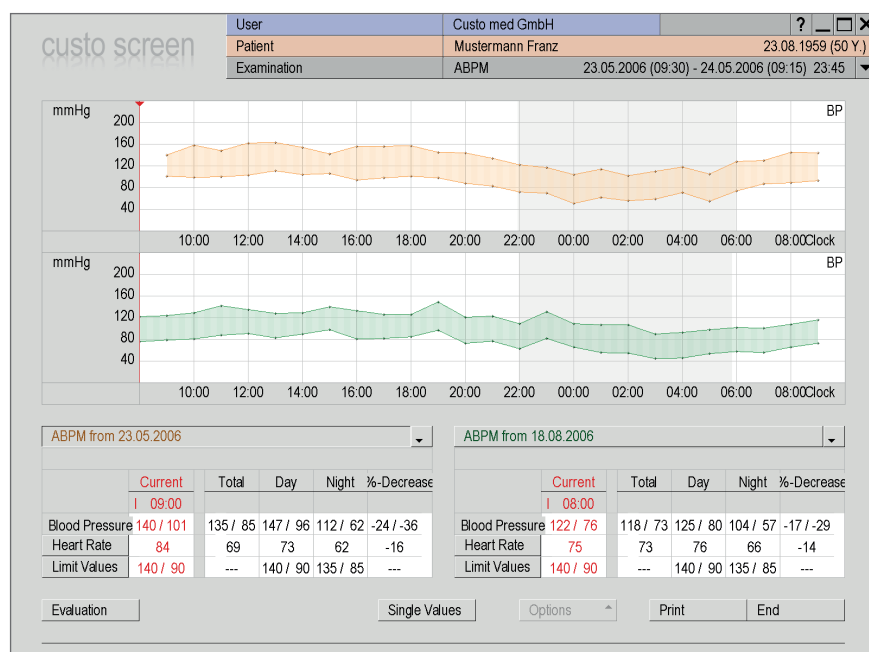
Display of all existing ABPM evaluations of a patient in bar chart format with mean values



06.4.3 Comparison (Evaluation > Comparison)

Comparison of the current evaluation with an additional one.

Use the arrow buttons ① to select other evaluations of the patient for a comparison.



06.4.4 Comparison with hourly values (Evaluation > Comparison > Hourly Values)

Simplified comparison view with the hourly mean values in ABPM curves

06 Working with the evaluation



Tips for working
in the tabular view

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

> In order to delete measurements
choose the measurement to be de-
leted in the top table with a mouse
click. Open the context menu
with a right click and select **Delete
Measurement** there.

User		Custo med GmbH		?		X	
Patient		Mustermann Franz		23.08.1959 (50 Y.)			
Examination		ABPM		23.05.2006 (09:30) - 24.05.2006 (09:15)		23:45	

	sys/dia mmHg	MAP mmHg	PP mmHg	HR BPM	Comments
1 09:30	138 / 106	116	32	86	
2 09:45	142 / 97	112	45	82	
3 10:00	153 / 92	112	61	71	
4 10:15	173 / 107	129	66	73	
10 10:54	149 / 98	115	51	66	R
11 11:00	139 / 100	113	39	65	
12 11:15	147 / 93	111	54	66	

	Total	Day Phase	Night Phase
Period	09:30 - 09:15	05:58 - 21:56	21:56 - 05:58
Blood Pressure	136 / 85	148 / 97	112 / 62
Heart Rate	70	74	62
Measurements	101	83	18
Valid Measurements	80 (79%)	63 (75%)	17 (94%)

	Average	SD	Average	SD	min.	max.	%>LV	Average	SD	min.	max.	%>LV	%-Dec.
SYS mmHg	136	20	148	14	117	186	68	112	9	102	129	---	-25
DIA mmHg	85	18	97	11	70	132	71	62	10	50	83	---	-37
MAP mmHg	102	18	114	11	85	145	---	79	9	67	98	---	-31
PP mmHg	50	10	51	11	21	82	---	49	4	40	57	---	-4
HR P/min	70	10	74	10	61	103	---	62	4	56	72	---	-17

Comparison Chart Hourly Values Options Print End

06.4.5 Table (Evaluation > Table)

Listing of all individual measurements 2 and overview table with mean, minimum and maximum values for the complete recording. The "Valid measurements" line shows the portion of successfully performed measurements 3.

User		Custo med GmbH		?		X	
Patient		Mustermann Franz		23.08.1959 (50 Y.)			
Examination		ABPM		23.05.2006 (09:30) - 24.05.2006 (09:15)		23:45	

	sys/dia mmHg	MAP mmHg	PP mmHg	HR BPM	Comments
09:00	140 / 101	114	38	84	
10:00	158 / 99	118	59	70	
11:00	148 / 100	116	48	66	
12:00	162 / 103	123	58	68	
13:00	163 / 111	128	52	84	
14:00	154 / 104	121	50	80	
15:00	142 / 106	118	36	78	

	Total	Day Phase	Night Phase
Period	09:30 - 09:15	05:58 - 21:56	21:56 - 05:58
Blood Pressure	136 / 85	148 / 97	112 / 62
Heart Rate	70	74	62
Measurements	101	83	18
Valid Measurements	80 (79%)	63 (75%)	17 (94%)

	Average	SD	Average	SD	min.	max.	%>LV	Average	SD	min.	max.	%>LV	%-Dec.
SYS mmHg	136	20	148	14	117	186	68	112	9	102	129	---	-25
DIA mmHg	85	18	97	11	70	132	71	62	10	50	83	---	-37
MAP mmHg	102	18	114	11	85	145	---	79	9	67	98	---	-31
PP mmHg	50	10	51	11	21	82	---	49	4	40	57	---	-4
HR P/min	70	10	74	10	61	103	---	62	4	56	72	---	-17

Comparison Chart Single Values Options Print End

06.4.6 Table with hourly values (Evaluation > Hourly Values > Table)

Simplified measurement table with the hourly mean values 4.

sys/dia mmHg	MAP mmHg	PP mmHg	HR BPM	Comments
140 / 101	114	38	84	
158 / 99	118	59	70	
148 / 100	116	48	66	
162 / 103				
163 / 111				
154 / 104				
142 / 106				
Total				
09:30 - 09:15				
136 / 85				
70				
101				
Measurements 80 (79%)				
Average	SD			
136	20			
85	18			
102	18			
50	10			

Assessment of day average value

Day average 148 / 97 mmHg (135/85)

Standard <135 / no

Slight hypertension 135-159 / 85-99 yes

Medium hypertension 160-179 / 100-109 no

Severe hypertension >180 / >110 no

Decrease day - night average value

Variance systole day - night Lowering 25 % (normal) Day 148 mmHg Night 112 mmHg

Variance diastole day - night Lowering 37 % (normal) 97 mmHg 62 mmHg

[Report Normal] Adjusted Value 10 %

Allocation of single measurements compared to the limit values:

Systole Day 82 % > 135 mmHg (Pathologically) Diastole Day 85 % > 85 mmHg (Pathologically)

Night 17 % > 120 mmHg (normal) Night 11 % > 75 mmHg (normal)

[Report Pathological] Adjusted Value 35 %

Apply Report End

Night Phase	min.	max.
1:56 - 05:58		
112 / 62		
62		
18		
17 (94%)		

06.4.7 Automatic report (Evaluation Interface > Context Menu > Autom. 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 report** to transfer the results into the unconfirmed report.

User		Custo med GmbH		?	
Patient		Mustermann Franz		23.08.1959 (50 Y.)	
Examination		ABPM		23.05.2006 (09:30) - 24.05.2006 (09:15) 23:45	

sys/dia mmHg	MAP mmHg	PP mmHg	HR BPM	Comments
09:00 140 / 101	114	38	84	
10:00 158 / 99	118	59	70	
11:00 148 / 100	116	48	66	
12:00 162 / 103	123	58	68	
13:00 163 / 111	128	52	84	
14:00 154 / 104				
15:00 142 / 106				

Unconfirmed report 23.05.2006 09:30

There is a slight hypertension with increased 24-hr blood pressure average value. The night-time blood pressure dipping is normal (Decrease > 10% of day to night average value). More than 35% of all systolic and diastolic single measurements by day are above the limit value.

F5 F9

F6 F10

F7 F11

F8 F12

Hide Modules Confirm Cancel

Period	Blood Pressure	Heart Rate	Measurements	Valid Measurements
09:30 - 09:15	136 / 85	70	101	80 (79%)

Average	SD	min.	max.	%>LV	%-Dec.
SYS mmHg 136	20	102	129	---	-25
DIA mmHg 85	18	50	83	---	-37
MAP mmHg 102	18	67	98	---	-31
PP mmHg 50	10	40	57	---	-4
HR P/min 70	10	74	103	---	-17

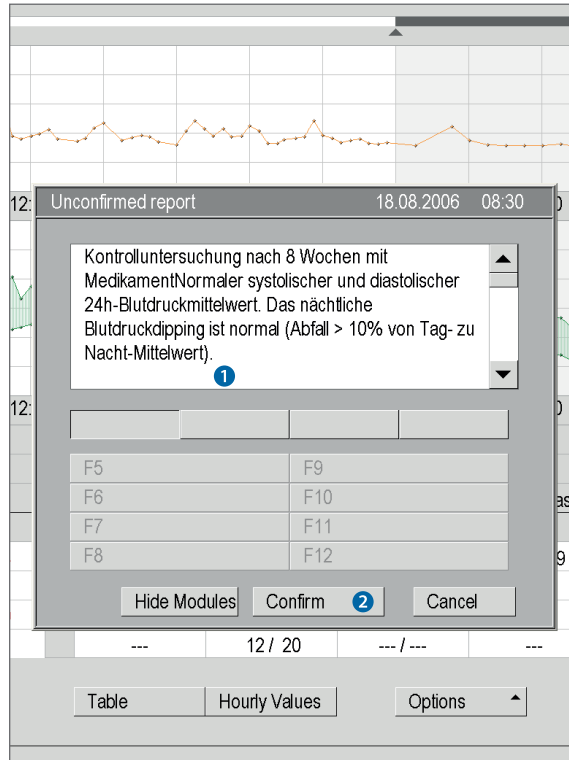
Comparison Chart Single Values Options Print End

06.4.8 Unconfirmed report (Evaluation Interface > Context Menu > Report)

Unconfirmed report with results from the automatic report.

Click on **Confirm** to convert the unconfirmed report to a report.

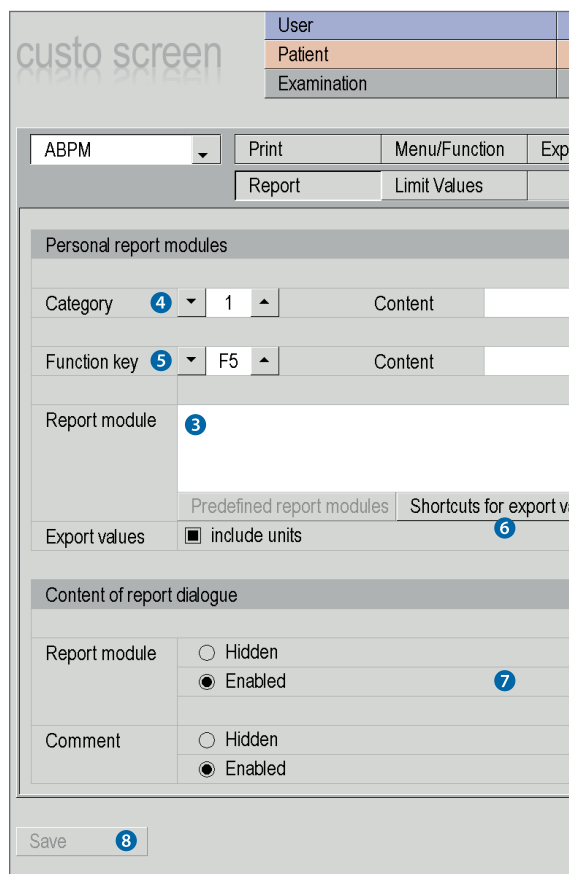
06.5 Confirm the evaluation



The unconfirmed report is 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 unconfirmed report becomes a report.

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



Text modules for writing reports

On the **Examination**, **ABPM**, **Settings**, **Diagnostic**, **Report** page you can create report modules for confirming an evaluation **3**. The text modules are called during the confirmation via keyboard commands (F5 to F12). It is possible to create up to four groups **4** with eight text modules for each group (F5 to F12) **5**.

A report module can be created from normal text as well as variables. When you use the report module in the unconfirmed report, the actual value from the evaluation is used instead of a variable and inserted in your report text. The structure of a variable is @VARIABLE (e.g. average systole day: @SYS_T_MT). The **List of export elements** **6** button provides you with a list containing all the available variables.

If the text modules should be shown in the unconfirmed report window, make sure that the **Show always** **7** option is activated. Alternatively, the text modules can be shown in the report dialog via the **Texts** button.

Click on **Save** **8** to apply your text modules and settings.

06.6 End the evaluation

The evaluation is closed with the **End** button. The end dialogue is opened. The status of an examination can be changed here ❶.

➤ Confirmed ❷

A confirmed evaluation can be reset to "Not confirmed" by deselecting the "Confirmed" option (e.g. if reporting has not yet been completed).

➤ 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 examination.

User	Custo med GmbH
Patient	Mustermann Franz
Examination	ABPM 18.08.2006

Total	Day	Night	%-Decrease
118 / 73	125 / 80	104 / 57	-17 / -29
73	76	66	-14
---	140 / 90	135 / 85	---
---	12 / 20	--- / ---	---

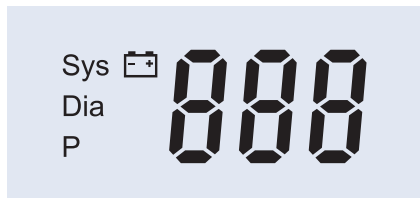
06.7 Archive evaluations (optional)

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

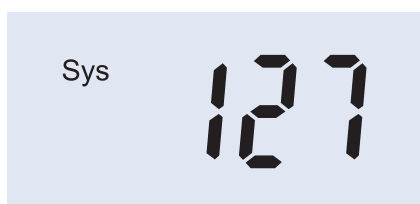
During archiving, the evaluations are moved to a directory on your hard disc, which you can then save on a data carrier (CD, DVD, etc.).

07.1 Measurement and status indication on the display



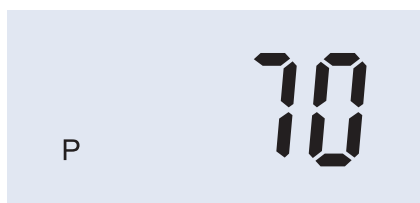
Elements in the display

Sys:	Systolic blood pressure
Dia:	Diastolic blood pressure
P:	Pulse
Battery:	Lights 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 the data transfer between the recorder and the PC...

"PC" is shown in the display
(the diode of the infrared interface custo com IR flashes)



In the event of faulty measurements...

an error code is shown in the display, e.g. "E06"

07.2 Error codes and their causes *)

E04	Blood pressure values exceed limit values Sys: < 70 mmHg > 270 mmHg Dia: < 40 mmHg > 155 mm Hg Sys - Dia: < 15 mmHg, HF: < 35/min > 220/min ➤ Measurement is repeated automatically
E05	Pressure discharge rate outside the given limits Cause: valve is leaky or defective ➤ Customer service required
E06	Disturbed measurement Cause: too many movement artefacts ➤ Attach the cuff carefully ➤ Keep the arm steady during measurement
E17	Pressure increase is too slow Cause: cuff is not tight (defective), valve is leaky ➤ Check the cuff (O ring in connector) ➤ Customer service required
E18	Pressure increase is too fast Cause: cuff tube is kinked, valve system is clogged ➤ Align the cuff tube ➤ Otherwise contact customer service
E19	Discharge period is too long Cause: cuff tube is kinked, valve is defective ➤ Customer service, if multiple occurrences during a recording
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 carefully ➤ Keep the arm still during measurement
E25 - E28	Error when determining systole Cause: systole lies above the pump up pressure, movement artefacts ➤ Attach the cuff carefully ➤ Keep the arm still during measurement

*) A repeat measurement is automatically performed two minutes after a failed measurement.
 Customer service is always required for all error codes which are not listed. Please contact your authorised custo med dealer.

07.3 Limit values for blood pressure measurement

The limit values are defined as follows in custo diagnostic:

► Adults

Day phase

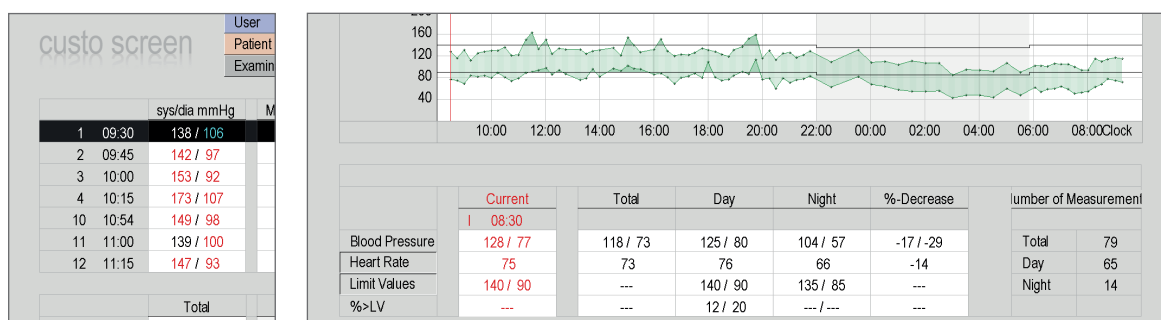
Systole 135 mmHg
Diastole 85 mmHg

Night phase

Systole 120 mmHg
Diastole 75 mmHg

Measurements for which these values are exceeded are displayed in red font in the evaluation. If required, the limit values for the current evaluation can be modified via the **Options** menu in the **Limit values** dialogue. To change the limit values permanently, enter the required values under **Examination**, **ABPM**, **Settings**, **Diagnostic**, **Limit Values**.

In the ABPM chart (initial screen), you can fade in auxiliary lines at the level of the fixed limit values by clicking on the **Limit Values** button (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 and adolescents up to 16 years

Boys	Day		Night		Girls	Day		Night	
Height	Sys	Dia	Sys	Dia	Height	Sys	Dia	Sys	Dia
120 cm	123	85	104	63	120 cm	120	84	107	66
130 cm	125	85	107	65	130 cm	124	84	109	66
140 cm	127	85	110	67	140 cm	127	84	111	66
150 cm	129	85	113	67	150 cm	129	84	112	66
160 cm	132	85	116	67	160 cm	131	84	113	66
170 cm	135	85	119	67	170 cm	131	84	113	66
180 cm	137	85	122	67	180 cm	131	84	114	66

07.4 Abbreviations in the evaluation

Ps	Systolic blood pressure
Pd	Diastolic blood pressure
Pav	Mean (average) arterial blood pressure $P_m = (P_s - P_d) : 3 + P_d$
PP	Pulse pressure $PD = P_s - P_d$
HR	Heart rate
A	Additional measurement measurement which has been triggered 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 of custo screen 300		
Measurement method	Oscillometric measurement procedure automatic zero balancing	
Measurement 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. 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	Small (Children)	20 – 24 cm
	Default (in the scope of delivery)	24 – 32 cm
	XL	32 – 40 cm
	XXL	38 – 50 cm
Data transfer	Infrared interface custo com IR, with USB port (IrDA standard)	
Voltage supply	3 Mignon 1.5 Volt, Type AA 3 accumulators, Ni-MH, 1,2 Volt, at least 1500 mAh	
Operating conditions	Temperature	+10°C ... +40°C
	Air humidity	30 ... 80% rH
	Air pressure	700 ... 1060 hPa
Transport and storage conditions	Temperature	-20°C ... +45°C
	Air humidity	30 ... 80% rH
	Air pressure	700 ... 1060 hPa
Dimensions	Size	approx. 100 * 66 * 26 mm (L * B * H)
	Weight	approx. 112 g (with batteries)
Classification	Device with internal power supply Class IIa Type BF DIN EN 60601-1, DIN EN 1060-1 to 1060-4, IEC 80601-2-30	

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 must meet the minimum requirements of the operating system used. custo diagnostic requires additional RAM (256 MB). Ensure that there is enough free hard disk space for the custo diagnostic evaluations.	
File size of the evaluations	Holter ECG ABPM Resting ECG Stress ECG CPET Spirometry Rehab	approx. 15 MB (max. 60 MB) approx. 128 KB (max. 512 KB) approx. 200 KB (approx. 10 sec ECG) approx. 6 MB (approx. 20 min. ECG) see Stress ECG approx. 50 KB (max. 256 KB) approx. 6 MB (approx. 45 min. training session)
Hardware & ports	DVD or CD-ROM drive USB ports	

07.6 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.

07.7 Manufacturer declaration regarding EMC (electromagnetic compatibility) according to DIN EN 60601-1-2:2007

► Manufacturer's Declaration – electromagnetic emissions

The custo screen 300 ABPM recorder is designed for operation in the electromagnetic environment stated below. The customer or user of the custo screen 300 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 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	Class B	custo screen 300 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 ABPM recorder is designed for operation in the electromagnetic environment stated below. The customer or user of the custo screen 300 should make sure 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 the custo screen 300 requires continued function, even if interruptions in the energy supply occur, it is recommended to supply the custo screen 300 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

► Manufacturer's Declaration – electromagnetic immunity

The custo screen 300 ABPM recorder is designed for operation in the electromagnetic environment stated below. The customer or user of the custo screen 300 should make sure 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	<p>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.</p> <p>Recommended protective distance:</p> <p>$d = (3.5/U_1) \sqrt{P}$</p> <p>$d = (3.5/E_1) \sqrt{P}$ 80 MHz to 800 MHz</p> <p>$d = (7/E_1) \sqrt{P}$ 800 MHz to 2.5 GHz</p> <p>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).</p> <p>According to an examination on-site <i>a)</i> the field strength of stationary radio transmitters should be inferior to the compliance level with regard to all frequencies.</p> <p>In the vicinity of devices carrying the following symbol, interferences are possible:</p> 
Radiated HF transients according to IEC 61000-4-3	3 V/m 80 MHz to 3.0 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

custo screen 300 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 maintaining 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.

Nominal power of the transmitter W	Protective distance depending on the transmitting frequency in m		
	150 kHz to 80 MHz $d = (3.5/U_1) \sqrt{P}$	80 MHz to 800 MHz $d = (3.5/E_1) \sqrt{P}$	800 MHz to 2.5 GHz $d = (7/E_1) \sqrt{P}$
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.

07.8 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

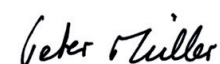
Certificate registration no.: EGII-130001-002-1

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



07.9 Shutdown, storage, transport

Shutdown and storage



Clean and disinfect the custo screen 300 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 the custo screen 300 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 custo screen 300 such that the device is protected against impact, moisture and dust.

The device must meet operation conditions when put back into operation, e.g. operating temperature (*see 07.5 Technical data...*).

Ambient conditions for storage and transport



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

07.10 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 waste electrical and electronic equipment). The device must not be disposed of as normal domestic waste.



The original packaging of custo screen 300 is recyclable (cardboard/waste paper).

07.11 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.

User	Custo med GmbH	1	?	_	□	×
Patient		2	2			
Examination		3	3			▼

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

User	Custo med GmbH	4	?	_	□	×
Patient	Mustermann Franz	5	4			23.08.1959 (50 Y.)
Examination	ABPM	6	5			▼

LEFT-CLICK

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

RIGHT-CLICK

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

Tip: keyboard navigation

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



Keyboard shortcuts

End, Cancel	Patient master data
Confirm, continue	Evaluation search
Program Information	Evaluations last opened
User main menu	Waiting room list
Patient main menu	Quick print
Examination main menu	Options menu
	Open unconfirmed report



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