VALUE-ADDED DIAGNOSTICS

Product Catalogue

New technologies in cardiopulmonary diagnostics

custo·med
EXCELLENCE IN DIAGNOSTICS

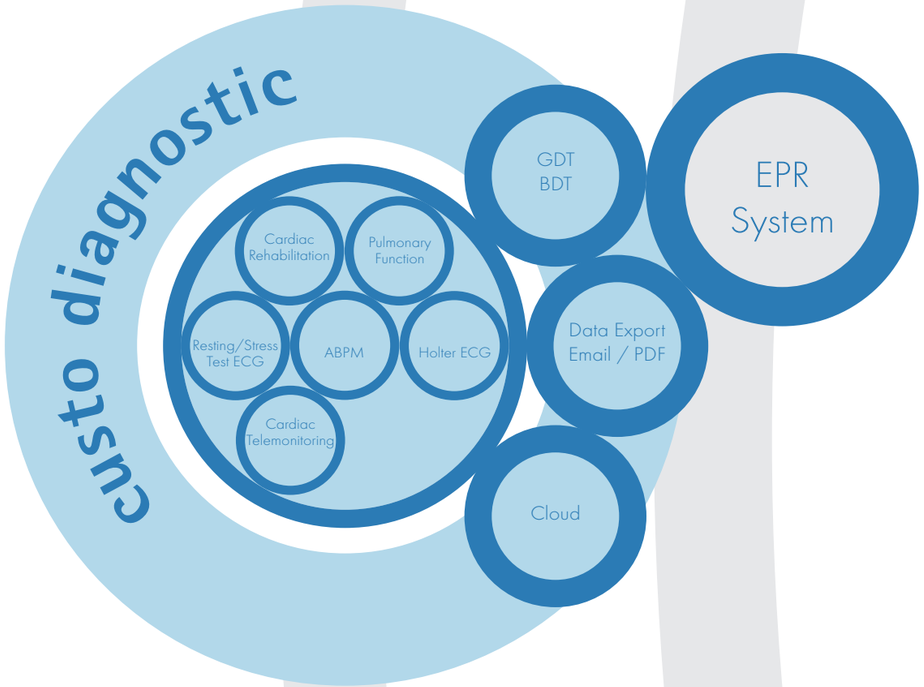
Our brand inspires innovation in cardiovascular diagnostics and efficient data flows in your IT environment. A committed team and competent sales and service partners take care of smooth workflows for you and your employees. We are able to respond flexibly to your organisational needs and requirements. All necessary steps, the preparation of the patient, data transfer from the devices and report generation are made available on each computer monitor in the network.

No matter if your installation is working on a single-user workstation or on a laptop, in a small PC network or in a large hospital - your custo med solution will be a profitable investment for the future.

Hans-Jörg Hoffmann
Sales & Marketing

Contents

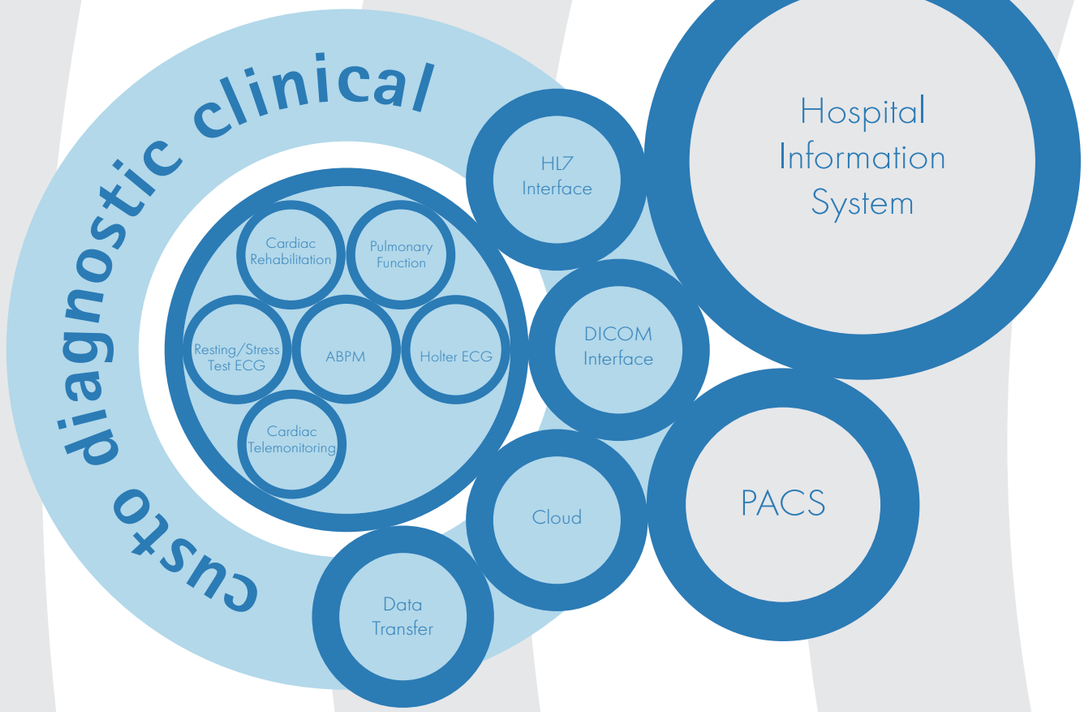
custo diagnostic for doctor's offices



custo diagnostic at a glance:

- Consistent work in all applications
- Continuous patient management
- Extensive search functions
- Paperless working
- GDT / BDT interface to your EPR system
- All evaluations and reports can be sent via email and as PDF files
- Integrated patient administration / Database
- Time and cost saving creation of reports
- Expandable at any time thanks to its modular structure
- Electronic archiving

custo diagnostic clinical for hospitals



custo diagnostic clinical at a glance:

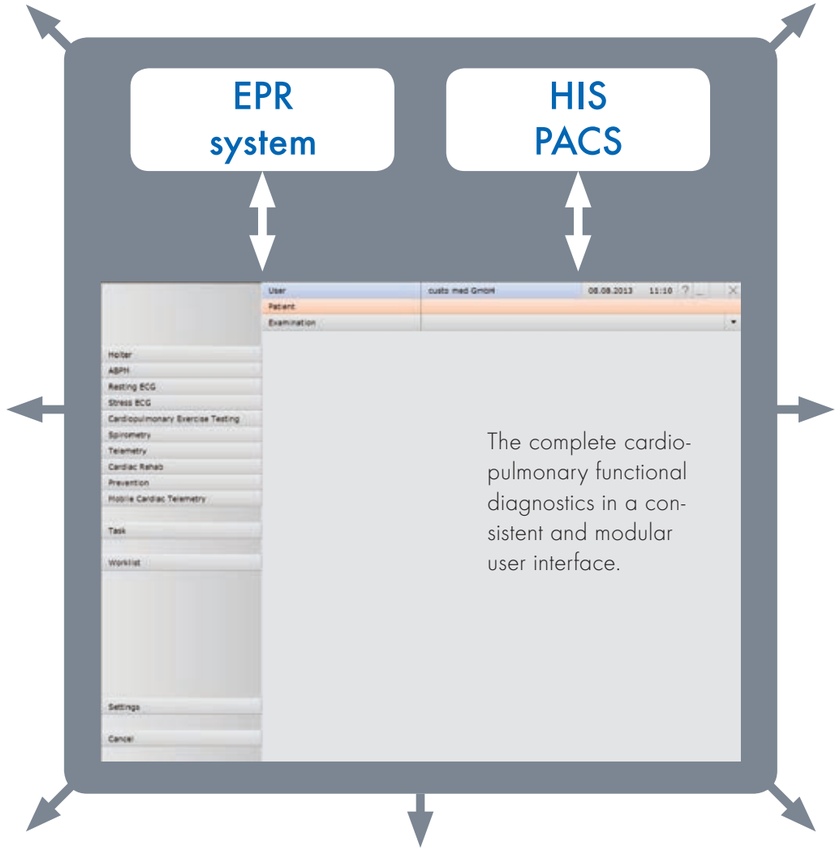
- Central, intuitive software platform for all applications
- Job list as central starting point for task management
- Reconciliation between ad hoc examinations and emergency ECGs
- Task-related administration of Holter devices
- Optimised workflow in the creation of reports due to adaptable filter functions in the evaluation search
- Extended operating range due to wireless devices (Bluetooth)
- Satellite system functionality for network independent examination
- Automatic import of SCP / FDA XML data from standalone ECG writers
- Cost-optimised floating licence model

Software - custo diagnostic / custo diagnostic clinical

Resting ECG

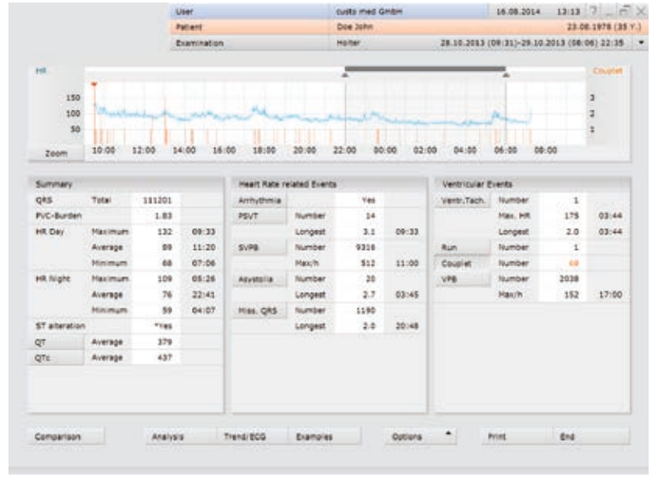
custo diagnostic always allows smooth data exchange with your EPR system via an internal BDT / GDT interface.

custo diagnostic clinical allows optimal workflows with the Hospital Information System via an internal HL7 interface. For communicating effectively with the PACS of your hospital, the system uses an internal DICOM interface.

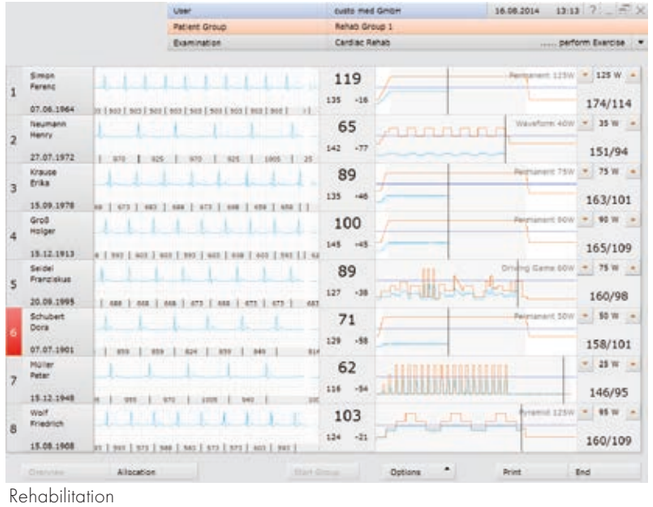


ABPM

Stress Test ECG

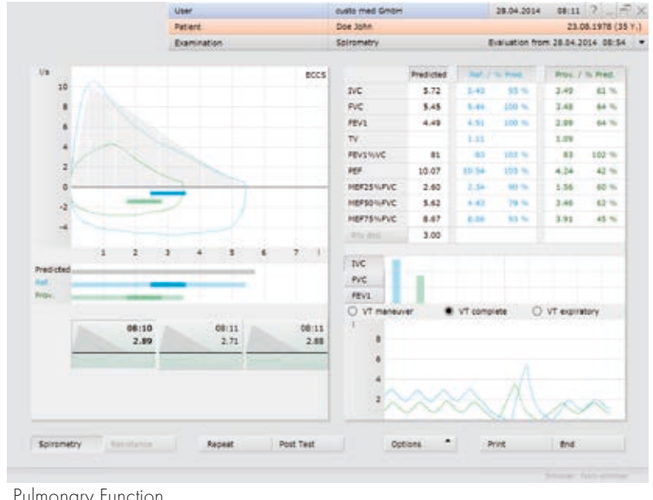


Holter ECG



Rehabilitation

Telemonitoring



Pulmonary Function

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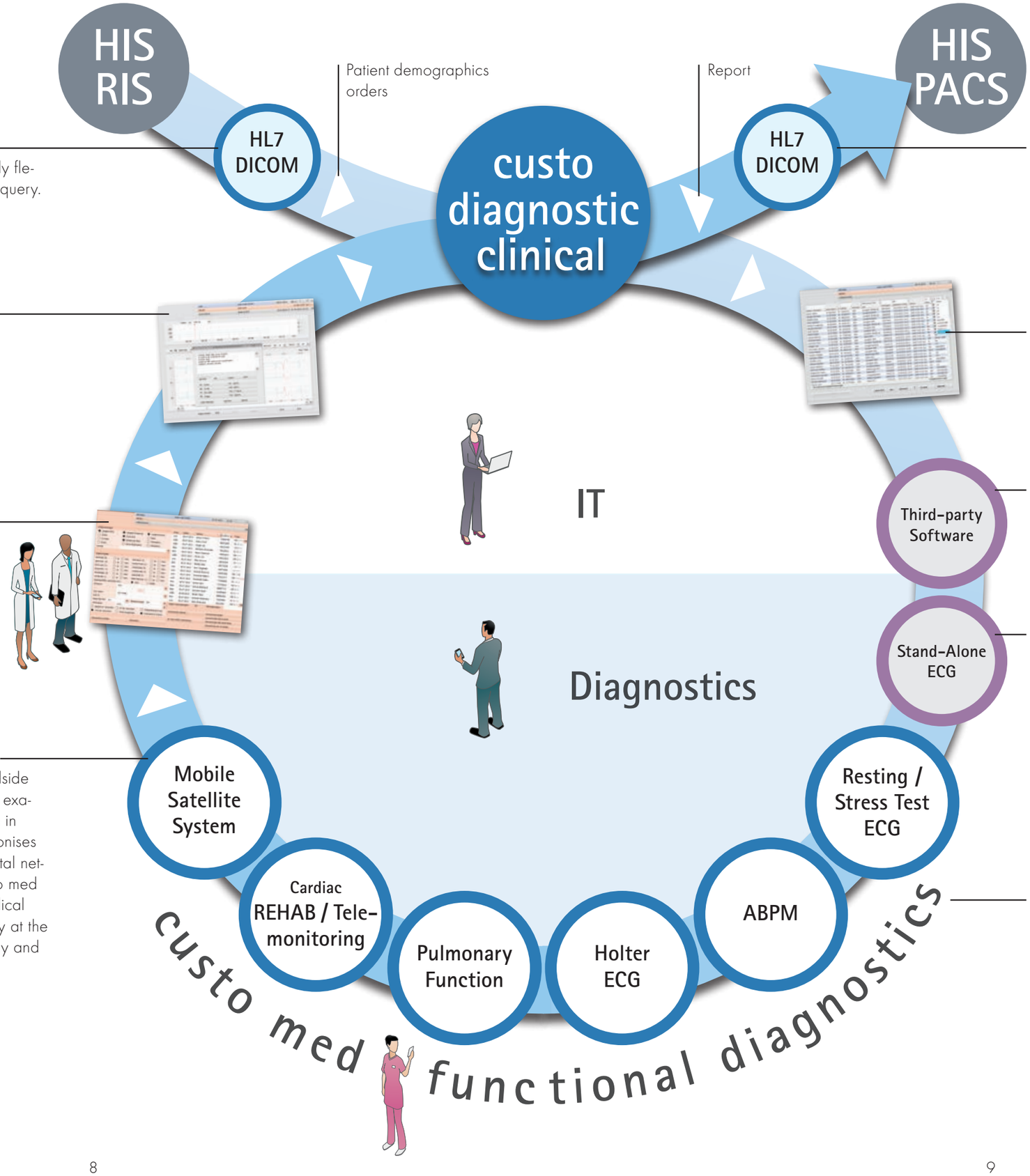
The clinical custo med workflow



Patient data and order information are transferred to the database via the highly flexible HL7 interface or DICOM worklist query.

Fast and comfortable generation of reports through freely definable text modules.

The customised evaluation search provides direct access to a list of open reports

The satellite feature of custo diagnostic allows examinations at the patient's bedside or at remote locations. The worklist and examination functionality are also available in offline mode. The mobile system synchronises itself automatically as soon as the hospital network is re-connected. With mobile custo med solutions or already existing on-site medical carts examinations can be made directly at the patient's bedside, independent of energy and network.

The finished report including measured values is transferred to HIS or PACS via HL7 or DICOM.

The job list presents all examination orders. The medical technician starts the further process with a click.

Diagnostic software systems of other vendors can be integrated via custo connect. Finished examination reports can be imported directly into the custo diagnostic patient record.

Existing compatible ECG writers of other manufacturers can be comfortably integrated into the workflow via the SCP / FDA-XML interface.

In combination with custo med devices, the custo diagnostic system represents the central and consistent platform for all cardiopulmonary examinations in functional diagnostics.

Resting / Stress Test ECG

A modern doctor's office without the consistent use of PCs and networks cannot be imagined today. EPR software or Hospital Information Systems permit easy access to all patient data from each workstation.

The requirements for modern ECG diagnostics have changed fundamentally. Whereas conventional ECG writers used to be "linked" with PCs to save data electronically, "real" PC-ECGs have established themselves in the meantime. Only an external ECG amplifier remains connected with the PC, amplifying the patient's ECG signals and transmitting them digitally and directly to the computer.
The complete display of the measurement and the analysis of the ECG are then carried out by the PC. Integrated databases save resting and stress test ECGs of an arbitrary number of patients electronically. Previous evaluations can be recalled from the network terminals and be displayed at any time. Nevertheless, if paper documentation is required (e.g. for a referral, discharge letter etc.), it can be comfortably printed with the connected PC printer on normal paper.

custo med has met these requirements by introducing the 12-channel resting/stress test ECG modules custo cardio 100 and custo cardio 200, devices that satisfy any request without losing track of efficiency. Development has focused on economic arguments such as expandability, modularity and sustainability but also on aspects like ease of use and the ability to meet easily and quickly the standard requirements of an office schedule.

When developing custo cardio 200, a closed ECG application system with integrated suction unit as well as an ECG module, our engineers have focused - beside the evident medical quality - on hygiene. custo cardio 200 is the only suction system worldwide which has been awarded the hygiene certificate of the German Society for Hospital Hygiene.

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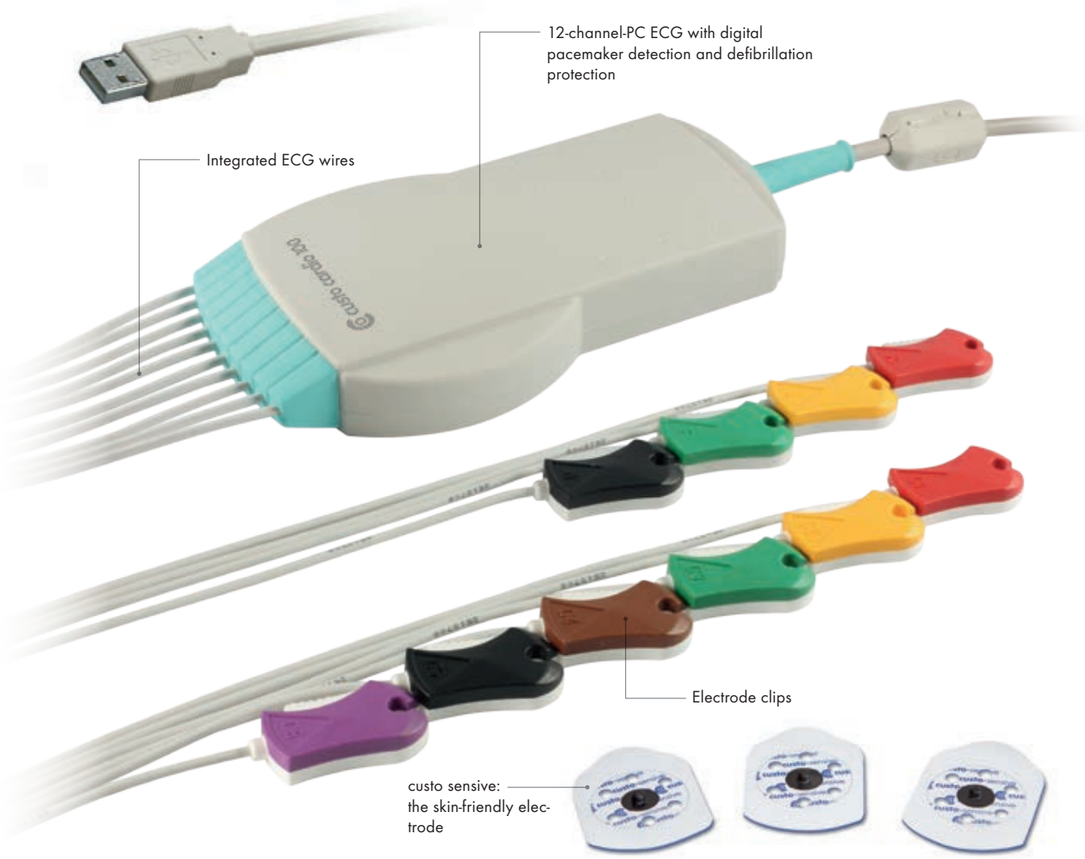
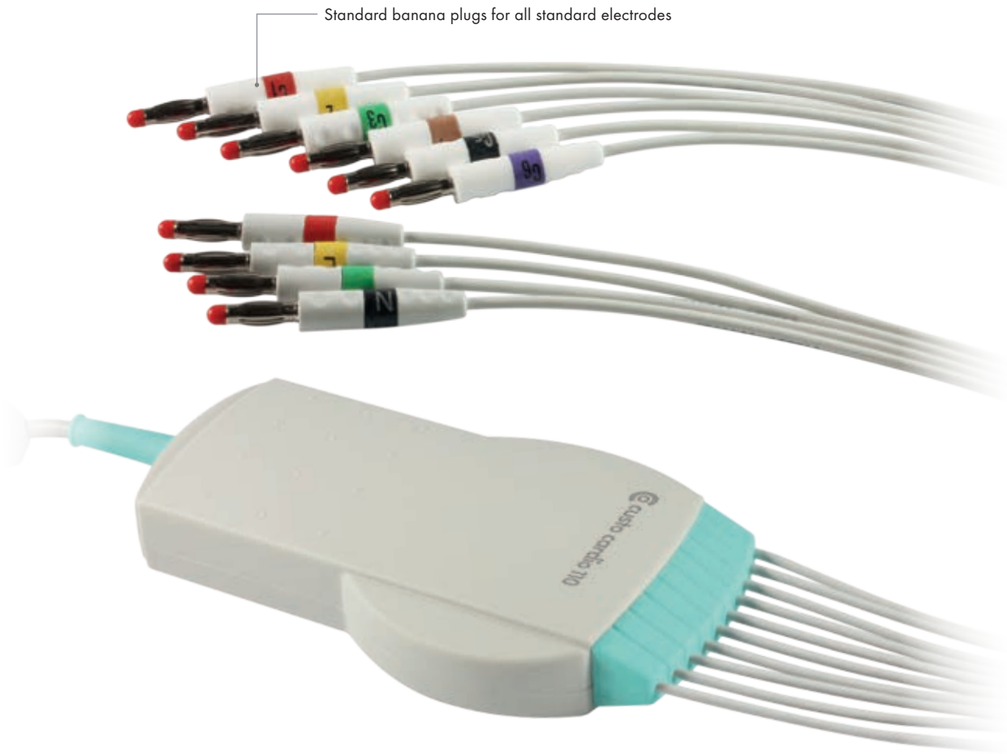


• custo cardio 100 is a 12-channel PC ECG with integrated wires, USB port and electrode clips. The device is defibrillation-proof and guarantees reliable pacemaker detection. Due to the flexibility of the ECG module, ECG recording and display is possible at any time and any place, whether on a PC, notebook or tablet. In line with this, we offer the custo sensive self-adhesive electrodes for optimum ECG signal quality, excellent skin-compatibility and high efficiency.

- Sampling rate 1000 samples/sec. Extremities & chest wall (1 ms)
- 4000 samples/sec. Pacemaker (0.25 ms)
- Defibrillation protection electric strength (proof voltage) 5000 V, (Recovery time < 10 s)
- Software filter & functions line filter, muscle filter, AD filter (anti-drift)
- Pacemaker detection
- Electrode check with automatic indication of quality
- Dimensions approx. 160 * 85 * 25 mm (L * W * H)
- Weight approx. 330 g



• Offers the same features as custo cardio 100, but is additionally equipped with standard banana plugs for all standard electrodes.

- Sampling rate 1000 samples/sec. Extremities & chest wall (1 ms)
- 4000 samples/sec. Pacemaker (0.25 ms)
- Defibrillation protection electric strength (proof voltage) 5000 V, (Recovery time < 10 s)
- Software filter & functions line filter, muscle filter, AD filter (anti-drift)
- Pacemaker detection
- Electrode check with automatic indication of quality
- Dimensions approx. 160 * 85 * 25 mm (L * W * H)
- Weight approx. 330 g

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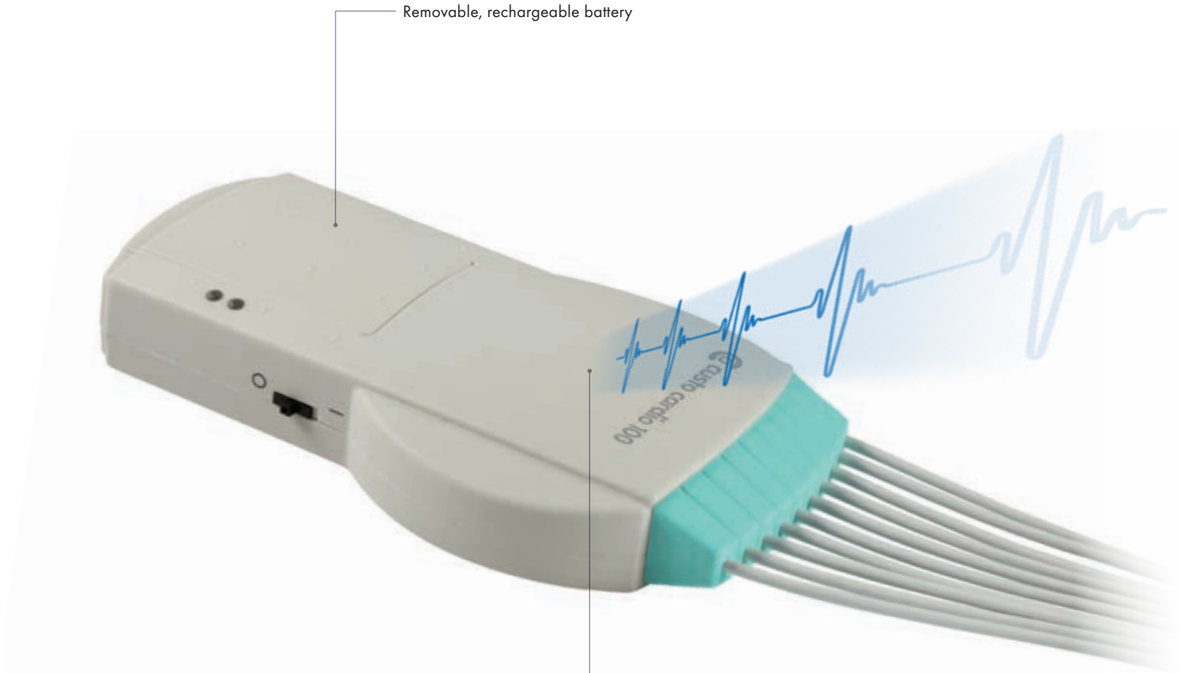
Resting/Stress Test ECG - **custo cardio 100 / 110 BT**



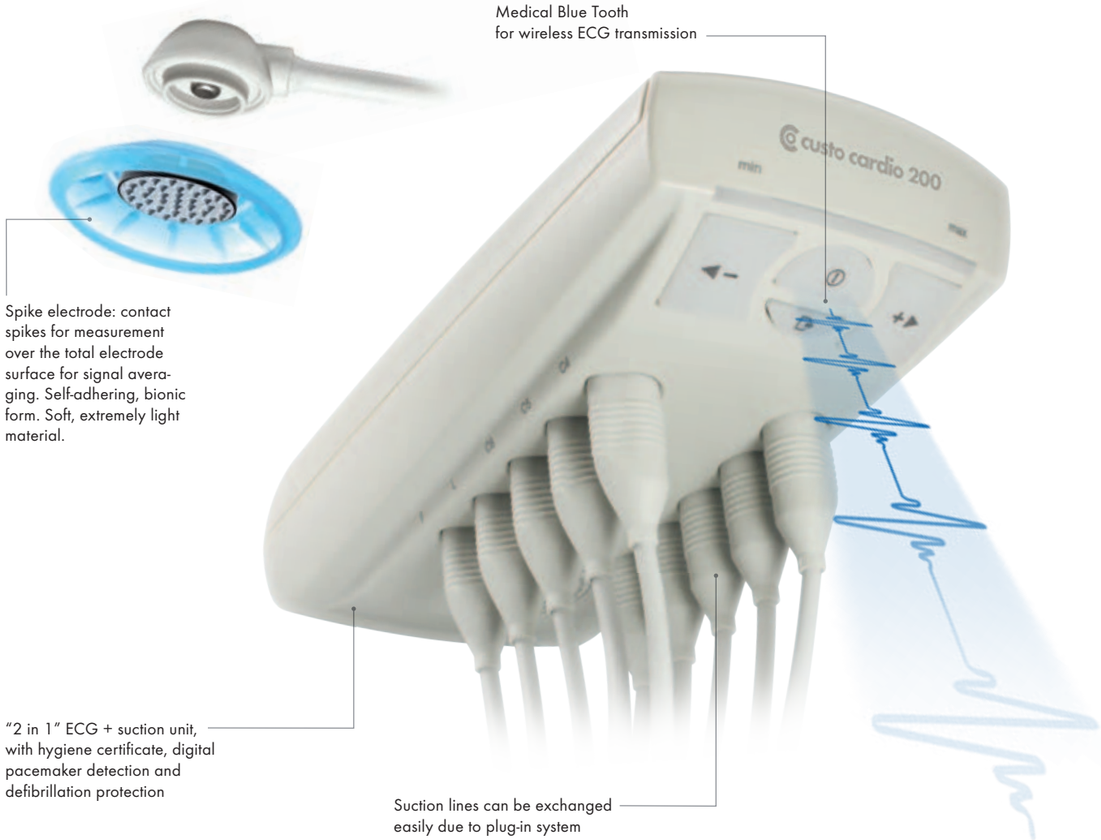
• Offers the same features as custo cardio 100/110, but is additionally equipped with rechargeable battery and Medical Blue Tooth for wireless ECG transmission. This system provides advantages particularly with regard to treadmill stress tests because the ECG module and the patient are treated as a unit and there is no disturbing connection cable to the PC.

- Sampling rate 1000 samples/sec. Extremities & chest wall (1 ms)
- 4000 samples/sec. Pacemaker (0,25 ms)
- Defibrillation protection electric strength (proof voltage) 5000 V, (Recovery time < 10 s)
- Voltage supply: lithium ion battery (4 hours operating time per battery)
- Software filter & functions line filter, muscle filter, AD filter (anti-drift)
- Pacemaker detection
- Bluetooth coverage up to 10 m
- Dimensions: approx. 160 * 85 * 25 mm (L * W * H)
- Weight custo cardio 100: approx. 295 g (incl. battery)
- Weight custo cardio 110: approx. 275 g (incl. battery)

Resting/Stress Test ECG - **custo cardio 130**

• Offers the same features as custo cardio 100, but additionally includes a standard port for the use of external patient cables or suction units.

- Sampling rate 1000 samples/sec. Extremities & chest wall (1 ms)
- 4000 samples/sec. Pacemaker (0.25 ms)
- Defibrillation protection electric strength (proof voltage) 5000 V, (Recovery time < 10 s)
- Software filter & functions line filter, muscle filter, AD filter (anti-drift)
- Pacemaker detection
- Electrode check with automatic indication of quality
- Dimensions: approx. 160 * 78 * 32 mm (L * W * H)
- Weight approx. 425 g
- Connection with 15-pole ECG input jack (D-SUB fitting or Siemens Plug)



custo cardio 200

sets new standards in functionality, operability, quality of data transfer and in the field of hygiene. Exchangeable, re-usable electrodes assure that every patient gets a hygienically impeccable electrode. It is not necessary to go through any time-consuming disinfection procedures or residence times. Following nature's example, our engineers have managed to implement the unmatched functionality of an octopus sucker into the orbiters of custo cardio 200. As a result, the system can reduce the required suction pressure significantly. This is definitely a convenience feature for patients.

Certificate of Hygiene

• custo cardio 200 is a resting/stress test ECG and a suction unit all in one. This technological innovation sets standards in functionality, operability and quality of data transfer. custo cardio 200 is the only suction system that has passed a clinical hygiene test. After intensive, comparative test series custo cardio 200 has been awarded the hygiene certificate of the German Society for Hospital Hygiene, as the only product.

Due to its bionic features the electrode can be applied quickly and safely. It is not necessary to shave skin, thanks to the spiked, patented contact areas. The gentle application automatically reduces suction pressure to the required minimum. Workflow is optimised due to PC control and the automatic detachment of electrodes after the recording has been finished. The integrated ventilation programme of the suction lines increases life span of the system.

- Sampling rate 1000 samples/sec. Extremities & chest wall (1 ms)
- 4000 samples/sec. Pacemaker (0,25 ms)
- Defibrillation protection electric strength (proof voltage) 5000 V, (Recovery time < 10 s)
- Suction capacity 6 steps, 0 – 280 mbar (in 40 mbar steps)
- Software filter & functions line filter, muscle filter, AD filter (anti-drift)
- Pacemaker detection
- Electrode check with automatic indication of quality
- Bluetooth coverage up to 10 m
- Dimensions: approx. 250 * 110 * 60 mm (L * W * H)
- Weight: approx. 785 g
- Optionally with Bluetooth
- The only suction system with hygiene certificate of the German Society for Hospital Hygiene
- Skin-friendly application, perfect for patients taking anticoagulant drugs
- Automatic suction power regulation (gentle application)
- Patented, spiked contact areas
- Quick application of electrodes and automatic detachment
- Options of mobile use
- Electrodes and suction lines can be easily exchanged
- ECG and suction unit in one device

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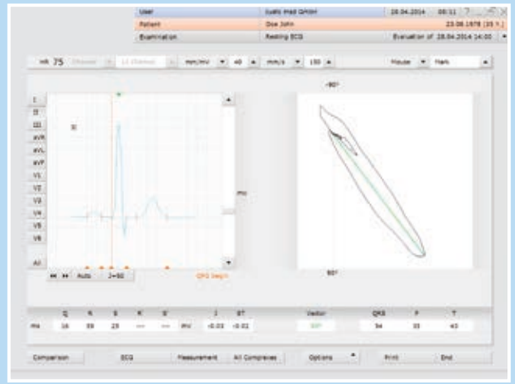
1 ECG overview

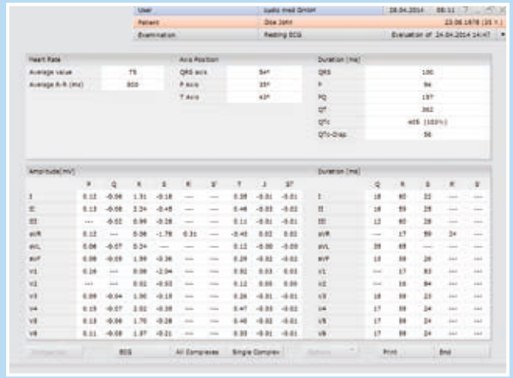
2 Analysis



5 Cumulative complex single display

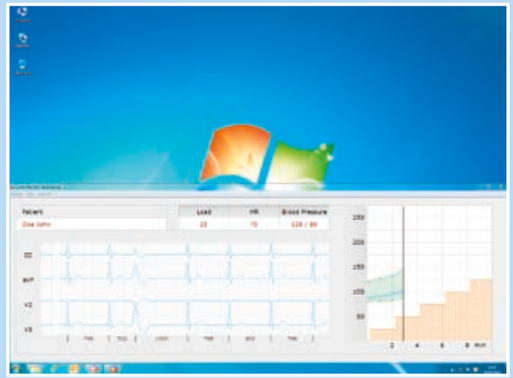
6 Report manager

3 Cumulative complexes



4 Measurement table

7 Stress test overview



8 Network monitoring

1 ECG overview
In the ECG overview the ECG is displayed in a 12-channel system over the complete recording period. This view allows the setting of amplitude, speed and channel selection individually, so that all details of each lead can be interpreted precisely. The zoom function and the calipers are helpful for parameter calculation. Parts of the ECG can be marked and thus be found again immediately. It is possible to compare two arbitrary resting ECGs by using the comparison function.

2 Analysis
Beats of a defined area of the ECG are marked by default, which are later used for parameter calculation. It is possible for the user to modify the selection of these beats. This allows receiving a measurement of the recorded ECG that is adapted to the user's needs.

3 Cumulative complexes
This view displays the already measured cumulative complexes of the ECG in a 12-channel mode. The set measurement lines specify the measuring points of each cumulative complex. So the user can quickly recognize changes in a QRS complex.

4 Measurement table
The tabular display of the measured values offers a general overview of all determined parameters, as for example axis position, times and amplitude values of each measuring point. They are clearly displayed on one screen.

5 Cumulative complex single display
In the single complex display the cumulative complex of a channel is at first shown enlarged. With the help of movable measurement lines the user is able to redetermine the measuring points manually. An overlay function arranging the cumulative complexes of all channels on top of each other, serves to determine the measuring points exactly. The vector loop of the ECG is automatically displayed.

6 Report manager
Due to the text modules which can be generated individually, the report manager offers an effective facility to create reports that are timesaving, precise and significant. It is possible to allocate arbitrary texts to four groups with eight function keys each. Within these texts various variables can be incorporated, containing measured values and indications as to the corresponding evaluation. The best way to write a complete report text - quickly and safely.

7 Stress test overview
In the stress test summary all data and the recorded 12-channel ECG are clearly displayed on a screen. All described functions are available as with the resting ECG. In addition, the ST table and the recorded ST segment of each channel can be displayed. The cumulative complex display, the measured value table and the single complex display are available for each single load step. The step comparison function allows the comparison of arbitrary load steps within the stress test. The ECG display as well as the cumulative complex display (up to seven views) of the load steps can be compared to each other.

8 Network monitoring
By means of network monitoring the physician can monitor a current resting or stress test ECG from his or her workstation simultaneously. All the collected data and the ECG are transferred in real time. It is possible for the physician to supervise the stress test on his monitor without being physically present in the examination room.

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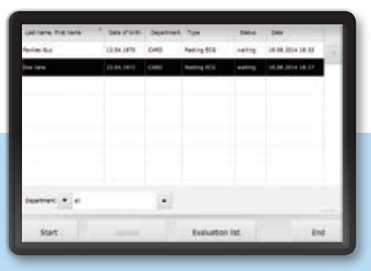
Resting ECG System - **custo cardio 100 BT**

custo cardio touch: custo diagnostic, without mouse and keyboard

Easy access to the main functions



Directly select the examination order in the custo diagnostic worklist

... or use the convenient name search.

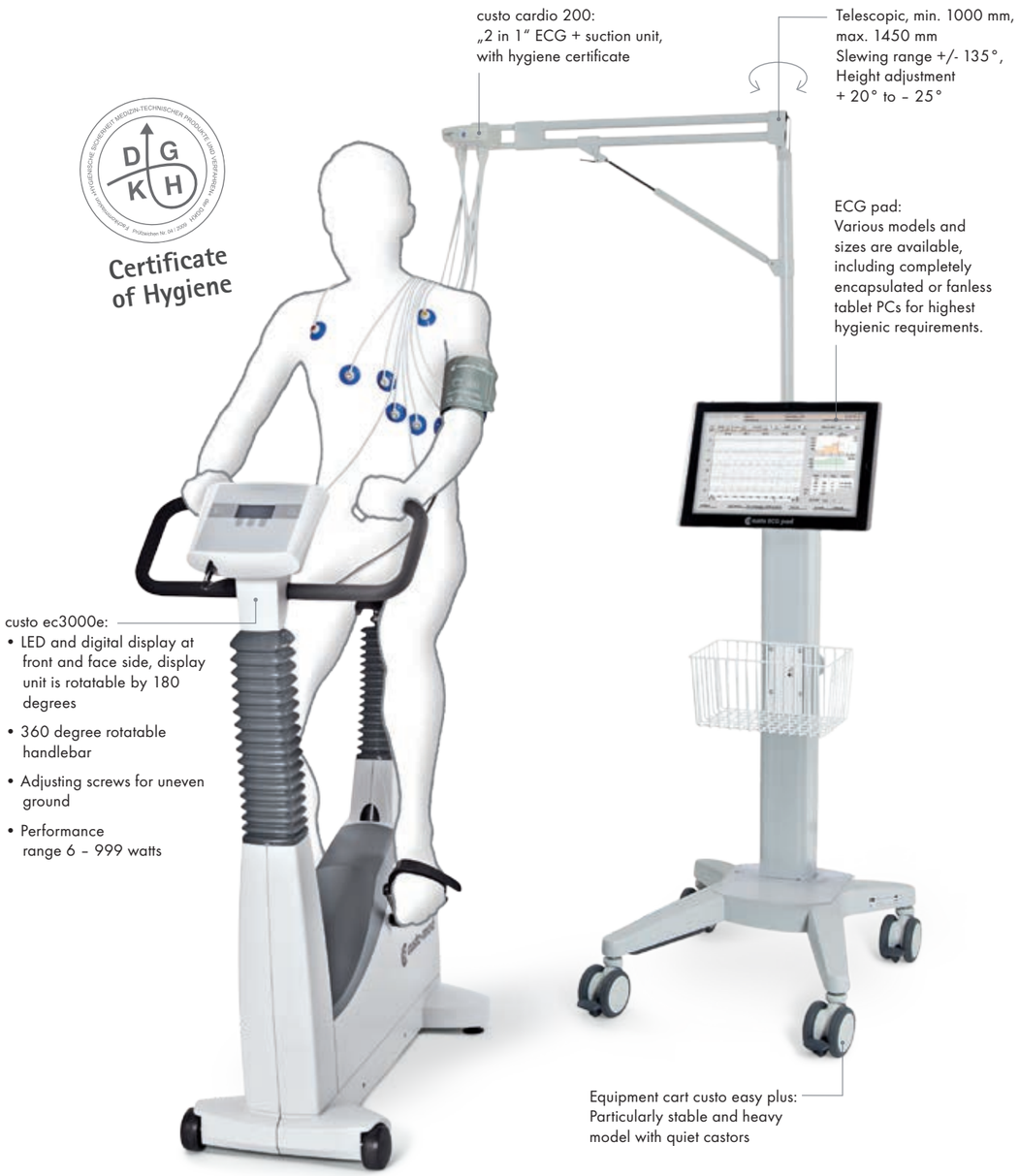
Resting ECG System - **custo cardio 200 BT**

High-resolution ECG display for quality check. Recording with just a tap of your finger on the start symbol.

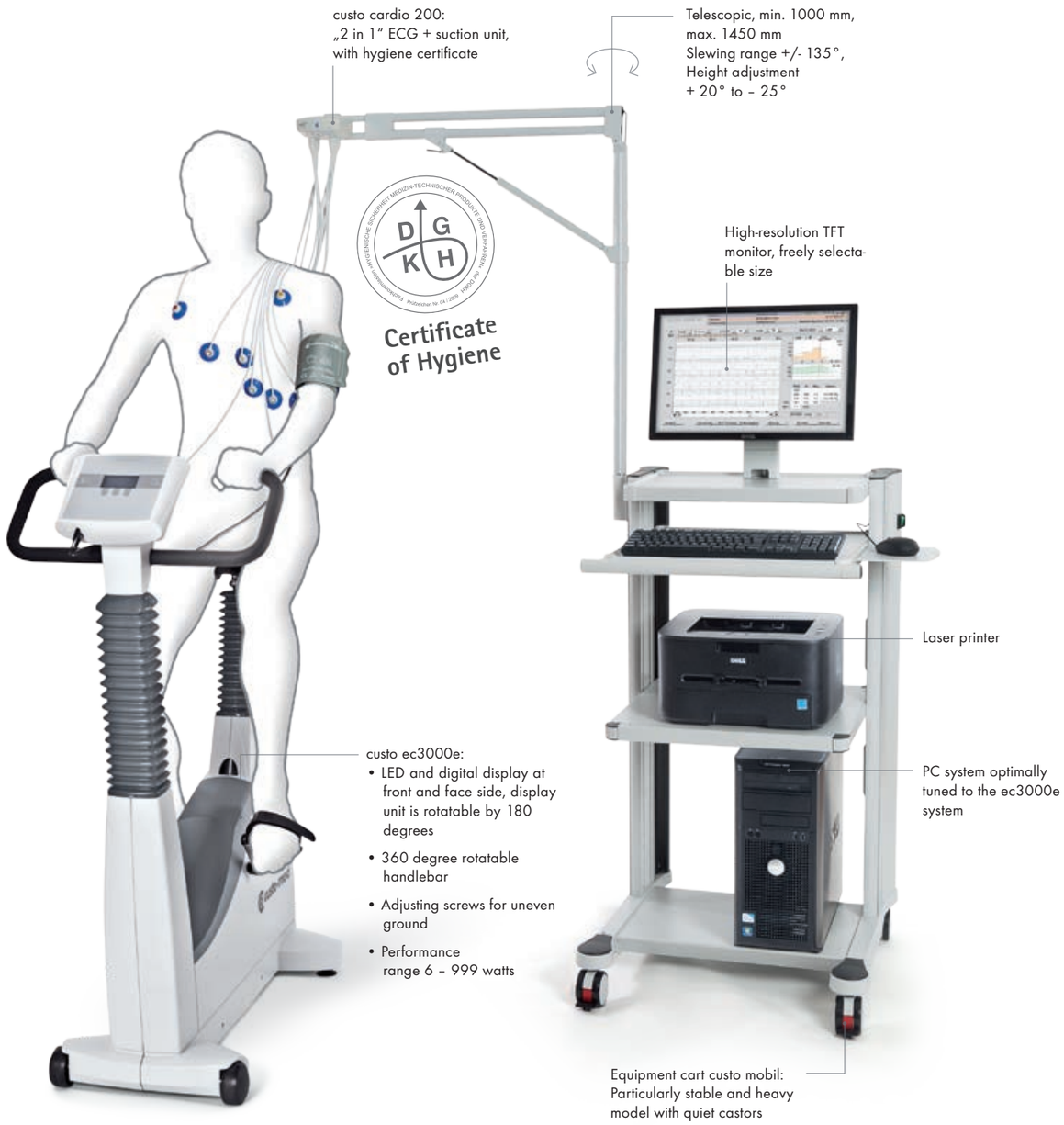
Enter additional information without mouse and keyboard.

Close with automatic interpretation or generate your report with the custo diagnostic text modules

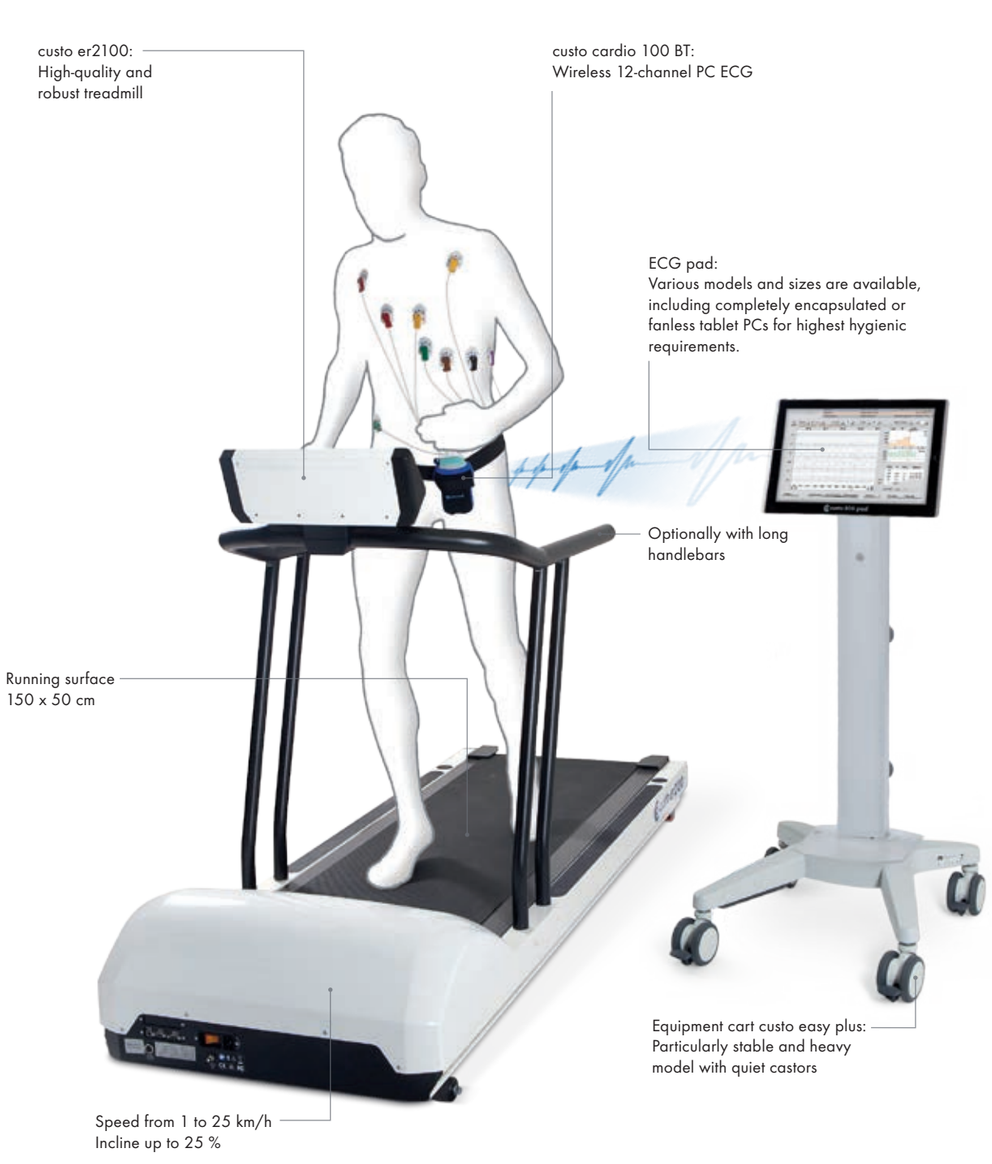
Stress Test System - **custo ec3000e touch**



Stress Test System - **custo ec3000e**



Stress Test System - **custo er2100 touch**



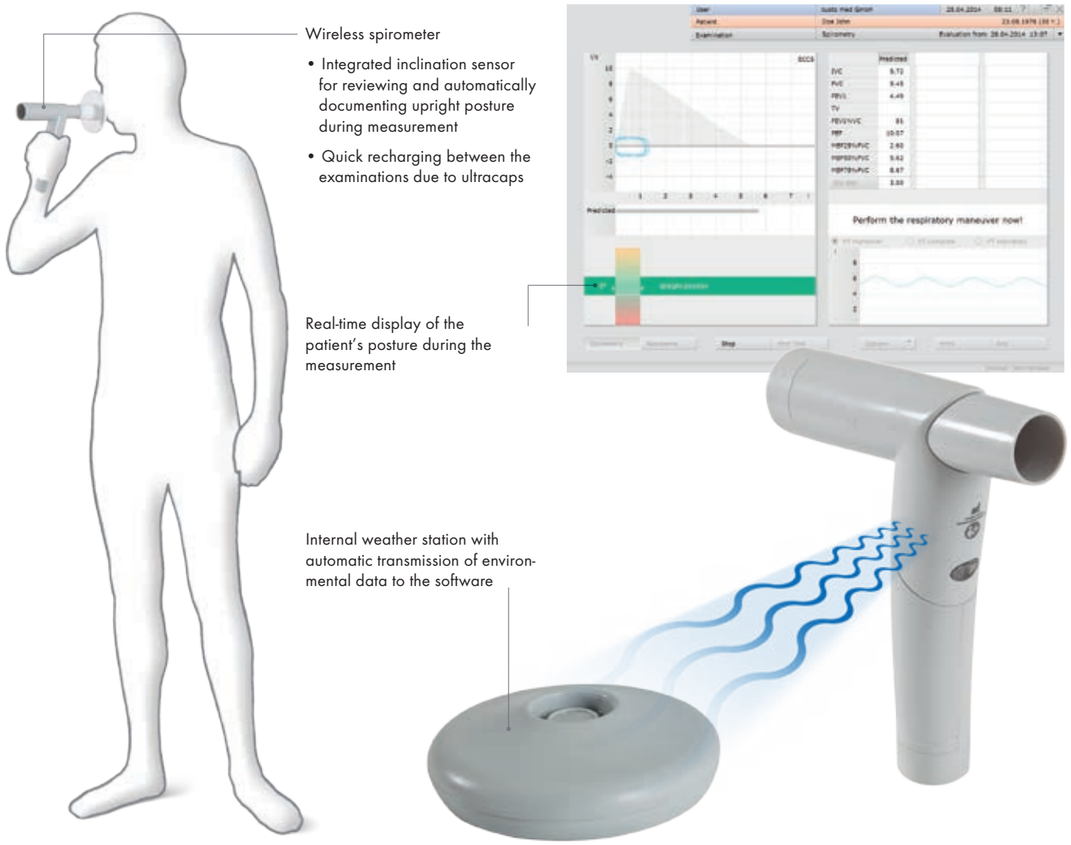
CPET System - **custo mc3000e**

Pulmonary Function

Respiratory tract diseases, particularly allergic reactions of the bronchial system, belong to the most frequent diseases today. A reliable pulmonary function test is an essential instrument with preventive medical examinations as well as an optimal check-up of therapeutic measures.
It is the aim of a pulmonary function test to detect as exactly as possible the functional status of the respiratory system and of the lungs, in individual cases or in cases of population groups at risk. In many cases of lung disease, ventilation and blood circulation of the lungs are not well coordinated and consequently not enough oxygen is being absorbed. Therefore, the aim must be to detect diseases in their early stages and to relate them causally. The efficiency of initialised therapies is to be monitored and preventive measures are to be supported.
Standard examinations are carried out with a spirometer that can be upgraded with supplementary measuring methods according to the selected equipment technology. This allows working on special questions. The measured values are compared with predicted values.

• custo spiro mobile allows precise measurements in just one breathing manoeuvre, even if house calls are made. custo spiro protect – the gold standard in bacterial and viral filters – gives your patients maximum protection against infection. It is not necessary to disinfect the measuring head in a time-consuming procedure and product lifetime is significantly increased.

- Predicted value tables: EGKS, Zapletal, Polgar 79, Polgar 71, Quanjer, Crapo, Morris, Hankinson, HSU, Ulmer, Austrian reference values, Knudson, Cherniack, Schindl, Baur
- Accuracy according to ATS standards, ISO 23747
- Dimensions: approx. 140 * 150 * 45 mm (L * W * H)
- Weight: approx. 330 g



• custo spiro air with integrated inclination sensor for reviewing and automatically documenting upright posture during measurement. The integrated weather station automatically transmits environmental data to the software.

- Predicted value tables: EGKS, Zapletal, Polgar 79, Polgar 71, Quanjer, Crapo, Morris, Hankinson, HSU, Ulmer, Austrian reference values, Knudson, Cherniack, Schindl, Baur
- Accuracy according to ATS standards, ISO 23747
- Size of measuring head approx. 190 * 150 * 30 mm (L * W * H)
- Weight: approx. 240 g
- Size of base station: approx. 130 * 130 * 30 mm (L * W * H)
- Weight: approx. 300 g

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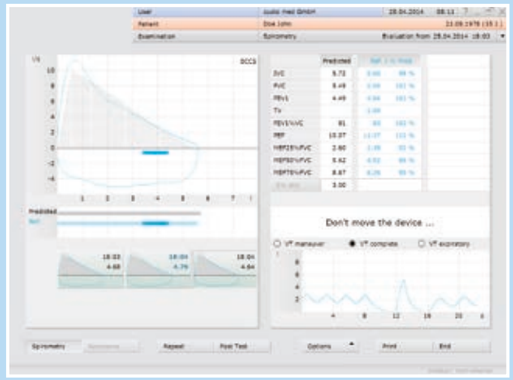
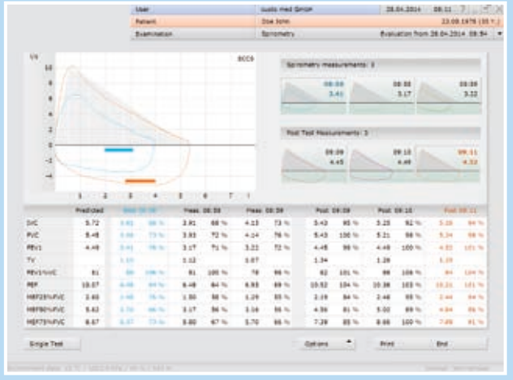
1 Posture

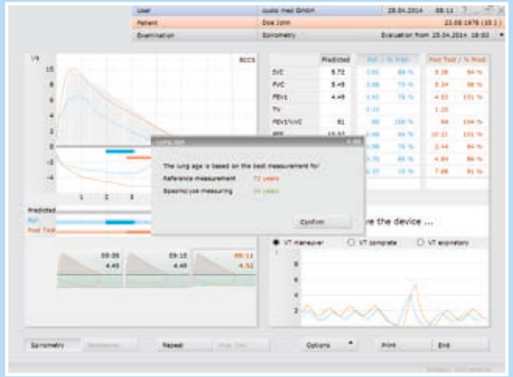


2 Measurement



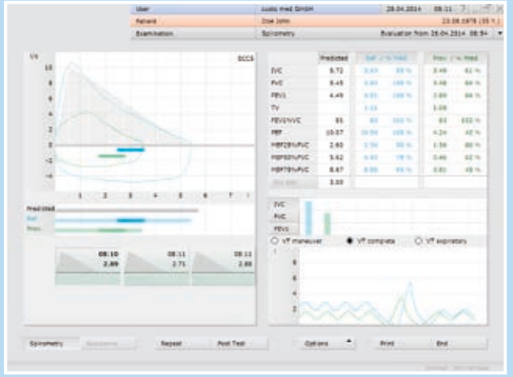
5 Review of progress

6 Child animation



3 Lung age

4 Miller's Prediction Quadrant



7 Provocation

8 Comparison

1 Posture
The optimum patient posture is a prerequisite for obtaining usable measurement results. custo spiro mobil or custo spiro air determine the patient's posture by means of an inclination sensor in real-time and present it graphically. The automatic review of the upright posture enables reproducible results.

2 Measurement
During the measurement all relevant data can already be seen on the screen. Due to several curve displays, the quality of the patient's cooperation can be evaluated immediately. Up to 6 repetitions of a measurement allow the physician to select the best measurement and to recognise suboptimal patient cooperation easily.

3 Lung age
The automatic calculation of the lung age (according to the guidelines of the German Respiratory Tract League e.V.) serves as a communication basis for talking with the patient about his or her current health condition.

4 Miller's Prediction Quadrant
The Miller's Prediction Quadrant provides a simple graphic prognosis of respiratory disorders and their severity. The quadrants are divided into obstruction and restriction and the cross marks the point for which the test results are characteristic.

5 Review of progress
The progress review provides an overview of reproducibility of several measurement series within an examination and their documentation. This procedure provides an objectified statement on measured values, especially in doctor's offices with occupational focus, for example if work-related influences are to be excluded.

6 Child animation
The child animation "Schnaufi, der Drache" ("Schnaufi the dragon") is a motivation tool, not only for children.

7 Provocation
Provocation or spasmolysis are measurement methods with which deteriorations or improvements of respiratory function can be tested and documented, by giving drugs.

8 Comparison
The comparative function serves as long-term overall survey of the patient's health condition.

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Holter ECG

The most frequent causes of death in the western world are cardiovascular diseases. In this context, the sudden cardiac death is one of the main problems. In Germany ten people per hour die of a sudden cardiac death. Patients particularly at risk are those who have already had a myocardial infarction.
In addition, there is a high incidence of cardiac irregularities, over 80% of which are high frequency arrhythmias such as ventricular tachycardia, ventricular flutter and fibrillation. A small share is bradycardiac, i.e. low-frequency cardiac irregularities. The earliest possible recognition of the high-risk patient is essential for starting suitable therapies and for reacting to complications in time.
For diagnostics this means a particular challenge, since methods of examination are required which take into account the individual habits of the patient. In Holter monitoring, the electric activity of the heart is recorded over a period of usually 24 hours, at least 18 hours. During the recording process data are registered in a recorder and are then evaluated on the PC by means of analysis software.

Holter monitoring systems have been successfully developed by custo med for more than 30 years and they are sold worldwide. The custo tera Holter ECG concept has been implemented in close cooperation with users in hospitals and doctor's offices. Even the basic version offers all functions that make it possible to create a Holter ECG report within a short time.
Additionally, our software solutions provide detailed RR variance examinations or comprehensive possibilities of reanalysis. The modular Holter monitoring system allows intelligent and economic solutions with a maximum amount of flexibility. The integration to existing network environments and the complete data exchange with hospital information or EPR systems is easily possible. Comfortable additional functions turn the system into an efficiently working evaluation centre for Holter ECG multi-user systems.

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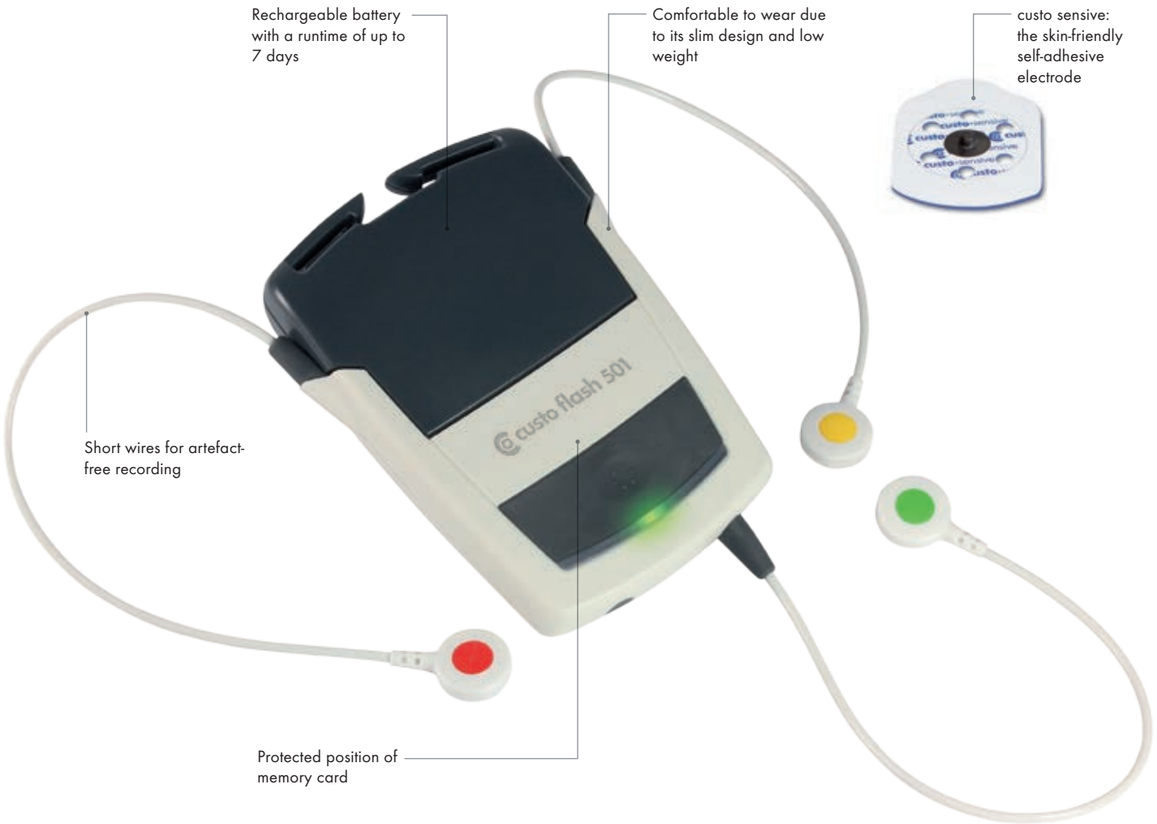
Holter ECG - custo flash 501



• custo flash 501 is the Holter ECG recorder for facility sharing and evaluation centres. With two ECG channels and short, integrated ECG wires for artefact-free 24 hours of ECG recording. The slim design of the recorder and the use of only three self-adhesive electrodes per recording session are features that provide high wearing comfort and favourable operating costs. In line with this system, the custo sensive self-adhesive electrodes ensure optimum ECG signal quality, best skin compatibility and high efficiency.

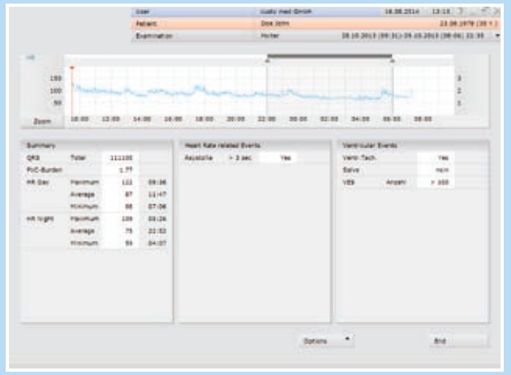
- Recording channels: 2
- Sampling rate 2.5 ms ± 0.1 % per channel
- Battery runtime up to 7 days
- Recording time 24 hours
- Storage medium SD card
- Data transfer via USB card reader
- Voltage supply: Lithium ion battery 3.7 V, 1500 mAh (approx. 2 hours charging time)
- Display & control elements, operating status display with LED, patient marker button
- Dimensions: approx. 95 * 65 * 17 mm (L * W * H)
- Weight: approx. 98 g (incl. battery)

Holter ECG - Software for Multi-User Evaluation Systems

If there is only low demand for long-term ECG examinations in a doctor's office, we recommend participating in a multi-user evaluation system. In this case, the office only needs to acquire a recorder. The holter online system provides a comfortable and low-cost solution for multi-user evaluation systems with solid-state memory technology.

The ECG data are sent to the centre with the holter online software via email or remote data transfer. The integrated short analysis function allows the user to receive preliminary information about important pathological events without having to wait for the complete report from the centre.

This system works completely paperless. ECG data are transferred to the centre via email and the report is sent back again as PDF file via email, too. If no email function is available, the printouts can be sent directly to the doctor's office by means of a PC fax, there they are received again paperless by a PC fax.



1 Short analysis

2 Validation

1 Short analysis
After data have been downloaded and the ECG data have been transmitted to the centre, the short analysis displays important events such as frequent extra systoles, ventricular tachycardia or asystoles together with the heart rate trend. It is not necessary to wait for the final report from the centre.

2 Validation
It is possible to validate the ECG analysed by the centre on one's own PC. For that purpose, the analysis is sent back by the centre as an ECG data set and is then imported into the holter online program. This allows viewing, editing any parts of the Holter ECG or marking interesting ECG episodes and printing them with different resolutions.

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• custo flash 500 is the flagship Holter ECG recorder with three channels, short integrated ECG wires and continuous ECG recording up to seven days. The slim design of the recorder and the use of only three self-adhesive electrodes per recording session are features that ensure high wearing comfort and low operating costs. In line with this, the custo sensive self-adhesive electrodes provide optimum ECG signal quality, best skin compatibility and high efficiency.

- Recording channels: 3
- Sampling rate: 2.5 ms ± 0.1 % per channel
- Recording up to 7 days (with one battery charge)
- Storage medium SD card
- Data transfer via USB card reader
- Voltage supply: Lithium ion battery 3.7 V, 1500 mAh (approx. 2 hours charging time)
- Display & control elements, operating status display with LED, patient marker button
- Dimensions: approx. 95 * 65 * 17 mm (L * W * H)
- Weight: approx. 98 g (incl. battery)

• custo flash 510: Specifications as custo flash 500, additionally with digital pacemaker detection and measurement of pacemaker pulse width.

- Recording channels: 3
- Sampling rate: 2.5 ms ± 0.1 % per channel
- Recording up to 7 days (with one battery charge)
- Storage medium SD card
- Data transfer via USB card reader
- Voltage supply: Lithium ion battery 3.7 V, 1500 mAh (approx. 2 hours charging time)
- Display & control elements, operating status display with LED, patient marker button
- Dimensions: approx. 95 * 65 * 17 mm (L * W * H)
- Weight: approx. 98 g (incl. battery)

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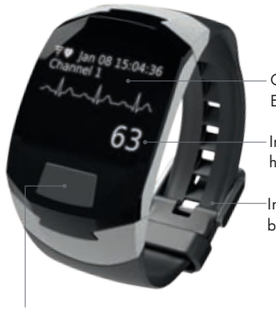
Holter ECG - **custo watch**



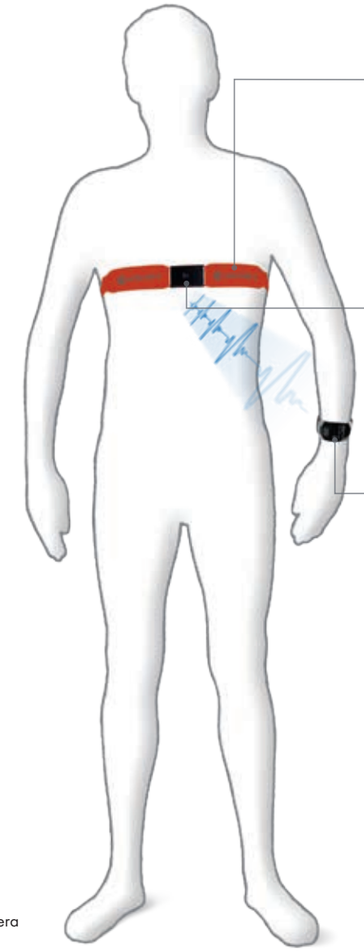
O-LED display for ECG check

Indication of heart rate

Interchangeable bracelets

Marker button

custo docking station
- Recharging of custo guard and custo watch
- Fast transfer of Holter ECG data to the PC
- Compatible with Holter ECG evaluation software custo tera



custo belt 3:
- Without adhesive electrodes
- Novel belt technology for 3-channel ECG recording
- Reusable
- Machine washable
- High wearing comfort
- With certificate of biocompatibility

custo guard 3:
- 3-channel ECG transmitter
- Waterproof, extremely lightweight
- Energy-saving wireless transmission of ECG signal to custo watch

custo watch:
- Signal testing of ECG channels
- Adjustable patient display
- Interchangeable bracelets
- Waterproof, extremely lightweight
- Recording time: 24 h

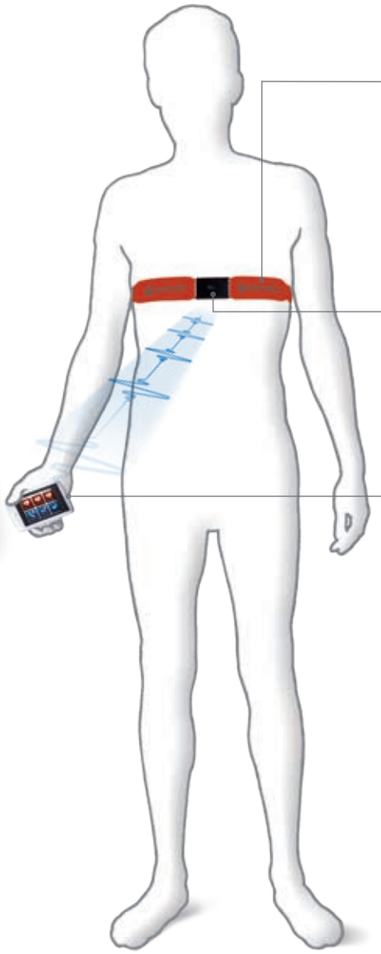
• custo watch – the result of consistent development work: The Holter ECG is recorded with a lightweight chest belt, transmitted wirelessly to the ECG watch and is saved there. It comes without adhesive electrodes or wires but with a high degree of patient comfort and an attractive design.

custo watch:
- Recording channels: 3
- Adjustable sampling rates 125 Hz, 250 Hz, 500 Hz, 1 kHz
- Voltage supply: Lithium polymer battery with 280 mAh (approx. 1 hour charging time)
- Recording time: 24 hours
- Waterproof according to IP65 code
- Dimensions: approx. 55 * 38 * 15 mm (L * W * H)
- Weight: 50 g

custo guard 3:
- Recording channels: 3
- Voltage supply: Lithium polymer battery with 105 mAh (approx. 1 hour charging time)
- Battery runtime: approx. 2 days with 1 kHz sampling rate, approx. 60 days in standby mode
- Waterproof according to IP65 code
- Dimensions: approx. 70 * 42 * 12 mm (L * W * H)
- Weight: 27 g

custo docking station:
- Micro USB port
- Dimensions: approx. 140 * 92 * 95 mm (L * W * H)
- Weight: 300 g

Holter ECG - **custo kybe**



custo belt 3:
- Without adhesive electrodes
- Novel belt technology for 3-channel ECG recording
- Reusable
- Machine washable
- High wearing comfort
- With certificate of biocompatibility

custo guard 3:
- 3-channel ECG transmitter
- Waterproof, extremely lightweight
- Energy-saving wireless transmission of ECG signal to custo kybe

custo kybe:
- Continuous ECG recording (from 24 h up to 6 months)
- ECG check in display
- Display of patient name possible
- Intelligent marker button
- Automatic check of ECG quality
- Hint if signal quality is insufficient

• Holter ECG system for continuous, mobile cardiac patient monitoring. With this system it is possible to record ECG continuously, from 24 hours up to 6 months. The intelligent patient marker button provides the attending doctor with valuable additional information. The automatic functional check of the complete system guarantees ECG recording with constant ECG quality.

custo guard 3:
- Recording channels: 3
- Voltage supply: Lithium polymer battery with 105 mAh (approx. 1 hour charging time)
- Battery runtime: approx. 2 days with 1 kHz sampling rate, approx. 60 days in standby mode
- Waterproof according to IP65 code
- Dimensions: approx. 70 * 42 * 12 mm (L * W * H)
- Weight: 27 g

custo kybe:
- Interfaces: USB 2.0, Micro USB, Micro SD card up to 64 GB
- Storage capacity 3-channel-ECG: 1 GB: 29 days, 8 GB: 232 days
- Voltage supply: Lithium polymer battery with 3800 mAh (approx. 2 hours charging time)
- Battery runtime: 24 hours minimum
- 3.5 inch resistive touch display
- Dimensions: approx. 135 * 70 * 23 mm (L * W * H)
- Weight: approx. 230 g

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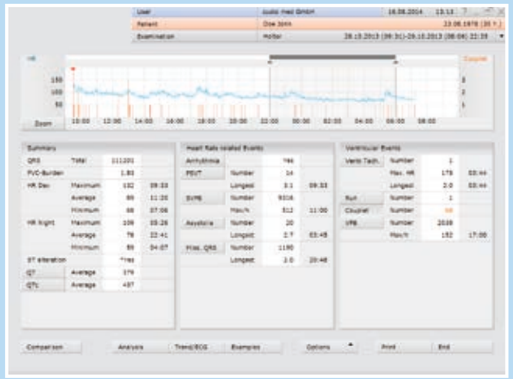
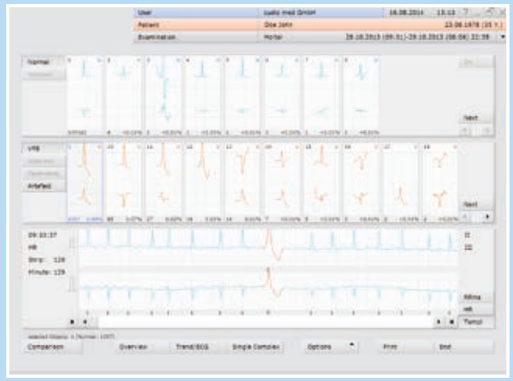


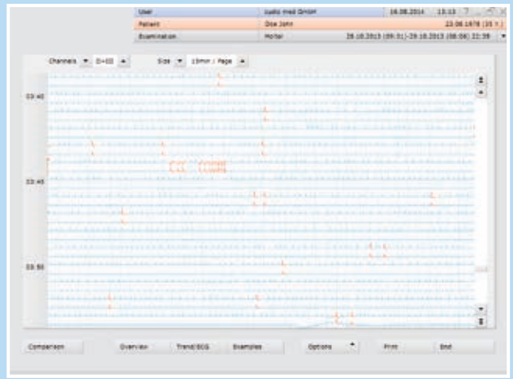
1 Evaluation overview page

2 Examples

3 Trend ECG

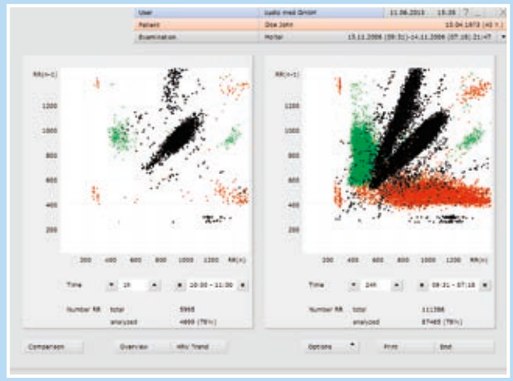


4 Template analysis



5 Complete ECG

6 ST analysis



7 HRV analysis

8 Pacemaker analysis

1 Evaluation overview page
The summary of the 24-hour recording is available immediately after the recorder data have been downloaded and the analysis of the saved ECG has been made. All pathological events with indication of appearance and maximum frequency are displayed in it. The most pathological value is particularly pointed out according to its point in time and duration.
The heart rate trend is graphically displayed, simultaneously with a freely selectable pathology. With a mouse click (see orange mark) the display of the corresponding ECG example is directly called up together with all the important indications. The pathology trend curve that is displayed simultaneously allows fast access to further events of the same type. The clearly structured user interface with its extensive editing functions facilitates the quick validation of the results.

2 Examples
The environment of the ECG example – essentially with the assessment of longer episodes (e. g. tachycardia) – can be displayed at any time. Arbitrarily long ECG sections can be marked for a later report, with selectable resolution and writing speed.

3 Trend ECG
Interesting episodes can be marked, edited and be printed directly. With a caliper, sections of the ECG example can be easily measured. With the help of the trend ECG the 24-hour long-term ECG can be viewed completely.

4 Template analysis
The analysed morphology classes ("templates") are displayed with the indication of type and the frequency of appearance. Individual morphology classes can be edited or summarised. A new analysis of the recorded ECG with modified parameters is possible at any time.

5 Complete ECG
In particular cases of evaluation, it may be necessary to have an overview of a longer section of the recorded ECG. It is possible to run the complete 24-hour ECG in one- or two-channel mode with configurable amplitude and speed on the screen. Editing individual or several examples is possible at any time.

6 ST analysis
The results of the ST segment analysis are displayed as a trend curve. The analysis additionally saves up to 3000 measured ST examples. The system supports extensive display options of these examples with ST trend display and direct allocation of the corresponding continuous ECG, together with appropriate printout options. It is also possible to search for ECG sections with a particular ST behaviour and to edit the gauge marks.

7 HRV analysis
The examination of heart rate variability in the time spectrum as well as in the frequency spectrum can be precisely followed thanks to the high-resolution ECG analysis of the custo tera system. All standard trends (e.g. SDNNS, ANN5, RMSSD, pNN50) are displayed. For interesting positions the corresponding ECG is immediately displayed. A two-dimensional "scatter plot" shows the time-related behaviour of consecutive RR intervals.

8 Pacemaker analysis
The pacemaker spikes registered by the recorder are analysed according to their time-related behaviour, the individual pacemaker data (starting frequency, frequency window and others) being considered. In addition, the system examines whether a pacemaker pulse is followed by a corresponding myogenic response. The results are displayed after having been edited accordingly (including, among other things, summary, trend and selected examples).

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Ambulatory Blood Pressure Monitoring

The ambulatory 24-hour blood pressure measurement creates an extensive profile of the blood pressure behaviour. The exact determination of blood pressure values - differentiated according to day and night phases - is indispensable for a validated diagnosis and therapy follow-up.

The custo screen system variants provide customised solutions and are thus tailored to the use in practice. custo med supplies suitable software solutions for all customary PCs, meeting the highest demands from recorder programming through suitable documentation to optimum database archiving. Data are transferred via infrared technology (IRDA). The custo screen recorder uses the oscillometric measuring procedure.

An ergonomic shape, attractive design and the very low weight ensure high wearing comfort for the patients. Due to the extremely quiet mode of operation the patient does not perceive the recorder as a technical foreign body. The individual measuring operations are finished within 30 seconds.

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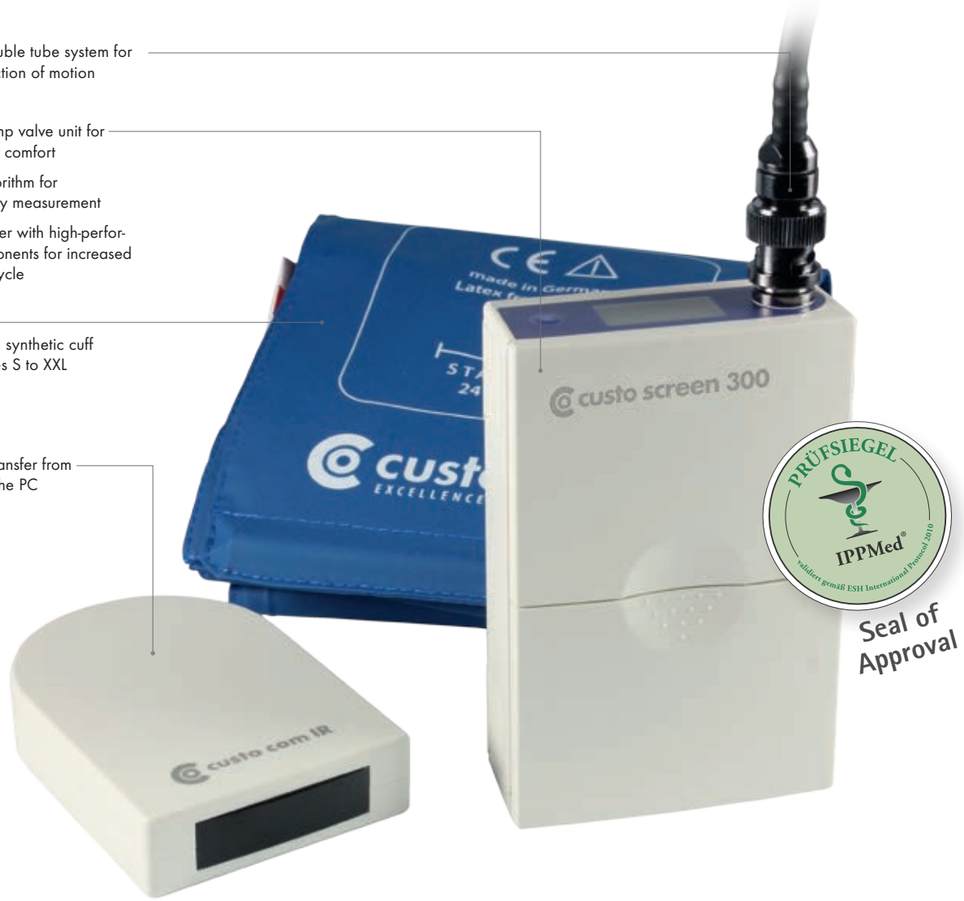
ABPM - custo screen 300

High-quality double tube system for significant reduction of motion artefacts

- Low-noise pump valve unit for higher patient comfort
- Adaptive algorithm for patient-friendly measurement
- Robust recorder with high-performance components for increased product life cycle

Skin-friendly, easy-to-disinfect, synthetic cuff available in sizes S to XXL

Wireless data transfer from the recorder to the PC

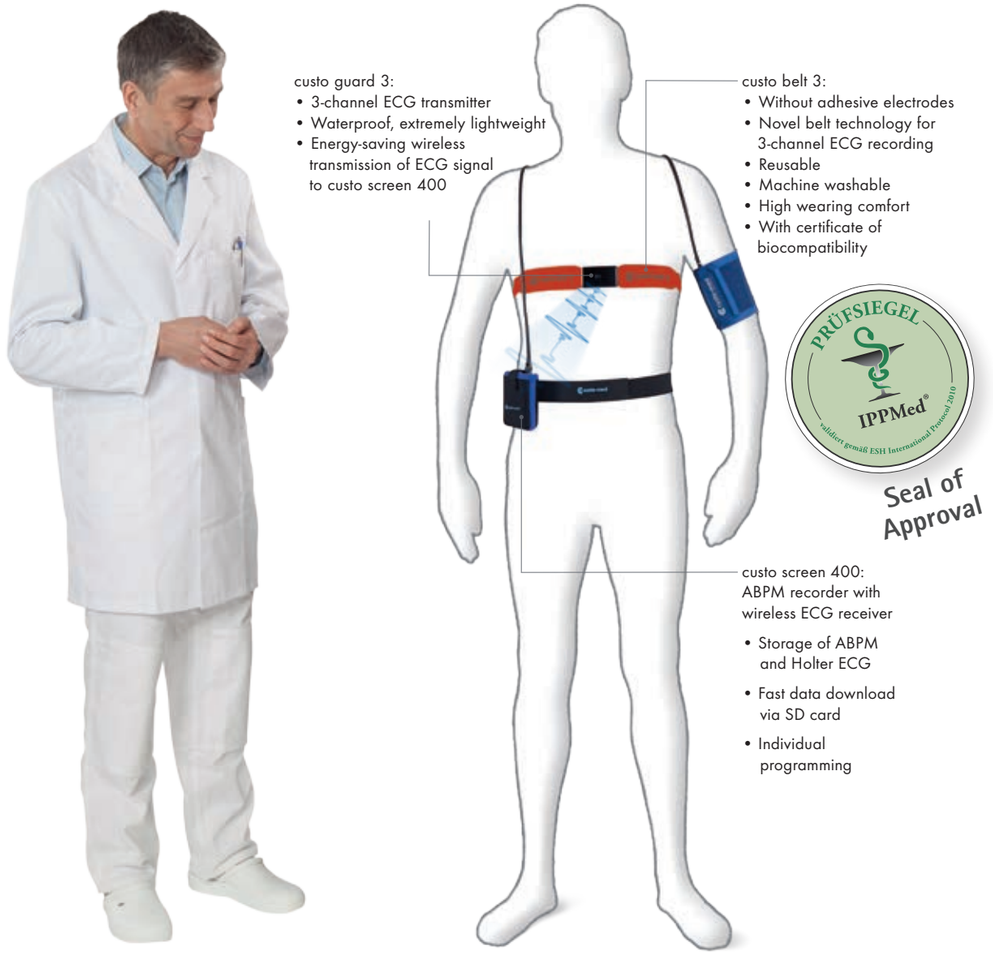


Seal of Approval

• custo screen 300 is the first ABPM recorder worldwide validated according to the new, more stringent requirements of the European Society of Hypertension (ESH-IP 2010 protocol). The measurement technology specially developed for this system improves artefact suppression significantly. The automatic day and night recognition, the very short inflating and deflating times as well as the low-noise operation of the recorder ensure high patient comfort.

- Oscillometric measuring procedure, automatic null balancing
- Measuring range of heart rate 35 – 220 beats / min.
- Systolic blood pressure 70 – 270 mmHg
- Diastolic blood pressure 40 – 155 mmHg
- Max. cuff pressure: 300 mmHg
- Max. number of measurements: 512
- Max. recording time: 72 hours
- Duration of a measurement < 30 seconds
- Standard measurement intervals: day phase every 15 min., night phase every 30 min., if required creation of additional phases
- Intervals adjustable between 5 and 90 min., setting of individual profiles
- Cuff sizes Small (children) 20 – 24 cm, Standard 24 – 32 cm, XL 32 – 40 cm, XXL 38 – 50 cm
- Infrared data transfer via custo com IR
- Voltage supply: 3 Mignon 1.5 Volt, type AA or 3 rechargeable batteries, Ni-MH, 1.2 Volt, min. 1500 mAh
- Dimensions approx. 100 * 66 * 26 mm (L * W * H)
- Weight approx. 172 g (incl. batteries)

Holter ECG + ABPM - custo holter ABPM



custo guard 3:
- 3-channel ECG transmitter
- Waterproof, extremely lightweight
- Energy-saving wireless transmission of ECG signal to custo screen 400

custo belt 3:
- Without adhesive electrodes
- Novel belt technology for 3-channel ECG recording
- Reusable
- Machine washable
- High wearing comfort
- With certificate of biocompatibility

Seal of Approval

custo screen 400: ABPM recorder with wireless ECG receiver
- Storage of ABPM and Holter ECG
- Fast data download via SD card
- Individual programming

• custo screen 400 is validated according to the new, more stringent requirements of the European Society of Hypertension (ESH-IP 2010 protocol), as is custo screen 300. The custo holter ABPM system is the innovative solution for simultaneous recording of Holter ECG and long-term blood pressure. The system provides high wearing comfort without disturbing or fault-prone Holter ECG cables. From the economic point of view, the custo holter ABPM also excels because it works without adhesive electrodes and ECG wires.

custo screen 400 corresponds to custo screen 300, with the following additional features:
- Maximum recording time: 24 hours with simultaneous reception and storage of ECG
- Storage medium mini SD card
- Data transfer via USB card reader

custo guard 3:
- Recording channels: 3
- Voltage supply: Lithium polymer battery with 105 mAh (approx. 1 h charging time)
- Battery runtime approx. 2 days with 1 kHz sampling rate, approx. 60 days in standby mode
- Waterproof according to IP65 code
- Dimensions approx. 70 * 42 * 12 mm (L * W * H)
- Weight 27 g

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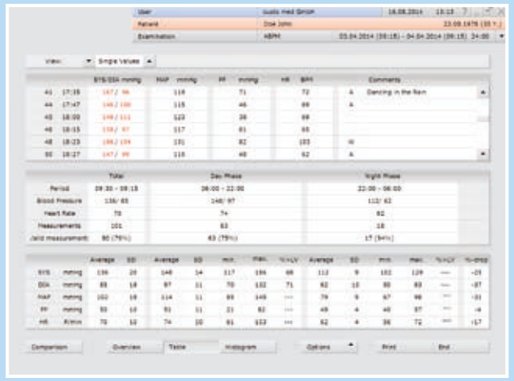
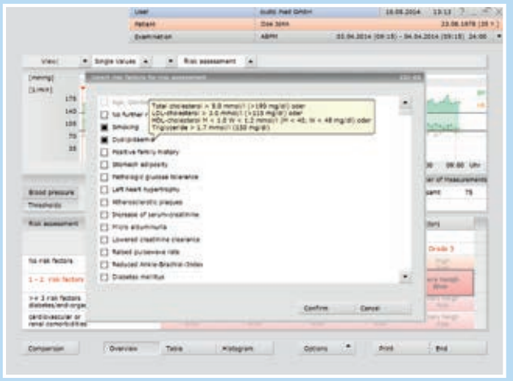
1 Summary of ABPM recording



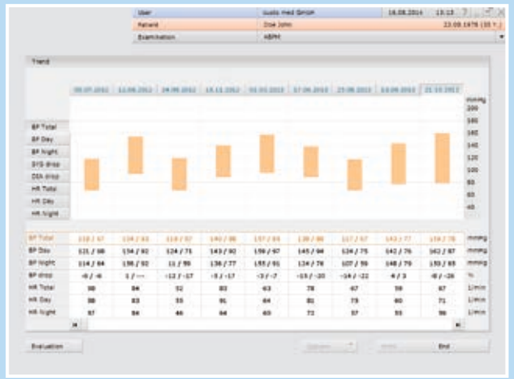
2 Tabular display

5 Risk stratification



6 Risk factors

3 Comparison of evaluations



4 Overview of several evaluations

7 Automatic proposal

8 custo holter ABPM Holter ECG + ABPM

1 Summary of ABPM recording
In addition to the graphic display of the blood pressure curve, all measured values (systole, diastole, mean arterial pressure, pulse pressure amplitude etc.) are presented numerically.

2 Tabular display
The tabular display points out an overview of all performed measurements. The recordings from the patient's diary can be taken over to the table easily. Among other things, the table shows the weighted average, the standard deviation and the proportional nocturnal dipping.

3 Comparison of evaluations
An efficient review for evaluating a drug therapy can be easily done by comparing two evaluations. Any preliminary examinations can be compared with the current examination precisely in time.

4 Overview of several evaluations
It is equally possible to evaluate a long-term therapy with the custo screen program.
All the recordings of a particular patient are presented side by side in the time-dependent course. Individual evaluations can be targeted and accessed at any time.

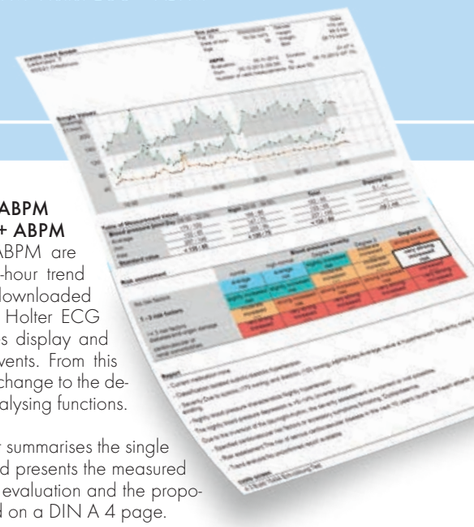
5 Risk stratification
This additional module combines blood pressure severity with cardiovascular risk factors and determines the patient's individual risk according to these parameters. The definition of blood pressure severity and the classification of risk factors are in accordance with the current guidelines of the German Hypertension League (DHL)

6 Risk factors
The risk factors are selected by simply clicking the checkboxes. They are saved and automatically integrated into the evaluation when further recordings are made. If risk factors change an adaption can be made at any time.

7 Automatic proposal
In the proposal, the classification and the severity of hypertension, the nocturnal blood pressure behaviour and the risk factors are indicated. Furthermore, the risk in percentage for heavy cardiovascular disease within the next 10 years is displayed. This proposal can be automatically taken over into the EPR system.

8 custo holter ABPM Holter ECG + ABPM
Holter ECG and ABPM are displayed as a 24-hour trend after having been downloaded and analysed. The Holter ECG additionally includes display and frequency of the events. From this start page you can change to the detailed views and analysing functions.

Printout: The printout summarises the single values in a chart and presents the measured value table, the risk evaluation and the proposal clearly arranged on a DIN A 4 page.



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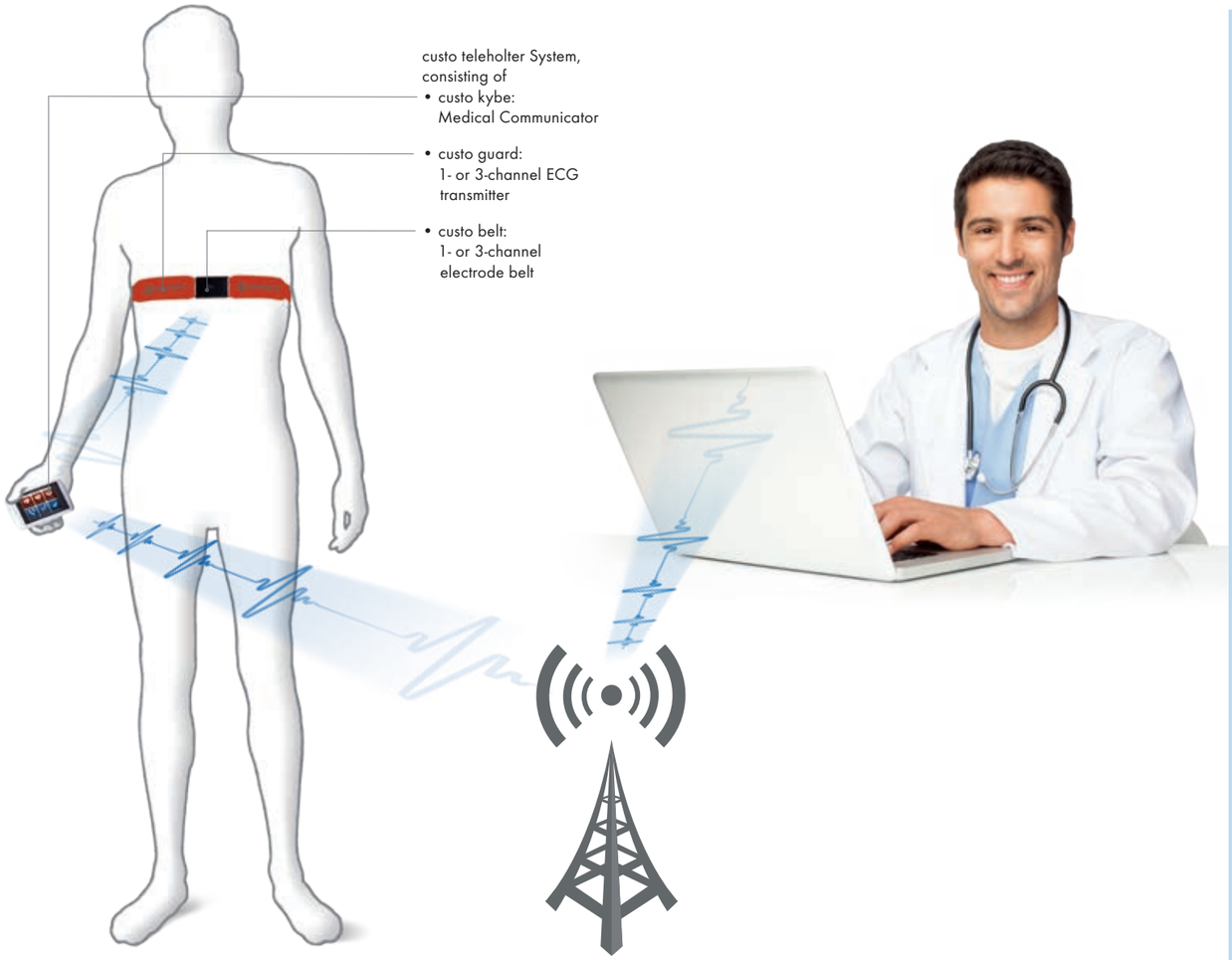
Telemonitoring

In Germany, there are about 8 million treated diabetics, 3 to 5 million people with pulmonary diseases and about 1.8 million patients with chronic heart failure. Moreover, the number of patients suffering from chronic illnesses is age-related and the number of cases will continue to increase as demographic transition advances. On the other hand, the number of those who are able to provide professional help is decreasing: physicians, nurses and therapists. Obviously, gaps in healthcare coverage are arising. They manifest themselves not only in terms of shortage of physicians in rural areas but also in terms of long waiting periods for specialist treatments.
The application of telemedicine is one means to keep the efficiency and quality of care of chronically ill people on today's high level or even to increase it.

One application area of telemedicine in which vital sign data are exchanged between patient and physician is telemonitoring. In telemonitoring, the physician and the patient are physically separated from each other during treatment and care for most of the time. However, they are linked with each other via an appropriate telematics infrastructure that complies with medical standards. The benefits for both patient and doctor are obvious:

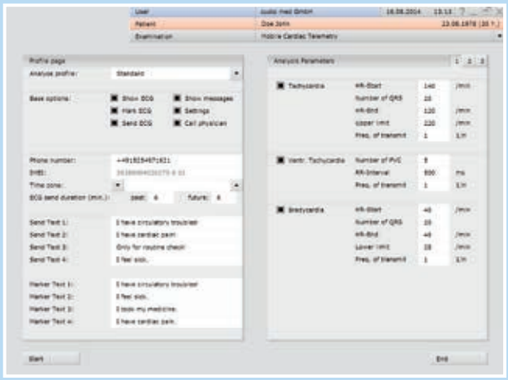
- Quality of treatment and quality management are increased
- Guideline-based treatment is supported
- Patient commitment regarding therapy and self-management are increased
- The patient's quality of life and safety are increased
- The number of urgent emergency cases is decreasing

Starting from our core competency, the recording, processing and visualisation of the ECG signal, we have developed the teleholter® custo kybe. custo kybe is able to store ECG data continuously over months. An analysing algorithm implemented in custo kybe detects arrhythmias and transmits these events to the physician's custo kybe center automatically. Data are transmitted via mobile telephony. custo kybe is designed as a multi-parametric acquisition system and beside the ECG, further sensors such as SpO2, blood glucose or blood pressure will be integrated shortly.
With custo kybe, the physician is able to cover the whole range of patient care – from the known and proven 24h long-term ECG examination (custo kybe as Holter monitor) to telemetric care of almost arbitrary duration (custo kybe as teleholter®). custo med remains true to the company's philosophy, in accordance with our customers and users:
We bring together patient and attending physician with safe and reliable diagnostic systems!



• custo teleholter analyses and saves a complete ECG in arbitrary length. Arrhythmias are automatically detected and transferred to the attending physician. Telephony and SMS functions as well as fully integrated software, flexible and adaptable to the needs of physician and patient, complete the capabilities of custo teleholter as a versatile and modern telematics device.

1 List of events



2 Configuration page

3 Request ECG

4 ECG online streaming

custo guard 1/3:
- Recording channels: 1/3
- Voltage supply: Lithium polymer battery with 105 mAh (approx. 1 hour charging time)
- Battery runtime approx. 2 days with 1 kHz sampling rate, approx. 60 days in standby mode
- Waterproof according to IP65 code
- Dimensions: approx. 70 * 42 * 12 mm (L * W * H)
- Weight: 27 g

custo kybe:
- Interfaces: USB 2.0, Micro USB, Micro SD card up to 64 GB
- Storage capacity 3-channel-ECG: 1 GB: 29 days, 8 GB: 232 days
- Voltage supply: Lithium polymer battery with 3800 mAh (approx. 2 hours charging time)
- Battery runtime: 24 hours minimum
- 3.5 inch resistive touch display
- Dimensions: approx. 135 * 70 * 23 mm (L * W * H)
- Weight: approx. 230 g

1 List of events
In the list of events all events of a patient are presented. These events are classified and can be freely edited. A difference is made between events detected automatically, those actively sent by the patient and ECG data requested by the doctor.

2 Configuration page
The custo kybe is configured via this page. The configuration parameters of custo kybe can be modified from the custo kybe center by remote control at any time.

3 Request ECG
As custo kybe continuously saves the ECG, previous ECG data can be requested selectively, precisely timed and in arbitrary length via this function.

4 ECG online streaming
With this function, custo kybe continuously transmits ECG in real-time which is being continuously displayed by the custo kybe center.

Cardiorespiratory Polysomnography

The prevalence of sleep-related respiratory disorders (SRRD) is approximately 3 - 4 % of the total population with a frequency peak being composed of male patients between 45 and 65 years.

The most frequent types of sleep-associated respiratory disorders are obstructive apnoea and hypopnoea. The Obstructive Sleep Apnoea Syndrome (OSAS) is characterised by repeated episodes of respiratory stops (apnoea) or reduced respiration (hypopnoea), caused by a total or partial occlusion of the upper respiratory tract. These symptoms are typically accompanied by decreasing blood oxygen level, compensatory breathing efforts and arousal from sleep at the end of an episode. The terminating arousals cause a fragmentation of sleep during the night, which often results in a considerable reduction of recuperative sleep.

The consequences are:
- Cardiovascular diseases caused by cardiac reaction
- Hypertension (approx. 50 – 70 % of OSAS patients!)
- Strokes
- Mild to excessive daytime sleepiness
- Reduced cognitive performance due to hypoxia

Although the OSA-syndrome with its serious consequences has been clinically known for decades, there is still an enormous number of undiagnosed patients needing medical treatment. In Germany alone this number is estimated to approx. 800,000 patients.

After an anamnesis with suspicion of OSAS there are only two possibilities for a physician to get a high-quality diagnosis:
- Admission to a sleep laboratory in hospital
- Ambulatory screening at the patient's home

Advantages of ambulatory screening (homecare) compared with polysomnographic recording in the sleep laboratory
- Recording in a familiar environment under usual conditions
- Minimisation of the "first-night" effect
- Multiday recording and follow-up checks
- Cost-effective alternative to sleep laboratory
- No long waiting periods

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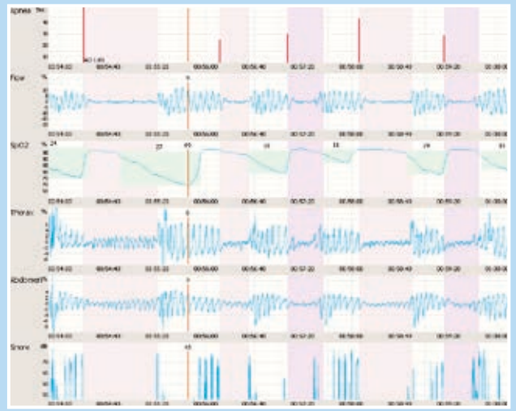
• The characteristic features of custo night 310 are its compact and ergonomic design, easy handling by lack of function keys as well as high wearing comfort. A complete apnoea diagnosis (basic diagnosis) is possible with the application of only a few sensors. Optionally, the system can be extended by additional sensors such as PLM or 1-channel-ECG.

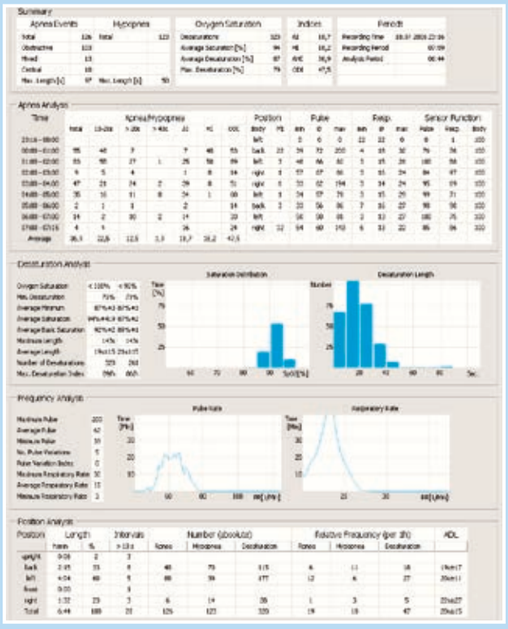
- Recording of respiration via patient-friendly triple thermistors (oral/nasal)
- Recording of snoring sound via an integrated microphone
- Recording of pulse oximetry
- Recording or heart rate
- Recording of body position (5 positions)
- Registration of abdominal and thoracic respiratory movements
- Measurement of mask pressure (with therapy follow-up)
- Recording and documentation of pulse wave
- Duration of recording: up to 7 nights
- Transmission time: approx. 40 seconds
- Voltage supply: 2 Mignon 1.5 Volt, type AA or 2 rechargeable batteries, Ni-MH, 1.2 Volt, min. 1500 mAh
- Dimensions: 110 * 62 * 28 mm (L * W * H)
- Weight: approx. 120 g

OPTIONAL:

- One-channel ECG
- PLM sensor (periodic leg movement)

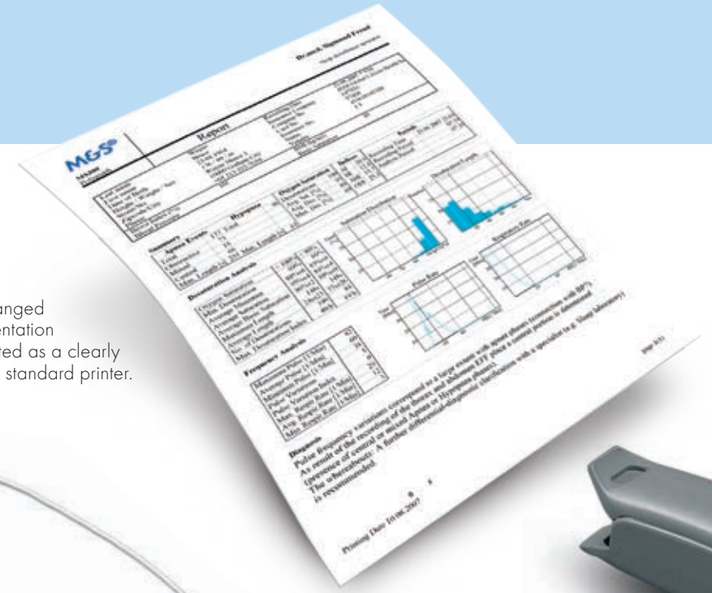


For validating the automatic detection of apnoea and hypopnoea phases, the physician can switch over to the editing mode with a mouse click. As an example, the chart shows the 5-minute section of a screening with a sequence of apnoea and hypopnoea phases. The physician can skip from one phase to the next one quickly. The order of trends and signals is freely configurable.



All analysis results are summarised in a table. Editable fields are prepared for apnoea analysis, desaturation analysis, frequency analysis and the list of events. In addition, the evaluation can be entered in another field.

All results can be arranged arbitrarily for documentation and they can be printed as a clearly arranged report on a standard printer.



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Cardiac Rehabilitation

More than one million people per year are rehabilitated in Germany, a large part of them being involved in ambulatory or stationary cardiac rehabilitation after cardiac and cardio-surgical treatment. Cardiac rehabilitation also has to comply with the standards of evidence- and guideline-based treatment, standards that have been valid in medicine for decades. Both in the stationary and in the ambulatory environment this requires a complete and fully integrated solution, collecting and documenting the data of treatment and care on-site. Among the different therapy modules applied in cardiac rehabilitation, endurance training on treadmills and ergometers still plays an important role, as well as training outside.

All these requirements are fully met by our hardware and software solutions from the custo cardio concept segment. We combine top flexibility with the advantages of uninterrupted ECG recording in real-time. In the stationary sector, cardiac monitoring can be performed of up to 32 patients simultaneously.

The high-quality ECG is recorded and entirely documented. The coach and the patient have the free choice, both in terms of training equipment and arrangement of the training programme. No matter if rotation or interval training, free training, inside or outside, each training session is completely documented and can be analysed after termination, individually or in comparison with the ones that have been performed so far. Thus improvements in training as well as the success of cardiac rehabilitation are visualized, immediately and easily.

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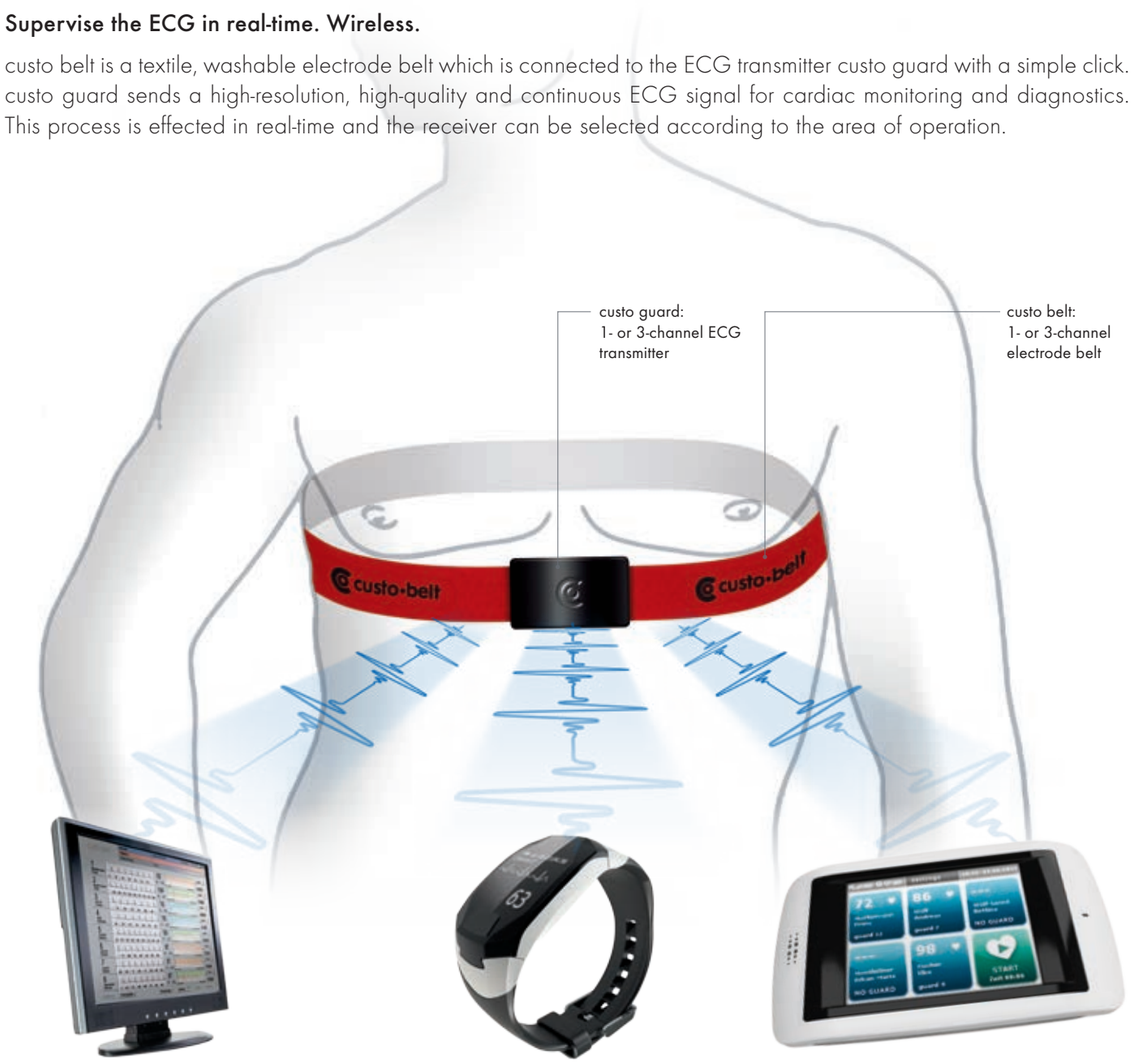
Supervise the ECG in real-time. Wireless.

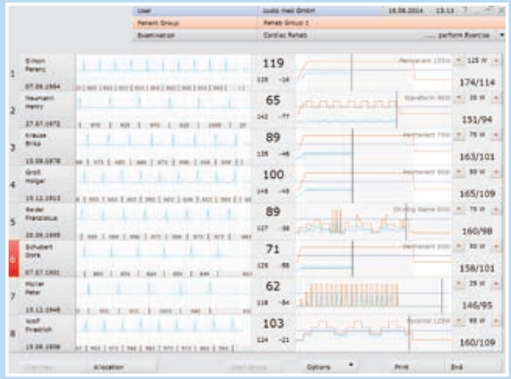
custo belt is a textile, washable electrode belt which is connected to the ECG transmitter custo guard with a simple click. custo guard sends a high-resolution, high-quality and continuous ECG signal for cardiac monitoring and diagnostics. This process is effected in real-time and the receiver can be selected according to the area of operation.



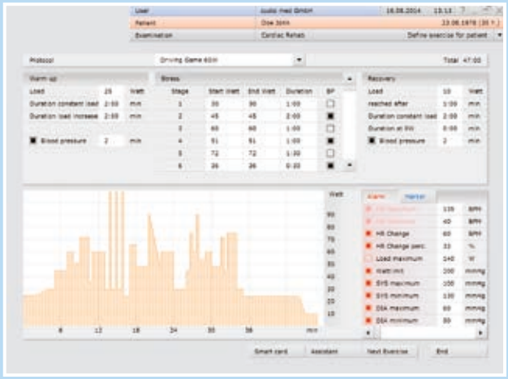
PC System
The classic stationary version:
8 training areas are displayed per monitor, with ECG and training profile. Up to 32 patients can be monitored simultaneously. The functions group start and stop allow comfortable process control. Subsequent start of additional patients during the current training is possible.

custo watch
The mobile indoor/outdoor single version: custo watch is a mobile ECG receiver in the form of a watch that continuously saves the ECG of the person who wears it. If desired, it displays the current heart rate and can be freely configured. After the watch has been detached, data are downloaded to the Rehab system via a docking station and saved.

custo kybe
The mobile indoor/outdoor group version: custo kybe is a mobile ECG receiver in the form of a smartphone which records ECG data of up to 5 patients simultaneously and also displays the individual ECG. All data are saved and available for later analysis at any time.



1 ECG monitoring



2 Definition of training programmes

3 Control of training

4 Therapy follow-up / Summary

1 ECG monitoring
Up to 8 patients per monitor. Freely combinable training machines such as ergometer, treadmill or cross trainer, independent of manufacturer. Training parameters can be freely set. Modification of load is possible at any time.

2 Definition of training programmes
Easy selection of training by means of already predefined sets. Individual adaptation to the current patient. Limit values can be set for alarm functions.

3 Control of training
Clearly arranged tab system in the open training area. Fast access bar for modifying the most important parameters as well as flow control. The complete ECG can be displayed and printed at any time.

4 Therapy follow-up / Summary
Clearly arranged display of incoming stress test ECG, summary of the performed rehab training units and final stress test. It is possible to change to the detailed view of the stress test or to the individual trainings.

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Profit from the free, manufacturer-independent choice of training equipment.
The cardio concept offers the therapist new possibilities of cardiac rehabilitation, from interval through rotational training up to comparative training methods. All data can be observed by means of real-time ECG via a central cardio concept monitor.

With this new state-of-the-art technology the therapist is free to select the optimum rehab method. The patient wears the recording device on the body during the whole rehab training. Thus the ECG recording is not bound to any special endurance machine. Consequently, the therapist has the free choice between ergometer, treadmill, cross trainer or floor exercise - everything is possible now.

All custo med training machines are equipped with Medical Blue Tooth, so that the recorded data are transferred to the therapist's central custo cardio concept monitor wirelessly. The therapist can observe the cardiovascular effects of each single training method in real-time and react immediately by adapting the training or choosing another training method.

Advantages:

- Wireless, adhesive-electrode-free and waterproof ECG module for direct application on the patient's body
- Reusable, textile and washable ECG belt
- Use of already existing training machines
- Individual training procedures on different endurance training machines
- Excellent ECG signal quality, even when exercising on a treadmill
- Up to 32 patients can be monitored simultaneously

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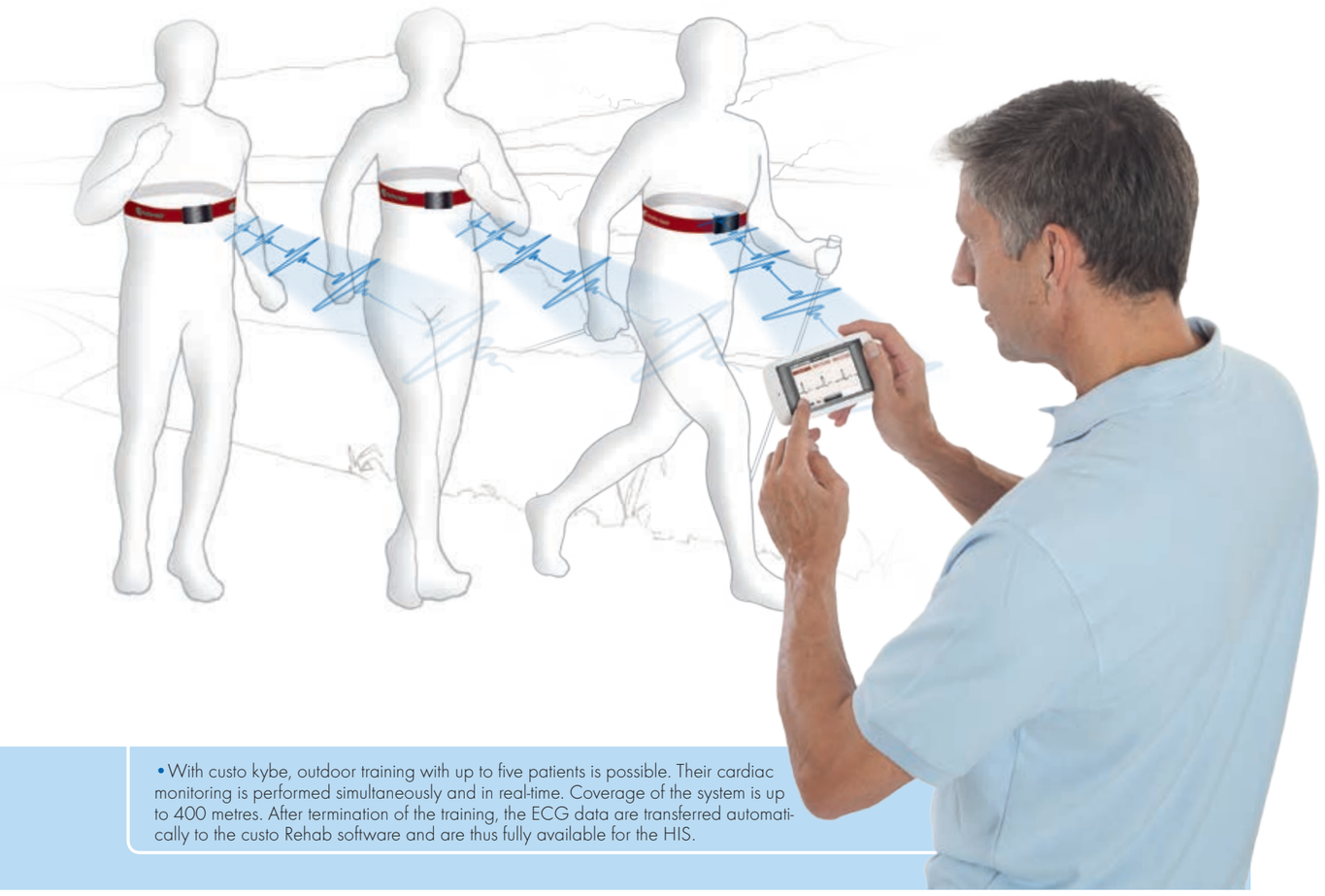

• With custo kybe, outdoor training with up to five patients is possible. Their cardiac monitoring is performed simultaneously and in real-time. Coverage of the system is up to 400 metres. After termination of the training, the ECG data are transferred automatically to the custo Rehab software and are thus fully available for the HIS.

custo guard 1/3:

- Recording channels: 1/3
- Voltage supply: Lithium polymer battery with 105 mAh (approx. 1 hour charging time)
- Battery runtime approx. 2 days with 1 kHz sampling rate, approx. 60 days in standby mode
- Waterproof according to IP65 code
- Dimensions: approx. 70 * 42 * 12 mm (L * W * H)
- Weight: 27 g

custo kybe:

- Interfaces: USB 2.0, Micro USB, Micro SD card up to 64 GB
- Storage capacity 3-channel-ECG: 1 GB: 29 days, 8 GB: 232 days
- Voltage supply: Lithium polymer battery with 3800 mAh (approx. 2 hours charging time)
- Battery runtime: 24 hours minimum
- 3.5 inch resistive touch display
- Dimensions: approx. 135 * 70 * 23 mm (L * W * H)
- Weight: approx. 230 g

Definition of training group

The therapist can create a training group of up to five patients per one custo kybe. In addition to patient data, the upper and lower limits of heart rate can be determined for each patient individually. Afterwards, the defined training group is imported into custo kybe from the PC via USB.

Beginning of training

All participants of the training group automatically connect themselves to custo kybe and custo guard continuously transmits the ECG. On the display of custo kybe each participant is presented with name and current heart rate. The therapist can start the training by pressing the start button.

Performance of training

After having activated the start button, custo kybe starts recording the ECG signals. In the overview display patient name and the corresponding heart rate are always shown. If the heart rate exceeds its upper limit or falls below its lower limit, an acoustic alarm signal will be issued and the patient concerned will be highlighted in red.

ECG display during the training

By clicking on the patient in question, it is possible to change from the overview page to the ECG display of this patient. The amplitude of the ECG is freely scalable.
With a click on the back button you can switch to the overview page.

Termination of training

In order to finish the training it is sufficient to click on the stop button. The recording is then terminated.

Evaluation of training

The stored ECG data from the training are transferred from custo kybe to the custo Rehab software via USB or SD card, where they can be handled by using the full range of Rehab software functions. After data download, custo kybe can be programmed for a new training group.

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custo med - distributor:

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Contact:
custo med GmbH
Leibnizstraße 7
85521 Ottobrunn
Germany

Phone: +49 89 71098 00
Fax: +49 89 71098 10
internet: www.customed.de
e-mail: info@customed.de