# Innovative system solutions Networked technologies in cardiopulmonary diagnostics































Since 1982, our brand has been well-known for networked system solutions in cardiopulmonary diagnostics. In cooperation with committed and competent sales and service partners we offer professional solutions taking account of your individual organisational requirements and IT structures. No matter if your installation is based on a stationary or mobile system, a single-user workstation or multi-site network solution, in a general practice or in a hospital – your modular custo med system will be a profitable investment for the future.

Our innovative solutions are developed by dedicated teams at our company headquarters in Ottobrunn near Munich. Numerous custo med users are served by reliable contact persons from authorized sales and service companies throughout Germany and in more than 40 countries.

Our collaboration with regional suppliers is strictly monitored, as is our company's quality management system, which gets recertified annually through audits.

Hans-Jörg Hoffmann, Managing Director

Users - Joy Clofferace

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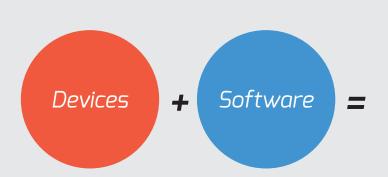
Find out more about custo med at **www.customed.de** and on our YouTube channel:



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# **Complete care with custo med**Clinical engineering and software from one source

The custo diagnostic software, combined with the custo med devices, is a central platform for all cardiopulmonary examinations in functional diagnostics.



### Diagnostic platform for

- Resting and Stress ECG
- Holter
- ABPM
- Spirometry
- Cardiac Rehabilitation

## Our devices for cardiovascular diagnostics: Clinical engineering made in Germany

Our devices cover any area of cardiopulmonary diagnostics in daily GP or hospital routine. Due to our long-standing experience in the development of medical technology and the production on-site in Germany, we can offer the best quality.



#### Resting ECG / Stress ECG

custo cardio 300 custo cardio 400 custo cardio 400 accu

#### Holter

custo guard holter

#### ABPM

custo screen 300 custo screen 310

#### Holter + ABPM

custo holter ABPM (combined recorder)

#### **Spirometry**

custo spiro mobile

#### Cardiac Rehabilitation

custo guard



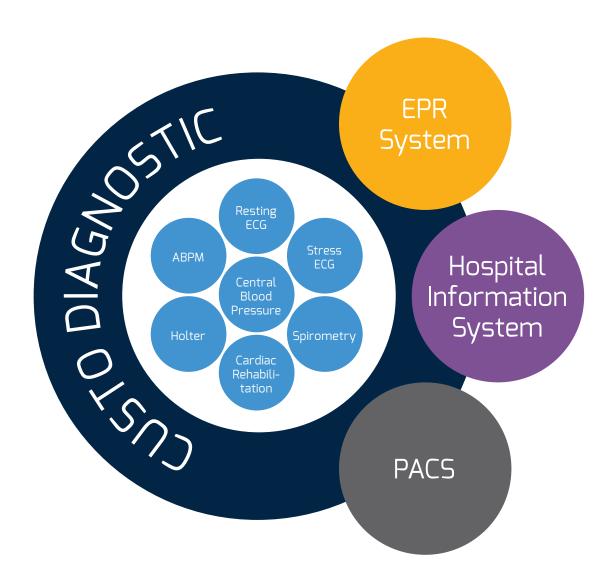




## Our software for cardiovascular diagnostics: custo diagnostic und custo diagnostic clinical

Our software integrates the complete cardiopulmonary functional diagnostics in one consistent and modular user interface and allows you to work flexibly in all application areas.

From individual workstations to multi-site solutions – whether in a general practice or a hospital network: thanks to our modular structure and various expansion stages, we offer the right solution for every user.







# Cardiopulmonary diagnostics for the GP

custo diagnostic for general practitioners integrates the entire cardiopulmonary functional diagnostics in one consistent and modular user interface. custo diagnostic enables unimpeded data exchange with your EPR system by means of a proper GDT interface.



## Your requirements in the general practice

To ensure efficient and trouble-free daily work in the general practice, a number of factors have to be considered. At custo med, we understand what you need to obtain flawless results in cardiopulmonary functional diagnostics.

> "How can I give my patients the best possible treatment?"

As a **physician**, I pay attention to:

- Efficient task management
- Individualisation of personal job management
- · Paperless working with complete diagnostics
- Structuring of report creation

"Where can I adapt practice workflows and save resources?"

As a **GP manager**, I pay attention to:

- Optimisation of GP workflows
- Patient management
- Easy communication within the practice
- Data security
- A cost-effective **GP** management

"How can I optimise mu workflow and save time?"



- · Support of job management
- · Saving of time
- · Mobility and flexibility of terminal equipment





"How do we connect our EPR system as securely and easily as possible?"

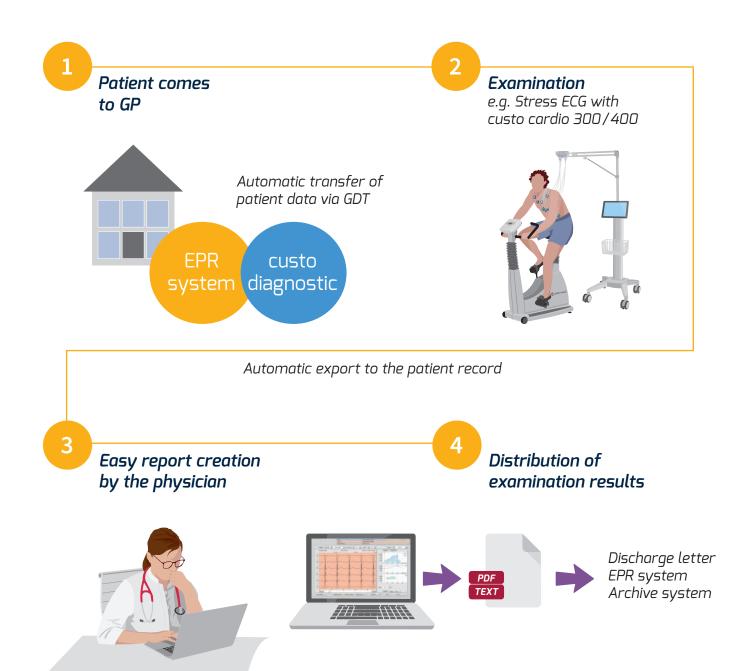
As a technical supervisor I focus on:

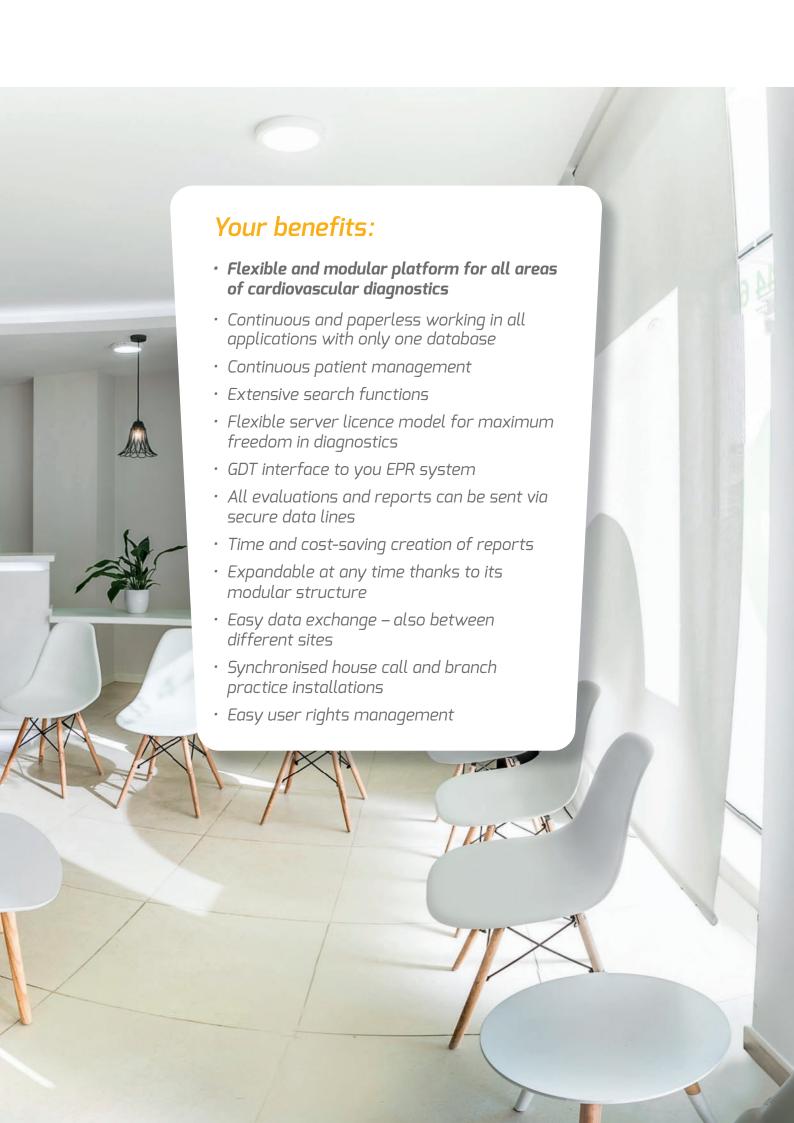
- Network-independent processes
- · Integration of third-party products
- · Easy maintenance
- · Standardised interfaces

# custo diagnostic

## Maximum freedom and safe diagnostics with efficient workflows

You can start your custo med examination from your EPR system with only one click. The sophisticated data transfer is made via a simple working interface which can be individually configured if required. PDF documents can be easily and quickly exported via GDT. In addition, the examination results can be called up immediately on all workstations in your general practice.





# Women's hearts beat differently!

Gender differences in cardiopulmonary diagnostics









## Just a small difference?

## Gender Medicine – optimized medicine for everyone!

It is well known that women and men show different symptoms of coronary heart disease. In the past, medical knowledge and its implementation were exclusively focused on men. Nowadays, it is scientifically accepted that men and women show different results with the same therapy. Therefore, it is necessary to make gender-specific distinctions already in diagnostics. For this reason, custo med has integrated this classification into its various modules.

### Gender Medicine in custo diagnostic

#### **Resting ECG**

- QT analysis
- · Interpretation takes into account gender differences

#### **Stress ECG**

- · Limit values are genderspecific configurable
- Calculation of the target load (also age adjusted)

#### Holter

 Gender-specific HRV differences in vegetative diagnostics (also age adjusted)

#### **ABPM**

- · Limit values are genderspecific configurable
- Risk factors adjusted: For men > 55 For woman > 65

#### **Central Blood Pressure**

· Augmentation index, Augmentation pressure, pulse wave and PWV are gender-specific determined

#### Spirometry

- Limit values are genderspecific configurable
- All target values are gender-specific

Resting- & Stress-ECG

Holter

**ABPM** 

Spirometry

Cardiac Rehab



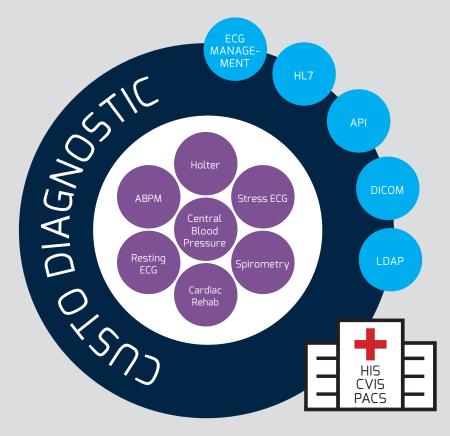




# IT solutions and clinical engineering from one source

Today, everyday routine in a hospital is mainly about seamless integration, safe and fast workflows as well as user-optimised solutions. With our diagnostic platform "custo diag-nostic clinical", we provide a modular solution for cardiovascular diagnostics. You receive our service, hardware and software from one single source – for more efficient daily work.

### The custo med functional diagnostics at a glance:



## Your requirements in hospital

In order to get a perfect network in hospitals, many factors have to be considered. At custo med, we understand what you need to obtain flawless cardiopulmonary diagnostics.

"Which benefits do I get from digitalisation in cardiovascular diagnostics?"

For me as a **manager or consultant** in a hospital it is primarily the following topics that matter:

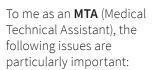
- · Process optimisation
- · Cost transparency
- Future-proof platform solutions
- Data security
- Integration of third-party products

"How can I deliver my diagnostic reports quickly and securely?"

As a **physician** I pay attention to:

- · Efficient task management
- Individualisation of personal job management
- Paperless working with complete diagnostics
- Structuring of report creation

"How can I optimise my workflow and save time?"



- Support of job management
- Saving of time
- Mobility and flexibility of terminal equipment



"How do we link our clinical engineering with IT"

As a **technical supervisor** I attach much importance to:

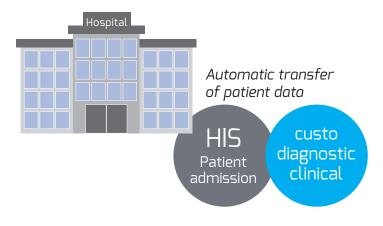
- Network-independent processes
- Integration of third-party products
- · Easy maintenance
- Standardised interfaces

## For more efficiency and safety – our digital path in cardiovascular diagnostics

ADT | ORM | DICOM 

Creation of patient and examination request

Carrying out the examination

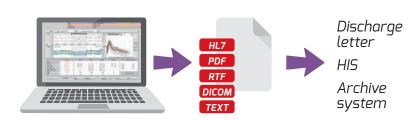


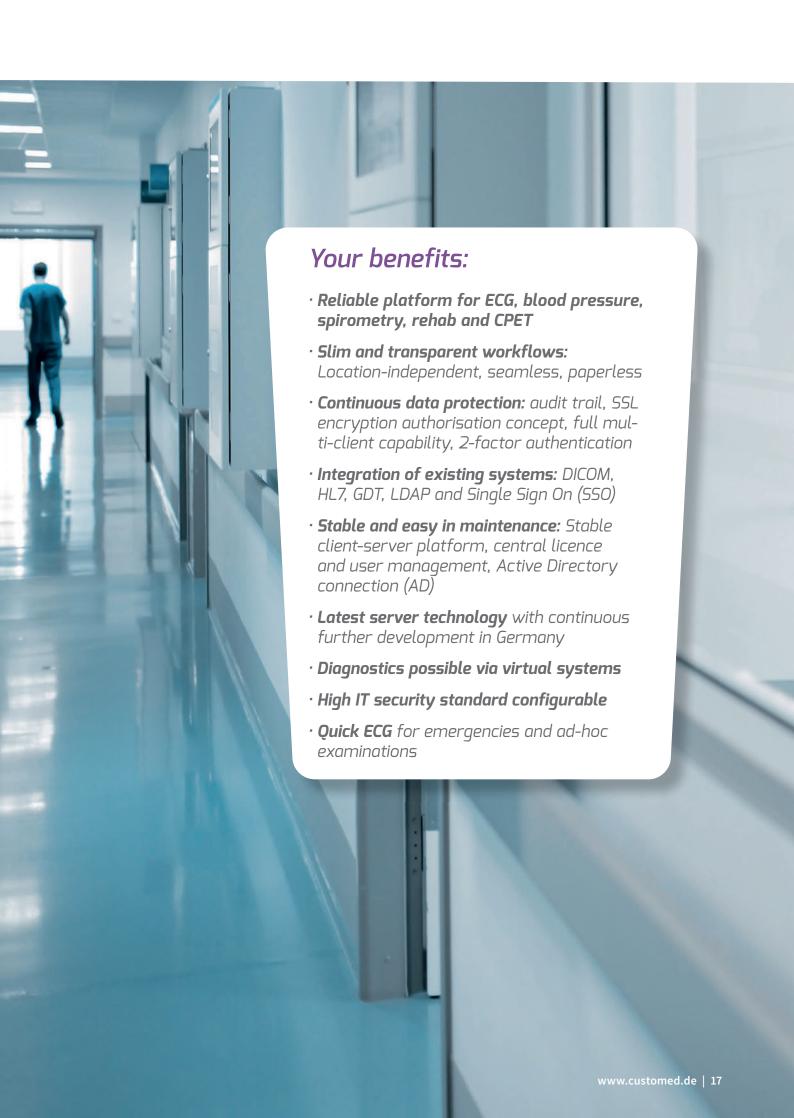


| SAFE:
| Clear, paperless flows for all examinations
| INTEGRATED:
| Seamless workflows via DICOM, ADT, ORM
| CENTRALISED:
| Fully synchronised workflows

Distribution of examination results















## custo diagnostic clinical:

Your diagnostic platform for the future!

### Safe

- Stable client-server platform
- Audit trail/activity logging
- Password policy
- Data access only after secure authentication
- User based access rights
- Anonymisation function in case of support
- Multi-client capability for logical data separation
- · Built-in integrity check

## Integrated

- LDAP/AD connection for continuous user management
- · Integration of existing systems with HL7, DICOM, **GDT** platform
- Completely digital workflows
- Lean and transparent workflows
- · Simple data exchange, even between different locations
- Satellite system decentralised ECG recording possible

## **Centralised**

- New system and database architecture: fast implementation in any IT environment
- Central update management: fast deployment of new versions
- Central licence management: licences are available where they are needed
- Centralised user rights management
- · Centralised and secure data storage



custo clinical light: Our entry-level solution for connecting to your HIS: Even with just a few stand-alone systems, you can realise the benefits of integrated paperless working. Get in touch with us!

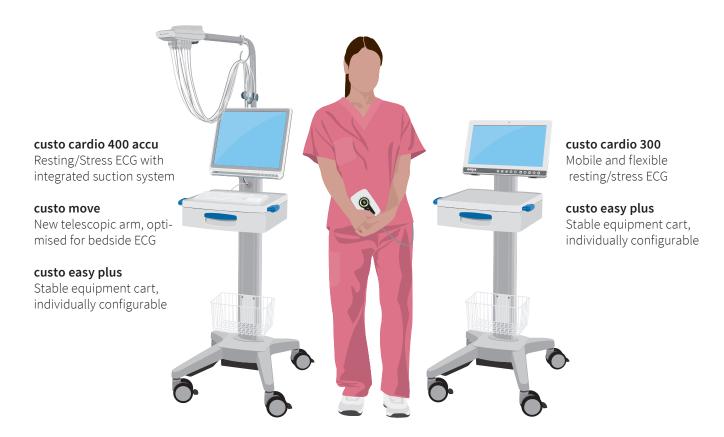
We would be happy to work with you to develop your customised custo clinic solution. You can reach our healthcare IT team at: clinical@customed.de



## Mobile ECG solutions

"Bring the ECG to the patient, not the patient to the ECG"

Paperless working means more than doing without a printer. Due to the intelligent combination of smart ECG modules and modern IT components you create flexible, adaptable and low-maintenance ECG solutions for all requirements. From the fully-fledged ECG system with suction unit and rechargeable battery supply to the slim ECG with touch control.





## custo clean

## Hygienic and safe – the disposable bags for your custo med devices

Hygiene for medical staff and patients as well as device protection against contamination and humidity have already become more important in the past years. Our product line "custo clean" consists of disposable bags for your custo med devices in order to optimise hygiene. Thanks to the internal adhesive closure, the devices are nearly completely surrounded and there is a threefold protection: protection for you, protection for your patient and protection for your devices.

#### Your benefits:

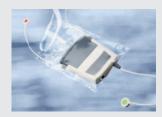
- · Protects patients and medical staff
- · Extends lifetime of the devices
- Easy to handle
- · Time-saving preparation of devices
- · 100 % recyclable

custo clean WA3 for custo guard holter with custo wing





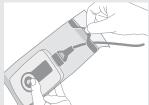
custo clean FL for custo flash 500/510/510V/501





custo clean CR3 for custo cardio 300





custo clean CA3/CA4 for ECG cable guard 3/4





custo clean SC for custo screen 300/310





custo clean CR3 ergo for custo cardio 300 in stress testing









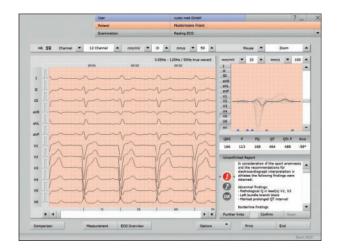
# Resting and Stress ECG

To meet the increased requirements for modern ECG diagnostics, we offer the two 12-channel resting and stress ECG systems custo cardio 300 and custo cardio 400 which will leave no wish unfulfilled. Thanks to comprehensive accessories and modular combination variants, both systems enable the user to work comfortably in the most diverse working environments.

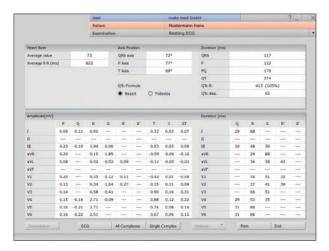


# Resting ECG features in the custo diagnostic software

- The complete ECG at a glance! In the ECG overview, the ECG is shown in 12-channel mode over the total recording period. This view allows to set and display amplitude, speed and channel selection individually, so that all details of each lead can be seen.
- The **tabular view of measured values** provides you with a comprehensive overview of all determined values such as axis position, times and amplitude values of each measurement point. All this is presented well-arranged on one screen page.
- The **view of the single beat analysis** is as much part of the module as the **view of summary complexes** and the option of recording a rhythm stripe.
- The area to be analysed is automatically adjustable or freely selectable.
- The **evaluation comparison** allows to compare two evaluations of a patient in detail and with only one mouse click.
- The **automatic ECG interpretation** offers many different options, including a paediatric interpretation.
- The module offers a **sports ECG** for analysing competitive athletes.
- Comprehensive measured value tables support the **automatic measurement and interpretation**.
- The **automatic proposal with text modules to be created individually** is an efficient means for generating precise and significant report texts in a short time.
- The **printout** summarises all results and the proposal on one page, clearly arranged.



Sport ECG as an option



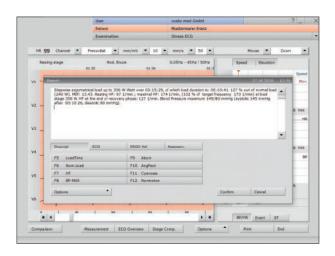
Tabular view of all measured values

## Stress ECG features in the custo diagnostic software

- In the stress test overview, all the data and the recorded 12-channel ECG are shown well-arranged on one screen page. Exactly as in the resting ECG, all described functions are available here as well.
- The automatic proposal with text modules to be created individually is an efficient means for generating precise and significant report texts in a short time.
- The view of the single beat analysis is as much part of the module as the view of summary complexes which are saved in all load steps.
- Control of treadmills, recumbent and reclining ergometers. With an integrated interface, this is even done fully-automatically.
- The module offers predefined standard profiles with the option of configuring them freely. The user can intervene in the load profile manually, even during a current stress test.
- In addition to the ECG lead, the measured values of blood pressure, SpO<sub>2</sub> and lactate can be automatically recorded and displayed as a trend..
- Comprehensive measured value tables support the automatic measurement and interpretation.
- Beside the **detailed documentation** of the stress ECG on the monitor, the module has got **versatile** messaging options with acoustic or visual signals.
- The ST segments are continuously measured and can be displayed with the trend view of all 12 channels incl. reference view and graphics.
- The **printout** summarises all results and the proposal on one page, clearly arranged.



Clear total view of all important values



The automatic proposal

## custo cardio 300 12-channel resting and stress ECG of the future

custo cardio 300 is our 12-channel resting and stress ECG for mobile use. Due to the wireless operation and the possibility to work on several workstations with one device, maximum flexibility is guaranteed. custo cardio 300 is the perfect solution for your resting and stress ECG, not least thanks to its modular operability (various patient cables, connection to suction unit, etc.).









#### Your benefits

- · Allows wireless and mobile working
- · Fast and clearly structured PC ECG due to perfect data transfer
- · Maximum flexibility due to exchangeable patient cables and workstations
- · Connectable to a suction system
- · Automatic 10-second ECG
- · Check of electrode quality at a glance
- · Start/Stop button on the device or on the PC
- · Approx. 10 hours battery runtime
- · Easy and inexpensive extension to CPET is possible
- · Complete remote control is possible
- · Easy and fast disinfection
- · Easy, patient-related use due to hygienically optimised capacitive key
- USB or BT (with accu or battery)



## custo clean CR3 and CR3 ergo Hygienic and safe – the disposable bag for custo cardio 300

- · Protects patients and medical staff
- Extends lifetime of the devices
- · Easy to handle
- · Time-saving preparation of devices
- · 100 % recyclable







## custo cardio 400 accu

# Autonomous 12-channel resting and stress ECG with integrated suction system

custo cardio 400 accu is the new, battery-operated 12-channel resting and stress ECG with integrated suction unit. It can be wirelessly integrated into your WiFi network and is thus independent of the conditions on site. Due to the exchangeable, reusable suction electrodes, a hygienic and sustainable application is guaranteed.

#### Your benefits:

- Certificate of hygiene of the German Society for Hospital Hygiene
- · Perfect suction capacity in six steps
- · Stable and fast data transfer
- · Coloured view of the different modes
- No room dependency, can thus be applied with full flexibility and mobility
- · More than 100 resting ECGs with one battery charge
- · Reusable electrodes\*
- custo move telescopic arm\*\*

#### Accessories

- Reusable suction electrodes\* in various designs (standard, hair und small)
- Exchangeable suction lines
- \*\* The robust custo move telescopic arm, designed for mobile use, completes the system and is easy-to-handle and hygienically optimised due to hidden cables



## custo cardio 400

## 12-channel resting and stress ECG with integrated suction system

custo cardio 400 is our resting and stress ECG with suction system in one device. It sets new standards in functionality, operability and hygiene. After intensive testing, custo cardio 400 has been awarded with the certificate of the German Society for Hospital Hygiene (just like custo cardio 200). By means of exchangeable, reusable suction electrodes a totally hygienic and sustainable application is guaranteed.

#### Your benefits:

- · Hygiene certificate of the German Society for Hospital Hygiene
- · Suction capacity in six steps (0 280 mbar)
- · Perfect data transfer via USB and BT
- · Coloured view of the different modes

#### \* Reusable electrodes

- · Gentle application due to adapted suction pressure
- · Electrodes and suction lines can be easily exchanged
- · Cleaning of suction lines by automatic blowing after each examination

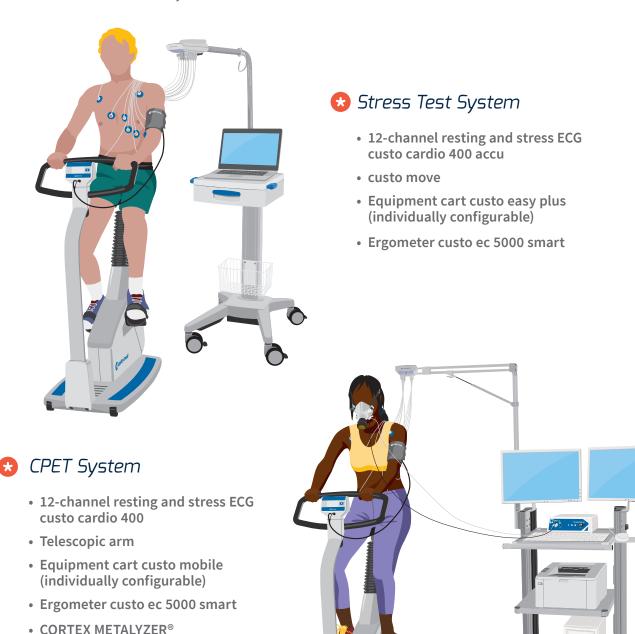
#### Accessories

- · Reusable suction electrodes in various designs
- Exchangeable suction lines
- Different telescopic arms for use on the equipment cart or for wall mounting

## ECG solutions on-site Resting and stress systems

Paperless working means more than doing without a printer. Due to the intelligent combination of smart ECG modules and modern IT components you create flexible, adaptable and low-maintenance ECG solutions for all requirements. From the fully-fledged ECG system with suction unit and rechargeable battery supply to the slim device with touch control.

The equipment of an ECG system is always individual. Here, we present a number of reasonable combinations. Please contact your custo med dealer for details and individual solutions.









## Treadmill System

- 12-channel resting and stress ECG custo cardio 300
- Equipment cart custo easy plus (individually configurable)
- Treadmill





### Mobile ECG 300/400

• 12-channel resting and stress ECG custo cardio 300

or

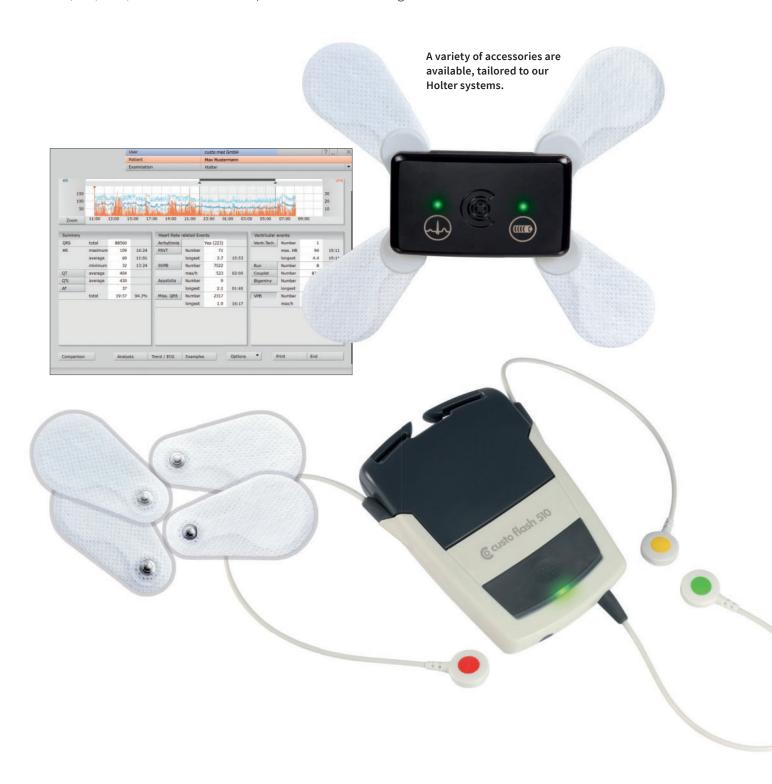
- 12-channel resting and stress ECG custo cardio 400 accu with telescopic arm custo move
- Equipment cart custo easy plus (individually configurable)





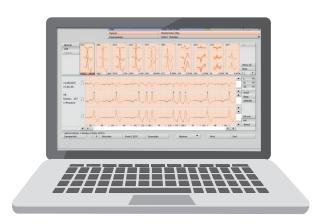
# Holter

Cardiovascular diseases are the most frequent cause of death in Germany. Patients particularly at risk are those who have already had a myocardial infarction. The earliest possible detection of a patient at risk is essential to start suitable therapies. With our two Holter systems custo guard holter and custo flash 500/510/510V/501 we have created perfect solutions for diagnostics.



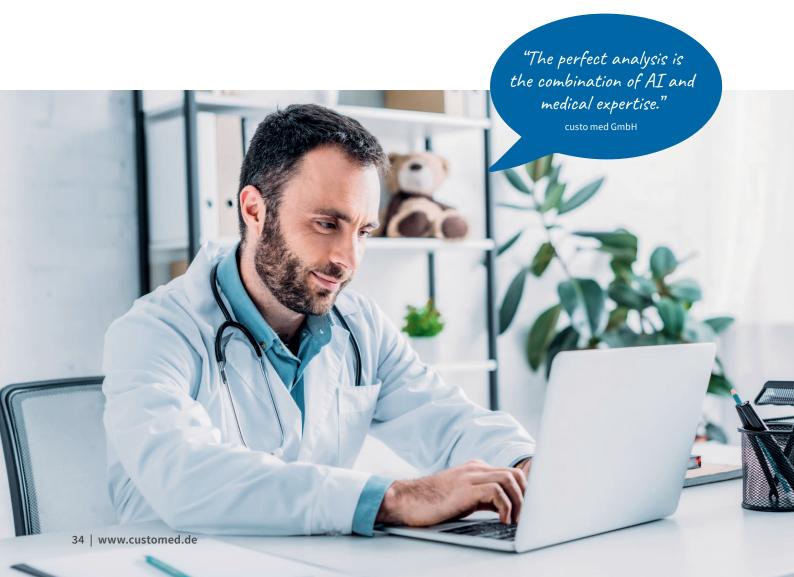
# **NEW: The most intelligent Holter analysis**Deep learning in ECG diagnostics

Electrocardiography has been an established and indispensable diagnostic procedure for over 100 years. The limitations of traditional algorithm-based Holter ECG evaluation can be overcome with the help of deep learning. custo diagnostic 5.9 provides you with this new technology for almost perfect analysis of the Holter ECG.



#### Your benefits

- Save time and increase efficiency during evaluation
- The most accurate Holter ECG algorithm currently validated on the market
- State-of-the-art technology
- Future-proof due to continuous further development
- More safety in diagnostics





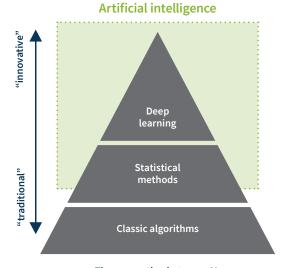




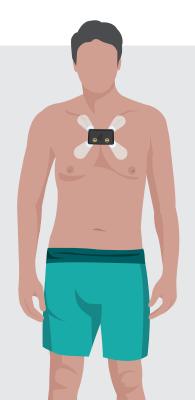
### Deep learning in custo diagnostic

- · The specifically validated "Convolutional Neural Network" replaces limited algorithms and achieves a sensitivity / specificity for QRS and PVC detection of over 99 / 97 %.
- · The robust, efficient and highly precise neural network detects relevant QRS or PVC complexes even in noisy ECG data.
- · By combining state-of-the-art machine learning approaches, the complexity of ECG signal processing can be continuously improved in the future.
- · Validation study\* according to MDR using standardized and own databases (MIT, AHA, NST, CST).

<sup>\*</sup> Kraft, D.; Bieber, G.; Jokisch, P.; Rumm, P. End-to-End Premature Ventricular Contraction Detection Using Deep Neural Networks. Sensors 2023, 23, 8573. https://doi.org/10.3390/s23208573



The connection between AI, machine learning and algorithms



### PVC detection algorithms in comparison

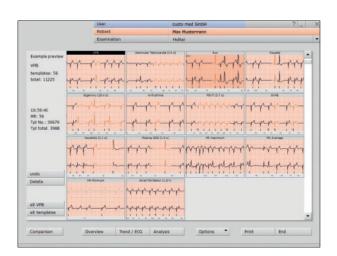
Algorithm	Database	Sensitivity	Specificity
Kraft et al*	MIT-11	99,1 %	97,6 %
de Chazal et al	MIT-11	77,5 %	90,6 %
Jiang and Kong	MIT-11	94,3 %	95,8 %
Ince et al	MIT-11	90,3 %	92,2 %
Kiranyaz et al	MIT-11	95,9 %	96,2 %
Zhang et al	MIT-11	97,6 %	97,6 %
Liu et al	MIT-11	91,6 %	95,6 %

# Holter features in the custo diagnostic software

- Directly after data download from the recorder and analysis of the saved ECG, the **summary of the Holter recording is available as an overview.** Here, all pathological events are shown, indicating occurrence and maximum frequency.
- The **trend view** gives an **overview of all events in the examination period** in an interactive table. Each event can be selected with a mouse click and be shown in the ECG trend.
- The **template view** provides a quick overview of all beat types (normal, ventricular, pacemaker beat).
- In the **example view** all events are displayed. When an example type is double-clicked, all single examples of the selected arrhythmia are shown.
- The **total ECG** gives a good overview in freely selectable sizes (from 30 minutes to 30 seconds per page).
- In addition to the number of **spikes and the pacemaker width**, the **pacemaker page** shows a number of useful parameters (pulse width, A, V trigger, etc.).
- All **analysis parameters** are based on the latest studies. However, they can be **adjusted according to one's needs if required.**
- The **evaluation comparison** enables the detailed comparison of two evaluations of a patient with only one mouse-click.
- With the **report manager**, you can create significant reports in a very short time. The **export elements** and **text modules** are very helpful here.
- The **printout** summarises all important aspects (also self-configured ones) and proposals in a clear overview.



Clearly arranged total view of all the important values

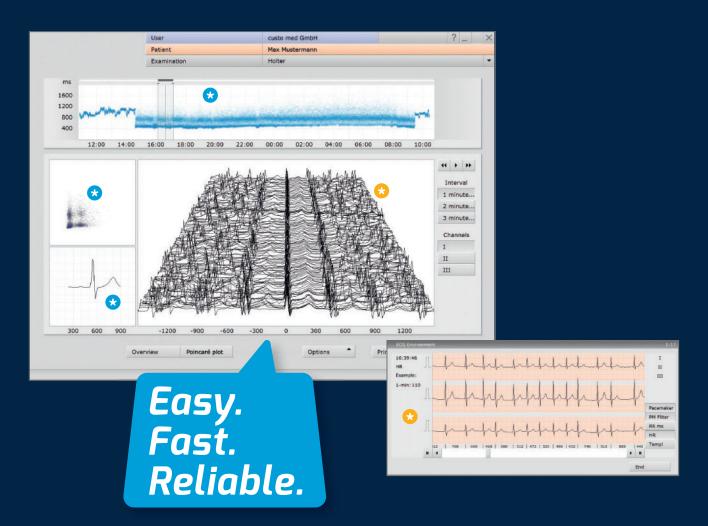


Exemplary overview of all events



## custo AF Diagnostics:

## Detect Atrial Fibrillation at a Glance!



### Identification

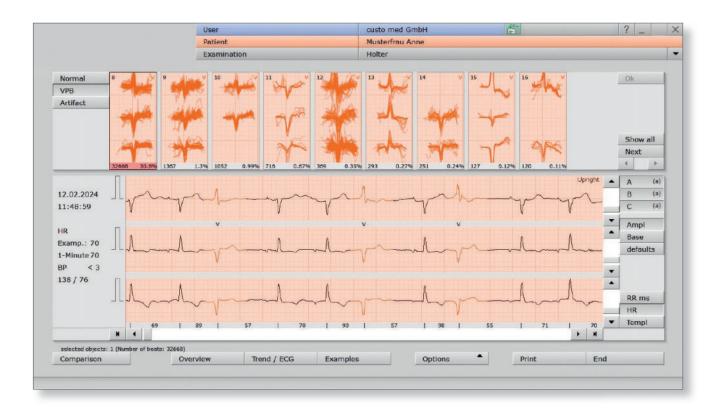
- which may deviate from sinus rhythm can be well identified.
- The Poincaré plot shows, if there are cardiac arrhythmias or atrial fibrillation.
- The summation complex allows visualisation of whether a P-wave is existent or not.

### Verification

- In the mountain view ECG, the beginning and end of a paroxysmal fibrillation episode can be simply and quickly recognized.
- The original ECG allows a definitive evaluation. Now unclear and uncertain diagnoses with respect to atrial fibrillation belong to the past.

### Template analysis

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



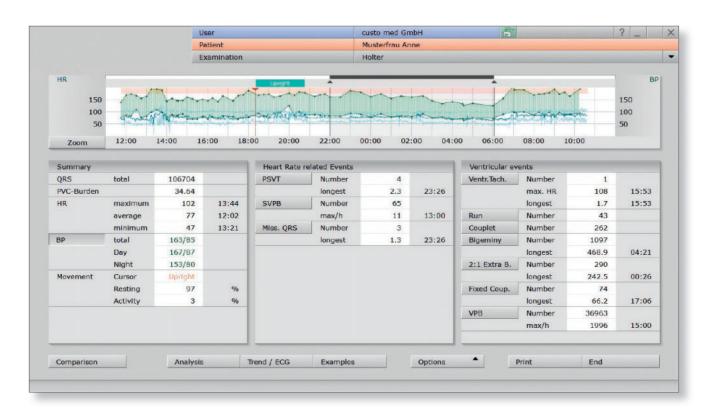
## ANS Diagnostics – the modern form of HRV analysis

With ANS Diagnostics, stress burden and sleep quality can be identified at a glance. The chrono-cardiogram enables an objective view of sleep quality. With the sympathovagal quotient, presented in red and blue, it is possible to evaluate rapidly if a stress situation is actually given.

The target values are from the database of the Human Research Institute, Weiz (Direction: Univ. Prof. Dr. Maximilian Moser). Therefore, a reliable group comparison as well as a classification of the patient according to age and gender is possible.

### ABPM and Holter: custo holter ABPM

In the simultaneous recording of Holter and ABPM, the values are shown in compact and clearly structured format so that they can be seen at a glance. It is possible to change to detailed views and analysing functions at any time.





#### Normal blood pressure

Example of a Holter ECG + ABPM recording: 32-year-old man, good regulatory capacity



#### Increased blood pressure

Example of a Holter ECG + ABPM recording: 39-year-old man, increased blood pressure due to stress

# **custo guard holter with custo wing**Modern Holter with novel patch electrodes

custo guard holter is our modern Holter ECG recorder that combines the benefits of both long-standing experience and continuous development. It excels in high patient comfort, is compact and lightweight, and comes without any disturbing cables or belts. With three channels, motion and pacemaker detection as well as an almost unlimited recording time of several months, the custo guard holter is the perfect solution for an excellent long-term ECG.









### Your benefits:

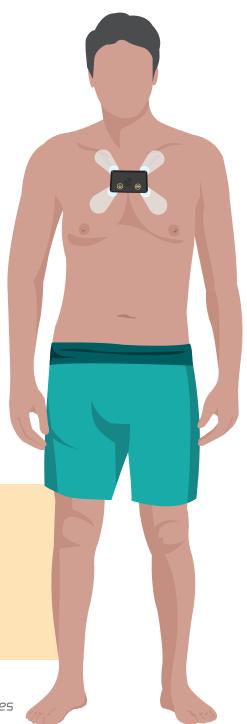
- · 3 channels with two independent leads
- · Completely wireless and perfect for hygienic application
- · Optimum recording quality with the custo wing electrode
- · Fast and stable device communication and data transfer
- · Short battery charge times
- · Pacemaker detection
- · Position and motion detection
- · Check for correct application through PC monitoring
- · Bluetooth Low Energy for mobile applications
- · LED status display for charge status and HR detection
- · Protection class IP65: perfect for disinfection
- Very long recording time (several months)
- · Running time up to 7 days with only one battery
- · Very small and lightweight with only 30 g
- · Docking station custo base with one or six spots for device communication and as charging station

#### Various electrode applications are possible:

- · Special disposable electrode custo wing: Artefact reduction and signal optimisation due to decentral connections and fully covered adhesive surface – material made of breathable nonwoven fabric
- ECG cable quard 3 and ECG cable quard 4
- · custo belt 3

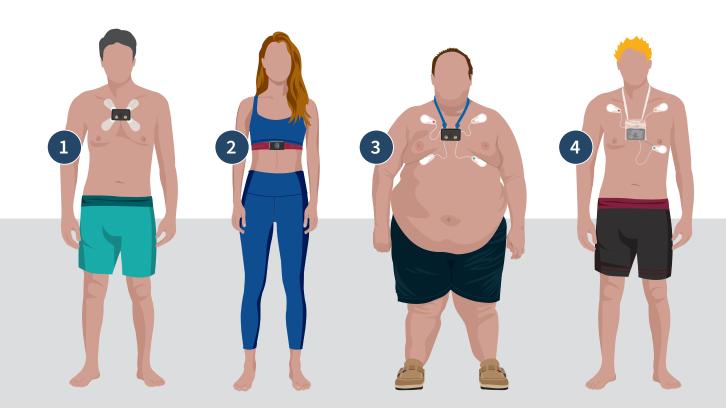
#### Intelligent interface (quard holter viewer) in custo diagnostic

- · Display for recording stand-by mode and particular device states
- · Various configurations and recording modes are possible



## Types of application custo guard holter The perfect Holter ECG for every patient

For reliable and safe diagnostics as well as maximum wearing comfort, there are four different types of application for the custo guard holter. Depending on the patient's anatomy, they have their advantages.





## custo quard holter with custo wing

- · Perfectly suited for adults of normal weight, children and toddlers
- · First-class ECG quality due to movable patch electrodes with decentralized lead
- High wearing comfort
- · Three ECG channels
- · Can be easily combined with the hygiene bag custo clean WA3
- · Perfectly adaptable to the individual anatomy of the patient
- · Without disturbing cables, can thus be freely positioned



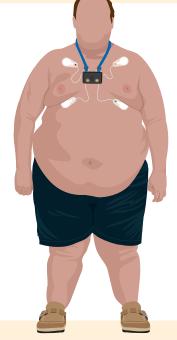


- custo guard holter with custo belt 3
  - · Special belt technology for ECG recording with high wearing comfort
  - · Three ECG channels
  - · Completely without cables or adhesive electrodes
  - · Can be perfectly taken off and put on by yourself
  - · Reusable and machine washable with certificate of biocompatibility
  - Extension is possible with custo belt extender
  - · Ideal for a wearing time of more than three days

## 3 custo quard holter with ECG cable quard 4

- · Perfectly suited for heavily overweight adults and patients with special anatomy
- · Three ECG channels
- · Flexible positioning due to four adhesive electrodes (can also be additionally fixed with a fifth electrode)
- · Can be easily combined with the hygiene bag custo clean CA4





## 4 custo guard holter with ECG cable guard 3

- · Perfectly suited for reasonably priced ECG measurement
- · Can be easily combined with the hygiene bag custo clean CA3
  - · Analogous to the custo flash 5xx family
  - Three ECG channels
  - · Can be additionally fixed with a fourth
  - · Also available with longer cables, to carry out measurements on babies





## custo flash 500 | 510 | 510V

# Classic Holter ECG recorder with 7 days of recording time

custo flash 500/510/510V is our classic Holter ECG recorder with three channels and integrated ECG cables for continuous ECG recording up to seven days without battery change. In line with this, there are different electrodes to provide optimum ECG signal quality and best skin compatibility. The recorder can be applied in just a few steps and allows fast and safe routines for the practice staff and the patients. 1-2-3 – ready!

### Your benefits:

- · Robust construction for long lifetime
- Easy to disinfect
- Low operating costs and long lifetime: record 7 x 24 hours with only one battery cycle
- · Short cables for artefact-free recording
- · Skin-friendly adhesive electrodes
- · Slim design and low weight for comfortable wearing with the neck belt
- · Protected position of memory card
- custo flash 500/510V with integrated pacemaker detection
- · custo flash 510V for ANS diagnostics

#### Accessories

- Neck and chest belt
- Various bags
- Adhesive electrodes custo wing and custo sensive
- Disposable bags custo clean FL
- Card reader
- Exchangeable battery
- Charger



## custo flash 501

## Holter ECG recorder for evaluation centres and multi-user systems

custo flash 501 is our easy and robust Holter ECG recorder for multi-user evaluation centres. In line with this, we offer the custo wing or custo sensive self-adhesive electrodes for optimum ECG signal quality and best skin compatibility. The recorder can be applied in just a few steps and allows fast and safe routines for the practice team and the patients.

#### Your benefits:

- · Easy, safe data transfer
- · Manual start without software
- · Robust design for long lifetime
- Easy to disinfect
- · Low operating costs and long lifetime
- · Short cables for artefact-free recording
- · Skin-friendly adhesive electrodes
- · Slim design and low weight for comfortable wearing with the neck belt
- · Protected position of memory card

#### Accessories

- Neck and chest belt
- Various bags
- · Adhesive electrodes custo wing and custo sensive
- Disposable bags custo clean FL
- · Card reader
- Exchangeable battery
- Charger



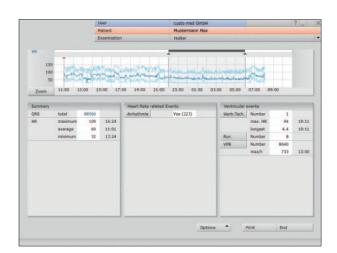
## custo holter online

## Multi-user diagnostic service provider: ways for senders

If there is low demand for Holter examinations, it is recommended to participate in multi-user evaluation centre for which the single GP only has to invest in an inexpensive recording device and the holter online software. **The ECG data are sent to the evaluation centre via encrypted data transfer by the holter online software.** If online data transfer is not desired, the ECG data can also be transmitted via USB stick. The holter online system complies with DSGVO.



#### Beside the integrated short analysis, the holter online software provides two different options:



#### Integrated short analysis

#### Short analysis

The integrated short analysis function provides the user in the general practice with preliminary information about important pathological events. The analysed ECG is sent as a printout.

#### Option 1: Visualisation

The analysed ECG is sent online.

#### **Option 2: Reanalysis**

It is possible to analyse and confirm the ECG analysed by the evaluation centre on one's own PC.



# custo medical protector

Safety socket instead of isolating transformer

Any connection of two or more devices creates a system. If it contains at least one medical electrical device (ME equipment), the entire unit becomes a medical electrical system (ME system).

With the custo medical protector safety socket, all the requirements of a medical electrical system are met. With the type test EN 60601-1, 3rd edition, the required proof of suitability was provided.

The medical protector is our easy solution for safe and trouble-free medical electrical systems:



Inexpensive to purchase



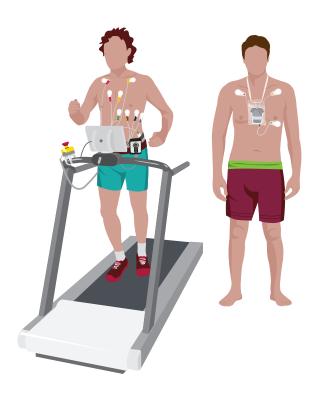
Easy and trouble-free to use



Safe to operate

# **custo wing**The patch electrode for the perfect ECG!

No matter if Holter, resting or stress ECG – with the novel patch electrode custo wing the ECG will be excellent. Due to a hybrid gel, it is perfectly suited for all application areas. The decentral snap fastener connection is fixed by an additional adhesive zone, so that artefacts caused by cable movements can be excluded. This ensures perfect signal quality.



#### Your benefits:

- · Hybrid gel for Holter, resting or stress ECG
- Artefact reduction and outstanding signal quality due to decentral connection and fully covered adhesive surface
- Large gel surface for reducing contact resistance
- Open-pored and breathable carrier material
- Very good initial and long-term adhesion (also with sweat)
- Biocompatibility
- Optimum storage due to resealable packaging
- Fast and decent removal due to prepunched carrier material









## Suction electrode – ECG belt – patch electrode Electrode innovations from the ECG specialist!

#### 2009: Suction electrode

With the exchangeable and reusable suction electrodes for custo cardio 200/400. custo med has introduced a completely new kind of electrode to the market and received a clinical certificate of hygiene.

### 2014: custo belt

This first medical ECG belt makes it possible to get a perfect 3-channel ECG without disturbing cables. It is washable, reusable and highly comfortable for the patient to wear.

### 2021: custo wing

The custo wing electrode now combines the benefits of the suction electrode and the custo belt. In combination with the new Holter ECG recorder custo quard holter, it provides an optimum, autonomous 3-channel Holter ECG. Thanks to the hybrid gel it is also excellently suited for stress ECG.







## **ABPM**

Ambulatory Blood Pressure Monitoring plays an important role in diagnostics and therapy of arterial hypertension. It allows to draw conclusions on the performance relations between the heart and the cardiovascular system, and it is the gold standard in diagnosing and treating hypertension. The custo screen system variants enable customised solutions and thus individually tailored use in practice and hospital. custo screen 310 is the first recorder capable of determining the central blood pressure by means of pulse wave analysis.





# ABPM features in the custo diagnostic software

- **Summary of an ABPM recording:** Beside the graphic view of the blood pressure progress, all measured values (systole, diastole, mean arterial pressure, pulse pressure amplitude etc.) are shown.
- Clearly recognisable and changeable day/night phase and clear display of dipping behaviour at a glance.
- The **evaluation comparison** enables a detailed comparison of two arbitrary evaluations.
- In the **trend view,** it is possible to trace the progress of different indicators over several evaluations. Thus, the check-up of a long-term therapy is facilitated.
- In the **automatic proposal**, the classification and severity of hypertension, the nocturnal blood pressure behaviour as well as the risk factors and their potential consequences are specified.
- Simple reporting with text modules and, in risk stratification, also with a reference to the findings.
- The **printout** includes the single values, the measured value table, the risk assessment and the proposal, clearly arranged on one page.
- Measurement results which are implausible (for example outliers) can be excluded from the statistical analysis.
- All recorder activities are logged so that all interactions are visible.





## Recognise the risk!

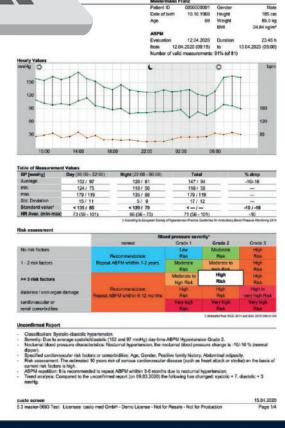
## Risk stratification in custo diagnostic



With the software package "screen professional", the 10-year risk of a patient for severe cardiovascular disease can be determined.

The risk stratification combines the blood pressure severity with the cardiovascular risk factors and determines the individual risk for the patient. The cardiovascular risks are important for both diagnosis and prognosis of the blood pressure disease.

It gives a clear, simple view and quickly supplies reports thanks to the automatic proposals.

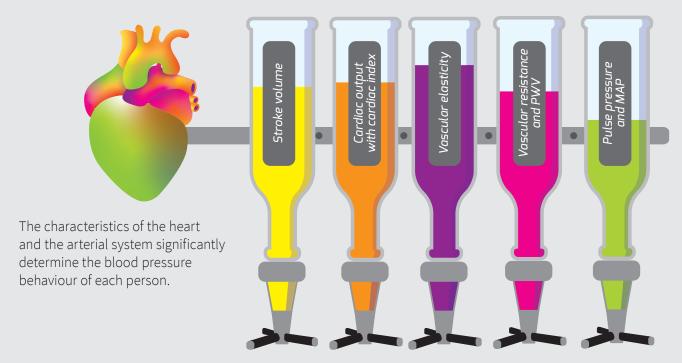


# **NEW: Hemodynamic Phenotypes**Tracking down the cause of hypertension!

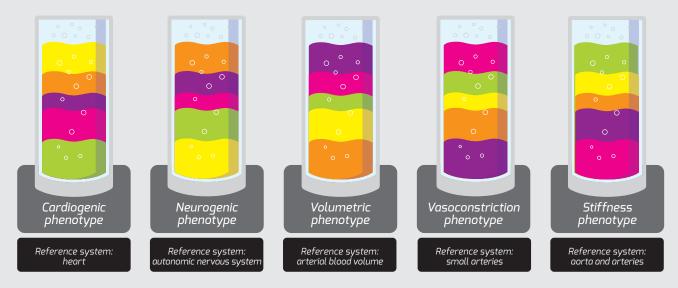
Arterial hypertension varies from patient to patient. Our new, clinically validated phenotype analysis provides, for the first time, cardiovascular parameters derived from a 24-hour ABPM. These form the basis of the identification of five hemodynamic phenotypes which provide indications of the cause of hypertension. If this is known, patients can be treated specifically.

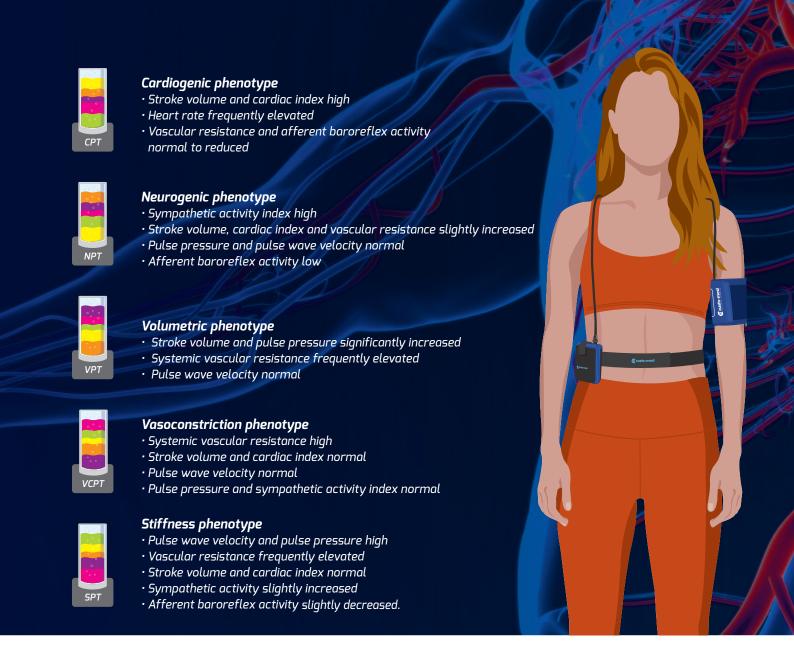
## Hypertension hemodynamics with ABPM

Each phenotype is blended from five "ingredients" (cardiovascular parameters):



The "blends" of cardiovascular parameters result in five hemodynamic phenotypes:





## Hemodynamic phenotypes in custo diagnostic

The 24-hour ABPM is still the gold standard for guideline-compliant detection of hypertension. Targeted treatment is possible with the help of phenotype analysis, as this provides the physiological causes of hypertension. In custo diagnostic, the cardiovascular parameters are visualised, and the results of the ABPM and the phenotype analysis are described in detail.



#### Phenotype analysis – a validated procedure:

With the help of the 24-hour ABPM and the software module Phenotypes, it is possible to reliably determine stroke volume, cardiac output, arterial compliance and systemic vascular resistance\*.

The applicability of the hemodynamic phenotypes in everyday clinical practice was validated in a cross-sectional study with approximately 7,500 patients.\*\*

- Álvarez-Montoya, D., Madrid-Muñoza, C., Escobar-Robledoa, E., Gallo-Villegas, J. and D. Aristizábal-Ocampoa (2021): A novel method for the noninvasive estimation of cardiac output with brachial oscillometric blood pressure measurements through an assessment of arterial compliance. Blood Pressure Monitoring 26(6): 426-434
- \*\* Aristizábal-Ocampo, D., Álvarez-Montoya, D., Madrid-Muñoz, C., Fallon-Giraldo, S., Gallo-Villegas, J. (2023): Hemodynamic profiles of arterial hypertension with ambulatory blood pressure monitoring. Hypertension Research 46(6):1482-1492







## custo screen 300

## The fast and safe way to get a valid report!

Oscillometric long-term blood pressure measurement is still the gold standard in diagnosing and treating arterial hypertension. custo screen 300 was one of the first ABPM systems to be successfully validated according to the strict specifications of the ESH-IP-2010 protocol. Thanks to validation, we can guarantee precise and reliable measurement results and artefact suppression has also been significantly improved. The automatic day/night detection, faster inflation and deflation times and the recorder's low-noise operation ensure a high level of patient comfort.

## Perfect results due to the tube-in-tube system and upper arm-adapted measurement:

Our high-quality tube-in-tube system has been developed to minimize movement artefacts and thus achieve extremely precise measurement results. It also helps to improve patient safety by making unintentional kinking more difficult and allowing accumulated air to escape in emergencies.



Thanks to the option of adapting the measuring pressure to a wide range of upper arm circumferences (upper arm-adapted measurement), we achieve the most accurate measurement results possible.

Our specially adapted cuffs (latex-free) are available in all sizes, from pediatric to XXL.



Validation custo screen 300: http://www.dableducational.org/ sphyamomanometers/devices\_3\_ abpm.html#AbpmTable



- measurement
- · Adaptive algorithm for gentle measurement
- · Robust recorder with high-performance components for a long product life cycle
- · Fast data transfer from the recorder to the PC NEW: connection with BLE (Bluetooth Low Energy)

#### Accessories

- · custo multi com/com IR as a transfer option
- · Hygiene set custo screen protect
- · Various cuffs
- · Carrying bag and belt
- · Disposable bags custo clean SC

# **Children are not just small adults**The custo screen system in pediatric mode

With the integration of the pediatric mode into the custo screen recorders, we have created one of the first ABPM systems that can be used to measure both children and adults. The pediatric mode is validated according to the ESH-IP-2010 protocol, with special consideration of the requirements for children.

#### Your benefits:

- Special pump with reduced volume when inflating, for a gentler measurement process
- · High safety due to double pressure relief valve
- · Special child cuffs with low volume
- Threshold values for children according to pediatric cardiology quideline

· Exchangeable top covers with set of motifs





**3 to 5 years** Cuff size: Pediatric 14 – 20 cm



**5 to 8 years** Cuff size: Small 20 – 24 cm



**9 to 12 years** Cuff size: Standard 24 – 32 cm



#### German Society of Pediatric Cardiology Excerpt: 4.1 Blood Pressure Measurement

"...The devices used to measure blood pressure are to be validated for children (www.dableducational.org) and the measurement process is to be standardised. As there are strong intra- and inter-individual variations in blood pressure, several single measurements are necessary which have to be verified in ambulatory 24-hour monitoring. It makes sense to measure blood pressure in all children from the age of 3 years, on the occasion of each physical examination as well as in the context of preventive check-ups."

(S2k Leitlinie Pädiatrische Kardiologie, Pädiatrische Nephrologie und Pädiatrie: Arterielle Hypertonie; Seite 5; http://www.kinderkardiologie.org/fileadmin/user\_upload/Leitlinien/LL\_Arterielle\_Hypertonie.pdf)

## custo screen 310

# ABPM recorder for measuring central blood pressure and pulse wave!

Up to a third of all hypertension patients remain undetected or get limited treatment with conventional blood pressure measurement on the upper arm. In ABPM, it is the central blood pressure that provides a comprehensive view of the actual blood pressure situation, as it directly affects the organs. custo screen 310 determines the central blood pressure using the validated Antares algorithm.









#### Your benefits:

- · High measurement accuracy Our solution provides a very high coherence with invasively measured values.
- · Validated procedure Accuracy has been proved in a multicentre validation study (according to ARTERY protocol).
- · All-in-one device The central and brachial blood pressure values, including a pulse wave analysis as single measurement and as 24-hour measurement (ABPM) are available in one device
- · No additional examinations The pulse wave analysis is made automatically during the standard blood pressure measurement.
- · Skin-friendly, easy-to-disinfect, synthetic cuff available in sizes 5 to XXL (latex-free)
- · High-quality double tube system for significant reduction of motion artefacts
- · Low-noise pump valve unit for patient-friendly measurement
- · Night mode for a restful sleep
- · Adaptive algorithm for gentle measurement
- · Robust recorder with high-performance components for a long product life cycle
- · Fast data transfer from the recorder to the PC

#### Validation custo screen 300 | 310 | pediatric:

www.ncbi.nlm.nih.gov/pmc/articles/PMC4027883/pdf/vhrm-10-303.pdf www.mdpi.com/2077-0383/8/7/1073/pdf link.springer.com/article/10.1007/s00431-017-2874-3



## Type I or type II device?

The main advantage of a type II device – like custo screen 310 – is that the measurement of brachial and central blood pressure is possible in only one measurement. And this on the basis of pulse wave data and without being dependent on device characteristics or additional patient data.

	Type I device	Type II device (custo med)
Input parameter	Systolic values (brachial) MAP age   height   sex Oscillometric signal	Oscillometric signal
Number of measurements	1 – 2	1
Calibration	necessary	not necessary
Result	Depends on calibration	Corresponds to the invasively measured blood pressure*
Independent of patient data	No	Yes

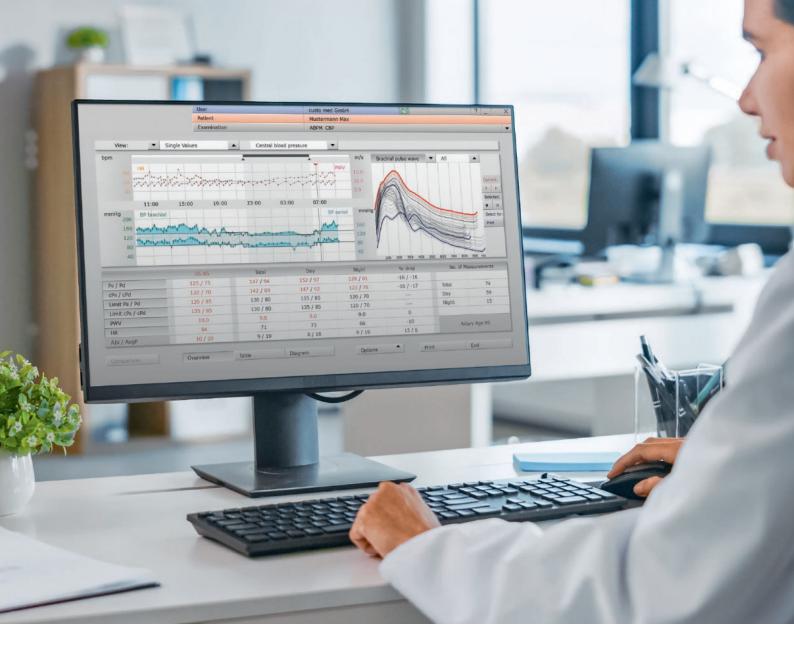
## Central blood pressure and pulse wave analysis in custo diagnostic

The central blood pressure is determined with the help of a pulse wave analysis. It serves for better characterising different types of high blood pressure. Central and peripheral blood pressure may deviate strongly from each other, depending on age, risk factors and condition of arteries.

In custo diagnostic, the central blood pressure is calculated using the validated Antares algorithm\*. In addition to the familiar blood pressure parameters of the brute measurement, the pulse wave analysis provides the following highlights:

- Pulse wave velocity: Overview of the variability of the pulse wave velocity over the course of 24 hours.
- Comparison of the **brachial with the central blood pressure** curve at a glance.
- View of the brachial **pulse wave shape** for each measured value.
- The **arterial age** provides information on the actual condition of the vessels.
- Determination of the augmentation index and the augmentation pressure.

Dorr, M.; Richter, S.; Eckert, S.; Ohlow, M.-A.; Hammer, F.; Hummel, A.; Dornberger, V.; Genzel, E.; Baulmann, J. (2019): Invasive Validation of Antares, a New Algorithm to Calculate Central Blood Pressure from Oscillometric Upper Arm Pulse Waves. Journal of Clinical Medicine. 8 (7): 1-15



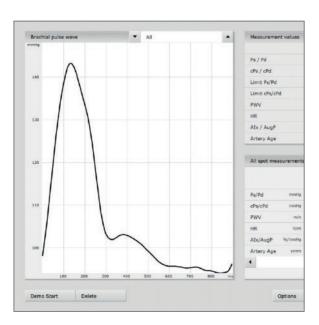
## Spot measurement with custo screen 310

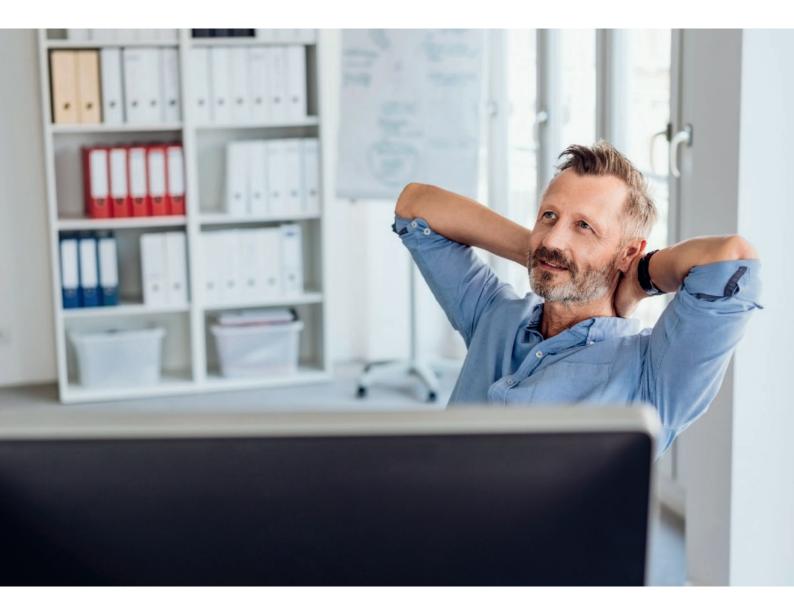
If pulse wave velocity is suspicious, the spot measurement can justify an ABPM in order to verify suspected hypertension. In the spot measurement, the brachial pulse wave is displayed graphically.

Beside the measurement of long-term blood pressure, the software module allows a spot measurement (single measurement) to assess the cardiovascular risk. Pulse wave velocity is the crucial indicator here.

#### The spot measurement includes the following values:

- Brachial and central blood pressure
- Pulse wave velocity
- Heart rate
- Artery age
- Augmentation index
- Augmentation pressure





## Combined Holter Measurement

In the cardiovascular continuum of hypertension patients, cardiac arrhythmias such as atrial fibrillation or ventricular premature beats may occur in every stage of hypertension. With increasing severity of hypertension, the severity of arrhythmias rises and reaches the highest incidence and prevalence rates with severe cardiac insufficiency, as final point of the cardiovascular continuum. Although a significant relation between advanced hypertension and increasing cardiac arrhythmias is observed in clinical practice, there is hardly any association between hypertension and rhythm management in diagnostics or therapy. Due to a combined ABPM / Holter ECG measurement, the frequency of supraventricular and ventricular premature beats as well as the risk for arrhythmia can be identified beside the severity of hypertension and the resulting cardiovascular prognosis. Consequently, a therapy can be started at an early stage.

## custo holter ABPM

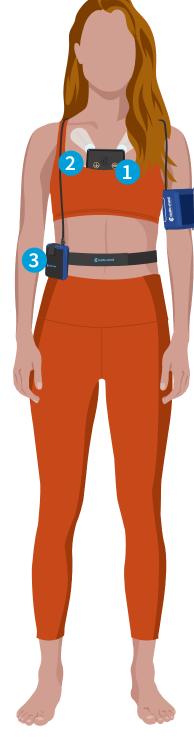
## Synchronous recording of Holter and ABPM

Works with any new custo screen recorder!

The combination of custo screen 300/310 and custo guard holter is the perfect solution for simultaneous recording of Holter and ABPM. The system provides high wearing comfort without disturbing and artefact prone Holter cables.

- Holter device custo quard holter:
  - · 3-channel lead without any cables
  - · Up to 7 days recording time
  - Pacemaker detection
- Innovative electrodes custo wing:
  - · Easy placement due to snap fasteners
  - · Ergonomic shape and adhesive on the whole surface, for extraordinary recording quality
  - · Perfect for Holter ECG thanks to particular material properties
- 3 ABPM recorder custo screen 300/310
  - · Extremely robust recorder for long product life cycle
  - Validated according to ESH-IP 2010
  - · Measuring the central blood pressure with custo screen 310







## **Spirometry**

Respiratory tract diseases, particularly allergic reactions of the bronchial system, belong to the most frequent disorders. A reliable pulmonary function test is an essential instrument for both preventive health checks and the optimum follow-up of therapeutic measures. In many lung diseases, ventilation and blood circulation of the lungs are not well coordinated and consequently not enough oxygen can be absorbed. Therefore, the aim must be to detect diseases at an early stage and to treat them conscientiously.

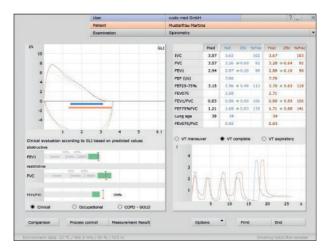




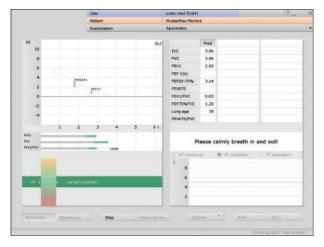
## Spirometry features in the custo diagnostic software



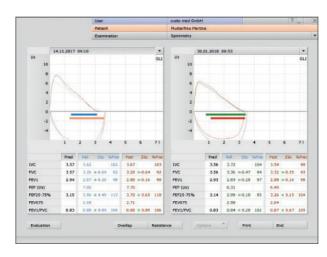
- Immediate view of all relevant spirometry parameters (FEV1, FVC, FEV1/FVC (Tiffeneau Index), etc.)
- Evaluation of results **according to the guidelines** based on national and international predicted authors, for example GLI reference values
- 360-degree view of the examination results (from a clinical and occupational-medical aspect, COPD-GOLD)
- Automatic report with explanation of diagnosis
- Z-score trend: Comparison over several measurements (days/weeks/months) are possible with a patient
- Test methods spasmolysis and provocation
- Clearly structured therapy check-up by means of the automatic long-term trend
- Child animation "Schnaufi the Dragon"



Clearly arranged total view of all relevant values



Real-time view of the patient's body position during the measurement



Efficient therapy check-up by means of comparison function

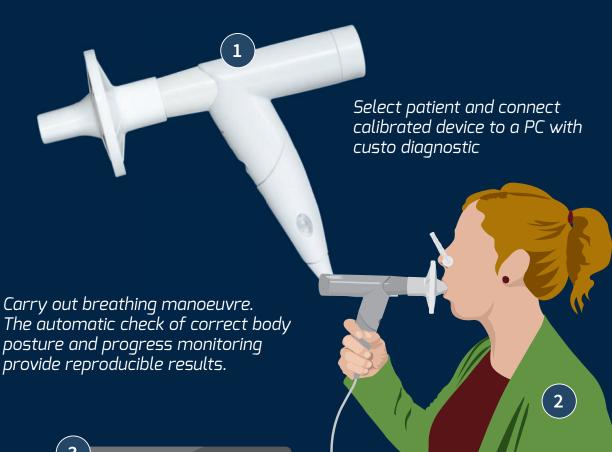


Child animation "Schnaufi the Dragon"



## Precise measurements easy, fast and without errors:

Spirometry by "plug and play"



The measured values are compared to predicted values, shown on the screen at a glance and saved.





## custo spiro mobile Precise Measurements in Spirometry

With the spirometer custo spiro mobile, all the spirometry standard tests can be carried out quickly and exactly. The examination can be considered from three different aspects (clinical, occupational-medical, COPD-GOLD).

#### Your benefits:

- · Particularly solid measuring head, made of high-strength ceramics inside
- · Exchangeable adapter
- · Measuring sensor system with pressure sensor for more precise measurements
- · Easy and safe handling
- · Electronic adaptation of calibration
- · Integrated tilt sensor for monitoring body position during the measurement
- · Mobile use on all PCs due to USB port

#### Accessories

- Hygiene filter custo spiro protect
- · Nose clip
- Exchangeable adapter
- · Various mounts for safe depositing on the table or equipment cart
- Calibration pump



## **custo spiro protect:** Safety in Spirometry

custo spiro protect is a highly efficient bacterial and viral filter for spirometry. Offer your patient the best possible protection at an economic price.

- High bacterial and viral filtration efficiency (min. 99,999 %)
- · Laser-sealed housing for maximum tightness
- · Filter surface protection against impurities
- · Patient-friendly mouthpiece
- · White polypropylene housing
- · Electrostatic filter core
- · ISO 10993-1



## **Cardiac Rehabilitation**

Modern rehab is not just a matter of time and safety. There are many other factors which make an existing rehab system operate efficiently. The rehab solution from custo med uses your existing devices, and what's more, it allows enhancing the mobile flexibility of applications. The most important aspect however is: you create a perfect workflow with custo med.



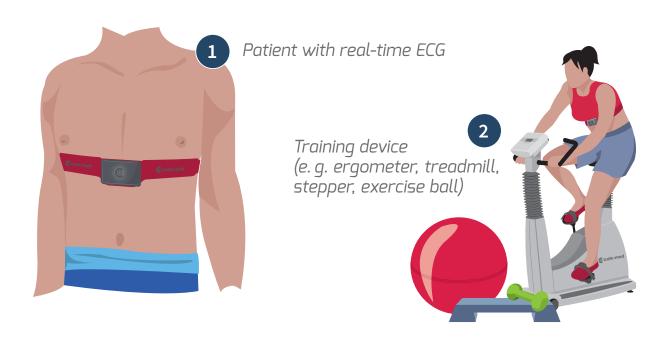






## Cardiac rehab totally easy!

To perform an effective rehab, you need a perfect ECG, various training devices and good software. With these three "ingredients" and the patient, a complete cardiac rehab is possible.





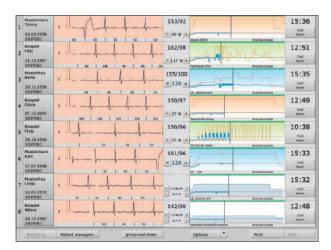
PC system with custo rehab, the medical rehab software of custo diagnostic

## **Cardiac Rehabilitation** in the custo diagnostic software

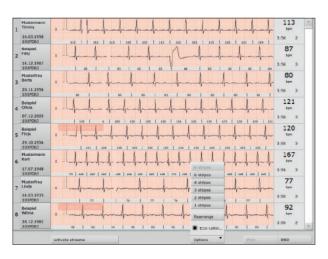
- ECG quality view with a variety of view options available
- Complete ECG can be scrolled backwards / forwards
- Short printout of ECG (one click), printout of a 60-second ECG strip
- · Variety of predefined training units for ergometer and treadmill
  - · Predefined standard and interval trainings
  - · Load, heart rate and SpO<sub>2</sub>-controlled trainings
  - · Adjustable load reduction when reaching the training heart rate
- Configuration assistant for self-defined trainings
- · Modification of training in the current training, diverse modification options depending on training method
- Training table for data of all patients / training table for all evaluations of a patient



Configuration assistant: Easy first step in the rehab module



Group control: Start up to 32 patients at the same time.



#### **Network monitoring**

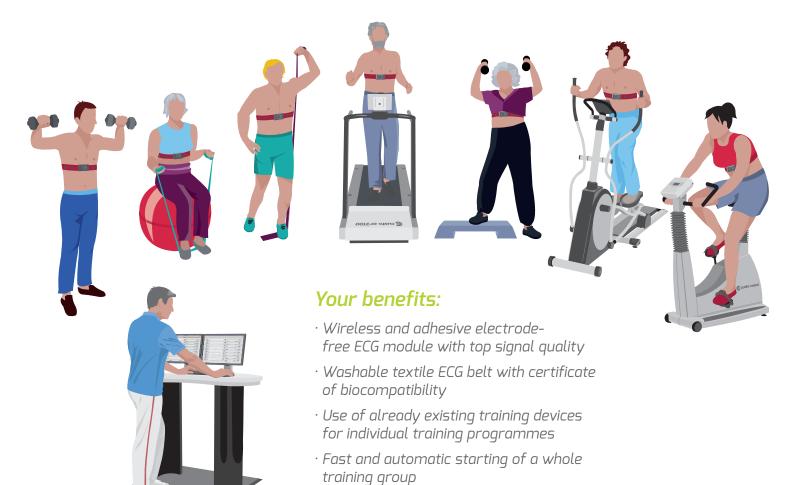


**Training success** 



## custo guard with custo belt ECG in real-time - anytime and anywhere!

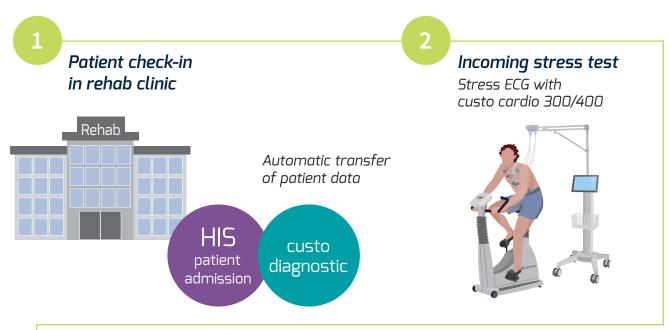
Cardiac rehab from custo med provides the therapist with completely new opportunities in choosing the therapy method. The patient receives just a small, light-weight ECG module which is clamped to a textile washable ECG belt, without cables. The patient wears the ECG module on the body during the whole rehab training. Consequently, the ECG recording is not bound to any endurance training equipment and the therapist has free choice of training devices. All data can be monitored by means of real-time ECG via a central monitor, from which up to 32 patients can be observed simultaneously.



· Up to 32 patients can be monitored

simultaneously

## For more efficiency and safety -The digital rehab workflow in only 4 steps:



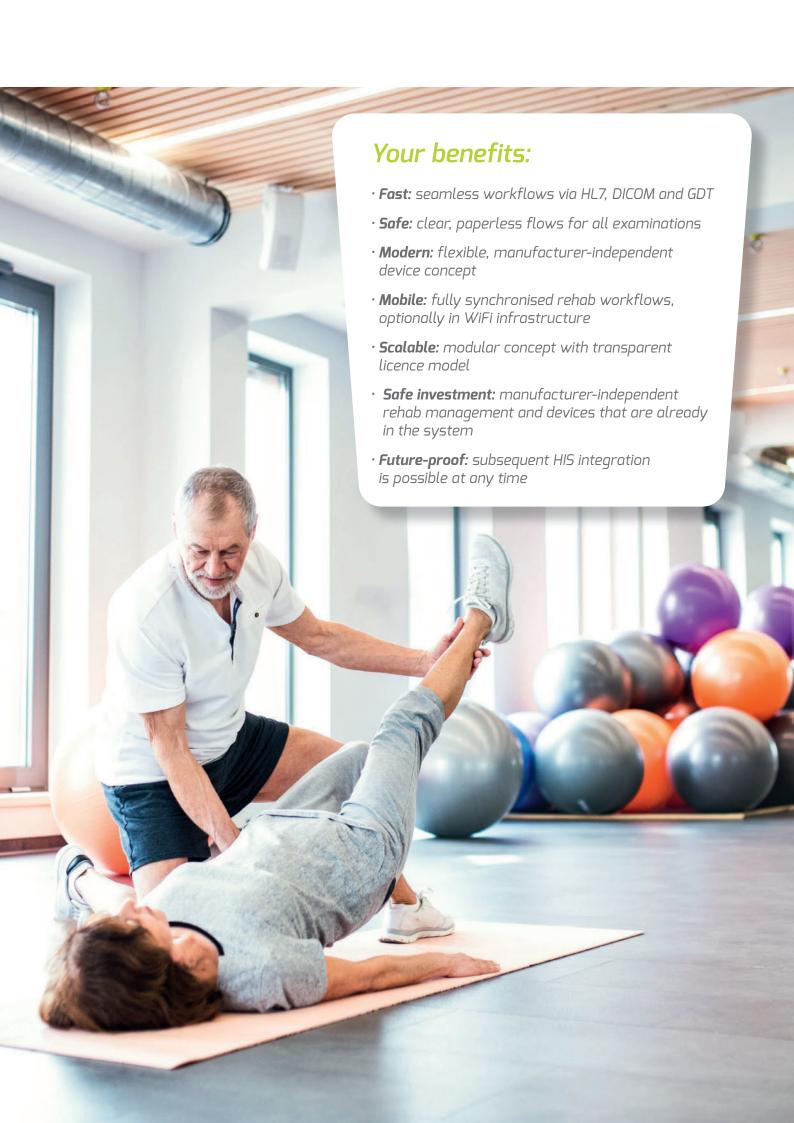
#### Registration and automatic calculation of training zones



### Outgoing stress test Stress ECG with custo cardio 300/400



Automatic evaluation of therapy result







The quality management system of custo med GmbH has been certified by TÜV Süd Product Service GmbH - in accordance with the provisions of Annex IX Chapters I and III, Regulation (EU) 2017/745.

Only authorised personnel may modify any medical-electrical systems. Any modification must be documented in accordance with a system declaration.

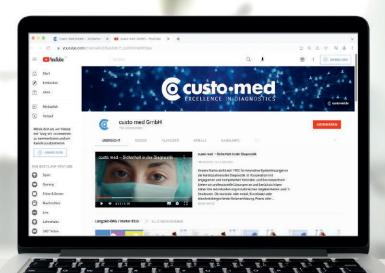
For the product-specific standards to be used, please refer to the instructions for use, which can be found at https://www.customed.de/information/technical-documentation/operating-manuals

DK-2290 | EN-V001 | 06.2024 · Subject to technical modifications.

#### custo med GmbH

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Find out more about custo med at **www.customed.de** and on our YouTube channel:





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