

HEALTH IS THE HEART OF OUR BUSINESS.



# DIAGNOSTIC SYSTEMS FOR HEART AND LUNGS



MANAGE COMPLEX DATA EASILY

**AMEDTEC** *ECG<sub>pro</sub>*<sup>®</sup>

# DRIVEN BY ONE IDEA

## WHO WE ARE

High-tech and healthcare: AMEDTEC is continuing the work that was started fifty years ago as a national enterprise with the design of the 6-lead electrocardiograph (ECG). Since then, measuring and medical technology from the German state of Saxony has become known throughout the world.

AMEDTEC Medizintechnik Aue GmbH was founded in 1998 with this knowledge in mind.

Six engineers came together to work as development service providers, creating hardware and software for leading international manufacturers of 12-lead and Holter ECG systems.

In parallel to this, the company concentrated its efforts on the expansion of cardiopulmonary data management systems, focusing primarily on networks, interface integration, data exchange and interoperability between hospital information systems and private practices. AMEDTEC transformed from a pure service and development company into a manufacturing company and, from 2006 onwards, became a supplier of integrated solutions. The company launched its own system – AMEDTEC *ECGpro*® – on the market. This technology completely revolutionises ECG diagnostics. It meets the premises of modern medicine as well as the high demands of data communication.

AMEDTEC *ECGpro*® is at the heart of all our products. It allows data to be recorded, analysed and exchanged for 12-lead ECGs (resting and stress test), Holter ECGs, blood pressure monitoring, ergospirometry, body plethysmography and spirometry.

In cooperation with Geratherm Respiratory, a manufacturer of medical devices used for pulmonary function testing, AMEDTEC offers an entire range of products for cardiopulmonary function diagnostics. Whether used in hospitals or medical practices, AMEDTEC stands for innovation and lasting value.

## HOW WE SEE OURSELVES

AMEDTEC represents the innovative strength of medium-sized German companies. Living up to the tradition of ambitious inventors and developers, we are devoted to one thing: customer satisfaction. We are committed to this every single day.

The AMEDTEC system solutions and products are used for diagnosing cardiopulmonary function. We believe this to be our particular responsibility.

### MEDICAL TECHNOLOGY FOR THE GOOD OF MANKIND

There's always room for improvement. We reinvest the bulk of our profits into optimising our technology or in developing new products. We work closely with our customers and with practitioners to develop powerful, yet intuitive products. It does not matter whether you are a patient, doctor or medical assistant – when it comes down to it, you need a reliable, easy-to-use application.

We therefore maintain a constant dialogue, both inside and outside the company.

### LISTEN. CONSIDER. OFFER INTEGRATED SOLUTIONS

AMEDTEC takes the requirements of users and the needs of patients seriously. This is why we provide an excellent level of service with prompt assistance from our experienced staff. You can rely on an international sales network and professional customer service. After all, we invest our knowledge entirely in medical progress.

### THE IMPORTANCE OF QUALITY

AMEDTEC operates in a manner consistent with its corporate policy: All AMEDTEC products meet the strict standards of medical technology. Thus, we have based our quality management system on these – it is certified in accordance with DIN EN ISO 13485 and DIN EN ISO 9001. Our quality assurance system is certified in accordance with the European 93/42/EEC Medical Device Directive, Annex II.

After all, top quality is the sum of all details.

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### DATA MANAGEMENT

The data from all AMEDTEC function diagnosis modules converges in the central data management system AMEDTEC *ECGpro*®.

AMEDTEC *ECGpro*® can be flexibly integrated with the information systems used in hospitals or medical practices via HL7, DICOM and BDT/GDT.

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### RESTING ECG STRESS TEST ECG

The 12-lead resting ECG from AMEDTEC is built as a modular software system, which enables you to record and analyse both 10-second resting ECGs and longer rhythm ECGs with or without arrhythmia detection quickly and easily.

Performing an ergometry test is easy with the AMEDTEC stress test ECG system. By adding a spirometry testing unit with respiratory analysis functions, you can easily turn the measuring station into a high-value ergospirometry testing system.

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### AMBULATORY BLOOD PRESSURE MONITORING HOLTER ECG

The AMEDTEC Holter ECG is a complete long-term ECG system with an optimal workflow. It provides a fast and accurate analysis of Holter ECG recordings made in either 3 or 12-channel mode.

The AMEDTEC *ECGpro*® Holter-RR system records up to 72 hours of ambulatory blood pressure. Thanks to the device's Auto Feedback Logic (AFL), the patient endures only minimum discomfort.

A user guide allows you to prepare the ambulatory blood pressure recorder quickly and easily with patient data and the required monitoring protocol.

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### MONITORING AND REPORTING MODULES

The AMEDTEC software AMEDTEC *ECGpro*® is the all-rounder for recording, analysing, presenting and archiving cardiac stress and pulmonary function tests. It can be easily integrated into your hospital information system (HIS) or your practice software.

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### TECHNICAL DATA

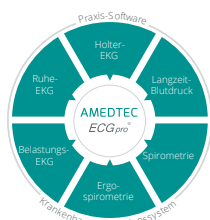
Take a look at our product specifications, where you will find all the important technical information related to the individual devices.

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### SERVICE CONTRACT CUSTOMER SERVICE LEASING, CONTACT

Professional customer service is part of the AMEDTEC philosophy. We deal with your enquiries and orders promptly and offer fast and competent solutions for technical problems.

Full service: AMEDTEC equips hospitals and medical practices with measuring stations and data management systems. We also supply accessories and consumables. Thus, our customers can plan ahead with certainty. Contact us for more information.



# AMEDTEC DATA INFORMATION SYSTEM

## AMEDTEC *ECGpro*<sup>®</sup> DATA MANAGEMENT

### HIGH LEVEL OF SECURITY

Benefit from the efficiency of professional data management.

AMEDTEC *ECGpro*<sup>®</sup> takes into account the sensitivity of medical diagnostics. The Microsoft SQL Server provides an advanced, solid platform for storing and recording data. All cardiopulmonary measuring stations are connected to the AMEDTEC *ECGpro*<sup>®</sup> database via high-speed data cables. Storing the data on a central server guarantees that the data is secure and that all information is available whenever it is needed. Devices that work offline synchronise automatically by replicating the data as soon as a network connection is detected. User-specific settings and the assignment of privileges or login details protect the system against unauthorised access.

### FLEXIBLE INTEGRATION

Economic efficiency calls for future-proof solutions. AMEDTEC *ECGpro*<sup>®</sup> ensures communication via HL7, DICOM and GDT interfaces. The data management system is designed so that it integrates smoothly with existing HIS, picture, archiving and communication systems (PACS) or practice software environments. The AMEDTEC GDT server manages and transfers data from external systems. Data from selected ECG devices is also transferred.

### SIMPLER WORKFLOWS

Would you like external analyses without the risks? With Interlink, AMEDTEC *ECGpro*<sup>®</sup> ensures the fast, secure transmission of recorded data or diagnostic reports via the internet.

Would you like to view ECG curves during the test? AMEDTEC *ECGpro*<sup>®</sup> Online transfers ongoing ECGs to all authorised workstations in real time.

## AMEDTEC *ECGpro*<sup>®</sup> WORKFLOW

### MORE EFFICIENT DIAGNOSTICS

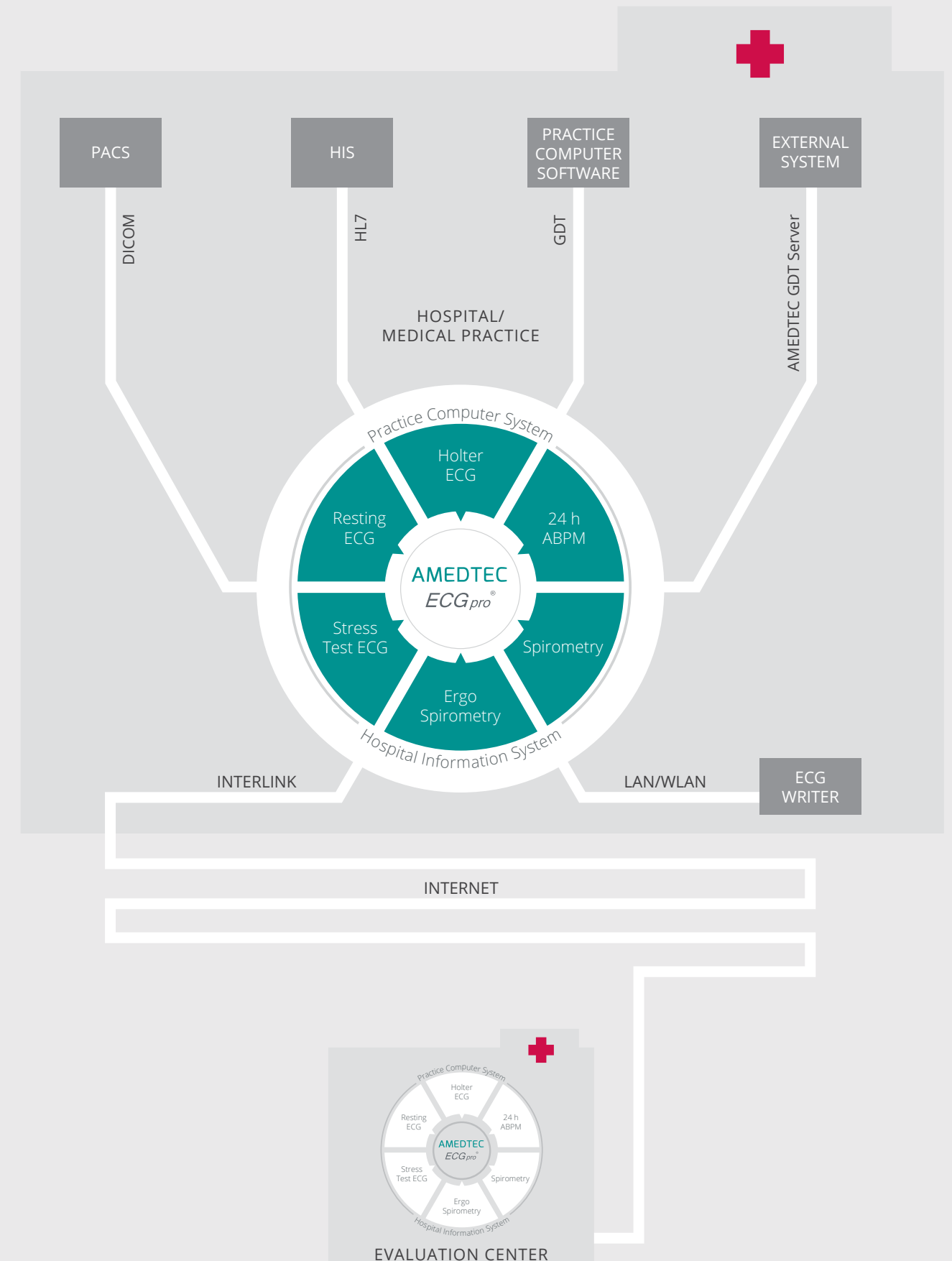
AMEDTEC simplifies the complexity of cardiopulmonary tests.

AMEDTEC *ECGpro*<sup>®</sup> Workflow directs all relevant information to the right place at the right time. It does not matter whether you work in a medical practice or hospital – the system is bi-directional, reliable and, if required, completely paperless. Examination requests can be created directly in the HIS, PACS or practice software. AMEDTEC *ECGpro*<sup>®</sup> accepts these and forwards them to the workstation or measuring station. The request is added to the worklist.

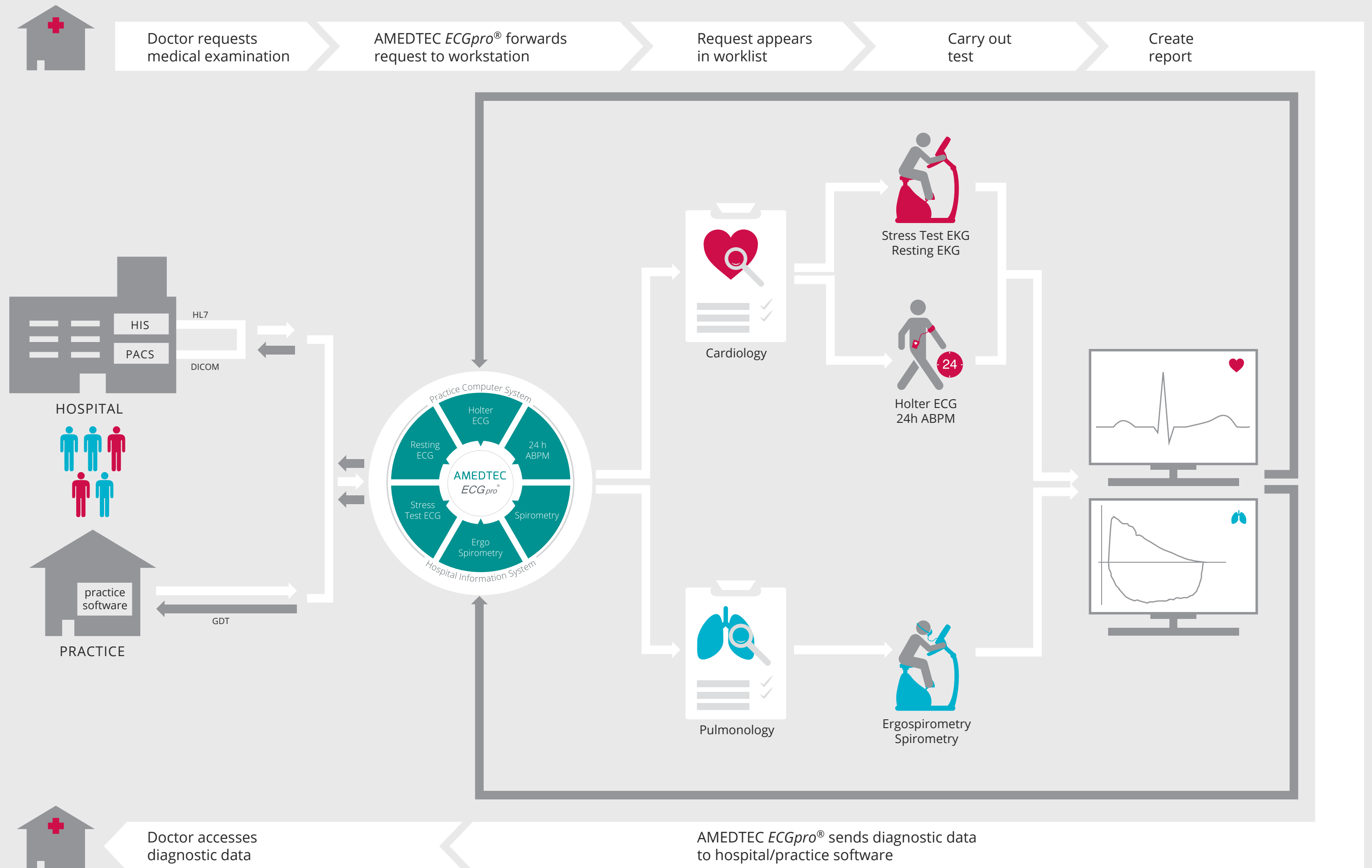
### PERFECTLY ORGANISED

When the diagnosis is complete, the worklist is updated automatically. The results are forwarded immediately to the HIS, PACS or practice software. With just a few clicks, the doctor has the test results in electronic form.

AMEDTEC *ECGpro*<sup>®</sup> supports case-based invoicing and enables you to archive data digitally.



WORKFLOW





# CARDIOPART 12 RESTING ECG



## WITH OR WITHOUT CABLES

Whether you wish to record automatic 10-second resting ECGs or longer rhythm ECGs – the CardioPart 12 Resting ECG is ideally suited both for use in laboratories and for mobile use. The Hannover ECG Program HES<sup>®</sup>, which has been validated by an independent test centre, is used to interpret the results.

## PRODUCT DETAILS

- One-button operation
- Simply press the start button on the CardioPart 12 Blue to start the ECG recording
- Check the recording quality prior to the ECG recording
- Switch between preconfigured ECG views while recording
- Many configuration options → compile individual diagnostics programs even for geriatrics and paediatrics
- Predefined text blocks help you write the final report
- Wide selection of print formats → easy to add other formats
- Strict hygiene standards
- Integrated in the AMEDTEC ECG<sub>pro</sub><sup>®</sup> data management system

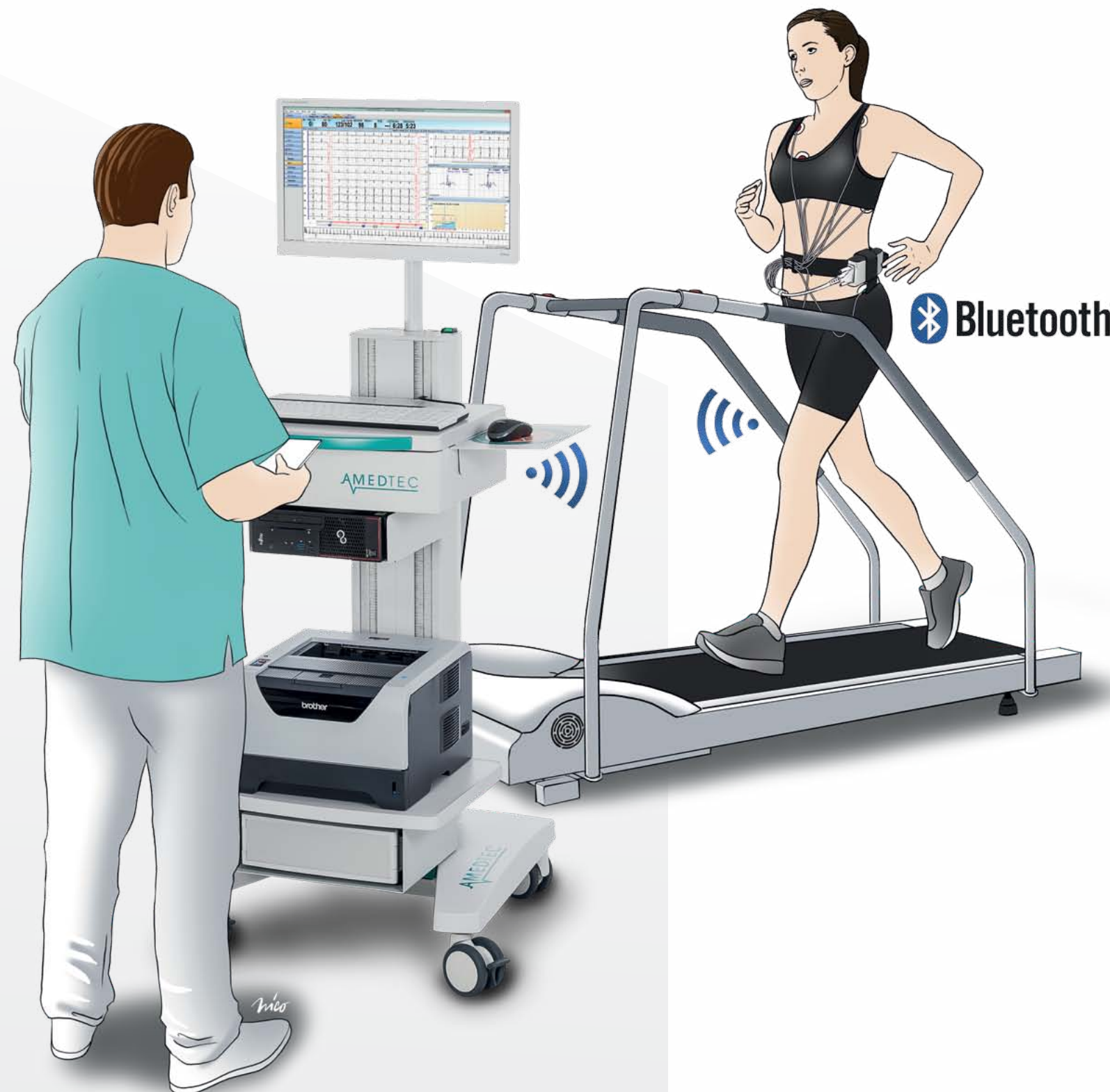
# CARDIOPART 12 STRESS TEST ECG

## SIMPLE. SAFE. EFFECTIVE.

The CardioPart 12 Stress Test ECG scores highly for its absolute precision, intuitive menu guidance and extreme flexibility. The automatic ST, HR and rhythm monitoring is carried out during the ECG monitoring. Current cardiac events appear immediately in a separate window.

## PRODUCT DETAILS

- CardioPart 12 ECG recording device with USB or Bluetooth connection
- Ideal for sports medicine → wireless data transfer (e.g. treadmill)
- Optional control of treadmill or bicycle ergometer and stress echo couch from one measuring station
- One-button operation → user is guided through the test step by step
- Check the recording quality of each electrode prior to the test
- The stress test ECG can run fully automatically → without any operator intervention
- Load values can be changed manually at any time within the automatic stress test procedure
- Print (automatic/manual) ECG sections or successive sequences during the test
- Retrospective view of the entire 12-lead ECG → analyse anomalies in context
- Automatic final report → editable, predefined text blocks
- Network-wide view of ECG curves in real time for all authorised users using AMEDTEC *ECGpro*<sup>®</sup> Online
- Configure a wide range of diagnostic programs yourself
- Create your own load profiles as a slope and/or ramp
- Wide selection of print formats → easy to add other formats
- Integrated in the AMEDTEC *ECGpro*<sup>®</sup> data management system





# HOLTER ECG EP8



## ECG PRESENTATION WITHOUT COMPROMISES

The Holter ECG EP8 is an outstanding performer within the field of long-term diagnostics. This EP820 lightweight recorder weighs less than 56 grams (including battery), ensures minimum patient discomfort and provides excellent signal quality. The analysis software is based on accurate algorithms and delivers precise measurement data. Programs developed specifically for paediatrics allow appropriate interpretation of the ECG for children.

## PRODUCT DETAILS

- Easy preparation of the recorder
- Automatic patient assignment when importing the recording
- Multi-day recording (→ 7 days) without data reduction or compression deficiencies
- Rhythm analysis using parameters that can be configured specifically for ECGs
- Intelligent pacemaker analysis
- Differentiation between atrial and ventricular pacing spikes
- Risk management using ischaemia, QT and HRV analysis
- Detection of atrial arrhythmia
- Creation of automatic reports that can be edited and configured
- Integrated in the AMEDTEC *ECG<sub>pro</sub>*<sup>®</sup> data management system



# HOLTER-RR AMBULATORY BLOOD PRESSURE MONITORING



## NON-INVASIVE DIAGNOSTICS.

Meaningful data: The Holter-RR guarantees reliable, ambulatory blood pressure monitoring. The Auto Feedback Logic (AFL) allows quiet, fast readings with low cuff pressure. Threshold tables for children and young people are integrated for precise interpretation.

## PRODUCT DETAILS

- Stable ambulatory blood pressure monitoring
- Multi-day recording (up to 72 hours)
- Comparison of various test series
- Definition of multiple day and night intervals
- Fast, convenient preparation of the recorder
- Automatic patient assignment when importing the recording
- Patient-friendly monitoring thanks to adaptive cuff inflation
- Validated in accordance with the European Society of Hypertension (ESH International Protocol) and the British Hypertension Society (BHS A/A Grading)
- Integrated in the AMEDTEC *ECG<sub>pro</sub>*<sup>®</sup> data management system



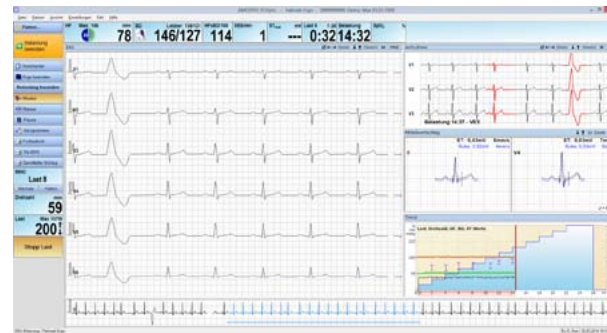
# MONITORING AND REPORTING MODULES

## ♥ CARDIOPART 12 RESTING ECG



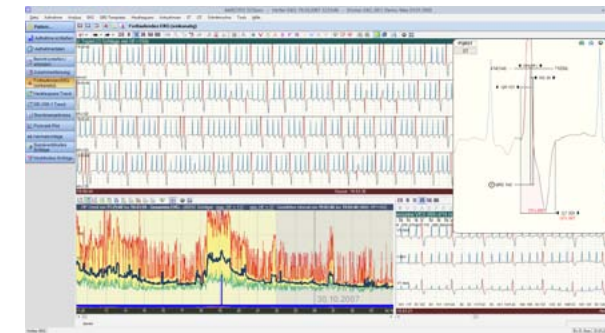
Electrodes application and signal quality check

## ♥ CARDIOPART 12 STRESS TEST ECG



Ongoing ergometry with arrhythmia detection

## ♥ HOLTER ECG



Full disclosure ECG with HF trend and enlarged single beat

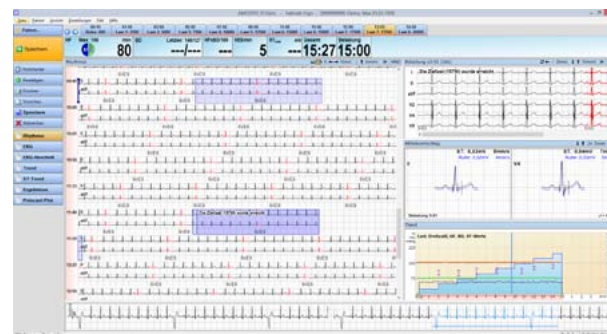
## ♥ HOLTER-RR



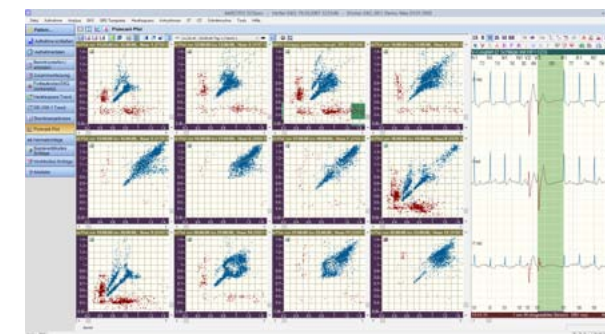
Configurable overview



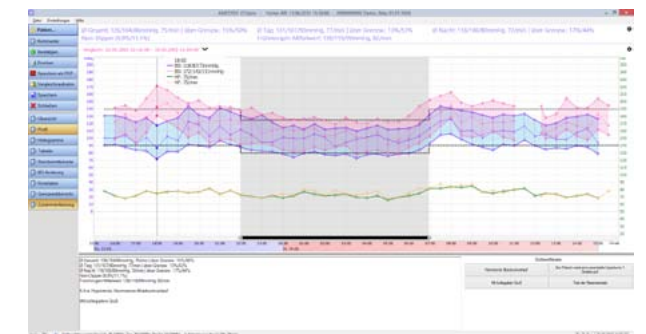
Results



Rhythm overview



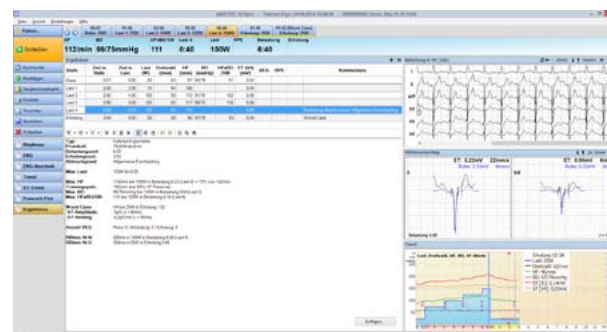
Heart rate variability (HRV)



Test series comparison



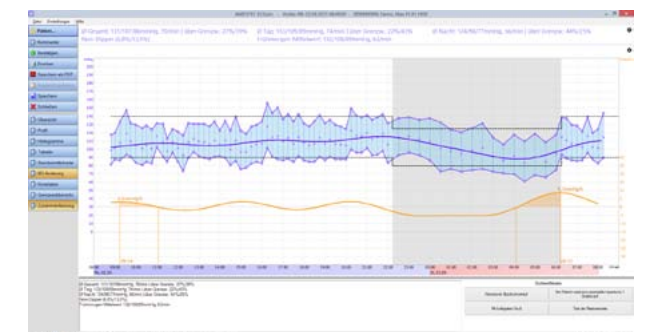
Ongoing ECG recording



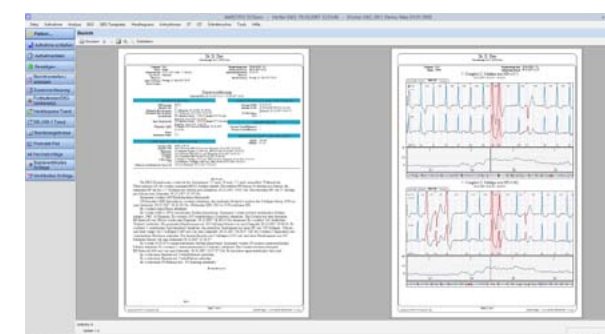
Results table and summary



Rapid detection of atrial arrhythmia



Change in blood pressure with early morning rise



Report creation

TECHNICAL DATA

CARDIOPART 12 BLUE / BLUE-P

Dynamic range	+/- 316 mV DC
Sample rate	8000 Hz [125 µs] for each of the 10 electrode channels
Resolution	1 µV/LSB [0.01 mm]
Frequency range	0 – 150 Hz
Pacemaker detection	Digital monitoring of all electrodes
Input impedance	> 50 MOhm
Electrodes check	Frequency analysis and impedance measurement
Input protection	Against defibrillator shock <sup>1)</sup> and HF from surgery devices
Patient cable connection	15-pin D-Sub for 10-lead patient cable
Applied part	Type CF
PC interface	Bluetooth Class 1 or Class 2
Power supply	2 Mignon AA alkaline or rechargeable batteries
R wage trigger output	Via separate radio module
Dimensions	110 mm x 64 mm x 28 mm
Weight	160 g
Standards	DIN EN 60601-1; DIN EN 60601-2; DIN EN 60601-2-25; DIN EN 60601-2-51; ANSI/AAMI EC 11

CardioPart 12 Blue



CardioPart 12 USB



CARDIOPART 12 USB / USB-P

Dynamic range	+/- 316 mV DC
Sample rate	8000 Hz [125 µs] for each of the 10 electrode channels
Resolution	1 µV/LSB [0.01 mm]
Frequency range	0 – 150 Hz
Pacemaker detection	Digital monitoring of all electrodes
Input impedance	> 50 MOhm
Electrodes check	Frequency analysis and impedance measurement
Input protection	Against defibrillator shock <sup>1)</sup> and HF from surgery devices
Patient cable connection	15-pin D-Sub for 10-lead patient cable
Applied part	Type CF
PC interface	USB 2.0 (5 meter USB cable)
Power supply	Via the USB port of the PC
R wage trigger output	Via LPT port of the PC
Dimensions	95 mm x 64 mm x 28 mm
Weight	90 g
Standards	DIN EN 60601-1; DIN EN 60601-2; DIN EN 60601-2-25; DIN EN 60601-2-51; ANSI/AAMI EC 11

Supported HIS, PACS and BDT/GDT communication	CardioPart 12 Blue/USB	CardioPart 12 Blue-P/USB-P (specifically for medical practices)
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BDT/GDT	✓	✓
HL7/DICOM	✓ (Option)	-

Available ECG options	CardioPart 12 Blue/USB	CardioPart 12 Blue-P/USB-P (specifically for medical practices)
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<i>m</i>	Resting ECG with automatic measurement	✓	-
<i>mr</i>	Resting ECG with automatic measurement and rhythm ECG option	✓	✓
<i>i</i>	Resting ECG with automatic measurement, interpretation and rhythm ECG option	✓	✓
<i>s</i>	Resting and stress test ECG with measurement, interpretation and rhythm ECG option, ST measurement, control of ergometers and blood pressure meters	✓	✓
<i>as</i>	Resting and stress test ECG with measurement, interpretation and rhythm ECG option, ST measurement, arrhythmia analysis, control of ergometers and blood pressure meters	✓	-

1) The patient cable or suction electrode system must feature a protective resistor of 10 kOhm in each of the cables. Protection against defibrillator discharge is only ensured through the use of a patient cable or suction electrode system of this type.



MOTION PC

CPU	Intel® Processor
Operating system	Windows® 8.1 Pro
	Windows® 7 Professional 64-bit
Durability	MIL-STD-810G certified
	IP54 certified (water, dust and splash resistant)
	Scratch-resistant and break-resistant Corning Gorilla® Glass display
	Rubberised for shock dampening
	Magnesium-alloy internal frame
Screen	Ergonomic handle helps prevent drops
	10.4" XGA (1024 x 768) View Anywhere® display with projective capacity 10-point Touch TFT FFS+ LED backlight with durable
	Corning Gorilla® Glass
System memory	Solid State Drive (SSD)
Integrated communications	IEEE 802.11ac Wi-Fi® and Bluetooth® 4.0
I/O ports	Docking station connector
Additional information	1D/2D barcode reader
Dimensions	256 mm x 256 mm x 24.3 mm
Weight	1.50 kg
Battery	Battery life up to eight hours



Docking station with USB and LAN connectors as well as battery charger



Barcode scanner, e.g. for fast patient searches using a barcode label



HOLTER EP 820/EP 820-12

Dimensions	Size	68 mm x 53 mm x 16 mm (L x W x H)
	Weight	42 g
	Operating position	Any orientation
Electrical data	Gain settings	0.5 x, 1 x and 2 x
	Connector	26 pin
	Patient cable	4, 5, 7 or 10 wire
Function	Recording channels	3 or 12
	Sensitivity	2.5 µV / LSB
	Recording	Full disclosure
	PC interface	USB 2.0 or card reader
	Sample rate	10,000/s (PM detection)
	Frequency range	0.05 Hz to 60 Hz, -3 dB
	ECG signal view	Via LCD at hook-up or on demand
	Pacemaker detection	Permanently
Battery	Battery type	1 AAA battery, 1.5 V alkaline, lithium, or NiMH
	Recording time (3 channels)	Alkaline: ≥ 96 h
	Recording time (12 channels)	Lithium: ≥ 168 h Alkaline: ≥ 48 h



HOLTER-RR

Pressure measurement range	Systolic 60 to 290 mmHg Diastolic 30 to 180 mmHg
Accuracy	+/- 3 mmHg in the range indicated
Static pressure range	0 to 300 mmHg
Pulse range	30 to 240 beats per minute
Method	Oscillometric
Measurement intervals	0, 1, 2, 4, 5, 6, 12 or 30 measurements per hour
Monitoring protocols	2 programmable and 7 fixed protocols
Storage capacity	300 measurements
Operating temperatures	+ 10° C to + 40° C
Operating humidity	15 % to 90 %
Dimensions	128 mm x 75 mm x 30 mm
Weight	Approx. 240 g incl. rechargeable batteries
Power supply	2 Mignon AA alkaline or rechargeable batteries
Interfaces	Cable: serial interface RS232, converter for USB, Infrared, Bluetooth Class 1
Standards	DIN EN 60601-1, DIN EN 60601-2, EN 1060-1, EN 1060-3, R&TTE directive 1999/5/EC



MEDICAL BIKE L

Braking System	electromagnetic eddy current brake Range 7 - 1000 Watt
Display	3,5" LED/LCD-Display LED-display on front side
Configuration options	adjustable handlebar angle 360° Handlebar Q-Factor similar to racing bikes Saddle adjustment range 300 mm
Dimensions	Approx. 1050 mm x 460 mm x 1140 mm (L x W x H)
Weight	63 kg
Maximum patient weight	180 kg
Power supply	100 - 240 V (160 Watt)
Interfaces	RS232, USB
Safety standards	IEC 60601-1:2005, ISO 13485:2003, ISO 9001:2008
Protection class	I

MODELS

	Electrical saddle height adjustment	Manual saddle height adjustment
medical bike L1	-	✓
medical bike L3	✓	-

OPTIONS/ACCESSORIES

multifunctional control unit  
7" Touchscreen-Display,  
SpO<sub>2</sub> for control unit including Touch Panel,  
Saddle extra large,  
Saddle for children,  
adjustable pedal crank,  
shortened saddle shaft



# SERVICE, SUPPORT, SAFETY



## PRODUCTS. OFFERS. ENQUIRIES.

Professional customer service is part of the AMEDTEC philosophy. We have built up a comprehensive service network to provide you with prompt and competent advice. AMEDTEC is represented in five locations across Germany. We work together with international sales partners to ensure our global market presence.



## REMOTE ASSISTANCE. REPAIRS. REPLACEMENT SERVICE.

### TECHNICAL PROBLEMS REQUIRE QUICK AND SIMPLE SOLUTIONS.

AMEDTEC has set up a service hotline under +49 (0)3771 59 82 750 for precisely this reason. You can reach the AMEDTEC support staff on Mondays to Fridays from 7 am to 5 pm. Smaller problems can be resolved directly over the phone. For more complex problems, our support staff will be able to help you by accessing your system remotely using the TeamViewer application. Our technicians will come out to you promptly upon request.

### IT IS BETTER TO PREVENT THAN TO REPAIR.

Checking your hardware and software regularly minimises the risk of technical faults or system incidents. With the AMEDTEC service contract you are on the safe side. If more extensive repair work is required, we will provide you with a replacement device.

### SAFETY FIRST.

According to regulation for medical device operators for some devices technical inspection test (MTK) are prescribed regularly. For other devices AMEDTEC recommend to perform technical and safety inspections (STK) every two years. AMEDTEC carries out these inspections – our service technicians are authorized in accordance with DIN EN 62353.



## UPDATES. ACCESSORIES. FINANCING.

### KEEPING UP WITH MEDICAL TECHNOLOGY.

The AMEDTEC update service keeps your AMEDTEC *ECGpro*® up-to-date. In the AMEDTEC user training you will learn about the new software features and find out about our product improvements.

### MEASURING STATION, PATIENT CABLE OR SINGLE USE FLOW SENSOR.

Full service means: AMEDTEC equips hospitals and medical practices with measuring stations and data management systems. We also supply accessories and consumables.

### FLEXIBILITY WHEN IT COMES TO FINANCING.

With AMEDTEC, you can plan ahead with greater financial security. Enquire about our leasing offers or financing packages. Your terms of payment can be adapted to satisfy your needs.

## INTERNATIONAL SALES AND SUPPORT DIVISIONS IN GERMANY

### REMOTE ASSISTANCE

In many cases, the AMEDTEC support staff will be able to help you by accessing your system remotely. To make use of this fast and efficient option, please download the TeamViewer application from our website onto your respective PC. Provided that there is a working Internet connection at that PC, the remote support can be initiated as soon as you provide us with your individual TeamView login details.



## WE MAINTAIN A CONSTANT DIALOGUE, INSIDE AND OUTSIDE THE COMPANY.

### CONTACT, SERVICE AND SUPPORT

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