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 specialist in pulmonary function diagnostics, 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 90/42/EEC Medical Device Directive, Annex II.

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

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.

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 AutoFeedbackLogic (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.

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.

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

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® Data Management

HIGH LEVEL OF SECURITY
Benefit from the efficiency of professional data management. AMEDTEC ECGpro® 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® 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® 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® 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® Online transfers ongoing ECGs to all authorised workstations in real time.

AMEDTEC ECGpro® Workflow

MORE EFFICIENT DIAGNOSTICS
AMEDTEC simplifies the complexity of cardiopulmonary tests. AMEDTEC ECGpro® 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® 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® supports case-based invoicing and enables you to archive data digitally.
WORKFLOW

Doctor requests test
AMEDTEC ECGpro® forwards request to workstation
Request appears in worklist
Carry out test
Create report

HIS
PACS
DICOM
HL7

AMEDTEC ECGpro®
Holter ECG
Resting ECG
Stress Test ECG
Spirometry
Ergo Spirometry

Cardiology
Stress Test ECG
Resting ECG

Pulmonology
Ergospirometry

PRACTICE
Practice software

HOSPITAL

Doctor accesses diagnostic data
AMEDTEC ECGpro® sends diagnostic data to hospital/practice software
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®, 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 to 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 ECGpro® data management system

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- wide selection of print formats easy to add other formats
- strict hygiene standards
- integrated in the amedtec ECGpro® 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® 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® 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 EP80 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 ECGpro® data management system
Holter-RR Ambulatory Blood Pressure Monitoring

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.

Non-invasive diagnostics:
- 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/V Grading)
- Integrated in the AMEDTEC ECGpro® data management system

Product Details
Monitoring and Reporting Modules

CardioPart 12 Resting ECG
- Electrodes application and signal quality check
- Ongoing ergometry with arrhythmia detection
- Results
- Ongoing ECG recording

CardioPart 12 Stress Test ECG
- Electrodes application and signal quality check
- Ongoing ergometry with arrhythmia detection
- Rhythm overview
- Results table and summary

Holter ECG
- Full disclosure ECG with HF trend and enlarged single beat
- Heart rate variability (HRV)
- Rapid detection of atrial arrhythmia
- Report creation

Holter-RR
- Configurable overview
- Test series comparison
- Change in blood pressure with early morning rise
- Change in blood pressure with early morning rise
## Technical Data

### CardioPart 12 Blue / Blue-P

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

### CardioPart 12 USB / USB-P

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

### Supported HIS, PACS and BDT/GDT communication

<table>
<thead>
<tr>
<th>Feature</th>
<th>CardioPart 12 Blue/USB</th>
<th>CardioPart 12 BlueUSB-P (specifically for medical practices)</th>
</tr>
</thead>
<tbody>
<tr>
<td>BDT/GDT</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>HL7/DICOM</td>
<td>✓</td>
<td>(Option)</td>
</tr>
</tbody>
</table>

### Available ECG options

<table>
<thead>
<tr>
<th>Feature</th>
<th>CardioPart 12 Blue/USB</th>
<th>CardioPart 12 BlueUSB-P (specifically for medical practices)</th>
</tr>
</thead>
<tbody>
<tr>
<td>m1 Resting ECG</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>m2 Resting ECG</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>s1 Resting and stress test ECG</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>s2 Stress test ECG</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>s3 Stress test ECG</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>s4 Stress test ECG</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>s5 Stress test ECG</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>s6 Stress test ECG</td>
<td>✓</td>
<td>✓</td>
</tr>
</tbody>
</table>

1) The patient cable or suction electrode system must feature a protective resistor of 10 kΩ/m 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
- Windows® 8.1 Pro
- Windows® 7 Professional 64-bit

Operating system
- MIL-STD-810G certified
- IPS4 certified (water, dust and splash resistant)
- Scratch resistant and break-resistant Corning Gorilla® Glass display
- Rubberised for shock dampening
- Magnesium-alloy internal frame
- Ergonomic handle helps prevent drops
- Display with protective capacity: 10-point Touch TFT FFS+ LED
- Backlight with durable Corning Gorilla® Glass

Screen
- Rubberised for shock dampening

System memory
- Solid State Drive (SSD)

Integrated communications
- IEEE 802.11ac Wi-Fi® and Bluetooth® 4.0

I/O ports
- Docking station connector
- 10/20 barcode reader

Additional information
- Dimensions: 256 mm x 256 mm x 24.3 mm
- Weight: 1.50 kg
- Battery life up to eight hours

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


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
- Recording time: Alkaline: ≥ 48 h

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

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

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

Braking system

Processor-controlled, speed-independent eddy current brake

Power range 5 – 1000 watts

Adjustable in 1 watt increments

Displays

LED/LCD display

LED display on front side

Display unit can pivot to 180°

Configuration options

Seat height 70 – 105 cm (manual adjustment)
or 70 – 102.5 cm (electrical adjustment)

Handlebar grip infinitely adjustable with 360° rotation

Ergonomic steering column adjustment

Adjusting screws for floor unevenness

Dimensions

Approx. 102 cm x 56 cm x 120 cm (L x W x H)

Approx 57 kg

Power supply

Integrated rollers in the base plate for easy moving

200 kg

85 – 264 V / 47 – 440 Hz / 40 – 65 W (medical power supply)

RS-232, USB, Bluetooth

Temperature range

+10 °C to +40 °C

20 % to 80 %

Relative humidity

Safety standards

DIN EN 60601-1, DIN VDE 0750-238

Protection class

Type BF

Risk class

MODELS

<table>
<thead>
<tr>
<th>Electrical saddle height adjustment</th>
<th>Integrated blood pressure measurement</th>
</tr>
</thead>
<tbody>
<tr>
<td>medical bike mb-1</td>
<td>–</td>
</tr>
<tr>
<td>medical bike mb-2</td>
<td>–</td>
</tr>
<tr>
<td>medical bike mb-3</td>
<td>✓</td>
</tr>
<tr>
<td>medical bike mb-4</td>
<td>✓</td>
</tr>
</tbody>
</table>

OPTIONS/ACCESSORIES

Ergonomic steering column adjustment

5.7” colour LCD display

Bluetooth interface

Crank shortener for children, adjustable
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 75 0 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.**
The German Medical Device Operator Ordinance requires operators of medical devices to perform technical inspections of the measuring system and technical safety inspections (STK/MTK) every two years. AMEDTEC carries out these inspections – our service technicians are authorised 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.

**MAINTAINING A DIALOGUE. INSIDE AND OUTSIDE.**

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 TeamViewer login details.

**CONTACT, SERVICE AND SUPPORT**

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Service phone no.: +49 (0)3771 59 82 750
Service e-mail: service@amedtec.de
Fax no.: +49 (0)3771 59 82 790