AMEDTEC ECG pro®

CardioPart 12 Blue

12-Lead ECG

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Instruction Manual

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CardioPart 12 Blue fulfils the essential requirements of the Medical Device Directive 93/42/EEC as well as the regulations of the Act on Medical Devices.

AMEDTEC Medizintechnik Aue GmbH maintains a certified quality management system according to DIN EN ISO 13485 and a certified quality assurance system according to Medical Device Directive 93/42/EEC, Annex II.

This Instruction Manual refers to the software version declared on the enclosed CD.

Index

Description

Fig. similar

CardioPart 12 Blue is a device for recording, diagnosis and digital storage of 12-channel ECGs.

The unit is supplied with the software **AMEDTEC *ECGpro***.

The device has been developed using the latest technological standards and meets all applicable requirements and standards. It falls within risk Class IIa according to MDD, Annex IX.

CardioPart 12 Blue is connected to a PC on which the AMEDTEC *ECGpro* user software is installed. The device converts the ECG signals recorded via electrodes into digital signals and transmits the digitized ECG wirelessly via Bluetooth to the software.

The software controls the device and displays the ECG on the monitor during recording. The user software also controls other devices, such as bicycle ergometers and blood pressure monitors. The recordings are saved after completion. Afterwards they can be viewed, edited and printed. Optionally, the recordings can be transferred to a hospital or practice network for further use. The unit reads and processes data from the hospital information system and practice software.

All features and their operation are described in the **AMEDTEC ECGpro CardioPart 12** manual.

The software runs locally or in a network.

The software was developed for the Windows operating system and runs on PCs with Intel or Intel-compatible processors. Information about the supported operating systems can be found in the **AMEDTEC *ECGpro* installation manual** in the section **Hardware and software requirements**.

The CardioPart 12 Blue is available with the following options

- *m* Resting ECG with automatic ECG measurement
- *mr* Resting ECG with automatic measurement and rhythm ECG
- *i* Resting ECG with automatic measurement, interpretation and rhythm ECG
- *s* Resting and exercise ECG with measurement, interpretation and rhythm ECG, ST measurement, control of ergometers and blood pressure monitors
- *as* Resting and exercise ECG with automatic measurement, interpretation and rhythm ECG, ST measurement, online arrhythmia detection, control of ergometers and blood pressure monitors

The following **P-Series** devices are designed for **use in medical practices**. Recordings made with these devices **cannot be exported via the DICOM and HL7 interfaces**. Case or request numbers cannot be processed with recordings of these devices.

- *Pmr* Resting ECG for medical practices with automatic ECG measurement and rhythm ECG
- *Pi* Resting ECG for medical practices with automatic measurement, interpretation and rhythm ECG
- Ps Resting and exercise ECG for medical practices with measurement, interpretation and rhythm ECG tracing, ST measurement, control of ergometers and blood pressure monitors
- *Pmrs* Resting and exercise ECG for medical practices with automatic ECG measurement, rhythm ECG tracing, ST measurement and control of ergometers and blood pressure monitors

Intended Use

CardioPart 12 Blue and AMEDTEC *ECGpro* user software are designed for recording, analysing and storing 12-channel resting and exercise ECGs.

It can be used with adults, adolescents, children, infants and newborns of all ethnic groups.

CardioPart 12 Blue is intended for use in clinics, hospitals, medical care centres and doctors' surgeries.

The device is only to be operated on the patient on doctor's orders. The application of the electrodes as well as the operation of the instrument and the user software may only be carried out by trained and instructed medical personnel.

With the exception of the electrodes, CardioPart 12 Blue is not intended for direct contact with the patient's skin.

Indication

The resting ECG is used to clarify the following symptoms:

- Diseases of the cardiovascular system
- Myocardial ischemia
- Myocardial infarction in patients with chest pain
- Heart hypertrophy
- Cardiac arrhythmia
- Disorders of the electrophysiology of the heart
- Disturbances of the pacemaker and stimulus conduction systems

The resting ECG can also be used to screen for cardiac abnormalities and to evaluate pacemaker functions.

The exercise ECG is performed:

- for clarification of thoracic pain
- to record the physical resilience
- in patients with cardiac risk factors
- for the assessment of residual haemorrhage
  - after myocardial infarction,
  - after revascularisation using interventional techniques, or
  - after aortocoronary bypass surgery

Contraindications

Contraindications only apply to the exercise ECG:

- Acute coronary syndrome
- Symptomatic high-grade aortic valve stenosis
- Decompensated heart failure
- Acute pulmonary embolism
- Acute inflammatory heart disease
- Acute aortic dissection
- Blood pressure crisis at rest >180/100 mmHg
- Acute leg vein thrombosis
- Acute severe general illness
- Extracardiac diseases with clearly limited life expectancy (≤ 6 months)

Safety regulations

Safety symbol

This symbol indicates safety instructions that you must follow to the letter.

Instruction manual

Please read these instructions for use carefully

- Operate the CardioPart 12 Blue as described in this manual.
- Always keep these operating instructions within easy reach.
- Please observe the following safety information.
- The instruction manual is available in the software AMEDTEC ECGpro under the menu Help ► Documents.
- If you have any questions about operation, please contact your dealer or our service department.

Responsibility of the operator

The operator is responsible for the safe operation of the CardioPart 12 Blue and the associated devices. He must ensure the following:

- CardioPart 12 Blue and the software may only be used by trained medical personnel on the instructions of a qualified physician.
- The personnel must be trained by a medical product consultant. Participation in the training course must be documented.
- This instruction manual must be kept in such a way that it is accessible to users at all times.
- The device must be in a perfect technical condition. Defective parts and lines must be replaced immediately.
- When CardioPart 12 Blue is connected with other medical or non-medical devices, a 'medical electrical system' is created whose safety must be ensured. Medical electrical systems must be assessed according to the EN 60601-1 standard.
- The intervals for the performance of safety checks must be determined by the operator. AMEDTEC recommends that the device be subjected to maintenance and service every 2 years.
- Please contact your dealer or our service department with any questions regarding safety

Limitations and exclusions

The CardioPart 12 Blue is <u>not</u> approved for applications involving direct contact with the heart.

The device must not be used on the patient at the same time as HF surgical units.

The device must not be installed in an MRI laboratory.

The device is not a sterile product and therefore not suitable for use in a sterile environment.

Accessories

Only ever use the accessories that are listed in this operating manual. CE conformity only applies if you use these accessories.

Using any other patient cables, adapters and wires can result in the device malfunctioning, in reduced immunity to electromagnetic interference as well as in increased emitted electromagnetic interference.

Electrical Safety

The CardioPart 12 Blue is a Medical Electrical (ME) device. It fulfils all requirements for the safety of medical electric devices, in particular the requirements of DIN EN 60601-1, DIN EN 60601-1-2 and DIN EN 60601-2-25.

The device is intended to be used with a personal computer (PC). A PC as well as all other devices of communication technology like monitors or printers are, as a rule, **non-medical electric devices**. Such devices do not fulfil the requirements by the appropriate standards to the safety of **medical electric devices**. Particularly, this concerns the electric parameters. Therefore, special measures are to be taken to protect the patient against the dangers by electrical current caused by non-medical electric devices.

The most important contribution to the protection of the patient makes the CF-type applied part which isolates the patient from the PC. This isolation withstands a voltage of 4000 volts and protects the patient from unallowed current.

There are further hazards which can arise from the PC as well as from the other devices of the communication technology.

Absolutely observe the following hints:

1. Arrange **non-medical electric equipment (PC, printer, monitor)** in such a way that the distance between these devices and the patient is **at least 1.5 meters**. This minimum distance should prevent the patient from touching non-medical electric equipment directly or indirectly. An indirect contact with metallic parts of non-medical electric equipment is also given if a person touches the patient and these parts at the same time.

If the distance of at least 1.5 meters described above cannot not guaranteed, non-medical electric equipment must be used with a safety isolating transformer. This safety isolating transformer must fulfil the requirements of DIN EN 61558-2-4. This also applies for battery-powered notebooks or laptops if other devices are connected to them which in turn are connected to, e.g., the mains or network.

- ☞ Connect the devices either directly to the safety isolating transformer or use a power strip which is connected to the safety isolating transformer either fixed or by a special plug. This plug must be secured in such a way that it cannot be connected to a normal, non-isolated mains outlet.

  The devices must be connected by means of power cables which are secured or do not fit into non-isolated mains outlets either. Such secured or special cables / plugs shall prevent the devices from being plugged directly to the non-isolated mains, passing by the safety isolating transformer.
- ☞ Do not put the power strips on the floor.
- ☞ Do not exceed the socket board's permissible amperage.

Use the safety isolating transformer only for devices which belong to the system.
Make sure that the devices connected to the safety isolating transformer are otherwise connected to further non-medical electric devices outside of the system (i.e. LAN) also only by galvanically isolated signal lines.

Caution: Cables of a computer network (LAN) are typical electrically conducting connections which from the system to the outside. For network connections, always use a Medical Isolator MI 1005, item No. 001 831.

2. All devices of a system must be connected within the same circuit. Devices which are not connected in the same circuit must be operated with galvanic isolation.
3. Use only non-medical electric devices with CE marking. Only so you can be sure that these devices fulfil the appropriate standards.
4. Connect the patient cable or the suction electrode system to the ECG device, only, but never to any other device.
5. If not all the 10 electrodes are used (e.g., only R, L, F, N), place the unused electrodes (e.g., C1 - C6) in such a way that they cannot get in contact with any metallic parts. Do not touch unapplied electrodes during the ECG recording.
6. Only use accessories from AMEDTEC Medizintechnik Aue GmbH.
7. Always use the CardioPart 12 Blue with a properly closed battery compartment.
8. If you do not use the device for a longer time, remove the batteries for protection from damages and possible impairment of safety due to leaking batteries.
9. If, for any reason, the electrical safety should be impaired, the system must not be used!

Patient cable

Use patient cables labelled with **AMEDTEC** exclusively (see Optional accessories on page 35) and pay attention to the attached operating manual.

Screw the patient cable firmly to the device

- If the patient cable is connected to the patient's body via the electrodes, it must be connected to the device for safety reasons.
- Only disconnect the patient cable from the device for disinfection and in case of service. Reconnect it before entering the patient environment.
- In principle, the sequence is as follows:
  1. Always connect the patient cable to the device first.
  2. Only then connect the patient cable to the patient via the electrodes.
  3. After ECG recording, first disconnect the patient from the patient cable.
  4. Disconnect the patient cable from the device (if necessary) only after completing this step

If you use a suction electrode system instead of the patient cable, connect it using the **ECG adapter,** item no. 011.0270. Only ever use suction electrode systems that are supplied by AMEDTEC or whose usability has been confirmed by AMEDTEC.

Electrodes

Use electrodes that bear the CE Mark.
Pay attention to proven bio-compatibility. Otherwise, patients can suffer allergic reactions.

Defibrillation

The device is only protected from defibrillation if you use a patient cable labelled AMEDTEC (see Optional accessories on page 35). The patient cable contains components which limit the current from the defibrillator.

The patient cable is marked on the plug with the symbol for the defibrillation-protected applied part of the CF type.

The use of a different patient cable can lead to the destruction of the ECG device and to a reduction of the delivered defibrillator power.

This can reduce the effectiveness of the defibrillator impulse.

Please ask your dealer if you want to connect a suction electrode system or contact our Service Department directly.

Ambient conditions

The ECG device and the associated information technology equipment (PC, monitor, printer, etc.) must not be used in an environment where there is a risk of explosion or where there is an oxygen-enriched environment, or in rooms containing flammable gases such as anaesthetics.

The ECG device is not splash-proof. Avoid, therefore, every contact with liquids and do not use the device outdoors. The device has an ingress protection rating of IP20.

At strong temperature change, moisture can form inside the acquisition device. This is the case when the device is brought from a cold environment in a warm one. Use the device only when you are sure that the moisture has dried up.

If liquid has penetrated, the patient must be disconnected from the device immediately. Then the device is to be taken out of operation.

The interior of the device must be dried and, if necessary, cleaned and disinfected. After the closing of the device, a functional test and a safety-check are to be carried out.

For proper execution of these works, contact your supplier or our service.

The ECG acquisition device may be used at temperatures between +5°C and +40°C. At temperatures beyond this area, inexact reproduction of the ECG may occur.

Make sure that operating personnel are not subjected to ambient conditions under which electrostatic charging can occur. The humidity should be > 25%.
Do not wear clothing made of synthetic fibres and avoid unsuitable floor coverings (carpets).

Electrostatic discharges can be caused by touching the device, which can lead to malfunctions.

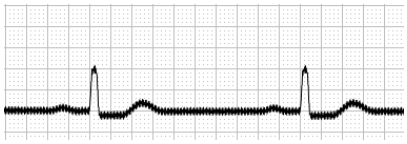
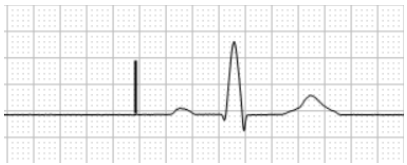
In extreme cases, electrostatic discharges can lead to recording of the ECG being interrupted briefly. In this case, the Bluetooth connection to the PC is interrupted and the orange display goes out.

☞ If the display of the ECG does not continue within 15 seconds, switch the device off and on again.

Effects due to electromagnetic radiation

Electrical or magnetic fields can cause disturbances and affect ECG recording.

The ECG device must only ever be used in the electromagnetic environment stated in Section Guideline and Manufacturer's Declaration on Electromagnetic Compatibility of CardioPart 12 Blue on page 37.

Visible disturbance in the ECG	Possible cause	Measure
	Electromagnetic radiation can be caused by electro-medical equipment, radio equipment, communications and office technology equipment, as well as by electrical equipment. By overlapping interference frequencies, electromagnetic radiation results in a wide ECG curve. Low-frequency disturbances like mains hum, for example, can be identified clearly when the mains filter is deactivated.	Examine the site for devices that can emit electromagnetic radiation. Switch off these devices to determine whether that makes a difference. Change the location and the direction of the stretcher or the ergometer or the treadmill. High impedances between the skin and the electrode can increase the sensitivity of the device to electromagnetic disturbances. For this reason, pay particular attention when attaching the electrodes.
	If option **Show detected pacemaker by artificial 1 mV pulse** is activated, the system shows the position of the pacemaker spike on the ECG. Electromagnetic disturbances can lead to the system displaying pulses even though no pacemaker spikes are present.	Deactivate the option. High impedances between the skin and the electrode can increase the sensitivity of the device to electromagnetic disturbances. For this reason, pay particular attention when attaching the electrodes. Check the patient cable.

High impedances between the skin and the electrode can increase the sensitivity of the device to electromagnetic disturbances. For this reason, pay particular attention when attaching the electrodes.

Influence by other devices

Simultaneous use with a further device(s) which are also electrically connected to the patient may lead to malfunctions. If such further devices are connected, pay attention for changes in the ECG display.

Use of the CardioPart 12 Blue device next to other equipment or with other equipment in a stacked form should be avoided, as this could result in improper operation. However, if it is necessary to use it in the prescribed manner, the CardioPart 12 Blue and the other devices should be observed to make sure they are working properly.

Portable RF communications equipment (including their accessories such as antenna cables and external antennas) should not be used within 30 cm (or 12 inches) of ECG device parts and leads. Otherwise this may result in a reduction in performance.

If multiple devices are used on the patient at the same time, it must be ensured that the sum of the leakage currents of all the devices used does not exceed the permissible limit.

If multiple devices are used on the patient at the same time, it must be ensured that the sum of the leakage currents of all the devices used does not exceed the permissible limit.

Damage

Only acquisition devices with absolutely intact outer appearance may be used.
Damages to the enclosure can cause ineffective isolation of the applied part. This can cause hazards.

Also, make sure that the plastic isolation of the patient cable is intact. If the connection between plug and lead is not stable any more, this is not only a security risk, but malfunctions can also occur.

Never use an acquisition device whose enclosure or cables are damaged.
Do not bend the patient cable, and keep it away from sharp edges.

Repair

The ECG device may be repaired only by the manufacturer or by a contracting partner authorised for it. Actions by unauthorised companies or people can raise a potential hazard and lead to the loss of the guarantee. In a service case, contact your supplier or our service.

Do not make any changes on the device.
Each change compared to the as-delivered condition, can result in hazards.

Cleaning and disinfection

The user decides on the cleaning / disinfection for hygienic reasons as well as on the cleaning intervals.
Important! Strictly follow the product information and the security data sheets of the manufacturer of the cleaning agents and disinfectants for the use of these products, as well as the following, specific hints for cleaning / disinfection of the ECG device, the stress test belt and the patient cable.
In case of use of other disinfectants which are not recommended by AMEDTEC, the user is responsible for the proof of use without damage. Use only disinfectants which do not leave residues on the product and which are suitable for skin contact.

For the cleaning of the enclosure and the patient cable, AMEDTEC recommends a moist, uncoloured single-use cloth.
For the cleaning of the stress test belt, AMEDTEC recommends neodisher ® MediClean forte, an alkaline cleaning agent with tensides, made by Dr. Weigert GmbH & Co. KG.
For disinfection, the following products of Schülke & Mayr GmbH are recommended:

terralin® liquid
mikrozid ®AF
mikrozid ®sensitive

CardioPart 12 Blue

Clean and disinfect the device only after having removed the battery and if device is not connected with the patient.

Into this sensitive, electronic device no liquid may enter. Never dip the device into cleaning or disinfection liquid, even not partially. Never use a spray bottle to apply the disinfectant, but basically only a moist disinfection cloth or ready for use mikrozid ® sensitive wipes. Make sure that no excessive liquid is wiped over edges and openings of the case and can get then into of the device. Fortification of active substance leftovers may lead to oxidation effects with following loss of functionality. Vulnerable places are the plug opening and the battery compartment. Always remove all active substance leftovers after their reaction time, and really allow the device to dry up completely before using it again.
Should, nevertheless, liquid have penetrated into the device, immediately take it out of use and send it to AMEDTEC for inspection.

Notice: To guarantee the necessary hygienic standard with minimum disinfection expenditure, AMEDTEC recommends the use of

single-use hygienic bags (item No.: 016.0233) together with
single-use carrying strap (item No.: 019.0619).

By this kind of application, the CardioPart 12 Blue including the plug of the patient cable is protected against contact with the patient.

Patient cable

Never dip the patient cable into cleaning or disinfection liquid, even not partially. Never use a spray bottle to apply the disinfectant, but basically only a moist disinfection cloth or ready for use mikrozid ® sensitive wipes. Make sure that no excessive liquid enters the cable plug on wiping. Fortification of active substance leftovers at the plug contacts may lead to oxidation effects with following loss of functionality. Always remove all active substance leftovers after their reaction time, and really allow the cleaned / disinfected patient cable to dry up completely before using it again. Should, nevertheless, liquid have penetrated into the plug, immediately send the patient cable to AMEDTEC for inspection.

Stress test belt

We recommend manual cleaning in a dipping bath or ultrasonic bath of an application solution of 3% at maximum 40°C, over 5 – 10 min. The Velcro fastener should be closed during the cleaning. The neodisher ® MediClean forte application must be rinsed off completely with water (preferably fully desalinated). The ergometry belt can be disinfected in in a dipping bath. The disinfectant can be sprayed on or be applied by means of disinfection cloths.
In case of use of other cleaning agents, for example, commercial mild detergents up to 40°C, the user is responsible for the proof of use without damage. Use only disinfectants which do not leave residues on the product and which are suitable for skin contact.
Before reusing, really allow the disinfected stress test belt to dry up completely.

Safety-technical checks

Time interval

Performing of safety technical checks are recommended at regular intervals of 2 years.
For proper execution of these works, contact your supplier or our service

CardioPart 12 Blue ECG device

Isolation check

The isolation of the protective-isolated applied part must be checked. The test voltage must be applied between all electrodes, which must be short-circuited between each other and a metal foil which surrounds the enclosure in a distance of 8mm to the patient cable plug.

Test voltage: 1500 V_{rms} / 50 or 60 hertz
Test duration: 60 seconds

Leakage current measurement

The patient leakage current and the contact current must be measured.

Checking for mechanical damages

The mechanical check is a visual control. The following is to be paid special attention to:

1. The enclosure must not show any damages.
2. The plug of the patient cable should be fixed firmly, and it may not move with screwed catch.
3. The patient cable must not show any damages. Make sure that plugs or clips are firmly fixed at the cable.

System

Always check the whole system. In any case, include the **safety isolating transformer** as well as the PC and all other electrically connected equipment.

Isolation check

The system includes several isolations. They have to be checked individually and successively. For the check, the devices have to be electrically separated. For the test voltage, refer to the safety standard of the concerned device.

Leakage current measurement

For measurement of the leakage currents, all devices must be electrically interconnected according to their intended use.

Safety-technical checks are to be carried out by instructed qualified personnel.
Please, contact our services.

Functional checks

1. Neither with each other nor with the cable screen, the electrode cable of the patient cable may have an electrically conducting connection.
   Also, high-resistance connections lead to falsifications of the ECG. High-resistance connections are difficult to ascertain. Therefore, use an appropriate measuring instrument.
   In principle, the same applies to the application suction electrodes.

   Wiring of the plug connector:

	Screen	N	R	L	F	C1	C2	C3	C4	C5	C6
Contact	6	14	9	10	11	12	1	2	3	4	5

2. Connect a calibrated signal transmitter of a sinusoidal voltage of 10 hertz / 2 mVss successively to the electrode cables R, L, F, C1 to C6. The remaining 9 electrodes are interconnected and form the reference point.
   Use lead set I, II, III, aVR, aVL, aVF, C1 to C6, and switch off all filters.
   Taking into account the lead calculation, the signals displayed must not deviate more than 5% from the rated value on all leads. Check this either on the monitor or on the printout.

Functional checks must be carried out by instructed qualified personnel.
Please, contact our services.

Service

If a device or equipment is required to be sent back to AMEDTEC, e.g. for inspection or repair, it must be properly cleaned and disinfected by the owner beforehand.
Please send a written confirmation about that process with the shipment.

Service phone number

You can reach our support team under the telephone number: +49 3771 59827 50.

Design and Operating Elements

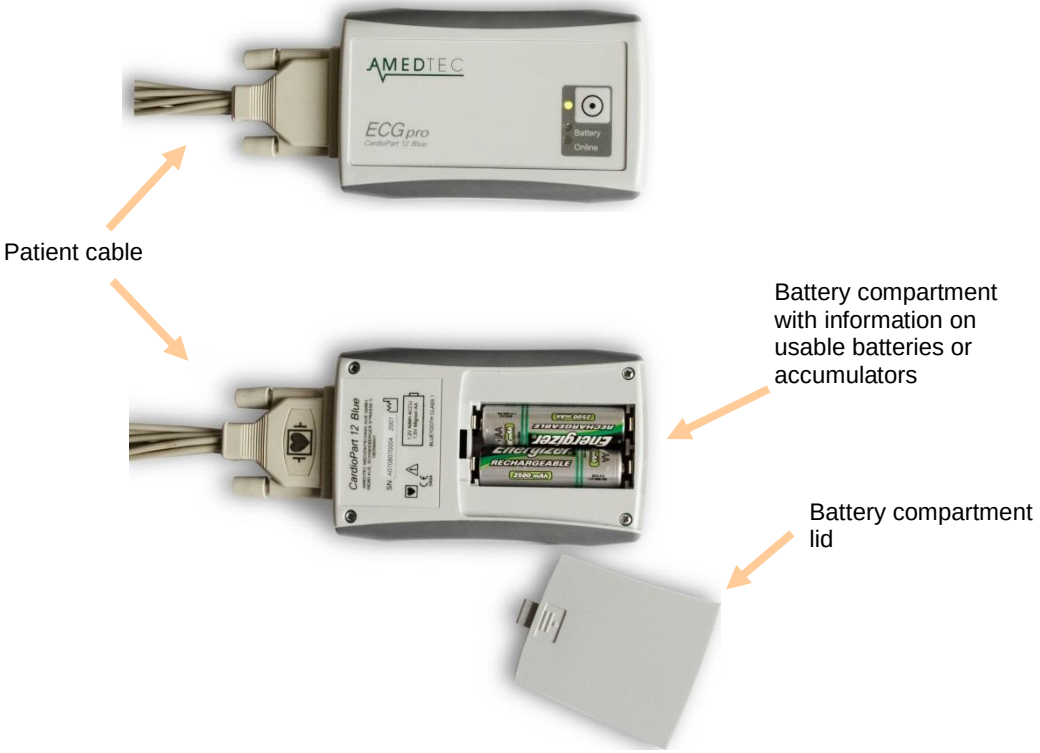
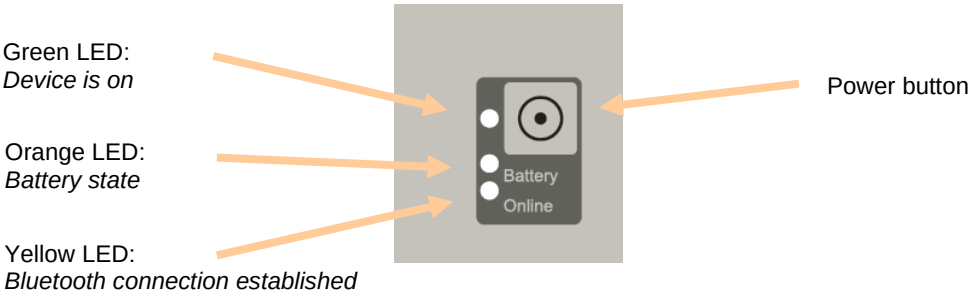


Fig. similar



Note: If your device shows a serial number greater than A101107093, the Power button additionally can be used to start and stop ECG recordings. For this feature, please read the **Settings** manual, section ***CardioPart 12 Blue***.

Putting into Operation

Connecting Devices

1. Mains Connection

Operate all devices which belong to the ECG system in the same circuit. Such devices - besides PC, monitor and printer - may be suction electrode equipment, bicycle and treadmill ergometers, blood pressure measuring instruments and others.

Arrange **non-medical electric devices (PC, printer, monitor)** in such a way that the distance between these devices and the patient is **at least 1.5 meters**. If this distance is not guaranteed, these devices must be operated through a safety isolating transformer.

Pay attention to chapter Safety regulations **on page 7.**

2. CardioPart 12 Blue ECG device

To use the device, the accompanying AMEDTEC *ECGpro* software must be installed on the PC.

- ☞ If the AMEDTEC *ECGpro* software has not been installed on the PC yet, perform the installation at first. Use the included setup CD and follow the hints of the installation instructions.
- ☞ Connect the supplied Bluetooth adapter to a free USB port of your PC.
  When you connect the device to a USB 2.0 port for the first time, it will be automatically installed by Microsoft operating systems.

Insert charged accumulators or new batteries into the ECG device. Pay attention for the right polarity.

Switch the device on. The switched-on state is indicated by a green LED.

Notice: **If not used, the device switches off itself automatically after 5 minutes. So, the connection should be made by this time.**

Please pay attention the maximum number of PC pairings is 16 for every CardioPart 12 Blue.

In order to reset the pairing list, devices up to S/N A1308070602 need to be sent in to AMEDTEC.

For devices with S/N A1308070603 and later, the pairings can be reset by yourself:

1. Switch on the CardioPart 12 Blue device
2. Press and hold the power button for about 10 seconds until the *Battery* and *Online* LEDs start light up. Then release the power button.
3. Wait for about 1 second, and then press and hold the power button again. → Both LEDs start flashing. – Keep the button pressed, until the LEDs have stopped flashing! Only then release the button.
4. The device's pairing list has been erased, and the device can be paired again for 16 times.

Now select and enable the recording device in **AMEDTEC *ECGpro*** software. Please read the section 3.12.1 CardioPart 12 Blue in manual AMEDTEC ECGpro – Options. For reading this document start AMEDTEC *ECGpro* and open the PDF - document in menu "*Help* | *documents*".

3. Stress Test Equipment

Connect to the PC a bicycle ergometer or treadmill ergometer if you wish to carry out stress tests.

AMEDTEC *ECGpro* controls the bicycle and treadmill ergometers listed on page **20** of chapter **Stress Test Settings.**

☞ Connect the RS232 interface of the exercise equipment with a RS232 interface of the PC. For the types EGT and Ergoselect, use the **Elmed / ergoselect interface cable**, Art. No. 018.0102. Should no RS232 interface be available, use an USB converter.

> Not all USB converters are suited for the connection of stress test equipment.
> Therefore, we strongly recommend using the USB-to-serial converter, Art. No. 001 659, from AMEDTEC.

4. Blood Pressure Meter

Use a bicycle ergometer with integrated blood pressure module or an external blood pressure meter if you wish to measure the blood pressure automatically.

AMEDTEC *ECGpro* controls the following blood pressure meters:

- *Tango* blood pressure meter
- *Cycle* blood pressure meter
- *Spengler* blood pressure meter
- *Metronik BL-6* blood pressure meter

Connecting the Tango blood pressure meter to CardioPart 12 Blue

☞ Connect Tango's RS232 interface with the **CardioPart 12 Blue → PC QRS Trigger receiver module**, Art. No. 016.0270.

☞ Use the USB plug to connect the receiver module to a USB port of the PC.

☞ Connect the Tango's QRS Trigger inlet with the BNC plug of the receiver module.

☞

Connecting the Cycle blood pressure meter

☞ Connect the RS232 interface of the blood pressure meter with a RS232 interface of the PC. Use the **Tango-PC RS cable**, Art. No. 001.585. If no RS232 interface is available, use an USB-to-serial converter at the PC.

> Not all USB converters are suited for the connection of blood pressure meters.
> Therefore, we strongly recommend using the USB-to-serial converter, Art. No. 001 659, from AMEDTEC.

Connecting the Spengler blood pressure meter

☞ Connect the USB interface of the blood pressure meter with an USB port of the PC.

Connecting the Metronik BL-6 blood pressure meter

☞ Connect the RS232 interface of the blood pressure meter with a RS232 interface of the PC. Use the **Elmed / ergoselect interface cable**, Art. No. 018.0102. Alternatively, you can use the USB cable included with your blood pressure meter to make a USB connection.

General Settings

1. Installation the AMEDTEC *ECGpro* User Software

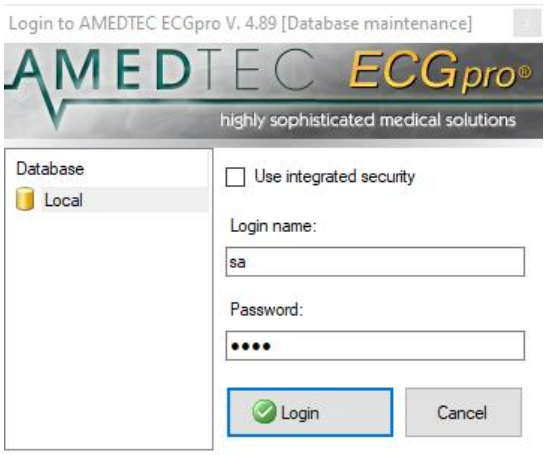
If the AMEDTEC *ECGpro* software has not been installed on the PC yet, perform the installation at first. Use the included setup CD and follow the instructions of the **AMEDTEC *ECGpro* Installation Manual**.

2. User Management

Launch AMEDTEC *ECGpro* as described in section **Start of Program** at page **22**.

Should the login fail, check whether you are logged in the user management as an active user.

☞ In the Windows start menu, chose: **Start ▶ Programs ▶ AMEDTEC ECGpro ▶ AMEDTEC ECGpro User Management**. The AMEDTEC *ECGpro* login for the database administration appears



☞ Log in with "sa" as username and with the „Strong password " used on installation of the MSSQL server.

If you are a Windows administrator for the PC on which the database is installed, you can log in with integrated security. In this case you need no password.

If your installation is a network, you must also have administrator's rights for the PC on which the data bank is installed.

☞ Enable the checkbox **Use integrated security.**

Now your Windows username is displayed, and you can log in. Refer to section **User login** on page **22**.

If you log in once again, the option **Use integrated security** can be already activated.

☞ Log in as active user.
For that, read section **User administration** in the **AMEDTEC *ECGpro* settings** instruction manual.

☞ If necessary, create more users. You can do that also at any later time by opening the **User Management** in "*File* | *Settings...* | *Security* | *User Administration"*.

3. CardioPart 12 Blue ECG Device

Upon delivery, ECG device is not factory-selected for acquisition. Before the CardioPart 12 Blue can be used, it must be activated and added to the list of the available devices.

☞ Make sure that the interface for the Bluetooth adapter was installed, and that the adapter was connected to the PC.

☞ Open "*File* | *Settings...* | *Devices* | *CardioPart 12 Blue*" and enable the **Use CardioPart 12 Blue** checkbox.

☞ Switch *CardioPart 12 Blue* on.

☞ Start searching *CardioPart 12 Blue* by clicking **Search** in the list of the available devices.
As a result of search, the acquisition device is indicated in the list.

☞ Activate or deactivate devices by clicking the corresponding check box.

4. Clinic Data

☞ In menu "*File* | *Settings...* | *General* | *Clinic data",* enter name, address and phone number of the practice or hospital.
These data are printed out by the ECG modules every time.

5. Selecting Test Procedures

☞ In menu "*File* | *Settings…* | *12 Lead ECG* | *Test procedures*", select from the group **Test procedures** which test examinations should be carried out in this job.

☞ Deactivate all the other test procedures.

☞ Deactivate all test procedures if the job should not be used for ECG acquisitions.

6. Selecting Starting Behaviour

- ☞ Open "*File* | *Settings…* | *General* | *Environment*".
- ☞ Select **Start up with Test procedure** if programme should return to a preset test procedure after the program start and after the saving.
  By default, the **Resting 12** procedure is set. To change this setting, select a different procedure. The procedures enabled in the preceding point are offered for selection.
- ☞ Select **Start up with Module: Data Management** if you always wish to start in the patient or acquisition administration, and if you also wish return there after saving.

7. Print Formats

- ☞ Open "*File* | *Settings…* | *12-Lead ECG* | *Printing*".
- ☞ For each of the record types of resting ECG, Rhythm ECG and Stress test ECG, create a set of print formats by moving formats from the left selection box to the right one. From these print formats, you can make your choice then for every printing process.
- ☞ In the **Used printing formats** box, you can activate the check box for the formats which should be printed by default.
- ☞ For every test procedure, print formats and printing parameters can differ from the values set here. For that, read section **Examinations** in the **AMEDTEC *ECGpro* settings** instruction.

8. Printer

By factory selection, the ECG is printed on your **System Default Printer**.
You can select a different printer.

- ☞ Open "*File* | *Settings…* | *General* | *Printer and Scanner*" and select a **Default printer**.

Stress Test Settings

1. Exercise Equipment

☞ Activate the bicycle / treadmill ergometer and make the necessary settings in the device driver.
For that, read section **Devices** in the **AMEDTEC *ECGpro* settings** instruction.

AMEDTEC *ECGpro* controls the following ergometers and treadmills:

Device	Settings in AMEDTEC *ECGpro*
Bicycle ergometer ergoselect 50, 100, 50, 200, 400, 600, 1000, 1100, 1200, 4, 5, 10, 12	*File* | *Settings...* | *12 Lead ECG* | *Bicycles* | *ergoselect*
Viasprint 200P	*File* | *Settings...* | *12 Lead ECG* | *Bicycles* | *ergoselect*
Supine ergometer ergoselect 1000 L	*File* | *Settings...* | *12 Lead ECG* | *Bicycles* | *ergoselect*
Stress echo cardiography ergometer ergoselect 1200 EL	*File* | *Settings...* | *12 Lead ECG* | *Bicycles* | *ergoselect*
Stress Echo Table 100 MED	*File* | *Settings...* | *12 Lead ECG* | *Bicycles* | *ergoselect*
Bicycle ergometer ergometrics 900	*File* | *Settings...* | *12 Lead ECG* | *Bicycles* | *ergometrics 900*
Bicycle ergometer EGT 2100 / 2200	*File* | *Settings...* | *12 Lead ECG* | *Bicycles* | *EGT 2100 / 2200*
Bicycle of manufacturer Lode	*File* | *Settings...* | *12 Lead ECG* | *Bicycles* | *Lode*
Bicycle ergometer mb1 … mb4	*File* | *Settings...* | *12 Lead ECG* | *Bicycles* | *medical bike*
Bicycle ergometer SanaBike 150 / 250	*File* | *Settings...* | *12 Lead ECG* | *Bicycles* | *SanaBike 150 / 250*
Treadmill ergometer RAM 770, RAM 860, RAM 870	*File* | *Settings...* | *12 Lead ECG* | *Treadmill* | *RAM*
Treadmill ergometer RAM 880, RAM 890	*File* | *Settings...* | *12 Lead ECG* | *Treadmill* |*RAM*
H/p/cosmos treadmill ergometer	*File* | *Settings...* | *12 Lead ECG* | *Treadmill* | *h/p/cosmos*
Treadmill Trackmaster	*File* | *Settings...* | *12 Lead ECG* | *Treadmill* | *Trackmaster*
Treadmill Daum	*File* | *Settings...* | *12 Lead ECG* | *Treadmill* | *Daum*
Treadmill Lode	*File* | *Settings...* | *12 Lead ECG* | *Treadmill* | *Lode*
Treadmill T-2000 / T-2100	*File* | *Settings...* | *12 Lead ECG* | *Treadmill* | *T-2000 / T-2100*
Treadmill Quinton	*File* | *Settings...* | *12 Lead ECG* | *Treadmill* | *Quinton*
Treadmill ACT	*File* | *Settings...* | *12 Lead ECG* | *Treadmill* | *ACT*

☞ Change the settings of the exercise equipment.
For that, read section **Devices** in the **AMEDTEC *ECGpro* settings** instruction and follow the instruction manual of the exercise equipment.

2. Blood Pressure Meter

☞ Activate the blood pressure meter and make the necessary settings in the device driver.
For that, read section **Devices** in the **AMEDTEC *ECGpro* settings** instruction.

Device	Settings in AMEDTEC *ECGpro*
Tango blood pressure meter	*File* | *Settings...* | *12 Lead ECG* | *NIBP measurement devices* | *Suntech Tango*
Cycle blood pressure meter	*File* | *Settings...* | *12 Lead ECG* | *NIBP measurement devices* | *Suntech Tango*
Spengler blood pressure meter	*File* | *Settings...* | *12 Lead ECG* | *NIBP measurement devices* | *Spengler SCVL-2007*
Metronik BL-6 blood pressure meter	*File* | *Settings...* | *12 Lead ECG* | *NIBP measurement devices* | *Metronik BL-6*

☞ Change the settings of the blood pressure meter.
For that, read section **Devices** in the **AMEDTEC *ECGpro* settings** instruction and follow the instruction manual of the blood pressure meter.

If the Tango blood pressure meter is used, the QRS trigger outlet must be enabled.

Tango blood pressure meter and *CardioPart 12 Blue*

☞ In "*File* | *Settings...* | *12 Lead ECG* | *ECG Devices* | *CardioPart 12 Blue*, enable the checkbox **Enable QRS trigger**.

☞ Enter the code of the **CardioPart 12 Blue → Tango-PC QRS trigger receiver module** in the field **Code of QRS trigger unit**.
For that, read section **Devices / *CardioPart 12 Blue*** in the **AMEDTEC *ECGpro* settings** instruction.

3. Stress Protocol

By factory selection, every test procedure has one stress protocol.

If you wish to use a different protocol

☞ In "*File* | *Settings …* | *12-Lead ECG* | *Test procedures*", select the test procedure which you want to select a different protocol for.

☞ Click the **Exercise Options** tab.

☞ Select a **stress test protocol**.

If you wish to modify a protocol

☞ Open "*File* | *Settings...* | *12-Lead ECG* | *Protocol*".

☞ Select the protocol you wish to modify.

☞ Change the load, the length of the load stages, or the times for blood pressure measurement and for saving of ECG sections.
For that, read section **12-Lead ECG / Protocols** in the **AMEDTEC *ECGpro* settings** instruction.

The following pages will give a general survey about handling the program. For detailed information read the Instruction Manual on the AMEDTEC *ECGpro* CD or in menu "*Help* | *Documents*".

Start of Program

Start

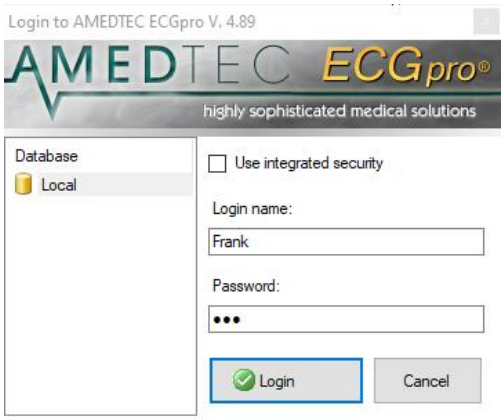
Start AMEDTEC *ECGpro*.

- ☞ Double click on the desktop icon or
- ☞ Select in the Windows Start menu:
  Start ▶ All Programs▶ AMEDTEC ECGpro ▶ AMEDTEC ECGpro.

Alternatively, the program can also be started automatically by a link in Auto Start.

User login

AMEDTEC *ECGpro* requires the legitimation of the user who wants to operate the program.
Therefore, at program start, a login dialog is displayed.



- ☞ Enter user name if it is not automatically displayed. (Note: If the current Windows user login is also known to the AMEDTEC *ECGpro* database, it is automatically entered into the Login Name field.)
- ☞ Enter your password.
- ☞ Click on **Login** or press the **ENTER** key.
- ☞ Enable the option **Use integrated security** if you wish to abandon the login on future usage. In this case, *ECGpro* will take over your user data from the Windows registration.
  Through enabling this option, the input fields become inactive.
  Pay also attention to the notes hereunto in the instruction manual **AMEDTEC *ECGpro* Settings** in paragraph **User management**.

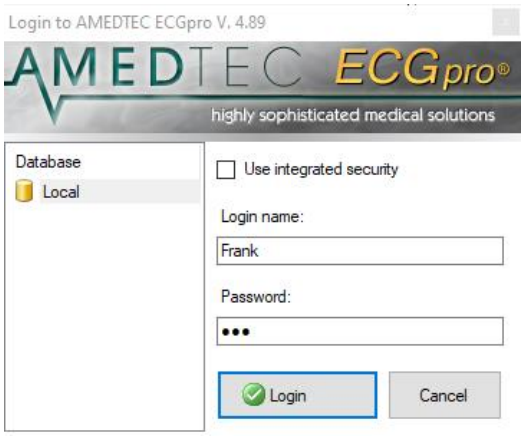
Logging in as another user...

Use this function if

- you wish to log in to an AMEDTEC *ECGpro*, where another user is already logged in or
- you wish to disable the option **Use Integrated Security**.

Proceed as follows:

- Open the menu "*File* | *Login as another User…*"
  (the function is not active while recording ECG and while reviewing a recording).



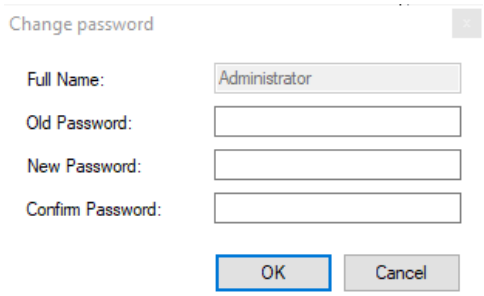
- Disable the option **Use Integrated Security** if it is enabled.
  The input fields become active.
- Enter user name and password.
- Click on **Login** or press the **ENTER** key.

Changing Password

If you wish to replace your previous password by a new one, proceed as follows:

- Open the menu "*File* | *Change Password…*"

This file entry will be only available if you are not logged in with **Integrated Security**.



- Enter previous and new password.
- Enter your new password again to confirm it.
- Click on **OK** or press the **ENTER** key.

Start Options

The program either starts

- in the module **Data Management** or
- with test procedure **Stat ECG**, see paragraph **Recording an Stat ECG** on page **25** or
- with test procedure **Resting ECG**, see paragraph **Recording Resting ECG** on page **27** or
- with test procedure **Rhythm ECG** or
- with test procedure **Stress Test ECG**, see paragraph **Recording Stress Test ECG** on page **29**.

The selection of the start-up option is described in the instruction manual **AMEDTEC *ECGpro* Settings** in paragraph **General, Environment**.

Patient Data

If you have not changed factory settings, you should start with button **Select patient** after launching the program.

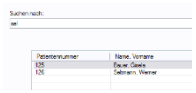
1a **In ECG acquisition choose the patients data.**

- ☞ Open the dialogue **Patient details** with this button.
- ☞ Enter patient number partly or completely, patient's last or first name completely or first characters or date of birth completely into this field 

.
- ☞ Start your search with button 

.

A list of all patient data that contain the entered character string in any place is displayed.



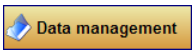
Example:

Choose the string **sel**. **Sel** is found in the last name **Sel**tmann but not in the first name Gi**sel**a.

- ☞ Click on the button 

. The input dialogue **Patient details** opens.

1b **In Data Management select the patient.**

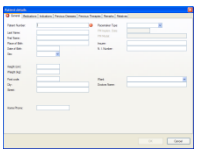


- ☞ Select the patient in **Data management** on file card **Search.** (for search function see point 1a).

2a **New Patient**

- ☞ Use this button if you wish to add data for a new patient.

2b **Choose patient data**



- ☞ In the menu „*File* | *Settings...* | *Database* | *Patient details*" you can define the fields you want to use and which of them have to be filled. Furthermore is it possible to change field's names.

The system checks certain entries for plausibility. In case of blinking exclamation signs, the entry is not accepted. Check your entry for correctness.

3 **Patient**

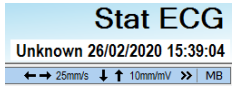
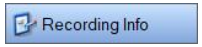
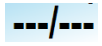
- ☞ If patient is already selected (name in head line) this button opens the dialogue with patient data.
- ☞ If no patient is selected this button opens the dialogue for searching a new patient or for entry new patient data.

ECG-Recording

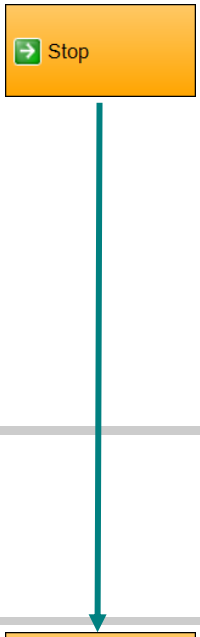
Recording an Stat ECG

Use the Stat ECG if patient details are not yet available in system. Later, if patient data are known to AMEDTEC *ECGpro*, the recording can be assigned to this patient.
A Rhythm variant is also available in AMEDTEC ECGpro for the Stat procedure. This program saves the ECG over a longer period with several analysed strips.

Use the functions under Option only if you want to deviate from the standard.

		Routine	key-board	Options	
1	**Select the Stat ECG.** **No input of patient data will be done.**		Crtl+1	Alternatively you can select the **Stat Rhythm ECG** in menu „*File* | *Settings...* | *12 Lead ECG* | *Test Procedures*“ if a device with option mr, i, or as is connected.	
					Click the white area and change the predefined string for a better tagging of the patient (e.g. „accident on side“).
2	**Apply the electrodes.** **Incorrectly applied electrodes blink. Note the graphs indicating the hook-up quality. Check the ECG traces.**				Enable the filter only if no sufficient acquisition can be achieved.
			F3		Enter a remark.
			Shift+F3		Start a connected blood pressure device or
			Click		enter the blood pressure value manually.
3	**Start the acquisition** **The button becomes only active if all electrodes are applied correctly.**		F2 or 		
			Crtl+S		You can start even if the electrodes applied insufficiently.
			Crtl+A		Start the recording for exactly 10 seconds. Electrode errors restart the timer. After 10 seconds the timer stops the recording automatically.

4 Stop and check the recording



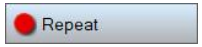
F2
or

In contrary to the Resting ECG, the Stat ECG does not stop automatically. A manually stop is necessary!
In headline the main measurement values for the last 10 seconds of ECG are displayed.

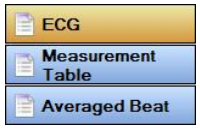
Crtl+T

Alternatively, you can stop with this button.

Crtl+S
Crtl+A



If necessary, repeat the recording in manual mode or in automatic mode. In this case, you will delete the already recorded data.



Click the button **ECG** for checking the multi-channel ECG strips.

Click the button **Measurement Table** for displaying measurement values in QRS, P wave and T wave in every lead.
Click the button **Averaged Beat** for displaying enlarged beat, to measure it and to correct the wave margins.

5 Print the ECG

Crtl+F

If you want to display the print preview, click this button.

Crtl+P

Print the record in the standard format. The name entered in point 1 of this table will be used as Patient Information.
Right click one of this buttons for opening the dialogue **Format selection**. Here you can select other print formats or set other printing parameters.

6 Save the recording

F2

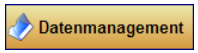
The saved recording you will find in Data management on file card **Unassigned recordings**.

Crtl+X

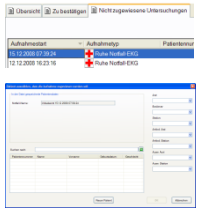
If you do not want to save the record, click this button.

7 Assign the recording to an patient

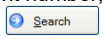
After creating the patient data in Data Management, the recording can be assigned.



Open the Data management.



Open the file card **Unassigned recordings**. Double click the recording you wish to assign to an existing patient. If patient doesn't exist you can create a new patient.

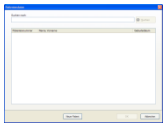
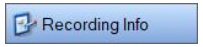
Enter patient number, patient's first or last name partly or completely and click the button 

.
A list of all patient data that contain the entered character string in any place is displayed. Select the relevant patient and click the button **OK**.

Recording Resting ECG

Below the essential steps for recording resting ECG are described. Provided are the default settings for AMEDTEC *ECGpro*. If you have modified the system (like adding new test procedures or link to medical information system) variations of the following description may occur.

Use the functions under Option only if you want to deviate from the standard.

		Routine	key board	Options
1	**Select the test procedure**		Crtl+2	For adding, deleting or modifying test procedures select the menu: „*File* | *Settings...* | *12 Lead ECG* | *Test Procedures*“.
2	**Search the data of the active patient or enter new patient data.**		F2	If you have chosen Test Procedure from Data Management the active patient is selected already. Check the patient name in head line. If heretofore no patient is selected the dialogue **Patient details** will open. Enter to the field **search:** the surname, the first name, the patient number partially or complete. Start the search function with button  . Select the relevant patient from the list. 
3	**Apply the electrodes.** **Incorrectly applied electrodes blink. Note the graphs indicating the hook-up quality. Check the ECG traces.**			 Enable the filter only if no sufficient acquisition can be achieved.
			F3	 Enter a remark.
			Shift+F3	  Start a connected blood pressure device or Click  enter a blood pressure value manually.

4 Start the acquisition

The button becomes only active if all electrodes are applied correctly.

F2
or

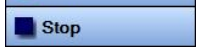
Crtl+A 

You can start even if the electrodes are applied insufficiently.

Crtll+R 

The system starts a timer which stops the record after 10 seconds. You can restart the timer within 10 seconds. The acquisition starts from the beginning.

Crtl+S 

Crtl+T 

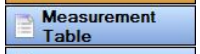
You can start and stop the acquisition manually.

5 Check the acquisition

Crtl+S
Crtl+A 

If necessary repeat the acquisition in manual or in automatic mode.

Click the button **ECG** for reviewing the multi channel ECG.



Click the button **Measurement table** for displaying measurement values of Q, R, S waves, of ST range and of P wave.

Click the button **Averaged Beat** for displaying the calculated beat as one channel or as multiple channels with wave points.

Crtl+B 

You can mark your remarks and the diagnosis as validated. The validation mark includes the date and the full username, as it was entered in the user management.

6 Print the acquisition

Crtl+F 

Display the print preview (standard print format) on display.

Crtl+P 

Print the record in the standard format.

Right click one of the both buttons for opening the dialogue **Print format selection**. In this dialogue you can select the print formats and you can change the print parameters.

7 Save the recording

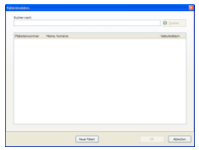
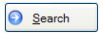
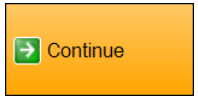
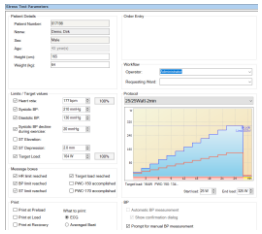
F2

Crtl+X 

Stop here if you do not wish to save the recording.

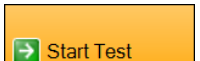
Recording Stress Test ECG

Use the functions under Option only if you want to deviate from the standard.

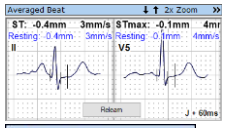
		Routine	Key board	Option
1	**Select the Stress Test procedure.**		Crtl+7	Customise your test procedure in menu: „*File* | *Settings…* | *12-Lead ECG* | *Test procedures* | *Bicycle Stress Test*“ (or. „Treadmill Stress Test“).
2	**Select the data of the active patient.**	 		If you have opened data management before or you have recorded an resting ECG, the patient is selected already. Click the button **OK**. If no patient is selected, the dialogue for searching or creating an patient is automatically opened. Use the field **Search for**: ☞ Enter Patient number, patient’s last or first name partly or completely into this field. ☞ Start your search with the button  or press the **ENTER** key.
3	**Check the Stress Test parameters**			 Check the patient data. Check the limit values beyond which messages should be displayed. If necessary, select another **protocol** or customise the selected **protocol** or change **Start-Load** or **End-Load**. Check the setting for printing and automatic measuring blood pressure.
4	**Apply the electrodes.** **Incorrectly applied electrodes blink. In the ECG preview, Check the acquisition quality.**		F3	 Enable the filter only if no sufficient acquisition quality can be achieved.  You can enter a remark.

5 Start the Stress Test.

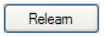
The button becomes only active if all electrodes are applied correctly.



F2
or



Wait until an averaged beat is indicated.

Use the button 

to repeat the averaged beat calculation if the quality of the indicated averaged beat is insufficient.
You can place a label and letter it.

F4

F6

Stop the multi-channel ECG and turn back to see events again and to print.

F5

Save the last 10 seconds as an ECG section.

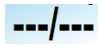
Print the continuous ECG. Click once more to stop printing.

Print the last 10 seconds as an ECG section.

Print the averaged beat of the last 10 seconds.

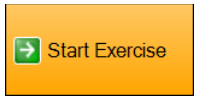
Crtl+
F3

Start the connected blood pressure device
or

Click 

enter the blood pressure value manually.

6 Start the exercise



F2

Crtl+
F3

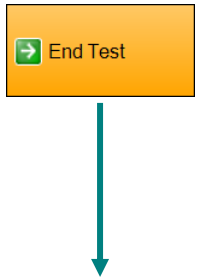
Correct the automatically measured blood pressure value within one minute if required. After one minute a new input is interpreted as new blood pressure value.

Crtl+↑
Crtl+↓

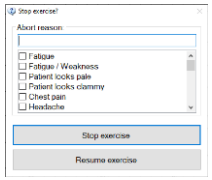
Click ↑ to increase the load and ↓ to decrease it.

At any time, you can switch to the next load stage or maintain the actual load stage as long as you like.

7 **Stop the load before the set exercise time if the state of the patient requires this.**



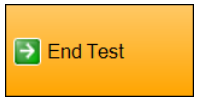
F2



Enter a reason for the cancellation of the strain.
Alternatively you can continue with the load.

During Recovery stage you can open the dialog to enter Abort Reasons with that button.

8 **Stop the Stress Test.**



F2
or

9 **Check the acquisition.**

F2

Leaf through the whole ECG. Use the views as shown on the right.

In the **Summary** view , enter your findings.

Crtl+B

You can perform a confirmation of the diagnosis. Your username is added then together with datum and time to the diagnosis or to the remark.

Crtl+F

You can view at the standard formats in the preview on the monitor.

Crtl+P

Print the recording in the standard format.

10 **Save the record.**

F2

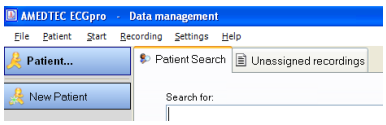
Crtl+X

Stop here if you do not wish to save the record.

Opening ECG acquisitions

Stored recordings are displayed in Data Management.

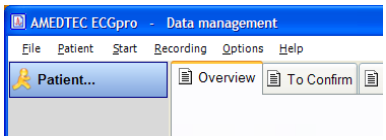
☞ For opening an recording change to **Data Management**.



☞ Click the file card **Patient Search.**

☞ For searching an patient read **Recording Resting ECG**, chapter **Select patient** .

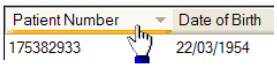
☞ For fast finding an specific patient in a long list use the dialogue **Patient details**.



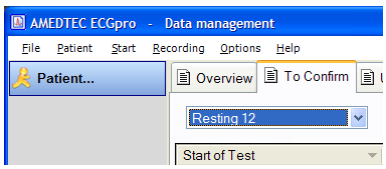
In a new system the file card **Overview** is not activated. For using the file card move the item **Overview** in "*File* | *Settings…* | *Database* | *Data management*" to box **Used tab pages**. Leave the settings and restart AMEDTEC *ECGpro*.

☞ Click the file card **Overview**.

The file card Overview displays a list of patient data on the left and a list of acquisitions according to the selected patient on the right.



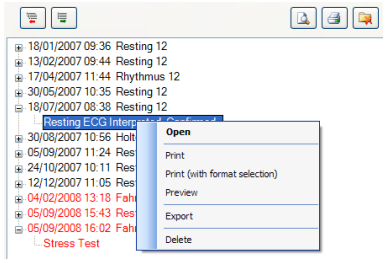
☞ For sorting the patient list (sort for patient number, sort for patient name) click the field in the headline.



☞ Alternatively you can use the file card **To Confirm.**

☞ Open the drop down box for selecting filters. With help of filters you can restrict the list by assigned tests or by recording time.

The file card **To Confirm** displays only unconfirmed recordings. After checking and confirming the test by an physician the entries disappear.



☞ Click the button to display the information of all ECG acquisitions.

☞ For opening an ECG acquisition double click the entry
or
open the context menu through right click on an recording and click the entry **Open**.

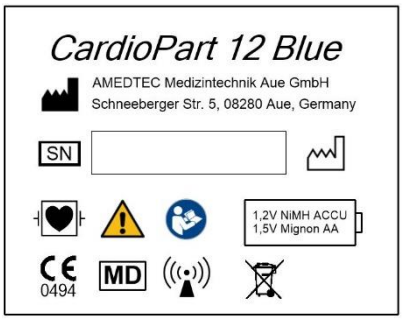
The recording list on file card **Overview** and on patient file card are identical.

It is important to note that confirmed recordings can't be modified. Functions like adding remarks, moving measurement points or correcting diagnosis are not possible.

Type Plate and Symbols

Information on the type plate:

- Designation of device
- An optional letter „T“ next to “CardioPart 12 Blue” denotes devices with a QRS trigger module.
- Manufacturer’s address
- Serial number and year of manufacturing
- Symbols



Symbol	Description
SN	Device number/serial number
	Manufacturer
	Year of manufacture
CE 0494	CE marking with Notified Body: SLG Prüf- und Zertifizierungs GmbH, Burgstädter Straße 20, 09232 Hartmannsdorf, Germany
MD	The device is a Medical Device.
	Defibrillation protected ECG input of type CF. Attention: Part of the defibrillation protection is in the patient cable. The device is protected against defibrillation only when the supplied patient cable is used.
	Warning, observe safety instructions!
	Follow the instructions for use!
	Hints on the use accumulators or batteries
	Hints on RF communication equipment
	Products marked with a crossed-out wheeled bin must not be disposed of with household waste. See section Disposal on p. 40.

Technical Data

Dynamic range	+/- 316 mV DC
Sampling frequency	8000 Hz for each of the 10 electrodes [10 x 8000 / second]
Resolution	1 µV / LSB [0.01 mm]
IMRR	> 120 dB
Frequency range	0.05 - 150 Hz
Pacemaker detection	Digital monitoring of all electrodes
Input impedance	> 50 MOhm
Input protection	Against defibrillator pulses[1)] and energy from HF-surgery devices
Electrode test	Frequency analysis and impedance measurement
Patient cable connection	15 Pin D-Sub
Application part	Type CF isolation voltage 4000 V
PC interface	Bluetooth 2.0 classes 1 or 2
Power supply	2 Mignon AA batteries or accumulators
QRS trigger	by ISM-radio Module[2)]
Dimensions	110 mm x 64 mm x 28 mm
Weight	160 g
Operating mode	Continuous operation
Ambient conditions	
Operation	Temperature: +5°C to +40°C
	Relative humidity: > 25%, < 85% non-condensing
	Atmospheric pressure: 70kPa to 106kPa
Transport and storage	Temperature: -25°C to +70°C
	Relative humidity: < 95% non-condensing
Standards	DIN EN 60601-1; DIN EN 60601-1-2; DIN EN 60601-2-25

[1)] The patient cable or the suction electrode system must have a protective resistance of 10 kOhm in every electrode cable.

[2)] Version “T”, only

RF communication equipment:

Type	Frequency / Band	Channel width	Modulation	Emitted energy
Bluetooth	2.402 GHz through 2.483 GHz	1 MHz	GFSK, PI/4-DQPSK, 8-DPSK	+16 dBm
AMEDTEC Trigger	433.9 MHz	64 kHz	2-FSK	+6 dBm

Optional accessories

Designation	Order No.
CardioPart 12 Patient Cable, 10-wire/Banana/IEC/1,53m	011.0227
CardioPart 12 Patient Cable, 10-wire/Pinch/IEC/1,53m	011.0228
CardioPart 12 Patient Cable, 10-wire/Snap/IEC/1,53m	011.0229
CardioPart 12 Patient Cable, 10-wire/Pinch/IEC/1,05m	011.0237
CardioPart 12 Patient Cable, 10-wire/Snap/IEC/1,05m	011.0238
CardioPart 12 Patient Cable, 10-wire/Banana/AHA/1,53m	011.0241
Stress Belt CardioPart 12 USB / Blue	016.0234
ECG Adapter (for vacuum equipment)	011.0270
Limb clip electrode Ag/AgCl	011.0280
Chest suction electrode Ag/AgCl	011.0281
Bluetooth USB Dongle	100 107
Charger incl. 4 rechargeable batteries	001.427

Troubleshooting

Error at ECG recording

The system displays electrodes with inadequate contact as a flashing icon.
If it is not possible to record any more ECGs, the system hides derivations on the screen.

- ☞ In these cases, check attachment of the electrodes and/or the patient cable.
- ☞ Pay attention to the information about Influence by other devices on page 11

If an electrode is not returning any more ECG signals, this can lead to several derivations being hidden. The table below gives you an overview of the 12-channel ECG.

Faulty electrode		Hidden leads	Displayed leads
IEC	AHA		
N	RL	All	None
R	RA	I, II, aVR, aVL, aVF, C1 …C6	III
L	LA	I, III, aVR, aVL, aVF, C1 …C6	II
F	LL	II, III, aVR, aVL, aVF, C1 …C6	I
C1	V1	V1	I, II, III, V2, V3, V4, V5, V6
C2	V2	V2	I, II, III, V1, V3, V4, V5, V6
C3	V3	V3	I, II, III, V1, V2, V4, V5, V6
C4	V4	V4	I, II, III, V1, V2, V3, V5, V6
C5	V5	V5	I, II, III, V1, V2, V3, V4, V6
C6	V6	V6	I, II, III, V1, V2, V3, V4, V5

General error

In most cases, warnings and error messages of the AMEDTEC *ECGpro* software are self-explaining. Particularly, this refers to:

- Connection issues:
  Make sure that the **CardioPart 12 Blue** device is switched on, that other devices do not inadequately interfere with the Bluetooth communication, and that the Bluetooth link is not blocked by too large distances or relevant obstacles in between. Also, note the **Guideline and Manufacturer's Declaration on Electromagnetic Compatibility of CardioPart *12* Blue** on page **37**.

- Power supply:
  Please check the batteries regarding capacity, state of charge, and age.

In all other cases, please contact our support (ref. page **14**).

Guideline and Manufacturer's Declaration on Electromagnetic Compatibility of CardioPart 12 Blue

The ECG device is determined for operation in an electromagnetic environment as specified below. The customer or user of the device should make sure that it is used in such an environment.

Emission test	**Test level**	**Compliance level**	
RF emissions CISPR 11	Group 1, Class B	Group 1, Class B	The device's RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.

Immunity test	**IEC 60601-1-2 test level**	**Compliance level**	**Electromagnetic compliance guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV contact ±2, ±4, ±8, ±15 kV air	±8 kV contact ±2, ±4, ±8, ±12 kV air	Floors should be wood, concrete or ceramic tile. If the floors or clothing are covered with synthetic material, the relative humidity should be at least 30%.
Conducted disturbances, induced by radio frequency fields IEC 61000-4-6	3 V_{rms} 150 kHz - 80 MHz 6 V_{rms} 150 kHz - 80 MHz in ISM band	3 V_{rms} for input/ output lines 6 V_{rms} for input/ output lines in ISM band	Portable and mobile RF communications equipment should be used no closer to any part of the unit, including cables, then the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance: d = 1.17$\sqrt{P}$
Radiated RF-disturbance variables acc. to IEC 61000-4-3	3 V/m 80 MHz - 2.7 GHz	3 V/m 80 MHz - 2.7 GHz	d = 1.17$\sqrt{P}$ for 80 MHz through 800 MHz d = 2.33$\sqrt{P}$ for 800 MHz through 2.7 GHz d: distance in m P: transmitted power in W The field strength of stationary radio transmitters [a)] should be less than the compliance level [b)] at all frequencies according to an on-site test. Interference may occur in the vicinity of equipment marked with the following symbol: 
RF wireless communication equipment IEC 61000-4-3	Test frequencies between 385 MHz and 5785 MHz acc. to table 9, IEC 60601-1-2:2014	Test frequencies between 385 MHz and 5785 MHz acc. to table 9, IEC 60601-1-2:2014	
Power frequency (50 Hz) magnetic field IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

At 80 MHz and 800 MHz, the higher frequency range applies.

These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

[a)] Field strengths from fixed transmitters, such as base stations for radio (cellular / cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To access the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the ECG device is used exceeds the applicable RF compliance level above, then the device should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the device.

[b)] Over the frequency range from 150 kHz through 80 MHz, field strengths should be less than 3 V/m.

Recommended protective distances between portable and mobile HF-telecommunication devices and the ECG device

The ECG device is intended for use in electromagnetic environments in which the RF disturbances are controlled. The user of the device can help to prevent electromagnetic interference by maintain a minimum distance between portable and mobile RF communication equipment (transmitters) and ECG device – as recommended below, according to the maximum output power of the communication equipment.

Rated maximum output power of transmitter W	Separation distance according to frequency of transmitter m		
	150 kHz - 80 MHz	80 MHz - 800 MHz	800 MHz - 2.7 GHz
	$d = 1.17\sqrt{P}$	$d = 1.17\sqrt{P}$	$d = 2.33\sqrt{P}$
0.01	0.12	0.12	0.24
0.1	0.37	0.37	0.74
1	1.17	1.17	2.33
10	3.69	3.69	7.38
100	11.70	11.70	23.30

For transmitters rated at a maximum output power not listed above, the recommended separation d in meters can be estimated using the equation applicable to the frequency of the transmitter in watts according to the transmitter manufacturer.

At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Warranty

1. For its devices purchased in the EU, AMEDTEC Medizintechnik Aue GmbH ensures a warranty of 12 months ex delivery. The warranty applies to all lacks that can be attributed to defects of fabrication or of material.
2. The warranty does not apply to damages that can be attributed to normal wear, wilful damage, misuse, negligence, abnormal environment conditions, improper treatment, non-observance of the instruction manual, disregard of oral or written instructions, incorrect installation, unauthorized modification, or repairs through persons not authorized by AMEDTEC.
3. Not covered by this warranty are expendables such as (but not limited to) electrodes, rechargeable and non-rechargeable batteries, battery contacts, sleeves, cables and hoses, depending on the device type.
4. Upon a legitimate warranty claim, AMEDTEC Medizintechnik Aue GmbH can in its sole discretion repair the device in question or substitute it by a device of the same type or by a device serving the same purpose and corresponding to the same or a more recent state of the art. Devices or components returned within the scope of the corrective maintenance or of the substitution change into the ownership of AMEDTEC Medizintechnik Aue GmbH.
5. AMEDTEC Medizintechnik Aue GmbH can conduct an on-site repair or authorize a contracting partner to conduct the repair or substitution.
6. If AMEDTEC Medizintechnik Aue GmbH or an authorized contracting partner of AMEDTEC Aue GmbH performs a warranty service, the warranty period will not be extended thereby.
7. Legitimate evidence for the warranty is the purchase invoice or any other voucher on which the date of purchase appears. Any warranty claim has to be asserted within a term of two months after notice towards the distributor or directly towards AMEDTEC Medizintechnik Aue GmbH.
8. AMEDTEC Medizintechnik Aue GmbH is only liable in case of gross negligence or intent. The claim for damages is, depending on the device type, limited to the predictable and contract-typical damage.
   The limitation of liability does not apply to cases where liability is obligatory. These are claims asserted according to the product liability law or in case of harms to body and health, or loss of life.
9. Further claims from this warranty are excluded. AMEDTEC Medizintechnik Aue GmbH is especially not liable for business interruptions or loss of profits.
10. If a damage is not a matter of warranty case although it has been asserted as such, it is left to the discretion of AMEDTEC Medizintechnik Aue GmbH to charge the arisen costs for the service partly or completely.

(000-0326-2_02 M0750)

Disposal

In Germany, the disposal of the ECG device is regulated by the „Electric and electronic device act – ElektroG“.

Do not dispose the device as domestic waste, and not at collecting points for electrical appliances and electronics devices.

Inform your supplier. He will take the device back.

You may also send the device directly to our address indicated below.

Regulations in other countries may differ. Please follow the regulations applicable for you.

Due to ongoing development, AMEDTEC reserves the right to change specifications and documentation without prior notice.

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