AMEDTEC ECGpro®

Holter-RR

Ambulatory Blood Pressure Monitoring System

ABPM Recorder: Holter-RR

Instruction Manual

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This ambulatory blood pressure monitoring (ABPM) system AMEDTEC *ECGpro* Holter-RR, created from the ABPM software Holter-RR, manufacturer: AMEDTEC Medizintechnik Aue GmbH, CE 0494, and the ABPM recorder device Holter-RR, manufacturer: I.E.M. GmbH, CE 0044, is a system according to Directive 93/42/EEC, article 12, and complies with the essential requirements of MDD 93/42/EEC as well as the regulations of the Medical Devices Act.

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

The Holter-RR NIBP device complies with the requirements of the ESH (European Society of Hyper-tension), and has a BHS (British Society of Hypertension) A/A grading.

AMEDTEC *ECGpro* Holter-RR is a medical device of risk class IIa in accordance to MDD 93/42/EEC, annex IX.

The device complies with the requirements of the applicable standards, particularly

- DIN EN ISO 80601-2-30 „Medical electrical equipment – Part 2-30: Particular requirements for the basic safety and essential performance of automated type non-invasive sphygmomanometers“,
- DIN EN 60601-1 „Medical electrical equipment – Part 1: General requirements for basic safety and essential performance“ and
- DIN EN 60601-1-2 „Medical electrical equipment – Part 12: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic disturbances – Requirements and tests“.

This instruction manual refers to the software version declared on the enclosed CD.

1 Intended Use

AMEDTEC *ECGpro* Holter-RR is a system for the recording, storage and analysis of ambulatory non-invasive blood pressure recordings over typically 24 to 72 hours.

The system consists of the “Holter-RR” blood pressure monitor/recorder, and the accompanying analysis and data-handling computer software “Holter-RR”, being an integrated part of the AMEDTEC *ECGpro* software suite.

It is intended to be a diagnostic aid for doctors to detect and treat patients which suffer from blood pressure disorders. The blood pressure recorder measures the patient’s blood pressure during the application period, while the software takes over the preparation of the recorder for each next patient, as well as downloading, saving, analyzing, editing and outputting the data.

The software is intended for use by healthcare professionals. Also, the recorder is to be hooked up to the patient by medical professionals which must be familiar with the safety and maintenance instructions of this manual. Furthermore, the staff must inform the patient about the behavior during the test as well as restrictions that could lead to incorrect measurements and thus possibly to misdiagnosis (handling, safety instructions). This is laid out in the appropriate sections of this manual and on the patient's diary which the patient shall write during the examination.

AMEDTEC *ECGpro* Holter-RR can work on stand-alone computers or in network environments.

The blood pressure measurement works by the oscillometric method in accordance with IEC 80601-2-30 regarding tolerances for manometers and measured values, max. pressure change for BP determination and max. cuff pressure (here also EN 1060-3).

The computer used for AMEDTEC *ECGpro* Holter-RR, and all the IT equipment connected to it must comply with the requirements of DIN EN 62368-1 "Equipment for Audio / Video, Information and Communication Technology - Part 1: Safety Requirements".

⚠ *While the Holter-RR recorder is connected to the computer, it must not be attached to the patient.*

1.1 Indication

The use of AMEDTEC *ECGpro* Holter-RR is indicated for any purpose in the diagnosis and control of blood pressure disorders (e.g., hypertension, hypotension, borderline hypertrophy or impaired renal function). Institutions of use are medical practices, clinics, hospitals and other medical care departments.

1.2 Contraindication

⚠ *The Holter-RR ABPM recorder must not be used to monitor the blood pressure in newborns (aged up to 1 month) nor without supervision in infants, or in patients of unsound mind, especially not in unconscious persons. There is a risk of strangulation due to pressure hose and cuff.*

Furthermore, the recorder must not be used for blood pressure monitoring during surgery or for alarming monitoring (e.g. on intensive care wards).

The recorder must not be used in airplanes.

2 Safety Instructions

Read the following information and instructions carefully! They directly affect the safety of patients and personnel. Instruct your patients and personnel accordingly!

- **Possible side effects:**
  - In some patients, especially when suffering from coagulation disorders or under anticoagulant treatment, petechial bleeding or subcutaneous hematomas are possible.
  - Danger of blood flow interruptions as a result of constant cuff pressure or too frequent measuring!
- A blood pressure measurement can be stopped anytime by pressing the red start/stop key on the recorder.
- Patients must be instructed that in case of pain due to the measurements, they shall abort running measurements, switch and take off the recorder and inform the doctor.
- A shoulder belt or pressure hose which entangles the patient's neck can lead to strangulation! The personnel shall always draw the patient's attention to the fact that the cuff must be worn on the upper arm, only, and care must always be taken to ensure that neither the shoulder belt nor the pressure hose can ever become wrapped around the neck. The pressure hose should therefore always be worn under the outer clothing – even at night.
- Prior to an ABPM recording, the doctor must examine the patient and be convinced that the measurements are not going to negatively affect and disturb the blood circulation of the patient.

  In this course, the number of measurements per hour of the used measurement protocol must be taken into account. The more frequently the blood pressure is measured, the higher is the danger of effects on the blood circulation.
- The cuff must not be used on wounds, on limbs where an intravascular access or intravascular therapy or an AV shunt is present, or on the arm on the side of a mastectomy.
- The inflation of the cuff can cause temporary loss of functionality of monitoring devices placed on the same arm.
- The equipment must not be used in the vicinity of MRI scanners.
- In accordance with the Intended Use, a blood pressure recorder which is connected to the computer must not be attached to the patient.
- While the recorder is connected to the patient, it must not get in contact with metallic voltaged parts.
- The recorder must not be operated without properly closed battery compartment.
- The recorder is protected against defibrillation shocks. This protection is mainly ensured by the electrically non-conductive materials of the housing and the pressure hose. Nevertheless, the patient must not be in touch with the recorder itself during a defibrillation.
- The pressure hose must not be bent, drilled, drawn, or knotted. Otherwise, erroneous measurements will be the result, or the cuff cannot deflate in proper time.
- The device is not water proof. This implies particularly that it must not be used when taking a shower or bath, and must only be cleaned with a damp cotton cloth.

  If any liquid should have penetrated, the recorder must not be used anymore! The patient or personnel shall switch off the device immediately. Send the equipment in for inspection.
- The patient must be instructed to switch and take the device off in case of malfunction.

- Risk of injury from allergic reactions to the cuff: The printing ink contains epoxy resin. In hypersensitive patients, the color may lead to allergic reactions in very rare cases. In case of pain or allergic reactions, the patient should turn off the device and remove the cuff.
- Impacts such as movements of the measuring arm, vibrations e.g. by driving car or using public transport during the measurement may lead to incorrect measurements. The patient should be advised to include these events in the patient diary. The doctor shall incorporate the diary in his analysis.
- In order to avoid incorrect blood-pressure measurements or damages, use AMEDTEC Holter-RR accessories (see page 42), only!

3 Installation and Setup

3.1 Introduction

A typical ABPM recording comprises three main steps:

1) The NIBP recorder is connected to a computer with AMEDTEC *ECGpro* installed and is prepared with a patient ID and the measurement protocol before each long-term recording.
2) The device is then applied to the patient whose ambulatory blood pressure it will measure over the next (typically) 24 hours, and the recording is started.
3) After the recording is finished, the device is taken off the patient and the recording is transmitted into the AMEDTEC *ECGpro* database from where it will be reviewed and analyzed.

3.2 Installing the Software Application

The Holter-RR ambulatory blood pressure analysis software is an integral part of the AMEDTEC *ECGpro* software suite. Prior to using the blood pressure module, install the AMEDTEC *ECGpro* software on your computer.

The computer software was made for Intel or Intel-compatible PCs running a Microsoft Windows operating system. For a detailed list of the supported operating systems, see section *Hardware and Software Requirements* of the *AMEDTEC ECGpro Installation Manual*.

You can choose whether to install a standalone system (where the software and the database are installed together on a single PC) or a client-server environment with a centralized database.

Insert the installation CD and install AMEDTEC *ECGpro* as described in the *AMEDTEC ECGpro Installation Manual* document.

3.3 Starting the Software

Launch the software by one of the following ways:

- Double-click on the desktop icon: 
- From the Windows Start menu, select ***Programs | AMEDTEC ECGpro | AMEDTEC ECGpro***.
- Start AMEDTEC *ECGpro* from within your practice software, if an appropriate link has been set up (primarily via the GDT interface).

In the following section 3.4 you learn how the blood pressure recorders are set up in the program. Chapters 4, 5 and 6 explain the handling of the software for preparing the recorders and reading back the measurements, as well as the analysis of the recordings.

Note: Depending on the purpose of each computer you can specify whether AMEDTEC *ECGpro* shall start up in the data management or rather directly in the Holter-RR main menu. You find this setting in AMEDTEC *ECGpro* via menu ***File | Settings… | General | Environment → Application startup → Startup module***.

For details about application settings, see the *AMEDTEC ECGpro Settings* document.

3.4 Setting up the Blood Pressure Recorders

3.4.1 Communications Mode – „co“

The communications mode is a special state of the Holter-RR recorder which is needed for transferring data from and to the PC. Only in this mode the recorder can communicate with the computer and vice versa.

The communications mode is indicated by the letters „***co***“ on the recorder display, as opposed to the current time in normal mode (in which BP measurements can be taken).

To put the device into „co“ mode, follow one of the next sections – depending on whether you connect the recorder to the PC by cable or via infrared.

To leave the “co” mode and switch back into measurement mode unplug the cable from the recorder or press any recorder key.

3.4.1.1 Wired Connection

1) Connect your Holter-RR recorder to the PC using your interface cable (USB and serial/RS-232 versions are available).

2) Switch the recorder on. The recorder’s battery voltage is shown on the display for about two seconds, before the letters “co” indicate that the recorder is in communications mode and is ready to talk to the PC.

3.4.1.2 Infrared Connection

1) First, make sure that the “IR-Med” infrared transmitter is plugged into the PC.

2) Switch the recorder on and wait for the initial self-test to complete (the LCD display counts down from 999:999 to 000:000). The test takes about 10 seconds. When done, the recorder time is shown on the display.

3) Now press the ***Start*** and ***Day/Night*** keys simultaneously. (Press and hold down and then press additionally.) The recorder should display a blinking “co” now. Otherwise, if you see “bt” or “PAIr” blinking, press ***Start*** again until “co” is displayed.

4) As soon as “co” is blinking, press the ***Event*** key to confirm the “co” mode. The letters stop blinking which indicates that the recorder is in communications mode now and is ready to talk to the PC.

5) Place the recorder in front of the “IR-Med” infrared transmitter in a distance of about 10-15 cm. There must be an unobstructed line of sight between the IR outlets of both the transmitter and the recorder.

3.4.2 Pairing Recorder and Software

Before the AMEDTEC *ECGpro* Holter-RR software can communicate with a recorder, the communications port must be made known to the software.
This is normally a one-time procedure. Only in case the communications cable or infrared receiver is attached to a different COM or USB port, this setting must be renewed.

1) Launch the AMEDTEC *ECGpro* software and enter the settings via menu ***File | Settings…***. From the left-hand side tree view select ***Holter-RR Recorder***.

   Tipp: You can find that item quickly by typing “*rr rec*” in the setting’s search field.

2) Make sure that the “***Enable Holter-RR Recorder***” checkbox is ticked.

3) Select your installed battery type from the dropdown list: 1.5 V batteries, or 1.2 V rechargeable batteries.

4) Click the ***Search*** button.

   The software will now search for the attached Holter-RR recorder. As soon as it is detected, the recorder emits a confirmation sound, and COM port and baud rate are displayed in the software.

If the search is not successful, make sure that:

- the recorder is in “co” mode
- the cable or IR receiver are properly connected to the PC
- in infrared mode: there is an unobstructed line of sight between the infrared outlet windows of the recorder and the IR receiver module.

4 Performing an Ambulatory Blood Pressure Recording

4.1 The Holter-RR Main Menu

The typical workflow in doing an ABPM is:

1) Set up the BP monitor with the patient ID and the desired measurement protocol,
2) Perform the 24-hour measurement itself,
3) Download and analyze the measurement values using the PC software.

Read the following sections for details of those steps.

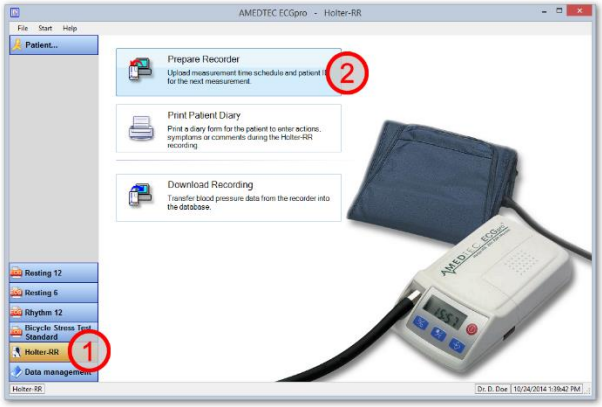


Figure 1: Holter-RR main menu

Steps 1) and 3) – recorder preparation and download – are initiated in the Holter-RR main menu. To open that menu screen, press the ***Holter-RR*** button ① in the lower left program area of AMEDTEC *ECGpro*.

4.2 Preparing the BP Recorder

Before starting the ambulatory BP measurement you want to **define the measurement protocol**, which specifies:

- how many readings the recorder shall take at which times of the day,
- whether it should indicate a measurement to the patient by a sound, as well as
- whether or not the patient should be able to see its own measured BP values on the recorder display.

Also, for the purpose of a comfortable workflow, you will typically **store a patient ID in the recorder**. By that, the recording will automatically be assigned to the correct patient record when the recorder comes back after the ABPM.

To prepare the Holter-RR recorder, connect it to your PC and switch it on. If you are using a cable connection, the recorder is in “co” mode by now. In case of an infrared link, follow the instructions in section *Communications Mode – „co“* on page 9 to switch the device into “co” mode.

Now enter the Holter-RR main menu (see previous section) and press the ***Prepare Recorder*** button (② in Figure 1).

If you have not yet selected a patient record (either by an appropriate search or by data transmission from practice or hospital information software), a search dialog will pop up, which lets you find the patient who is going to get the ABPM. Search for the patient now, or skip that step if you don’t want to store patient information in the recorder (it is, however, recommended to store the ID in the device for a safe assignment when reading the data back later).

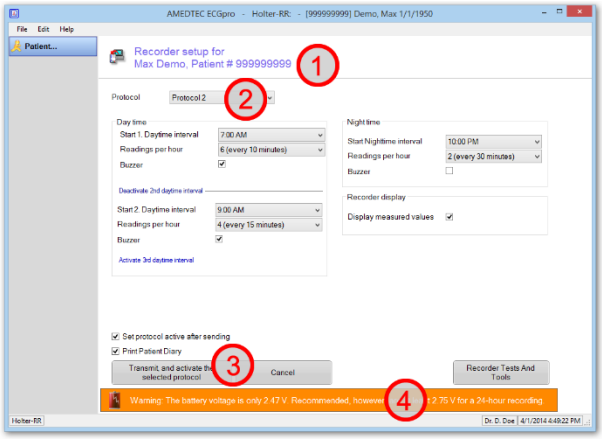


Figure 2: Measurement protocol screen

The measurement protocol screen opens up (Figure 2).

If the AA battery voltage is lower than 2.75 V, or lower than 2.4 V for rechargeable batteries, an orange warning bar ④ shows up on the bottom of the screen. It is strongly recommended to use fresh or freshly charged batteries for each recording! (The type of batteries in use is selected in the program settings under **File | Settings… | Holter-RR Recorder***).*

Work through the protocol screen in the following order:

1) Check the patient data in the upper area ① for correctness. Via the patient button on left-hand side, you may select a different patient or correct the patient demographics.

2) ***Protocol dropdown list*** ②: Select the desired protocol from this list. Protocols 1 and 2 can be edited and adapted to your needs, while protocols 3 to 9 are static ones.

   Note: Protocol 5 is suitable for night-time activity (e.g. night shifts); protocol 9 can be used for Schellong tests (one measurement every 2 minutes).

   Each protocol is made up of up to three daytime intervals and one nighttime interval. Each of them in turn consists of the following information:

   - ***Start time***: The full hour at which the interval begins.
   - ***Readings per hour***: Number of measurements the recorder will take per hour in the interval.
   - ***Buzzer***: If ticked, measurements are announced acoustically. This is essentially meaningful for daytime intervals in order for the patient to find a still, comfortable position for the measurement.
     During the night, however, the sound should be turned off.

   Note: The separation of the daytime into three intervals is only relevant during the recording time, i.e. for the measurement time regime. Later, for the diagnosis, these intervals are aggregated into one single daytime interval.
   If you actually do not need three different daytime intervals, deactivate the other interval(s).

3) ***Display measured values***: Tick this checkbox if blood pressure and heart rate values should be displayed on the recorder after automatic measurements, or unselect it if you don't want to disclose these values to the patient's eyes. Watching one's own BP can be a strong, negative psychological factor during the ABPM!

   Note: When a BP measurements is initiated manually by pressing the recorder's START button, the measured values will always be displayed – regardless of this setting.

4) ***Print Patient Diary***: Select this option in order to automatically have a diary form printed after sending the protocol into the recorder. Hand out the diary to the patient to fill in blood pressure relevant events during the examination. (See next section.)

5) ***Transmit, and activate selected protocol***: When all information are complete and correct, press this button ③ to send protocol and patient ID to the recorder, and – if selected – print the patient diary.

   If there are still data in the recorder memory you must commit to delete them now. Otherwise the procedure is aborted at this point.

   At this time, the recorder time is set automatically to the database computer time.

   Note: If necessary, you can also set the clock manually: Hold down the ***Start*** key and then press the ***Event*** key additionally. Being in the "Set time" mode now, the ***Start*** key increments the selected (blinking) digit, while the ***Event*** key selects the next one.

   A message box will inform you when the upload process is finished.

6) You may now detach the recorder from the computer, and optionally switch it off.

4.3 Patient Diary

You might want to print a diary sheet and hand it out to the patient. He/she shall document events or peculiarities during the examination day (and possibly night) which potentially affect the blood pressure. Examples are: Medication, indisposition, physical workout, times of getting up or going to bed.

The diary also contains information for the patient regarding the process of the ABPM and the recorder device handling. This information text can be customized in the application settings.

The diary can be printed automatically during the preparation of the Holter-RR recorder (see previous section), or at any time via the ***Print Patient Diary*** button from the Holter-RR main menu.

In the program settings under menu ***File | Settings… | Holter-RR | Holter-RR*** you'll find a tab page called ***Patient Diary***. There you can customize the diary layout, select whether or not the time column shall be prefilled with a selected time grid, customize the patient information text, and choose if the diary shall be printed automatically when a recorder is prepared a patient.

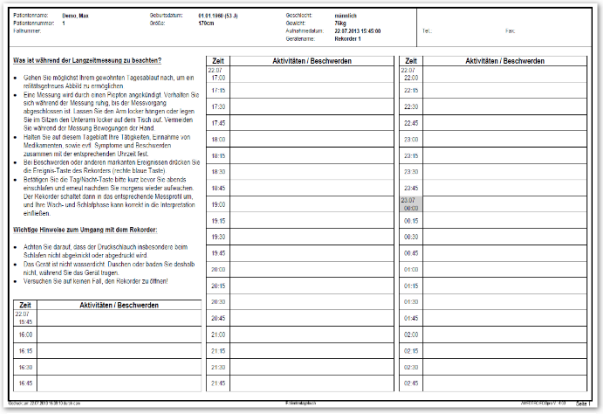


Figure 3: Patient diary with prefilled time column

4.4 Hooking up the Recorder

After preparing the Holter-RR recorder in the software, hook up device and cuff to the patient.

- *Do not attach the recorder to the patient while the device is connected to the PC! Always unplug the Holter-RR recorder from the computer before attaching it to the patient!*
- *For reproducible, correct blood pressure measurements, the correct cuff size is very important!*
  Measure the patient's arm circumference in the middle of his upper arm. A measuring tape comes with the Holter-RR recorder. The various cuffs are labeled with the corresponding range of arm circumferences. Cuffs sizes from 14 to 55 cm are available.

1) Select a cuff of correct size and apply it to the patient's upper arm. The cuff may be worn over light textiles like a shirt or blouse. Application to the bare arm, however, is recommended.
   - The cuff should sit about 2 cm above the elbow bend. It must fit firmly, so that it does not slide down, but without compressing the patient's arm. As a measure of thumb you should just still be able to put two fingers next to each other in between arm and cuff.
   - Note the "ART." symbol on the cuff: This must be positioned right above the patient's brachial artery. If the cuff fits correctly, its metal strip is on the outer side of the upper arm then.
2) The pressure hose shall leave at the upper end of the cuff, follow the arm and shoulder, and run back over the neck to the other side of the body.

⚠ *The hose must never be bended or kinked and should always allow the patient for free movements.*

3) Apply the recorder to the patient. It is recommended that the device be carried in the bag witch comes with it. Make sure that the pressure hose is connected firmly to the BP device.

Inform your patient that during a BP measurement (which is normally indicated by buzzer sound, if programmed so), he should:

- not talk
- sit down comfortably
- not cross his legs
- have his feet stand flat on the ground
- support the arm which is measured and keep the cuff at heart level height.

Note that the results of BP measurements are considerably influenced by the place or measurement (environmental conditions), body position, physical effort as well as physiological state of the patient (e.g. age, possible pregnancy, cardiac arrhythmia, diabetes, preeclampsia, renal disease, patient movement, tremors and chills).

4.5 Starting the Recording

After recorder and cuff have been applied, the patient should remain sitting for about 5 minutes before the ambulatory measurement is started.

1) Switch the recorder on by pressing the ***On/Off*** key. The device will perform an internal test during which it sort of counts down from 999:999 to 000:000. The test takes about 10 seconds; then the clock time is shown on the display.
2) Check that this time is correct!
3) Now press the ***Start*** key to take the first BP measurement and put the recorder into automatic measurement mode.

   Important: In order for the recorder to enter the automatic measurement process, a first manually triggered BP reading must be taken successfully.

   Carefully check the display after the measurement for plausible BP values or possible error codes.
   If the measurement was not performed successfully, please check the following possible issues, and repeat the recording.

   - Is the cuff is applied correctly?
   - Is the pressure hose intact and firmly connected to the recorder, and is not kinked or otherwise compressed?
   - Is the battery voltage is sufficient?

5) Once a successful initial measurement has been taken, the BP recorder is in the automatic measurement mode and will take BP readings accordingly to the programmed protocol. The complete recorder hook up is finished now.

5 Downloading Measurements from the Recorder

At the end of the acquisition, switch the recorder off by pressing the ***On/Off*** key ⏻ for about two seconds. Then detach device and cuff from the patient.

If you are using a cable connection (USB or serial cable), connect the device to your computer (the recorder must not be applied to the patient anymore at that time!) and then switch the recorder on. The recorder should show the letters “co” on its display which indicates that the communications mode is active.

In case of wireless connection via the infrared transmitter, switch the recorder into “co” mode manually according to section *Communications Mode – „co“* on page 9.

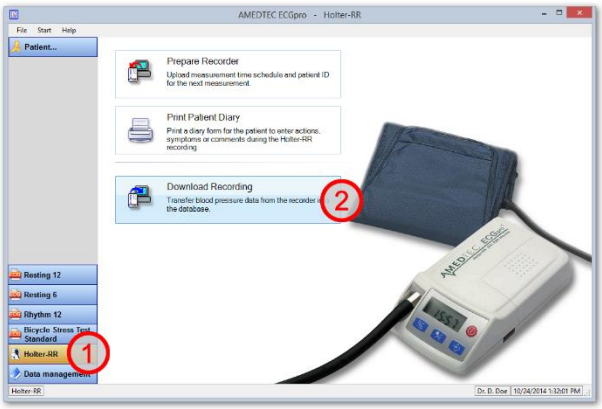
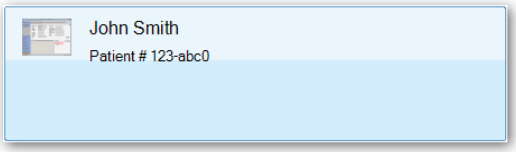


Figure 4: Holter-RR main menu

Launch the AMEDTEC *ECGpro* application and press the ***Holter-RR*** button ① to enter the Holter-RR main menu, and from there select the ***Download Recording*** button ②.

If the recorder was prepared with the patient data prior to the measurement, a button presents the patient data for your confirmation. If for any reason the patient data should are not correct, select a different patient record via the ***Patient*** button on the left-hand screen side.

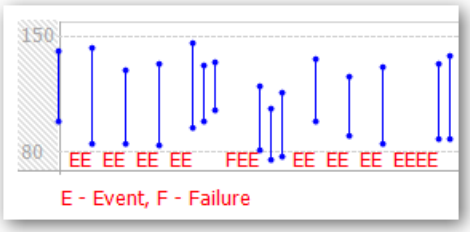


If a different patient record other than the one indicated in the recorder is active in the AMEDTEC *ECGpro* data management at that moment, an additional button with these data will be present. From both buttons select the correct patient record.

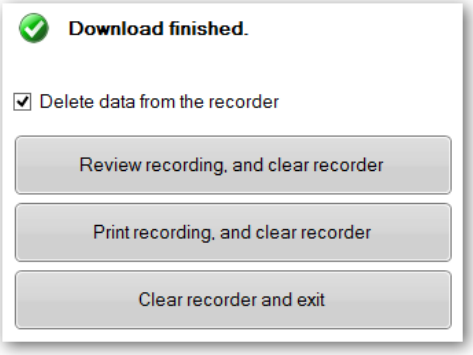
If neither the recorder nor the data management indicates a patient record, a patient selection dialog pops up.

Press the correct patient button to start the download and assign the ABPM measurements stored in the recorder to the corresponding patient record in the AMEDTEC *ECGpro* database.

As the download proceeds, the collected BP values as well as possible measurement failures are continuously displayed in a preview graph. This allows for a quick quality assessment of the recording. Successful BP readings are displayed by their systolic and diastolic values, while faulty measurements are indicated by the letter **F**, and events (e.g. Event button pressed) by an **E**.



By the time the download is finished, the complete recording has been stored to the database.



Now, choose how to continue:

- ***Review recording***: Opens and displays the recording in the Holter-RR review software.
- ***Print recording***: Prints the recording immediately – without displaying it on screen first.

  In the Holter-RR options you select what should be printed here (called “printing formats”). Find these settings via menu ***File | Settings… | Holter-RR | Printing***.

- ***Exit***: Return to the Holter-RR main menu. – No review or printing of this recording for the moment.

Delete data from the recorder: Select this checkbox if the recorder memory (measurements and Patient ID) shall be deleted at the moment of selecting one of the three actions described above (Review, Print or Exit). Typically, you'll want to select this option in order to ensure that the recorder will not accidently contain old data when being applied to the next patient.

6 Reviewing Recordings

6.1 Opening Recordings

There are multiple ways to find and open Holter-RR recordings:

- Immediately after the recording has been download into the database:

  Select the action button ***Review recording***. (See previous chapter *Downloading Measurements from the Recorder*.)

- From the AMEDTEC *ECGpro* data management:

  Search for the patient, and double-click the desired item in the patient's recording list.

  Alternatively you might want to utilize the file cards which provide various workflow and filtering capabilities. These file cards show, for example, the most recent recordings, recording with a pending confirmation state or those recording which are made for your department.

- From your practice computer software:

  If AMEDTEC *ECGpro* is linked up with you practice software via the GDT standard, recordings can be opened directly from within the practice software. Please see to your practice software's documentation or consult your IT dept. for setting this up.

6.2 Printing

There are multiple ways to find and print Holter-RR recordings:

- Immediately after the recording has been download into the database:

  Select the action button ***Print recording***. (See previous chapter *Downloading Measurements from the Recorder*.)

- From the AMEDTEC *ECGpro* data management:

  Search for the patient, select the required recording in the patient's ***recording list***, and choose one of the printing menus from the ***context menu or File menu***.

  Alternatively you might want to utilize the file cards which provide various workflow and filtering capabilities. These file cards show, for example, the most recent recordings, recording with a pending confirmation state or those recording which are made for your department. Again, find and select the recording, and choose one of the printing menus.

- When the recording is opened for review:

  Press the ***Print*** button on the left-hand side, or select one of the printing menus from the ***File*** menu.

When using the File | Print menu or the Print button, the pre-selected set of printouts (called "printing formats") is sent straight away to the default printer.
Both the printer and the default printing formats are chosen in the program settings. Enter the settings via menu ***File | Settings… | General | Environment*** to select the printer, and via ***File | Settings… | Holter-RR | Printing*** to select the printing formats you wish to be printed by default.

If you want to include or exclude one or more printing formats temporarily, print via ***File | Print with Format Selection***, or select the ***Printing dialog and preview…*** from the ***Print*** button's context menu.

A print preview is available via menu ***File | Print Preview…***, or again via the ***Print*** button's context menu.

6.3 Creating PDF Files

To create a PDF document of a Holter-RR recording, open that recording and press the ***Create PDF file*** button on the left-hand side. A Save As dialog opens up. Select folder and filename of the PDF file to create, and click the ***Save*** button.

PDF files created like that look largely identical to the paper printouts.

The pages (as known as "printing formats") to be included in the PDF file are selected in the Holter-RR settings. You find them via menu ***File | Settings… | Holter-RR | PDF export***.

Note: If AMEDTEC *ECGpro* is either linked up to your practice software via the GDT standard or to your HIS via HL7, the reporting can be configured to contain *automatically created* PDF files. (For HL7, this is a paid option.) Please see the GDT or HL7 settings documentation for details.

6.4 Confirming Recordings

Once a Holter-RR recording has been reviewed, it can be ***confirmed***. As a result, the recording becomes read-only and as such is protected against modifications as long as the confirmation is not revoked.

Also, a confirmation statement is added to the recording, which consists of the operator's name and date and time of confirmation. The statement appears on the BP profile printout, on PDF files, in the AMEDTEC *ECGpro* status bar, and in the remarks box.

Confirmed recordings are marked as such in the AMEDTEC *ECGpro* recording lists, and there is a predefined file card called "***To Confirm***" which in turn shows all recordings which are not yet confirmed.

To confirm a recording, open it for review and click the ***Confirm…*** button on the left-hand side.

Note that the ***Confirm…*** button changes into a ***Revoke confirmation…*** button. If the recording needs to be edited again, authorized personnel can take the confirmation back and make the recording writable again.

Note: User privileges are granted in the AMEDTEC *ECGpro* User Management.

6.5 Screens and Reports

Opening a Holter-RR recording means to load it into the Holter-RR review software. The following describes the software's user interface components.

On the left-hand side, you find most of the operating controls in form of buttons ①. The upper buttons mainly represent actions, like Print, Confirm or Save/Close.

Beneath of those follow buttons which activate the various screens and evaluations. There is always *one* evaluation visible at a time.

On top of the screen sits the ***measurement values panel*** ②. There you find major recording information like average BP and HR values during the day/night/overall intervals as well as the Dipping classification.

Below the measurement values you find the ***active screen*** which you select by one of the buttons on the left-hand side. In Figure 5, this is the ***Overview*** screen.

The ***Summary*** text field ④ in the lower display area holds any textual information you like to enter, e.g. anamnesis, diagnosis, therapy and so on. Press the Summary button to show or hide this text field.

Note: You can define the default screen (or “view”) that is opened initially whenever a Holter-RR recording is opened. To do so, activate the respective screen and select the menu ***Settings | Use Current View As Default***.

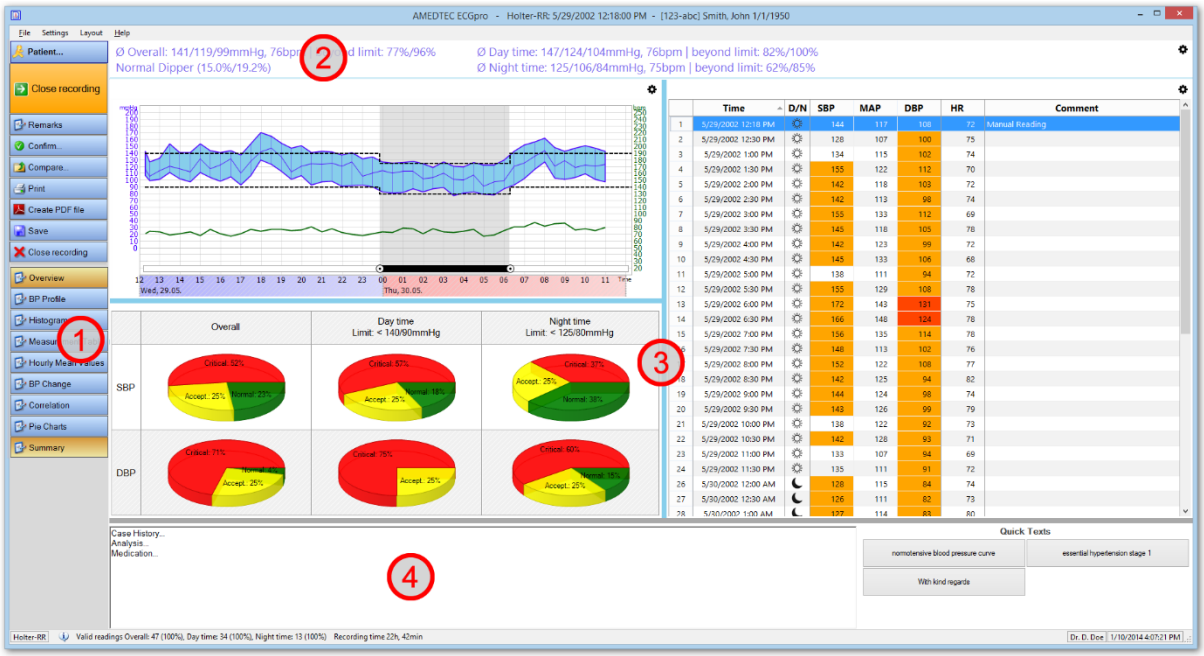
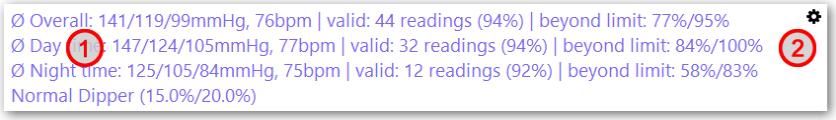


Figure 5: Holter-RR review software: Overview screen

6.5.1 Measurement Values Panel

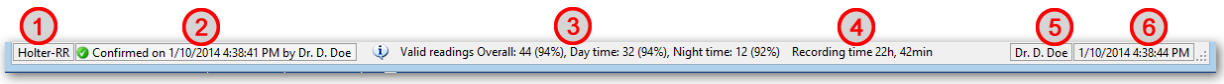


The measurement values panel displays the following information:

- Mean values of blood pressure (BP) and heart rate (HR) for day, night and overall intervals
- Percentage of recordings which are equal to or higher than the set limits. This refers to the limits set under “single values” (see section 6.5.13.1, *Blood pressure limits* on page 28)
- Dipping classification: Relative decrease of mean BP from day to night
- Number of valid readings compared to all readings. The latter include failure measurements and those which have been marked invalid by the operator.
- Early morning mean BP

Press the ***Settings button*** ② in the upper right corner of the measurement values area to configure which of the available information you want to see.

6.5.2 Status Bar



The status bar is located at the lower end of the AMEDTEC *ECGpro* application. It holds the following information:

① Name of the AMEDTEC *ECGpro* software module: “Holter-RR”, in this case.

② Confirmation statement (optional; present in confirmed recordings only)

③ Number of valid measurements in this recording, i.e. readings which are not detected to be failures and which have not be deactivated in the measurement table. In brackets is the share of all the recordings measurements.

④ Duration of the ABPM in hours and seconds, measured from the first valid measurement to the last

⑤ Name of the user logged in as specified in the AMEDTEC *ECGpro* user management

⑥ AMEDTEC *ECGpro* database clock time

6.5.3 Overview

The overview screen (see *Figure 5: Holter-RR review software* on the previous page) is divided into up to three compartments, which can be customized in number and contents. This provides a quick view on the most important screens and evaluations of the recording.

In the Overview screen, configure the panels via the ***Layout*** menu. For each of the three panels you specify if it is visible at all, and if so, what its content is. Your selection is stored automatically and will be applied from this time on.

The Overview is the Holter-RR default screen which comes up whenever a recording is opened as long as:

- you have not selected a different screen to be the default (via ***Settings | Use Current View As Default***), and
- your monitor has a resolution of <u>at least</u> 1400 pixels horizontally.
  Smaller screens typically won't provide enough room for the three Overview compartments. You can, however, select the Overview manually at any time and make it the default by the menu ***Settings | Use Current View As Default***.

6.5.4 Blood Pressure Profile

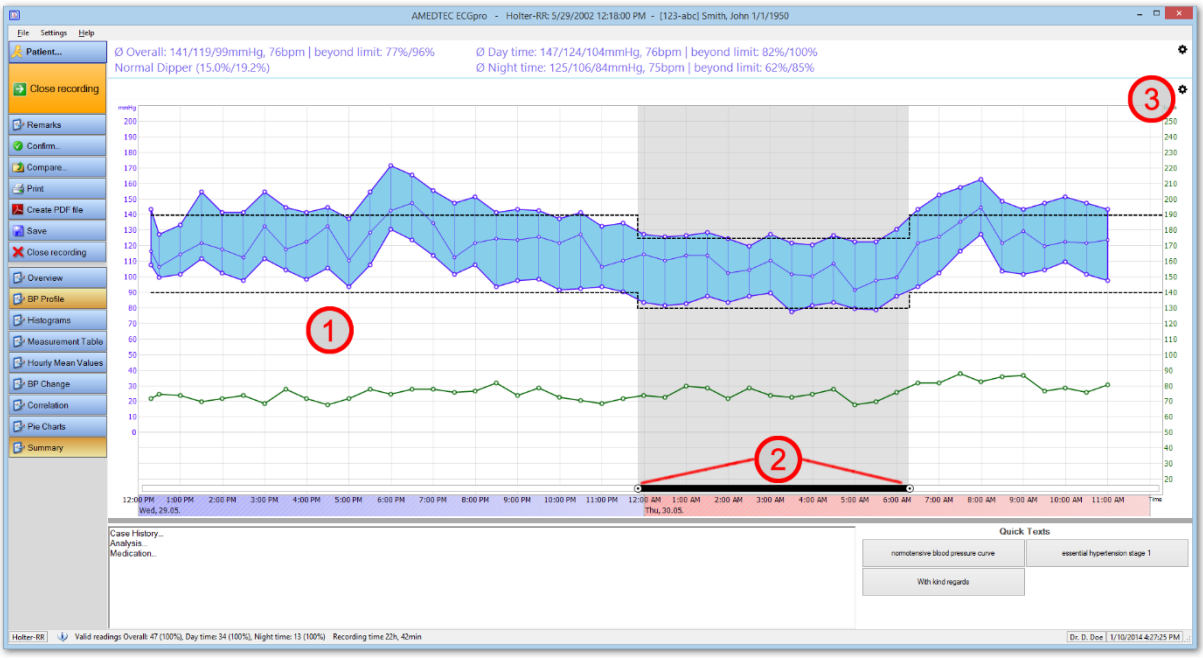


Figure 6: Blood pressure and heart rate profile

The BP Profile graphs the blood pressure (BP, left axsis) and heart rate (HR, right axis) over the time, together with the upper norm values regarding hypertension ①.

The time axis adapts itself to the length of the ABPM recording. The graph can display up to 3 days of BP measurements.
In recordings longer than this, only the first 72 hours are displayed. Nevertheless, all measurements of the recording are included in the measurement tables and statistics (average values, histograms, correlation…).

The BP and HR axes can be moved up and down by the mouse if required.

Day/Night sliders ②: If the day/night boundaries are not set correctly (e.g. if the patient did not use the Day/Night key when going to bed and getting up), drag the appropriate day/night slider to the correct the day/night time. Note that each two sliders cannot be closer to each other than 1 hour.
If you need to insert a completely new day/night transition, right-click on the day/night indicator bar.
In order to delete a day/night transition, right-click on the according day/night slider knob, and confirm via the menu that pops up.

Note: The patient should be urgently encouraged to press the recorder's Day/Night key when he goes to bed and again when he gets up. To have correct day/night boundaries is important for the ABPM analysis. The patient even benefits directly, especially when going to bed: By pressing the button the recorder switches immediately into the night time interval in which it typically will measure less often and without the initial buzzer sound.

The ***settings button*** ③ offers the following options:

- ***Show Battery Voltage***: Plots the recorder's battery voltage in the diagram. Can be of interest when tracking battery issues.
- ***Show MAP***: Displays or hides the mean atrial blood pressure (MAP).
- ***Candle Stick Graph***: Leaves out the connection lines between adjacent BP and HR values and creates a bar chart instead.
- ***Show Dots***: Each measurement value (SBP, DBP, MAP and HR) is highlighted by a surrounding circle.

The BP Profile is the Holter-RR default screen which comes up whenever a recording is opened if:

- you have not selected a different screen to be the default (via ***Settings | Use Current View As Default***), and
- your monitor has a resolution of less than 1400 pixels horizontally.
  On wider screens, the Overview is the default.

6.5.5 Histograms

The histograms represent the probability distribution of the three BP values (systolic or SBP, MAP, diastolic or DBP) as well as the HR. The measured values are grouped into classes which are 10 mmHg or 10 bpm wide, resp. This probability distribution is plotted in a bar chart ①.

Use the interval buttons for ***Overall***, ***Day*** and ***Night*** ② to restrict this evaluation to the respective time interval. The Day and Night views contain vertical lines at the positions of the upper systolic and diastolic limits, resp.

The ***settings button*** ③ offers the following options:

- ***Show numbers***: Prints the percentage value onto each bar.
- ***Show MAP chart***: Displays or hides the mean atrial blood pressure (MAP) chart.

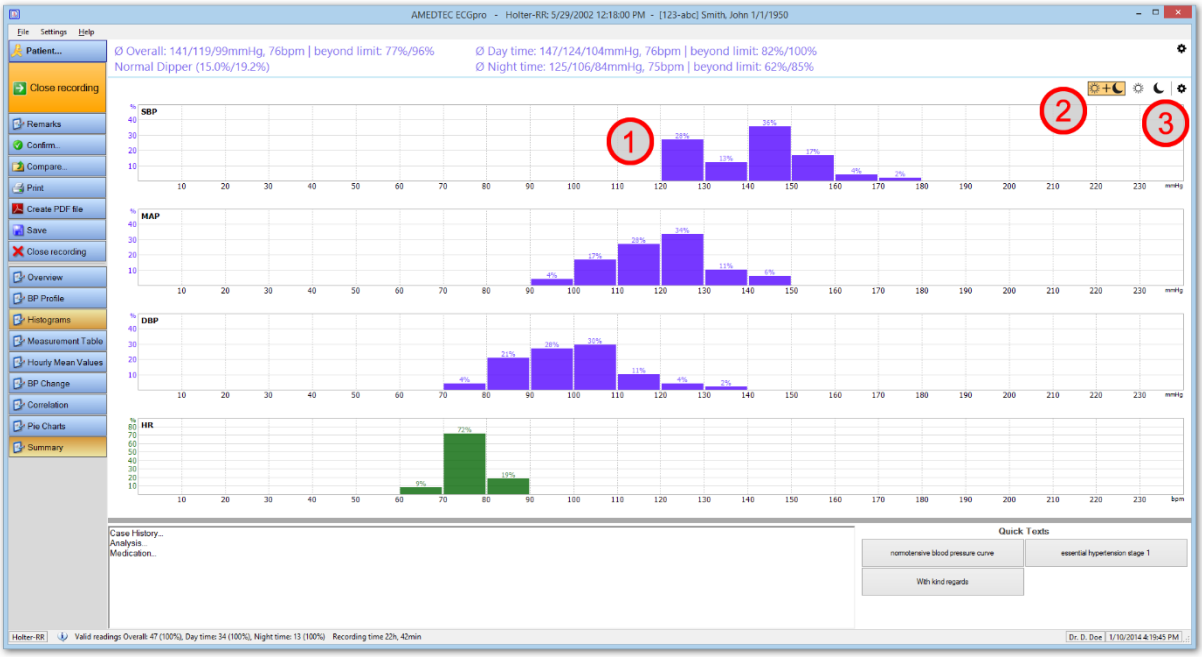


Figure 7: Histograms

6.5.6 Measurement Table

The measurement table lists all BP and HR readings together with date and time, interval (day or night) and comments. ①

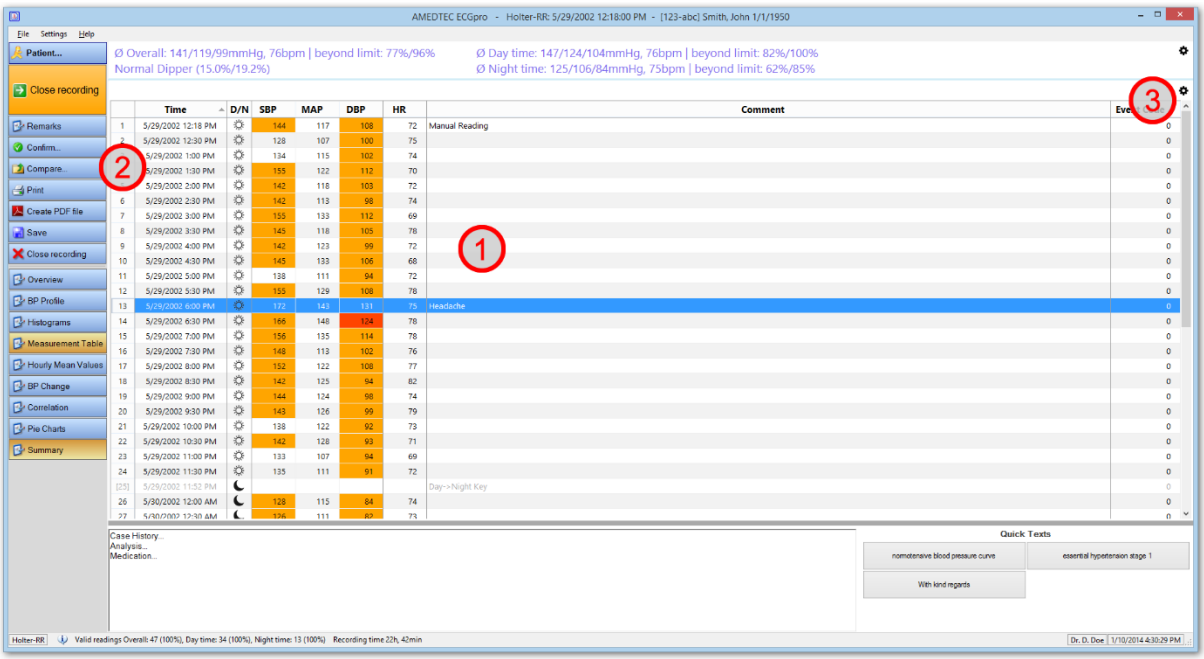


Figure 8: Measurement Table (extended mode with Event code column)

Blood pressure values equal to or greater than the set upper “single values limits” are marked by an ***orange*** colored cell background. (See section 6.5.13.1, *Blood pressure limits* on page 28.)

Regardless of the settings, systolic values greater than or equal to 180 mmHg and diastolic values greater than or equal to 120 mmHg are highlighted with a **red** *background color.*

Each reading can have a comment assigned which can be edited freely. The initial value indicates readings which were triggered manually or which were erroneous as well as events like pressed Day/Night or Event buttons.

Initially, the table is sorted by date and time. You can, however, ***sort*** it by a different column by ***clicking the respective column header***.

Deactivate / remove single readings: Faulty or otherwise invalid measurements can be deactivated by a ***click on the respective row header*** ②, i.e. the cell which contains the measurement number. Such readings won't be displayed in any graph nor will they be included in statistical considerations. They will, however, be counted in the number of invalid measurements. Click the row header cell again to reactivate the measurement.

Note: Measurements will not be deleted. Instead they are set inactive, but remain visible and documented in the measurement table.

The ***settings button*** ③ offers the following options:

- ***Extended Table***: The extended table contains an additional column which is the Event Code. This can help to track down measurement problems in more detail.
  Also, the standard table does not contain some events which are unimportant for the BP analysis, whereas the extended table does show them. Currently, these are the recorder on/off events.

6.5.7 Hourly Mean Values

The table of hourly mean BP and HR values represents both the average values during defined time spans of the day and the BP/HR variability in that time.

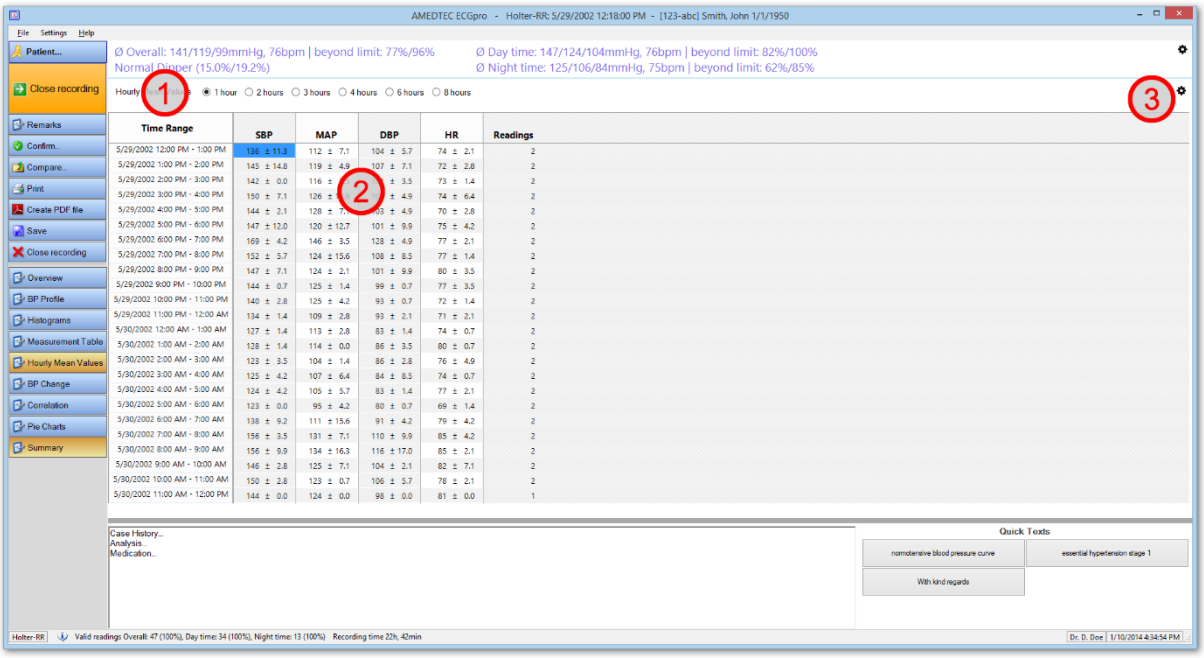


Figure 9: Table of hourly mean values

The arithmetic mean $\bar{x}$ as well as the empirical standard deviation s are calculated for the selected time periods of ***1, 2, 3, 4, 6*** or ***8 hours*** ① in length.

The applied formulas are as follows: $\bar{x} = \frac{1}{n}\sum_{i=1}^{n} x_i$ $s = \sqrt{\frac{1}{n-1}\sum_{i=1}^{n}(\bar{x} - x_i)^2}$

(With n being the number of measurements in the interval, and x_i being the measurement values.)

The last column of the table shows the number of measurements in the respective time interval.

The ***settings button*** ③ offers the following options:

- ***24 hours mode***: This is the default mode. All measurements of the entire recording are fitted into the 24 hours of *one* day according to their measurement time. This results in a maximum of possible 24 intervals (when selecting the 1-hour interval length). Therefore, this setting actually only has an effect on the resulting values if the recording took longer than 24 hours. Example: Say the recording took more than 24 hours, from 2013-12-01 8:00am to 2013-12-02 10:00am. In thas case, measurements performed between 8:00am and 9:00am from both days contribute to the same average value.

  To turn this aggregation off, deselect this menu item. The averaging intervals are then constructed in ascending chronological order starting at the beginning of the recording. Referring to the previous example, the table will then contain two intervals for the hour between 8:00am and 9:00am: one for 2013-12-01 and one for 2013-12-02.

- ***Separate SD column***: Select this option if you prefer separate columns for the standard deviation over the more compact, combined $\bar{x} \pm s$ (e.g. 134 ± 7.1) representation. The difference looks like that:

SBP
136 ± 11.3
145 ± 14.8
142 ± 0.0

←→

SBP	
Mean	SD
136	11.3
145	14.8
142	0.0

6.5.8 Blood Pressure Change

This diagram evaluates the rise and fall of the mean atrial blood pressure (MAP) over the recording time, whereat the early morning time is of particular importance.

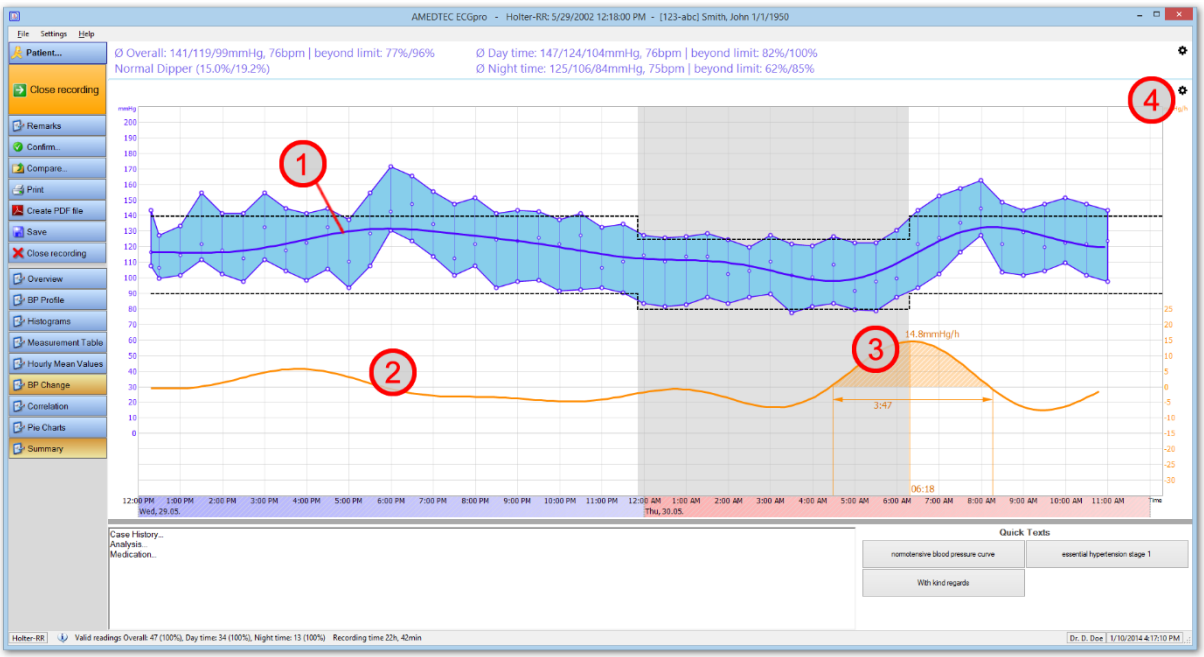


Figure 10: Blood pressure change incl. early morning analysis

In order to get a trend free of transient BP bursts or drops, a strongly smoothed curve is fitted through the measured MAP values. ①

Mathematically, this smooth MAP trend is derived by a transformation of the measured MAP signal into the frequency domain, the removal of the higher frequencies, and the subsequent inverse transform back into the time domain.

The change (i.e. the rise and fall measured in *mmHg/h*) of the MAP curve is graphed below the BP. ② Note the orange axis on the right!

Since the early morning time between 4am and 10am is of specialy interest, the maximum PB rise is detected in this time frame. If such a maximum is present, the orange curve is labled with that numerical value ③ and also the beginning and the end of this BP rise are detected. The area under the curve over the whole duration of the early morning BP rise is filled with a dashed orange.

The ***settings button*** ③ offers the following options:

- ***Show MAP***: Displays or hides the actual mean atrial blood pressure (MAP) values. This does not affect the interpolated MAP curve which is generally displayed in this screen.
- ***Candle Stick Graph***: Leaves out the connection lines between adjacent BP values and creates a bar chart instead.
- ***Show Dots***: Each measurement value (SBP, MAP, and DBP) is highlighted by a surrounding circle.

6.5.9 Correlation

This screen analyses the statistical correlation between systolic (SBP) and diastolic blood pressure (DBP).

Figure 11: Correlation between systolic and diastolic blood pressure

A scatter plot represents all measured BP values, i.e. every pair of systolic and diastolic values by dots (day time values) and triangles (night time values). ①

The software performs a linear regression analysis of the statistical linear relationship between systolic and diastolic BP, in both directions. The two resulting regression lines ① are drawn into the diagramm as an overlay to the BP values. The respective functional equations $DBP=f(SBP)$ and $SBP=f(DBP)$ are output in the left-hand diagram pane, together with the Pearson's correlation coefficient r ③.

Plotting both regression lines simultaneously supports the numerical correlation coefficient r visually:

- The closer both lines are to each other, the higher is the statistical linear dependence between the diastolic and systolic BP values, and the closer gets r towards ±1.
- The further the two lines spread away from each other (in the extreme case they are intersecting perpendicularly), the less dependent (statistically) are the diastolic values from the systolic ones, and the closer r tends towards 0.

Use the interval buttons for ***Overall***, ***Day*** and ***Night*** ② to restrict the evaluation to the respective time interval. In Day mode and Night mode, the systolic and diastolic upper norm values are plotted in the form of a horizontal and a vertical line, respectively.

The ***settings button*** ④ offers the following option:

- ***Extrapolate regression lines***: Select this option to extend the regression lines to the outer edges of the diagram. Deselect it to keep the lines inside of the scatter plot.

6.5.10 Pie Charts

This screen represents the ratio of normal and hypertonic blood pressure measurements of all measurements.

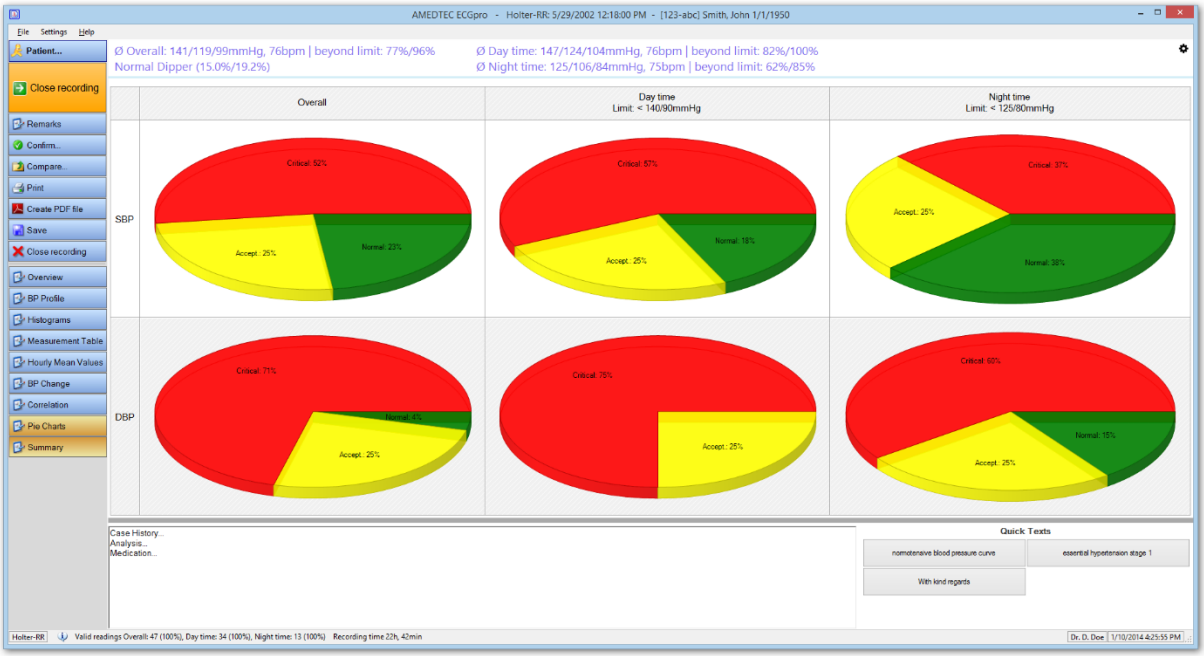


Figure 12: Pie Charts showing the ratio of normal to hypertensive BP values

The screen is made up of six pie charts: One systolic and one diastolic chart for each of the intervals Day, Night and Overall.

The ratio of normal and hypertonic measurements is represented by colored sections as follows:

Green	All measurements smaller than the set upper limit are considered **normal** and count into the green section.
Yellow	Measurement values in this sector are equal to or greater than the upper norm value. A fraction of up to 25% of all measurements is considered **acceptable** and counts into the yellow sector. The yellow sector will not get bigger than 25%; any higher share adds to the red sector.
Red	Measurement values in this sector are equal to or greater than the upper norm value. The share of measurements which are equal to or greater than the upper norm value that is bigger than 25% is draw in red. This fraction is considered **too high** or **critical**. So, the red sector is not present until the yellow fraction reaches 25%.

Note: This is a purely quantitative evaluation, rather than a qualitative one.

It does not matter how far certain BP values are beyond or below the upper norm values. Instead, the mere number of normal or hypertensive measurements is counted and rated by the ratio.

6.5.11 Summary

Enter your case history, analysis, medication, or any other text related to the recording into this text field.

Differently from the other screens discussed before, the summary textbox is not replaced by other windows/evaluations. Instead, by pressing the ***Summary*** button, this input area is switched on or off additionally to and independently from the other screens.

The right-hand side of that window provides you with ***Quick Text*** buttons. You can press them to insert the associated text block into the text at the current cursor position.
Configure those text blocks in the Holter-RR settings via menu ***File*** **|** ***Settings…*** **|** ***Holter-RR*** **|** ***Quick texts***.

You can also take advantage of the ***Auto replacement*** functionality in this text box, which replaces certain abbreviations or acronyms into longer texts.
Go to ***File*** **|** ***Settings…*** **|** ***General*** **|** ***Auto replacement*** to specify the list of auto replacement texts.

6.5.12 Comparing Recordings

If a patient record has assigned more than one Holter-RR recordings, a second recording can be displayed additionally to the one currently opened. While a Holter-RR recording is opened, use the ***Compare…*** button ① to select the comparison recording.

The two blood pressure profiles are super positioned, while an info area ② shows date and time of the comparison recording. Use the arrow symbol within the info area to select a different recording for comparison (if available), or to quit the comparison mode.

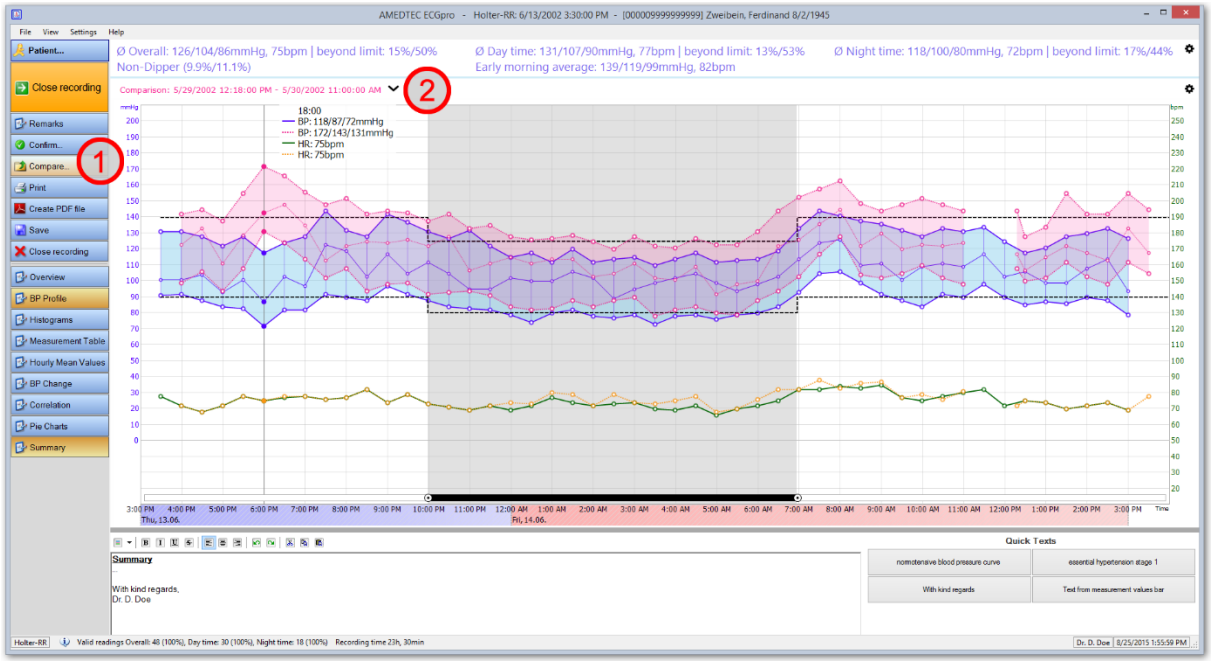


Figure 13: Comparing two recordings

6.5.13 Norm Values and Limits

6.5.13.1 Blood pressure limits

Upper blood pressure limits or norm values are used throughout the Holter-RR analysis to separate normotensive blood pressure values from hypertensive ones.

Throughout the Holter-RR analysis software, BP values are considered hypertensive if they are equal to or higher than these limits.

The default limits – which are applied to all new Holter-RR recordings – are set in the Holter-RR options under ***File | Settings… | Holter-RR | Holter-RR***.

Changes made to the default norm values will not affect existing recordings! To change the limits in an existing recording, open that recording and change the norms via the menu ***Settings | Norm Values and Limits***.

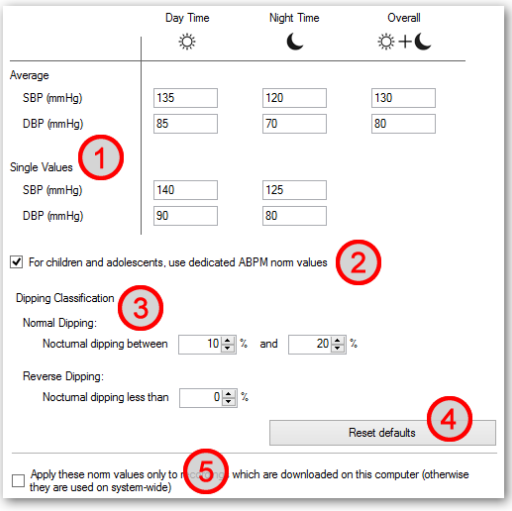


Figure 14: Norm value settings

The system uses two different kinds of upper limits ①:

- ***Average values***: These are applied to the average blood pressure. There is only a single place where these limits play a role: in the “norm values” column of the printed Results report behind the average day, night and overall BP values. These values are optional.
- ***Single values***: These limits are used almost everywhere throughout the software and are applied to every single BP reading. For instance, these limits are plotted in the BP Profile (by horizontal dashed lines), are applied in the measurement table (cell background is orange when the value is equal to or higher than one of these limits), and are used for calculating the fraction of hypertensive values in the Pie Chart evaluation.

Use the ***Reset defaults*** button ④ to restore the initial settings.

The system defaults are as follows:

Type	Limit (hypertensive from…)
Single Values Day time	140 mmHg syst., 90 mmHg diast.
Single Values Night time	125 mmHg syst., 80 mmHg diast.
Average Values Day time	135 mmHg syst., 85 mmHg diast.
Average Values Night time	120 mmHg syst., 70 mmHg diast.
Average Values Overall	130 mmHg syst., 80 mmHg diast.

For children and adolescents use dedicated ABPM norm values ②:
For children and adolescents, the following value can be applied automatically. Those are based on the guidelines for the management of arterial hypertension of the German Society for Pediatric Cardiology. (P95 percentiles stratified according to gender and height, adapted from Wühl et al. Values for 100 cm to 115 cm have been calculated by extrapolation, as well as the values for 180 cm to 185 cm in girls).

Boys

Height (cm)	Upper Limit (mmHg)		
	24h	Day time	Night time
100	114 / 77	116 / 82	104 / 62
105	115 / 77	117 / 82	105 / 62
110	115 / 77	118 / 82	106 / 62
115	116 / 77	119 / 82	106 / 62
120	117 / 77	120 / 82	106 / 64
125	118 / 77	121 / 82	108 / 63
130	119 / 77	121 / 82	110 / 64
135	120 / 77	126 / 82	111 / 65
140	121 / 77	126 / 82	113 / 65
145	123 / 77	127 / 81	114 / 66
150	124 / 77	128 / 81	116 / 66
155	126 / 77	130 / 81	117 / 66
160	127 / 77	133 / 81	118 / 66
165	129 / 78	135 / 82	119 / 66
170	131 / 78	138 / 82	121 / 66
175	133 / 78	140 / 83	122 / 66
180	134 / 78	142 / 83	124 / 66
185	136 / 78	144 / 84	125 / 66

Girls

Height (cm)	Upper Limit (mmHg)		
	24h	Day time	Night time
100	113 / 71	118 / 82	102 / 65
105	113 / 71	119 / 82	102 / 65
110	114 / 72	119 / 82	103 / 65
115	114 / 72	120 / 82	104 / 65
120	114 / 72	120 / 82	106 / 65
125	116 / 73	121 / 82	107 / 66
130	117 / 73	122 / 82	108 / 66
135	118 / 74	123 / 82	109 / 66
140	119 / 75	124 / 82	110 / 66
145	120 / 75	125 / 82	112 / 66
150	121 / 76	127 / 82	113 / 66
155	123 / 76	128 / 82	114 / 66
160	123 / 76	129 / 82	114 / 66
165	124 / 76	130 / 82	114 / 66
170	125 / 76	131 / 82	115 / 71
175	126 / 76	131 / 82	115 / 66
180	127 / 76	132 / 82	116 / 66
185	128 / 76	132 / 82	116 / 66

6.5.13.2 Dipping

Dipping ③ is the relative nocturnal blood pressure decrease compared to the day-time average blood pressure. It is calculated by the formula $Dipping\ [\%] = \frac{\overline{BP_{Day}} - \overline{BP_{Night}}}{\overline{BP_{Day}}} * 100.$

Dipping can be rated into four classes: Extreme Dipper, Normal Dipper, Non-Dipper and Reverse Dipper. (A Reverse Dipper means that the average night-time BP is higher than the day-time average.)

The default limits for this classification are as follows:

Dipping Classification	Explanation	Default dipping
Reverse Dipper	Nocturnal BP increase (systolic or diastolic), i.e., the night-time BP is higher than the day-time BP.	< 0 % (a nocturnal BP rise, actually)
Non-Dipper	The nocturnal BP decrease (systolic or diastolic) is below the Normal Dipper limits.	0 % – < 10 %
Normal Dipper	The nocturnal BP decrease (systolic and diastolic) is within the Normal Dipper limits.	10 % – 20 %
Extreme Dipper	The nocturnal BP decrease (systolic or diastolic), is beyond the Normal Dipper limits.	> 20 %

Use the ***Reset defaults*** button ④ to restore the initial settings.

Scope ⑤: By default, all AMEDTEC *ECGpro* computers share the same norm values and dipping settings. To have specific settings for the current computer, tick the checkbox ***Apply these norm values only to recordings which are downloaded on this computer***.

7 Holter-RR Blood Pressure Recorder

7.1 Device Keys

On/Off

Press this key to switch the recorder on or off.
In order to switch the device off, the keys must be hold down for at least 2 seconds.

If the recording must be interrupted, e.g. due to pain or bruising, the patient shall switch the recorder off and take both the device and the cuff off.

If the data transfer cable is plugged into the recorder at the time the recorder is switched on, the device will automatically switch into the communications mode (see *Communications Mode – „co“* on page 9). To leave the “co” mode press any device key or unplug the cable.

Start

Press this key to start the ambulatory blood pressure measurement. The patient can also take manual measurements by this key at any time.

Note that at least one successful BP reading must be taken this way before the recorder switches into the automatic measurement protocol. As long as no successful initial measurement has been done, the recorder will not take automatic measurements.

A measurement can always be aborted by pressing any key!

Day/Night

This key switches the recorder from day into night mode and vice versa if it is pressed within 4 hours before the programmed start time of the next interval.

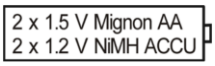
The patient should be instructed to press this key when he goes to bed and again when getting up in order to switch the recorder into the according daytime or night-time measurement mode. Doing so (rather than having the recorder change the interval itself at the programmed day or night time – which might be significantly later) improves the day/night analysis a lot.

For instance, if the night interval is programmed to start at 10pm, the patient can already switch into the night mode from 6pm on.

Event

The patient can press this key to manually start a blood pressure measurement and set an Event flag for this reading. This is indicated in cases of events which are potentially relevant to the blood pressure. Such can be: Ingestion of drugs, sickness, head ache, or physical activities. These events should be written down in the ABPM diary.

7.2 Symbols

	Read instructions for use!
	Types of supported power supply.
	FCC label for communication equipment
	The device emits electromagnetic radiation.
	MR-Unsafe: The device is hazardous in a MRT environment.
	Manufacturer
	Date of production in format YYYY-MM-DD
	Device serial number.
	The device must not be disposed of with the normal household waste but rather has to be returned to a recycling point for electrical and electronic appliances. You can obtain further information from your local authority, local waste disposal plants or specialist dealers.
	The device is protected against defibrillation shocks. Note that the protection is mainly ensured by the electrically non-conductive materials of the housing and the pressure hose. The patient must not be in touch of the recorder itself during a defibrillation.
	Consult the accompanying documents!
	The device meets the essential requirements of the European directives on medical devices (MDD).
	The device has a Bluetooth interface.

7.3 Technical Data

Measurement method:	Oscillometric
Measuring range:	Pulse: 30 bis 240 Schläge pro Minute Systolic BP: 60 – 290 mmHg Diastolic BP: 30 – 195 mmHg
Precision:	±3 mmHg in the range indicated
Static pressure:	0 – 300 mmHg
Heart rate range:	30 – 240 bpm
Measurement frequency:	0, 1, 2, 4, 5, 6, 12 or 30 measurements per hour
Measurement protocols:	9 protocols of 3 day time und 1 night time intervals each
Storage capacity:	300 measurements
Operating environment:	Temp.: +10 °C – +40 °C Humidity: 15 % – 90 %
Storage environment:	Temp.: -20 °C – +50 °C Humidity: 15 % – 95 %
Dimensions:	128 x 75 x 30 mm
Weight:	approx. 240 g incl. batteries
Power supply:	2 NiMH 1.2 V recharg. batteries (AA, Mignon), ≥ 1500 mAh each 2 Alkaline 1.5 V batteries (AA, Mignon) *1)
Data interfaces:	Interface cables: USB or RS232 Wireless: Infrared (proprietary infrared receiver „IR Med“)
Expected life time:	> 5 years (except for accumulator and cuffs)

*1) The capacity of NiMH batteries gradually decreases over life time and number of charge cycles. When the batteries are no longer sufficient for a whole recording time according to the programmed measurement protocol, they must be replaced. Alkaline batteries of different manufacturers can have different capacities. If batteries from one manufacturer are not sufficient for a whole recording time, suitable batteries from a different manufacturer must be used.

8 Troubleshooting

8.1 Main Sources of Error

With faulty measurements or connections, most often one or more of the following are found to be the source of error.

Issues with measurements:

- Artifacts due to arm or body movements during a blood pressure measurement
- Incorrect cuff size
- Lose connection of the pressure hose
- Kinked, drilled or squeezed pressure hose
- Slipped cuff
- Empty or defective batteries

Issues with the connection to computer:

- Interface cable connected to the wrong (unpaired) PC port
- Interface cable not properly or fully plugged in to recorder and/or PC
- Recorder not in ‘co’ mode
- Empty or defective batteries

8.2 Problem Analysis

The following table can help to track possible issues as they happen to appear during measurements and communication. Please also refer to the table of error codes on page 36.

Symptom	Possible cause	Mitigation
The first measurement is faulty, or the recording contains many erroneous readings.	The batteries are low early or are defective.	For every recording use fresh or freshly charged batteries. The battery voltage appears on the recorder display when it is switched on. The voltage must be **at least** 2.75 V with batteries, or 2.4 V with rechargeable batteries, for a typical 24-hour recording. Replace rechargeable batteries if their capacity is no longer sufficient due to their age/number of charge cycles.
	The cuff has not the correct size or is not applied correctly.	Always use a cuff which fits the patients arm. Use the supplied tape measure to determine the arm circumference. Make sure the cuff is applied correctly. (Ref. section 4.4, *Hooking up the Recorder*, on page 13.)

Symptom	Possible cause	Mitigation
	The patient has severe cardiac arrhythmia.	The recorder is not applicable for the patient.
The recorder does not contain any measurements.	The necessary initial manual blood pressure measurement was not done or was not successful.	After the Holter-RR recorder has been attached to the patient, take an initial measurement using the *Start* key  . Pay attention that this is a successful reading, i.e. no error code appears on the display and the measured values seem plausible. If necessary, reposition the cuff, check the batteries voltage, check the pressure hose, and repeat the measurement. As long as no manual reading has been take successfully, the recorder will not switch into automatic mode.
The recording is incomplete / too short.	The batteries became low early or are defective.	For every recording use fresh or freshly charged batteries. The battery voltage appears on the recorder display when it is switched on. The voltage must be **at least** 2.75 V with batteries, or 2.4 V with rechargeable batteries, for a typical 24-hour recording. Replace rechargeable batteries if their capacity is no longer sufficient due to their age/number of charge cycles.
	The recorder was switched off.	In the measurement table select the option Extended Table from the settings symbol (…), and watch for the "recorder switched off" events. Always advice the patients to NOT switch off the device since a complete recording – also during the night – is important for the diagnosis.
The blood pressure is taken every two minutes.	Measurement protocol 9 has been selected.	Choose the correct protocol. See 4.2, *Preparing the BP Recorder*, on page 11.
The recorder time show 01.01.2006 00:00 every time the batteries have been replaced.	The internal backup cell battery is low.	The backup cell needs to be replaced. Please contact your distributer or the AMEDTEC service.
The recorder does not contain a patient ID, or the recording is not automatically assigned to the correct patient.	The recorder has not been prepared with the patient data before the recording was started.	Prepare the recorder with the patient data before attaching the device to the patient. (Ref. section 4.2, *Preparing the BP Recorder*, on page 11.)

Symptom	Possible cause	Mitigation
The recording contains measurements of a previous recording.	The recorder memory has not been deleted before the recording was started.	Deactivate those measurement which do not actually belong to this recording in the measurement table. Ref. paragraph "***Faulty or*** otherwise invalidon page Faulty or otherwise invalid23. It is recommended to select the ***Delete the recorder memory*** at the end of downloading a recording into the database. (Ref. chapter *Downloading Measurements from the Recorder*, page 15.) Also, when the device is prepared for the next patient, the memory is automatically cleared. (Ref. chapter *Preparing the BP Recorder*, page 11.)
When trying to prepare or download the recorder the device is not found by the software anymore.	The USB cable has been attached to a different USB port than before.	1) Connect the recorder to the same USB port as before. or 2) Reassign the port. Open the settings via ***File | Settings… | Holter-RR | Holter-RR Recorder***, and click ***Search…*** while the recorder is connected and is in "co" mode. (Ref. chapter *Setting up the Blood Pressure* Recorder on page 9.)
	The recorder is not in "co" (communications) mode.	Switch the recorder into "co" mode. (See *Communications Mode – „co"* on p. 9.)

8.3 Table of Error Codes

The following table lists error codes which may be displayed on the recorder during measurements or data transfer, together with their possible cause and mitigation.

Error Code	Possible cause	Mitigation
Err 1	Not enough pulse beats detected.	
	1) Patient has severe arrhythmia.	1) Recorder not applicable.
	2) Patient is very obese.	2) Re-fit the cuff, pay attention to the correct size. Recorder might not be applicable.
	3) Arm was moved.	3) Avoid movement artifacts by holding the arm still during

Error Code	Possible cause	Mitigation
		measurements.
	4) If the detailed event code shows to be 28, the device's EEPROM is defective. To reveal event codes, switch the measurement table into *Extended mode*. (See also section *Measurement Table*, page 22.)	4) Send the recorder to AMEDTEC or a certified service partner for inspection.
Err 2	Pulse beats could not be detected reliably.	
	1) The arm was moved during the measurement → artifacts. 2) Cuff not correctly fitted to the patient's arm.	1) Body – particularly the arm – must be kept still during measurements. 2) Check the fit of the cuff and the unit.
Err 3	1) Blood pressure out of measurement range. 2) Movement artifacts. 3) Problems with the device pneumatic.	1) If this error continues to appear, the monitor might not be suitable for the patient. 2) Keep the arm still during the measurement process. 3) If the error is permanent with all patients, send the device in to AMEDTEC for inspection.
Err 4	1) Data transfer cable not correctly plugged into the recorder. 2) Pins of the transfer cable plug have suffered mechanical damage. 3) A measurement value has been not correctly transferred.	1) Plug the interface cable properly into the recorder and the computer. 2) Check the plug for damaged/bended pins. If that's the case, replace the cable immediately. 3) Start the data transfer again.
Err 5 **bAtt**	1) Battery voltage is too low. 2) Batteries are defective. 3) Battery contacts are corroded.	1) Replace the batteries. 2) The battery voltage is correct, but during cuff inflation, bAtt is shown on the display. Replace the batteries. 3) Clean the battery contacts with a cotton cloth and alcohol.
Err 6 **+ possibly continuous alarm until a key is pressed**	1) Pressure hose is blocked.	1) Check cuff and pressure hose for a blockage or kink. If no problem cannot be resolved, send the equipment in to AMEDTEC or service partner for inspection without delay.

Error Code	Possible cause	Mitigation
	2) Blood pressure cuff is not correctly connected to the recorder. 3) Pressure leakage in cuff or hose.	2) Connect the pressure hose properly and firmly to the recorder. 3) Check cuff and hose for defective locations, and replace these parts if necessary.
Err 7	The recorder memory has reached the maximum number of 300 measurements (incl. events). No more measurements can be stored.	After downloading a recording, clear the recorder memory. When preparing the recorder in the software for the next recording, the memory is also deleted. To delete the memory manually (CAUTION!), press the START key and hold it down. After 5 seconds, you will hear a single beep, than the number of the measurements is displayed, followed by “clr”. After further 2 seconds, the recorder memory is deleted, and you will hear 5 beeps. If the START is released earlier, the deletion is aborted.
Err 8	The measurement was aborted by a key press.	
Err 9 **+ possibly continuous alarm until a key is pressed**	1) Residual cuff pressure present. 2) Zero-point adjustment could not be performed successfully.	1) Wait for the cuff to deflate completely. 2) Send the recorder to AMEDTEC or a certified service partner for inspection.
Err 10 **+ continuous alarm until a key is pressed**	1) Serious fault due to pressure buildup outside the measurement process (pump has switched on illegally) 2) These error messages indicate a serious error in the recorder’s firmware code.	Send the recorder to AMEDTEC or a certified service partner for inspection immediately.

9 Maintenance

9.1 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. A written confirmation about that process needs to be sent with the shipment.

9.2 Metrological Control and Safety Checks

Medical device regulations which apply to your country might require regular metrological control for blood pressure monitors which include a recalibration if necessary. (In Germany, e.g., this is required every two years by §11, MPBetreibV.) Please refer to the medical device regulations applicable in your country.

The recorder stores a service timestamp, and the software informs the operator of due recorders every two years beginning 14 days before the due-date.

9.3 Cleaning and Disinfection

Cleaning and disinfection of the Holter-RR devices is a fundamental part of operator's responsibility for safety and hygiene.

Clean and disinfect recorder, cuff and pressure hose after every recording in compliance with the following instructions:

- The following detergents and disinfectants have been tested and are recommended:
  - terralin® liquid *(Schülke & Mayr)*
  - Isopropanol (70 %)

Never use detergents or disinfectants which leave residues or which are not suitable for contact with the skin.

Especially with respect to patients with intolerances (e.g. allergies) to disinfectants or their components, remove any residue by careful washing.

9.3.1 Blood Pressure Recorder

- Clean the recorder with a damp cotton cloth that is impregnated with a disinfectant. No corrosive or solvent-containing additives must be used! Make sure that no water gets into the unit! Particular attention here deserve the hose connection and the battery compartment.

IMPORTANT:

Do not use the recorder if any liquid could have penetrated into it.
Do not turn the device on, or turn it off immediately, resp.
Send the device to AMEDTEC or one of our certified service partners for inspection.

9.3.2 Cuff

- Initially, remove the pressure bladder carefully from the cuff sleeve.

- Bladder and pressure hose might be damaged by disinfectants!
  Wash the bladder with lukewarm water only, adding a mild cleaning solution if necessary, and wipe it off. Absolutely take care that no water enters the tube opening!

- The cuff cover may be washed at max. 30 °C with a mild detergent in the washing machine.

  The Velcro must always be fastened before washing.

  Do not use fabric softeners or other aids (e.g. disinfectant rinses, textile deodorants) and do not tumble dry!

9.3.3 Pouch

- Please clean the pouch only with a damp cotton cloth. Do not use corrosive liquids or solvents.

9.4 Rechargeable Batteries

Rechargeable batteries gradually lose their capacity over their lifetime. When the capacity is no longer sufficient for a whole recording, or if the batteries are damaged in any way, replace them immediately.

We recommend to use I.E.M. batteries as their quality and capacity have been tested. In any case use batteries with a capacity of at least 1500 mAh.

The Holter-RR recorder comes with nickel-metal hydride (NiMH) rechargeable batteries. The level of self-discharge of these batteries depends on the environmental temperature. It is recommended to leave the batteries in the charger until they are used.

Always follow the instructions of the battery charger!

Issues with the batteries often can be tracked by watching the battery voltage during the recording. You find it by opening the recording in the Holter-RR software, switching into the ***BP Profile*** screen and selecting the ***Show Battery Voltage*** option through the ***settings symbol*** ⚙.

At the beginning of a 24-hour recording, the voltage must be at least 2.75 V with batteries, or 2.4 V with rechargeable batteries. The current voltage is shown on the recorder display for some seconds when the recorder is switched on, or can be retrieved via the "***Recorder tests and tools…***" button in the Recorder Setup screen.
Please select the type of batteries which you use with the Holter-RR recorder in the program settings (***File*** **|** ***Settings…*** **|** ***Holter-RR Recorder***).

10 Warranty

1) For its devices purchased in the EU, AMEDTEC Medizintechnik Aue GmbH provides 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) Excluded from this warranty are expendables including batteries, rechargeable batteries, battery contacts, data cables, blood pressure cuffs, or pressure hoses.
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 evidences for the warranty are the bill 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.

11 Accessories Order List

Order Number	Item	Description
001 219	Serial interface cable (RS-232)	Interface cable to connect the Holter-RR recorder to a computer's serial (RS-232) port.
001 463	Combined USB/serial interface cable	Interface cable to connect the Holter-RR recorder either to a computer's serial (RS-232) port or to a USB port.
100 154	USB interface cable	Interface cable to connect the Holter-RR recorder to a computer's USB port.
001 464	Infrared transmitter "IR-med"	IR-med transmitter to connect the Holter-RR recorder via infrared to the computer. The transmitter is connected to a USB port.
001 772	Cuff NG XS	Arm circumference 14 - 21 cm
001 241	Cuff NG S	Arm circumference 20 - 24 cm
001 242	Cuff NG M	Arm circumference 24 - 32 cm
001 243	Cuff NG L	Arm circumference 32 - 38 cm
001 244	Cuff NG XL	Arm circumference 38 - 55 cm
001 762	Set of three cuffs	Set of three selectable cuffs. Specify the cuff sizes with the order.
001 364	Pressure hose extension, 50 cm	
001 437	Battery compartment lid	
001 467	Pouch with Velcro fastening	Pouch and shoulder strap for the patient to carry the Holter-RR recorder.
001 547	Air connector for cuff pressure hose	
001 611	Battery charger	
001 612	Rechargeable batteries, 2100 mAh, pack of 4	
001 613	Battery charger including 4 re-chargeable batteries, 2100 mAh	
001 677	Tape measure	Used to take the patient's arm circumfer-ence.

12 EMC guidance and manufacturer's declaration

Electromagnetic emissions

The Holter-RR blood pressure monitor is intended for use in the environment specified below. The customer or user of the Holter-RR pressure monitor should ensure that it is used in such an environment.

Electromagnetic emissions	**Compliance**	**Electromagnetic environment guideline**
RF emissions CISPR 11	Group 1	The Holter-RR blood pressure monitor uses RF energy purely for its own internal function. RF emissions are therefore very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Group B	The Holter-RR blood pressure monitor is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage supply network that supplies buildings used for domestic purposes.

Electromagnetic immunity

The Holter-RR blood pressure monitor is intended for use in the environment specified below. The customer or user of the Holter-RR pressure monitor should ensure that it is used in such an environment.

Immunity Test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment – guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	Portable and mobile RF communications equipment should be used no closer to any part of the Holter-RR blood pressure monitor, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance: $d = 1{,}17\sqrt{P}$ at 80 MHz to 800 MHz $d = 2{,}33\sqrt{P}$ at 800 MHz to 2.5 GHz d: Recommended separation distance in m P: Maximum output power rating of the transmitter in W Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, should be less than the compliance level in each frequency range. Interference may occur in the vicinity of equipment marked with the "non-ionizing radiation" symbol. 
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

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 assess 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 blood pressure monitor is used exceeds the applicable RF compliance level above, the Holter-RR blood pressure monitor should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the blood pressure monitor.

Recommended separation distances between portable and mobile RF communications equipment and the Holter-RR blood pressure monitor

The Holter-RR blood pressure monitor is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or user of the Holter-RR blood pressure monitor can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the blood pressure monitor as recommended below, according to the maximum output power of the communications equipment.

Separation distance according to frequency of transmitter in m

Rated maximum output power *P* of transmitter in W	**80 MHz to 800 MHz** $d = 1{,}17\sqrt{P}$	**800 MHz to 2.5 GHz** $d = 2{,}33\sqrt{P}$	**150 kHz to 80 MHz**
0,01	0,12	0,23	Not applicable
0,1	0,37	0,74	Not applicable
1	1,17	2,33	Not applicable
10	3,70	7,37	Not applicable
100	11,70	23,30	Not applicable

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.
NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

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