Anexa 7

Specificație Tehnică Completată

Anexa 7 Holter Tensiune Arteriala
Model Holter Tensiune Arteriala: BR-102 plus
Numar de inregistrare Holter TA DM000708728
Numar de inregistrare soft pentru interpretare DM000633964

Producător: SCHILLER AG
Țara: Elvetia

Specificarea tehnică deplină solicitată, Standarde de referință	Specificația tehnică propusă de ofertant
Configuratie să conțină minim: Manșetă mărimea M, husă cu cureau de umăr și talie, Cablu USB la PC Baterii reîncărcabile cu încărcător/stație de încărcare	Configuratie să conțină minim: Manșetă mărimea M, husă cu cureau de umăr și talie, Cablu USB la PC **DA, din BR-102 plus Technical data** Baterii reîncărcabile cu încărcător/stație de încărcare **DA, din BR-102 plus Technical data**
Posibilitatea de a alege intervalul de măsurare a tensiunii	Posibilitatea de a alege intervalul de măsurare a tensiunii **DA, pag.13 din BR-102 plus user manual**
Metoda de măsurare oscilometric minim 2 butoane de navigare sau buton multifuncțional	Metoda de măsurare oscilometric **DA, din BR-102 plus Technical data** 2 butoane de navigare sau buton multifuncțional **DA, din BR-102 plus Technical data**
Diapazonul de măsurare a tensiunii 25-300 mmHg Diapazonul de măsurare a bătăilor minimi 40-240 bpm	Diapazonul de măsurare a tensiunii 25-300 mmHg **DA, din BR-102 plus Technical data** Diapazonul de măsurare a bătăilor minimi 25-300 bpm **DA, din BR-102 plus Technical data**
Interval de măsurare 5-120 min	Interval de măsurare 5-120 min **DA, din BR-102 plus Technical data**
Posibilitatea ca pacientul să inițieze manual o măsurare	Posibilitatea ca pacientul să inițieze manual o măsurare **DA, din BR-102 plus Technical data**
Program de interpretare cu licență și cheile de acces inclusă:	Program de interpretare cu licență și cheile de acces inclusă, DARWIN2, **DA, din BR-102 plus Technical data**

Anexa 7

Funcționalitate de afișare a trendului tensiunii arteriale (Trend BP) – sau echivalent; Funcționalitate de afișare a histogramei valorilor de tensiune arterială (Histograma BP) – sau echivalent”.	Funcționalitate de afișare a trendului tensiunii arteriale (Trend BP) **DA, pag.79 din Medilog Darwin2_user manual** Funcționalitate de afișare a histogramei valorilor de tensiune arterială (Histograma BP) **DA, pag.84 din Medilog Darwin2_user manual**

Technical Data

BR-102 plus

System

Device
Dimensions: 100 x 68 x 28 mm (l/w/h)
Weight: 200 grams (including batteries)

Ambient condition
Temperature – Operation: 10 to 40 °C – Transport/storage: –10 to 50 °C
Humidity – Operation: 15 to 95 % non-condensing – Transport/storage: 10 to 95 % non-condensing
Pressure – Operation: 700 to 1060 hPa – Transport/storage: 500 to 1060 hPa

Electrical data
Power: 2 rechargeable NiMH batteries (≥ 2700 mAh), type "AA"[1]
Display: Colour OLED display with multi-language menu
Interface: USB interface for data transfer
PC Requirements: USB port
Data Storage: Flash memory and microSD card stores up to 400 readings and 30 s of voice recording

Blood pressure module
Programming: Menu guidance; 2 buttons
Measurement duration: 24 hours or 48 hours
BP Technique: Auscultatory (Korotkoff / Riva-Rocci) and oscillometric or only oscillometric, both with linear adjustable deflation
BP Range: 25 – 300 mmHg
HR Range: 25 – 300 bpm
Deflation Speed: 2 – 9 mmHg/s or automatic (3 mm/Hg per beat)
Recording programs: 4 programs with max. 8 modifiable measurements cycles
Measurement intervals: 5 – 120 min
Manual measurement: the patient can trigger an additional measurement at any time during a recording.

1 We recommend using SCHILLER batteries exclusively, as their capacity and quality has been tested. Care should always be taken that the batteries capacity equals or exceeds 2700 mAh.

Accessories

Standard
Schiller cuff (Size Adult M)
4 NiMH rechargeable batteries
Battery charger
Carrying pouch, patient belt and shoulder strap
USB interface cable
DARWIN2 Software
User guide

Optional
SCHILLER Cuff – **XS:** (14 – 20 cm) / 2.120063 (only oscilometric) – **S:** (18 – 24 cm) / 2.120064 – **M:** (25 – 35 cm) / 2.120065 – **L:** (30 – 36 cm) / 2.120066 – **XL:** (35 – 46 cm) / 2.120067 **SCHILLER Cuff D-ring** – **S:** cuff D-ring Small / 2.120076 – **M:** cuff D-ring Medium / 2.120077 – **S:** cuff D-ring Large / 2.120078 **SCHILLER Comfort sleeve** – **XS:** 2.120068 – **S:** 2.120069 – **M:** 2.120070 – **L:** 2.120071 – **XL:** 2.120072
Single use pouches (50 pieces) 2.156086
Carry case 2.156079

Warranty
See general terms of condition on www.schiller.ch

Standards

Certification
Safety Standards: IEC 60601-1; IEC 80601-2-30; ISO 81060-1; IEC 1060-3; IEC 60601-1-2
Protection Class: Internal power supply
Applied Part: BF according to IEC/EN 60601-1
Conformity: CE according to Annex II 93/42/EEC (medical devices)
Classification: IIa according to MDD 93/42/EEC
Notified body: CE 0123

Technical datasheet for Part no.: 2.500672 2018/09, EN

SCHILLER
The Art of Diagnostics

Headquarters: SCHILLER AG, Altgasse 68, CH-6341 Baar, Switzerland, Phone +41 41 766 42 42, Fax +41 41 761 08 80, sales@schiller.ch, **www.schiller.ch**

BR-102 PLUS
BR-102 PLUS PWA

24/48 Hour Ambulatory Blood Pressure Recorder

User Guide

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SCHILLER
The Art of Diagnostics

Sales and Service Information

The SCHILLER sales and service centre network is world-wide. For the address of your local distributor, contact your nearest SCHILLER subsidiary. In case of difficulty a complete list of all distributors and subsidiaries is provided on our internet site:

www.schiller.ch

Sales information can also be obtained from:
sales@schiller.ch

Address Headquarters

SCHILLER AG
Altgasse 68
CH-6341 Baar
Switzerland

Tel: +41 (0) 41 766 42 42
Fax: +41 (0) 41 761 08 80
sales@schiller.ch
www.schiller.ch

CE 0123

BR-102 plus / BR-102 plus PWA bears the CE-0123 mark (Notified Body TÜV-SÜD Produkte Service GmbH, Ridlerstr. 65, 80339 Munich, Germany), indicating its compliance with the essential requirements of the Annex I of the Medical Device Directive 93/42/EE regarding safety, functionality and labelling. The requirements apply to patients, users and third persons who come into contact with this device within the scope of its intended use.

Article no: 2.511076 Rev.: f
Issue date: 28.03.19
Corresponds to: DE version f

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1 Safety Notes

1.1 User Profile

Medical Personnel (Operator, User)

This blood pressure recorder as well as the analysis program are provided for the exclusive use of qualified physicians or trained medical personnel under their direct supervision.

Patient, Caregiver (for use in home environment)

After thorough instruction from the attending physician, the patient or his/her caregiver may use the device on their own (see chapter 4 Patient Information and chapter 10 Patient Diary).

1.2 Intended Use

- The BR-102 plus / BR-102 plus PWA is a non-invasive ambulatory blood pressure recorder. It uses auscultatoric and oscillometric signals, or purely oscillometric signals to measure the blood pressure of human beings. Systolic, diastolic, mean arterial pressure and heart rate are measured. The BR-102 plus / BR-102 plus PWA is intended as an aid to diagnosis and treatment when it is necessary to measure an adult or adolescent patient's blood pressure over an extended period of time (up to 24 48 hours). Further, with each measurement, the PWA data will be saved for subsequent external assessments.
- The BR-102 plus / BR-102 plus PWA can be used for adults and children (3 years old onwards) of both sexes and all ethnic origins.
- This blood pressure recorder can be used on pregnant patients or patients suffering from pre-eclampsia.
- Patients with special needs such as children, the elderly, the disabled, or people lacking the capacity for judgement must be accompanied by a caregiver who will supervise the actions as well as monitor the recording.

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1.3 Contraindications

- The BR-102 plus / BR-102 plus PWA has **not** been designed for, and must not be used for the following patients:
  - neonates and children under the age of 3.
  - Patients who must undergo invasive blood pressure monitoring.

1.4 Responsibility of the User

- The numerical and graphical results as well as any interpretation suggested by the device must be examined with respect to the patient's overall clinical condition and the quality of the recorded data.
- The indications given by this equipment are not a substitute for regular checking of vital functions.
- The responsibilities of the personnel for the operation and maintenance of the device must be specified.
- Ensure that personnel have read and understood these operating instructions. In particular this section safety notes, must be read and understood.
- Damaged or missing components must be replaced immediately.
- The operator is responsible for compliance with all applicable accident prevention regulations and safety regulations.
- The safety, reliability and performance of the unit can only be guaranteed when the maintenance intervals, as stated in the Maintenance section of this user guide, are observed.
- No modification of this equipment is allowed.

1.5 Organisational Measures

- Before using the unit, ensure that an introduction regarding the recording functions and the safety precautions has been provided by a medical product representative.
- Observe the operating instructions and maintenance instructions and keep these operating instructions in an accessible place for reference when required. Make sure that they are always complete and legible.
- These operating instructions do not override any statutory or local regulations, or procedures for the prevention of accidents and environmental protection.

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1.6 Maintenance

- There are no serviceable parts inside. Refer servicing to qualified technician authorised by SCHILLER only.
- Do not use high temperature sterilisation processes (such as autoclaving). Do not use E-beam or gamma radiation sterilisation.
- Do not use solvent or abrasive cleaners on either the unit or cable assemblies.
- Do not, under any circumstances, immerse the device or cable assemblies in liquid.

1.7 Hygiene

- For cleaning and disinfection observe the legal requirements applicable.
- Only use cleaning agents and disinfectants recommended by SCHILLER. Unsuitable agents can damage the device. Clean and disinfect the device in accordance with the instructions given in this book.

1.8 Safety Conscious Operation

- Make sure that the staff have read and understood the operating instructions - particularly this Safety Notes section.
- Immediately report any changes that impair safety (including operating behaviour) to the person responsible.
- Only use accessories and other parts recommended or supplied by SCHILLER AG. Use of other than recommended or supplied parts may result in injury, inaccurate information and/or damage to the recorder.

1.9 Safety Facilities

- Connecting the unit to a PC with defective cables may constitute a danger to life. Therefore:
  - Do not connect the BR-102 plus / BR-102 plus PWA to any PC if the earth connection is suspect or if the mains lead is damaged or suspected of being damaged.
  - Damaged cable connections and connectors must be replaced immediately.

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1.10 Operation with other Devices

- Only use accessories and other parts recommended or supplied by SCHILLER AG. The use of other than recommended or supplied parts may result in injury, inaccurate information and/or damage to the device.
- Accessory equipment must be certified according to the respective IEC standards (e.g. IEC/EN 60950 for data processing equipment and IEC/EN 60601-1 for medical equipment). Furthermore, all configurations shall comply with the valid version of the system standard IEC/EN 60601-1. Everyone who connects additional equipment to the signal input part or signal output part configures a medical system, and is therefore responsible that the system complies with the requirements of the valid version of the system standard IEC/EN 60601-1. If in doubt, consult the technical service department or your local representative.
- The BR-102 plus / BR-102 plus PWA is safe during defibrillation. However, as a safety precaution remove the cable assembly between the recorder and the PC and when possible, remove the BR-102 plus from the patient before defibrillation.
- The BR-102 plus / BR-102 plus PWA complies with EMC regulations for medical products which afford protection against emissions and immunity. However, the possibility exists that high frequency disturbance from other devices can affect the recorder's operation.

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1.11 Safety Symbols and Pictograms

1.11.1 Symbols used in this Document

The safety level is classified according ANSI Z535.4. The following overview shows the safety symbols and pictograms used in this manual.

⚠ DANGER — For a direct danger which could lead to severe personal injury or to death.

⚠WARNING — For a possibly dangerous situation, which could lead to serious bodily injury or to death.

⚠ CAUTION — For a possibly dangerous situation which could lead to personal injury. This symbol is also used to indicate possible damage to property.

 For general safety notes as listed in this chapter.

 **Note** For possibly dangerous situations, which could lead to damages to property or system failure. **Important** or helpful user information.

 Reference to other guidelines.

1.11.2 Symbols on the Device, Batteries, and Accessories

 The recorder/component can be recycled.

CE 0123 Notified body of the CE certification (TÜV P.S.).

 Manufacturer address and manufacturer date

 Type BF equipment, safe for external applications.

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Symbol for the recognition of electrical and electronic equipment.

Recycle the recorder and batteries separately from other waste. Equipment/components and accessories no longer required must be disposed of in a municipally approved collection point or recycling centre. Alternatively, you can return the equipment to your supplier or SCHILLER AG for disposal. Improper disposal can harm the environment and human health.

NiM

NiM

BR-102 plus / BR-102 plus PWA battery type 2 x AA 1.2 V / 2700 mAh, NiMH. Use NiMH charger only.

Do not disassemble, mutilate, incinerate, or heat. Do not short circuit a battery. May cause burns. At the end of a battery's life, do not dispose in household waste. Batteries must be disposed of in a municipally approved collection point or recycling centre. To prevent the possibility of battery leakage, always remove the batteries from the device when not used for prolonged periods.

IP42

(with carrying pouch)

According DIN VDE 0470 PART 1 /EN 60529 / IEC 529

Protection against deposits of dust and protection against spray water. (The first digit indicates the protection of the equipment against ingress of solid foreign bodies and dust and the second digit indicates the degree of protection of the equipment inside the enclosure from ingress of water).

Read and follow the instructions in the accompanying documentation.

- Do not tumble dry
- Do not use bleach to clean the pouch.
- Do not iron

- Dry Clean
- Wash the pouch at a temperature of 30° C and the cuff at 40°C.
- Select gentle or delicate cycle.

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2 Introduction

The SCHILLER BR-102 plus / BR-102 plus PWA is an Ambulatory Blood Pressure Recorder used for single and long-term recordings. The device can take up to 100 measurements over a 24 hour recording period, and up to 200 measurements over a 48 hour recording period. All recorded data is stored in an internal memory and can be uploaded to the medilogDARWIN2 program. The recorder has four recording programs that can be defined by the user with individual time and interval settings for each program. This enables long-term blood pressure measurements to be taken at pre-set intervals for different patients and conditions.

Standard

- BR-102 plus Ambulatory Blood Pressure recorder Standard, or BR-102 plus PWA (Pulse Wave Analysis)
- Four rechargeable AA NiMH batteries
- Battery charger unit
- Cuff size ‘M’ (medium) adult, and pressure hose with microphone
- Comfort Sleeve size ‘M’ (medium) adult
- Securing pouch with shoulder and waist-strap
- medilogDARWIN2 software
- USB cable
- BR-102 plus / BR-102 plus PWA user guide

Cuffs and Accessories

Cuffs are available in sizes ‘XS’ (extra small, Osc. only), ‘S’ (small), ‘M’ (medium), ‘L’ (large), and ‘XL’ (extra large). A list of these and other accessories are given at the end of this book (see Accessories, page 64)

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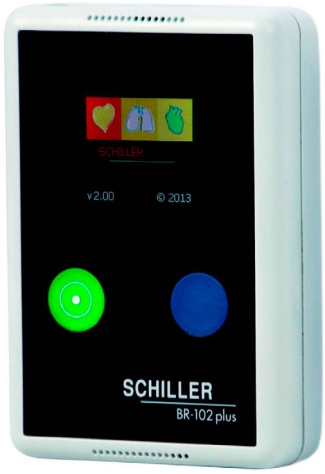
2.1 BR-102 plus / BR-102 plus PWA

The recorders are available as follows:

2.1.1 BR-102plus



The Standard BR-102 plus is identified by the black front casing. There are two measurement methods available as follows:

- Option 1 employs the auscultatory (Riva-Rocci, Korotkoff) method of measurement, with an oscillometric method as back-up. This means that when a clear measurement cannot be obtained with the auscultatory method, the oscillometric value is used. If a clear measurement cannot be obtained with either method the BP measurement is retaken. It is not possible to define oscillometric as the primary measurement method.
- Option 2 employs the oscillometric method only. Note that with this recorder no microphone is provided with the cuff.

2.1.2 BR-102 plus PWA

The BR-102 plus PWA (Pulse Wave Analysis) is identified by the white front casing and takes measurements using the auscultatory (Riva-Rocci, Korotkoff) method with oscillometric as back-up.

The setup and settings of the BR-102 plus PWA, measurement interval, cuff application, and start and stop procedure are all identical to the standard unit.

To obtain the extra data needed for PWA, the measurement cycle differs from standard BP measurement. After every individual measurement (and the SYS and DIA values recorded), the cuff is again inflated to the diastolic pressure. This pressure is then held for 10 seconds while the PWA data is obtained. After 10 seconds the cuff is again deflated and ready for the next programmed measurement.

An outline of PWA principal is given at the end of this book (see BR-102 plus PWA, page 66).

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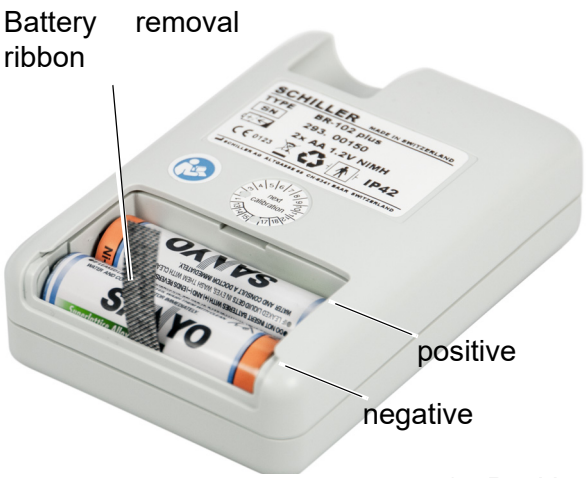
2.2 The medilog®DARWIN2 Program

The medilogDARWIN2 program supplied with the recorder is used to display, save, edit, analyse and print recordings. In addition to blood pressure recordings, the medilogDARWIN2 can upload and view Holter ECG recordings and SpO_2 recordings. Details of the program are given in the medilogDARWIN2 user guide (see Documentation, page 64).

2.3 Inserting/Changing the Batteries

- ▲ Use **NiMH rechargeable batteries** supplied or recommended by SCHILLER. Full capacity of new NIMH batteries are only reached after three charge/discharge cycles.
- ▲ **Eneloop Pro** NiMH rechargeable batteries (Panasonic 2450 mA) or **Energizer Ultimate Lithium** batteries (ENERGIZER L91-FR6) can also be used.
- ▲ **Do not mix batteries**. Only use two batteries of the same type.
- ▲ **Do not use any other type of battery.** The capacity of other battery types may not be sufficient for a 24-hour recording and the battery capacity symbol may be incorrect.

1. Open the battery compartment by pressing and sliding the battery cover away from the recorder.
2. Use the battery removal ribbon to remove the two batteries.
3. Insert two fully charged batteries.
   – Ensure that the battery removal ribbon is positioned under the batteries so that the batteries can be removed from the recorder when depleted.
   – Ensure that the batteries are inserted with the correct polarity as shown.



Battery compartment cover. Position in grooves and slide until clicked secure.

4. Position the battery cover in the cover slides and slide back in place until it clicks to secure.

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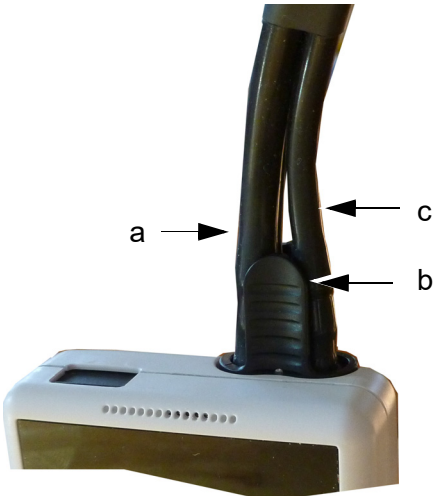
- The battery capacity indicator is detailed in the operating section (see Battery Status for NiMH Rechargeable Batteries, page 20).
- Battery charging details, disposal, and safety relevant precautions are detailed in the maintenance section (see Battery Maintenance, page 53).
- Battery and battery charger part numbers are detailed at the end of this book (see Accessories, page 64).

2.4 Connecting the Pressure Hose and Microphone

The hose / microphone assembly can only be inserted in one direction. Take care when positioning the assembly not to damage any connectors. Do not pull directly on the hose or microphone cable.



Position the pressure hose connector **(a)** and attach to the BR-102 plus / BR-102 plus PWA by gently pressing until the connector clicks in place. If the version is with a microphone **(c)**, the plug is combined with the hose and the assembly is inserted into BR-102 plus / BR-102 plus PWA at the same time.

Removing the Pressure Hose

Gently press the securing catch **(b)** to release and remove the hose connector (and microphone jack plug) from the BR-102 plus / BR-102 plus PWA.

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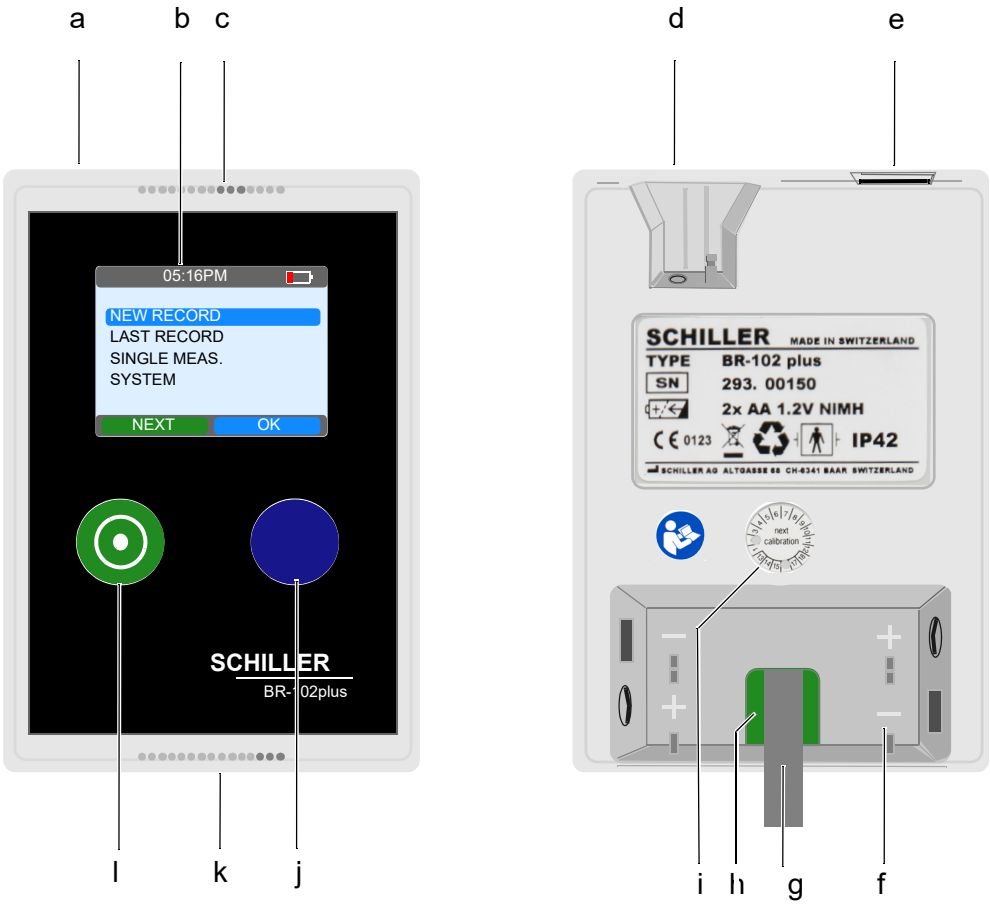
2.5 Main Components of the Device



(a) USB cable connection
(b) OLED display
(c) Loudspeaker
(d) Microphone connector jack plug and patient cuff connection recess
(e) USB connector
(f) Battery recess (battery cover removed)
(g) Battery removal ribbon
(h) Micro SD card recess (under battery removal ribbon)

The micro SD memory card is for service only and is used for software updates or storage of raw data for test purposes.

(i) Calibration label
(j) Programming function key
(k) Microphone for recording patient identification
(l) Programming function key and ON/OFF key

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2.5.1 Operating and Display Elements

Menu option selection and control of the BR-102 plus / BR-102 plus PWA is with two function keys. The **green and blue function information boxes** at the bottom of the screen indicate the function that will be carried out when the **green and blue function keys** are pressed:

Left Green Key Functions:

ON/OFF: (Switch-Off from main menu only)

Next: (next menu item)

No: (do not confirm selection)

Meas: initiate a measurement (during the recording)

Holding the key stops the recording

Break: Halts an ongoing measurement

Stop: Stops a recording in progress

Back: Back to last menu

Right Blue Key Functions:

OK: (confirm menu selection)

Change: (toggle through options)

Yes: (confirm selection)

Meas: initiate a measurement (during the recording)

Start: Starts the acoustic record of the patient ID

Stop: Stops a recording in progress

2.5.2 Switching on

Press the green ON/OFF key. The display shows an introduction screen and copyright message for a few seconds and then the main menu is displayed. If an unformatted micro SD card is installed, you are prompted to format the card when the recorder is switched on, and again when a recording is started.

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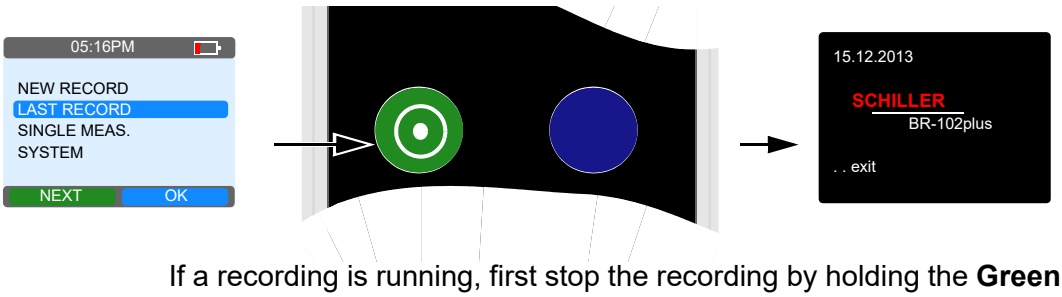
2.5.3 Switching Off

With the **main menu displayed** and the cursor at any position**,** press and hold the **Green control button for 4 seconds**. When the button is released, the device is switched off.



If a recording is running, first stop the recording by holding the **Green control button for 4 seconds** and confirming that the recording will be stopped (see Stopping the Recording, page 39). Then enter the main menu and switch off as described above. Any recorded data is saved when the recorder is switched off.

When no recording is running, the recorder switches off automatically after 5 minutes if no keys are pressed.

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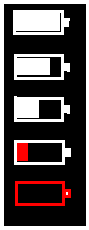
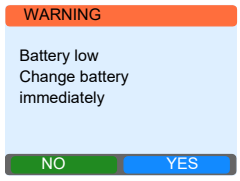
2.5.4 Battery Status for NiMH Rechargeable Batteries

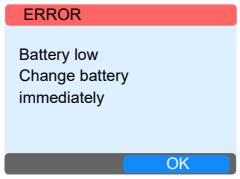
The battery status display is a guide to battery capacity when using **NiMH rechargeable batteries** supplied or recommended by SCHILLER. If **Energizer Ultimate Lithium Batteries** are used, a different battery symbol is displayed (see next page).



Full
80%
Half full
Low capacity (20%)
Empty

The battery symbol in the upper right of the screen, indicates the battery status. When the battery is full, the symbol is filled and gives an indication of current battery capacity as it reduces during the recording. The empty symbol indicates that the capacity is limited and that the batteries should be changed. If the batteries are not changed during this period, a warning message is given that the batteries must be changed. If the batteries are still not changed an error message is displayed before the recorder switches off (see next page).





- An audible and visual indication is given during recording when battery capacity is limited. When the indication is given and the recording is to be continued, we recommend that the batteries are replaced at the first opportunity.
- When recording is stopped because of low battery capacity, and the batteries are replaced within 5 hours of the recorder switching off, the recording will continue (see Changing the Batteries During a 48 Hr Recording, page 38)

Battery Condition

Batteries deteriorate over time and must be replaced. An indication of battery condition is given when batteries are first placed in the recorder after a full charge, as follows:

Battery Indicator	Battery Recording Capacity
Full (100%)	24-hour recording is possible.
80%	24-hour recording should be possible.
Half full (50%)	Single measurements only will be possible. The batteries should be replaced.
Low capacity or empty	A 24-hour recording is not possible. Replace batteries.

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2.5.5 Battery Display for Energizer Ultimate Lithium Battery

If **Energizer Ultimate Lithium** batteries are used, the battery status display is shown blue and always ‘full’. This is because the voltage hysteresis curve for these types of battery is not linear and the device cannot accurately determine battery capacity. When battery capacity is very limited the change battery messages (shown above) are still displayed but the time interval between the messages is reduced.

2.5.6 Time Display

The current time is displayed in the top line of the display. The format of the time display can be set to 24 hour or 12 hour display (am/pm displayed) - this setting is defined in System setup (see DATE /TIME, page 25).

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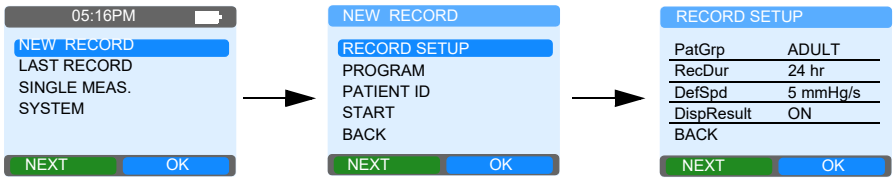
2.6 Menu Structure

The menus are selected with the green function key (**Next)**. A selected menu is opened with the blue function key (**OK**) and values selected with the blue function key (**Change**). Depending on the selected menu, the button functions will change.



The position in the menu is indicated on the top line as shown in the example above for new record. Select the item with the green button and confirm with the blue key.

i In all displays, the top line is colour coded to give an indication of the type of message that is displayed as follows:

05:16PM	Grey: Main Menu
RECORD SETUP	Light Blue: Information or setup screen.
ERROR	Red: Error message (for example, battery capacity limited, no data available when requested, etc.).
WARNING	Orange: Warning message or question (for example, battery capacity critical, Format SD card).
CONFIRMATION	Green: Confirmation message (for example, SD card formatted successfully).

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2.6.1 Menu Overview

Main Menu	Sub Menu 1	Value/Info	Sub Menu 2	Value/Info	Sub Menu 3	Value/Info
NEW RECORD	RECORD SETUP	Defines the recording parameters	Patient Group	Adult / Child - Maximum initial pressure for adult is 300mmHg and for a child 210mmHg.		
			Record Duration	24/48 Hours		
			Deflation speed	2, 3, 4, 5, 6, 7, 8, 9 mmHg/s or Auto (3mmHg / heart beat).		
			Display Result	ON / OFF. Displays the cuff pressure during a measurement and displays the result on the screen after a measurement has been taken. When Off is selected measurements are not displayed during, nor after a measurement. Note: When Off is selected, the first two measurements taken are always displayed to enable checking. The recommended setting is Off to prevent patient concern during the recording.	
	PROGRAM	Defines the program parameters	Select program A, B, C, D	Select one of four individual recording programs A, B, C, D. The programs are defined in **Program Setup** below.		
			PROGRAM SETUP	A, B, C, D - Four individual BP measurement programs (A, B, C and D) can be defined. Each individual program has up to 8 cycles with separate start time BP measurement interval for each cycle.	Change / Next 1. Define the start time by pressing **change.** The time counts up in 10 minute intervals. 2. When the desired start time is shown press **next**. The measurement interval is highlighted. 3. Press **change** to select a BP measurement interval of: 5, 10, 15, 20, 30, 60, or 120 minutes. 4. Press **next** to define the next start time. 5. Continue until all desired start times (with measurement interval) are defined for the selected program. When less than 8 cycles are required pressing next twice returns to the previous menu.
	PATIENT ID		Record Voice		Start	Start Voice Recording.
					Stop	Stop Voice Recording.

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Main Menu	Sub Menu 1	Value/Info	Sub Menu 2	Value/Info	Sub Menu 3	Value/Info
			Play Voice	Plays recorded patient identification.	Stop	Stop Playing Voice.
	START		Do you want to start a BP Recording?	Yes / No - Confirm Recording start. Confirmation of recording start is given, followed by REC: BP recording and the time of the next measurement (this is displayed for approximately 5 seconds).	BP recording . Next Meas. .. 09.15	Press either of the two function keys for approximately a second to take an extra measurement during the recording. Press either of the two function keys when a measurement is being taken to interrupt a measurement being taken during the recording.
	BACK	Return to main menu.				
LAST RECORD	RECORD DATA	Date and time, patient group, record duration, deflation speed, number of measurements.	OK	Press OK again to return to the previous menu.		
	PATIENT DATA	Play voice ID. Note: If started from a PC the patient data is also displayed.	Stop	Stops voice		
	MEASUREMENTS	Displays results of stored recording.	Back / Next	Press back / next to go back to last record, forward to next record. Press and hold the back / next for approximately 2 seconds to return to the last record menu.		
	BACK	Return to main menu.				
SINGLE MEASUREMENT	PATIENT GROUP	Adult / Child - Maximum initial pressure for adult is 300mmHg and for a child 210mmHg.				
	DEFLATION SPEED	2, 3, 4, 5, 6, 7, 8, 9 mmHg/s or Auto (3mmHg / heart beat).				
	PULSE BEEP	Audible beep with detected heart rate.	On / Off			

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Main Menu	Sub Menu 1	Value/Info	Sub Menu 2	Value/Info	Sub Menu 3	Value/Info
	START	Measurement starts and value displayed.	OK Measurement is displayed (or an error message is given). Press OK again to return to the previous menu. BREAK Interrupt measurement: Press the break button when a measurement is being taken to interrupt the measurement.			
SYSTEM	SETTINGS		Language	ENG, DEU, FRA, ITA, SPA, POR, SWE, RUS.		
	DATE / TIME		Date Format	• DD.MM.YYYY • MM/DD/YYYY • yyyymmmdd • ddmmmyyyy • YYYY-MM-DD • YYYYMMDD	Set date	Set current date in the format defined.
			Time Format	12, 24 hour	Set time	Set current time in the format defined.
	SYSTEM INFO	Serial number, Hardware and pneumatic index, software version, control (date that the next test (MTK) is due), SD card capacity (if inserted)				
	SERVICE AREA	Service information and check screens	Test Calibration	In this menu option the BP measurement can be checked against a calibrated manometer (see Measurement Check, page 54).		
			Hardware Setup	This is an information screen for Factory use only and requires a password to enter.		
			LOG-BOOK	This details the number of measurements made and the number or errors registered.		
	BACK	Return to main menu.				

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3 BP recording

3.1 Safety

⚠WARNING

- ▲ Danger of unnoticed necrosis especially in patients with decreased pain sensitivity (due to medication), or with older patients with decreased blood circulation of the extremities. Only carry out long-term measurement with these patients under constant medical supervision.
- ▲ Possibility of strangulation especially in young or older patients, patients with reduced mobility, or patients susceptible to drowsiness due to drugs, etc. The danger increases at night. Only carry out long-term measurement with these patients under constant medical supervision.
- ▲ In some patients petechiae, haemorrhages or subcutaneous haematomas may occur. All patients must be told when putting on the cuff that if they experience pain during the recording they should switch off the equipment and inform the doctor.
- ▲ The cuff must not be attached to a limb that is already used for interventions such as:
  - infusions
  - SpO_2 measurement (loss of data can occur during cuff inflation)
  - if an arterio-venous shunt is present.
- ▲ When a five minute measurement interval is defined for recordings of 24h duration or more, bruising or decreased blood circulation can occur in the arm. Only carry out recordings with 5 minute measurement intervals under constant medical supervision.
- ▲ It must be certain that, according to the health of the patient, the use of the device will not damage blood circulation in the arm.

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⚠ CAUTION

- ▲ To prevent excessive pressure, it is important to choose the correct cuff size and to check that the correct setting is used in the menu setup (**Record Setup > Patient Group > Adult / Child**).
- ▲ The cuff must not be placed over or near a wound that could cause further injury.
- ▲ As with occasional blood pressure measurement, petechial bleeding can occur in patients with coagulation disorders or having anticoagulant treatment even with the correct cuff size.
- ▲ In patients who have had a single mastectomy, the cuff can be placed on the opposite arm.
- ▲ When the patient is monitored by an ME unit, loss of data can occur from the arm during cuff inflation at the ME equipment.
- ▲ During long term recording, the area where the cuff is attached must be checked regularly for signs of ischaemia, purpuras and/or neuropathy.
- ▲ To prevent incorrect measurement results, ensure that the tube is not pinched or compressed.
- ▲ A cuff that is applied to a patient in the recumbent or sitting position is normally located at the same level as the heart. However, if the cuff is located at a level higher than the heart (for instance if the arm of a patient in bed is lifted), this may result in lower-than-actual measurement readings (approx. 7.5 mmHg per 10 cm rise).
- ▲ The unit is safe during defibrillation. However, as a safety precaution, when possible remove the cuff and microphone before defibrillation and, if connected remove the USB connector from the recorder and the PC.
- ▲ Do not touch the unit casing during defibrillation.
- ▲ If the unit gets wet accidentally, switch off and dry with a cloth.
- ▲ If the unit is accidentally immersed in liquid, remove the batteries and return to SCHILLER for checking.

i A list of BR-102 plus error messages is given in the Maintenance section (see Error Messages, page 57).

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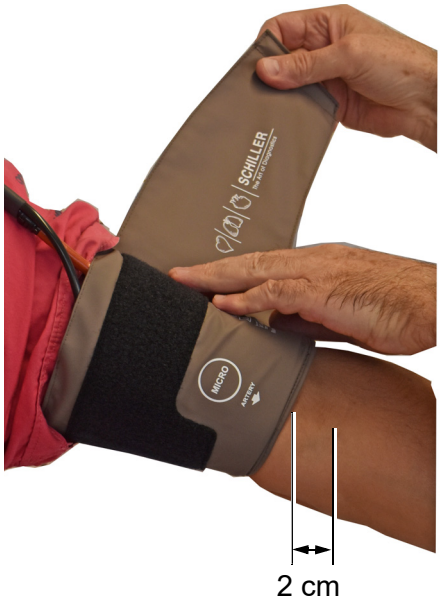
3.2 Applying the Cuff

The BR-102 plus is supplied with one of two cuff types. Both are applied in the same way. The D-ring cuff instructions detailed here give general guidelines and apply to both types of cuff.

3.2.1 Cuff Type with D-ring

1. Instruct the patient to remove upper clothing.
2. Select the appropriate cuff size according to the patient's upper arm. Different cuff sizes are available dependent of type of cuff:

To fit arm size Midpoint Arm Circumference [cm]	Cuff Designation
14 - 20	XS (Child, Osc only)
18 - 24	S (Small Adult, Child)
25 - 35	M (Adult)
30 - 36	L (Large Adult)
35 - 46	XL (Extra Large, Wide, Adult)
Note: A cuff that is too small for the patient may give over measurements. Similarly, a cuff that is too large for the patient may give under measurements.	



3. Uncover the **left** upper arm of the patient. (The cuff is designed to fit the left upper arm, but can be placed on the right arm if required.)
4. Locate the brachial artery above the elbow bend inside the upper arm.
5. Position the microphone (marked **Micro**) over the brachial artery and secure cuff.
   - Wrap the cuff around the upper arm in such a way that the patient can still bend arm (the bottom edge of the cuff should be 2 cm away from the elbow bend).
   - Tighten the cuff and secure with the velcro strip. The cuff must be tightened to such an extent that it fits properly on the upper arm and is prevented from moving.
   - To avoid a venous congestion don't tighten the cuff too firmly.
   - The pressure hose and microphone cable must point to the patient's shoulder.
6. Place the pressure hose so that it is loosely positioned behind the patients neck.
7. Connect the pressure hose and microphone cable (if not already connected) to the recorder (see Connecting the Pressure Hose and Microphone, page 16).

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8. Secure BR-102 plus / BR-102 plus PWA to the right or left side of the patient for preference using the holding pouch and belt
   – Ensure that there is enough slack not to strain the hose when the patient moves. Ensure that the patient is comfortable.
   – Tape can be used to secure the tubing to the body if required.
9. When the cuff and device are comfortably positioned, the patient can replace upper clothing.

- The oscillometric version does not contain a microphone however, the cuff is placed in the same manner.
- It is recommended that the patient wears a t-shirt over the tubing to help hold the tubing in place. This can be covered with for example, a loose fitting shirt.

⚠ CAUTION

▲ To help keep the hose in position and prevent strangulation, the T-shirt and/or outer clothing must remain on at night or be replaced by the patient`s normal night wear over the hose.

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3.2.2 Cuff Type without D-ring

The cuff is positioned, and the hose routing and unit positioning is the same as for the cuff with the buckle.

3.2.3 Patient Comfort Sleeve

If the Patient comfort sleeve is to be used, the sleeve can be positioned on the patients arm and then the cuff applied. Alternatively attach the sleeve to the cuff with the velcro strip before applying to the patient and then apply the cuff and sleeve together to the patient.

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3.2.4 Fixing the Microphone Directly on the Upper Arm

If the patient‘s pulse is weak the microphone may be removed from the cuff and placed directly on the upper arm to obtain more secure measurements. A shaped adhesive pad is a standard accessory for this purpose. To place the microphone directly on the arm proceed as follows:

1. Carefully pull the microphone out of the cuff - Do not strain (see Disconnecting the Pressure Hose and Removing the Microphone and Bladder, page 47).
2. Remove the foam rubber microphone insert from the adhesive pad and place the microphone in the pad (metallic (patient) side outwards), and press to secure with the adhesive.
3. Using an alcohol solution (standard surgical strength) thoroughly clean the patient‘s arm around the brachial artery area.
4. Wrap the cuff around the uncovered upper arm in such a way that the brachial artery is freely accessible. The pressure hose and microphone cable face towards the patient's shoulder.
5. Locate the brachial artery, remove the plastic adhesive protector and fix the microphone to the patient by applying gentle pressure so that the adhesive holds the microphone.
6. Shift the cuff towards the elbow so that the patient can still bend his lower arm (the bottom edge of the cuff should be 2 cm away from the elbow bend). Outside the cuff, the microphone cable forms a small loop. Fix with adhesive strips if necessary.
7. Tighten the cuff and close it with the fixation wrap as previously described.

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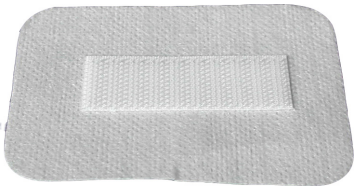
3.2.5 Securing the Cuff with the Fixation Pad



A velcro cuff fixing pad is a standard accessory that‘s available to help secure the cuff from dislodging during long term measurement.

Attach the cuff to the patients upper arm as follows:

1. Using an alcohol solution (standard surgical strength) thoroughly clean the patient‘s upper arm in the area where the pad will be attached.
2. Remove the plastic adhesive protector of the velcro securing pad.
3. Place the pad on the patient‘s upper arm and apply gentle pressure to secure (the exact location will depend on the size of the patients arm and the size of the cuff used).
4. Position the cuff so that the velcro securing flap on the cuff matches with the securing pad on the patient‘s arm, and secure..

i The velcro plaster (set of 10), and the adhesive plaster for the microphone (set of 10), are available from your local agent.

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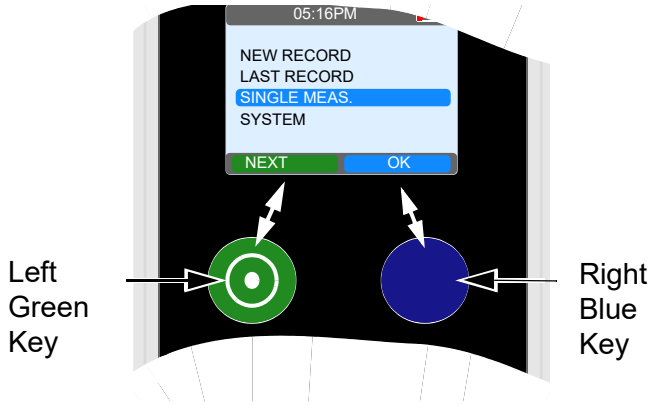
3.3 Single Measurement

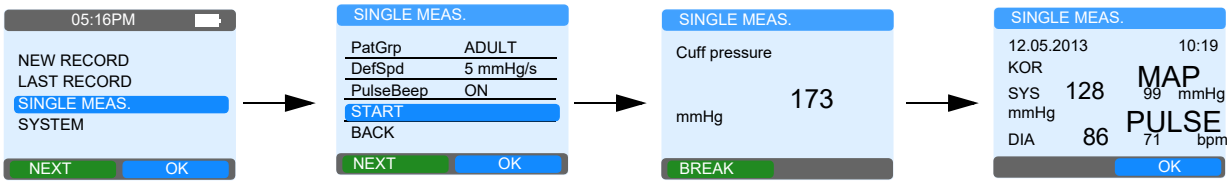
1. Apply the cuff as previously described.
2. Select **Single measurement** from the main menu:



3. Using the buttons on the recorder, select:
   – Patient Group - **Adult / child**
   – Deflation Speed - **2 to 9 mmHg** in 1 mmHg steps, or **Auto.**
   – **Pulse beep** - on or off. The recorder gives an audible beep with the detected heart rate.

i When **auto** setting is defined, the deflation rate is set for the detected heart rate at 3 mmHg per heart beat. The heart rate is ascertained when the cuff is inflating.

4. Select **START**



5. The cuff pressure is displayed when the measurement is being taken.
6. On completion the single measurement is displayed with the following information:
   • Date and time of the measurement
   • Recording method used:
     – KOR = Auscultatoric (Korotkoff/Riva-Rocci)
     – OSC = Oscillometric
   • Measurement:
     – SYS = Systolic Pressure [mmHg]
     – DIA = Diastolic Pressure [mmHg]
     – MAP =Mean Arterial Pressure (MAP) in mmHg.
     – Pulse = Pulse rate [bpm] (beats per minute)

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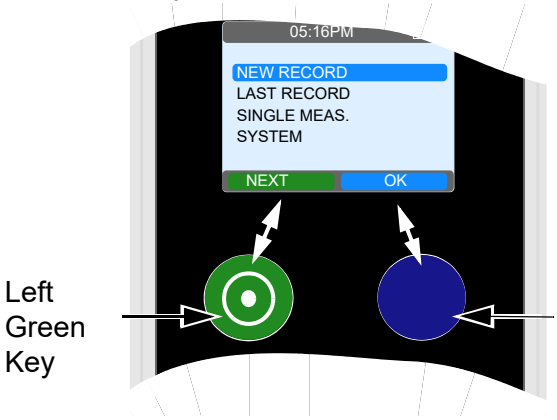
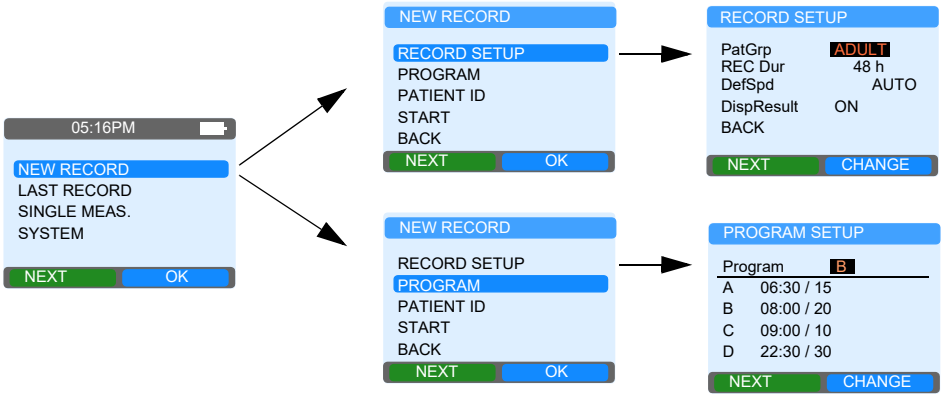
3.4 Long Term Recording

A long term recording can also be started and the recording times defined from the medilogDARWIN2 program. See the user guide for details.

Use the function keys on the recorder to select all settings



Settings are made for patient group (adult or child), recording duration, and deflation speed. In addition four recording time and measurement interval programs are defined (A, B, C and D). Each program has up to eight start times when measurement intervals can be defined.



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3.4.1 RECORD SETUP

Select **Record Setup** to define the following settings:

- Patient group: **adult or child**
- Duration: **24 hours or 48 hours**
- Deflation speed: **2, 3, 4, 5, 6, 7, 8, 9 mmHg/s**, or **Auto**. The **Auto** setting sets the deflation speed according the heart rate.

3.4.2 Program

Selecting a Program

Enter program setup and select **Change** to select the program (A, B, C or D). The recording program defined is used when a long term record is started.

Defining the Recording Programs

Enter the program setup start times, sleep times and duration for the four programs.

Highlight the recording program to be set and set the start time and measurement duration for each entry. Up to 8 separate start times can be defined with the BP measurement interval defined for each start time.

1. Define the start time by pressing **change.** The time counts up in 10 minute intervals.
2. When the desired start time is shown press **next**. The measurement interval is highlighted.
3. Press **change** to select a BP measurement interval of: 5, 10, 15, 20, 30, 60, or 120 minutes.
4. Press **next** to define the next start time.
5. Continue until all desired start times (with measurement interval) are defined for the selected program.

When less than 8 starts are required pressing next twice returns to the previous menu. A minimum of 2 start times must be defined.

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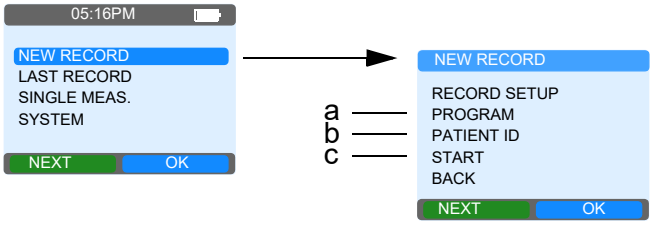
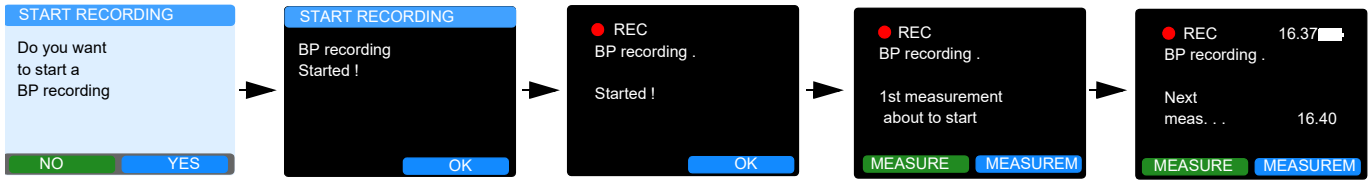
3.4.3 Starting a Recording

1. Position the cuff on the patient (see Applying the Cuff, page 28).
2. Insert fully charged batteries in the BR-102 plus / BR-102 plus PWA (see Inserting/Changing the Batteries, page 15).
3. Check that the correct time (and date) is displayed. These can be changed in **System Setup**.
4. Select **NEW RECORD**.



5. Select **Program (a)** - check/set recording and program setup (see previous page).
6. Select **Patient ID (b)** to record or listen to the audible Patient ID.
   - The audible patient ID can be played back at the end of the recording and registered when the recording is uploaded to the DARWIN2 program.
   - Select **Start Recording** and speak the patient data into the device.
   - Speak clearly into the microphone. Hold the unit approximately 15 - 20 cm distant. To ensure recording clarity, do not hold the unit too far away.
   - Select **Stop Recording** when the Patient ID has been stated.
   - The recording time allowed for Patient ID is up to 30 seconds.
7. Select **Start (c)** to start the recording. You are prompted to confirm.



8. After confirming the recording screen is displayed. The initial measurement will be taken within a minute.

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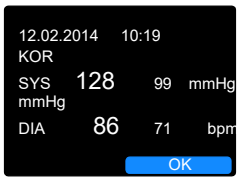
9. Check that the initial measurement is successful.

Initial Measurement Check

After the first measurement (on the resting patient), it is recommended that the following is checked to help ensure that the recording is successful:



- Ensure that a BP reading has been obtained and is displayed on the BR-102 plus / BR-102 plus PWA.
- Check that the measurement has been taken using the auscultatory method (**KOR** displayed next to the measurement, below the time). Note: If the cuff does not have a microphone (or an unsuccessful auscultatory measurement has been taken) **OSC** is displayed.
- If the measurement has not been taken correctly check the cuff placement and microphone position.
- Check the battery display and ensure that it still shows full capacity.

10. After checking the first measurement and battery display, position the BR-102 plus / BR-102 plus PWA in the pouch and secure.

  – Subsequent measurements are taken as defined for the program selected.
  – During BP measurement, the ascending/descending cuff pressure is shown. After a measurement has been taken, the result is displayed for approximately one minute (see Displaying a Recording on the BR-102 plus, page 39).

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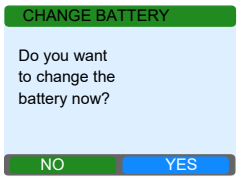
3.4.4 Changing the Batteries During a 48 Hr Recording

An interrupted recording during battery change (unit is switched off), is automatically continued when battery replacement occurs within 5 hours and the unit is switched on again.

For a 48 hour recording the batteries must be changed. An audible alarm and visual indication is given when the batteries must be changed.

Preventive changing the batteries after 24 hours

1. Press the blue button for 4 seconds. Confirm message **"Change battery"** again with the blue button.

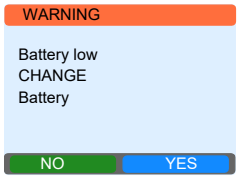


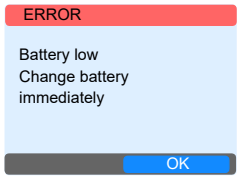
2. Remove the batteries and replace with the fully charged batteries supplied. Observe correct polarity.
3. Press the green button to switch the unit on. The following message is displayed:

BP recording . Next measurement. . xx:xx

Changing batteries when following audible and messages are displayed:

The batteries must be changed when an audible indication is given and the message **Battery LOW - change battery** is displayed.





Proceed as follows:

1. Confirm **"Change battery"** with the blue button.
2. Remove the batteries and replace with the fully charged batteries supplied. Observe correct polarity (see Inserting/Changing the Batteries, page 15).
3. Press the green button to switch the unit on. The following message is displayed:

BP recording . Next measurement. . xx:xx

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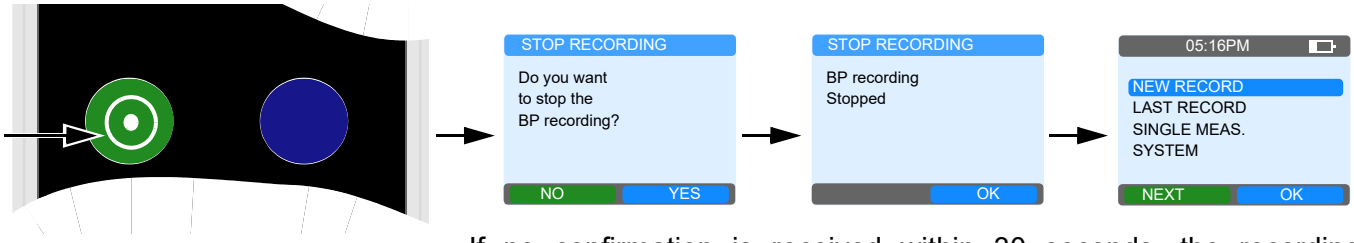
3.4.5 Stopping the Recording

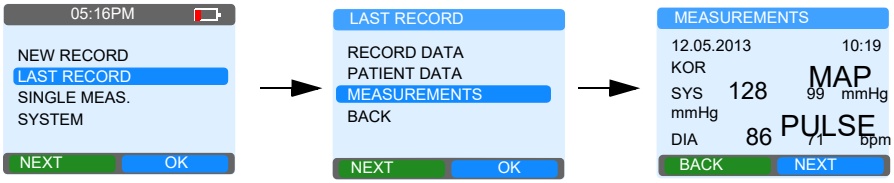
The recording will stop automatically after 24 or 48 hours and no user intervention is required. The recorder can however, be stopped manually if required. Do this as follows:

Press and hold left green **Function key** for 4 seconds and confirm with **YES - blue right Function key**.



If no confirmation is received within 30 seconds, the recording continues.

3.4.6 Displaying a Recording on the BR-102 plus



1. Select **Last Record** from the main menu.
2. Select **Measurements** to display all measurements.
3. The measurements are displayed giving:
   - Date and time.
   - Measurement method:
     KOR = Auscultatoric (Korotkoff/Riva-Rocci)
     OSC = Oscillometric
   - Systolic Pressure in mmHg.
   - Diastolic Pressure in mmHg.
   - Mean Arterial Pressure (MAP) in mmHg.
   - Pulse rate (PULS) in beats / minute (bpm).
4. **Next** continues to the following measurement and **Back** returns to the previous measurement.
5. To return to the main menu press **Back** for approximately 4 seconds. The recorder also returns to the menu automatically when no key is pressed for approximately one minute.

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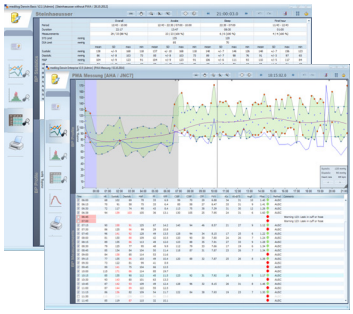
3.4.7 Uploading the Recording to the medilogDARWIN2

The recording can be reviewed, analysed and a report created with the medilogDARWIN2 program.

Connect BR-102 plus / BR-102 plus PWA to PC.



Use medilogDARWIN2 to retrieve data, analyse and edit.

Print report or save as PDF file.

Details of uploading a BP recording to the medilogDARWIN2 program is described in the medilogDARWIN2 user guide.

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4 Patient Information

WARNING

- ▲ Danger of strangulation. The shoulder strap or cuff tube can become entangled around the patient's neck and lead to strangulation. The danger increases at night. Ensure the patient is aware of the danger. The doctor should 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 strap nor the air tube ever become wrapped around the neck. The air tube must be positioned under a T -shirt or outer clothing that must continue to be worn at night over the tubing to help keep it secure.
- ▲ Tell the patient that if any numbness in the arm, chafing, pain or discomfort is experienced, the cuff must be removed and to contact the surgery.

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- ▲ Tell the patient not to get the unit wet - the unit is not waterproof and must remain dry. If the patient is permitted to take a bath or shower during the recording (e.g. when taking a 48 hour recording) it must be emphasised that the recorder and the cuff must be removed before taking a bath or shower. Instruction should be given on re-applying the cuff and attaching the device.

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4.1 General

Inform the patient about the use of the BR-102 plus / BR-102 plus PWA and instruct the patient on the following points:

- Explain to the patient how to place the cuff correctly and the times and intervals that measurements will be taken.
- The equipment must not be used in the vicinity of an MRI scanner.
- The performance of the BR-102 plus / BR-102 plus PWA can be affected by extremes of temperature, humidity and altitude.
- If taking a 48 hour recording, inform the patient how to change the batteries. Instruct the patient to keep replacement batteries in the bag or box provided and not to dispose of the old batteries. Spent batteries must returned in the bag or container provided.
- Tell the patient that during the measurement:
  - Noisy places should be avoided.
  - Not to move the arm during the measurements and a recommendation that where possible, the patient relaxes during the measurement process and does not speak.
  - Entries must be made in the patient diary during the long-term measurement.
- The pressure tube and cuff must not be knotted or stretched or subject to compression or restriction. The air tube may kink when inflated. It should be explained that particularly when sleeping, the equipment should be positioned in such a way that the tube cannot be compressed. If the patient is not fully competent, the equipment should be worn only under supervision.
- After an invalid measurement a second measurement will be initiated immediately.
- The recorder should not be turned off during the recording.

4.2 Taking an Extra Measurement

To take an extra BP measurement during the recording, press either of the **control buttons to display the recording screen.** Then with the recording screen displayed, press either of the control buttons again for approximately one second to start a measurement. Record the measurement in the patient diary.

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4.3 Interrupting a measurement during the recording

To interrupt a measurement, press either of the **control buttons** during the measurement. This will deflate the cuff. An interrupted measurement will be recorded with an error and will not be repeated. The next measurement will take place according to the schedule.

Every extra measurement or interrupted measurement should be entered in the patient diary together with the time, reason, activities being undertaken at the time of occurrence, and the symptoms.

The template for the patient diary is stored on the software CD as a Word file and as a pdf file. An example is given at the end of the book.

4.4 Extended 48-Hour Recording

The patient must be instructed how to change the batteries for an extended recording (see Changing the Batteries During a 48 Hr Recording, page 38).

It is recommended that the patient receives two fully charged batteries that can be used for replacement. These must be placed in a small box or plastic bag to help prevent a short circuit of the battery. The patient should return the spent batteries in the same container.

If the patient is old or in any way confused, consider asking the patient to return to the surgery for battery replacement.

4.5 BR-102 plus PWA Unit Measurements

The BP measure interval, cuff application, and the start and stop procedure are identical to the standard unit. However, after every individual measurement, the cuff is again inflated to the diastolic pressure and held at that pressure for 10 seconds while PWA data is obtained. After 10 seconds the cuff is again deflated and ready for the next programmed measurement.

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5 Cleaning

5.1 Important Information

⚠ CAUTION

- Some patients have intolerances (e.g. allergies) to disinfectants or their components. If you have such a patient or you are not sure, remove possible residues with careful washing.

- Do not autoclave the unit or any accessories.
- Do not immerse the device in liquid. If liquid does penetrate the unit, switch it off immediately and send it to SCHILLER for testing.
- **Never** use a wet or dripping cloth and **never** spray the equipment with detergent. Otherwise, the detergent may seep under the edges of the keyboard or penetrate the device and destroy the electronics.
- Use of cleaning solutions which have a high acid content or are otherwise inappropriate can cause damage to the equipment, including cracking and deterioration of the plastic case.
- Always follow the mixing/diluting instructions provided by the manufacturer of the cleaning solution.
- The pressure tube and microphone cable must not be exposed to excessive mechanical stress. Whenever disconnecting, hold the plug/connector and not the cable.
- When cleaning, ensure that all labels and safety statements, whether etched, printed or stuck to the unit, remain in place and remain readable.

5.1.1 Non-admissible detergents

Never use products containing the following:

- Ethyl alcohol
- Acetone
- Hexane
- Abrasive cleaning powder
- Plastic-dissolving products

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5.1.2 Admissible detergents

- 50% solution isopropyl alcohol
- neutral, mild detergent
- all products designed for cleaning plastic.

5.1.3 Cleaning the Device

Before cleaning the unit or any accessories, thoroughly inspect them. Look for any signs of damage and any improper mechanical function of buttons or connectors.

The casing of the BR-102 plus / BR-102 plus PWA and the cable assemblies can be cleaned with a cloth slightly moistened (not wet) on the surface only. Where necessary a domestic non-caustic cleaner or 70% alcohol solution can be used for grease and finger marks. Wipe the equipment with a cloth **slightly moistened** (**not wet**) with one of the approved solutions listed above. Wipe off any excess cleaning solution. Do not let the cleaning solution run into or accumulate in connector openings, latches, or crevices. If liquid gets into connectors, dry the area with warm air, and then check the equipment to confirm that it operates properly.

5.1.4 Cleaning the Pressure Hose/Microphone Cable Assembly

1. Before cleaning, inspect the hose/cable for damage. Gently bend and flex all parts of the assembly. Inspect for splits in the sheathing, damage or extreme wear, exposed wires, or bent connectors.
2. Wipe the equipment with a cloth **slightly moistened** (**not wet**) with one of the approved solutions listed above. Gently grip the cable with the damp cloth in the centre of the cable and slide the cable through the cloth 20 cm at a time until clean.

⚠ CAUTION

– Do not clean the whole length in one single action as this may cause bunching of the sheathing.
– Wipe off any excess cleaning solution. Do not let the cleaning solution run into or accumulate in connector openings, latches, or crevices. If liquid gets into connectors, dry the area with warm air

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5.2 Cleaning the Cuff and Pouch

5.2.1 Cleaning the Cuff

- Do not use bleach
- Do not iron
- Do not tumble dry
- Do not spin dry

- Observe the following when washing:
  - Program setting of 40°C (104°F)
  - Select gentle or delicate cycle.
  - Use a mild washing powder. Do not use biological powder be-cause of possible allergic reactions.
  - Do not use fabric softeners, textile deodorants or any other addi-tives - these solutions may leave residues and damage the mate-rial.
- Leave cuff to dry naturally.

The cuff must be washed or disinfected after every long-term measurement using any of the following methods:

In a Standard Washing Machine

- Prepare Cuff (see next page).
- Fold the cuff and secure the cuff with the velcro strip.
- Place the cuff in a cleaning bag.

Dry Clean

- Prepare the cuff in the same way as for washing.

Disinfection

- Disinfect by gently wiping the cuff with an approved hospital grade disinfectant (see Sterilisation, page 51).

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5.2.2 Cuff Preparation

Two types of cuff are available: Cuff type with a D-ring and cuff type without a D-ring. Both are available in various sizes. The cuff preparation procedure for cleaning is the same for both type and all sizes.

Disconnecting the Pressure Hose and Removing the Microphone and Bladder

Before cleaning, the microphone and the bladder must be removed from the cuff and the pressure hose disconnected.

1. Disconnect the pressure hose from the cuff inflation bladder connector by twisting the connector a quarter turn.
2. Gently remove the microphone from the microphone pouch by pushing on the outside of the cuff to move the microphone along the pouch channel until it can be removed from the cuff.

⚠ CAUTION

▲ Do not pull on the microphone lead when removing the microphone as this can cause damage to the connections.

3. Remove the bladder from the cuff.
4. Fold the cuff and secure the cuff with the velcro strip.
5. Place the cuff in a cleaning bag and wash.

Re-inserting the Microphone and the Bladder and Connecting the Pressure Hose

1. Gently slide the microphone in the microphone pouch and push fully home from the outside of the cuff. Ensure the microphone is fully home and occupies the area indicated by the micro designation printed on the cuff.
   – The metallic (yellow) side of the microphone must be facing upwards when inserting in the cuff (the metallic side faces the patient).
   – Ensure that the microphone is correctly inserted in the cuff. It must fully reach the bottom of the pouch.
2. Replace the bladder in the cuff - ensure that the bladder is flat and not twisted in the cuff.
3. Connect and secure the pressure hose to the cuff bladder connector with a quarter turn.

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Bladder hose and connector

Gently push the microphone out of the cuff and disconnect the pressure hose from the bladder (connector quarter twist).

Remove the bladder from the cuff.

After washing re-insert the bladder in the cuff.

Push the microphone until home in the micro pouch.

Reconnect the pressure hose to the cuff bladder.

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5.2.3 Cleaning the Pouch (as well as the Shoulder and Waist strap)

Clean the pouch with a damp cotton cloth (do not use corrosive liquids or solvents) or can be washed in a washing machine at 30°C using a mild washing powder (do not spin). Do not use fabric softeners or other aids (e.g. disinfectant rinses). These solutions may leave residues and damage the material. The Pouch is not suitable for drying in a tumble dryer.

- Do not use bleach
- Do not iron
- Do not tumble dry.
- Do not expose neoprene pouch to direct sun light

Wash the pouch at a temperature of 30° C with a normal washing powder. Select gentle or delicate cycle. Leave cuff to dry naturally.

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5.2.4 Disinfection

The user (doctor) decides, whether and when disinfection of the cuff sleeve is necessary for reasons of hygiene. Use commercially available disinfectants intended for clinics, hospitals and practices to disinfect the device. Disinfect the unit in the same way as described for cleaning (see Cleaning the Device, page 45). For cleaning and disinfecting the cuff, wipe with a damp cloth. SCHILLER has tested and recommends the following solutions:

- Terralin Liquid (manufacturer: Schuelke & Mayr)
- Promanum N (manufacturer: B. Braun)

Additionally, the cuff can be disinfected with the following:

- Cidex
- Sporicidin
- Mikrozid
- Isopropyl alcohol 70%
- Ethanol 70%
- Buraton fluid

It is vital to observe the manufacturer's instructions for the use of these products. Always leave the cuff to dry completely.

When using other disinfectants not recommended by SCHILLER, the user is responsible for proving harmless application.

⚠ CAUTION

▲ Never use disinfectants that leave a residue on the product or which are unsuitable for use in contact with skin.

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5.2.5 Admissible Disinfectants for the Casing

- 50 % isopropyl alcohol
- Propanol (50 %)
- Ethyl hexanal
- Aldehyde (2-4%)
- Ethanol (50%)
- All products that are suitable for ABS plastic

5.2.6 Non-admissible disinfectants

Never use products containing the following:

- Organic solvents
- Ammonia-based detergent
- Abrasive cleaning agents
- 100% alcohol, Virex, Sani-Master
- Sani-Cloth®, Ascepti® or Clorox® wipes
- HB Quat®
- Conventional cleaner (e.g. Fantastic®, Tilex® etc.)
- Conductive solution
- Solutions or products containing the following ingredients:
  - Ketone (for ex. acetone)
  - Ammonium chloride
  - Betadine
  - Chlorine, wax or wax compound
  - Sodium salt

5.2.7 Sterilisation

The cuff can be sterilised with Ethylene oxide gas. Prepare the cuff as detailed previously. After sterilisation the parts that were exposed to the gas must be aired.

⚠ CAUTION

▲ All relevant regulations and safety precautions must be complied with.

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6 Maintenance

All maintenance work must be carried out by a qualified technician authorised by SCHILLER AG. Only maintenance procedures given in this book may be carried out by the user.

The following table indicates the maintenance intervals, the maintenance requirement, and the person authorised to carry out the procedure.

Interval	Maintenance	Responsible
Every 6 months	• Visual inspection of the monitor, cables and tubes and cuff (see below).	➜ User
Every 24 months	• Measurement calibration.	➜ SCHILLER AG authorised service centre.

6.1 Visual Inspection

Visually inspect the unit, cables, connectors, tubing and cuff for the following:

- Device casing not broken or cracked.
- Display not broken or cracked.
- Microphone cable sheathing and connectors not damaged, no kinks.
- No kinks, abrasion or wear in the tubing assembly.
- Pressure bladder and tube connector in good condition.
- No excessive soiling or damage of the cuff and velcro fastening.

⚠ CAUTION

▲ Do not use if the unit, or any cable assembly or accessory, is damaged.

▲ Defective units, damaged cables, or damaged accessories must be replaced immediately.

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6.2 Battery Maintenance

- The batteries require no maintenance during their life.
- The life cycle of the batteries is approximately 500 charge / discharge cycles.
- To prevent the possibility of battery leakage, always remove the batteries from the device when not used for prolonged periods.

6.2.1 Charging the Batteries

- Full capacity of new NIMH batteries are only reached after three charge/discharge cycles.
- Totally discharged batteries require approximately three hours to be fully charged (with two batteries in charger), or six hours (with four batteries in charger).
- Charged batteries lose their charge when removed from the charger unit. Therefore to ensure full capacity only remove the batteries from the charger immediately before taking a recording.
- No harm will be done to the batteries by leaving them in the charger unit.

Remove the batteries from the BR-102 plus / BR-102 plus PWA (see Inserting/Changing the Batteries, page 15), and place in the battery charger unit. Leave the batteries in the charger unit until fully charged (see battery charger operating instructions).

6.2.2 Battery Disposal

WARNING

▲ Explosion hazard! Batteries may not be burned or disposed of domestic refuse.

▲ Danger of acid burns! Do not open the batteries.

The batteries must be disposed of in municipally approved areas or sent back to SCHILLER AG.

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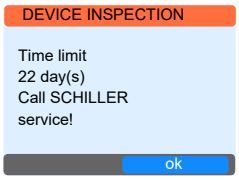
6.3 Calibration



The unit must be returned to a SCHILLER approved centre for calibration at the interval defined by local regulations or at least every two years. A reminder message is displayed 30 days before calibration is due and counts down the subsequent days every time the unit is switched on.

The message is displayed for approximately 60 seconds before the main BR-102 plus / BR-102 plus PWA menu is displayed. Select OK to display the main menu immediately for normal use.

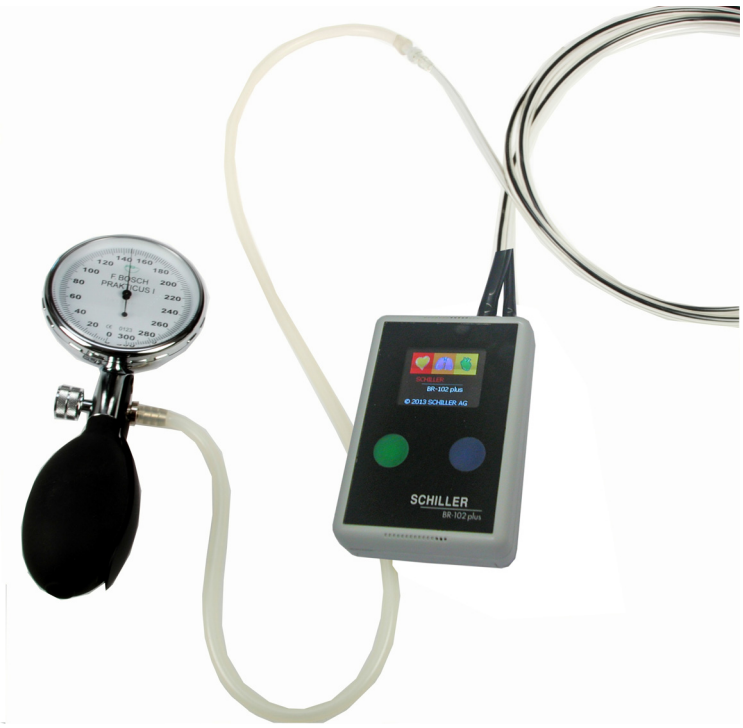
6.4 Measurement Check

A service option is incorporated in the BR-102 plus / BR-102 plus PWA to check the measurement accuracy and the correct functioning of the overpressure valve. This option can be performed at any time to check the unit‘s integrity.

6.4.1 Equipment Required

- Calibrated Manometer (purchased locally)
- BR-102 plus / BR-102 plus PWA connector and hose assembly.

6.4.2 Setup



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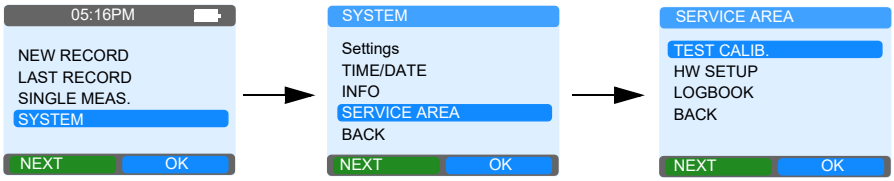
6.4.3 Measurement accuracy

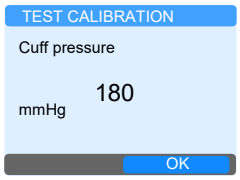
1. Remove the pressure hose and microphone from the BR-102 plus / BR-102 plus PWA and connect the manometer to the unit as shown.

The setup shown is an example connection only. Dependent on the type of manometer and hose connector used, the cuff connector can be removed from the BR-102 plus / BR-102 plus PWA and connected directly to the manometer.

2. Select **System > Service Area > Test Calibration.**



3. Pump once or twice to pressurise to approximately 200 mmHg.



4. The pressure will slowly drop. Check the reading on the BR-102 plus / BR-102 plus PWA against the calibrated pressure gauge. The two measurements should be within 3 mmHg. After 120 seconds the BR-102 plus / BR-102 plus PWA releases the pressure.

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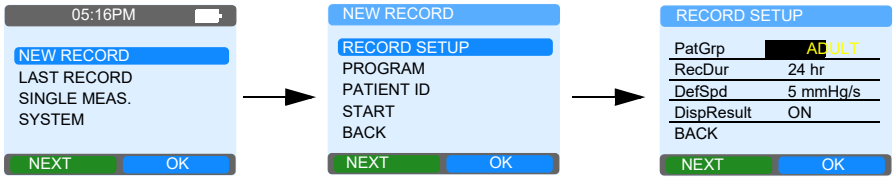
6.4.4 Overpressure Relieve Valve

The overpressure relieve valve can be checked for correct release for both the adult settings and paediatric setting.

Adult

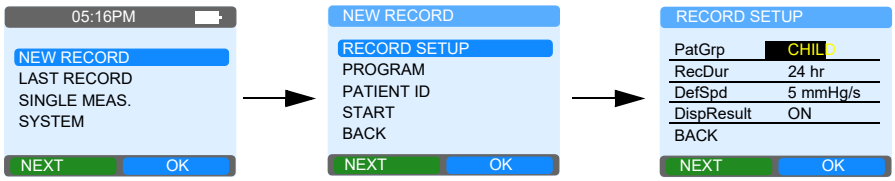
1. Set / check that Adult is set in the record setup. This can be done for single measurement or new record:



2. Setup and enter the calibration screen as detailed on the previous page.
3. Pump to 300 mmHg. Slowly continue to pump and check that the overpressure valve activates (a pressure hiss is heard and the cuff rapidly deflates) at **320 mmHg ± 10 mmHg**.

Paediatric

1. Set the record setup to Child. This can be done for single measurement or new record:



2. Setup and enter the calibration screen as detailed on the previous page.
3. Pump to 200 mmHg. Slowly continue to pump and check that the overpressure valve activates (a pressure hiss is heard and the cuff rapidly deflates) at **225 mmHg ± 5 mmHg**.

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6.5 Error Messages

The following is a list of the error message that can appear on the device. A common occurrence of errors is movement or a noisy environment during measurement. In most cases checking the hose connections and cuff placement, and then retaking the measurement without moving the arm will solve the error.

6.5.1 Error Message Table

No.	Message	Cause	Remedy
51	Battery low	• Battery voltage too low to take a measurement.	➜ Replace with fully charged batteries.
52	Valve/pump	• Valve or pump is defective; air leak.	➜ Check pneumatic system. Check that tube is secured and that the connectors at both ends are securely in place. Check for holes or air leaks in the cuff bladder and pressure hose; contact service department.
120	Signal disturbed	• Disturbances in measurement signal.	➜ Perform measurement in quiet environment; avoid moving the arm during measurement.
122	Cuff pressure	• Too much residual air in cuff bladder.	➜ Ensure that cuff is completely decompressed before commencing a measurement.
123	No cuff	• No pressure (<3 mmHg) 10 sec after inflation; leak in the cuff or hose.	➜ Connect cuff; check hose connections.
124	Measur. break	• Measurement stopped manually.	➜
126	Measurement time	• Measurement time too long; hose, cuff or pump is defective.	➜ Check hose connections. Check hose and bladder for defects. Contact service department.
127	Cuff loose	• Pressure too low (<10 mmHg) 10 sec after inflation.	➜ Check cuff; if necessary tighten it more firmly.
128	Pump time	• Pump-up time too long (50/60 sec, depending on patient type, C/A); hose, cuff or pump is defective.	➜ Check cuff and hose. Contact technical service.
130	Overpressure	• Device automatically shut off by relief valve.	➜ Maximum pressure reached.
140	Meas. invalid	• Evaluation impossible (KOR).	➜ Check position of microphone; repeat measurement.
150	Meas. invalid	• Evaluation impossible (OSC).	➜ Check cuff; avoid moving the arm.
180	No signal	• Pressure reached 70 mmHg and no Korotkoff signal detected.	➜ Connect microphone. Check microphone position.
181	Weak signal	• Pressure reached 50 mmHg and no Korotkoff signal detected.	➜ Place microphone over brachial artery; ensure that the microphone is correctly orientated (metallic side towards arm).

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No.	Message	Cause	Remedy
182	Signal disturbed	• Too much interference in Korotkoff signal.	➜ Perform measurement in quiet environment; avoid moving the arm during measurement.
190	No signal	• Pressure reached 50 mmHg and no pulse detected (OSC).	➜ Check cuff.
191	Weak signal	• Less than 8 pulse beats detected (OSC).	➜ Check cuff.
192	Signal disturbed	• More than 200 pulse beats detected (OSC).	➜ Avoid moving the arm during measurement.
198	DIA not detected	• Minimum pressure reached without diastolic value detected (OSC).	➜ Avoid moving the arm during measurement.
199	SYS not detected	• Minimum pressure reached without systolic value detected (OSC).	➜ Avoid moving the arm during measurement.
200	No pulse	• No pulse detected (OSC).	➜ Repeat measurement; check cuff.
201	Pulse > max.	• Too many pulse beats detected (OSC).	➜ Perform measurement in quiet environment; avoid moving the arm during measurement.
202	Pulse < min.	• Too few pulse beats detected (OSC).	➜ Repeat measurement; check cuff.
210	No pulse	• No pulse detected (KOR).	➜ Connect microphone; Check position of microphone. Ensure that the microphone is correctly orientated (metallic (yellow) side towards arm).
211	Pulse > max.	• Too many pulse beats detected (KOR).	➜ Perform measurement in quiet environment; avoid moving the arm during measurement.
212	Pulse < min.	• Too few pulse beats detected (KOR).	➜ Place microphone over brachial artery; ensure that the microphone is correctly orientated (metallic (yellow) side towards arm).
238	Min. pressure	• Minimum pressure reached without measurement result.	➜ Repeat measurement.
239	Max. pressure	• Maximum pressure reached without measurement result.	➜ Repeat measurement.
255	Internal error	• Device is defective.	➜ Contact technical service.
322	No measurements available	• No recording stored. • No recording has been made. • Incorrect initialisation of a recording. • Error in the recording storage.	➜ Take/ retake a recording.
323	No patient data available	• No patient data has been recorded.	➜ Enter patient data.
324	SD-card missing	• SD card not inserted. For PWA recording an SD card is necessary.	➜ Insert an SD card.

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7 Technical Data

Device Name	BR-102 plus / BR-102 plus PWA
Dimensions	100 x 68 x 28 mm (l x w x h)
Weight	200 grams (including rechargeable batteries)
Display	Graphical colour OLED with multi-language menu
Power Supply	
Power consumption	2.4 V, 4.0 VA
Batteries	Type AA, 2 rechargeable NiMH, 1.2 V, 2700 mAh
Capacity	24 hours (approximately 100 measurements can be performed) Battery capacity indicated on the display
Data Storage	Flash memory with capacity for over 400 measurements and 30 sec. of voice recording Additionally Storage: micro SD card
Interfaces	USB 2.0 interface for data transfer
Programming	Menu guidance; 2 buttons
Recording Protocols	Four programmable interval groups (each group has 8 measurements)
Measurements	
Methods of measurement	**BR-102plus** Auscultatory (Korotkoff / Riva-Rocci) with additional oscillometric method as backup or only oscillometric, both with linear adjustable deflation rate. **BR-102 plus PWA** Same as BR-102 plus but with additional 10 second oscillometric signal recording for PWA.
Measurement duration	24 hours or 48 hours
Measuring range	
Blood pressure	25 to 300 mmHg (± 3 mmHg)
Heart rate	25 to 300 bpm (25 to 100 bpm ≤ ± 2%) (100 to 200 bpm ≤ ± 4%) (200 to 300 bpm ≤ ± 5%)
Deflation rate	2 to 9 mmHg/s, automatic (3 mmHg / heart beat)
Measurement intervals	5 to120 min

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Safety Standards	IEC 60601-1 ISO 81060-1 IEC 80601-2-30 IEC 60601-1-2 (EMC)
Protection Class	Internal power supply
Protection Class of Casing	IP42 when using the carrying pouch
Applied Part	BF according to IEC/EN 60601-1
Conformity	CE 0123 according to Annex II 93/42/EEC (medical devices)
Classification	IIa according to MDD 93/42/EEC
Trusted Accuracy	The BR-102 plus / BR-102 plus PWA is clinically validated to all internationally recognised organisations: – BHS (in progress) – ESH (2002) – AAMI SP10:2002
Environmental conditions (Operation)	
Operating temperature	• + 10°C to + 40°C (+ 50°F to + 104°F)
Relative humidity	• 15 % to 95 % (non-condensing)
Pressure during operation	• 700 hPa to 1060 hPa
Environmental Conditions (storage and transport)	
Transport temperature	• - 10°C to + 50°C (+ 14°F to + 122°F)
Storage temperature	• + 5°C to + 50°C (+ 41°F to + 122°F)
Relative humidity (storage and transport)	• 10 % to 95 % (non-condensing)
Pressure (storage and transport)	• 500 hPa to 1060 hPa

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7.1 Preventing electromagnetic interferences

"Non-ionic electromagnetic radiation"

The user can help avoid electromagnetic disturbances by keeping the minimum distance between **portable** and **mobile** HF telecommunication devices (transmitters) and the BR-102 plus / BR-102 plus PWA. The distance depends on the output performance of the communication device as indicated below.

HF source Wireless communications devices	Transmitter frequency [MHz]	Testing frequency [MHz]	Max. Power P [W]	Distance d [m]
Various radio services (TETRA 400)	380-390	385	1.8	0.3
- Walkie-talkies (FRS) - Rescue service, police, fire brigade, servicing (GMRS)	430-470	450	2	0.3
LTE band 13/17	704-707	710/745/780	0.2	0.3
- GSM800/900 - LTE band 5 - Radio telephone (microcellular) CT1+, CT2, CT3	800-960	810/870/930	2	0.3
- GSM1800/1900 - DECT (radio telephone) - LTE Band 1/3/4/25 - UMTS	1700-1990	1720/1845/1970	2	0.3
- Bluetooth, WLAN 802.11b/g/n - LTE Band 7 - RFID 2450 (active and passive transponders and reading devices)	2400-2570	2450	2	0.3
WLAN 802.11a/n	5100-5800	5240/5500/5785	0.2	0.3

⚠ CAUTION

- ▲ **Portable** HF telecommunication devices must not be used within a radius of 0.3 m from the BR-102 plus / BR-102 plus PWA and its cables.
- ▲ Do not place the BR-102 plus / BR-102 plus PWA on top of other electric/electronic devices - i.e. maintain a sufficient distance to other devices (this includes the patient cables).

For permanent HF telecommunication devices (e.g. radio and TV), the recommended distance can be calculated using the following formula: $d = 0.6 \times \sqrt{P}$. (The formula is based on the max. immunity level of 10 V/m in the frequency domain of 80 MHz to 3000 MHz).

d = recommended minimum distance in meters
P = transmitting power in Watts

i For more information on operation in an electromagnetic environment according to IEC/EN 60601-1-2, please consult the service manual.

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7.2 Classification

7.2.1 Clinical Tests

The BR-102 plus / BR-102 plus PWA fulfils the requirements of the ESH (European Society of Hypertension). Blood pressure measurements determined with this device are equivalent to those obtained by a trained observer using the cuff/stethoscope auscultatory method, within the limits prescribed by the American National Standard, Manual, electronic or automated Sphygmomanometers.

The blood pressure classification is according to standards specified by the World Heath Organisation (WHO) and the Guidelines for management of hypertension: report of the fourth Working Party of the British Hypertension Society, 2004 BHS IV, B Williams et al: J Hum Hyp (2004); 18: 139-185.

7.2.2 Classification of Blood Pressure Levels in Adults

Category	Systolic blood pressure [mmHg]	Diastolic blood pressure [mmHg]
Blood pressure		
Optimal	<120	<80
Normal	<130	<85
High normal	130-139	85-89
Hypertension		
Grade 1 (mild)	140-159	90-99
Grade 2 (moderate)	160-179	≥110
Grade 3 (severe)	≥180	≥110
Isolated systolic hypertension		
Grade 1	140-159	<90
Grade 2	>160	<90

- Based on clinic blood pressure and not values for ambulatory blood pressure measurement.
- Threshold blood pressure levels for the diagnosis of hypertension using self/home monitoring are greater than 135/85 mm Hg.
- For ambulatory monitoring 24 hour values are greater than 125/80 mmHg.
- If systolic blood pressure and diastolic blood pressure fall into different categories the higher value should be taken for classification.

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7.2.3 Classification of Blood pressure in Children and Adolescents

Age		High to Normal [mmHg]	Significant Hypertension [mmHg]	Severe Hypertension [mmHg]
6 - 9 years	SYS	114 - 121	122 - 129	≥130
	Dia	74 -77	78 -85	86
10 - 12 years	SYS	122 - 125	126 - 133	≥134
	Dia	78 -81	82 -89	90
13 - 15 years	SYS	130 - 135	136 - 143	≥144
	Dia	80 -85	86 -91	92
16 - 18 years	SYS	136 - 141	142 - 149	≥150
	Dia	84 -91	92 -97	98

Adapted from the Fourth Report on the Diagnosis, Evaluation, and Treatment of High Blood Pressure in Children and Adolescents. Paediatrics 2004 Aug;114 (Suppl 2:) 555-76

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8 Accessories

⚠WARNING

▲ Always use SCHILLER replacement parts and disposables, or products approved by SCHILLER. Failure to do so may endanger life and invalidate the guarantee.

Your local representative stocks all the disposables and accessories available for the BR-102 plus / BR-102 plus PWA. A comprehensive list of all SCHILLER representatives can be found on the SCHILLER website (www.schiller.ch).

8.1 Documentation

Part Number	Description
2.511043	medilogDARWIN2 User Guide DE
2.511044	medilogDARWIN2 User Guide EN
2.511045	medilogDARWIN2 User Guide FR
2.511064	medilogDARWIN2 User Guide ES
2.511065	medilogDARWIN2 User Guide SV
2.511066	medilogDARWIN2 User Guide RU
2.511067	medilogDARWIN2 User Guide ZH-S
2.540045	BR-102 plus / BR-102 plus PWA Recurrent test and service handbook

8.2 General Accessories

Part Number	Description
2.156077	Premium reusable pouch red BR-102 plus / BR-102 plus PWA.
2.156079	Premium accessories case red including reusable pouch red.
2.156086	Holter pouch single use, white, set of 50
2.156088	Shoulder and waist strap for pouch red BR-102 plus / BR-102 plus PWA.
2.200119	Battery Ni-MH AA BR-102 plus / BR-102 plus PWA, BP-200 plus, rechargeable.
2.200179	Charging unit BR-102 plus / BR-102 plus PWA, BP-200 plus, MS-12blue, 90-264 VAC (4 batteries can be charged at the same time).
2.310215	USB / mini USB cable for MT-101, BR-102 plus / BR-102 plus PWA, BP-200plus.

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8.3 Cuff and Cuff Accessories

Part Number	Description
2.100325	Velcro plaster for BR-102, BR-102 plus / BR-102 plus PWA, BP-200plus, set of 10.
2.100326	Adhesive plaster for microphone, BR-102, BR-102 plus / BR-102 plus PWA and BP-200 plus, set of 10.
2.100050	Tube for BP cuffs 2008 and 2014 BR-102 plus for oscillometric measurement only
2.120054	Tube for BP cuffs 2008 and 2014 BR-102 plus for oscillometric measurement only
2.120063	BP velcro cuff 2014, size XS, BR-102 plus for oscillometric measurement only
2.120064	BP velcro cuff 2014, size S, BR-102 plus, BP-200 plus
2.120065	BP velcro cuff 2014, size M, BR-102 plus, BP-200 plus
2.120066	BP velcro cuff 2014, size L, BR-102 plus, BP-200 plus
2.120067	BP velcro cuff 2014, size XL, BR-102 plus, BP-200 plus
2.120068	Comfort fleece size XS, package of 10, for BP cuff 2.120063
2.120069	Comfort fleece size S, package of 10, for BP cuff 2.120064
2.120070	Comfort fleece size M, package of 10, for BP cuff 2.120065
2.120071	Comfort fleece size L, package of 10, for BP cuff 2.120066
2.120072	Comfort fleece size XL, package of 10, for BP cuff 2.120067
2.120080	BP cuff D-Ring, size S, BR-102 plus, BP-200 plus
2.120081	BP cuff D-Ring, size M, BR-102 plus, BP-200 plus
2.120082	BP cuff D-Ring, size L, BR-102 plus, BP-200 plus

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9 BR-102 plus PWA

9.1 Overview

The clinical usefulness of central blood pressure (BP) as an index of risk for cardiovascular disease and the augmentation index (AIx) is often cited with relation to sex, age and heart rate. Arterial stiffness is an important determinant of cardiovascular risk and the augmentation index (AIx) is a measure of wave reflection and thus systemic arterial stiffness derived from the ascending aortic pressure waveform.

The central arterial pulse wave is the sum of the forward pressure wave generated by left ventricular ejection and a backward propagating wave that is subsequently reflected from the peripheral site. The time point at which these forward and backward propagating waves merge and the amplitude of the reflected (backward) wave affect the level of central BP.

9.2 Measurements

After every BP measurement, the cuff is again inflated to the diastolic pressure and held for 10 seconds while PWA data is obtained (see BR-102 plus PWA Unit Measurements, page 43).

9.3 Display of Pulse Wave Analysis

Pulse wave analysis is based on arterial blood pressure curve containing haemodynamic information that exceeds peripherally measured blood pressure. This is used to analyse the central aortic pulse wave. The medilogDARWIN2 displays the following values:

- Central blood pressure
- Central pulse pressure
- Augmentation pressure
- Augmentation index
- AIx@75 [90% confidence interval]
- Peripheral resistance
- Pulse Wave Velocity [PWV]

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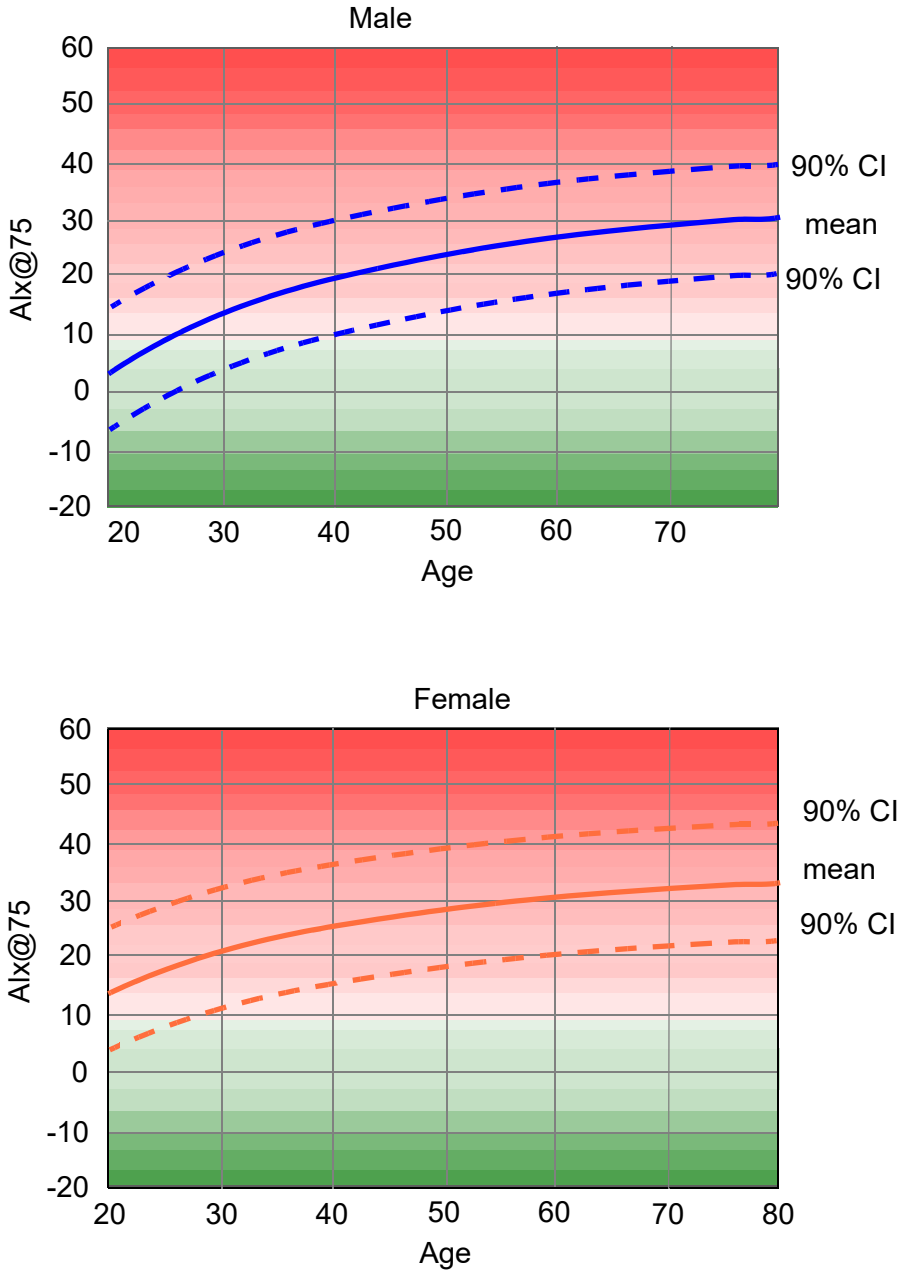
9.4 Method

Ten pulse waves are filtered and averaged to determine the central arterial pulse wave. The augmentation index is standardised for a pulse rate of 75 bpm (see reference [1]). This parameter is then described as AIx@75.



Average value and 90% confidence interval for the AIx@75

AIx@75 has been analysed in a representative cross-section of the population (see reference [2]), and an age-dependent estimate for the AIx@75 plus the respective confidence interval have been assessed. These relevant analyses have also shown that there is a significant difference for the average AIx@75 between men and women.

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Based on research with a surveyed cross-section of the population of about 2,000 people average values and 90% confidence interval were determined. An increase of the AIx until the 55th year has been identified and after the 55th year the increase slows for both sexes. The level difference of the AIx between the sexes is about 8 to 10%. If the measured values exceed the sex- and age-specific interval, further examinations according to the European examination guidelines for hypertension [3] are recommended in order to detect the reason for the dysfunction.

1. Wilkinson I.B. et al. Heart Rate Dependency of Pulse Pressure Amplification and Arterial Stiffness. American Journal of Hypertension 2002;15:24-30.
2. Fantin F. et al. Is augmentation index a good measure of vascular stiffness in the elderly? Age and Ageing 2007; 36: 43-48.
3. The Task Force for the Management of Arterial Hypertension of the European Society of Hypertension (ESH) and the European Society of Cardiology (ESC). 2007 Guidelines for the management of arterial hypertension. European Heart Journal 2007; 28: 1462-1536.
4. European Heart Journal (2010) 31, 2338–2350 doi:10.1093/eurheartj/ehq165. Determinants of pulse wave velocity in healthy people and in the presence of cardiovascular risk factors: ‘establishing normal and reference values’.

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10 Patient Diary

10.1 Patient Diary Example

The patient diary template is delivered with the unit (in Word format and PDF format) for direct printing. A sample is reproduced on the following pages for information or copying if required.

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SCHILLER BR-102 plus / BR-102 PWA
Patient Diary

Patient ID: .....

Patient name: .....

Date: ..... Beginning of the recording: .....

WARNING

- If you experience any numbness in the arm, chafing, pain or discomfort remove the cuff and contact your doctor immediately.
- Danger of strangulation from the hose. Wear a T-shirt or continue to wear normal outer clothing over the tubing at night to help keep it secure.
- For patients with special needs such as children, the elderly, the disabled, or people lacking the capacity for judgement, their caregiver needs to operate the recorder and monitor the recording.

Caution

- The unit is not waterproof, do not get wet - remove the recorder and cuff if you take a bath or shower.
- To avoid a malfunction of the device, keep sufficient distance (at least 30 cm) to other electrical / electronic devices (e.g. Smart Phone).

DURING THE RECORDING

- Do not to move the arm during the measurements.
- Avoid noisy areas when a measurement is being taken.
- After an invalid measurement a second measurement will be initiated immediately.
- The unit must continue to be worn during the night time period. Wear a T-shirt or continue to wear normal outer clothing over the tubing at night to help keep it secure.

Control buttons ⇨

BR-102 plus Standard

- If you carry a PWA recording device, a second measurement will be performed after each measurement: the cuff is inflated again and the pressure is maintained for about 10 seconds before the air is deflated again and the recorder is ready for the next measurement.

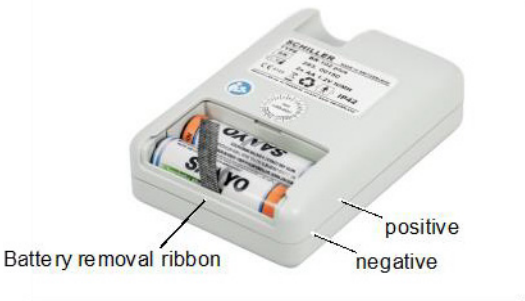
BR-102 plus PWA

Taking an extra measurement during the recording

The unit takes measurements at predetermined intervals. Extra measurements can be taken at any time, press either the green or the blue control button to display the measurement screen and press again to take an extra measurement.

Interrupting a measurement during the recording

To interrupt a measurement, press either of the control buttons during the measurement. The next measurement will take place according to the schedule.



Battery compartment cover. Position in grooves and slide until clicked secure.

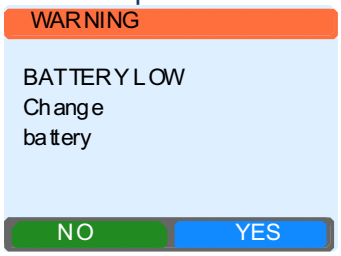
SCHILLER BR-102 plus / BR-102 PWA
Patient Diary

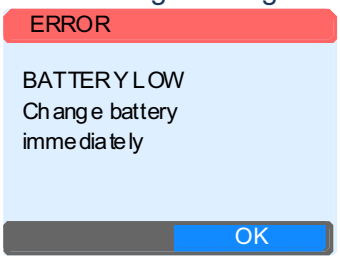
Changing the Batteries During a 48 Hr Recording

- Preventive changing the batteries after 24 hours

1. Press the blue button for 4 seconds. Confirm message **"Change battery"** again with the blue button.
2. Remove the batteries and replace with the fully charged batteries supplied. Observe correct polarity.
3. Press the green button to switch the unit on. The following message is displayed: **Blood pressure measurement Next Meas. .. . xx:xx**
4. Make an entry in the patient diary.

- Or when the audible beep is heard and one of the following messages are displayed:





1. Confirm the 'Change battery' message with the blue button.
2. Remove the batteries and replace with the fully charged batteries supplied. Observe correct polarity.
3. Press the green button to switch the unit on. The following message is displayed: **Blood pressure measurement Next Meas. .. . xx:xx**
4. Make an entry in the patient diary.

Do not dispose of the old batteries - return to the surgery.

Cuff placement

The cuff should be placed on the left upper arm approximately 2cm above the elbow so that the forearm can move. Position the red flap (indicating the position of microphone) on the inside of the arm. The pressure tube points towards the shoulder. Tape can be used to secure the tubing to the body if required. Place the device in the pouch and secure with the pouch straps. Wear a t-shirt over the tubing to help secure the tubing in position.

Make an entry in this diary (next page) if you experience any dizziness, palpitations, chest pain, etc. Also make an entry when the batteries are changed, an extra measurement is taken, or for any other event.

SCHILLER BR-102 plus / BR-102 PWA
Patient Diary

Time	Event / Comment

SCHILLER BR-102 plus / BR-102 PWA
Patient Diary

Time	Event / Comment

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Americas
SCHILLER Americas Inc.
Doral, Florida 33172

North America:
Phone +1 786 845 06 20
Fax +1 786 845 06 02
sales@schilleramerica.com
www.schilleramerica.com

Latin America & Caribbean
Phone +1 305 591 11 21
Fax +1 786 845 06 02
sales@schillerla.ch
www.schillerla.ch

Asia
SCHILLER Asia-Pacific / Malaysia
52200 Kuala Lumpur, Malaysia
Phone +603 6272 3033
Fax +603 6272 2030
sales@schiller.com.my
www.schiller-asia.com

Austria
SCHILLER Handelsgesellschaft m.b.H.
A-4040 Linz
Phone +43 732 70 90
Fax +43 732 757 000
sales@schiller.at
www.schiller.at

China
Alfred Schiller (Beijing) Medical Equipment Co.,Ltd.
100015 Beijing, China
Phone +86 010 52007020
Fax +86 010 52007020-8016
info@schillerchina.com
www.schillermedical.cn

Croatia
SCHILLER d.o.o.
10000 Zagreb
Phone +385 1 309 66 59
Fax +385 1 309 66 60
info@schillerzg.hr
www.schiller.hr

France
SCHILLER Médical
F-67160 Wissembourg
Phone +33 3 88 63 36 00
Fax +33 3 88 63 36 49
info@schiller.fr
www.schiller-medical.com

France (distribution France)
SCHILLER France S.A.S.
F-77608 Bussy St Georges
Phone +33 1 64 66 50 00
Fax +33 1 64 66 50 10
contact@schillerfrance.fr
www.schiller-france.com

Germany
SCHILLER Medizintechnik GmbH
D-85622 Feldkirchen b. München
Phone +49 89 62 99 81 0
Fax +49 89 609 50 90
info@schillermed.de
www.schillermed.de

Hungary
SCHILLER Diamed Ltd.
H-1141 Budapest
Phone +36 1 383 4780 / +36 1 460 9491
Fax +36 1 383 4778
info@schillerhungary.hu
www.schillerhungary.hu

India
SCHILLER Healthcare India Pvt. Ltd.
Mumbai – 400 059, India
Phone +91 22 6152 3333 / 2920 9141
Fax +91 22 2920 9142
sales@schillerindia.com
www.schillerindia.com

Poland
SCHILLER Poland Sp. z o.o.
PL-02-729 Warszawa
Phone +48 22 843 20 89 / +48 22 647 35 90
Fax +48 22 843 20 89
schiller@schiller.pl
www.schiller.pl

Russia & C.I.S.
AO SCHILLER.RU
125040 Moscow, Russia
Phone +7 (495) 970 11 33
Fax +7 (495) 956 29 10
mail@schiller.ru
www.schiller.ru

Serbia
SCHILLER d.o.o.
11010 Beograd
Phone +381 11 39 79 508
Fax +381 11 39 79 518
info@schiller.rs
www.schiller.rs

Slovenia
SCHILLER d.o.o.
2310 Slovenska Bistrica
Phone +386 2 843 00 56
Fax +386 2 843 00 57
info@schiller.si
www.schiller.si

Spain
SCHILLER ESPAÑA, S.A.
ES-28232 Las Rozas/Madrid
Phone +34 91 713 01 76
Fax +34 91 355 79 33
schiller@schiller.es
www.schiller.es

Switzerland
SCHILLER-Reomed AG
CH-8953 Dietikon
Phone +41 44 744 30 00
Fax +41 44 740 37 10
sales@schiller-reomed.ch
www.schiller-reomed.ch

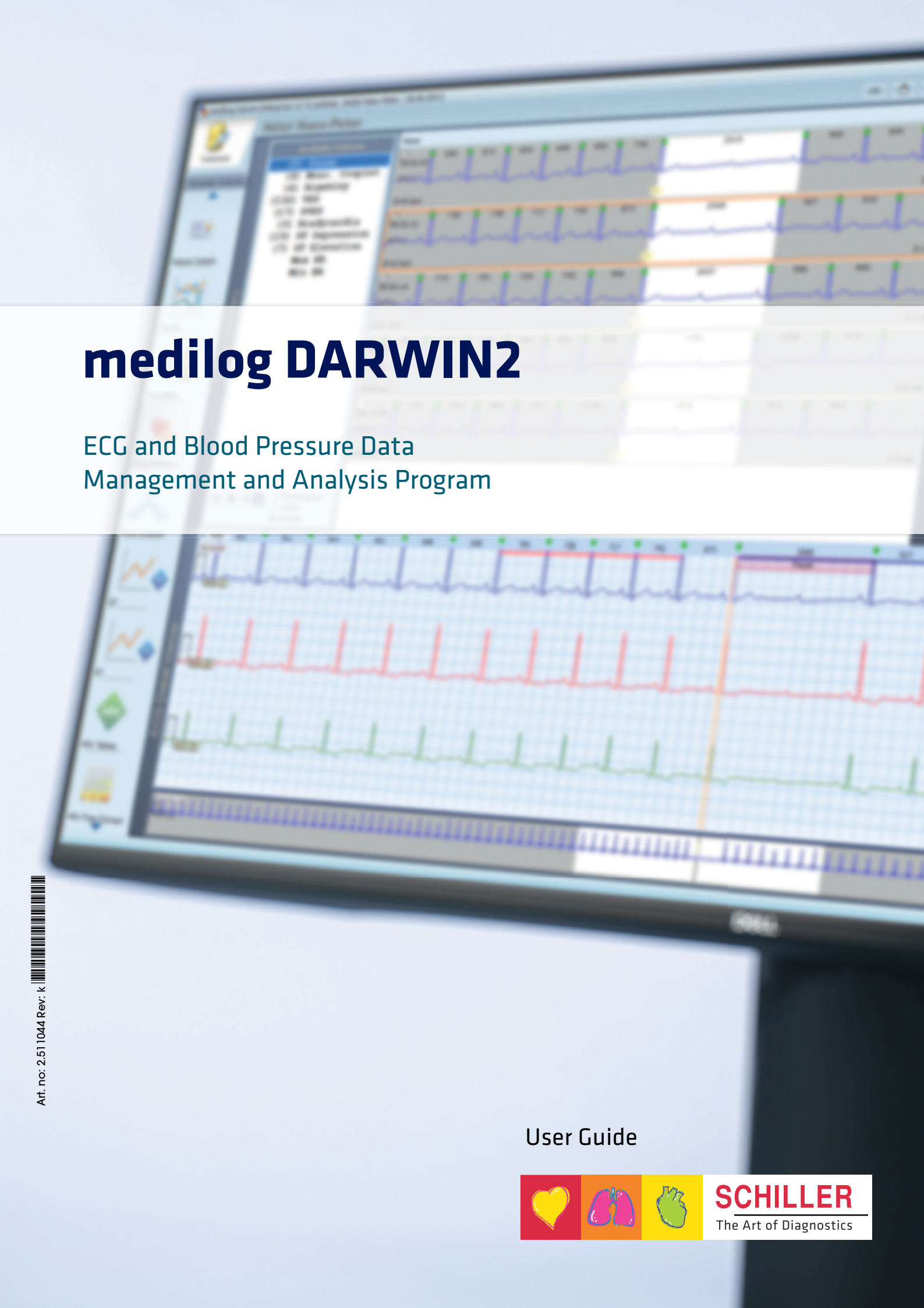
Turkey
SCHILLER TÜRKIYE
Okmeydani-Sisli – Istanbul
Phone +90 212 210 8681 (pbx)
Fax +90 212 210 8684
info@schiller.com.tr
www.schiller-turkiye.com

United Kingdom
SCHILLER UK
Bellshill, ML4 3PR
Phone +44 1698 744 505
Fax +44 1698 744 474
sales@schilleruk.com
www.schilleruk.com

DESIGNED AND MANUFACTURED IN SWITZERLAND

SCHILLER
The Art of Diagnostics

Headquarters: SCHILLER AG, Altgasse 68, CH-6341 Baar, Switzerland, Phone +41 41 766 42 42, Fax +41 41 761 08 80, sales@schiller.ch, www.schiller.ch



medilog DARWIN2

ECG and Blood Pressure Data Management and Analysis Program

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User Guide

SCHILLER
The Art of Diagnostics

Sales and Service Information

The SCHILLER sales and service centre network is world-wide. For the address of your local distributor, contact your nearest SCHILLER subsidiary. In case of difficulty, a complete list of all distributors and subsidiaries is provided on our internet site:

www.schiller.ch

Sales information can also be obtained from: sales@schiller.ch

Address Headquarters

SCHILLER AG
Altgasse 68
CH-6341 Baar
Switzerland

Phone: +41 (0) 41 766 42 42
E-mail: sales@schiller.ch
Web:www.schiller.ch

If any serious incident has occurred concerning the device, it must be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.

EC REP

Schiller Medizintechnik GmbH
Otto-Lilienthal-Ring 4
85622 Feldkirchen
Germany

CE 0123

The **medilog DARWIN2** bears a CE marking and a **MD** symbol indicating the item is a medical device. The CE marking number '0123' is the accredited Notified Body (NB) number from TÜV SÜD Product Service GmbH (Ridlerstr. 65, 80339 Munich, Germany). The device is in compliance with the EU MDR 2017/745.

The requirements apply to patients, users and third persons who come into contact with this device within the scope of its intended use.

Article No: 2.511044 Rev: k
Issue date: 2024-01-17
SW version: ≥ 2.11
Translation: Original

SCHILLER
The Art of Diagnostics

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1 Safety Notes

1.1 Intended Purpose

medilog DARWIN2

medilog DARWIN2 is a data management and analysis program for the electronic storage, transfer, display and processing of physiological signals and medical patient information combined with long-term continuous ECG or ambulatory blood pressure monitoring devices.

The **medilog DARWIN2** software functions include:

- Displaying and analysing physiological signals (ECG, heart rate, ECG-derived respiration, SpO_2, BP measurement, BP pulse wave analysis).
- Calculating and displaying the statistical values of those data.
- Detecting and classifying heart activities (atrial, ventricular) and arrhythmias.
- Configuring long-term continuous ECG Holter devices and automated non-invasive sphygmomanometer blood pressure devices.

1.2 Limitations and Restrictions

The software is NOT intended to be used:

- To control the heart rate, ECG and other physiological signals.
- For the monitoring of vital functions, especially in intensive care.

1.3 Indications

1.3.1 Indications for a long-term continuous ambulatory Holter ECG

Software functions of **medilog DARWIN2** related to the long-term continuous ambulatory Holter ECG analysis are intended for patients who may benefit from a long-term continuous Electrocardiographic (ECG) recording. Patients that may benefit include those with complaints of palpitations, syncope, chest pain, shortness of breath or those that need to be monitored to assess cardiac and cardiovascular function.

Holter is a diagnostic tool used in the following applications:

- Cardiac arrhythmias
- Atrial fibrillation
- Atrial and ventricular tachyarrhyhthmia
- AV blocks
- Bradycardia
- Congenital heart disease
- Heart failure
- Ventricular arrhythmias
- Hypertrophic cardiomyopathy
- Coronary artery disease
- Superventricular arrhythmias
- ST-depression/elevation
- QT prolongation

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- Long QT syndrome

and for:

- Following up on pacemaker therapy
- Screening of respiratory events
- Analyse Heart-Rate-Variability (HRV)
- Following up during clinical research studies

1.3.2 Indications for an ambulatory blood pressure monitoring

Ambulatory blood pressure monitoring is a diagnostic tool to aid diagnosis and clinical decision-making for the following:

- Arterial hypertension
- Masked hypertension
- White-coat hypertension
- Resistant hypertension
- Arterial hypotension
- Cardiovascular disease prevention
- Peripheral artery disease
- Cardiovascular disease during pregnancy

1.3.3 Indications for a Pulse wave analysis

Pulse wave analysis is a diagnostic tool for the following clinical applications, among others:

- Cardiovascular risk prediction
- children and adolescents with type 1 diabetes
- Aortic diseases
- Hypertension

1.3.4 Indications for a SpO_2 analysis

To display the functional oxygen saturation of arterial haemoglobin (%SpO_2). Optionally, this can support the screening of respiratory events based on ECG.

1.4 Intended Users

medilog DARWIN2 is intended to be operated only by or following instruction and under the direct supervision of a licensed physician.

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1.5 Patient Target Group

There are no restrictions regarding the height, weight, strength, sex or ethnicity of the patients.

There is no age limit for software functions related to long-term continuous ambulatory Holter ECG, indications for ambulatory blood pressure monitoring and SpO_2 analysis.
The patient target age group of a device used to provide physiological signals should be observed.

The pulse wave analysis functions are only intended for adults (greater than 21 years of age).

1.6 Context of Use

medilog DARWIN2 is intended for use in hospitals, medical facilities or medical practices.

medilog DARWIN2 is intended for Windows (client and server) operating systems, running on standard or virtualised computers connected across standard TPC/IP networks.

1.7 Responsibility of the User

- This software must only be used by qualified doctors or trained medical personnel.
- The numerical and graphical results and any interpretation given must be examined together with the overall clinical condition of the patient and the general recorded data quality.
- Any automatic analyses performed by the **medilog DARWIN2** can contain errors or misinterpretations. Make sure that a trained professional verifies all analysis results.
- To avoid errors, enter the patient details carefully before each recording and cross-check the settings. Also, check on the recorder to see if the patient details have been transferred correctly. Refer to the relevant user manual of the recorder in use. Moreover, check the patient data when reading the finished recording from the recorder's memory card to avoid mixing up recordings and patients.
- Extra care must be taken when processing anonymous recordings (recordings with no patient data has been entered) to avoid mixing up recordings and patients.
- Do not delete recordings directly from the installation folder. The only acceptable way of deleting a recording is to use the Delete function in the Database screen (refer to Database Screen, page 14).
- Before releasing a recording, check the Noise directory, especially the episodes that were excluded automatically and potentially noisy (refer to Noise directory, page 43).
- Ensure that the personnel have read and understood this user guide. In particular, the safety notes in this section must be read and understood.

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1.8 Organisational Measures

- Before using the software, ensure that a medical product representative has provided an introduction regarding the functions and the safety precautions.
- Keep this user guide and any other support documentation in an accessible place for reference when required. Make sure that all documentation is always complete and legible.

1.9 Networks and Internet

- Appropriate security measures must be applied to protect the patient data stored in the **medilog DARWIN2**. If your system performs information exchange via file folders (for example, HL7, BDT/GDT), folders must be protected from unauthorised access. If your system performs information exchange via TCP communication (for example, HL7), access to the network must not be available to unauthorised personnel. Patient security and the security of the network are the sole responsibility of the user.
- SCHILLER takes no responsibility for the configuration of Microsoft Windows.
- Running the **medilog DARWIN2** on a PC connected to an IT network could result in previously unknown risks to patients, operators or third parties. The responsible organisation must identify, analyse, evaluate and control any additional risks from the **medilog DARWIN2** connected to IT networks, including other equipment. Subsequent changes to the IT network might introduce new risks and require additional analysis.

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1.10 Safety Symbols and Pictograms

1.10.1 Symbols used in this document

The following overview shows the safety symbols and pictograms used in this manual.

⚠ CAUTION	▲ This symbol warns of a dangerous situation that could lead to personal injury and/or indicate possible property damage.

For general safety notes as listed in this chapter.

This symbol warns of dangerous situations that could damage property or system failure and provides other important user information.

Reference to other guidelines

1.10.2 Symbols used on the label

For general symbols, refer to the Appendix - Symbols, page 115

Consulting the user guide is mandatory before using the program.

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2 Introduction

2.1 What is medilog DARWIN2

The **medilog DARWIN2** is a data management program for the storage, analysis and diagnosis of Holter ECG and Ambulatory Blood Pressure Monitoring (ABPM) recordings, including:

Holter ECG recordings

- Heart Rate Variability (HRV) analysis
- Respiration/EDR analysis
- QT, ST and atrial analysis

Long-term BP measurements (ABPM)

- Pulse wave analysis

The interface, as well as analysis functions and reports, are fully configurable according to the user's requirements and include the following features:

- Archiving, editing, diagnostic and validation functions
- On-screen measurements, editing of global measurement points and interpretations
- Patient data editing
- Selectable print formats
- Patient and recording search function
- PDF report generation
- Role-based login
- Assignment of recordings for analysis and editing by other users
- Worklist function in connection with HL7/BDT/GDT/SCHILLER Server

2.1.1 medilog DARWIN2 versions

The **medilog DARWIN2** comes in four versions. A licence, provided via a soft licence, is required to use all Holter ECG functions. The Basic version does not require a licence and provides full BP function analysis but has limited ECG functions (resting ECG only). The four versions are as follows:

medilog DARWIN2 Basic

The free Basic version includes the following features:

- Starting of ABPM and Holter ECG Holter recordings
- Import of Holter ECG and ABPM recordings
- Blood pressure analysis (including PWA) with full editing functions
- Viewing of ECG recordings (no editing)
- Browsing databases and patients
- Examination of existing PDF reports
- Archiving, exporting and deleting recordings
- Analysis of the HRV frequency domain (Fire-of-Life) of recordings made with AR12plus HRV (single channel)
- Full disclosure
- BDT/GDT connectivity
- Networking option, HL7, and other options
- medilog Liberty Scanlab upload

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medilog DARWIN2 Office

In addition to the features of the Basic version, the **medilog DARWIN2** Office version includes the following:

- ADAPT advanced beat analysis
- ST analysis
- QT analysis
- Templates
- Pacemaker analysis
- HRV time domain analysis
- Beat meter

medilog DARWIN2 Professional

Designed for small to mid-sized Holter scanning centres with the demand for fast AF detection. In addition to the **medilog DARWIN2** Office version, the Professional version includes the following:

- HRV time and frequency domain analysis
- Fire-of-Life
- Detection of atrial fibrillation based on the P-wave analysis and ECHOView

medilog DARWIN2 Enterprise

The Enterprise version includes true atrial analysis and EDR analysis (ECG-derived respiration) and includes the same features as the **medilog DARWIN2** Professional version with the following additional features:

- EDR analysis
- SpO_2 values
- medilog Liberty Scanlab software

2.1.2 Overview of recording formats

The **medilog DARWIN2** can read and analyse data from any of the following sources:

SCHILLER medilog Holter recorders

- medilog AR
- AR12plus, AR4plus, FD5plus
- FD12plus
- AR12, AR4

SCHILLER blood pressure recorders

- SCHILLER BR-102 plus
- SCHILLER BR-102 plus PWA

SCHILLER Holter ECG recorders

- SCHILLER MT-101

DARWIN exported data

- Recordings from the DARWIN program (.daw files)

MIT recordings

- Refer to physionet.org

Miscellaneous

- ER900

2.1.3 medilog Liberty Scanlab

The **medilog DARWIN2** can be used together with the medilog Liberty Scanlab interface. medilog Liberty Scanlab is intended for the cooperation between registered physicians and scanlabs, which provide analyses of Holter ECG recordings. For more information, refer to the medilog Liberty Scanlab user guide sections medilog Liberty Scanlab Integration, page 21 and medilog Liberty Scanlab Installation and Settings, page 110, in this user guide.

2.1.4 Method for HR calculation

A configurable number of the preceding R-R intervals (default number: 3) calculates the mean HR. This setting is completed in the Arrhythmia configuration (refer to Arrhythmia Configuration, page 95, menu option Minimum/Maximum HR).

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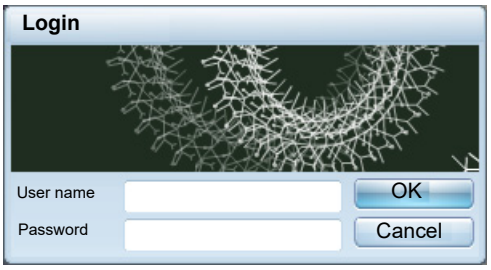
3 medilog DARWIN2 Program Overview

3.1 Login

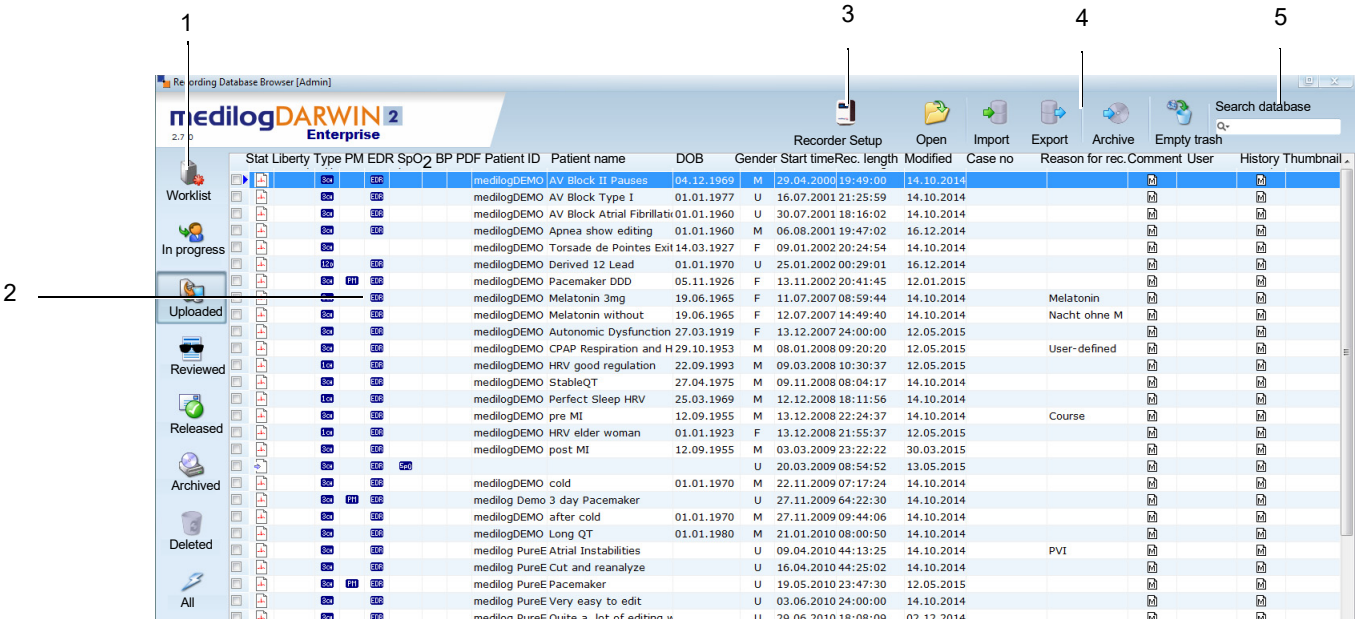
Double-click on the Program icon and enter the user name and password to log in:



Check the user rights and software version if a menu item or function described in this user guide is unavailable. Contact your system administrator.

3.2 Database Screen

The database screen is usually the first screen displayed when logging in.



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(1) **Recording lists:** In this area, the different lists of recordings can be displayed:
- Worklist: items sent to the program via Hospital Information System (HIS) for recording. With a double-click on the recording, the Recorder setup dialogue (see (3) below) is opened.
- In progress: ongoing recordings
- Uploaded
- Reviewed: recordings that have been reviewed but not yet released
- Released: recordings that have been analysed and released (refer to Print reports, page 54)
- Archived
- Deleted
- All

(2) **Recordings:** All recordings in the selected list. The recording information includes:
- Selection box: tick this box to select a recording
- Status: In progress, analysed, released, archived
- Type: 1 ECG channel, 3 channels, 12-lead derived
- PM: pacemaker measurement
- EDR: ECG-derived respiration signal available
- SpO_2: SpO_2 measurement
- BP: blood pressure measurement
- PWA: blood pressure measurement with pulse wave analysis
- PDF: double-click to open the PDF report (refer to Print reports, page 54)
- Comment: hover the mouse over the icon in this column to display the comments for this recording, if available, or double-click the icon to open the Comment window.
- History: see Comment above.
- Thumbnail: a small print screen of the recording can be shown here for an overview.
- Liberty: if an external measurement has been uploaded via Liberty, this is indicated by a globe icon.
- Order ID from SEMA, BDT/GDT or HL7, depending on the configuration.

(3) **Recorder setup:** refer to Starting a Recording, page 16.

(4) **Toolbar:** the tools vary from screen to screen and include:
- Open: open the highlighted recording. A recording can also be opened with a double-click.
- Import: indicate the location (drive or directory) and the data format the program must look for. Data formats include DARWIN exported files (.daw), recordings from various medilog recorders, MIT recordings (for scientific purposes) and Miscellaneous formats. Click Scan to start the search.
- Export: mark a recording and click Export. Then select the target folder and file format and click Export.
- Archive: mark a recording and click Archive. Then select the target folder and file name and click Start. The archiving progress is indicated by a progress bar. Refer to Automatic archiving, page 109.
- Restore: use this function to restore and delete recordings from the archive.
- Poll recorders: use this function to manually search for recorders (that is, Schiller MT-101 recorder: some recorders are not displayed automatically)
- Delete: this function moves the recording into the trash
- Empty trash: permanently delete recordings from the trash
- Liberty sync: synchronisation with medilog Liberty Scanlab to receive recordings analysed by a scanlab. Refer to Uploader, page 21.

(5) **Search database:** select the search criteria by clicking the Magnifying lens icon and entering the search term: all patients/recordings matching the criteria are listed.

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3.3 Starting a Recording

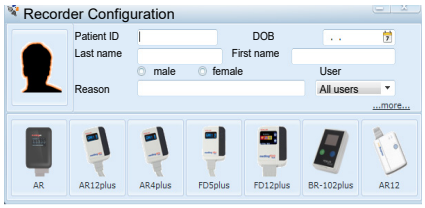
There are three possibilities for starting a recording:

1. Initiate a recording on the recorder (refer to the recorder's user guide for more information)
2. In **medilog DARWIN2**, select Recorder Setup in the Database screen (refer to Database Screen, page 14, and 3.3.1 below)
3. In **medilog DARWIN2**, perform a worklist item (refer to Database Screen, page 14).

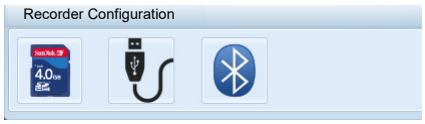
Below, only initiation via the **medilog DARWIN2** is described. For information on how to start a recording from the recorder, refer to the recorder's user guide.

- ▲ To avoid errors, enter the patient details carefully before each recording and cross-check the settings. Also, check on the recorder to see if the patient details have been transferred correctly.
- ▲ To avoid mixing up patients and recordings, record the patient data when the recording is initiated on the recorder (see the user guide for more information).
- ▲ Moreover, check the patient data when reading the finished recording from the recorder to avoid mixing up recordings and patients.

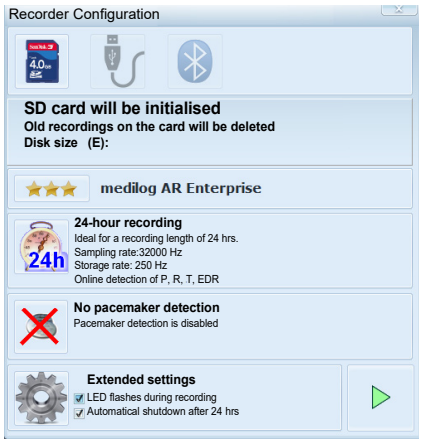
3.3.1 Configuration of medilog AR recorders



Click the Recorder setup icon (refer to Database Screen, page 14) to configure a recorder.
Enter the patient details or click the picture to select a patient from the database.
Then select the recorder at the bottom. If your recorder is not shown in this list, it must be activated in the Admin tool (refer to Local Component Setup, page 105).



The dialogue shown on the left is displayed.
Select your preferred setup option: memory card, USB or Bluetooth. For more information about these options, see below.



Configuration with a memory card

Click the Star icon to select the recorder version (Office, Professional or Enterprise, refer to Licence upgrade for medilog AR recorders, page 111).
Perform the settings:

- – Recording profile: select 24-hours recording duration, 72-hours, Open end recording, or Scientific. For more profile information, refer to the **medilog DARWIN2** user guide.
- – Activate or deactivate pacemaker detection: when this option is activated, the type of pacemaker must be specified.
- – Extended settings
- – Patient data is written to the memory card when clicking the green Arrow icon. Instructions are given on how to start the recording and where to place the electrodes. Additionally, you can print a patient diary template. Refer to the recorder user guide for more information.

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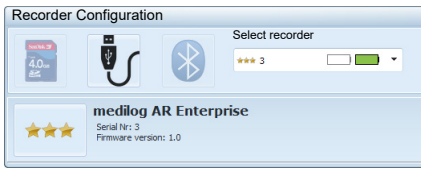


Configuration via USB

In the recorder editions (Office, Professional, Enterprise, refer to Licence upgrade for medilog AR recorders, page 111), the serial number and battery state are displayed. Click the drop-down list to select from all available recorders.

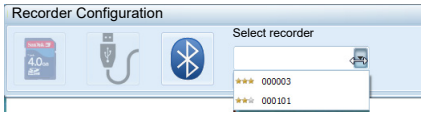
Click the Star icon to start the configuration of the selected recorder.

Click on the recorder name to perform the settings:

- Recording profile: select 24-hours recording duration, 72-hours, Open end recording, or Scientific. For more profile information, refer to the medilog AR user guide.
- Activate or deactivate pacemaker detection: when this option is activated, the type of pacemaker must be specified.
- Extended settings
- Patient data is transferred to the recorder when clicking the green Arrow icon. Instructions are given on how to start the recording and where to place the electrodes. Additionally, you can print a patient diary template. Refer to the recorder user guide for more information.

Configuration via Bluetooth

A recorder must first be paired with the PC to use a Bluetooth connection (refer to the user guide of the recorder for more information). Pairing is only necessary once.
Since the end of 2021, the medilog AR recorder has been equipped with a new Bluetooth module that uses the new Bluetooth LE communication standard. Bluetooth LE is only supported by Windows 10 or higher; therefore, medilog AR recorders can only be configured via Bluetooth with Windows 10 or higher.



Select the recorder from the drop-down list.

In the recorder editions (Office, Professional or Enterprise, refer to Licence upgrade for medilog AR recorders, page 111), the serial number and battery state are displayed.

Click the Star icon to start the configuration of the recorder.

Perform the settings:

- Recording profile: select 24-hours recording duration, 72-hours, Open end recording, or Scientific. For more profile information, refer to the medilog AR user guide.
- Activate or deactivate pacemaker detection: when this option is activated, the type of pacemaker must be specified.
- Extended settings
- Prepare the patient, connect the electrodes and check the ECG signal by clicking the Magnifying glass icon, then start the recording (refer to the recorder user guide for more information).

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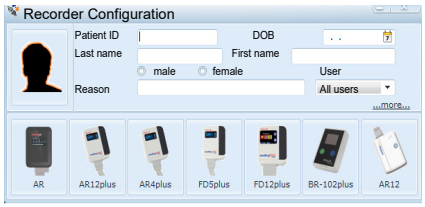
During a recording, checking the live ECG via Bluetooth connection is possible by opening the Recorder setup and double-clicking on the recorder in the list.

Note that recordings cannot be transmitted via Bluetooth due to the large data volume.

When a recording is started from the **medilog DARWIN2**, the settings described above are applied for the current recording.

▲ At the start of the recording, double-check the patient data to avoid mixing up patients and recordings.

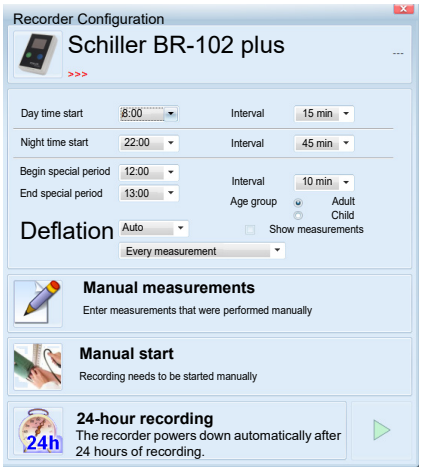
3.3.2 Configuration of BR-102 plus recorders (ABPM)



Click the Recorder setup icon (refer to Database Screen, page 14) to configure a recorder.

Enter the patient details or click the picture to select a patient from the database.

Then select the recorder at the bottom. If your recorder is not shown in this list, it must be activated in the Admin tool (refer to Local Component Setup, page 105).



BR-102 plus recorders must be connected to the PC via a USB cable.

The following settings can be made:

- Start of Day/Night period (that is, awake/asleep period) and measurement intervals
- Begin and end of the special period and measurement interval during this period (different to the day/night measurement interval).). When the patient is known to take medication or if the patient exercises, this is often used.
- Deflation speed: select a value between 2 and 9 mmHg/s or Auto
- Age group
- Show measurements: if this is activated, the measured BP values are shown on the recorder during acquisition
- PWA profile: select as follows:
  - Every measurement: PWA is recorded for each measurement.
  - Every other measurement: PWA is recorded for every second measurement.
  - Baulmann profile: at the beginning of the recording, PWA is measured four times in 5-minute intervals (according to Arterial stiffness and pulse wave analysis: consensus paper on basics, methods and clinical applications, Dtsch Med Wochensr 2010;135: 4-14. J. Baulmann et al., Arterielle Gefässsteifigkeit: section Praktische Hinweise zur Durchführung der Gefässsteifigkeitsmessung, page 11).
- Manual measurements: add BP values that have been measured manually.
- Manual or Automatic start: when Manual is selected, the recording is started manually on the BR-102 plus recorder at a later stage. When Automatic is selected, the recording starts immediately after pressing the green Arrow icon. See the following.
- Recording length: select 24-hours or 48-hours.
- Press the green Arrow icon to write the configuration to the memory card and either start the recording directly (when Automatic is selected, see above) or prompt the user to start the recording manually on the recorder (when Manual is selected, see above).

When a recording is started from the **medilog DARWIN2**, the settings described above are applied for the current recording.

▲ At the start of the recording, double-check the patient data to avoid mixing up patients and recordings.

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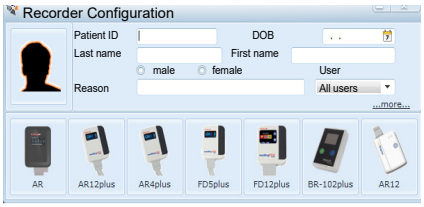
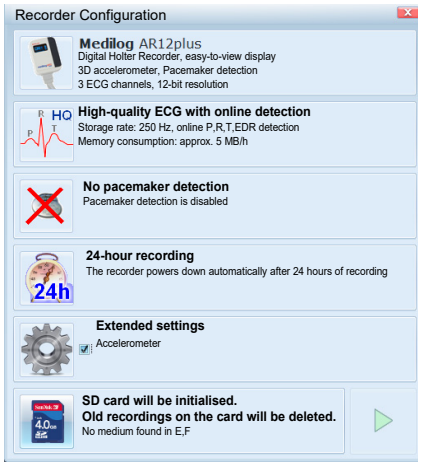
3.3.3 Configuration of all other recorders



Click the Recorder setup icon (refer to Database Screen, page 14) to configure a recorder.
Enter the patient details or click the picture to select a patient from the database.
Then select the recorder type at the bottom. If your recorder is not shown in this list, it must be activated using the Admin tool (refer to Local Component Setup, page 105).



The following dialogue is displayed for various Holter ECG recorders. Note that this dialogue and the options available may vary depending on your recorder.

- Select the storage rate: low power, long run for long recordings with a lower resolution; Scientific for scientific use only; High-quality ECG with online detection for clinical use.
- Activate or deactivate pacemaker detection: when this option is activated, the type of pacemaker needs to be selected.
- Recording length: select 24, 48 or 72 hours or an open-ended recording. When Open end recording is selected, the recording continues until the batteries are empty, until no memory space is left, or until the recorder is turned off.
- Extended settings: enable or disable the accelerometer (if available).
- Select an SD card or Bluetooth connection by clicking on either symbol (for more information about both options, see below).

Configuration via a memory card

Select to initialise the memory card and delete old recordings. The patient data is written to the memory card when clicking the green Arrow icon. To start the recording, insert the memory card into the recorder, confirm the patient data, and start by pressing the Play icon.

Configuration via Bluetooth

A recorder must first be paired with the PC to use a Bluetooth connection (refer to the user guide of the recorder for more information). Pairing is only necessary once.

In the recorder setup, select Bluetooth instead of memory card (see above) if you wish to establish a Bluetooth connection to the recorder to prepare a recording. Scan for Bluetooth-enabled devices by clicking the green Arrow icon.
A list of all available recorders within range is displayed. Double-click to select a recorder or highlight the recorder and click Open: battery level and electrode status are shown.
The ECG channels (live ECG) are then displayed so that the quality can be checked.
Ensure the memory card is inserted in the recorder, and click the green Arrow icon.
You are then prompted to check and confirm the patient data. The recording is started on the recorder by pressing the red Play icon.
During a recording, checking the live ECG via Bluetooth connection is possible by opening the Recorder setup and double-clicking on the recorder in the list.

Note that recordings cannot be transmitted via Bluetooth due to the large data volume. When a recording is started from the **medilog DARWIN2**, the settings described above are applied for the current recording.

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3.4 Receiving a Recording

▲ At the start of the recording, double-check the patient data to avoid mixing up patients and recordings.

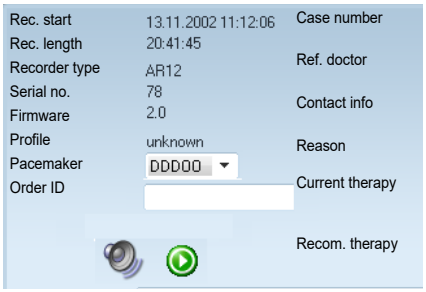
Usually, recordings are received by reading the recorder's memory card on the PC; however, some recorders offer the possibility to directly connect the recorder to the PC (for example, via a USB cable) to download the data (BR-102 plus, medilog AR).

3.4.1 Receiving a recording via a memory card

1. Insert the memory card into the PC.

To enable automatic polling for new recordings by the Observer tool, ensure that the correct drives are selected in the Admin tool (refer to Local Component Setup, page 105).

2. The Observer automatically detects the new recording (refer to DARWIN Observer, page 110) and displays the patient name and recording duration in a new window. If the patient name is incorrect or has not been configured at the start of the recording, you can now edit/enter it by clicking OK to download the recording data.
3. Confirm with OK to upload the recording into the Database screen folder Uploaded (refer to Database Screen, page 14).
4. Double-click the recording to open.



5. The recording start time, length, etc., are displayed on the Recording data screen. Review and edit the recording information, such as Case No. referring doctor, and playback the patient data recorded via the microphone on the recorder by clicking the Play icon (also refer to Recording information, page 35).
6. If available, enter the information from the patient diary; refer to Patient diary, page 37.

▲ To avoid mixing up patients and recordings, record the patient data (voice recording) when the recording is initiated on the recorder (refer to the user guide for more information).

▲ In addition, check the patient data when reading the finished recording from the recorder to avoid mixing up recordings and patients.

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3.4.2 Receiving a recording via USB (BR-102 plus, medilog AR)

1. Switch on the recorder and connect it to the PC using a USB cable.
2. The Observer automatically detects the recorder (refer to DARWIN Observer, page 110), downloads the patient and recording data and displays the patient data and recording length in a new window.
   If the Observer does not detect the recorder automatically, open the Observer program and click the button to initiate a recorder search manually. The Observer shows the detected recording.

The rest of the import process is identical to the process via the memory card detailed above (refer to Receiving a recording via a memory card, page 20).

▲ To avoid mixing up patients and recordings, record the patient data (voice recording) when the recording is initiated on the recorder (refer to the user guide for more information).

▲ In addition, check the patient data when reading the finished recording from the recorder to avoid mixing up recordings and patients.

3.5 medilog Liberty Scanlab Integration

medilog Liberty Scanlab is an interface for registered physicians to upload recordings for analysis, review and report generation by a scanlab (refer to the medilog Liberty Scanlab user guide art. no. 2.511368 for more details).
Registered physicians can use a web-based interface to upload recordings or an existing **medilog DARWIN2** installation (the free Basic version).
For analysis, review and report generation, scanlabs require the **medilog DARWIN2** Enterprise version (refer to medilog Liberty Scanlab Installation and Settings, page 110).

3.5.1 Uploader

The uploader is a registered physician who collaborates with a scanlab to have longterm ECG recordings analysed, edited and reports generated.

The procedure for the uploader is as follows:

1. Perform long-term ECG recording with an approved recorder
2. Upload recording via a web browser or **medilog DARWIN2** and enter/edit patient data.
3. Upload supporting documents (that is, patient diary) in PDF format
4. Receive email notification when the analysis is complete (if configured)
5. View the report and changes made via a web browser or in the **medilog DARWIN2** (button Liberty synchronisation, refer to Database Screen, page 14)
6. Print the report if required.

➜ For more information, refer to the medilog Liberty Scanlab user guide

3.5.2 Analyst (editor)

Typically, the analyst is a scanlab performing long-term ECG recording analyses for registered physicians.

The procedure for the analyst is as follows:

1. Open an uploaded recording in **medilog DARWIN2** (in folder Uploaded, marked as Liberty Scanlab upload, refer to Database Screen, page 14), analyse and edit it and generate a PDF report
2. Release the recording, the uploader is notified by email (if configured)

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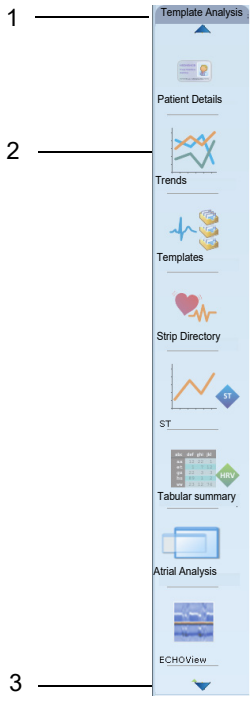
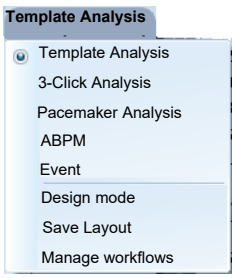
3.6 Controls

The **medilog DARWIN2** is based on workflows. These workflows can be adjusted to the user's requirements so that only the modules necessary for the user are displayed in the workflow bar. The module's order can also be adapted so the user can work through the workflow from top to bottom, minimising the risk of accidentally skipping a step.

3.6.1 General workflow



The workflow bar is displayed on the left side of the screen. Use this bar to switch from one workflow step to another (1). The current step (layout) is highlighted. A step is a collection of modules, and steps are arranged in a logical sequence to accomplish a task. To go to a different step, click on the icon in the workflow bar (2).
Click or move the cursor over the Blue arrows at the top or bottom (3) to display more steps within a workflow, or use the mouse wheel to scroll up or down.



Click on the workflow's name at the top (1) to switch to another workflow or to access the workflow settings; the following menu is displayed (see left).
The menu options at the top indicate the other workflows.
At the bottom, three additional menu options are available:

- Design mode: select this option to switch to the design mode. In this mode, you can rearrange and resize the module windows, see the following.
- Save layout: save the current workflow layout.
- Manage workflows: edit, rename and delete workflows; see the following.

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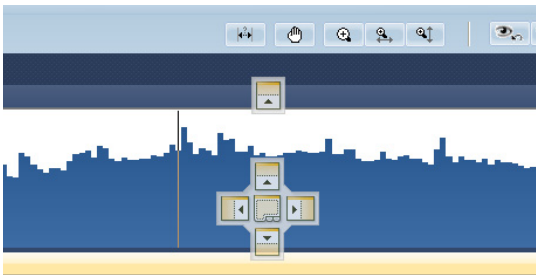
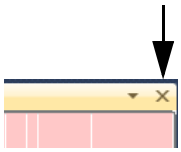
3.6.2 Workflow settings

Design mode

In this mode, the modules can be freely resized, moved or deleted from a workflow. Selected modules are highlighted in yellow. Click on the module's title bar to move it; a module can be floating or docked in a specific location with the help of the docking icons (see the example below). It is also possible to use a second screen: in this case, drag the floating module to the second screen.



Hover the mouse over the border between the two modules, and an icon is displayed to resize the module  .



Click the **X** icon (see left) to delete a module from the workflow. Select the menu option again to exit Design mode.

Save layout

The changes made in Design mode are only permanently saved if you select Save layout from the menu.

Manage workflows

Manage workflows and screen layouts by selecting menu options. Add, delete, or rename workflows and layouts. Save these settings as defaults or restore to start fresh.

Icon modules

Click the Modules icon in the top right corner of the screen  to select additional modules for display.

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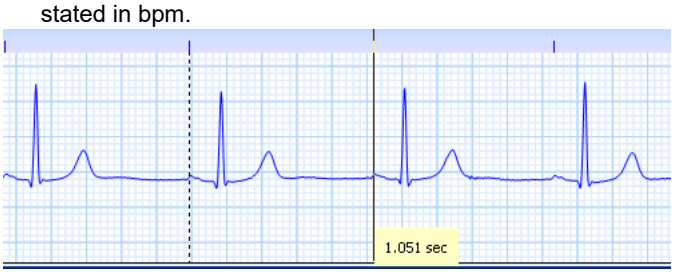
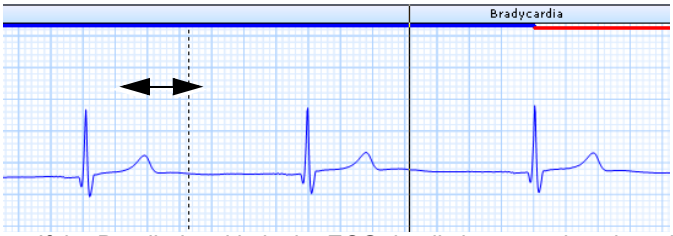
3.6.3 Toolbar

The following toolbar is displayed at the top of the screen when a recording is open.

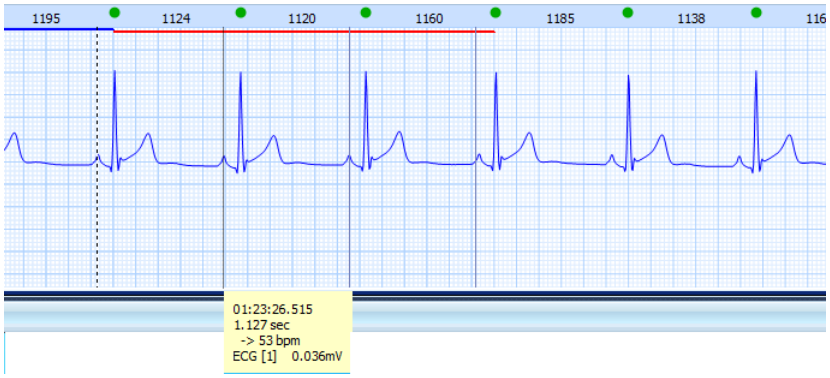
(1) **Measure tool:** Select this tool to measure distances in the ECG detail viewer (refer to HRV, page 56) and any other modules. To do so, click on the start point of the measurement and drag the mouse to the end point. A dashed line indicates the start of the measurement and the end point by a solid line; the distance is given in seconds, and the HR corresponding to the selected interval is stated in bpm.



Click and drag the left dashed line to move the two lines together, keeping the initial distance from each other.



If the Detailed tooltip in the ECG detail viewer settings is activated, the position in the recording (time), the HR corresponding to the selected interval and the amplitude (mV) at the cursor's position are also indicated, this, in addition, to the distance of the interval in seconds. Moreover, three intervals are measured at the same time.



(2) **Hand icon:** Allows you to drag the displayed section. Press the left-mouse key and drag as required.

(3) **Zoom tools:** Zooming is possible in the strip modules (ECG detail viewer, Signal viewer). The following tools are available:

– **Zoom:** A magnifying glass is displayed instead of the cursor. Click and drag the mouse over the area that you want to zoom. Click again in the zoomed area to return to the normal view.

– **Zoom in the X and Y direction:** Use these tools to zoom an area in the X-axis or Y-axis. Alternatively, press and hold the Shift key and, at the same, time mark

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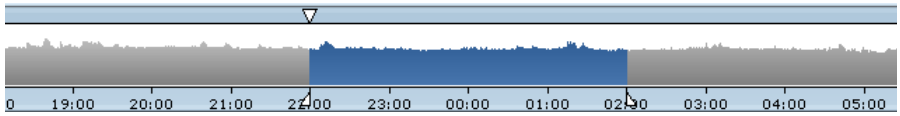
the segment with the mouse to zoom. This feature is only available in some modules, such as ECG detail and signal viewer.

– **Magnifying glass**: Click the Toolbar icon to display a Magnifying glass that enlarges the area around the mouse cursor. Click again to hide the Magnifying glass.

(4) **Show custom range/entire recording:** Select the Show custom range icon in the toolbar to select the range for display. Alternatively, for recordings that lasted several days, you can also select day 1, day 2 and upwards. In the Time navigation module, the displayed range is indicated in blue.

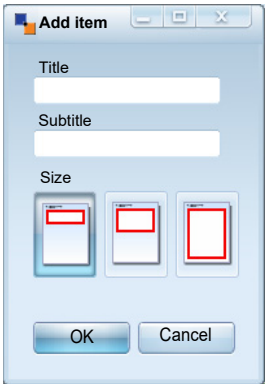


Click the Show entire recording icon in the toolbar to display the entire recording.

(5) **Position in the recording:** You can also use the interface in the toolbar 16:33:36.4 to jump to a specific point in the recording. Place the cursor in the time field and enter the requested time. Use the Arrow icons to jump to the previous/following cursor position.

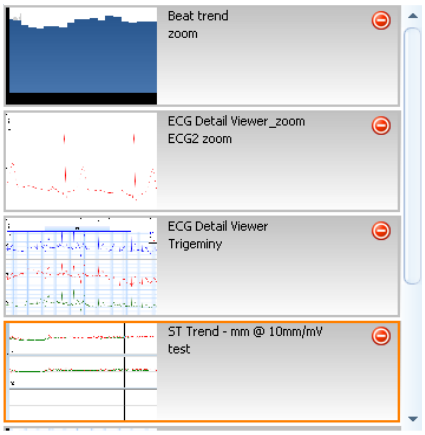
(6) **Undo/Redo:** Use these icons to undo/redo an editing action.

(7) **Print queue:** You can add selected recording segments to the report from most modules.



Select the required segment, right-click and select the menu option Add to the print queue. The following dialogue is displayed (see left).

Enter a title and subtitle and choose whether the segment should be printed on a third, half or full page.
Print queue uses the settings used in the current module, that is, amplitude (mm/mV), speed (mm/s), ECG channels, and comments.



The currently selected items are shown when you click the Print queue icon. A double-click displays a larger version of the item in a separate window. Use the red Delete icon in the top right corner to delete the item from the print queue.
Right-click on an item to rename and print the item individually.

(8) **Modules icon:** For more information, refer to Modules, page 28.

(9) **Settings icon:** For more information, refer to General settings, page 93.

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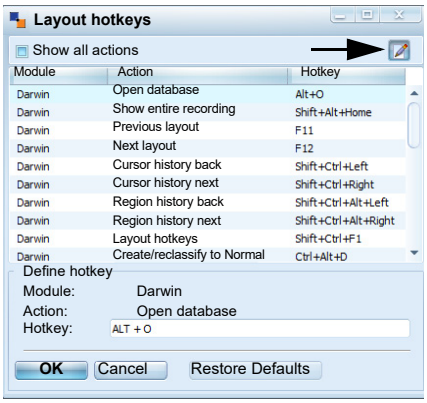
3.6.4 Selection tools

There are several ways of selecting a recording segment in the ECG detail viewer, trend, atrial analysis strip, ECHOView etc., to exclude channels/segments, and set the arrhythmia type:

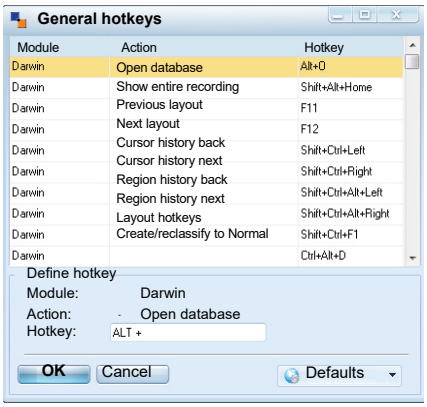
- Press and hold the Ctrl key and simultaneously mark the segment with the mouse; the segment is highlighted and selected. A menu has several options: exclude channel, set arrhythmia type, delete pacemaker spikes, etc. The menu options depend on the module.
- In the ECG detail viewer, set a marker by selecting Set marker via the right-mouse click menu; this marker indicates the start of a segment. Select Range to set the end point of a segment and select the type of arrhythmia to be assigned to the segment, or choose to exclude a channel. Alternatively, you can select the recording from the start to the current position or from the current position to the end of the recording Range (start current), Range (current end). It is especially useful to exclude, for example, the last 15 minutes of a recording which can be noisy due to loose electrodes.

3.6.5 Shortcuts



Many functions in the medilog DARWIN2 software can be controlled by mouse clicks and shortcuts. To check which shortcuts are available for the current layout, open the Settings menu and select Layout hotkeys. A dialogue with all active shortcuts is displayed. Activate the option Show all actions to display even features without a shortcut assigned.

To edit a shortcut, click the Edit icon (see left) and, assign another key combination to an action, then save the changes. The next time the dialogue is opened following shortcut changes, the Restore defaults icon is displayed. Click the Restore icon to restore the default shortcuts.



To display all shortcuts (not just for the current layout), open the Settings menu and select Configure hotkeys. A dialogue with all shortcuts is displayed. Highlight the required shortcut and assign another key combination. Save the changes.

If you open this dialogue again after having changed shortcuts, the Restore defaults icon is displayed: click this icon to discard your changes and restore the default shortcuts.

It is possible to set the current shortcuts as defaults for the entire system; however, it depends on user rights.

3.7 Log Off

Log off by clicking the **X** icon (see left). Any changes performed in the Arrhythmia strips, Beat types, and Templates, for example, are saved automatically.

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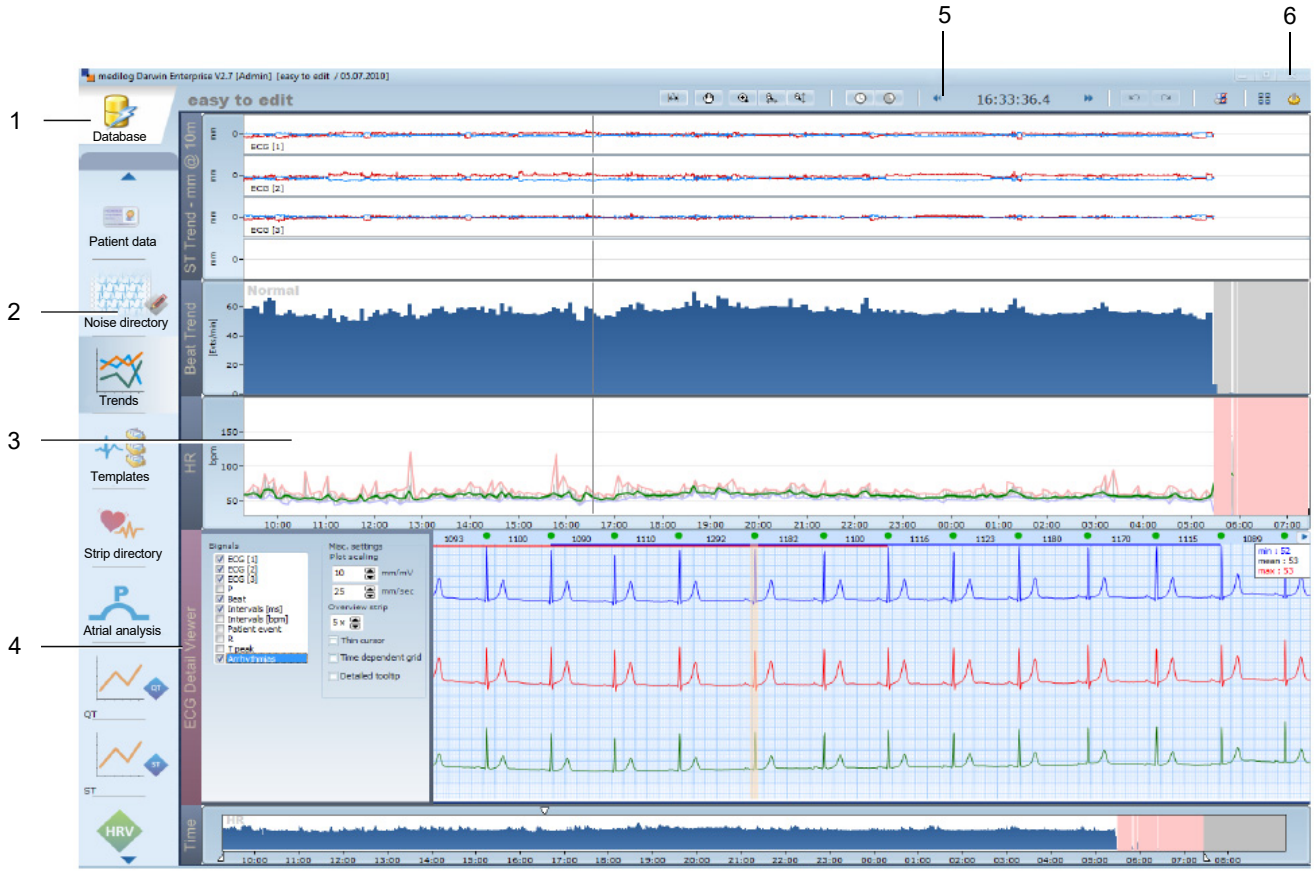
4 ECG Analysis

4.1 Example Screen

Screens vary depending on the user's rights, role and function. The following elements are present when a recording is open.



(1) **Database icon:** select this icon to return to the initial Database screen.

(2) **Workflow bar:** different workflows are set up to facilitate day-to-day work. The individual steps within the workflow are displayed on the left-hand side of the screen. For more information, refer to General workflow, page 22.

(3) **Data modules:** various data modules are displayed in the centre of the screen. The modules here depend on the workflow steps and user role (refer to Workflow settings, page 23).

(4) **Module settings:** click on the bar on the left-hand side of a module to access the module's settings.

(5) **Toolbar:** Refer to Toolbar, page 24

(6) **Exit:** Close the program by clicking the **X** icon.

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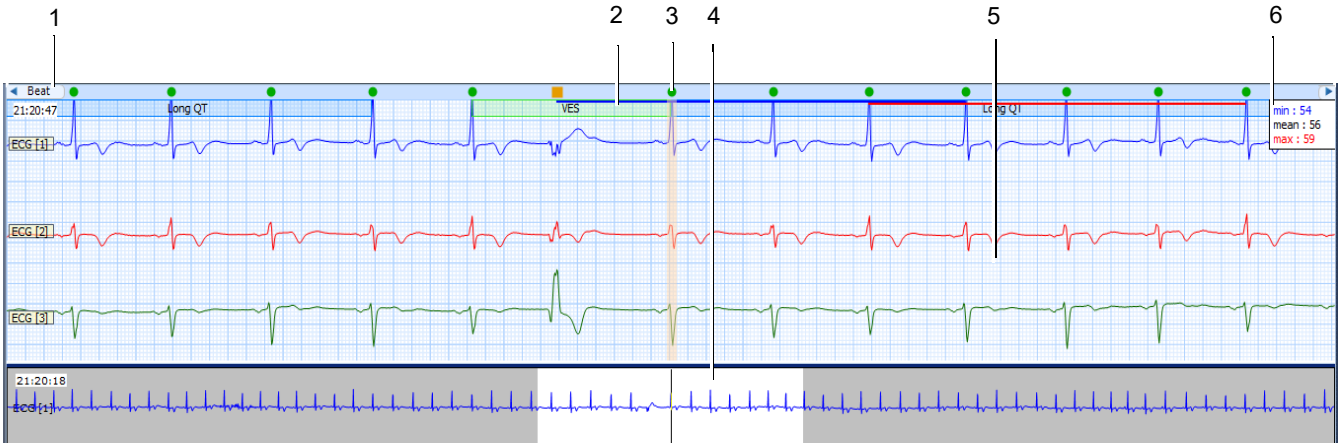
4.2 Modules

For each workflow and screen layout, different modules are used. The management of such modules is described in sections General workflow, page 22 and Workflow settings, page 23.
Below, all available modules are described in more detail.

Note that the modules available depending on the workflow and user settings, the software version (Basic, Office, Professional or Enterprise), the recorder used, and the number of ECG channels (3 or 12).
Note that changes to the recording are saved automatically when the recording is closed, the module step is changed, or the program is closed. An exception is the patient data: save the patient data by clicking Save.

4.2.1 ECG Detail viewer

This module shows the ECG curves in detail.



(1) At the top left, the additional information given in the top line is indicated here - in this example: Beat. Note that the information displayed here depends on the settings (see below). Click the black Arrow icons to jump to the next item, the next beat, etc.

(2) In this example, arrhythmias are displayed in the top line, here, VES. Normal beats are displayed as green dots, and arrhythmias as orange squares.

(3) An orange line indicates the current position in the recording.

(4) At the bottom of the module, the ECG overview is displayed. The white box indicates the current position in the recording. The scale can be changed in the settings (see below).

(5) Right-click anywhere in the ECG strip to add a segment to the print queue (refer to (7) Print queue, page 25). When you select Print or Add to print queue, you can drag the highlighted segment with the mouse to select the printed segment. Inhibited channels/segments are displayed in pink, excluded channels/segments are shown in grey. For more information on inhibited segments, refer to Full disclosure, page 52.

(6) In the top right, the segment's minimum, mean, and maximum HR value is shown. In addition, the minimum and maximum HR are indicated by blue (minimum) and red (maximum) horizontal lines at the top of the module.

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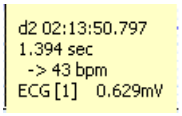
Settings

Perform the following settings:

- Signals: select the data to be displayed:
  - ECG channels 1, 2 and 3, or in case of a 12-channel recording: I, II, III, V1-V6, aVL, aVR, aVF
  - Beat: indication of N or V (normal or ventricular)
  - Patient event: display events entered by the patient during the recording
  - P, R, T peak: indication of P, R, T peak
  - Intervals: RR intervals can be shown in ms or bpm (refer to Miscellaneous Settings, page 93).
  - Arrhythmias
- Plot scaling: select the amplitude and speed of the ECG strip
- Overview strip: define the zoom of the overview strip (see the white area (4) above); for example, if 5x is selected, the displayed segment is 1/5 of the overview strip.
- Thin cursor: a thinner, black cursor is shown instead of the wide orange line
- Time-dependent grid: the grid is adapted according to the scaling.
- Detailed tooltip: instead of just the distance in seconds, this option gives you more measurement information:



  - d2: day 2 of the recording
  - Time
  - Interval measured in seconds
  - HR in bpm calculated for the interval
  - ECG channel
  - The amplitude of the ECG trace in mV at the cursor's position

Note that HR is calculated as follows:
The beat detection locates the beat and measures the RR interval. This value is used to calculate the HR according to the following formula:
Heart rate [/min] = 60 [s/min]/RR [s]

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Right-click menu options

Right-click anywhere in the ECG strip to access the following menu options:

- Show undocked: the module is displayed in a separate window
- Delete arrhythmia: delete the arrhythmia classification (this is only available with right-clicking on an arrhythmia)
- Modify arrhythmia: change the arrhythmia classification (this is only available with right-clicking on an arrhythmia)
- Set marker (see below)
- Range [marker - current]: mark the selected segment (from the marker to the current position) as follows: Remove exclusions, Exclude all channels, Exclude, Delete pacemaker spikes, Reclassify beats, or select the Arrhythmia classification.
- Range [start - current]: mark the selected segment (from the start of the recording to the current position) as follows: Exclude, Exclude all channels.
- Range [current - end]: mark the selected segment (from the current position to the end of the recording) as follows: Exclude, Exclude all channels
- Set as maximum/minimum HR of the entire recording. Note that if the maximum/minimum HR is not set manually via this setting, one maximum/minimum HR per hour is defined automatically.
- Beat meter: refer to Beat meter, page 31.
- Comment: add/edit a comment.
- Add to print queue: refer to (7) Print queue, page 25. When Add to print queue is selected, drag the highlighted segment with the mouse to select the segment to be printed.
- Print: direct printout on an external printer. When Print is selected, drag the highlighted segment with the mouse to select the segment to be printed.

You can change the beat type with a right-click on a beat (in the top line). Also, use shortcuts to reclassify the beat type (Ctrl + underlined character indicated in the menu). This option is only available if Beat is selected in the ECG detail viewer settings > Signals (see above).

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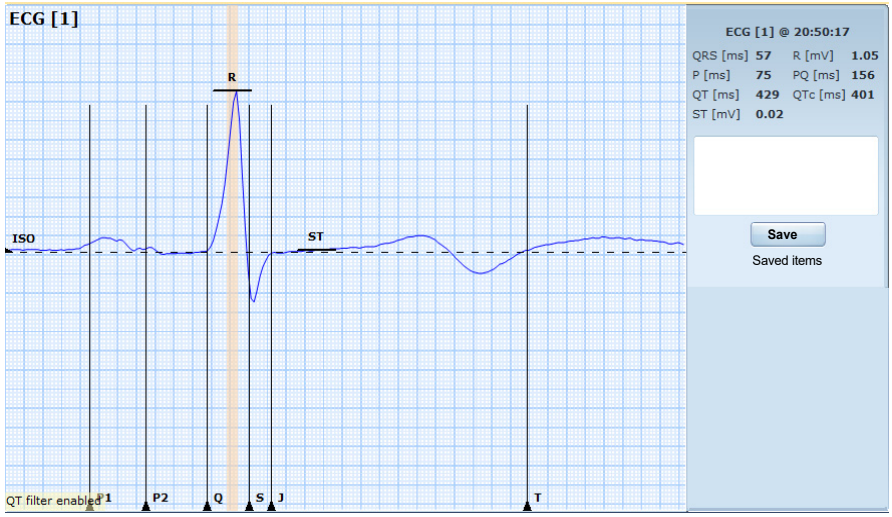
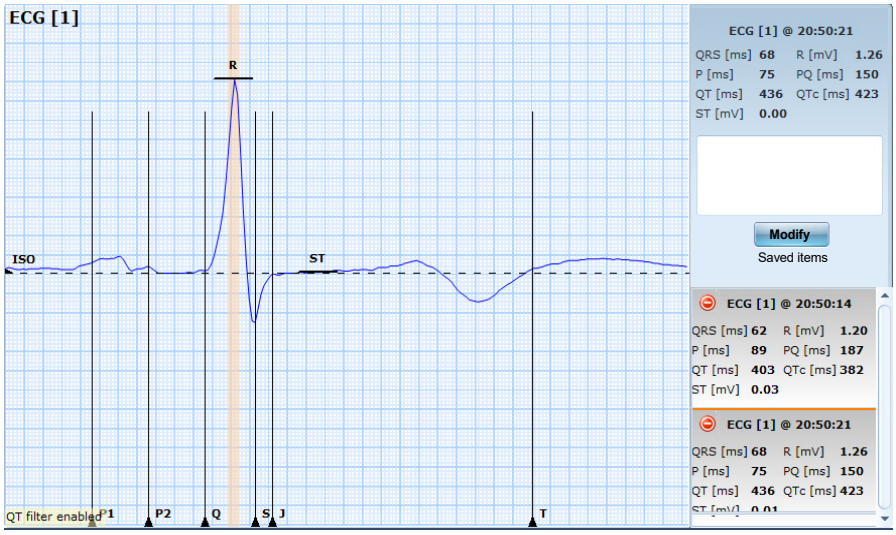
4.2.2 Beat meter

In this module, you can measure and edit QRS complexes. To do so, select a complex in the ECG detail viewer. The module then gives you a detailed view of the beat, including the values and positions for the P wave, R amplitude, J point etc.



Click and drag the measurement lines with the mouse to change the positions of the P wave etc. The values are given on the right-hand side. To save the changes, click Save. To delete the changes made to a complex, click the red Delete icon (see below).



Settings

In settings, you can select the ECG channel, the waveform's speed and amplitude, and the J point's position.

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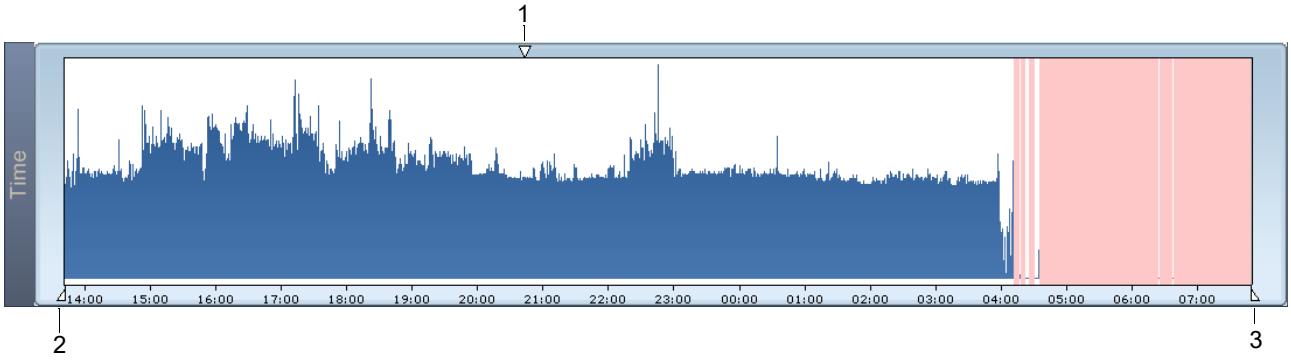
4.2.3 Time navigator



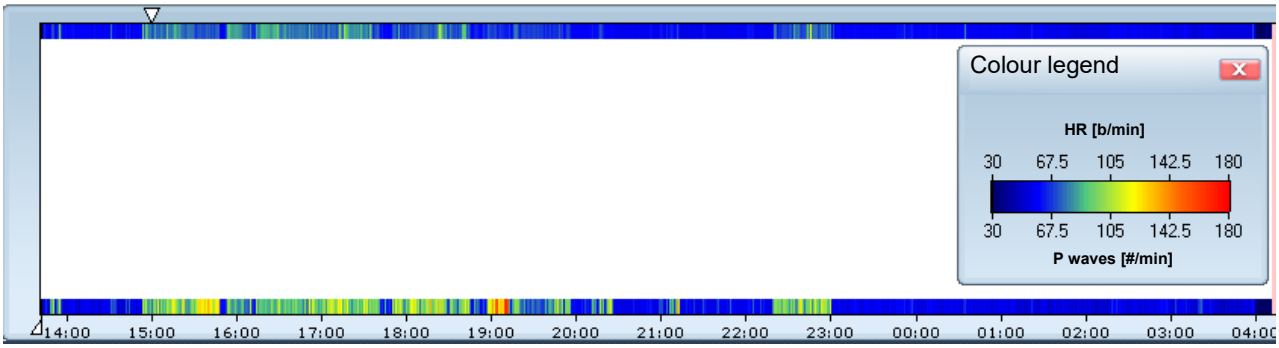
The time navigator provides an overview of the recording and shows either HR, P waves or PM events (this is defined in the settings and depends on the recorder used).
Excluded sections are displayed in light pink (see the example above, right-hand side).
The Arrow icon at the top indicates the current location in the recording (1). Drag the Arrow icons at the bottom (2 + 3) with the mouse to define the recording section for analysis. Sections that are not analysed are shown in grey.

Note that the colours described here may vary from your installation: the colours depend on the colour settings; refer to Colour Settings, page 94.

The right-click menu has the following menu options:

- Select the display range
- Set range start to ECG cursor: if this is set, only the recording segment starting at the cursor position is shown; refer to ECG Analysis, page 27, (5).
- Colour-coded trends/Legend; see below.

When a Colour-coded trend is selected, the trend data HR, P waves or PM events is displayed (see settings). Activate the Legend to display the Colour legend as shown below.



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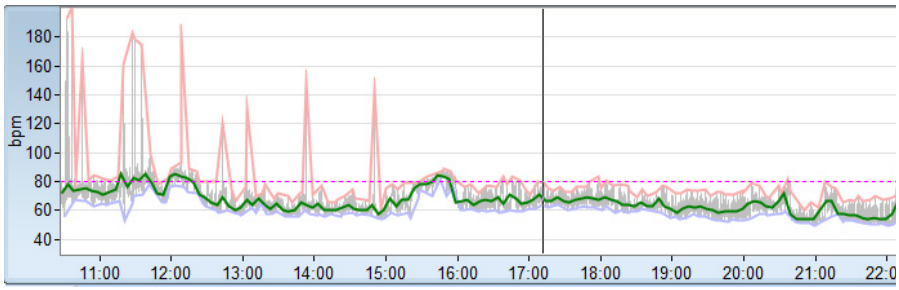
4.2.4 Range viewer

This module provides a trend overview. The signal can be defined in the settings:



In the example above, RR intervals are displayed. On the Y-axis, RR intervals are given in bpm; the timeline is shown on the X-axis. The red line represents the maximum value, the blue the minimum value and the green the mean value of a certain interval, for example, 5 minutes (see below). The original signal is displayed in grey.

Settings

- Select the signal to be displayed:
  - Respiratory frequency in cycles/min
  - Respiratory validity as a percentage. Quality index of the EDR calculation.
  - QPA: pulse-respiration quotient, the number of heart beats during one breathing cycle
  - EDR (change in amplitudes of R peak due to respiration activity)
  - HR/HR filtered
  - QT for channels 1, 2 or 3
  - QTc/QTc diff
  - QT
- Select to display the time axis, comments or show arrhythmias colour-coded at the top of the module.
- Select the scaling: mm/bpm, mm/%, mm/ms (depending on the selected signal) and sec/line.
- Smooth signal over X beats
- Minimum/maximum/mean: tick these boxes to display the minimum, maximum and mean values (see the example above) and select the averaging duration for the mean value in minutes. Minimum and maximum are the lowest/highest HR values for each 5-minute segment.
- Activate/deactivate Box plot view.
- Select Horizontal line at: select the level of a horizontal reference line; see the dotted line in the example above.

Note that the diagram presentation depends on the selected signal and the settings.

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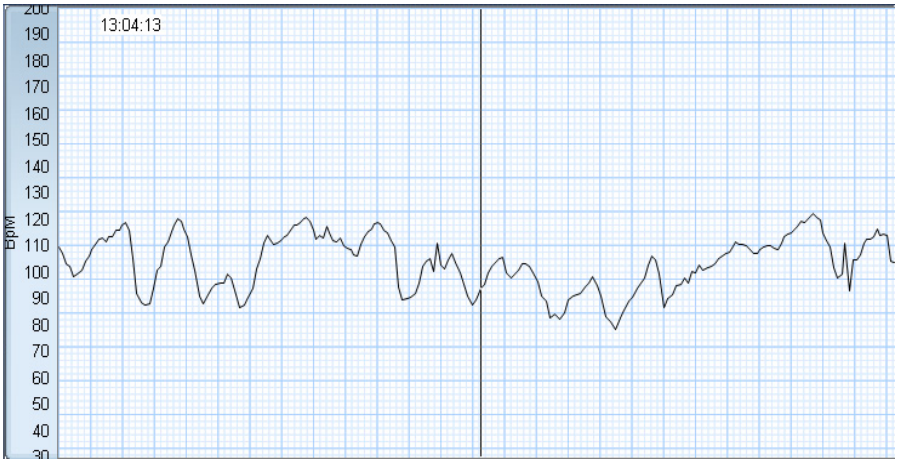
4.2.5 Signal viewer

One selected signal is displayed over the entire course of the recording, in this example, the filtered RR values:



Settings

- Select the signal to be displayed:
  - ECG, channel 1, 2 or 3
  - EDR/EDR filtered
  - HR/HR filtered
  - Respiration frequency in cycles/min
  - Respiration validity as a percentage
  - QPA: pulse-respiration quotient, the number of heart beats during one breathing cycle
  - Motion (movement signal)
    Note that the signals available depend on the recorder and the type of recording.
- Show comments
- Zoom in the direction of the Y-axis
- Set the speed and amplitude

Note that these settings vary depending on the selected signal.

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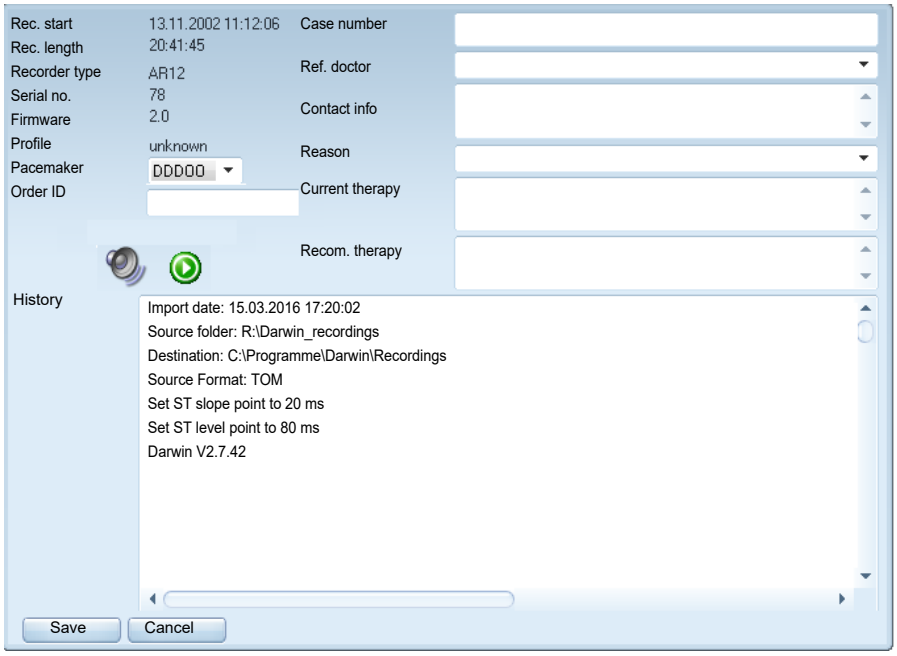
4.2.6 Recording information



The recording data module provides all data relevant to the recording:

- Recording start
- Recording length
- Recorder type, including serial no. and firmware version
- Profile: this is the recording type selected at the start of a recording
- Pacemaker: enable/disable the pacemaker channels. You are prompted to confirm and reanalyse the recording.
- Order ID: this ID is used in addition to the insurance number in connection with SCHILLER Server or HL7. Typically, the order ID is provided by the external system.
- The **Case number** (Visit ID) is a unique patient identification provided by the HIS (maximum 50 characters).
  For more information on the **Case number** (Visit ID) and validation options regarding the HIS, consult the user guide for the SCHILLER Server.

⚠ CAUTION

▲ The field **Case number** (Visit ID) must not be used to enter other types of information (for example, technician, department). Entering this type of information in the field **Case number** (Visit ID) may lead to patients being mixed up when the device is connected to the SCHILLER Server.

- Referring doctor and contact details
- Reason for referral
- Current and recommended therapy
- If available, patient data recorded via the microphone on the recorder can be played by clicking the Play icon.

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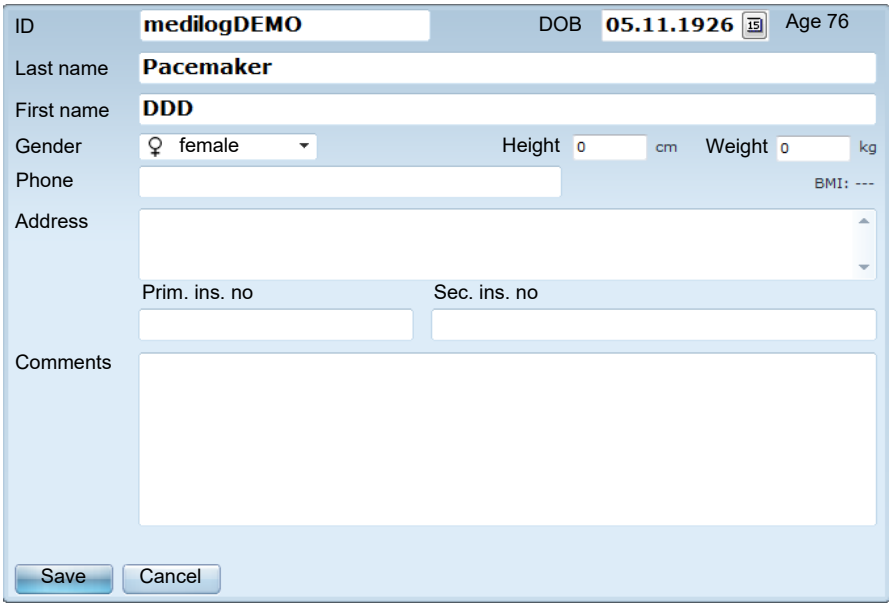
4.2.7 Patient data

Use this module to enter or edit the patient data, including ID, DOB, name, gender, height, weight, address details, insurance numbers and comments:



The labels for primary and secondary insurance numbers can be edited in the Admin tool > Extended settings > Pat. CustLabel 1/2 (refer to Local Component Setup, page 105).

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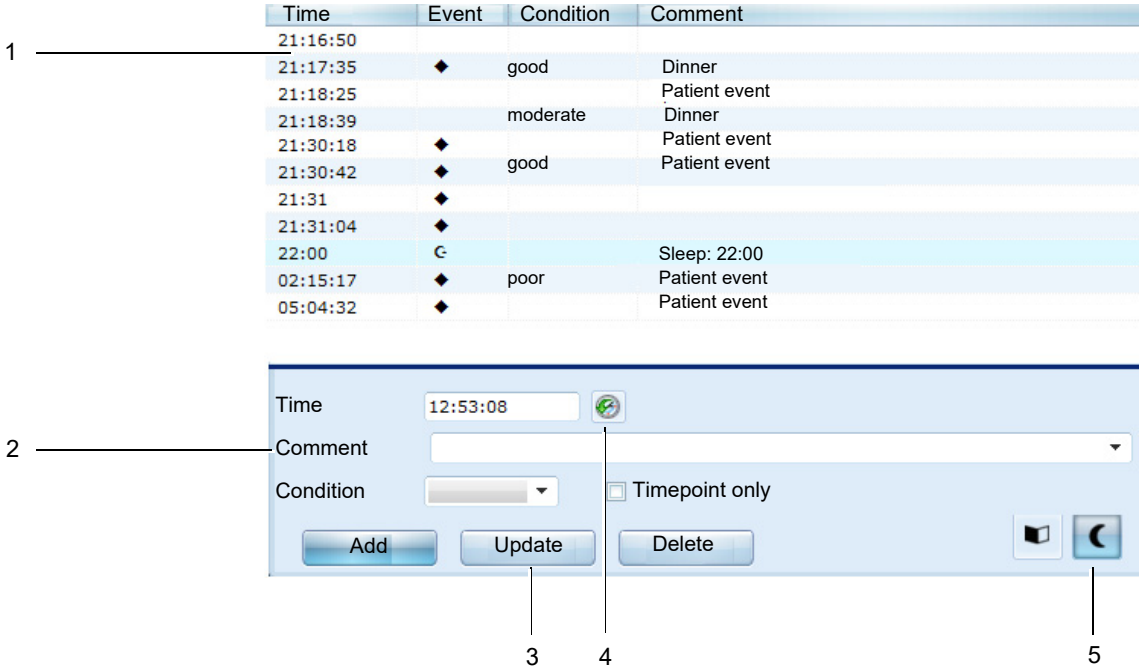
4.2.8 Patient diary

A diary can be created to provide more information on the recording and the patient's activities during the recording. The patient's activities, sleeping, computer work, and eating are entered in this diary. The diary can help judge the recording data.

The time must be entered in 24-hour format, i.e. 24:00 and not 12 PM.



(1) List of all diary entries.

(2) Add a new diary entry: indicate the start time and any comments about the patient's condition and select Timepoint only if the entry is just an event, as opposed to a longer time period.

(3) Click Add to add a new entry, Update to save changes, and Delete to delete a diary entry.

(4) Click this icon if you would like to link a patient event to a specific position in the recording (that is, the patient may have pressed the event button a couple of seconds too late; in this way, you can position the patient event correctly). To do so, select the event, click the icon (4) and then click the desired position in the recording (that is, in the ECG detail viewer) to position the event correctly. Doing so also ensures that the correct segment is displayed in the Strip directory or printed. Note that you can only reposition an event within 1 minute of its original location.

(5) Click the Moon icon to enter the sleep phase or the Book icon to enter activities during the day.

The default settings for the sleep period (Light off, Sleep, Awake) can be edited in the Admin tool > Extended settings (refer to Local Component Setup, page 105).

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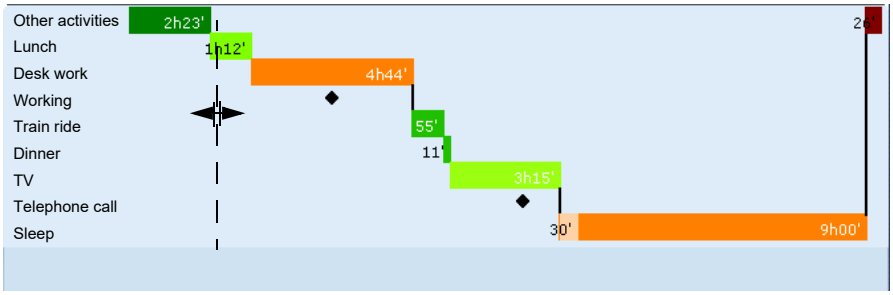
4.2.9 Patient diary graph

A graph of the patient diary can be displayed in this module.
Click the title bar on the left and select the type of display: Gantt diagram (see below) or Block diagram:



In the diagram, the diary entries are shown in colour (depending on the entered patient condition, the colour varies from red to green) and with event icons (if Timepoint only has been selected). Use the mouse to expand or shorten a diary entry (see the arrows in the illustration above).

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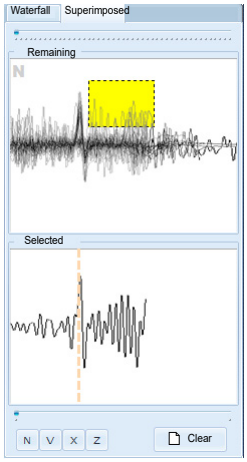
4.2.10 Template editor

The template module shows the beat morphology groups (called templates) detected by the beat analysis:

(1) List of all templates. For each template, the following information is provided:
- Classification: the highlighted template above (highlighted orange) is classified as normal beats (N).
- Right-click on a template to reclassify it or mark it as edited. Manually reclassified templates are indicated by brackets; for example, [N] instead of just N; edited templates are indicated by a green tick symbol .
- Number of beats: the number of beats contained in the template is given in the top right corner
- Toggle beats: use the Arrow icons at the bottom to jump to the next/previous beat. The beat number is shown.
- Pin icon: when the Pin icon is set the selected template remains activated and is shown in the Waterfall window; see (2) below, even if another beat in the ECG viewer is clicked.

(2) The beats of the highlighted template are displayed in this window. Select one of the tabs for display:



Superimposed: all beats are superimposed. If you wish to remove certain beats from the template, mark them by clicking and dragging the mouse over one part of the superimposed beats (see the yellow box left). The selected beat is displayed in the bottom window. You can then split that beat into a separate template by selecting a classification, N or V, or deselect by pressing Clear.

Moreover, a dotted orange line is shown in the bottom window, indicating the R peak. Move the dotted line to edit the R peak. In the dialogue shown, it is also possible to reclassify the beat.

When more than one beat is selected and displayed in the bottom window, use the slider to toggle between the beats and jump to the corresponding section of the ECG. Also, with a right-click in the top window, selecting the ECG channel to be displayed and reclassifying the template is possible.

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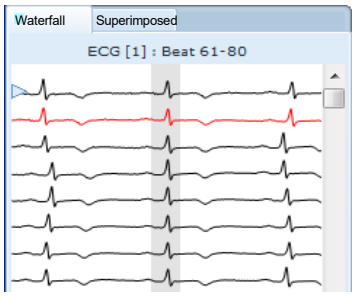
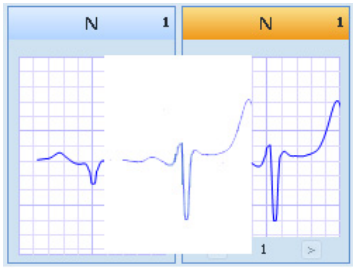


Waterfall: all beats are displayed below each other, showing one second before and after the complex.
Highlighted beats are marked red, press Ctrl or Shift to highlight several beats simultaneously. Use the scroll bar or the mouse wheel to scroll through the beats. This way, you can quickly check that all complexes have been classified correctly. If there is a complex that does not fit in the template, mark it and reclassify it via the right-click menu, or use shortcuts (press Ctrl + V to reclassify the beat as Ventricular: the shortcuts correspond to the letters used for the icons at the bottom of the screen, see (3) below).
Click and drag the Arrow icon on the left-hand side to increase the space between the individual beats.

(3) To reclassify a template, you can also highlight it in the main screen (see (1) above) and use the icons at the bottom to assign another classification:
- N: normal
- V: ventricular
- BBB: bundle-branch block
- J: junctional
- X: artefact
- Z: breaking artefact (the beats are excluded from the analysis)
- P: paced (only displayed for pacemaker recordings)
- Pa: atrial paced (only displayed for pacemaker recordings)
- Pv: ventricular paced (only displayed for pacemaker recordings)
- Pdc: dual-chamber paced (only displayed for pacemaker recordings)
- Pf: fusion paced (only displayed for pacemaker recordings)
- U1 - 4: defined by the user: to define this classification, right-click the icon and select “Edit user-defined templates”. Select the template, enter/change the name and define the classification.
- Split merged templates 



The user can manually merge templates by dragging a template with the mouse into another one.

Merged templates are indicated by the icon  . Click this icon to show the merged templates individually.

Settings
- Start/stop the reanalysis of the recording.
- Low amplitude ECG: this setting is only recommended for patients with low ECG signal amplitude. If this option is set and the signals are reanalysed. In that case, a more sensitive analysis algorithm is used to detect even low-amplitude QRS complexes, increasing the risk of muscle artefacts and noise being detected as R peaks.
- Select the channels to be analysed (3 channels)
- Set the speed and amplitude
- Show artefacts: templates classified as artefacts are displayed
- Revert order
- Group by type: templates are ordered by type
- Use filter
- Rearrange: apply the changes

For 12-channel ECGs, always select the channels with the highest quality for analysis.

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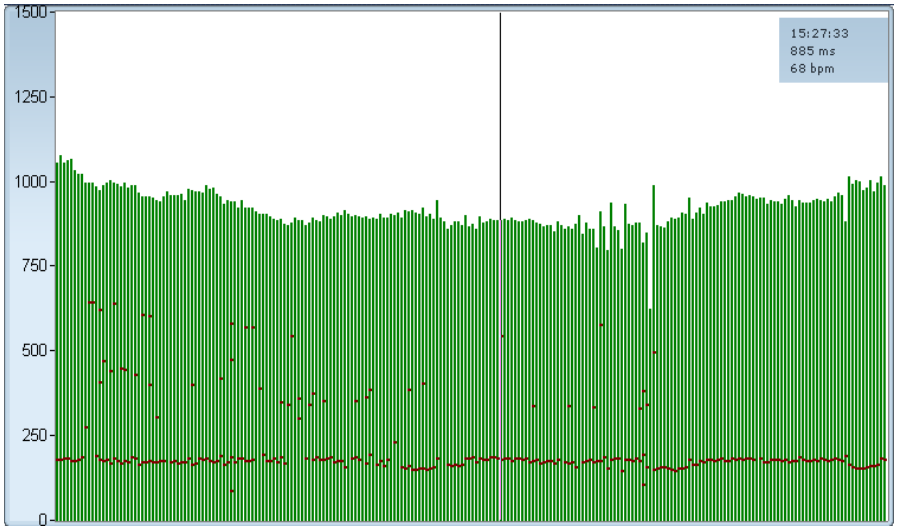
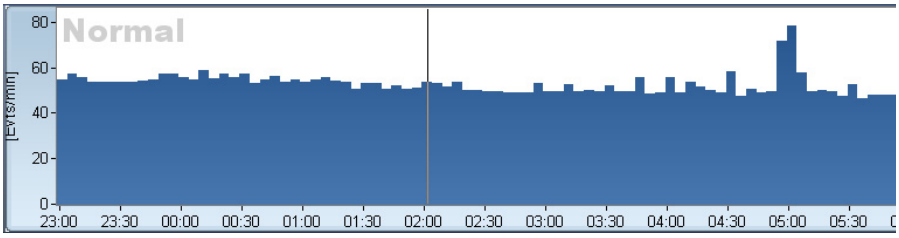
4.2.11 Tachogram

In this module, RR intervals are displayed as bars, their height reflecting the length of the interval. The peaks of the P waves are marked as red dots (depending on the recorder type used and if activated). An information box displaying the time, RR interval length and HR is shown in the top right. Ranges can be defined in the settings.



4.2.12 Beat trend

This module provides an overview of different beat trends:



This example displays the trend for normal beats (unit: events per minute). Right-click to add the segment to the print queue (refer to (7) Print queue, page 25).

Settings

Open the settings and select the type of beat to be displayed, the segment length and whether or not to show the time axis.

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4.2.13 Strip directory

In this module, all arrhythmia types detected in the recording are listed.

(1) List of detected arrhythmias with the number of events in brackets. Click on a type of arrhythmia to display the ECG strips for each event; see (2). Right-click on the list and select Show all (show all types of arrhythmias, even if no events have occurred) or Configure (refer to Arrhythmia Configuration, page 95).

(2) ECG strip for the selected arrhythmia type. These strips are sorted chronologically or according to severity (see (3) below). The four most severe strips are automatically added to the report (refer to Print reports, page 54), as indicated by the ticked boxes in the top left corner of the strip. Tick/untick any strips as required. The height of the strip can be adjusted by clicking and dragging the border of the orange box to make it narrower or wider.
Right-click on a strip to reclassify the arrhythmia, delete it or add it to the print queue.

(3) Use the icons at the bottom to order the ECG strips chronologically, by length or according to severity. Also, you can jump to the beginning/end or centre of an arrhythmia or any point of interest.

(4) Click the Arrow icon to add or modify a comment. The ECG detail viewer displays comments (refer to HRV, page 56).

Settings

- Select the ECG channel to be displayed
- Define the speed and amplitude
- Activate/deactivate beat information
- Show only strips that are marked for printing
- Reanalyse arrhythmias
- Configure the arrhythmia settings (refer to Arrhythmia Configuration, page 95)

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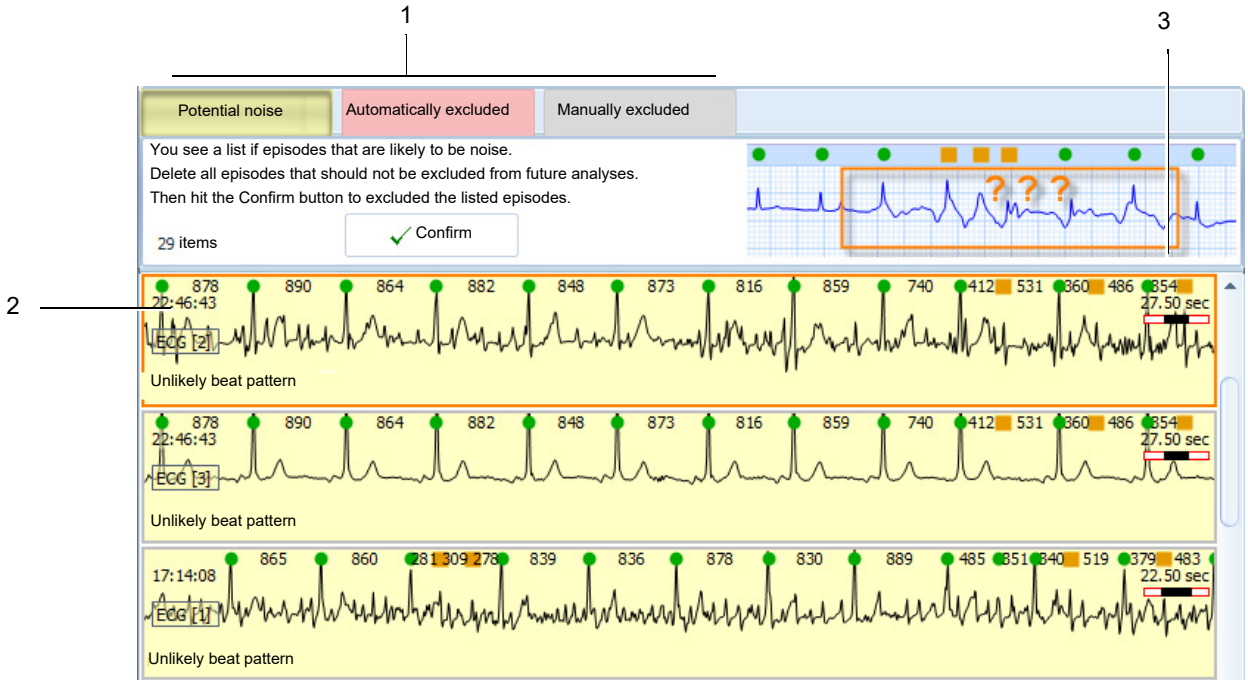
4.2.14 Noise directory

This module allows the user to analyse noisy and very long recordings more quickly and efficiently because of noisy episodes. For example, at the beginning or end of a recording, where noise may occur due to the patient moving or placement/removal of the electrodes, they are available for review in one module. Moreover, they are already classified to facilitate analysis for the user.

All ECG channels are analysed. Once all episodes have been reviewed, excluded, or included, a reanalysis needs to be run to guarantee that all displayed data is up to date. Therefore, it is recommended to perform this analysis before any other analysis steps are completed; you are prompted to reanalyse when the Confirm button is pressed:



(1) The noisy episodes are grouped into three categories, Potential noise, Automatically excluded and Manually excluded; refer to the following for more information.

(2) The selected episode is marked with an orange frame. The cursor in other modules (ECG detail viewer, Full disclosure etc.) is centred on the selected episode. For each episode, the following information is given:

- Time of occurrence
- ECG channel
- Reason for exclusion: Limits exceeded, Noisy signal, Low-amplitude ECG, Advanced pattern analysis (these are exclusions based on the analysis of R-R intervals, their variability and the ratio of normal and ventricular beats)
- Duration of episode

(3) The black bar indicates the position within the episode. Move the black bar with the mouse to scroll to the right or left.

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Potential noise

Potentially noisy episodes are grouped in this category. These episodes are highlighted yellow in the Full disclosure module.

Review the list and delete any episodes that have been categorised incorrectly and are not noisy. Mark an episode and delete it, or mark several episodes, press Ctrl while selecting with the left-mouse key and then Delete. Episodes which are deleted from this category are included again in the analysis.

Confirm the remaining noisy episodes by clicking the Confirm button or activate the right-mouse menu and selecting Confirm selected entries. By confirming noisy episodes, these are excluded from future analyses and are moved to the category Manually excluded (see below for more information).

Automatically excluded

Episodes which have been automatically excluded from the analysis are grouped here. These episodes are highlighted pink in the Full disclosure and ECG detail viewer modules.

Review the list and delete any episodes that have been categorised incorrectly and are not noisy. Mark an episode and delete it. Episodes which are deleted from this category are included again in the analysis.

Manually excluded

Episodes which have been manually excluded from analysis or have been confirmed manually are grouped here. These episodes are highlighted grey in the Full disclosure and ECG detail viewer modules.

Review the list and delete any episodes that have been categorised incorrectly and are not noisy. Mark an episode and delete it. Episodes which are deleted from this category are included again in the analysis.

Settings

- Define the speed and amplitude
- Use channel colours
- Sort by length
- Highlight beats
- Activate/deactivate the following criteria:
  - Limits exceeded
  - Noisy signal
  - Low-amplitude ECG
  - Advanced pattern analysis
  - Hide sinus rhythm episodes
  - Only complete exclusions (if all 3 channels have been excluded and no analysis is possible)

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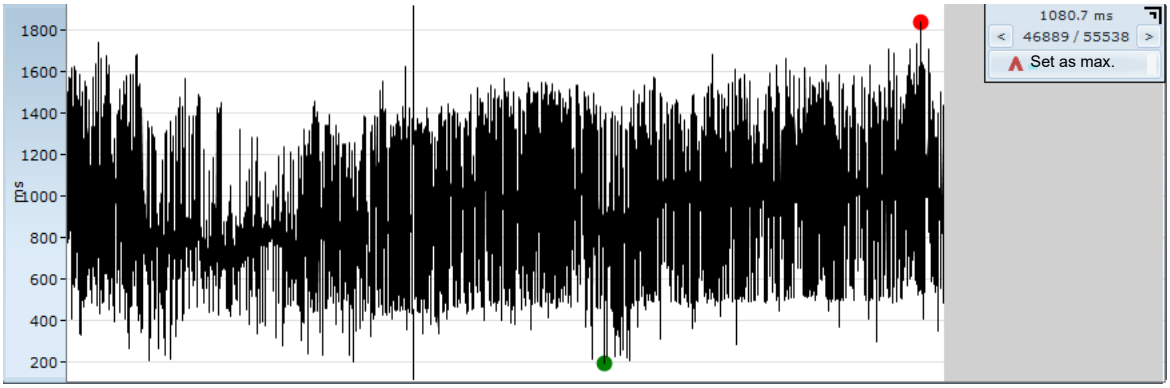
4.2.15 Minimum and maximum scanner

Use this module to quickly locate the shortest and longest RR interval or the highest or lowest HR.



In the fold-out menu, you can select:

- NN: intervals between beats classified as Normal
- RR: intervals between beats of any type
- Sin HR: HR is calculated over 3 beats, where all 3 beats must be classified as normal.
- HR: HR is calculated over 3 beats of any type (refer to Method for HR calculation, page 13).

The longest interval, or the highest HR, is marked with a red dot, and the shortest with a green dot.
For example, click on the minimum or maximum HR. If this is not a valid event, jump to the next event using the left/right arrow keys in the top right corner of the window or on the keyboard. When the correct interval is found, click the Set as minimum/maximum button.

If the minimum/maximum HR were set manually, only this ECG strip would be shown in the Strip directory for minimum/maximum HR. NN and RR intervals set here are printed on the final report on the detailed cover sheet (refer to Narrative summary, page 53).

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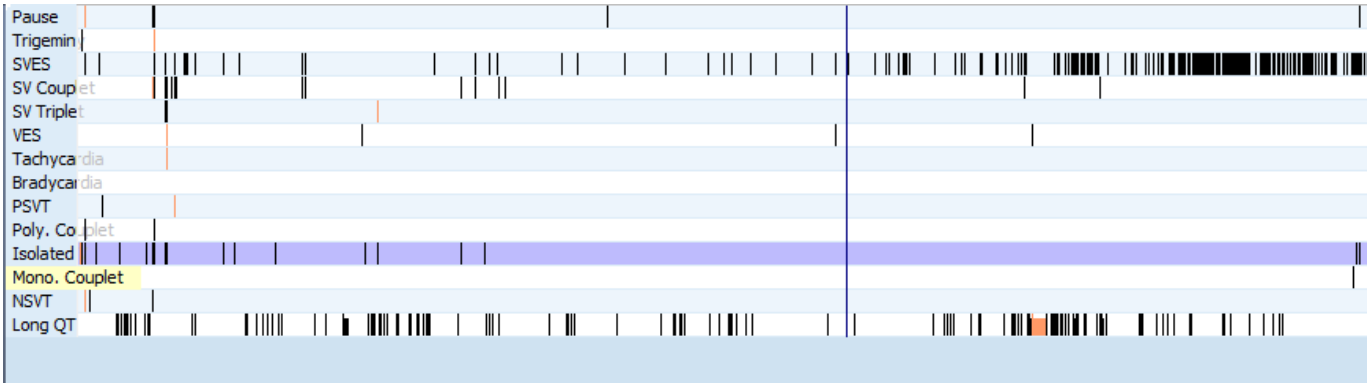
4.2.16 Arrhythmia trends

This module provides an overview of all arrhythmia events.



Click on any event to jump to the corresponding ECG segment.
The most severe events are marked orange.
Hover the mouse over the labels on the left to display the entire arrhythmia description.
By pressing Ctrl + Page up/down, you can jump to the previous/next arrhythmia within the same category.

Settings

- Select the arrhythmia types to be displayed by ticking the appropriate boxes.
- Activate the option Hide empty lines only to display arrhythmias that occur in the recording.
- If Colour-coded trends are activated, the same colours are used as in the Arrhythmia overview; refer to Arrhythmia overview, page 47; otherwise, the trends are given in black (see above).
- Show/hide the time axis.
- Show quantity: the number of arrhythmias is given on the left in brackets.

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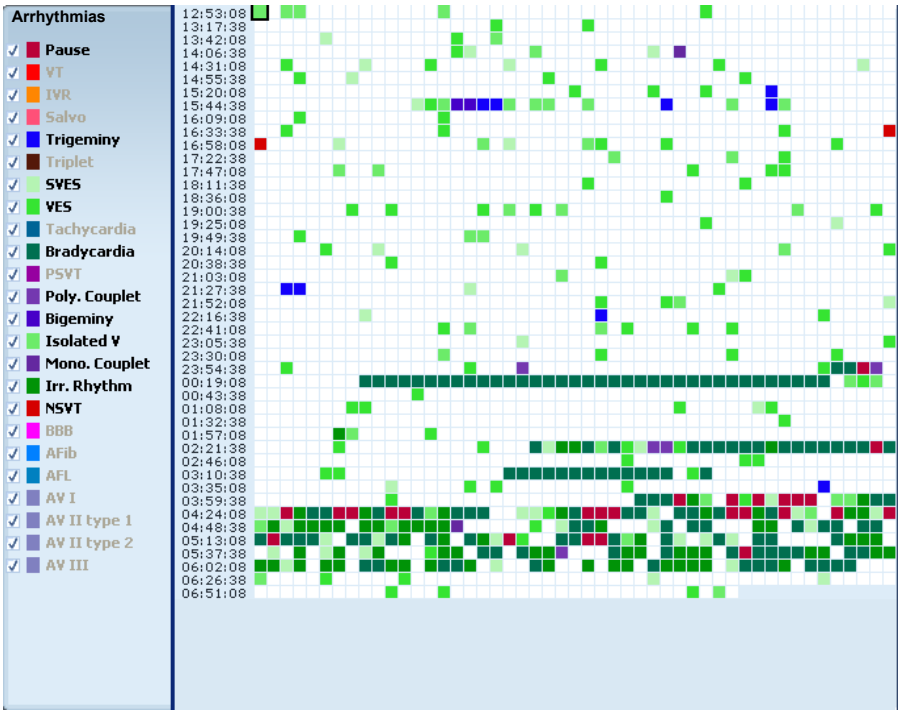
4.2.17 Arrhythmia overview

In this module, all arrhythmia events are listed in a colour-coded chart.



On the left-hand side, select the arrhythmias to be displayed. Arrhythmia types that occur in the recording are displayed in bold.

Click on an arrhythmia in the main chart to jump to the corresponding section of the ECG. Hover the mouse over an arrhythmia, and the time of occurrence is displayed. If two or more types of arrhythmia events occur in the same time span represented by one coloured box, the most severe arrhythmia is displayed according to the order of arrhythmias in the sidebar. Right-click on an arrhythmia event to add it to the print queue (refer to (7) Print queue, page 25).

Settings

Click the title bar on the left-hand side of the module to access the settings:

- Packed display: select this option to only display arrhythmias in the colour-coded charts
- Block size: select the duration represented by one colour block.

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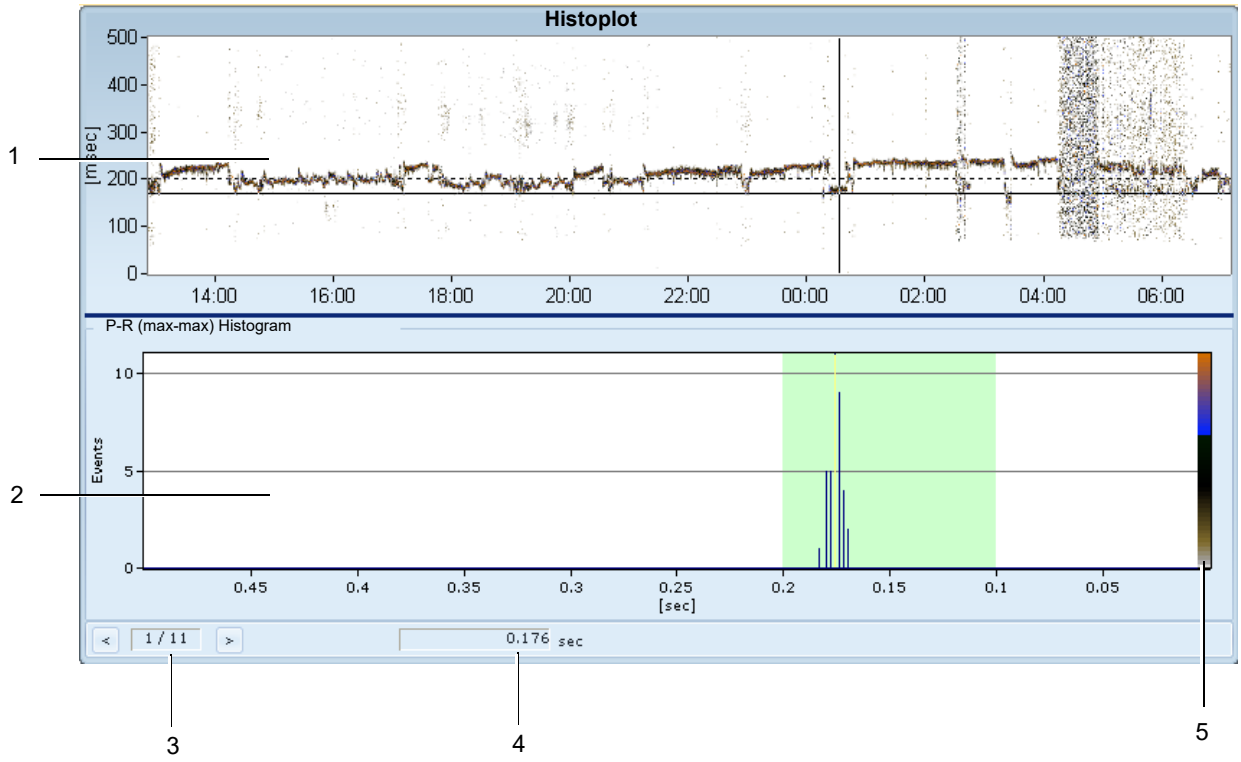
4.2.18 Atrial analysis

In this module, the PR intervals are analysed and displayed. PR intervals should be the same length; variations and longer PR intervals indicate atrial fibrillation or flutter.



(1) The Histoplot is a colour-coded representation of PR intervals throughout the recording. The dotted horizontal line shows the upper threshold value for the AV block, 200 ms. In the example above, the PR interval is below 200 ms at the cursor position and, therefore, normal. In most other sections, the PR interval is above 200 ms so that the AV block can be diagnosed. The recording section between 4 and 5 AM shows atrial fibrillation and atrial flutter between 5 and 6.30 AM.
To reclassify a segment, mark it by pressing Ctrl and simultaneously selecting the segment with the mouse; the reclassification menu is displayed.

(2) Click anywhere in the Histoplot to display the detailed Histogram. The interval duration is in seconds, and the number of intervals for each duration is shown for one segment. The segment length can be amended in the Settings menu, and the graph scale is adjusted automatically. The histogram is then colour-coded (see (5) below) and displayed in the Histoplot (1). The green area indicates the physiological range value, that is, below 200 ms.

(3) Click on a line in the Histogram to show the number of intervals. Use the arrow buttons to jump to the next/previous interval.

(4) The interval duration is given in seconds.

(5) Depending on the number of intervals, each bar of the Histogram is indicated in colour in the Histoplot (1). Low numbers are represented in blue; high numbers are in red.

Settings

In the settings, you can select the resolution, maximum PR interval, and segment length, invert the colours and show AF episodes.

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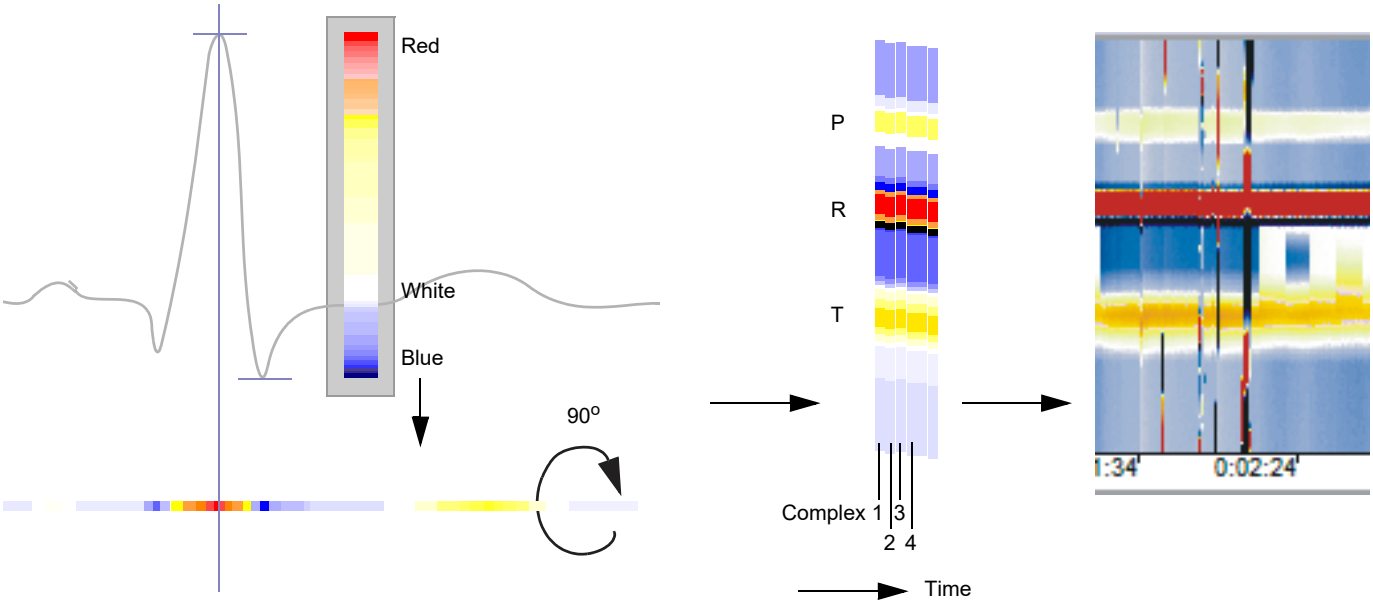
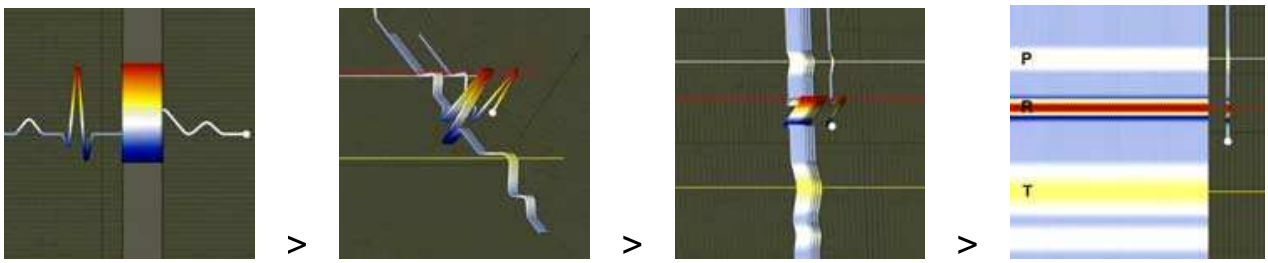
4.2.19 ECHOView

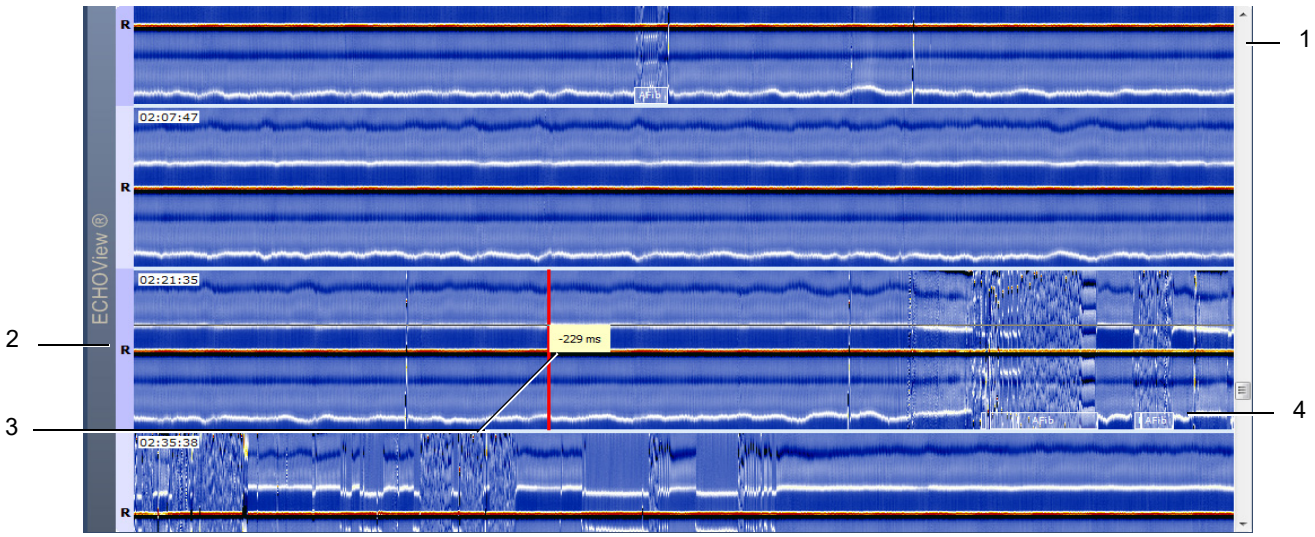
The ECHOView module provides an instant display of ECG changes during the recording. The program converts the QRS complexes to colour. It transforms the ECG data so that the user can summarise the ECG data and easily identify changes in QT intervals, PR intervals, arrhythmias and ST segments. This means that patterns not readily evident through traditional methods are displayed, allowing physicians to detect subtle temporal changes.

Method and analysis

1. Each QRS complex is coloured as follows:
   - Horizontal line (neutral isometric): white
   - Positive polarity: red scale (yellow, orange, red; the higher the voltage, the darker the red)
   - Negative polarity: blue (the lower the voltage, the darker the blue)
2. After the colour has been applied to the complex, the complex is converted to a single vertical coloured line.
3. Each QRS complex is then ordered sequentially in real-time, resulting in a multi-colour Echo display stretching from left to right.
4. Changes in the QRS complex and QRS trend are immediately visible.







(1) Use the scroll bar to scroll through the entire recording.

(2) The R peaks of the complexes are aligned, showing any changes in the QRS complex at a glance.

(3) Click anywhere in the ECHOView module to display the distance from the R peak in ms. In the example above, the distance between the P and R waves is 229 ms.

(4) Arrhythmias are detected automatically, and arrhythmia labels are given at the bottom of each row in the graph. To reclassify an arrhythmia, mark it by pressing Ctrl and, at the same time, selecting the segment with the mouse; the reclassification menu is displayed.

Settings

Access the settings and set the following:

- ECG channel to be displayed
- Time scaling (mm/s)
- Bandwidth (ms)
- Show/hide arrhythmias
- Activate/deactivate a filter
- Set contrast

To reclassify a segment or exclude a channel, select the segment by pressing Ctrl and simultaneously click and drag the cursor over the segment. Right-click to display the menu and select the arrhythmia.

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4.2.20 Tabular summary

This module provides an overview of selected arrhythmia and beat events.

Time	Min HR	Max HR	Pause	Tachy.	PSVT	Brady.	SVES	SV Couplet	SV Triplet	NSVT
Entire ...	44	64	131	1	4	14	611	1	1	5
Night	46	59	131	1	2	11	233			2
Day	44	68	98		2	3	378	1	1	3
13:41	47	59	82			1	12	1		
14:00	44	61	84			2	22			1
15:00	51	74	95				23			
16:00	56	78	98		1		34			
17:00	53	72	97				1/34			1
18:00	56	72	97							
19:00	55	67	86				66			1
20:00	50	58	80				60			
21:00	51	58	92		1		68		1	
22:00	53	66	131	1	1		37			1
23:00	49	60	78			2	41			

The number of events is given for each category and per time segment. Click any of the entries to move the cursor of the ECG detail viewer to the corresponding event. To jump to the next/previous event, use the Arrow icons. This event is then shown in the ECG detail viewer. With a right-mouse click, different scrolling options are available.

Settings

- Select the channels to be displayed:
  - HR
  - SV related (supraventricular)
  - AFib/AFL (atrial fibrillation/atrial flutter)
  - V related (ventricular)
  - Beats (number of supraventricular/N-SV/normal/ventricular beats, validity and the total number of beats).
    - **SV beats:** Beats covered by supraventricular arrhythmias (SVES, SV couplet, SV triplet, PSVT)
    - **N - SV beats** is the number of normal beats that are not part of SV beats
    - **Validity** is the percentage of beats used for calculation.
  - Paced beats (atrial/ventricular paced, DC paced, FTC, FTS), if available.
- Select the length of the time intervals
- Hide empty columns
- Show absolute values instead as a percentage
- Display type for arrhythmias:
  - Number of events
  - Duration of the arrhythmia
  - Relative duration
  - Number and duration

Method for determining a pause

A pause is 1880 ms after N and 2380 ms after V.

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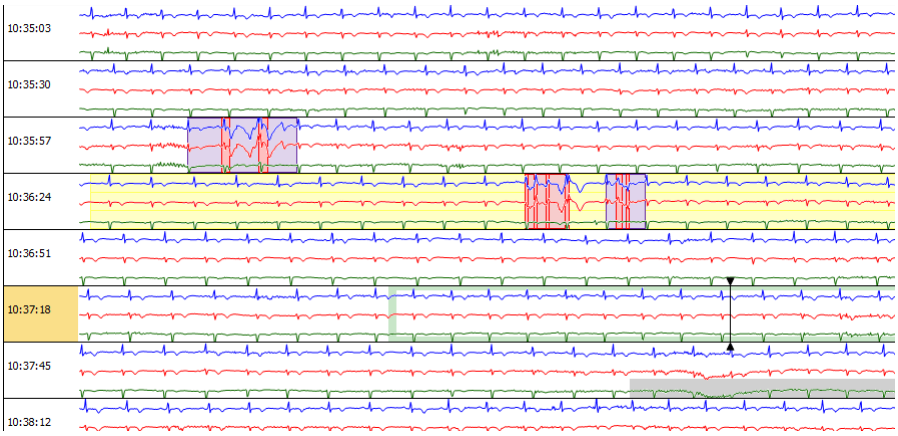
4.2.21 Full disclosure

The full disclosure module provides an overview of the entire recording:



Press Ctrl and simultaneously click and drag the cursor to include/exclude a segment, add it to the print queue, print it directly, or classify it as arrhythmia. In this example, arrhythmias (highlighted blue) and inhibited channels (highlighted grey) are displayed; note that this depends on the settings (see below).

Select Include all channels to include inhibited and excluded segments. Alternatively, to exclude/include channels, place the cursor, press the right-mouse button and select Set marker, go to the end of the segment required to highlight, select Range marker-current, and then Exclude/Include.

Inhibited segments are signals that have been inhibited automatically by the algorithm (that is, due to poor signal quality); excluded segments have been excluded manually by the user (refer to Selection tools, page 26).

Settings

Open the settings menu to select the following:

- Signals: ECG channels 1, 2 and 3
- Settings:
  - Set the amplitude (mm/mV) and speed (mm/s) for the display
  - Select the height of the individual rows (mm)
  - Activate/deactivate the following:
    Highlight beats: ventricular beats are highlighted in colour
    Show arrhythmias: all arrhythmias are highlighted; activate Colour-coded if required
    ECG detail range: the segment that is shown in the ECG detail viewer is highlighted in colour
    Show exclusions: exclusions are highlighted in colour
    Potential noise: potentially noisy segments are highlighted yellow (see above).

4.2.22 Print queue

Refer to (7) Print queue, page 25.

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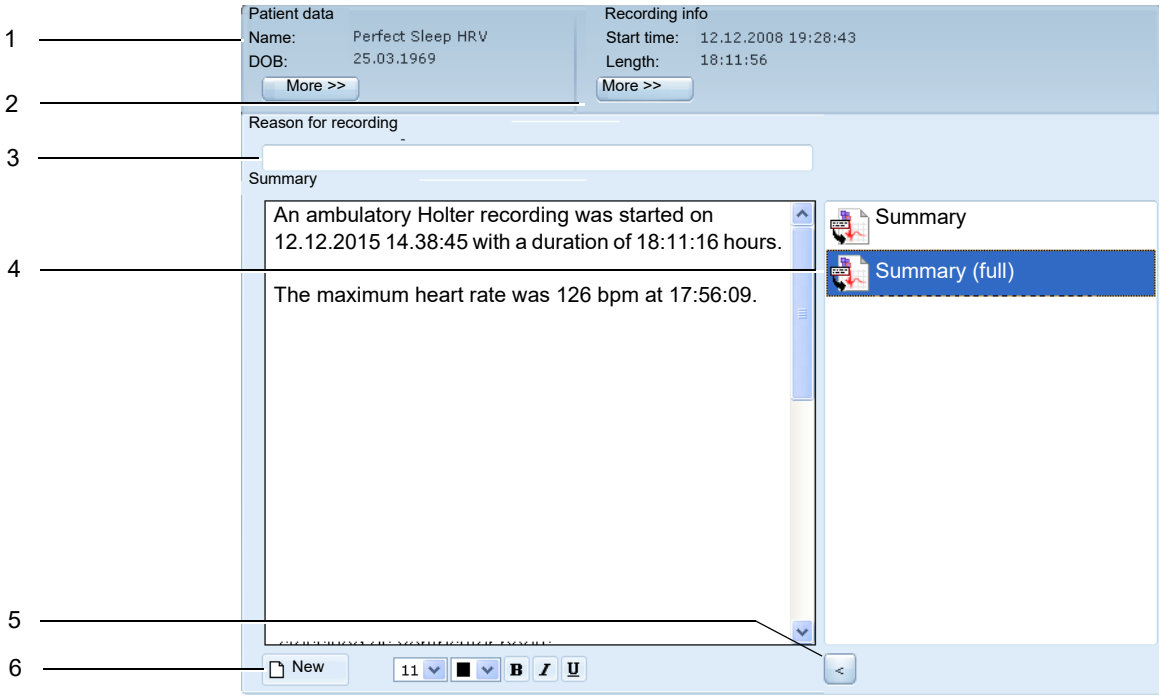
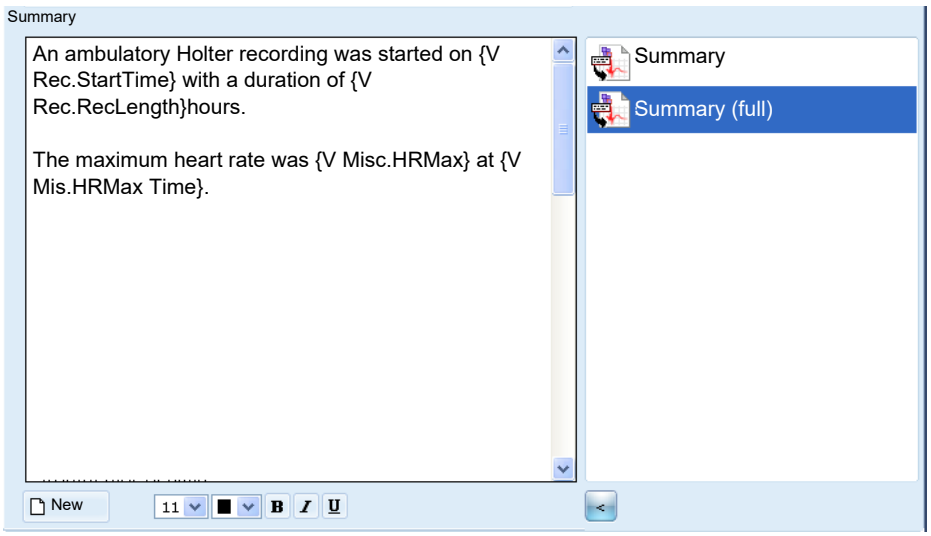
4.2.23 Narrative summary

This module provides a summary of the recording data, including the following:



1. Link to the patient data module
2. Link to the recording data module
3. Enter the reason for recording
4. Summary: select a summary template in the right-hand column and click the Arrow icon; see 5 below to add it to the summary. Press Ctrl. to select more than one item.
5. Add summary
6. In the toolbar at the bottom, you can clear the summary text (icon New) or change the font.

The text written in the summary window is automatically added to the report's cover sheet. A summary can also be created according to the user's requirements. To do so, click Ctrl when adding the text to the summary; see (4) and (5) above. The variables are displayed.

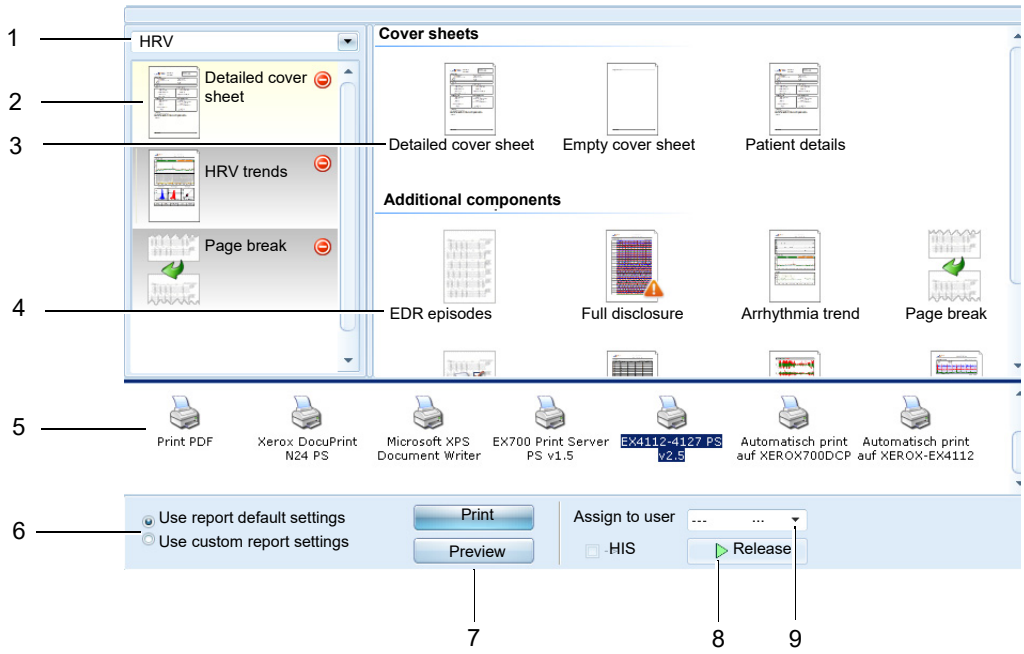


You can then edit the text and select the variables required. In this example, only variables concerning HR have been used.

▲ If a template with static text is created or overwritten, the same text is generated for all future measurements. Therefore, take special care when creating or overwriting templates.

4.2.24 Print reports

This module is used to compose reports for a recording:



(1) **Predefined reports:** Select a predefined report from this drop-down list if available. To customise predefined reports, see (2) below.

(2) **Report composition:** In this column, the selected report items are displayed. To delete an item, click the red icon. The right-click menu offers two menu options: Clear and Save composition. Select Clear to delete all items. Select Save composition to save the current report items as a predefined report; see (1) above. A dialogue is displayed, and you are prompted to enter a name.

(3) **Cover sheets:** When creating a report, select one of these cover sheets with a double-click. Right-click on a cover sheet to export it to a .rtf file (refer to Creating a custom report item, page 55). If you right-click anywhere else in this area, you can Add a custom report:
Select an.rtf file to import, enter a name and select whether the report is to be a Cover sheet or an Additional component; see (4) next page.

(4) **Additional components:** Select any of these items according to your requirements. Right-click on an item to delete or export it. Right-click anywhere else in this area to Add a custom report; see (3) above.

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Choose a Cover sheet before selecting Additional components.

The Cover sheets and Additional components are available depending on the administration settings for the user, the type of recording and the type of recorder used.

Contact your administrator if you require additional or different cover sheets or report items.

For some components, a warning icon is displayed indicating that the data content may be very large and that you should therefore consider generating a PDF report instead of printing:

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(5) **Printer:** select the printer

(6) Use default report settings/Use custom report settings

(7) Select **Preview** to view a PDF of the report or **Print** the report to the selected printer.

(8) Click **Release** to mark the recording as finished - the recording is moved into the folder Finished in the Database view, and the PDF icon indicates the finalised report (refer to Database Screen, page 14). Mark the box **HIS** to send the PDF report to the Hospital Information System (HIS), if available.

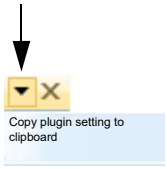
(9) **Assign** the recording to another user.

Creating a custom report item

When an existing report is exported to a .rtf file; see (3) above, the report variables are displayed:

··{T·Patient·Details}¤			
{T·Name}¤	·{V·Pat.SurName},·{V·Pat.FirstName}¤	{T·Rec.·start}¤	·{V·Rec.StartTime}¤
{T·ID}¤	·{V·Pat.CustomId}¤	{T·Length}¤	·{V·Rec.RecLength}¤
{T·Age}¤	·{V·Rec.PatAge}·{T·Date·of·birth}:·{V·Pat.DOB}¤	{T·Recorder}¤	·{V·Rec.RecorderTyp}·({V·Rec.RecorderSN}/{V·Rec.RecorderFirmware})¤
{T·Gender}¤	·{V·Pat.Gender}¤	¤	¤
{T·Address}¤	·{V·Pat.Address}¤	{T·Ref.Doc.}¤	·{V·Rec.RefDoctor}¤
{T·Phone}¤	·{V·Pat.PhoneNr}¤	{T·Contact}¤	·{V·Rec.RefDocContact}¤

{T·Reason·f.·rec}¤	{V·Rec.Reason}¤
{T·Medication}¤	{V·Rec.Therapy}¤



You can modify the report using these variables. Moreover, you can insert a screenshot of a specific module; to do so, activate the Design mode (refer to Workflow settings, page 23). Click the Triangular icon (see left) on the top right of the module and select Copy plugin settings to the clipboard. Then open the .rtf file in Word and insert (Ctrl + V) the screenshot and Save. You can import the modified .rtf file; see (3) above.

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4.2.25 HRV

HRV is the analysis of the beat-to-beat time intervals of the HR. The autonomic nervous system continuously adjusts HR in response to internal and external triggers like physical activation, stress, relaxation, recovery and sleep.

The autonomic nervous system consists of two parts:

- The sympathetic nervous system is activated to prepare the human body for physical activity.
- The parasympathetic nervous system (vagus) is responsible for relaxation/recovery periods/processes, for example, during sleep.

Internal and external rhythms influence many regulating systems of the human body. One of the most significant external rhythms is the day/night rhythm (circadian rhythm); it is therefore not surprising that many of the regulating systems in the body show a circadian rhythm; for example, the mean HR during the night is lower than during the day.

The heart is the centre of many regulating systems, meaning many body functions influence HR. This is because the heart is controlled by the autonomic nervous system, which is the controlling network of the human body.

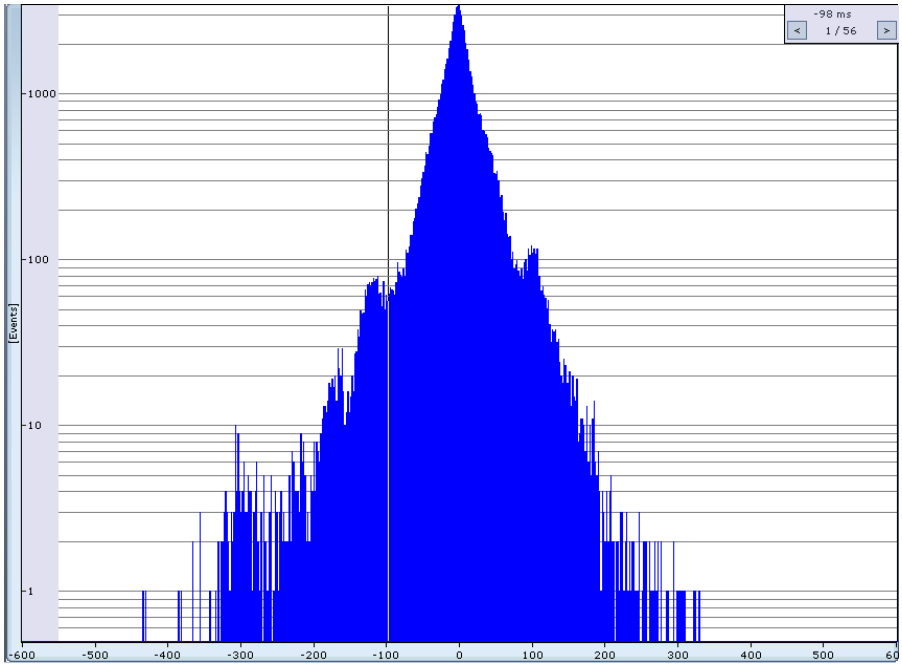
Decreased autonomic regulation is generally a sign of bad health. Using HRV analysis, it is also possible to validate the selected therapy. An increasing HRV (increasing autonomic regulation) shows that a therapy is effective.

HRV is a very efficient way to take a closer look at many regulating systems by just measuring the HR, and it can be used in a wide range of diagnostic applications, including:

- Sleep quality
- Apnoea-related hypertension
- Sleep apnoea-related cardiac arrhythmias
- Therapy validation
- Diabetic neuropathy
- Health management
- Preventive medicine
- Optimisation of physical training

HRV Differential histogram

This histogram shows the RR interval differences:



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The difference between two consecutive RR intervals is calculated and indicated in the histogram; the X-axis gives the difference in ms. The Y-axis provides the number of intervals; if you click in the histogram, the number of intervals and the difference in ms at the cursor's position are shown in the box at the top right. Click the right/left Arrow icons to jump to the next/previous RR interval displayed in the ECG detail viewer.

The smaller the blue area, the smaller the HRV.

Settings

Open this menu to perform the following settings:

- Log Y-axis: if this is activated, the Y-axis scaling is logarithmic
- Zoom to fit (horizontal)
- Resolution
- Mean value over: average the values over 1, 2, 3 or 4 intervals
- Export: export the values to a CSV file

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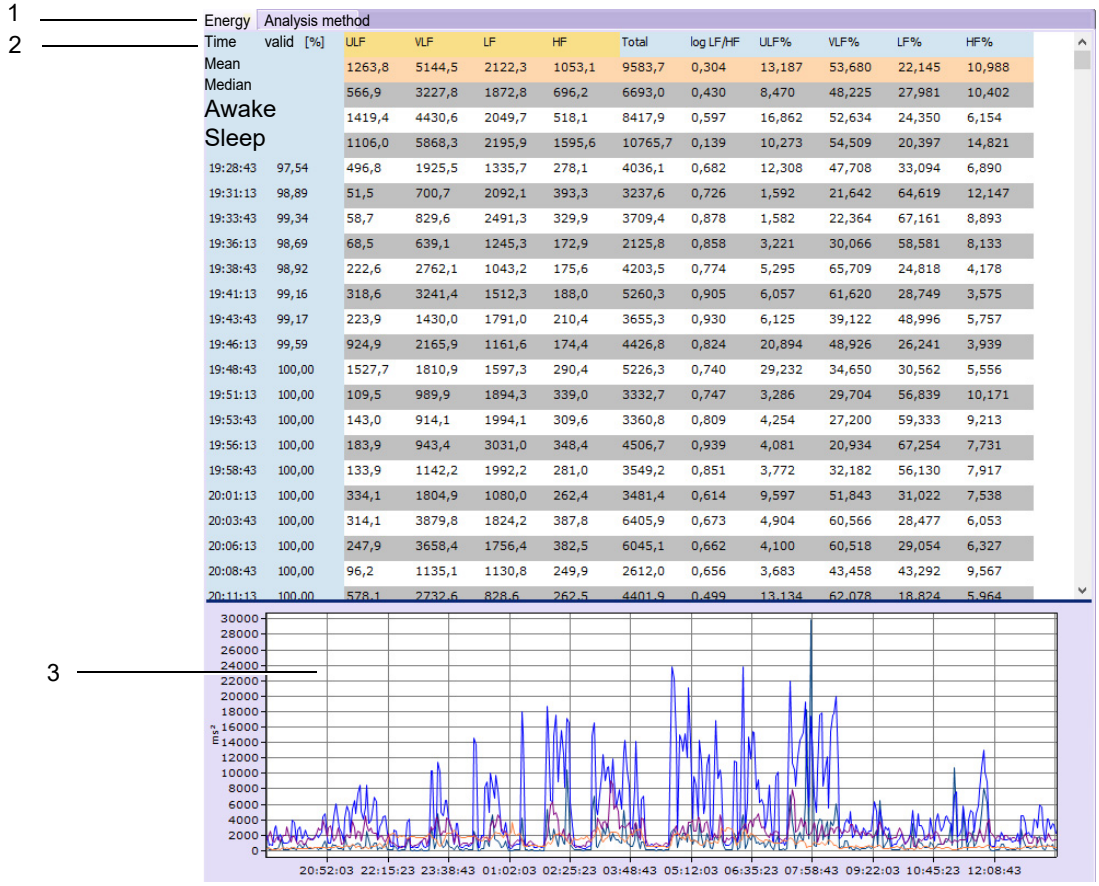
HRV Parameters and frequency domain

The common frequency domain analysis method is the application of the discrete Fourier transform to the beat-to-beat interval time series providing an estimate of the amount of variation at specific frequencies.



(1) Two tabs are available: Energy and Analysis method:
- **Energy:** values of the different HRV parameters for the frequency domain, that is, spectral power for the different frequency bands in ms^2:
- Ultra Low Frequency (ULF): frequency band 0 to 0.0033 Hz
- Very Low Frequency (VLF): frequency band 0.0033 to 0.04 Hz
- Low Frequency (LF): frequency band 0.04 to 0.15 Hz
- High Frequency (HF): frequency band 0.15 to 0.4 Hz
- Total: frequency band 0 to 0.4 Hz
- Log LF/HF: logarithm of the ratio between the spectral power in the LF and HF frequency bands.
- ULF%: the ratio between ULF and total
- VLF%: the ratio between VLF and total
- LF%: the ratio between LF and total
- HF%: the ratio between HF and total
- **Analysis method:** here, the frequency bands, including colour, are shown; the colours can be changed by clicking on the corresponding colour.

(2) Tabular view of all the values as described above

(3) Graphic representation of the spectral power values, according to the colours set in tab Analysis method. Press Shift and simultaneously click and drag the cursor to zoom a diagram segment. Click the Show entire recording icon in the toolbar (refer to Toolbar, page 24) to zoom out again.

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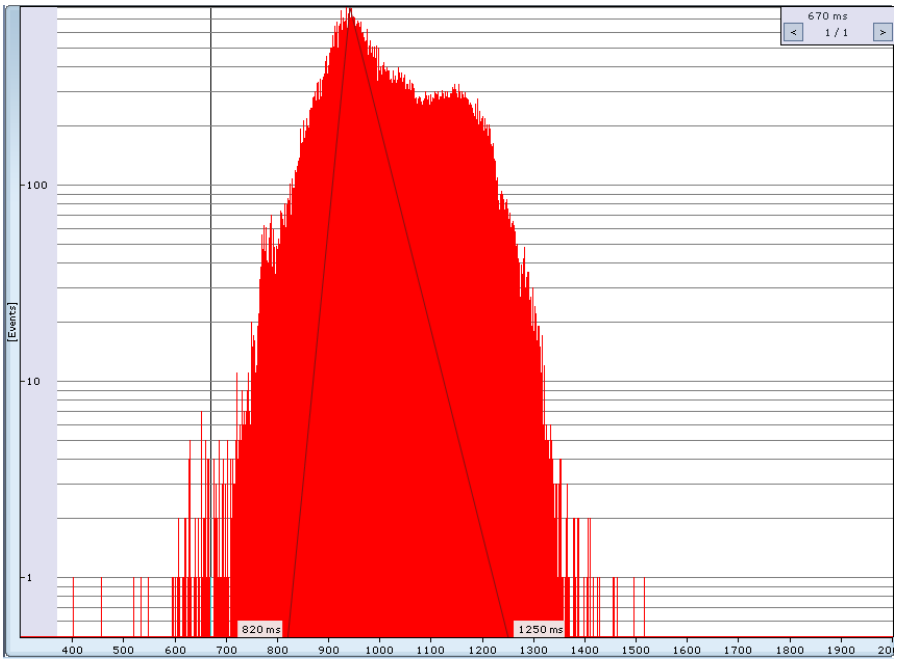
Settings

Configure the following settings:

- Configure: general HRV settings, refer to HRV Configure, page 62
- Zoom to fit: the diagram is automatically zoomed to fit all data
- Export: export the data to a CSV file

HRV Histogram

In this histogram, the RR intervals are displayed.



The X-axis gives the interval value in ms. The Y-axis provides the number of intervals; if you click in the histogram, the number of intervals and the interval value in ms at the cursor's position are shown in the box at the top right. Click the right/left Arrow icons to jump to the next/previous RR interval displayed in the ECG detail viewer.

Settings

In the settings menu, you can configure the following:

- Log Y-axis: if this is activated, the Y-axis scaling is logarithmic
- Show TINN: display the TINN curve, a geometric measurement of the Triangular index of the NN time distribution (baseline width). That is the baseline width of the triangular interpolation of the highest histogram peak of all NN intervals.
- Resolution
- Mean value over: average the values over 1, 2, 3 or 4 intervals
- Export: export the data to a CSV file
- Configure: general HRV settings; for more information, refer to HRV Configure, page 62

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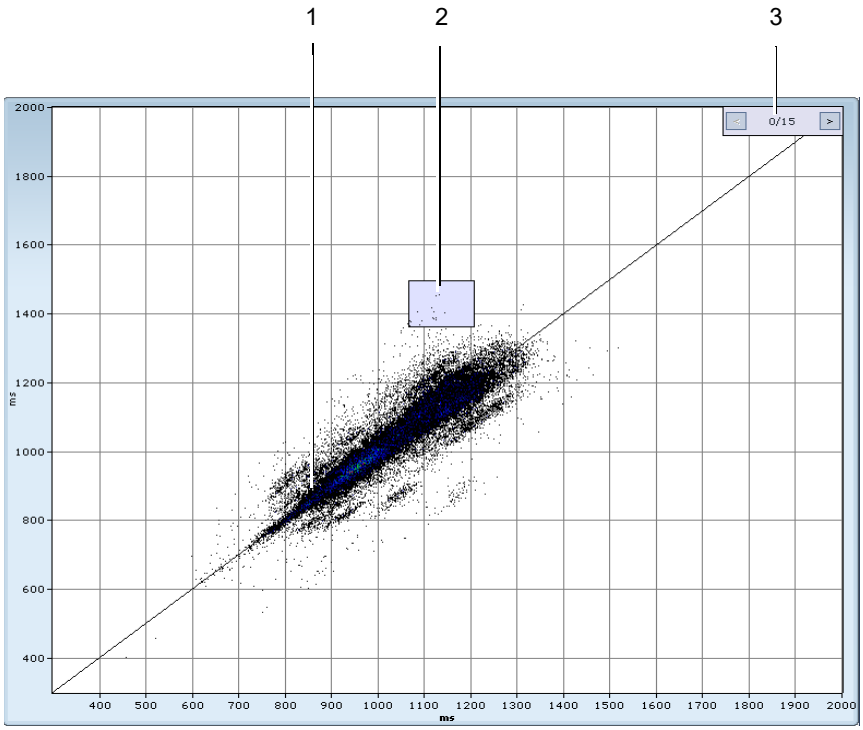
HRV Scatterplot

The scatterplot is also known as the Lorenz plot and is a two-dimensional histogram.



(1) Each dot represents two consecutive RR intervals: the first interval determines the position on the X-axis (horizontal), and the second interval the position on the Y-axis (vertical). The lower the HRV, the narrower the shape of the diagonal pattern.

(2) In this module, a magnifying lens is displayed instead of a cursor. Click and drag the magnifying lens to select an area and all intervals located in this area. Click anywhere in the module to deselect.

(3) The number of selected intervals is displayed at the top right. Use the arrow keys to jump to the next/previous interval. The interval is shown in the ECG detail viewer and other modules, for example, the HRV spectrogram.

Settings

The following settings are available:

- Resolution setting
- Controls: jump to the previous/next selected interval

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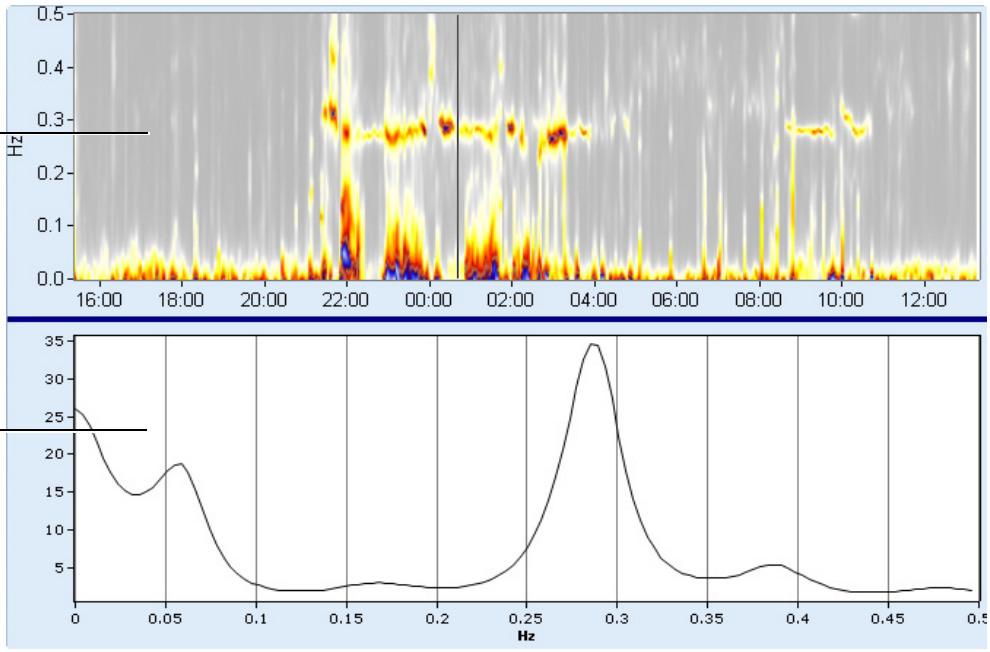
HRV Spectrogram



(1) The HRV Power Spectrogram (Fire-of-Life) is displayed at the top. In the HRV Spectrogram, each spectrum (power ms2) is drawn as a vertical colour-coded line along the time axis. The colour pixels in the Y-axis represent the specificity in the relevant frequency bands. The X-axis represents the duration of the entire recording. Grey shades are low power values; yellow shades are middle-range power values; blue to white shades are higher in the relevant frequency band. Use the right-click menu to add to the print queue.

(2) The power spectrum (in ms^2) at the cursor's position is displayed in this graph. The frequency is given at the bottom. Right-click to scale the graph and add it to the print queue.

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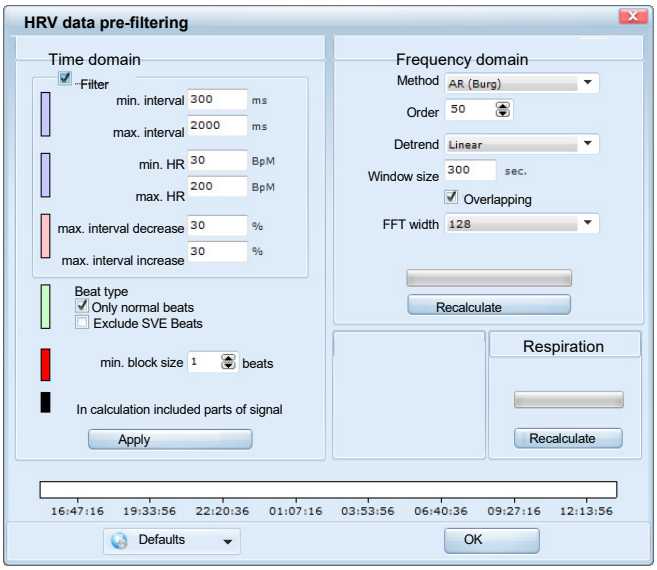
HRV Configure

Click the title bar on the left-hand side of the module to access the settings.



The settings menu also allows this dialogue from all other HRV modules.

Perform the following settings, if necessary:

- Time domain:
  - Activate/deactivate the filter and set the filter limits for interval length, HR and interval decrease
  - Beat type: only show normal beats; Exclude SVE beats
  - Select the minimum block size
  - Click Apply to apply the settings
- Frequency domain:
  - Method: select AR Burg or FFT Welch method:
    - FFT (Welch): the spectral estimator is calculated according to Welch's method
    - AR (Burg): the spectral estimator is calculated based on Burg's autoregressive model. For this option, the model order can be restricted (setting Order).
  - Detrend: select Linear, Mean or None; this refers to the detrending method of the HR. When the Mean is selected, the Mean value is subtracted. When Linear is selected, the HR trend is approximated by a line and then subtracted.
  - Window size: select the recording section in seconds. The spectral estimator is calculated individually for each section and displayed as a spectrogram (Fire-of-Life).
  - Overlapping: tick this option to overlap the recording sections for the calculation of the spectral estimator.
  - FFT width: this option is used to smooth the spectral estimators: the spectral estimator of a recording section is calculated from several spectral estimators within this section. The smaller this setting, the smaller the frequency resolution and the higher the smoothing effect.
  - Recalculate: recalculate the HRV data
- Respiration: recalculate the respiration signal
- Reset to system defaults/Reset to factory defaults/Save as system default
- At the bottom, the entire recording is displayed, and the included/excluded parts are shown in colour (see the colours in the time domain above).

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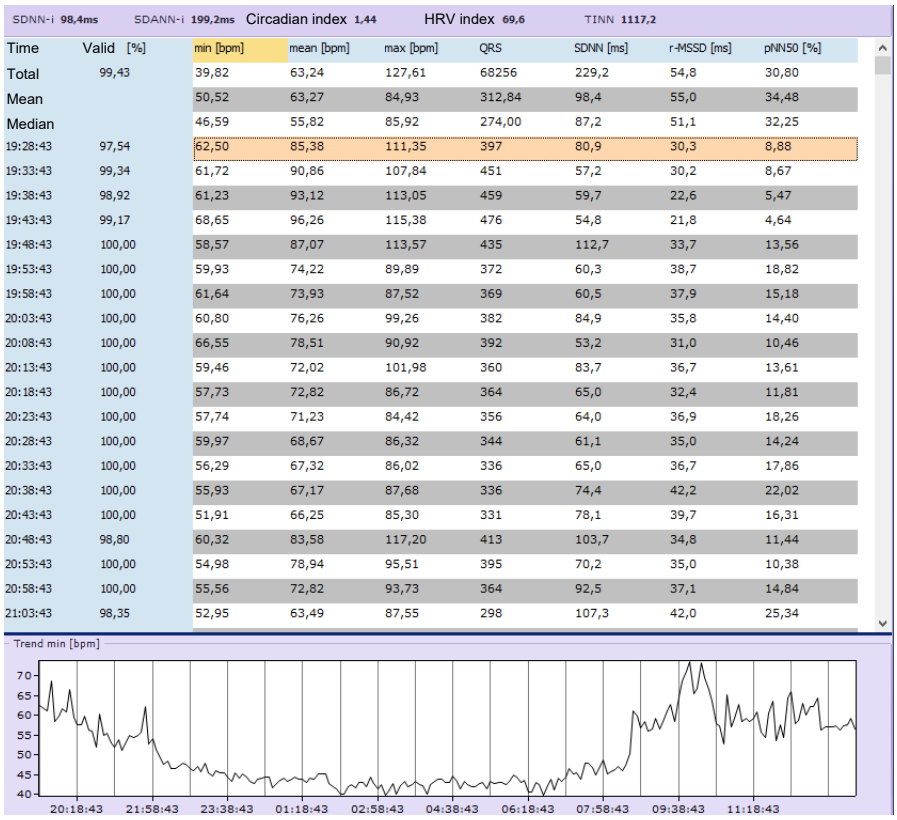
HRV Tabular summary



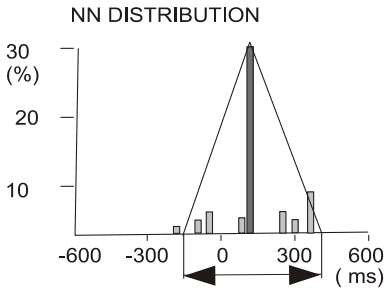
Time	Valid [%]	min [bpm]	mean [bpm]	max [bpm]	QRS	SDNN [ms]	r-MSSD [ms]	pNN50 [%]
Total	99,43	39,82	63,24	127,61	68256	229,2	54,8	30,80
Mean		50,52	63,27	84,93	312,84	98,4	55,0	34,48
Median		46,59	55,82	85,92	274,00	87,2	51,1	32,25
19:28:43	97,54	62,50	85,38	111,35	397	80,9	30,3	8,88
19:33:43	99,34	61,72	90,86	107,84	451	57,2	30,2	8,67
19:38:43	98,92	61,23	93,12	113,05	459	59,7	22,6	5,47
19:43:43	99,17	68,65	96,26	115,38	476	54,8	21,8	4,64
19:48:43	100,00	58,57	87,07	113,57	435	112,7	33,7	13,56
19:53:43	100,00	59,93	74,22	89,89	372	60,3	38,7	18,82
19:58:43	100,00	61,64	73,93	87,52	369	60,5	37,9	15,18
20:03:43	100,00	60,80	76,26	99,26	382	84,9	35,8	14,40
20:08:43	100,00	66,55	78,51	90,92	392	53,2	31,0	10,46
20:13:43	100,00	59,46	72,02	101,98	360	83,7	36,7	13,61
20:18:43	100,00	57,73	72,82	86,72	364	65,0	32,4	11,81
20:23:43	100,00	57,74	71,23	84,42	356	64,0	36,9	18,26
20:28:43	100,00	59,97	68,67	86,32	344	61,1	35,0	14,24
20:33:43	100,00	56,29	67,32	86,02	336	65,0	36,7	17,86
20:38:43	100,00	55,93	67,17	87,68	336	74,4	42,2	22,02
20:43:43	100,00	51,91	66,25	85,30	331	78,1	39,7	16,31
20:48:43	98,80	60,32	83,58	117,20	413	103,7	34,8	11,44
20:53:43	100,00	54,98	78,94	95,51	395	70,2	35,0	10,38
20:58:43	100,00	55,56	72,82	93,73	364	92,5	37,1	14,84
21:03:43	98,35	52,95	63,49	87,55	298	107,3	42,0	25,34

In this table, HRV parameters of the time domain analysis are displayed for each 5-minute time segment, as well as over the entire recording:

- Minimum/Mean/Maximum (bpm): minimum/average/maximum HR in bpm
- QRS: number of QRS complexes
- SDNN (ms): standard deviation of all analysed NN intervals, usually over 24 hours
- r-MSSD (ms): square root of the mean of the sum of the squares of differences between adjacent NN intervals
- pNN50 (%): percentage of adjacent NN intervals differing by more than 50 ms
- Valid (%): percentage of intervals used for the analysis

In addition, the following values are shown above the table:

- SDNN-i (ms): mean of the standard deviations of all NN intervals for all 5-minute segments of the entire (24-hour) recording.
- SDANN-i (ms): standard deviation of all Mean values of the time windows (the recording is split into time windows, but then the mean value of each time window is calculated. SDANN-i shows the standard deviation of these mean values).
- Circadian index: the ratio between the average HR at night and day.
- HRV index: heart rate variability triangular index. A geometric measurement gives the total number of intervals divided by the height of the histogram of all NN intervals.
- TINN: A geometric measurement of the Triangular index of the NN time distribution (baseline width). That is the baseline width of triangular interpolation of the highest histogram peak of all NN intervals.



At the bottom of the module, the trend of the selected value is displayed in the above example, minimum HR.

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Settings

In the settings menu, you can select the window width (the length of the time segments), export the values to a CSV file or reanalyse the data.

Moreover, you can select how the mean value is calculated:

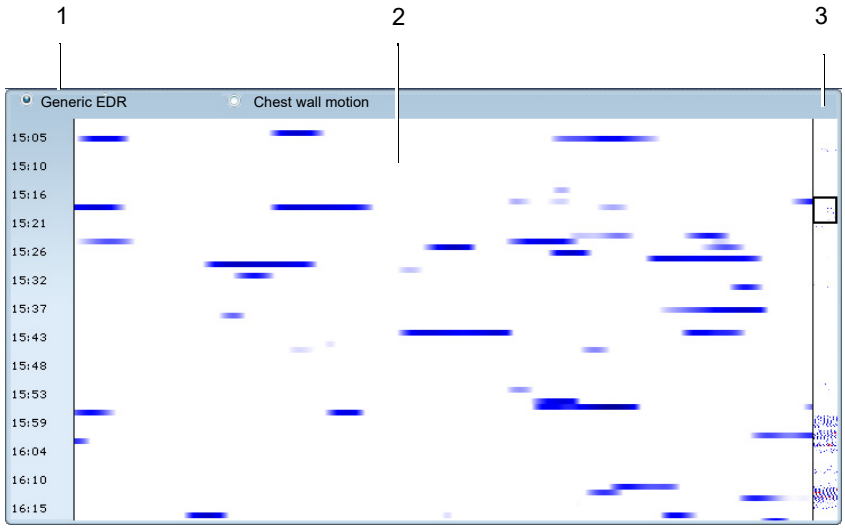
- fn(Mean(x))
- Mean(fn(x))

HRV Diary summary

Here, the HRV tabular summary is given, and the activities are entered in the patient diary instead of in the 5-minute time segments (see the tabular summary above).

4.2.26 EDR Overview

This module provides an overview of EDR episodes of the recording (EDR = ECG-derived respiration, that is, the change in amplitudes of R peak due to respiration activity)



(1) Select Generic EDR (shown in blue) or Chest wall motion (shown in black).

(2) In the middle section of the module, suspected EDR episodes are displayed along with the time scale. Click on a strip to jump to the corresponding ECG segment.

(3) Use the overview section on the right-hand side to jump to the required section of the recording.

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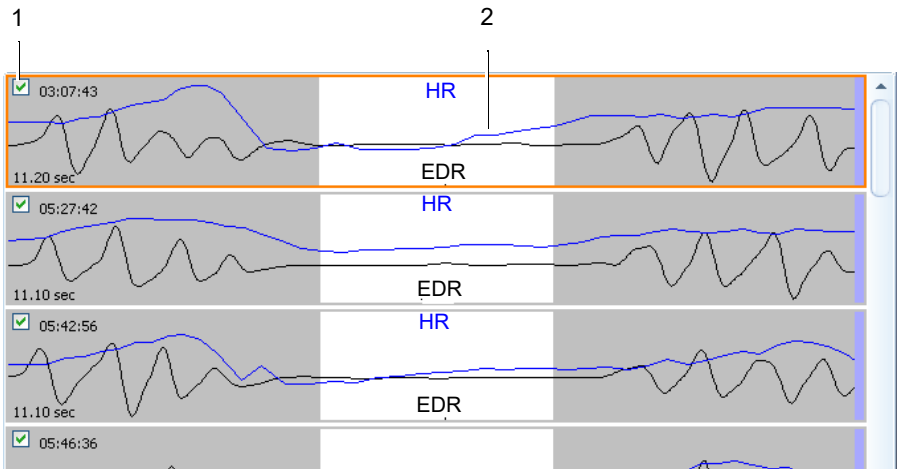
4.2.27 EDR Episodes

This module provides a different overview of potential EDR episodes of the recording (as per settings defined in the module EDR overview, see above), displaying the respiration and HR curve for the EDR episode:



The strips with potential EDR episodes are listed according to severity: length. In the middle section of the strip, the EDR episode is highlighted white (2). The HR curve is blue, and the respiration curve is black.

The four most severe episodes are automatically selected to be included in the report (1). Select/deselect any episodes by ticking the corresponding box. In the settings, you can choose to show deleted entries. If available, the SpO_2 value is also given here (refer to SpO_2, page 91).

4.2.28 EDR Configuration

The following settings are available:

- Calculate the signals: perform the calculation when settings have been modified
- Sensitivity: select the sensitivity for Chest wall motion (black) and the minimum EDR episode length in seconds. The values for sensitivity do not have a measuring unit and need to be set so that only segments with actual EDR episodes are displayed.
- Minimum EDR episode length in seconds
- EDR index: this index is calculated as follows: number of detected EDR episodes divided by the number of hours of sleep. This index is adjusted automatically when settings are modified.
- Found EDR episodes: the number of EDR episodes over the entire recording.
- Click the title bar on the left to export the overview data to a CSV file. The overview data file contains the following information, absolute start time (time), relative start time (seconds from the start of the recording) and length of EDR episodes. This data corresponds to the sensitivity and length settings; the EDR index and selected minimum EDR episode length are indicated.

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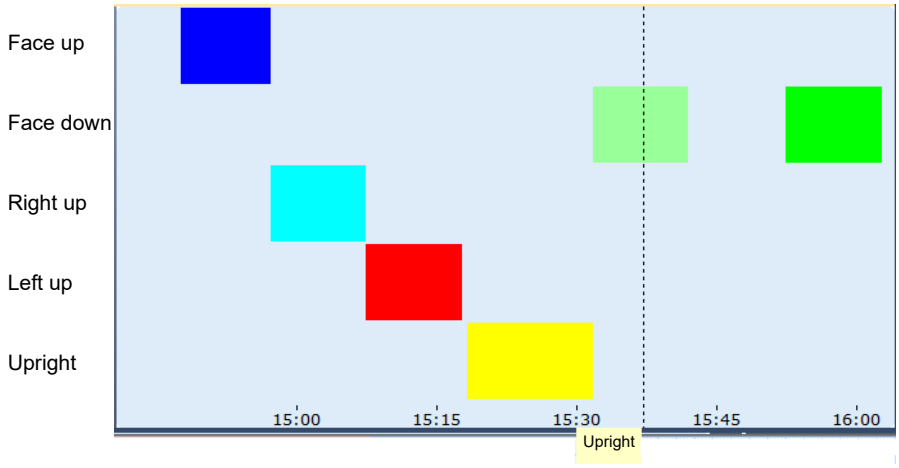
4.2.29 Body position graph

For recorders that are equipped with an accelerometer (that is, AR12 plus, FD12 plus), the patient's position during the recording is classified automatically and can be displayed graphically:



To reclassify the position, right-click in the graph and select the correct position. If one position is reclassified, all others are adapted accordingly; for example, if Face down has been assigned during the day, this is most likely incorrect and should be changed to Upright.

Available positions are Face down, Face up, Right up, Left up and Upright.

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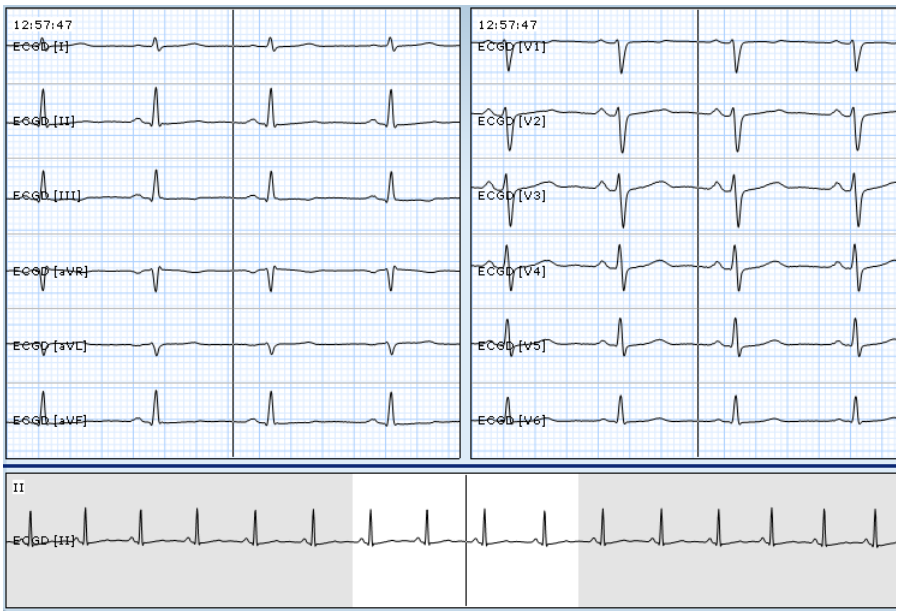
4.2.30 12-channel ECG

With the FD12plus recorder and a 10-lead patient cable, 12 ECG channels can be recorded. For such recordings, two modules are available:

Strip view

In this module, all 12 channels can be displayed simultaneously:



According to the settings, the ECG channels are displayed at the top. At the bottom, the overview strip is given.

Settings

- Select the signals (depending on the electrode position, not all of these might be available):
  - 12-lead
  - Wilson
  - Goldberger/Einthoven
  - Frank (XYZ)
- Set the amplitude and speed
- Select the channel and zoom in for the overview strip

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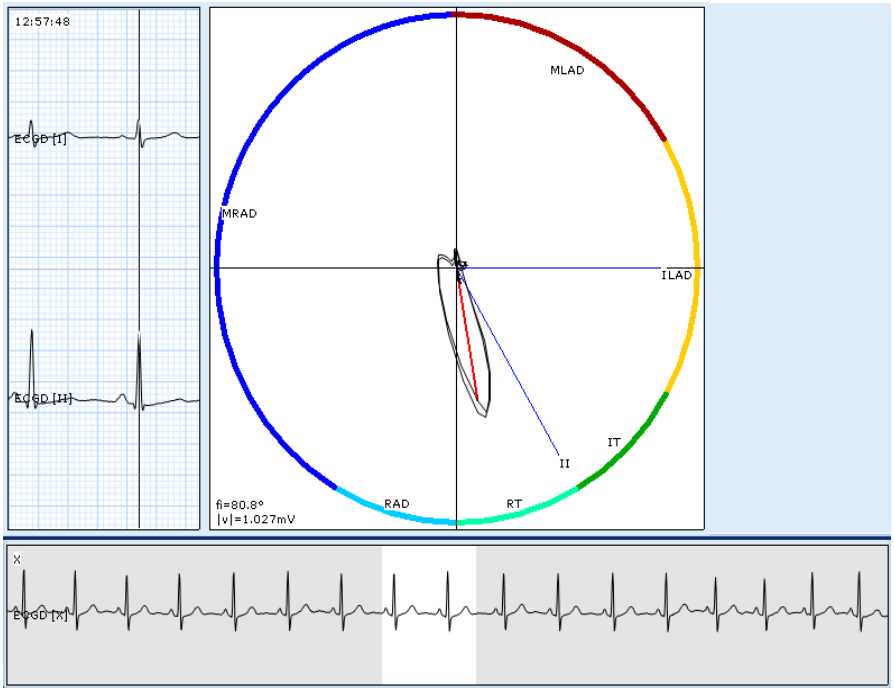
Cabrera circle

A vector cardiogram traces the direction and magnitude of the heart's electrical activity during a cardiac cycle. It is produced from the three orthogonal leads X, Y, Z. A 2D representation is shown to the right, two selected channels are displayed on the left, and the overview strip is given at the bottom. Move the cursor through one of the leads to replay the waveform. The vectors are written as the cursor moves.



Settings

- Select the signals for the two ECG channels displayed on the left
- Set the amplitude and speed
- Select the channel and zoom in for the overview strip
- When the maximum is selected, the maximum value of the complex is indicated in red
- Zoom

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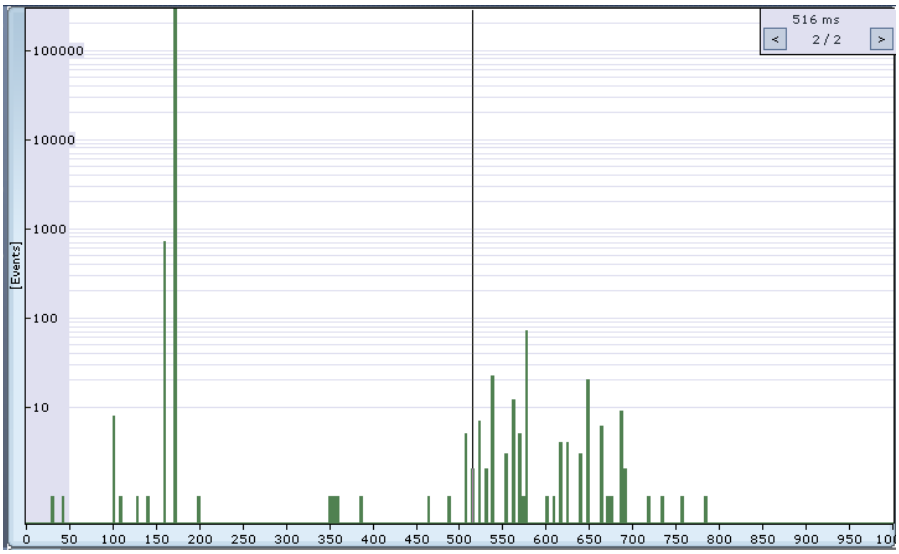
4.2.31 Pacemaker

PM-PM Histogram

This histogram indicates intervals of consecutive pacemaker spikes with length (in ms) given on the X-axis and events/min on the Y-axis.



Click on a bar of the histogram and use the Arrow icons in the top right corner to jump to the previous/next event. The corresponding ECG complex is shown in the ECG detail viewer.

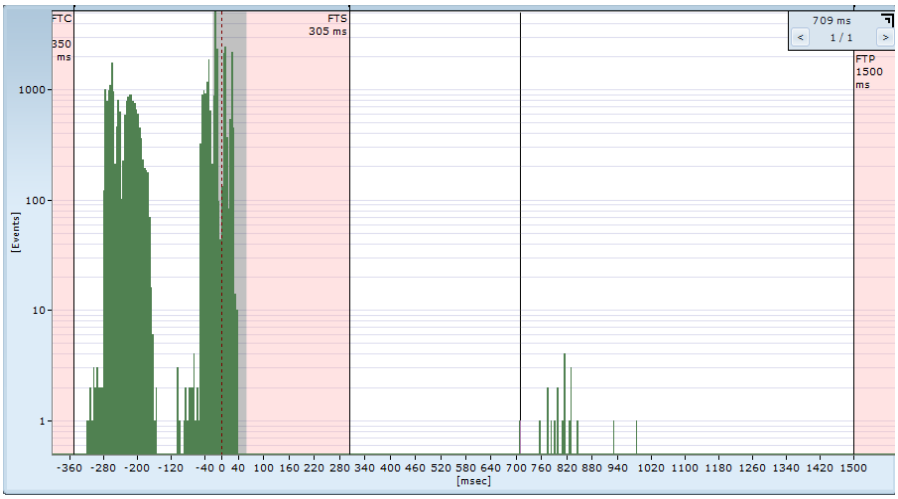
Settings

- Display logarithmic Y-axis
- Select the resolution
- Select the range of intervals displayed in ms
- Export the values to a CSV file

Art. no: 2.511044 Rev: k

PM-R Histogram

This histogram indicates intervals between PM spikes and R peaks with distance (in ms) given on the X-axis and events/min on the Y-axis. The distance is measured with the R peak as a reference point; -150 ms means 150 ms before the R peak.



Click on a bar of the histogram and use the Arrow icons in the top right corner to jump to the previous/next event. The corresponding ECG complex is shown in the ECG detail viewer.

The pacemaker impulses are classified according to the following criteria (refer to Pacemaker Analysis, page 97):

- FTC: failed to capture: a PM impulse was generated, but it did not trigger Myocardial depolarisation.
- FTS: failed to sense: PM failed to sense native cardiac activity, resulting in a pacemaker impulse that was not necessary.
- FTP: failed to pace: the PM failed to pace when necessary, for example, during a 2-second pause.
- These three groups are highlighted in pink (see above).

Settings

- Display logarithmic Y-axis
- Select the resolution
- Select the range of intervals displayed in ms
- Export the values to a CSV file

Tabular summary

For PM recordings, the tabular summary, refer to Tabular summary, page 51 provides the following additional information (also refer to Pacemaker Analysis, page 97):

- Undefined paced
- Fusion
- Pa: atrial paced
- Pv: ventricular paced
- Pdc: dual-chamber paced
- PM FTC: see above
- PM FTS: see above
- PM FTP: see above
- Total paced

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4.2.32 QT Summary table

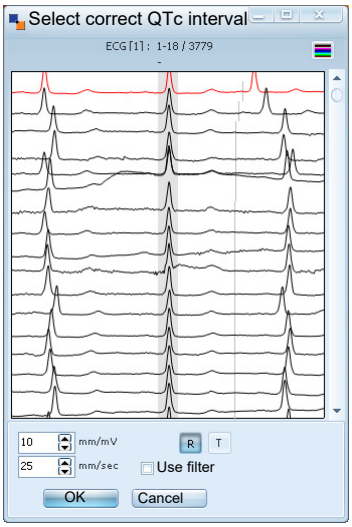
QT is the time between the beginning of the Q wave and the end of the T wave in the averaged ECG. The QT below table shows the measured and frequency-corrected maximum and minimum values per hour (QTc), the dispersion and the number of valid beats used for the calculation.

Time	Total beats	QTc min	QTc max	QTc mean
Entire rec.	95014	366	465	442
Day	53756	366	464	439
Night	41258	416	465	446
09:23:35	3119	410	458	440
10:23:35	1491	402	442	432
11:23:35	3350	409	453	433
12:23:35	3299	415	454	430
13:23:35	3837	416	451	433
14:23:35	1296	366	449	435

- Time: time segments, one hour each
- Total beats: valid beats per time segment and for the entire recording
- QTc min: minimum QTc value for the time segment
- QTc max: maximum QTc value for the time segment

Double-click on a value in the QTc Max or QTc Min column to only use correctly measured QT intervals.

The following dialogue is displayed:



- All beats are displayed below each other with the R peak marked grey (if activated) and the end of the T wave indicated by a grey line. The beats are ordered according to QT interval length, with the shortest (for QTc Min) or the longest (for QTc Max) at the top, respectively.
- Use the scroll bar on the right-hand side to scroll through the beats. Select the first beat for which the end of the T wave has been measured correctly. Click OK to discard all beats with shorter/longer QT intervals (shown above the selected beat). The QT interval of the selected beat becomes the new QTc minimum/maximum; all values are recalculated.
- When a beat is selected, the ECG channel, event number and QT interval (in ms) are displayed at the top.
- Press the icon at the top right to show the colour-coded view instead of individual beats if required.
- At the bottom, perform the following settings: select the speed and amplitude of the display, show/hide markings for the R peak and activate/deactivate the filter.

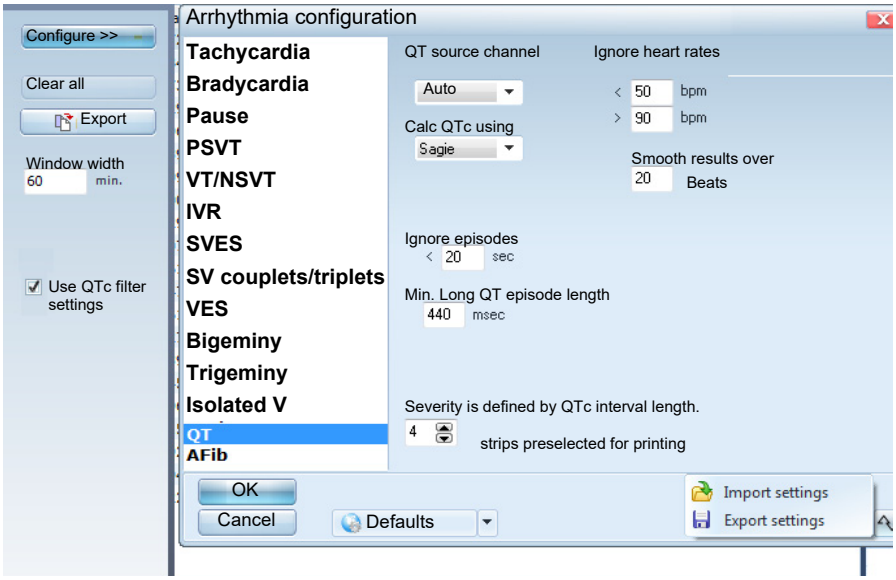
- QTc mean: mean QTc value for the time segment.

Long QT events are also shown in the Strip directory (refer to Strip directory, page 42).

Art. no: 2.511044 Rev: k

Settings

Select Configure to open the QT settings within the Arrhythmia configuration.



Select the QT Source channel: Auto detect or ECG channels 1, 2 or 3.
Select the calculation formula for the frequency correction:

– Bazett: the following formula is applied: $QTc = \frac{(QTtime)}{(\sqrt[2]{RRinterval})}$

– Fridericia: the following formula is applied: $QTc = \frac{(QTtime)}{(\sqrt[3]{RRinterval})}$

– Pfeufer: the following formulas are applied:

  For men:
  QTc [ms] = QT [ms] - (0.152 * (RR [ms] - 1000)) - (0.318 * (age [a] - 60))

  For women:
  QTc [ms] = QT [ms] - (0.154 * (RR [ms] - 1000)) - (0.207 * (age [a] - 60)) - 4.58

– Sagie: the following formula is applied:

  QTLC [s] = QT [s] + 0.154 (1 - RR [s])

Set to ignore HR ranges and episodes of a certain length and define the number of strips preselected for printing (refer to Strip directory, page 42).
It is also possible to reset to system/factory defaults, save as system defaults or import or export (save) the configuration (refer to Arrhythmia Configuration, page 95).

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4.2.33 ST Analysis

Notes

- ST segment analysis is performed on all ECG channels.
- Operator-selectable detection criteria for ST-segment shifts include:
  - ESC or AHA protocol
  - Relative or absolute ST value
  - The smoothing window averaged over 4 to 30 beats
- ST segment shifts are summarised in the reports as follows:
  - Episode by episode
  - Elevation or depression (in mV)
  - Duration of episode
- The following ranges for each episode are reported:
  - Slope as a global trend
  - Episode by episode: maximum of displacement and mean, maximum and minimum HR of reported/printed episode

4.2.34 ST Table

The ST table gives an overview of ST elevations and depressions for all channels and for the entire recording:

Episode	Channel	Start	Duration	Level [mV]
1		20:22:45	00:00:32	0.36
	3	20:22:45	00:00:32	0.36
2		23:40:30	00:04:18	0.11
3		02:22:49	00:52:32	0.15
4		04:58:53	01:22:45	0.15
	2	04:58:53	01:22:45	0.15
5		06:24:27	00:04:12	0.13
6		12:48:55	00:03:53	-0.15
	3	12:48:55	00:02:53	-0.15
	2	12:50:19	00:02:29	-0.15
7		13:10:25	00:05:14	-0.13
8		14:49:39	00:02:07	-0.11
9		16:36:07	00:00:53	-0.10
10		17:04:59	00:03:23	-0.26
11		17:28:06	00:01:06	-0.11
12		17:56:30	00:01:11	-0.27
13		19:04:19	00:02:47	-0.14
14		20:20:22	00:01:06	-0.39
15		21:27:04	00:00:32	-0.18
16		21:29:05	00:01:04	-0.16
17		21:34:26	00:01:06	-0.24

Click on an entry to display the ECG section and other modules in the ECG detail viewer.

The criterion for ST episodes can be configured in General settings > Arrhythmia configuration (refer to Arrhythmia Configuration, page 95).

ST episodes are detailed individually with start time, duration, level in mV and channel. ST depressions are highlighted blue, and ST elevations are highlighted orange.

Settings

Select to display all sub-folders (icon on the left) or only the top-level structure (icon on the right).

Highlight a table entry and click Delete or the DEL button to delete the event.

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4.2.35 ST Trend

The ST trend module overviews the ST intervals over the entire recording.
The red curve shows the Level (mV) and is the difference of the ST interval to the isoelectric line, measured at J point + 80 ms.
The green curve shows the Slope (in mV/s).
ST episodes (refer to ST Table, page 73) are highlighted blue (ST depression) or orange (ST elevation). At the bottom of the module, a strip summarises the ST episodes of all ECG channels.

Settings

- Select the ECG channels to be displayed
- Select the range
- Select the curves to be displayed: Level, Slope, time axis and ST episodes

Select Configure to open the Arrhythmia configuration and perform other settings.

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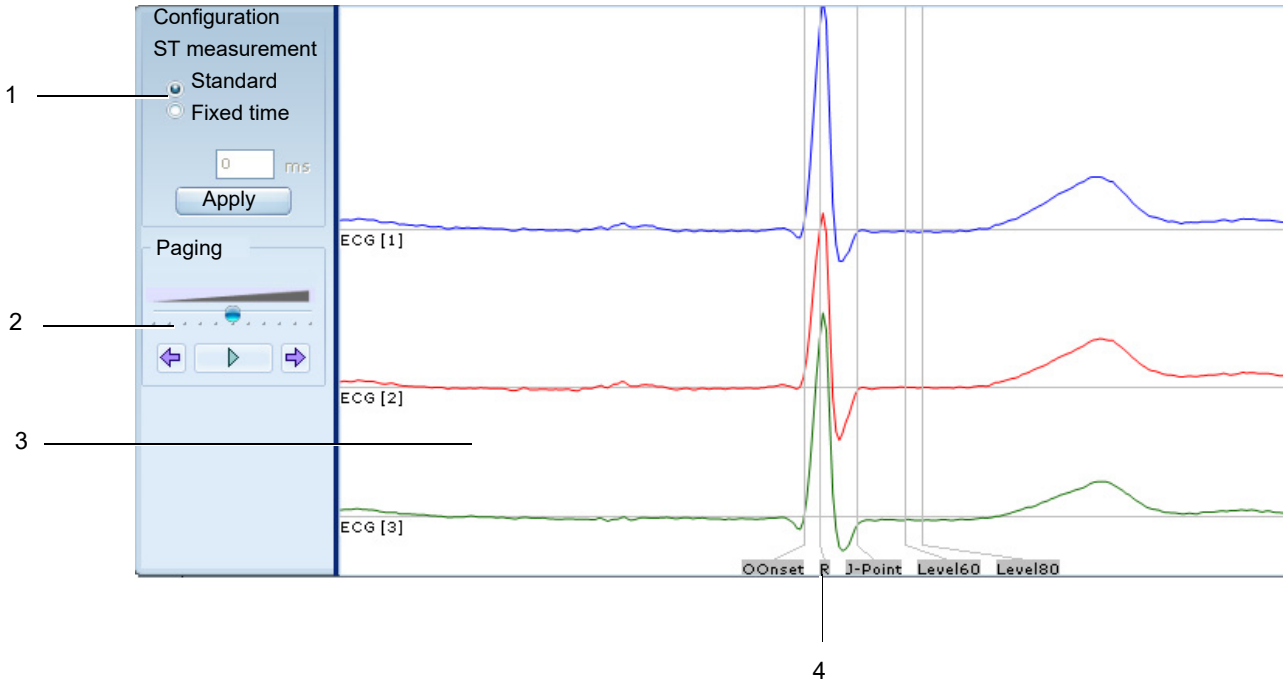
4.2.36 ST Meter



Define the settings for the ST analysis as follows:

(1) Select the ST measurement:
- Standard: standard setting and the ST level is measured 60 or 80 ms after the J-point, depending on the HR
- Fixed time: the ST level is measured at a fixed distance from the J-point

(2) Paging: Set the speed at which the recording is replayed, or use the Arrow icons to jump to the next/previous complex, one beat at a time

(3) All available ECG channels are displayed.

(4) The different measurement points are indicated at the bottom and are adjusted accordingly when a setting is changed.

Settings

Set the speed and amplitude.

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5 Blood Pressure Analysis

5.1 Overview of Pulse Wave Analysis

- ▲ For correct pulse wave analysis, patient data, date of birth and gender must be entered correctly.
- ▲ This feature is only available for patients 22 years old or older.

The clinical usefulness of central Blood Pressure (BP) as an index of risk for cardiovascular disease and the Augmentation Index (AIx) is often cited with gender, age and HR. Arterial stiffness is an important determinant of cardiovascular risk, and the AIx is a measure of wave reflection and, thus, systemic arterial stiffness derived from the ascending aortic pressure waveform. The AIx is defined by an augmentation to blood pressure in late systole, attributed to the early return of wave reflection from peripheral sites [5].
The central aortic pulse wave is the sum of the forward pressure wave generated by left ventricular ejection and a backward propagating wave that is subsequently reflected from the peripheral site. The time point at which these forward and backward propagating waves merge and the amplitude of the reflected (backward) wave affect the level of central BP.
The standard BP data and analysis screens are detailed in the previous section (refer to Blood Pressure Analysis, page 76).

5.1.1 Overview method

After the conventional BP assessment, the cuff records peripheral pulse waves at the diastolic level for approximately 10 seconds. This signal is digitised, and the algorithm is applied. Then the single pulse waves are verified, and the artefacts are removed. Aortic pulse waves are generated via a general transfer function [5]. Beats within those 10 seconds are filtered and averaged to determine the central arterial pulse wave. The augmentation index is standardised for a pulse rate of 75 bpm (see reference [1]). This parameter is then described as AIx@75.
AIx@75 has been analysed in a representative cross-section of the population (see reference [2]), and an age-dependent estimate for the AIx@75 plus the respective confidence interval has been assessed. These relevant analyses have also shown a significant difference in the average AIx@75 between men and women.

Based on research with a surveyed cross-section of about 2,000 people, average values and 90% confidence intervals were determined. Increased AIx until the 55th year has been identified; after the 55th year, the increase slows for both sexes. The level difference of the AIx between the sexes is about 8 to 10%, with females showing higher values. If the measured values exceed the sex- and age-specific interval, further examinations according to the European examination guidelines for hypertension [3] are recommended to detect the reason for the dysfunction.

Since guidelines recommend using PWA for risk stratification but provide no critical value, the patient's readings of PWV, AIx and pRes are matched with other patients based on population studies [4], [5]. This gives an idea of how the values perform compared to other people.

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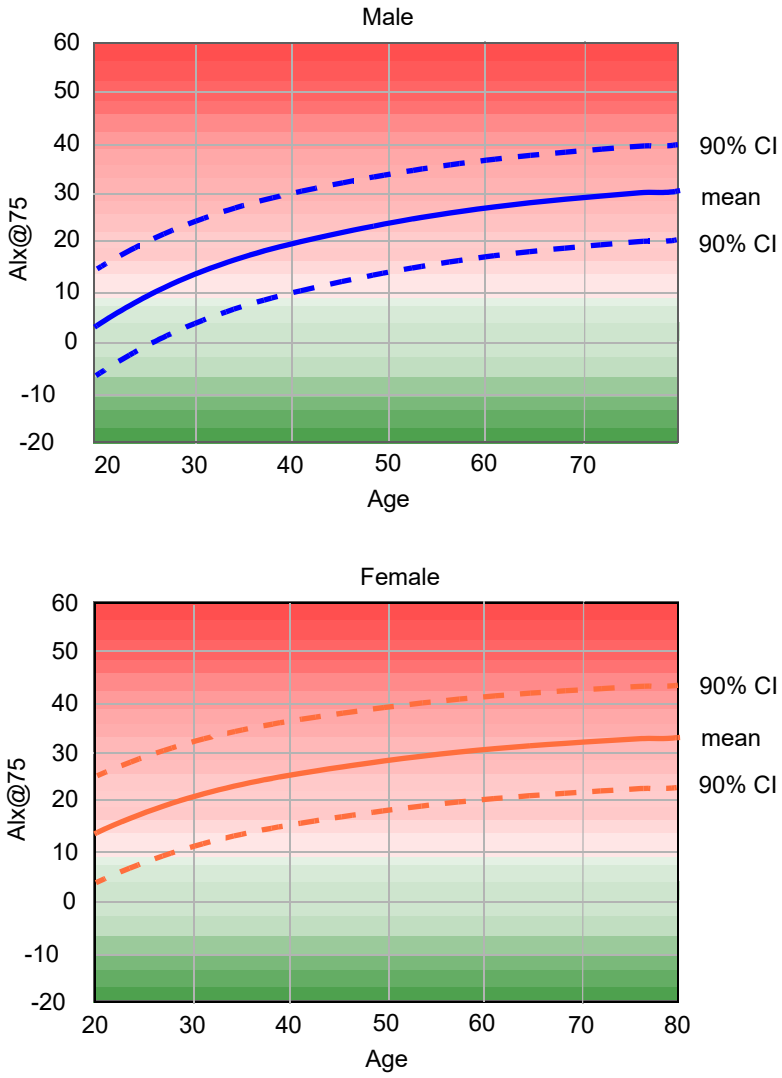

Average value and 90% confidence interval for the AIx@75

[1] Wilkinson I.B. et al. Heart Rate Dependency of Pulse Pressure Amplification and Arterial Stiffness. American Journal of Hypertension 2002;15:24-30.

[2] Fantin F. et al. Is the augmentation index a good measure of vascular stiffness in the elderly? Age and Ageing 2007; 36: 43-48.

[3] The Task Force for the Management of Arterial Hypertension of the European Society of Hypertension (ESH) and the European Society of Cardiology (ESC). 2007 Guidelines for the management of arterial hypertension. European Heart Journal 2007; 28: 1462-1536.

[4] European Heart Journal (2010) 31, 2338–2350 doi:10.1093/eurheartj/ehq165. Determinants of pulse wave velocity in healthy people and in the presence of cardiovascular risk factors: ‘establishing normal and reference values’

[5] Nunan et al.: Assessment of central haemodynamics from a brachial cuff in a community setting. BMC Cardiovascular Disorders 2012 12:48.

[6] Nunan et al.: Performance of pulse wave velocity measured using a brachial cuff in a community setting. Blood pressure monitoring, July 2014.

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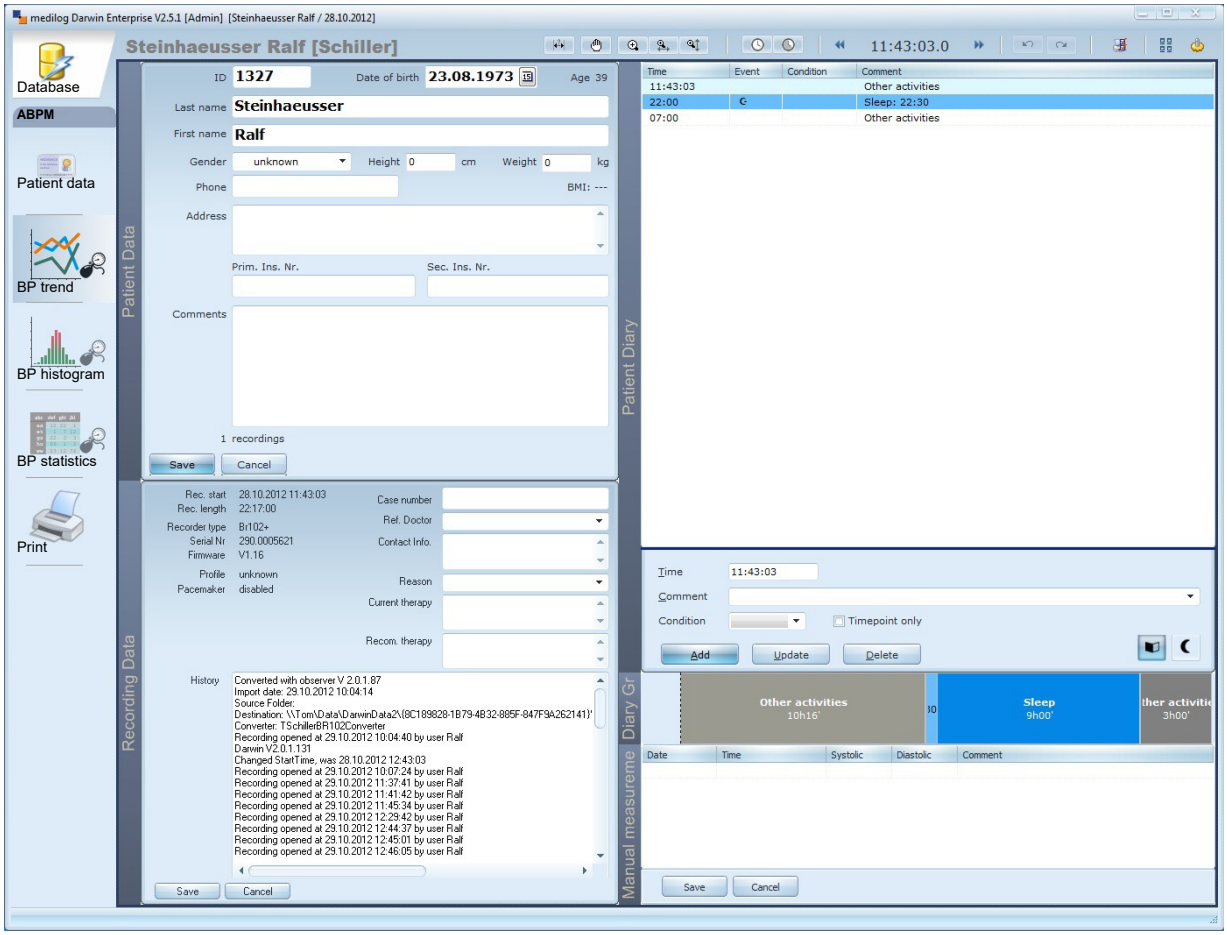
5.2 Overview of Patient Details and Recording



This screen provides an overview of the patient and the recording.

Patient Data (top left)

The top left section gives the patient details. These are fully editable (refer to Patient data, page 36).

Patient Diary (right)

This screen gives all entered event data. All event data is editable (refer to Patient diary, page 37).

Manual measurements (bottom right)

Any manually recorded BP values are shown here. Manual measurements are indicated by a triangle in the BP Measurement table (refer to BP Measurements, page 81).

Recording Data (bottom left)

The recording data area gives data, time recorder type and other data (refer to Recording information, page 35).

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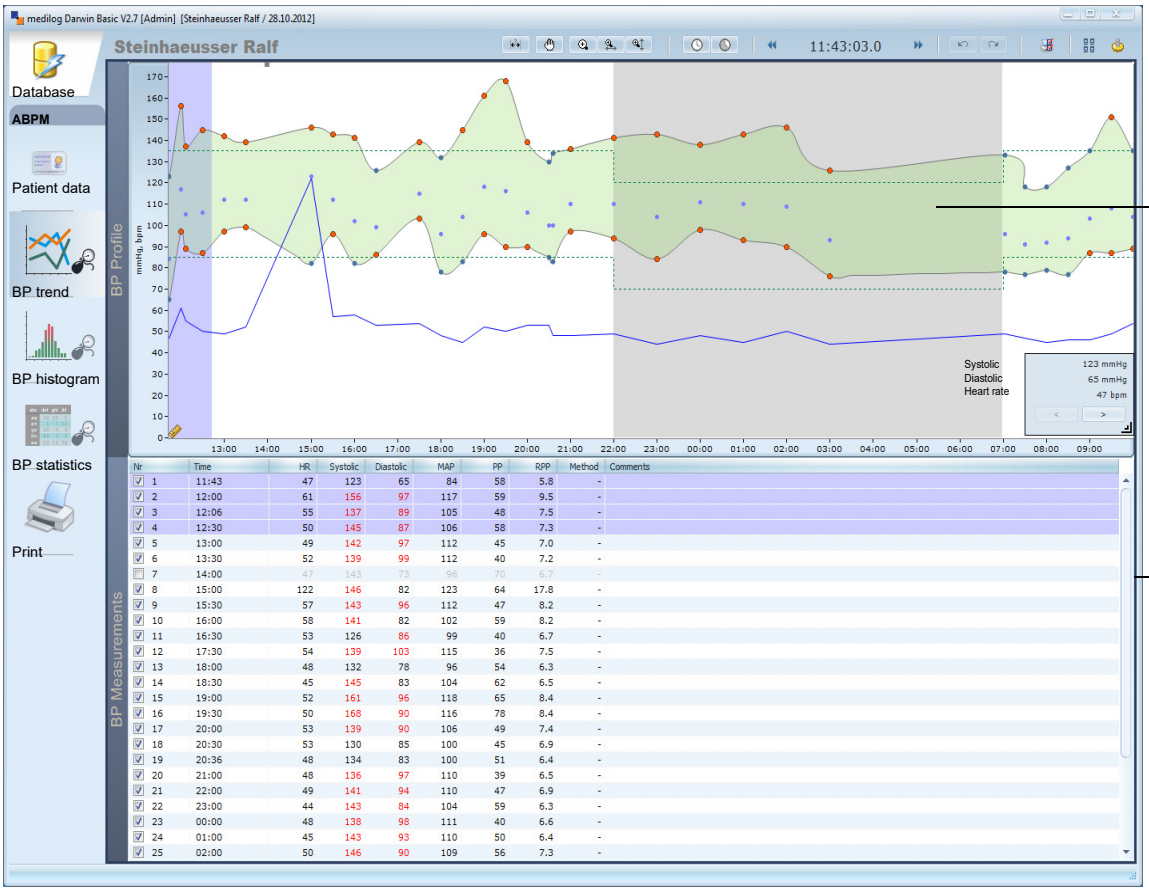
5.3 BP Trend



A graphical overview of the BP trend is displayed in the upper part of the screen. The lower part displays details of all the measurements. Click on a value in the graph (1) or scatterplot to highlight the corresponding value in the measurement table (2) and vice versa.

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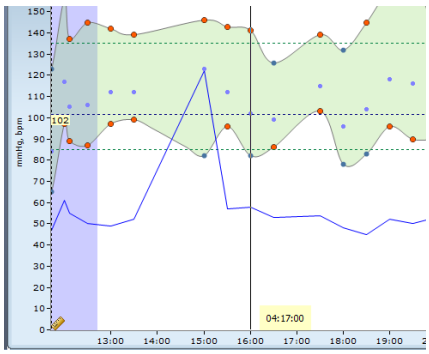
5.3.1 BP Profile

The trend graph displays the following data:

- Systolic BP: blue dots (red if the value exceeds norm values) at the top of the green area (refer to Setting the threshold and classification, page 80). Dotted horizontal lines indicate the threshold values.
- Diastolic BP: blue dots (red if the value exceeds norm values) at the bottom of the green area (refer to Setting the threshold and classification, page 80). Dotted horizontal lines indicate the threshold values.
- Mean Arterial Pressure (MAP): lilac dots in the middle of the green area
- Averaged MAP: purple line (PWA only)
- HR: blue line
- Failed or disabled BP measurements: indicated by the grey squares at the top of the graph.

The SYS and DIA BP and HR values are in the box in the bottom right corner of the graph.
The sleeping period is highlighted grey, and the first 60 minutes of the recording are highlighted lilac (white-coat syndrome, refer to Setting the threshold and classification, page 80).



In the bottom left corner, the calliper icon is shown. Click and drag with your mouse across the measurements: the time and value are given for the corresponding measurement.

When you access the right-click menu, the following options are available:

- Start/end of resting: click on the start of the sleep period, select Start of resting, drag the mouse to the end of the sleep period, and select End of resting. This setting is used in BP statistics (refer to BP Statistics, page 86).
- Legend: the information displayed in the BP profile is explained in a new window.
- Add to print queue (refer to (7) Print queue, page 25).
- Set as a thumbnail (refer to Database Screen, page 14).

Settings

Click on the BP profile settings bar (left of the graph) to define the display options and the type of graph**:**

- Select Standard or only minimum/maximum display
- Show/hide norm values (the limits defined in the BP configuration, refer to Setting the threshold and classification, page 80).
- Display Sys/Dia, MAP or HR signals
- The morning rise shows the BP changes during the waking up process: the BP rises while the patient is still asleep, reaches a maximum value and decreases again; these stages are displayed in the graph.

Setting the threshold and classification

Click the Configure icon (see the Settings above) to display blood pressure settings.

Load profile

Select between:

- AHA/JNC7 (American Heart Association/Joint National Committee)
- ESC/ESH (European Society of Cardiology/European Society of Hypertension)

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- Schiller

Settings

When the profile has been loaded, preset thresholds for day and night are set. These can be edited if required and saved as a new profile.

The recommended default values are as follows:
- AHA/JNC7: daytime: 135/85 mmHg; night-time: 120/75 mmHg
- ESC/ESH: daytime: 135/85 mmHg; night-time: 120/70 mmHg
- Schiller: daytime: 140/90 mmHg; night-time: 120/80 mmHg

White-coat analysis

Click the white-coat analysis box to highlight the first hour of the recording in both the graphical view and tabular view; this period is excluded from the analysis because BP values may be higher simply because the patient is in a doctor's practice and feeling anxious.

Classification

The BP classification (normal BP, hypertension) can be set to ESC or JNC7. The classification set here is used for the BP rating (refer to BP Rating, page 88).

Defaults

Select Save as system defaults or Restore to factory defaults.

5.3.2 BP Measurements

All hourly average values are listed in this table:
- HR
- Systolic, diastolic and MAP
- Pulse Pressure (PP), the difference between maximum systolic BP and minimum diastolic BP
- Rate Pressure Product (RPP), which is HR [bmp] x systolic BP [mmHg].

A blank triangle in the measurement table indicates manual measurements.

Pulse wave analysis measurements (PWA recordings only)

Pulse wave analysis is based on the arterial blood pressure curve containing haemodynamic information that exceeds peripherally measured blood pressure. This is used to analyse the central aortic pulse wave. Normal values are highly dependent on gender, age, blood pressure, etc. The PWA software uses patient data to provide a graphical indication based on measurements and underlying statistics.

The following values are given:

CSBP Central systolic blood pressure: calculated systolic BP in the heart [mmHg]

CDBP Central diastolic blood pressure: calculated diastolic BP in the heart [mmHg]

CPP Central pulse pressure: CPP = CSBP - CDBP [mmHg]

PWV Pulse wave velocity: (m/s) is a significant value indicator of arterial stiffness, and aortic PWV is often considered a direct measurement of aortic stiffness. PWV measures the speed of the arterial pressure waves travelling along the aortic and aortoiliac pathways. Higher arterial pulse wave velocity is indicative of stiffer arteries.

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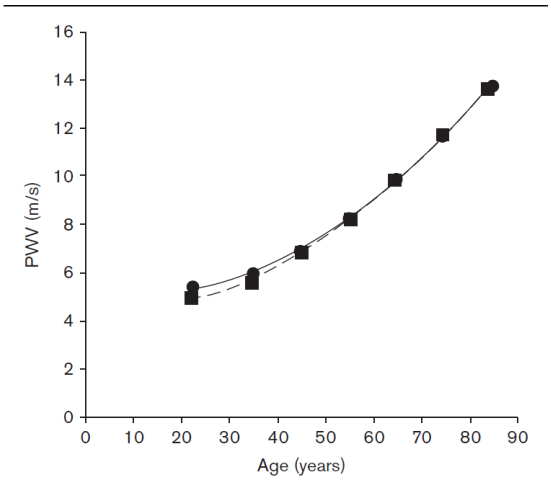
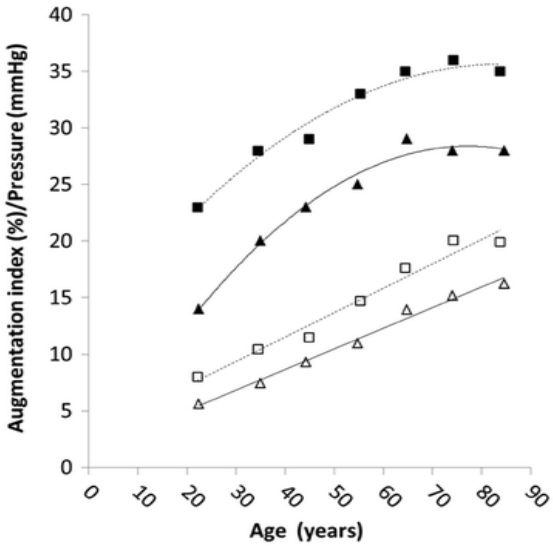


The regression curve represents age's effect on pulse wave velocity in the total sample population. Symbols represent male individuals (● - solid line) and female individuals (■ - dashed lines) (see Nunan et al. Performance of pulse wave velocity measured using a brachial cuff in a community setting. Blood pressure monitoring, July 2014).

AIx Augmentation index (%): is the measure of wave reflection and, thus, systemic arterial stiffness derived from the ascending aortic pressure waveform.



Regression curves representing the effect of age on augmentation pressure and index. Symbols represent augmentation pressure and augmentation index for males (▲ and Δ - solid line) and females (■ and □ - dashed lines) (see Nunan et al.: Assessment of central haemodynamics from a brachial cuff in a community setting. BMC Cardiovascular Disorders 2012 12:48.).

AIx@75 Augmentation index normalised for an HR of 75 bpm (90% confidence interval) [%]

AugP Augmentation pressure [mmHg]: the difference between the pressure value at the Inflection Point (IP) and the CSBP (refer to Central aortic wave, page 90)

PRes Peripheral resistance: [mmHg*s/ml]

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Q Quality of the measurement. Move the mouse over this column to display the pressure curve of the corresponding measurement. The colour coding provides a quick indication of the measurement quality:

- Green = good
- Yellow = questionable
- Red = no values obtained

Method Cuff-based auscultatory or oscillometric measurement.

Systolic and diastolic values that exceed the norm values are indicated in red (refer to Setting the threshold and classification, page 80).

The first 60 minutes of the recording are highlighted lilac (white-coat syndrome, refer to BP Statistics, page 86).

Tick the box of an individual measurement to disable it. Failed and disabled measurements are indicated by grey squares at the top of the BP profile.

Settings

Clicking the grey settings bar on the left-hand side of the measurement table gives the following settings:

- Display the following measurements:
  - Enabled - successful measurements that have a valid measurement value
  - Disabled - measurements that have been manually disabled. This is completed by highlighting a measurement in the table and removing the tick in the box.
  - Invalid - measurements that have been unsuccessful. That is measurements with a time stamp but no valid measurement values. Invalid and disabled measurements are indicated by grey squares at the top of the BP profile.
  - Activate/deactivate Peripheral BP and PWA (if available).

Exporting measurement summary

To export the measurement summary (in CSV format that can be opened in Excel), click Export. You are prompted to define where the file is to be saved.

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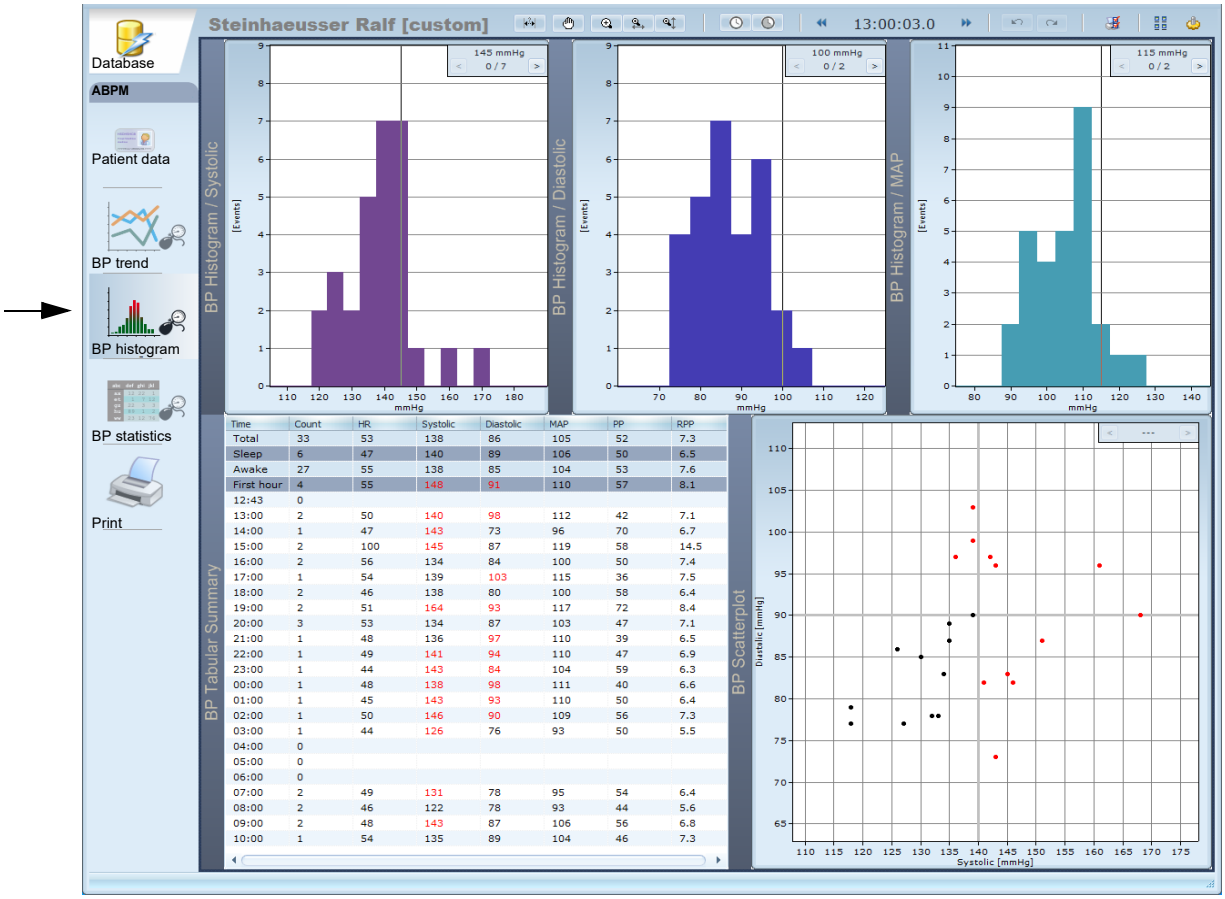
5.4 BP Histogram



The top area displays the number of measurements for the defined segment. The data for display is defined by clicking the grey settings bar on the left-hand side of the histogram to set the following data:

- Systolic BP
- Diastolic BP
- Mean BP (MAP)
- Pulse Pressure (PP)
- Heart Rate (HR)
- Rate Pressure Product (RPP), refer to BP Statistics, page 86)

The number of events (over 140 mmHg) is given on the Y-axis, and the unit is on the X-axis.

The awake or sleep period can be activated (or both combined). The resolution can be defined between 1, 5 or 10 (the width of each block represents 1, 5 or 10 mmHg).

The bottom left of the screen gives the averaged measurements (refer to BP Measurements, page 81). When a measurement is highlighted in the measurement table, the section in which the measurement is located in the histogram is indicated by a vertical line in all three graphs in the top section. Similarly, when the line is manually repositioned in the histogram, the individual measurement is highlighted in the measurement table.

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5.4.1 BP Scatterplot

The scatterplot displayed in the bottom right of the screen is also known as a Lorenz plot and is a two-dimensional histogram of Systolic and Diastolic pressure.
Each dot represents a BP value.

- The blue dots give the measurement values for the sleep period within the set limits.
- The red dots indicate the sleep and awake periods values that exceed the set limits.
- The black dots give the measurement values for the awake period within limits.
- The grey vertical (systolic limit) and the grey horizontal (diastolic limit) lines indicate the limits. Note that the limit lines are only displayed when only awake or sleep is defined in the settings. If both awake and sleep measurements are selected for display, there are two different limit settings and cannot be displayed.

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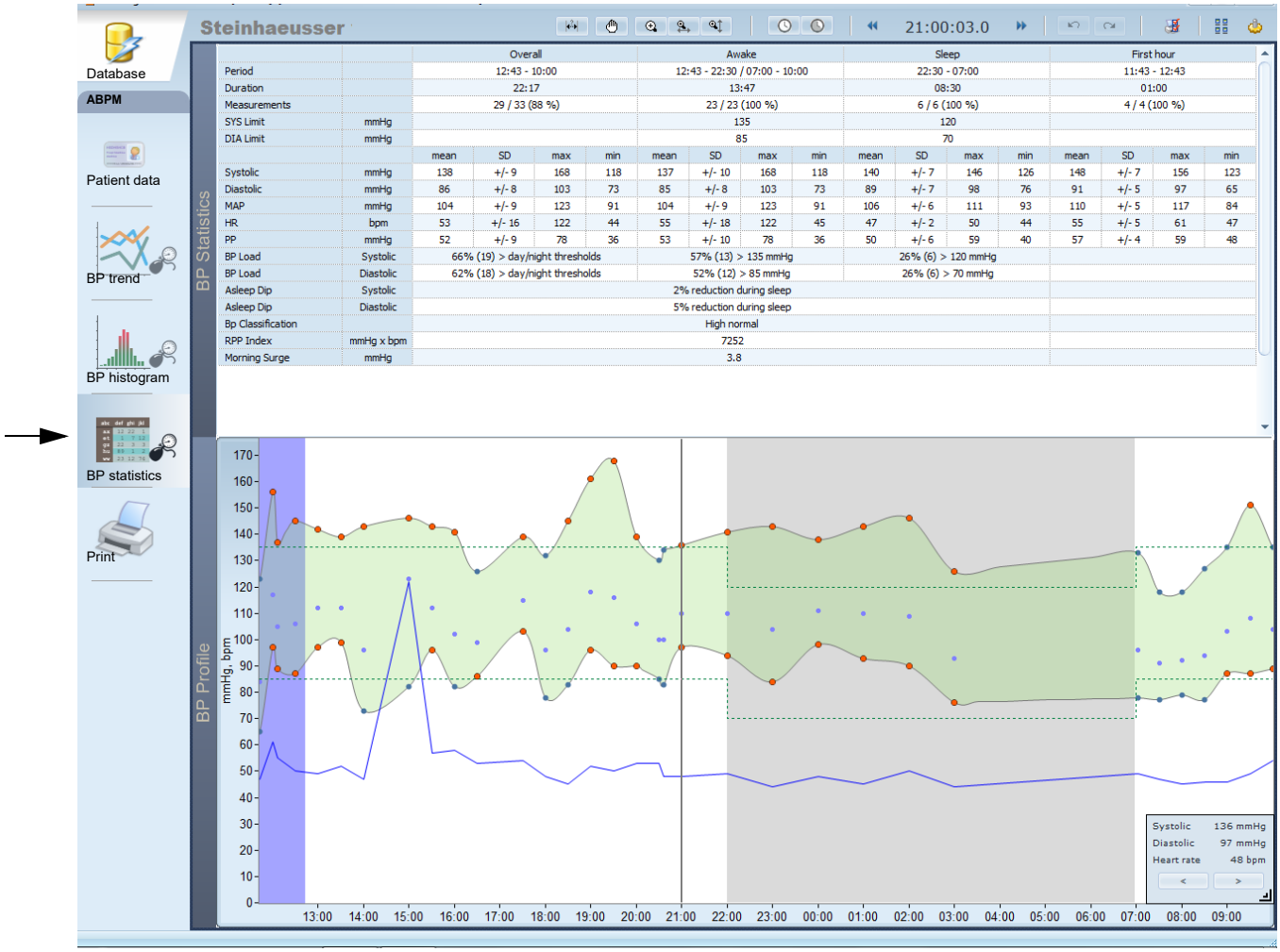
5.5 BP Statistics



		Overall				Awake				Sleep				First hour			
Period		12:43 - 10:00				12:43 - 22:30 / 07:00 - 10:00				22:30 - 07:00				11:43 - 12:43			
Duration		22:17				13:47				08:30				01:00			
Measurements		29 / 33 (88 %)				23 / 23 (100 %)				6 / 6 (100 %)				4 / 4 (100 %)			
SYS Limit	mmHg					135				120							
DIA Limit	mmHg					85				70							
		mean	SD	max	min	mean	SD	max	min	mean	SD	max	min	mean	SD	max	min
Systolic	mmHg	138	+/- 9	168	118	137	+/- 10	168	118	140	+/- 7	146	126	148	+/- 7	156	123
Diastolic	mmHg	86	+/- 8	103	73	85	+/- 8	103	73	89	+/- 7	98	76	91	+/- 5	97	65
MAP	mmHg	104	+/- 9	123	91	104	+/- 9	123	91	106	+/- 6	111	93	110	+/- 5	117	84
HR	bpm	53	+/- 16	122	44	55	+/- 18	122	45	47	+/- 2	50	44	55	+/- 5	61	47
PP	mmHg	52	+/- 9	78	36	53	+/- 10	78	36	50	+/- 6	59	40	57	+/- 4	59	48
BP Load	Systolic	66% (19) > day/night thresholds				57% (13) > 135 mmHg				26% (6) > 120 mmHg							
BP Load	Diastolic	62% (18) > day/night thresholds				52% (12) > 85 mmHg				26% (6) > 70 mmHg							
Asleep Dip	Systolic	2% reduction during sleep															
Asleep Dip	Diastolic	5% reduction during sleep															
Bp Classification		High normal															
RPP Index	mmHg x bpm	7252															
Morning Surge	mmHg	3.8															

The statistics table provides the following values for the recording divided into the following periods: Overall, Awake period, Sleep period, and the First hour of the recording. For each period, the following information is calculated:

Period — The start and finish of each period (or periods, for example, in the awake period and for 48-hour recordings).

Duration — The duration of the period (or combined time of all period segments).

Measurements — The total number of measurements taken in the period and the number that were successful (given as the number and the percentage).

SYS and DIA limits — The limits set for systolic and diastolic pressures (shown for the awake period and the sleep period only).

Averaged Measurements (mean, SD, maximum and minimum) — The averaged mean value, Standard Deviation (SD), and maximum and minimum values are given for systolic and diastolic pressure, MAP, HR, and Pulse Pressure (PP).

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BP Load

The number and the percentage of the total measurements exceeded the threshold limit for systolic and diastolic measurements.
The following values are calculated from the complete recording:

Asleep Dip

The percentage difference of the mean systolic and diastolic values between the awake and asleep periods. The following classifications have been defined for dipping:

- A positive percentage = Reverse dipping
- 0 to 10% reduction = Non-dipping
- 11 to 20% reduction = Normal dipping
- > 20% reduction = Extreme dipping

BP Classification

According to the classification standard set in the BP trend settings (refer to Setting the threshold and classification, page 80).

RPP Index

The Rate Pressure product is as follows:

- RPP index = the average systolic BP [mmHg] x average HR [bmp]

Morning Surge

The difference between the mean BP value two hours before and two hours after, given in mmHg.

Time index (systolic/diastolic)

This shows the number of times the systolic/diastolic pressure was higher than the defined limit as a percentage of the total.

Area index (systolic/diastolic)

This shows the area when the systolic/diastolic pressure was over the defined limit, in mmHg * h.

Standardised area index (systolic/diastolic)

Provides the normalised value of the area when the systolic/diastolic pressure was higher than the defined limit in mmHg.

PWA Recordings only

With PWA, averaged measurements for mean, standard deviation, maximum and minimum values are given for each period for the following values:

- CSBP
- CDBP
- CPP
- PWV
- AIx@75
- PRes
- AugP

Refer to Pulse wave analysis measurements (PWA recordings only), page 81, for definitions.

Settings

Activate/deactivate the peripheral BP, Time and area index, and PWA (if available).

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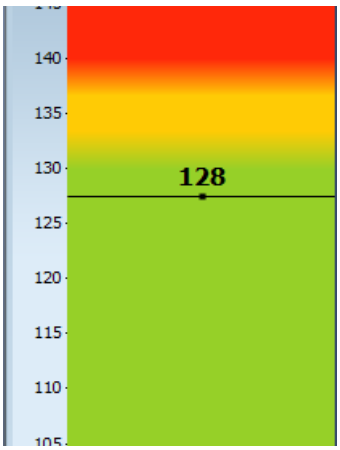
5.6 BP Rating



This module provides a quick overview of the BP values with a colour-coded graph.

- Green = Value within the limits
- Yellow = Value on the border
- Red = Value exceeds the limits

The rating is based on the classification defined in the BP configuration (refer to Setting the threshold and classification, page 80) or on the characteristic values given in the studies performed by Nunan et al. for AIx (Assessment of central haemodynamics from a brachial cuff in a community setting; BMC Cardiovascular Disorders 2012, 12:48), and Boutouyrie et al. for PWV (Determinants of pulse wave velocity in healthy people and in the presence of cardiovascular risk factors: 'establishing normal and reference values'; European Heart Journal (2010) 31, 2338-2350, downloaded here: https://biblio.ugent.be/input download?func=downloadFile&recordOId=1062922&fileOId=1063020. The number of study subjects: approximately 17,000), respectively.
The values are averaged over the entire duration of the recording.

In the settings, select the value displayed: Sys, Dia, PWV, AIx, PRes (refer to Pulse wave analysis measurements (PWA recordings only), page 81 for more information).

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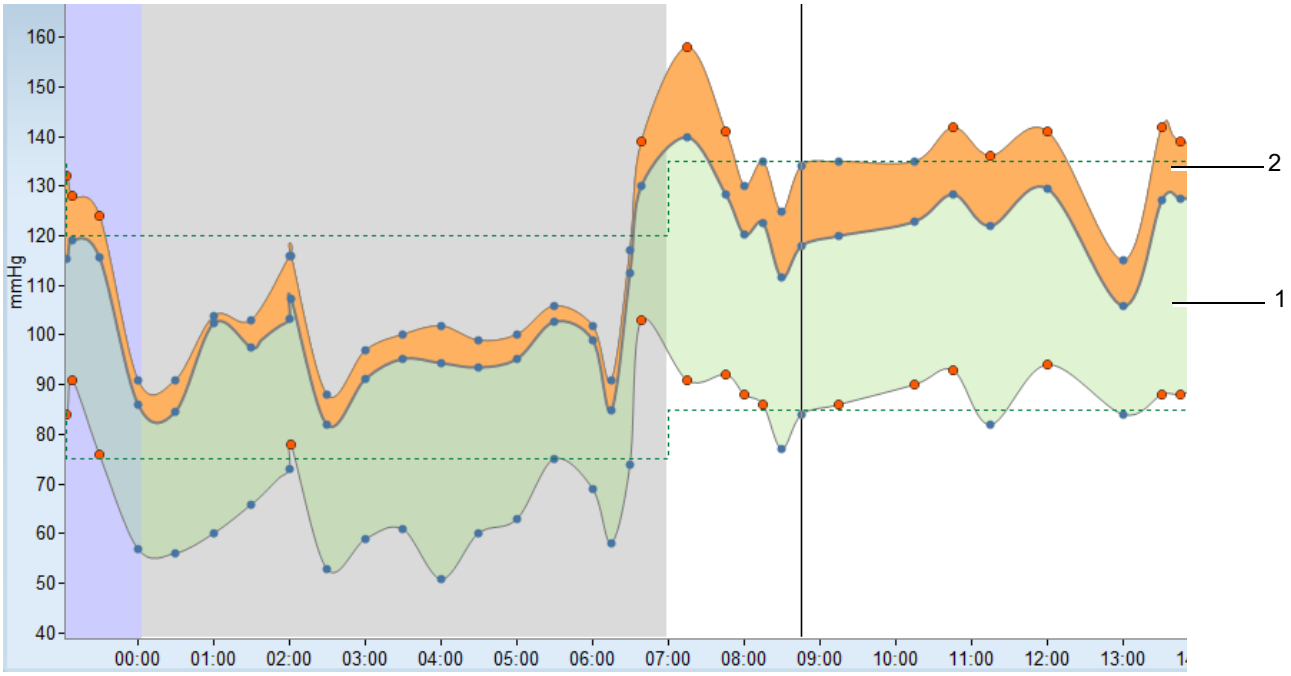
5.7 PWA Measurements (PWA recordings only)

5.7.1 Central BP profile

This module shows the calculated central systolic and diastolic blood pressures CSBP and CDBP. Three views are available as follows and can be defined in the settings.

In the settings, select the values to be displayed:

- BP quotient (PSBP/CSBP): peripheral systolic BP concerning the central systolic BP. A significant difference between PSBP and CSBP indicates high arterial stiffness (see below).
- PSBP and CSBP (see below)
- Central BP (systolic and diastolic): just the calculated central BP values are displayed.
- Norm values: a dotted green line indicates the threshold values for systolic and diastolic BP.
- Measurements: if this is activated, the CSBP and CDBP values are displayed in the bottom right corner.
- Time axis: show/hide



The central BP values are given in this view, framing the green area (1). In addition, the peripheral systolic BP is given, marking the border of the orange area (2). A large orange area (2) indicates high arterial stiffness, as the orange area shows the difference between the central and peripheral systolic BP.

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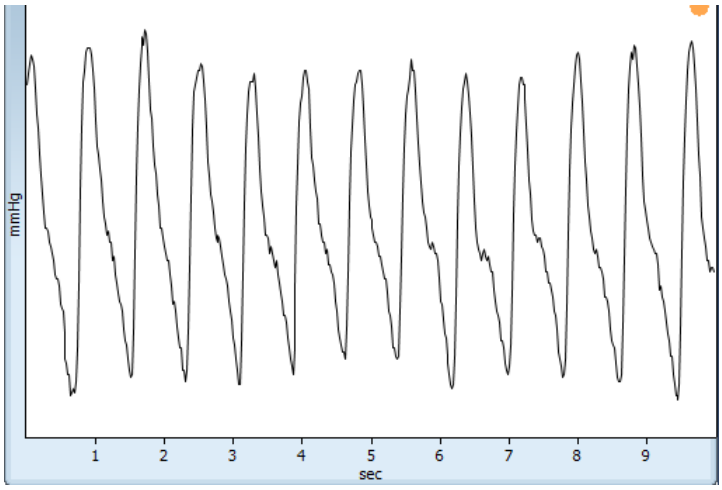
5.7.2 Pulse wave signal

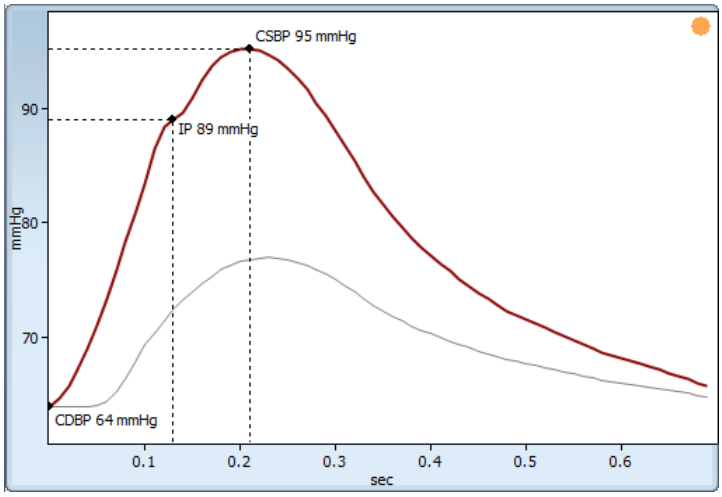
In this module, either the Peripheral pulse wave or the Central aortic wave is displayed (defined in the settings):

Peripheral pulse wave



The peripheral pulse wave is shown in mmHg. This curve is displayed to check the signal quality and is colour-coded in the top right corner. The peripheral pulse wave shows the pressure variation of the recorded peripheral BP during the PWA measurement interval (10 seconds).

Central aortic wave



The central aortic wave is calculated from the raw signal of all pulses within 10 seconds. It is calculated using a validated algorithm developed by the Austrian Institute of Technology called ARCSolver.

The central aortic pulse wave is the sum of the forward pressure wave generated by left ventricular ejection and a backward propagating wave that is subsequently reflected from the peripheral site. The time at which these forward and backward propagating waves merge the Inflection Point (IP) and the amplitude of the reflected (backward) wave affect the level of central BP.

Also, this graph indicates the Augmentation pressure: the AugP is the difference between the pressure value at the IP and the CSBP (see above). It indicates arterial stiffness: the augmentation in pressure caused by the reflected wave is higher when arteries are stiffer.

The measurement quality in both graphs is colour-coded in the top right corner.

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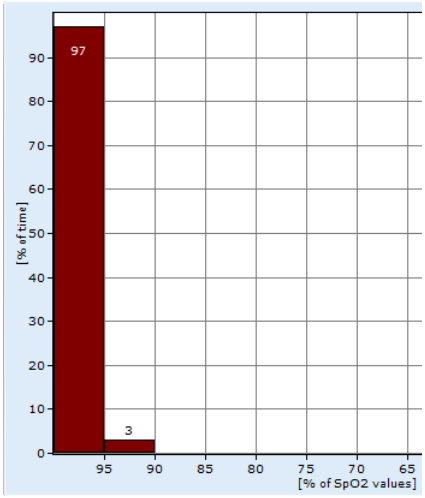
6 SpO_2

SpO_2 measurements are only possible with AR12plus and FD12plus recorders equipped with a SpO_2 sensor.

6.1 SpO_2 Overview



This module provides graphical information on the distribution of SpO_2 values: the X-axis indicates the SpO_2 value, and the Y-axis is the percentage of the time. In this example, 97% of the time, the oxygen saturation in the blood was between 95 and 100%

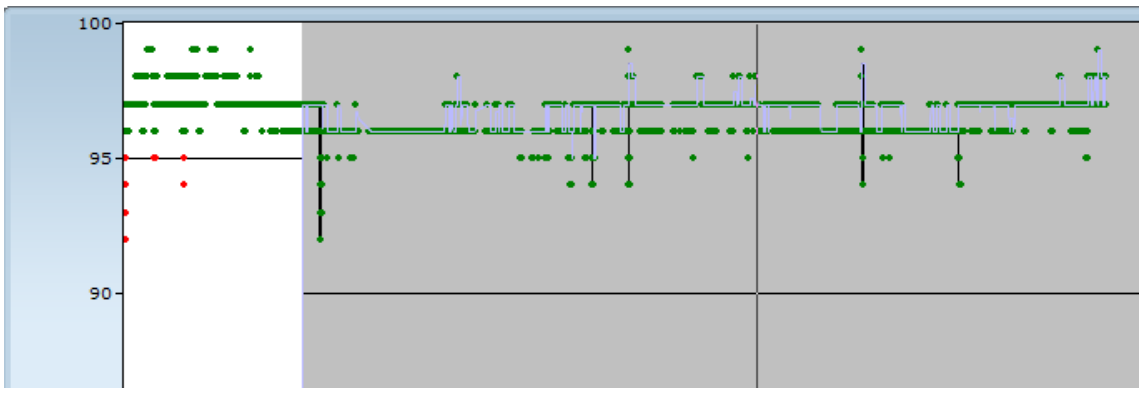
In the settings, you can set the threshold value for measurements that can be ignored, for example, below 70%. Also, you can set the threshold value for deviations that can be ignored, for example, more than 10%.

6.2 SpO_2 Trend

SpO_2 measurement values are indicated as coloured dots in the diagram. The threshold (see below) is shown as a black horizontal line. Values above the threshold are marked as green dots; values equal to or below the threshold are red.

The sleep phase (night) is marked as the grey segment. The SpO_2 value is also given in the EDR episodes (refer to EDR Episodes, page 65)

When you click on a value in the table, the corresponding value is displayed in various modules (SpO_2 trend, SpO_2 overview, EDR overview etc.).



Settings

- Select the threshold value for day and night.
- Basal SpO_2: average value of the last 40 seconds.
- SpO_2 episodes: desaturation episodes are displayed (refer to SpO_2 Statistics, page 92).

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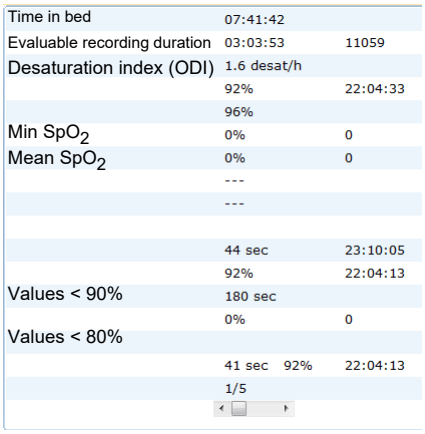
6.3 SpO_2 Statistics



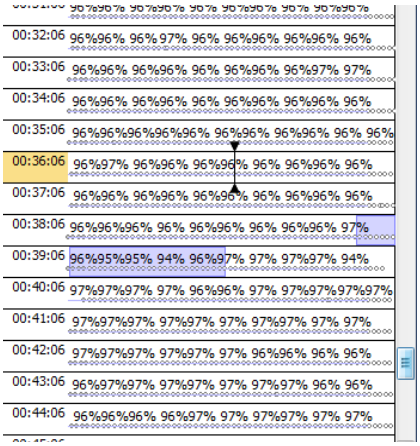
This module provides the following information:

- Time in bed: sleep period
- Evaluable recording duration: duration and number of values measured.
- Oxygen Desaturation Index (ODI): the number of times per hour of sleep the blood's oxygen level drops by 3% from the baseline value. Minimum/mean SpO_2 over the entire recording, including the time of occurrence.
- Number of values below 90/80% as a percentage and the number of values
- Longest/deepest desaturation episode: in seconds or as a percentage, respectively
- Duration of desaturation: total desaturation duration over the recording
- Artefacts
- Episodes: desaturation episodes are listed here. Click on the Arrow icons to jump to the next/previous episode.

When you click on a value in the table, the corresponding value is displayed in various modules (SpO_2 trend, SpO_2 overview, EDR overview etc.)

In the settings, you can set the threshold value for measurements that can be ignored below 70%. Also, you can set the threshold value for deviations that can be ignored, that is, more than 10%.

6.4 SpO_2 Full disclosure



This module provides an overview of the entire recording.

SpO_2 values as a percentage are given throughout the recording. The cursor indicates the current location. Move through the recording using the slider on the right side. Press Ctrl and simultaneously click and drag the cursor to measure the duration of a segment.

Settings:

- Strip scaling: changing of the time axis.
- Strip height: select the height in mm to adjust the presentation
- Show episodes: desaturation episodes are highlighted blue (refer to SpO_2 Statistics, page 92)
- Basal values: average value of the last 40 seconds.

When you click on a value in the table, the corresponding value is displayed in various modules (SpO_2 trend, SpO_2 overview, EDR overview etc.).

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7 General settings

Click the Settings icon on any screen  . Refer to ECG Analysis, page 27, to display the settings menu.

7.1 Miscellaneous Settings

- Show relative time: activate this option to display the time relative to the start of the recording (that is, the recording starts at 00:00 hours) instead of the real-time the recording was taken.
- Show calibration pulse: a calibration pulse of 1 mV is displayed in the ECG detail viewer.
- Show RR intervals in bpm, as opposed to seconds.
- Activate/deactivate a display filter and set the high- and low-pass frequency.

7.2 Report Settings

Here, user-specific report settings can be performed for the Strip directory and Full disclosure (if these are included in the report):

Strip directory

Select the amplitude (mm/mV), speed (mm/s) and strip height (mm) for strip items as well as the overview, and select the ECG channels to be included.
A preview is given on the right-hand side.

Full disclosure

Select the amplitude (mm/mV), speed (mm/s) and strip height (mm), and select the ECG channels to be included.
A preview is given on the right-hand side.

7.3 Calibrate Display Resolution

Perform the calibration described here to calibrate the display and ensure that parameter values are shown correctly on the screen.

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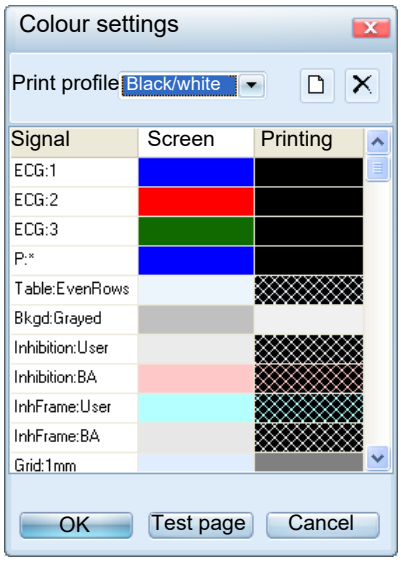
7.4 Colour Settings



- Select a print profile from the drop-down menu; the corresponding colours are listed below. It is recommended to first print a test page to check the settings.
- Change the colours as required by double-clicking on a colour. Select another colour from the palette. If necessary, save the modified print profile under another name.
- Delete a print profile.
- Print a test page with examples of each print profile.

7.5 Configure Hotkeys and Layout

Refer to Shortcuts, page 26.

7.6 Change Password

Enter the old password, then enter the new password twice and confirm with OK.

Note that this menu option might not be available depending on your user rights.

7.7 HRV Data Preparation

Refer to HRV Configure, page 62.

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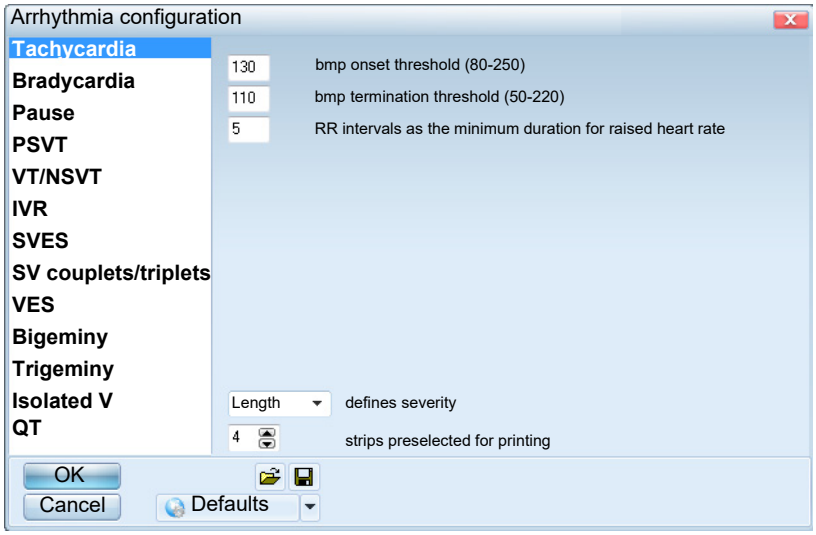
7.8 Arrhythmia Configuration



In this menu, all arrhythmia-related settings are defined.

The illustration above is an example; the other arrhythmia configuration dialogues may vary.

In the example above, the Tachycardia settings can be set:

- Lower (onset) threshold of tachycardia in bpm
- Upper (termination) threshold of tachycardia in bpm
- Minimum number of RR intervals for raised HR
- Severity: either defined by the Length of the event or by the maximum HR

Also, select the number of strips automatically added to the report for printouts (refer to General settings, page 93).

You can import the arrhythmia settings from a file (.DAS), save the values in a file (.DAS), set the values as default, reset the values to the default values or reset the values to factory defaults.

When the arrhythmia settings are changed, they are just changed for the open recording. If you want to make settings the new default settings for all recordings, click Defaults and select Save as the system default. NB: When the values are set as the system default, all future recordings that have not yet been imported use the new settings. If you open a recording that was analysed before you changed the default settings, the old settings are used. If you want to use the new settings, open the arrhythmia configuration dialogue, click Defaults and select Reset to system defaults. When you select Reset to factory defaults, your current and all future recordings use the factory default arrhythmia settings.

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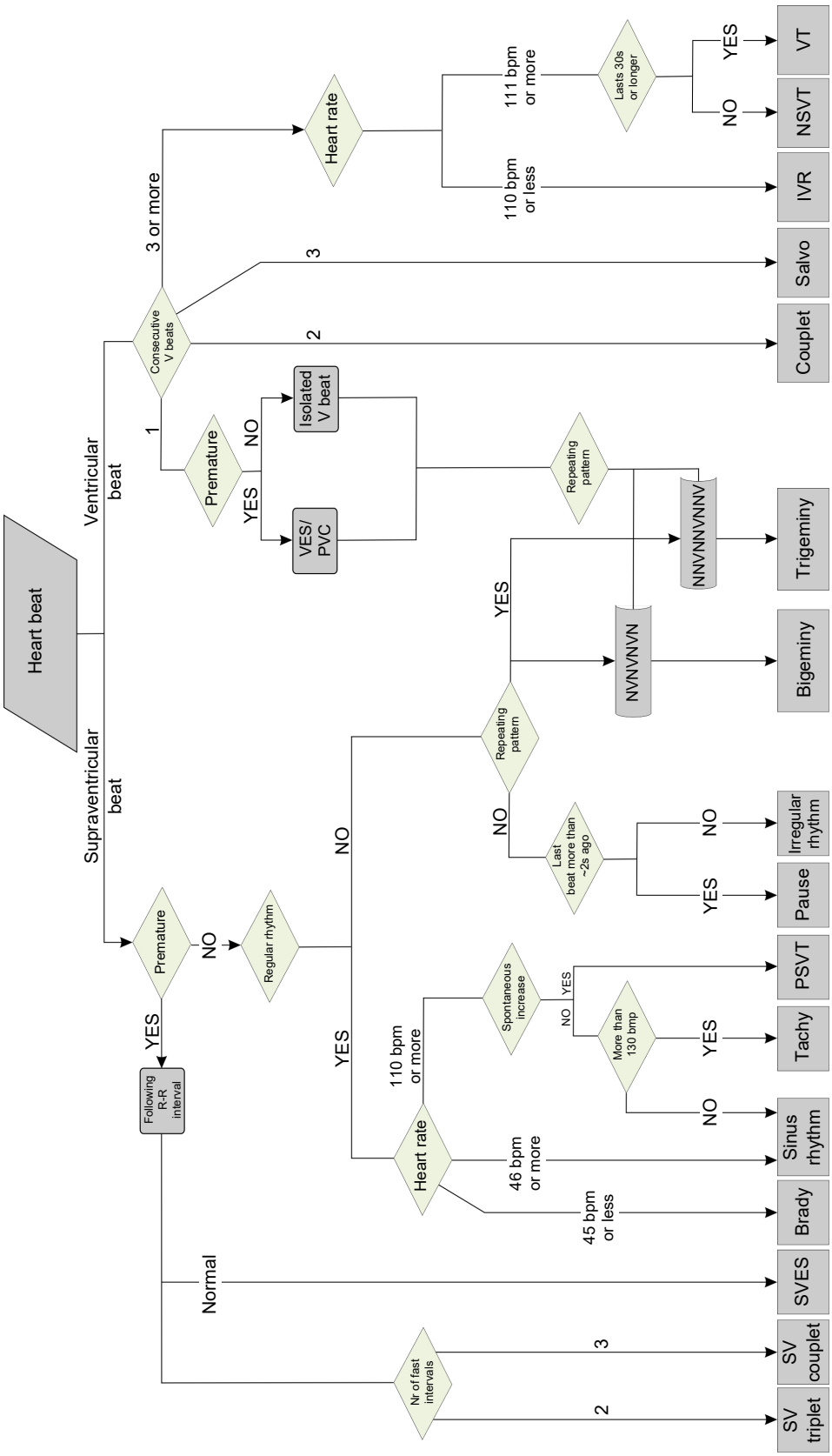
7.8.1 Information on arrhythmia definitions



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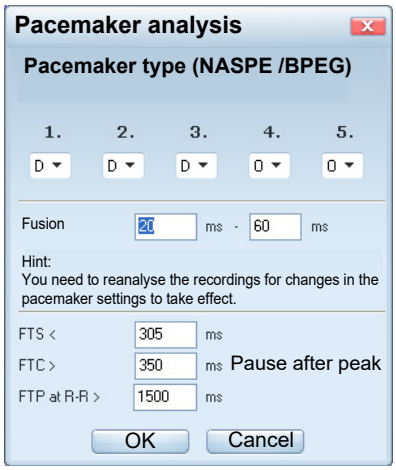
7.9 Pacemaker Analysis



- Select the PM type according to NASPE/BPEG codes.
- Fusion: Set the range in ms. If pacemaker spikes are detected within the given time range before and after the R peak of non-stimulated heart activities, they are called Fusion events.
- FTS <: Failed To Sense: If the interval between the PM spike and R peak is shorter than the value entered here, it is rated an FTS event.
- FTC >: Failed To Capture: If the interval between the PM spike and the following R peak is longer than the value entered here, it is rated an FTC event.
- FTP at RR >: Failed To Pace: If no heart activity and no stimulation is detected following the last stimulated or non-stimulated heart activity after the given interval, it is rated an FTP event.

Note that the pacemaker spikes are always analysed, and the PM can also be activated later, if necessary (refer to Recording information, page 35).

7.10 Blood Pressure Settings

Refer to Setting the threshold and classification, page 80.

7.11 Reanalyse

Use this menu option to reanalyse the recording, resetting it to the upload status. You are prompted to confirm the reanalysis.

Note that the excluded segments (including manually excluded segments) are not reanalysed when performing this task.
For more information on excluded segments, refer to Noise directory, page 43.

7.12 Info

Info provides additional information about the **medilog DARWIN2** program.

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8 Installation and Administrator Settings

8.1 Minimum Specification for the Computer System

The hardware for the **medilog DARWIN2** must comply with the following minimum specifications:

- Compliance with standard IEC 62368
- The latest supported version of Microsoft Windows OS
- Dual-core processor or higher
- At least 2 GB RAM
- At least 10 GB of free space on the hard disk
- Screen resolution: 1280*1024 pixels or higher
  - A screen resolution of 1920*1200 pixels is highly recommended
- USB port for the connection of the BR-102 plus PWA

Ensure all components have been installed correctly before starting the installation process for the **medilog DARWIN2** software.
The Windows device manager should not show any exclamation marks or question marks in the list of installed hardware.
If installing a new component, refer to the information in the documentation delivered with the hardware component.

8.2 Scope of Delivery

The **medilog DARWIN2** software pack includes:

- Short instructions to start the installation
- A **medilog DARWIN2** installation medium

All other documents referred to in this manual are in electronic form (Adobe PDF) on the medilog DARWIN2 installation medium. You must install a PDF Reader on your computer to read the documents.
Keep the **medilog DARWIN2** installation medium after the successful installation in a safe place which can be accessed only by the administrator.

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8.3 Installation

Installation of the software needs to be completed by an IT specialist.

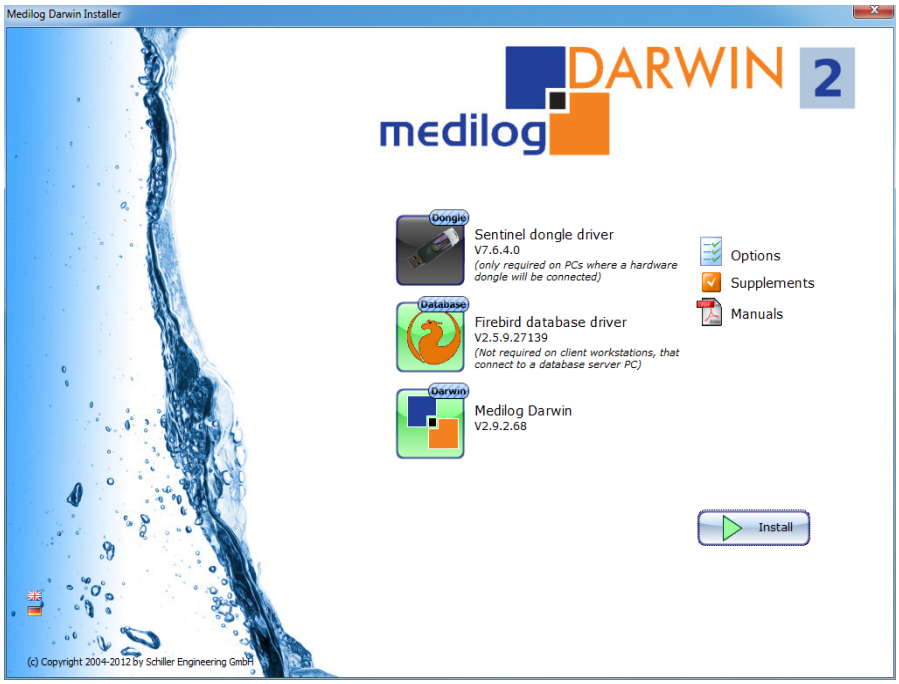
8.3.1 Scripted installation

If you want to perform an unattended (=automatic) installation/update, a batch file, Install_Scripted.bat, on the **medilog DARWIN2** installation medium in the Setup folder is available. Copy the file and adapt it to suit your needs. The comments provided in the file should give you all the information you need.

8.3.2 Installation on a single workstation

Insert the **medilog DARWIN2** installation medium into your computer. If the setup program does not appear automatically, open the autorun.exe file located in the root folder of the medium.

The following dialogue is displayed:



The installer indicates the system parts that need to be upgraded (highlighted in green). You can overrule the selection by selecting/deselecting the buttons.

To start the installation:

1. Press the **Install** button
2. Reboot the PC.

A **medilog DARWIN2** icon was created on your desktop, and the software is now ready for use.

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8.3.3 Client/server installation

If all clients are part of the same network, there are two ways how you can benefit from a **medilog DARWIN2** network installation:

- Multiple clients can connect to a common database
- Multiple clients share licences provided by a licence server.

Installation on the server

1. Create a folder, not a shared folder, where the database is stored (for example, C:\Darwin2\).
2. Create a folder for the RAW data (for example, C:\Darwin2\RawData). Make this a shared folder for which all **medilog DARWIN2** users have full read/write access.
3. Insert the **medilog DARWIN2** installation medium. The installer is opened. Click, Install.
4. Once the installation is complete, the Admin tool is opened. Before continuing, change the default Firebird password (refer to Firebird user and password, page 101)
5. Switch back to the Admin tool. Enter the server name (for example, ServerName), the desired database file name (for example, C:\Darwin2\Evolution2.fdb) and (if you have configured a custom Firebird user) the credentials of the custom Firebird user. A warning is displayed that the database does not exist, and you are asked if you want to create this database. Select Yes.
6. Once the database has been created, the Admin tool asks for a password. Log in with admin.
7. Enter the RAW data folder in UNC format.
8. Enter the network name of the PC as the licence server location.
9. Select Connect to licence server and install the Soft Licence keys.
10. Change the password for the Admin tool.

Note: If a Windows firewall is in use, the installer automatically opens the ports. If you use a different firewall program, ensure that port 1872 is open.

On the clients

1. Insert the installation medium and make sure only the **medilog DARWIN2** is installed. You do not need to install the database driver.
2. Once the installation is complete, the Admin tool is opened. Enter the server name (for example, ServerName), the database file name (for example, C:\Darwin2\Evolution2.fdb) and (if you have configured a custom Firebird user) the credentials of the custom Firebird user.
   - Note: If the Admin tool cannot connect to the database on the server, make sure that firewall programs allow access to port 3050 (type: TCP).
3. Once the **medilog DARWIN2** is installed, ensure your sensitive data is secure (refer to Securing the system, page 102).

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8.3.4 Firebird user and password

Firebird databases have a standard database superuser (SYSDBA). For security reasons, it is recommended to change the superuser password and create a designated database user for the **medilog DARWIN2**.

Securing Firebird database access

In the example below, the password of the sysdba-user is changed to myNewSysDbaPass and a database user MyDarwinUser with the password MyDarwinPassword is created. You can select the values as required.

You can perform the following actions as soon as the Firebird driver is installed:

- Open a command shell (click Start/run and enter cmd)
- Navigate to the Firebird installation path (enter cd \program files\Firebird\Firebird_2_5\bin)
- Enter the following commands:

// Change the password of the firebird superuser:
gsec -user SYSDBA -password masterkey -modify sysdba -pw myNewSysDbaPass
// Create a new user:
gsec -user sysdba -password myNewSysDbaPass -add MyDarwinUser -pw MyDarwinPassword

Setting custom database user name/ password in medilog DARWIN2

For the **medilog DARWIN2** to use a designated database user name/password, proceed as follows:

- Open the Admin tool
- Click the icon in the right corner of the DB name field to open the DB connection dialogue.
- Click the check box; Use a custom database user.
- Enter the desired values (for example, MyDarwinUser/MyDarwinPassword)

Making an old database accessible to a new user

If you created a database before setting up the new user, the new user has no rights to access this database. (In **medilog DARWIN2**, the error message, Could not determine the database version is displayed.)
The easiest way to grant access rights to the new user is to make a backup of the old database using the old user and restore it using the new user. The new user is now be the database owner.

To do so, enter the following commands:

// Back up the database:
gbak -B -USER sysdba -PASSWORD myNewSysDbaPass "C:\ProgramData\Darwin2\Evolution2.fdb" "C:\ProgramData\Darwin2\Evolution2.fbk"
// Move the old database out of the way (ATT: requires admin rights):
rename "C:\ProgramData\Darwin2\Evolution2.fdb" Evolution2_OldOwner.fdb
// restore database with new user:
gbak -R -USER MyDarwinUser -PASSWORD MyDarwinPassword "C:\ProgramData\Darwin2\Evolution2.fbk" "C:\ProgramData\Darwin2\Evolution2.fdb"

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8.3.5 Securing the system

Network security

Connections to the **medilog DARWIN2** database and HIS connection (if used) via HL7 or similar use network communication.

Some communication standards, like HL7, do not offer encryption. If software connects to the **medilog DARWIN2** using such a standard, communication is in plain text over the network. Also, communication with the Firebird database is unencrypted.

The network needs to be secured to prevent attackers from accessing sensitive data.

Recommended measures are:

- Restrict physical access to the network.
- Use a firewall so only the **medilog DARWIN2** workstations can connect to the firebird database.
- If you cannot restrict physical access to the network, you may want to use encryption/tunnelling for potential communication paths.

Explanation: An attacker who plugs into your network can use network sniffing software to listen to all network traffic and find unencrypted HL7 messages containing sensitive patient data. By setting up a secure tunnel, you can establish an encrypted communication path between two fixed points in the network. Communication between these points (for example, the HL7 caller on one side and **medilog DARWIN2** on the other) is secure and cannot be intercepted.

Restricting access to the PC

Attackers may try to install malicious software on servers/workstations to gain access to passwords or other sensitive data. To prevent this, restrict normal users from installing software.

Attackers may try copying the Firebird database file to access the stored information. To prevent this, restrict access to the database file's location. (You can remove read-access-permissions for all users for the folder where the Firebird database is stored as **medilog DARWIN2** accesses the database through a system service).

Audit log

From version 2.10, the **medilog DARWIN2** logs various events (failed login attempts, deleting a recording, report generation) in the Windows event service (Event source: MedilogDarwin). The **medilog DARWIN2** can be configured so that all workstations send these messages to a central event server (see AdminTool/Extended settings/ Misc/Audit log server). Specialised IDS/IPS HIDS software systems (for example, SIEM https://www.solarwinds.com/en/security-event-manager) that monitor these logs can be used to detect potential cyber attacks automatically.

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8.3.6 Installing medilog DARWIN2 updates

The update is first installed on the server, then on the workstations.
For installation on a single workstation (No client-server setup), only perform the steps listed under “On the server”.

On the server:

1. Make sure all instances of **medilog DARWIN2** applications (for example, **medilog DARWIN2**, Observer, DConnect) are closed, even on network connected workstations.
2. Back up the recordings database; refer to Backup database, page 108.
3. Install the new version of **medilog DARWIN2** as follows:
4. Insert an installation medium with the new version of **medilog DARWIN2**. The installation program should automatically start. If nothing happens, manually start the application "Autorun.exe" in the root folder of the installation medium. The installer automatically detects which parts of your installation can be updated to a newer version. The appropriate buttons are highlighted green, indicating that these parts are to be installed. You can overrule the selection by clicking on the appropriate buttons.
5. To start the installation process, click **Install**.
6. Test **medilog DARWIN2**: Open **medilog DARWIN2**, then open a recording. Verify the application starts and loads as expected.
7. Optional: Once the installation is finished, update the medilog Liberty Scanlab.

On workstations:

On workstations, you only need to install the new version of **medilog DARWIN2** without removing the old one. You do not need to update/install database drivers or perform backups.

8.3.7 Uninstall medilog DARWIN2

To remove **medilog DARWIN2** from a PC, use the Windows uninstall feature (Control panel) to remove all program parts; however, the recording database and raw data remain on the PC.

To remove the remaining data:

1. Delete the recording database (Evolution2.fdb)
2. Delete the raw data folder.

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8.4 Software Setup

There are other settings to be made to adapt the **medilog DARWIN2** software to the IT environment and the particular user requirements. A separate application has been programmed for those settings, allowing quick and easy setup. The Admin tool is automatically copied to the computer during the software installation.
After installation, the Admin tool is automatically started to perform the software's initial setup. You can run the Admin tool anytime by selecting the application from the Windows Start menu (All programs > DARWIN2 > Admin tool.exe).
When starting the Admin tool, you are asked to enter a password. At the time of installation, the password is: admin.

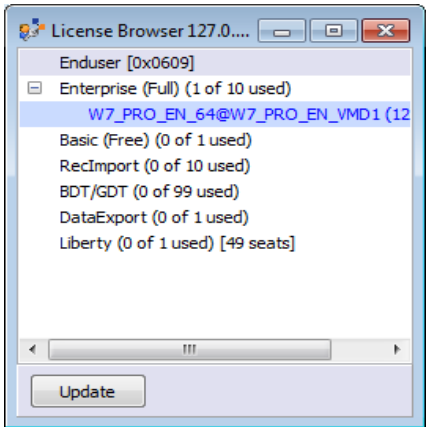
▲ The administrator must change the admin password when the Admin tool is used for the first time to prevent misuse.

8.4.1 Soft licences

1. The location of the licences server can be specified on the first page of the Admin tool.
2. After the correct licence server location is entered, click the Connect button. A window presents the Host ID, a value uniquely identifying the licence server PC.
3. Send this Host ID to your Schiller representative. One or more licence codes are returned to you.
4. For each licence code: Enter the licence code into the appropriate field and click Add licence. The window displays the number of licence files registered on your server; licences are available immediately.
5. Clicking the blue info icon starts the licence browser, which can be used to verify the correct operation.

8.4.2 Licence browser

For an overview of how many licences are in use, open the Licence browser application: DARWIN2 > LicSvrInfo.exe.



8.4.3 Automatic log off

After a certain period of inactivity (default value: 20 minutes), the user is logged off from the **medilog DARWIN2** and the licence is released. When the user moves the mouse again, **medilog DARWIN2** tries to get a licence, if available.

- Open the Admin tool > Settings > Extended settings > Licence hold duration to activate this setting and change the default value.

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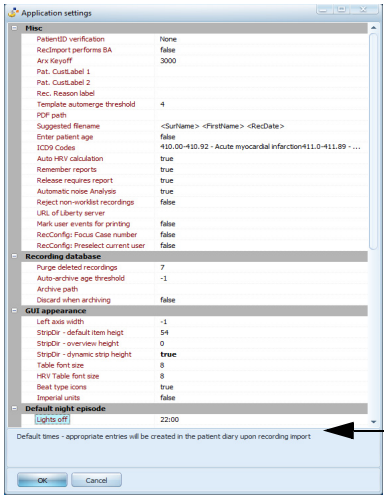
8.5 Database Setup

Using the Admin tool, you can set up the database location. Use the Pen icon to create a new database.
To connect to an existing database, enter the name and path to the database and the database user name and password as described above; refer to Firebird user and password, page 101.

8.6 Local Component Setup

In the **Setup** tab**,** you can adjust several parameters:

- Drive letters/drive types: enter any drives used to download recordings (for example, FlashCard drive F). Separate the drive letters with a comma but no extra spaces. This information is used for the DARWIN Observer (refer to DARWIN Observer, page 110). On how to receive a recording, refer to Controls, page 22.
- Look and feel: select the language and set the edition (refer to User Setup and Authentication, page 106, for more detailed information):
  - Full version
  - Professional
  - Office
  - Basic
- Report design items: enter the address of your hospital/private clinic in the text boxes. On the right side, use the Load Image button to upload your logo, which is printed in each report's report header.
- Recorder support: select all recorders that need to be supported by the software (refer to Software Setup, page 104)



- Extended settings: set options like Patient ID verification, Archive path, PDF path, default night settings, SEMA import path, and imperial units. Click an option to display additional information at the bottom of the window (see the arrow on the left).

- Reset to factory defaults: select the settings that need to be reset to the factory defaults. Note that greyed-out items have not been changed and still correspond to the factory defaults.

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8.7 User Setup and Authentication

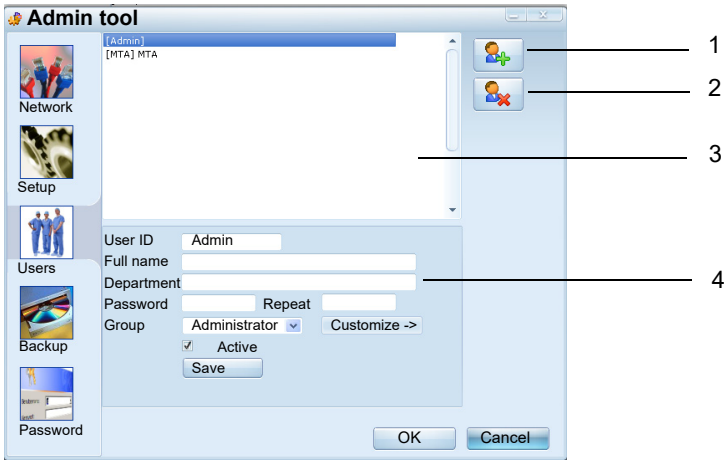
Different authentication methods are available; the method is selected in the Admin tool > Extended settings > User authentication > Authentication method.

In the Admin tool, you can also enable Two-factor authentication. If this option is activated, the **medilog DARWIN2** displays a QR code to each user at the next login. To set up the 2FA account, the code must be scanned with Windows authenticator, Google authenticator or similar. Then the **medilog DARWIN2** asks for a 2FA key which the authenticator app provides.

8.7.1 User setup in the admin tool

Before any users can access **medilog DARWIN2**, the administrator has to set up the database access and the relevant access rights for those users.

In the User tab, you can create users with the necessary access rights:



1. Add a new user.
2. Delete the highlighted user.
3. List of all users
4. User data:
   - User ID: enter a unique short name to identify the user. The User ID has to be entered together with the password at login.
   - Full name: this entry is optional; you can enter the user's full name for identification.
   - Department: this entry is optional. You can allocate the users here if several departments (for example, paediatrics and internal medicine) work with the medilog DARWIN2.
   - Password: enter a password for the user. There is no minimum length or other limitation, but using capitals, small letters, numbers and special characters in a password makes sense.
   - Repeat: for safety reasons, the password has to be entered again. It is not possible to copy and paste the password using the clipboard.
   - Group: with this setting, you select the user's access rights. Click Customize to view and edit access rights. Click an option to display additional information.

The following groups are available:

Default: users in this group have no restrictions (for example, they may delete recordings, change system default settings etc.). This template defines the standard values used by all other templates.

Administrator: full access to all functions of the **medilog DARWIN2**, like the Default group, and access to some special maintenance features.

Maintenance: like the Administrator group, this group has access to maintenance functions, but the user does not see the patient demographic data.

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Technician: The medical assistant can analyse recordings and mark them as “reviewed”. However, a user with more rights must release the recording.

– Active: this box must be activated for the user to log in to the program.

8.7.2 Single sign-on and Darwin user groups

When the **medilog DARWIN2** is started, it uses the same user name currently used as Windows login to identify itself in **medilog DARWIN2**.
If a user with that name does not yet exist in the **medilog DARWIN2** database, it is automatically created and assigned to the user group; Default. You can change the user group later in the Admin tool.

8.7.3 Windows users and Darwin groups

The **medilog DARWIN2** asks for a username/password upon startup. It then checks with Windows if this is a valid combination for a Windows user. If it is, the user may log in.
If a user with that name does not yet exist in the **medilog DARWIN2** database, it is automatically created and assigned to the user group "Default". You can change the user group later in the Admin tool.

8.7.4 Single sign-on and LDAP groups

LDAP offers the possibility of having a central server that manages all user accounts for a set of PCs. So if a new employee starts in a company, the admin only needs to set up an account on the central server, allowing the user to log on to all (or a defined number of) computers. The **medilog DARWIN2** can use this mechanism to check whether or not a user may use **medilog DARWIN2**.
With a single sign-on, the **medilog DARWIN2** uses the current Windows user name for authentication.
Using LDAP groups, it then checks the LDAP groups assigned to the user; for example, if Windows returns "medilogDarwin.Limited", the user is assigned to the user group, Limited, if available, and logged in with the privileges assigned to this group.

8.7.5 Windows users and LDAP groups

Ask for a username/password and check if this is a valid Windows user. Then get the user rights (=user group) from LDAP.

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8.8 Backup and Restore

8.8.1 Backup and restore system settings

Many settings in the **medilog DARWIN2** can be saved in a file for future maintenance and restore issues. This allows you to turn back to the previous settings. The following settings can be saved:

- Screen layouts and workflows
- Shortcuts for quick access
- Default arrhythmia settings (definitions which are used by the analysis module)
- Colour profiles for screen and printer
- Summary templates (text blocks which are used as a summary in the report)
- In-depth customisation: settings completed in the Admin tool, tab Setup, Extended settings

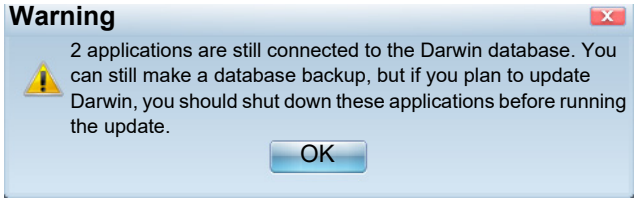
1. To back up the settings, press Backup, select the options and enter a file name and storage location.
2. To restore saved settings, press Restore, select the file and press OK.

8.8.2 Backup database

It is good practice to perform backups of the **medilog DARWIN2** database regularly. Back up the database before upgrading the **medilog DARWIN2** program to a newer version.

On the installation medium, a backup script can create a scheduled backup (\Admin\Backup\rotatingbackup.bat).
The script needs to be adapted to your system. The database path, firebird path and target path need to be defined. You can use the Windows task scheduler to generate an automated backup and store the backup data in a location accessible to authorised users only. Contact SCHILLER medilog for more information.

If an application is still running when you press Backup, the following warning is issued:



Press Backup in the Recording database section and specify the folder where the DB backup is to be stored.

Reports: If this box is ticked, the **medilog DARWIN2** creates a backup copy of all generated PDF reports. If you are creating the backup because you are about to update the **medilog DARWIN2**, you can untick this option. The reports are not stored in the database or modified during an update, and Unticking this option speeds up the backup.
Raw data: Tick this box to back up the ECG raw data. Backing up raw data requires a large amount of free disk space and can take a long period of time. Usually, it is unnecessary to back up raw data; when a later version of **medilog DARWIN2** is installed, the raw data is not modified at all.

Note that database backup is only possible to an empty target folder. If a file already exists in the target folder or the target folder does not exist, the backup process does not start.

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Start the backup by pressing OK. A copy of the current database and (if selected) the ECG raw data is saved in the target folder. Later, you can copy the created file(s) onto a separate backup medium.

Note that the current Administrator password is backed up together with the database. If the database is restored later, the password valid during the backup is restored automatically. If the ECG raw data and the database are to be restored, ensure that the database and the raw data are from an identical backup.

8.8.3 Restore database

Restoring the database must only be completed if no user is logged on. If need be, disconnect the network to avoid any unwanted login by other users.
During the database restore process, ensure the Observer application is not running as a background process. The Observer icon is shown in the Windows taskbar if the application is running. If necessary, close the application with a right-click on the icon. Then select the option Close from the context menu.

Press Restore in the Recording database section, enter the backup database's path and file name, and click OK to start the restore process.

8.8.4 Automatic archiving

The **medilog DARWIN2** offers a method to automatically archive recordings that have been released and not accessed for a specified period of time.
In the Admin tool, in the extended settings section Recording database, the following settings are available:

- Auto-archive age threshold
- Archive path
- Discard when archiving (optional)
- Delete .daw files after x days
- Permanently delete recordings after x days

Process:

- **Auto-archive age threshold:** All recordings marked as released and not opened for more than the specified number of days are archived to the path given in the Archive path. When archiving, if Discard is set, those recordings are not archived, but only the raw data is deleted, and the PDF remains.
- **Delete .daw files after x days:** archived recordings are deleted after the specified number of days. The database entries and the associated PDFs remain available.
- **Permanently delete recordings after x days:** database entries and the PDFs are deleted after the specified threshold.

To ensure that auto-archiving is possible, the application; ArchiveDaemon.exe must occasionally run on one of the workstations. This application can be put into the Start menu. Launching it from a Windows scheduler is recommended, ideally directly on the server and during nighttime when network usage is not an issue. To run the application manually, type; ArchiveDaemon into the Search field of

the Windows Start menu.

Attention new in V2.11.0:
When started without any parameter, ArchiveDaemon only lists all actions it would have performed using the current configuration and does not undertake any actual actions. This way, you can test your configuration. To tell ArchiveDaemon to perform the actions, call it with the command line parameter; -Execute.

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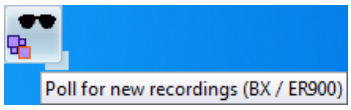
8.9 medilog Liberty Scanlab Installation and Settings

For installation procedures and necessary settings for medilog Liberty Scanlab, refer to the medilog Liberty Scanlab user guide (art. no. 2.511368).

8.10 DARWIN Observer

The Observer is an auto-run program that permanently searches the indicated drive(s) (usually the memory card reader drive) for new recordings that have not yet been imported to **medilog DARWIN2** (refer to Local Component Setup, page 105). When a recording is found, the patient data dialogue is displayed; if you click OK, the recording is imported and analysed in the medilog DARWIN2. When the program is opened later, the recording is listed in the database view as an Uploaded recording (refer to Database Screen, page 14). This tool is therefore required for the automatic import of ECG recordings.

If a new card reader is connected to the PC and a new card reader drive is detected, Observer asks the user if this drive should as well be monitored.



The Observer must be opened for the BX and ER900 recorders; the search starts manually (see left).

8.11 Changing Administrator Password

The password for access to the Admin tool software is changed in the Password tab. Enter the current password in the text field Old password (after the initial installation: admin). Enter the new password in the text field New password and again in Retype password. It is not possible to use the clipboard to copy and paste passwords.

▲ The administrator must change the admin password when the Admin tool is used for the first time to prevent misuse.

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8.12 Worklist with SCHILLER Server

For worklists via SCHILLER Server, items can be requested to be recorded by the **medilog DARWIN2**. SCHILLER Server uses device IDs to transmit such worklist items.

This applies to Holter ECG and BP recordings, including PWA. Once the recording is finished in **medilog DARWIN2**, it is transferred back to the SCHILLER Server as a PDF. When a recording is accessed in the SCHILLER Server, **medilog DARWIN2** is used to open, view and edit the recording.

For more information on SCHILLER Server integration, contact SCHILLER medilog.

8.13 Licence upgrade for medilog AR recorders

The medilog AR recorder is available in different versions, Office, Professional and Enterprise (for more information, refer to the medilog AR recorder's user guide, art. no. 2.511 345 EN).

Upgrading a recorder can be upgraded by purchasing a licence and utilizing the **medilog DARWIN2** program. To transfer the licence to the recorder, you must proceed as follows:

1. Connect the recorder via a USB port to the PC where the **medilog DARWIN2** is installed
2. Start the recorder configuration tool (refer to Configuration of medilog AR recorders, page 16)
3. Select medilog AR recorder
4. Make sure that the recorder you want to upgrade is selected
5. Right-click on the Star icon (that is, the button that shows the recorder's current version)
6. Select Install recorder licence from the popup menu. The recorder ID (unique identifier) is shown in a window:

7. Send the recorder ID to your Schiller representative. A licence code is then returned to you.
8. Enter the licence code into the appropriate field and click the green arrow. The recorder is updated immediately.

The licence is permanently valid and tied to a specific recorder, and it is not dependent on the **medilog DARWIN2** or the database.

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10 Appendix - Symbols

This appendix lists all general symbols that may be present on the device, label and accessories. Not all of those symbols are necessarily present on your device.

This appendix has its own article number, which is independent of the user guide's article number.

	Identification of the manufacturer
	Identification of the manufacturing date
	Identification of the distributor
	Identification of the importer
MD	Medical device
SN	Serial number
REF	Reference number
LOT	Batch code
GTIN	Global Trade Item Number
CAT	Catalogue number
QTY	Quantity
UDI	UDI: unique device identification as QR code machine readable and human readable as number (e.g. (01) 0 7613365 00210 2 (21)xxxx.xxxxxx)
	Number of pieces in the packaging
EC REP	Authorised European representative
CE XXXX	Notified body (e.g. CE 0123 marking notified body TÜV SÜD)

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	UKCA marking (UK Conformity Assessed)
	CE marking, affirms its conformity with European standards
	NRTL symbol (Nationally Recognised Testing Laboratory) TÜV SÜD as accredited NRTL certification provider
	Regulatory Compliance Mark for the Australian standards
	The device is recyclable
	Symbol for the recognition of electrical and electronic equipment. Device must not be disposed of in the household waste.
	Symbol for the recognition of a battery. Battery must not be disposed of in the household waste.
	The packaging is made in low density polyethylene and can be recycled.
	Federal law (USA) restricts this device to sale by or on the order of a physician
	Non ionising electromagnetic radiation. To indicate that the device contains a Radio Frequency (RF) transmitter to transmit data (e.g Bluetooth or WiFi)
	Contains a Bluetooth module
	Do not reuse
	Latex-free
	Use-by date (expiry date of battery, electrodes or other consumables)
	Temperature range for storage or transport, respectively
	Pressure range for storage or transport, respectively
	Humidity range for storage or transport, respectively

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	Consult instruction for use (indicates the need for the user to consult the instructions for use)
	Use within X days after opening (electrodes or other consumables)
	Keep dry (store in a dry location)
	Keep away from sunlight (protect from direct sunlight)
	Fragile, handle with care
	Transport upwards (this way up)
	Do not use hooks
	EIP = electronic information product (does not contain any toxic and hazardous substances or elements above the maximum concentration values (product can be recycled and re-used)).

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