

medilog DARWIN2

ECG and Blood Pressure Data
Management and Analysis Program

Art. no: 2.51.1044 Rev: k

User Guide





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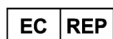
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If any serious incident has occurred concerning the device, it must be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.



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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.

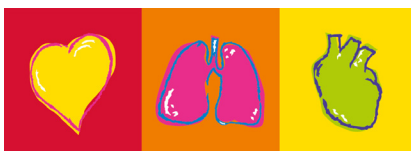


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Appendix - Symbols

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, SpO₂, 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 tachyarrhythmia
- AV blocks
- Bradycardia
- Congenital heart disease
- Heart failure
- Ventricular arrhythmias
- Hypertrophic cardiomyopathy
- Coronary artery disease
- Supraventricular arrhythmias
- ST-depression/elevation
- QT prolongation

- 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 SpO₂ analysis

To display the functional oxygen saturation of arterial haemoglobin (%SpO₂). 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.

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 SpO₂ 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 TCP/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.

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.
-

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.



▲ 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.

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 (AB-PM)

- 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

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
- SpO₂ 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.

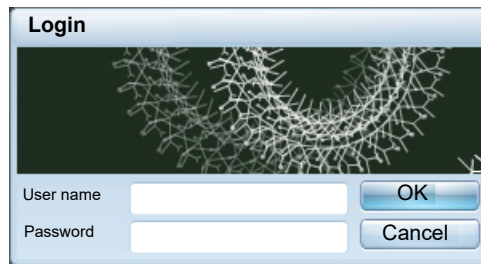
2.1.4 Method for HR calculation

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).

3 medilog DARWIN2 Program Overview

3.1 Login

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



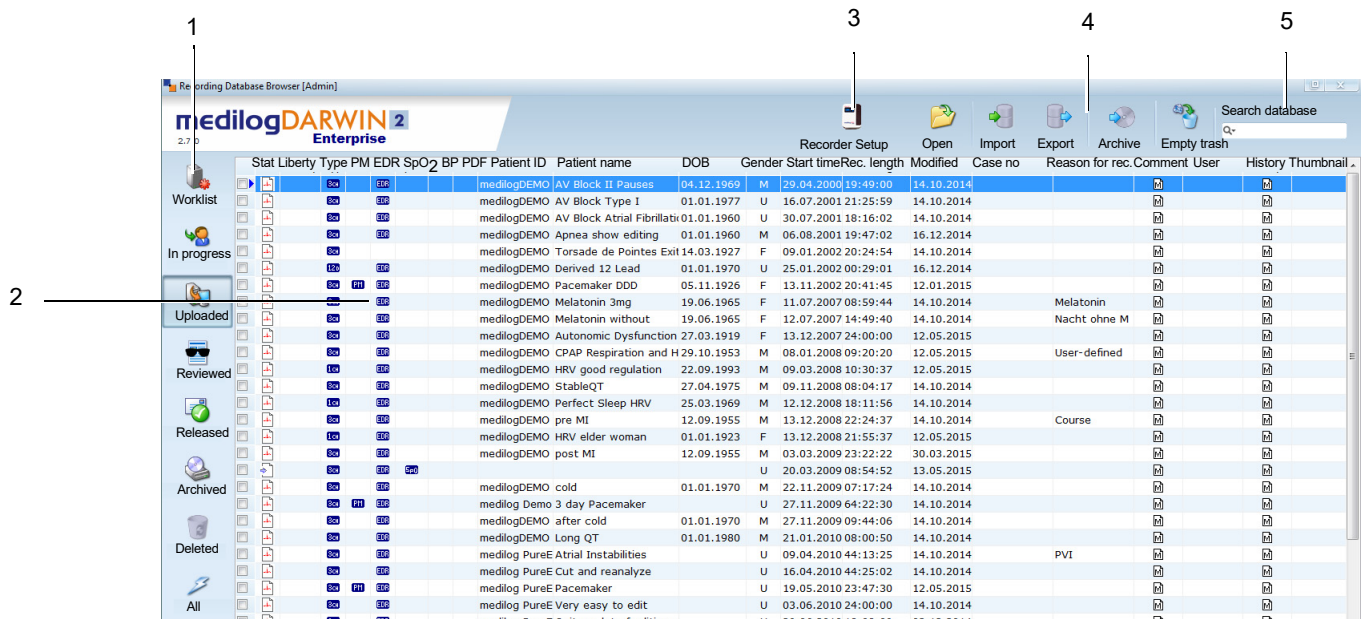
The login dialog box has a title bar 'Login'. It contains a background image of a neural network. Below the image are two input fields: 'User name' and 'Password'. To the right of the 'User name' field is an 'OK' button, and to the right of the 'Password' field is a 'Cancel' button.



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.



The screenshot shows the 'Recording Database Browser [Admin]' window. It features a sidebar on the left with icons for 'Worklist', 'In progress', 'Uploaded', 'Reviewed', 'Released', 'Archived', 'Deleted', and 'All'. The main area is a table with columns: Stat, Liberty, Type, PM, EDR, SpO2, BP, PDF, Patient ID, Patient name, DOB, Gender, Start time, Rec. length, Modified, Case no, Reason for rec., Comment, User, History, and Thumbnail. The table contains multiple rows of patient data. At the top right, there are buttons for 'Recorder Setup', 'Open', 'Import', 'Export', 'Archive', 'Empty trash', and a 'Search database' search bar. Numbered callouts 1 through 5 point to specific elements: 1 points to the 'Worklist' icon, 2 points to the 'Uploaded' icon, 3 points to the 'Recorder Setup' button, 4 points to the 'Archive' button, and 5 points to the 'Search database' bar.

- (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
 - SpO₂: SpO₂ 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.

3.3 Starting a Recording

There are three possibilities for starting a recording:

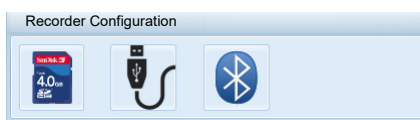
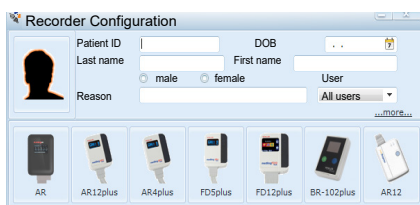
1. Initiate a recording on the recorder (refer to the recorder's user guide for more information)
2. In **medilog DARWIN2**, select Recorder Setup in the Database screen (refer to [Database Screen, page 14](#), and [3.3.1](#) below)
3. In **medilog DARWIN2**, perform a worklist item (refer to [Database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

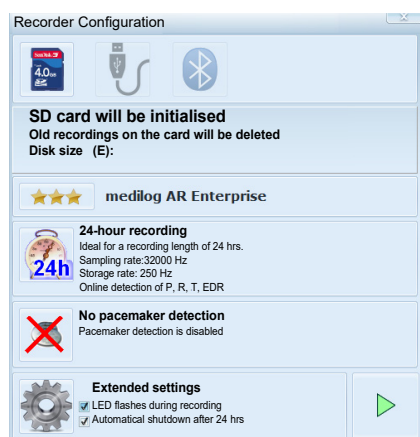
Select your preferred setup option: memory card, USB or Bluetooth. For more information about these options, see below.

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.





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.

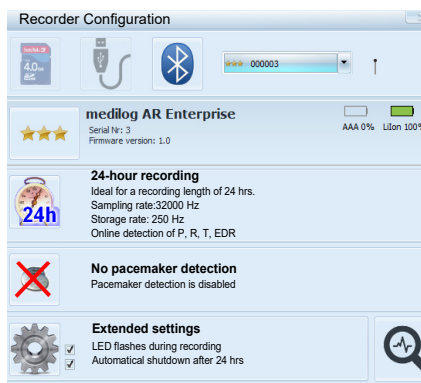
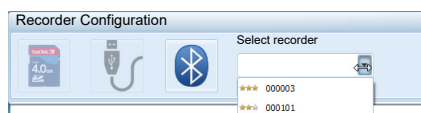
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Configuration via Bluetooth

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).



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.

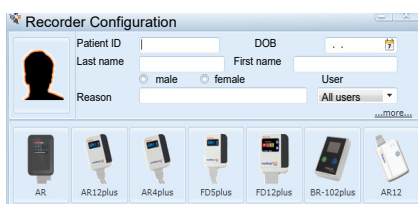
Note that recordings cannot be transmitted via Bluetooth due to the large data volume.

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



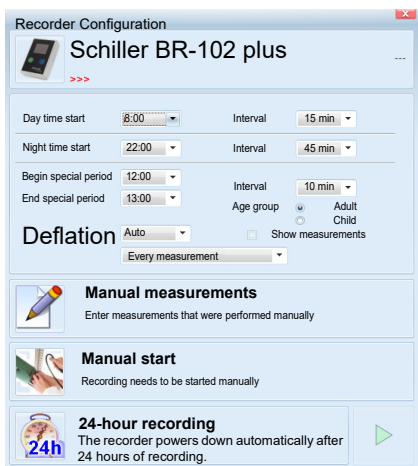
▲ At the start of the recording, double-check the patient data to avoid mixing up patients and recordings.

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).

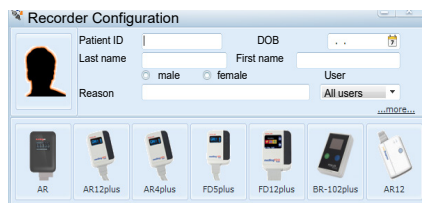


When a recording is started from the **medilog DARWIN2**, the settings described above are applied for the current recording.



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

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.

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.

Rec. start	13.11.2002 11:12:06	Case number
Rec. length	20:41:45	
Recorder type	AR12	Ref. doctor
Serial no.	78	Contact info
Firmware	2.0	
Profile	unknown	Reason
Pacemaker	DDDDQ	
Order ID		Current therapy
		Recom. therapy

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.

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.

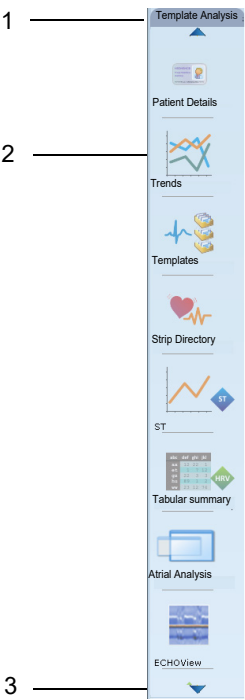
The procedure for the analyst is as follows:

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)

3.6 Controls

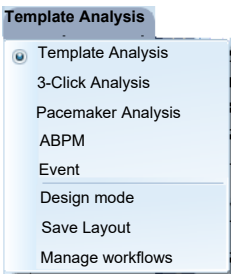
The **medilog DARWIN2** is based on workflows. These workflows can be adjusted to the user's requirements so that only the modules necessary for the user are displayed in the workflow bar. The module's order can also be adapted so the user can work through the workflow from top to bottom, minimising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

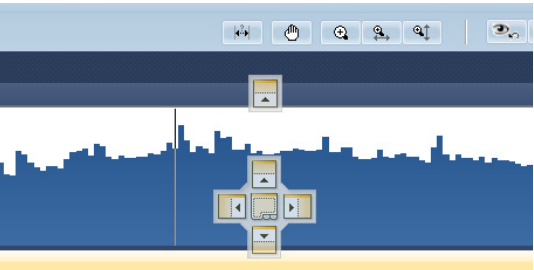
At the bottom, three additional menu options are available:

- **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.

3.6.2 Workflow settings

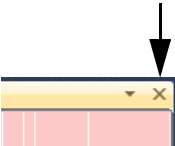
Design mode

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

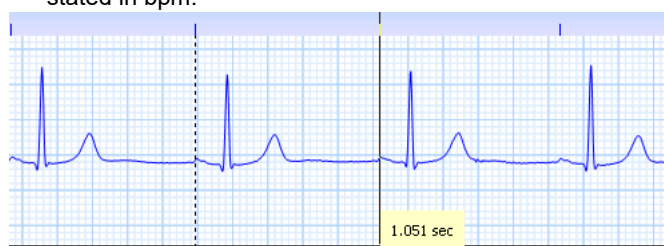
Click the Modules icon in the top right corner of the screen  to select additional modules for display.

3.6.3 Toolbar

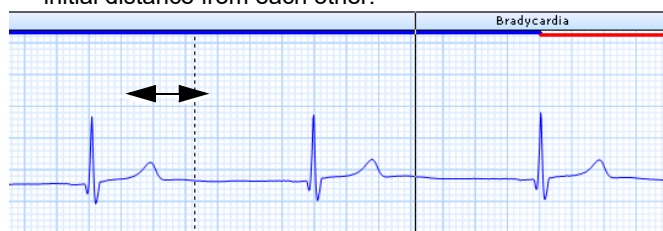
The following toolbar is displayed at the top of the screen when a recording is open.



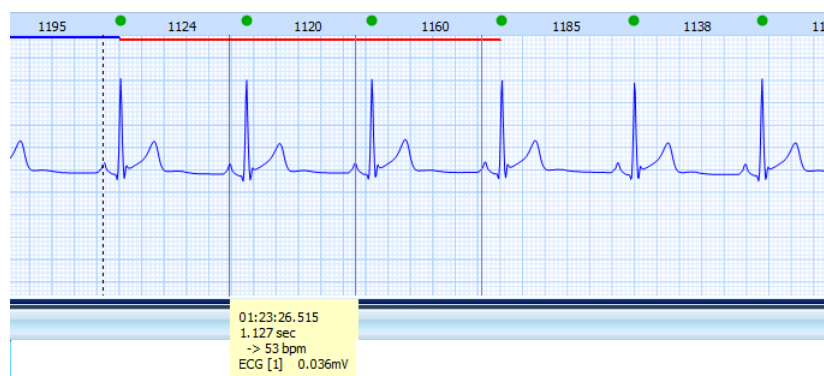
- (1) **Measure tool:** Select this tool to measure distances in the ECG detail viewer (refer to [HRV](#), page 56) and any other modules. To do so, click on the start point of the measurement and drag the mouse to the end point. A dashed line indicates the start of the measurement and the end point 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.

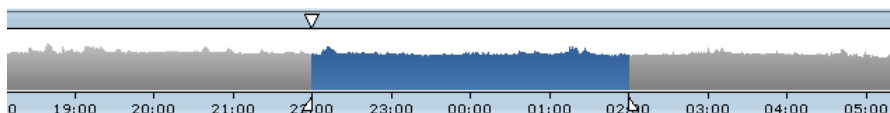


- (2) **Hand icon:** Allows you to drag the displayed section. Press the left-mouse key and drag as required.
- (3) **Zoom tools:** Zooming is possible in the strip modules (ECG detail viewer, Signal viewer). The following tools are available:
- **Zoom:** A magnifying glass is displayed instead of the 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

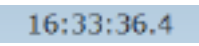
the segment with the mouse to zoom. This feature is only available in some modules, such as ECG detail and signal viewer.

- **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.



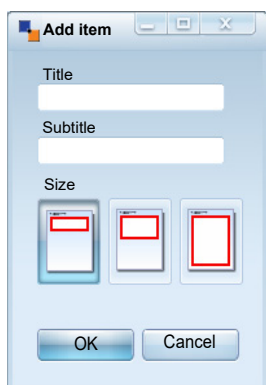
Click the Show entire recording icon in the toolbar  to display the entire recording.

- (5) **Position in the recording:** You can also use the interface in the toolbar  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.

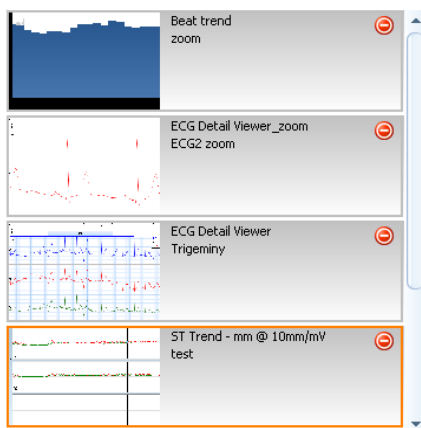
- (7) **Print queue:** You can add selected recording segments to the report from most modules.

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.

3.6.4 Selection tools

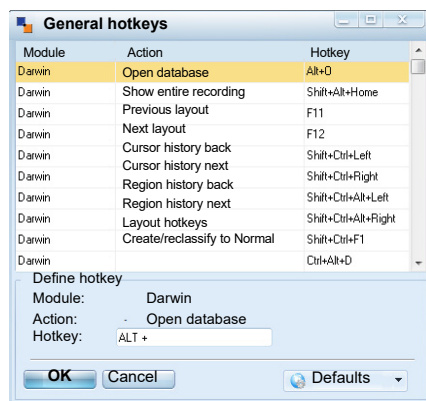
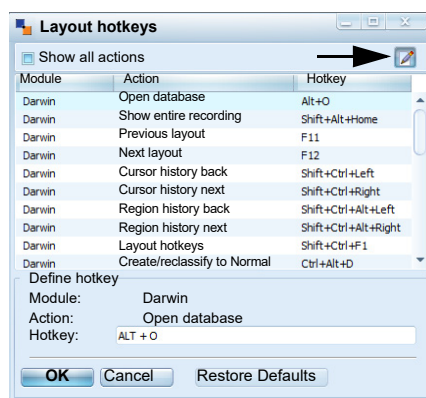
There are several ways of selecting a recording segment in the ECG detail viewer, trend, atrial analysis strip, ECHOView etc., to exclude channels/segments, and set the arrhythmia type:

- 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.



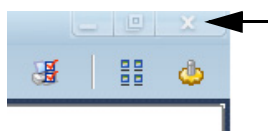
To display all shortcuts (not just for the current layout), open the Settings menu and select Configure hotkeys. A dialogue with all shortcuts is displayed. Highlight the required shortcut and assign another key combination. Save the changes.

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

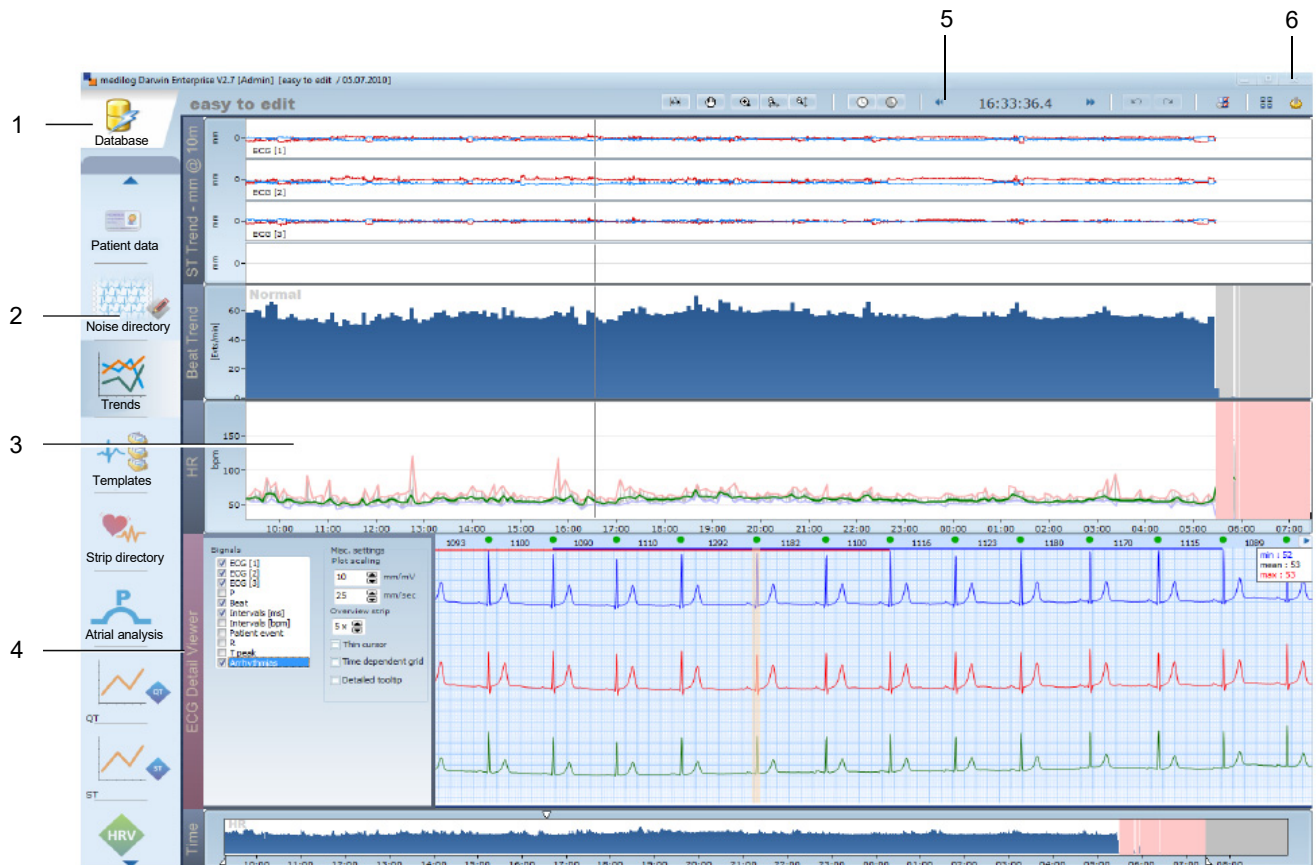
Log off by clicking the X icon (see left). Any changes performed in the Arrhythmia strips, Beat types, and Templates, for example, are saved automatically.



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.

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.

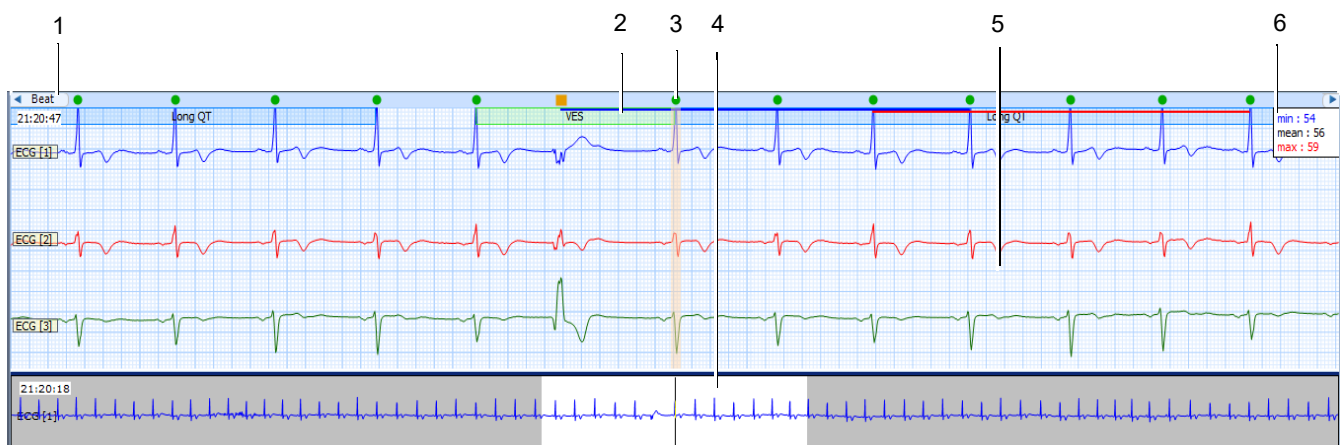


Note that the modules available depending on the workflow and user settings, the software version (Basic, Office, Professional or Enterprise), the recorder used, and the number of ECG channels (3 or 12).

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.

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

```
d2 02:13:50.797
1.394 sec
-> 43 bpm
ECG [1] 0.629mV
```



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]

Right-click menu options

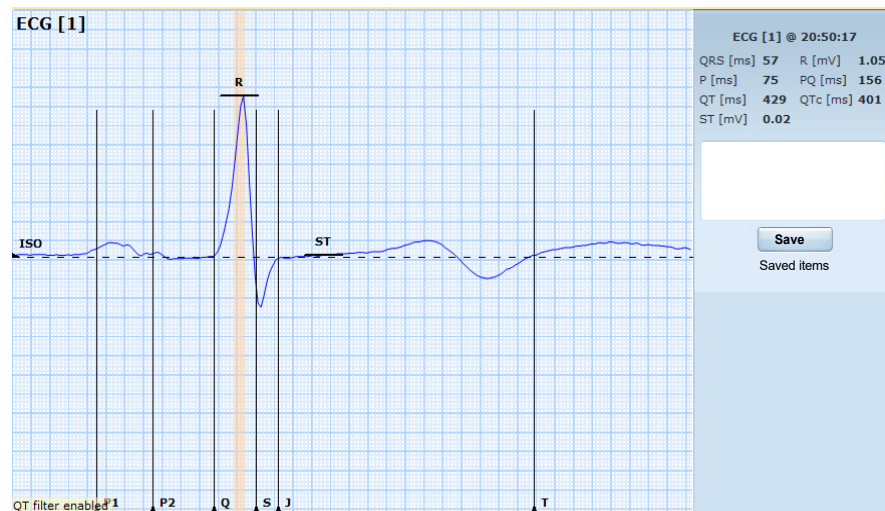
Right-click anywhere in the ECG strip to access the following menu options:

- 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.

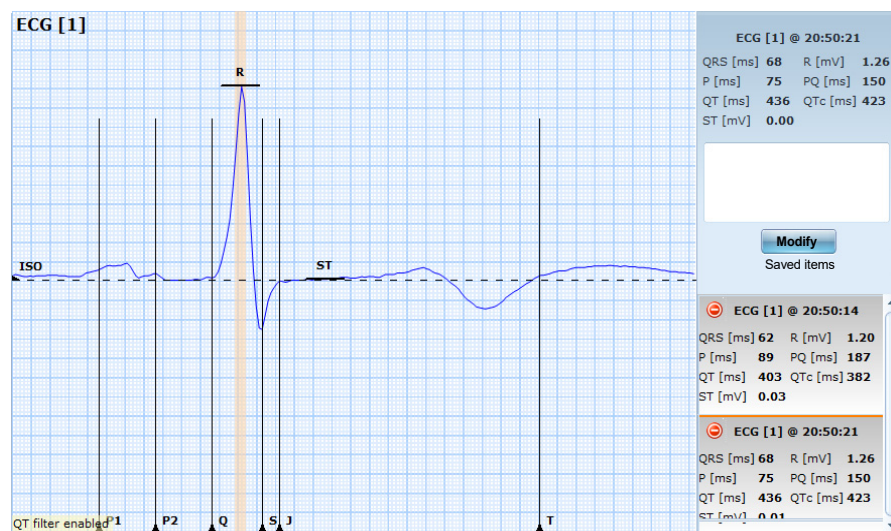
You can change the beat type with a right-click on a beat (in the top line). Also, use shortcuts to reclassify the beat type (Ctrl + underlined character indicated in the menu). This option is only available if Beat is selected in the ECG detail viewer settings > Signals (see above).

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.



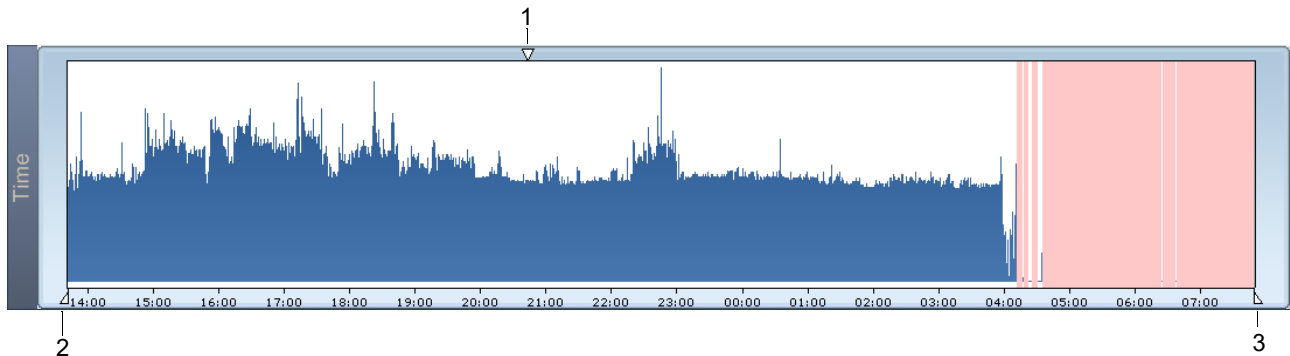
Click and drag the measurement lines with the mouse to change the positions of the P wave etc. The values are given on the right-hand side. To save the changes, click Save. To delete the changes made to a complex, click the red Delete icon (see below).



Settings

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

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.

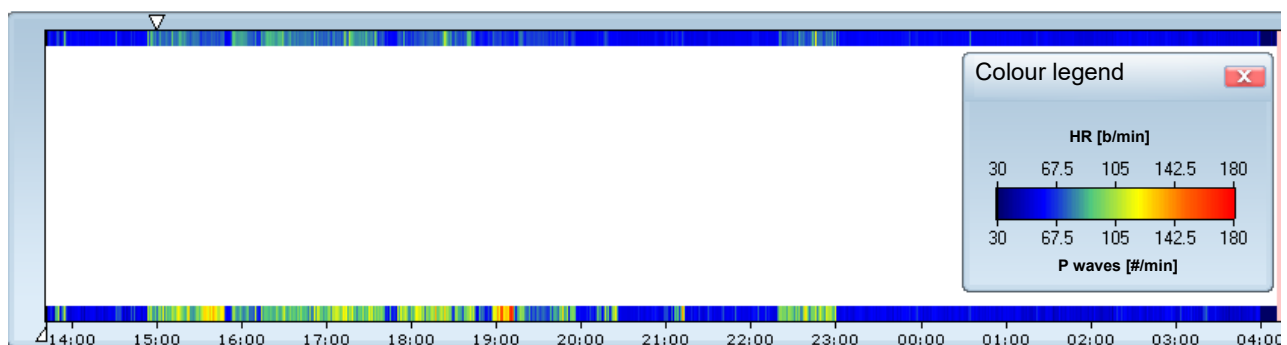
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Note that the colours described here may vary from your installation: the colours depend on the colour settings; refer to [Colour Settings, page 94](#).

The right-click menu has the following menu options:

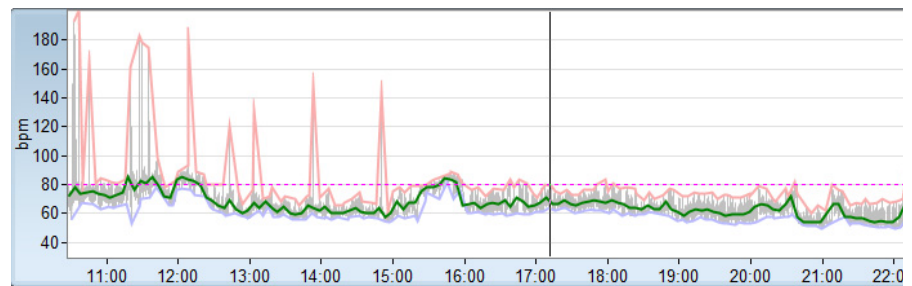
- Select the display range
- Set range start to ECG cursor: if this is set, only the recording segment starting at the cursor position is shown; refer to [ECG Analysis, page 27, \(5\)](#).
- Colour-coded trends/Legend; see below.

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.



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

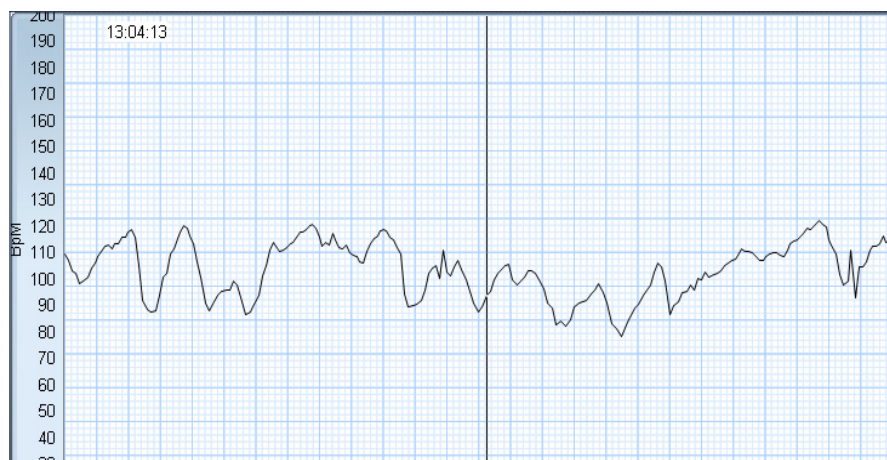
- Select the signal to be displayed:
 - Respiratory frequency in cycles/min
 - Respiratory validity as a percentage. Quality index of the EDR calculation.
 - QPA: pulse-respiration quotient, the number of heart beats during one breathing cycle
 - EDR (change in amplitudes of R peak due to respiration 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.

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.

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.

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:

ID	medilogDEMO		DOB	05.11.1926	Age 76
Last name	Pacemaker				
First name	DDD				
Gender	♀ female	Height	0	cm	Weight 0 kg
Phone					BMI: ---
Address					
	Prim. ins. no		Sec. ins. no		
Comments					
Save Cancel					



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](#)).

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.

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Time	Event	Condition	Comment
21:16:50			
21:17:35	◆	good	Dinner
21:18:25			Patient event
21:18:39		moderate	Dinner
21:30:18	◆		Patient event
21:30:42	◆	good	Patient event
21:31	◆		
21:31:04	◆		
22:00	C		Sleep: 22:00
02:15:17	◆	poor	Patient event
05:04:32	◆		Patient event

2

Time 12:53:08

Comment

Condition

☐ Timepoint only

Add Update Delete

3 4 5

- (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.

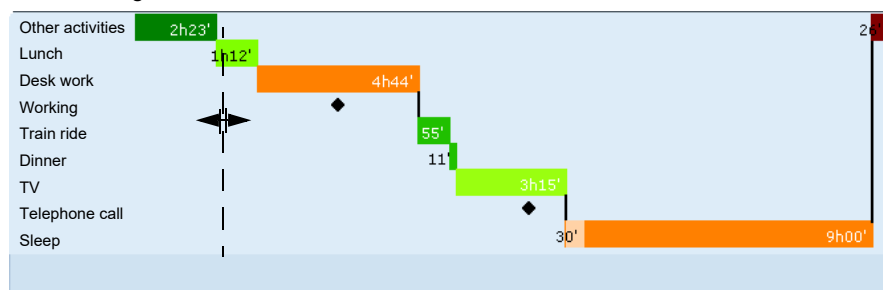
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The default settings for the sleep period (Light off, Sleep, Awake) can be edited in the Admin tool > Extended settings (refer to [Local Component Setup, page 105](#)).

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:



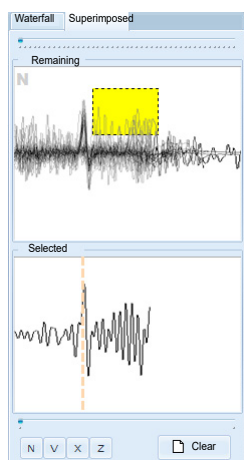
In the diagram, the diary entries are shown in colour (depending on the entered patient condition, the colour varies from red to green) and with event icons (if Timepoint only has been selected). Use the mouse to expand or shorten a diary entry (see the arrows in the illustration above).

4.2.10 Template editor

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



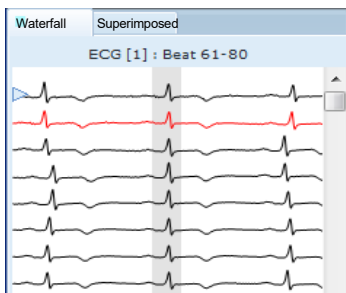
- (1) List of all templates. For each template, the following information is provided:
 - Classification: the highlighted template above (highlighted orange) is classified as normal beats (N).
 - Right-click on a template to reclassify it or mark it as edited. Manually reclassified templates are indicated 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.



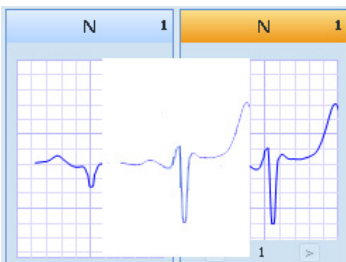
Waterfall: all beats are displayed below each other, showing one second before and after the complex.

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

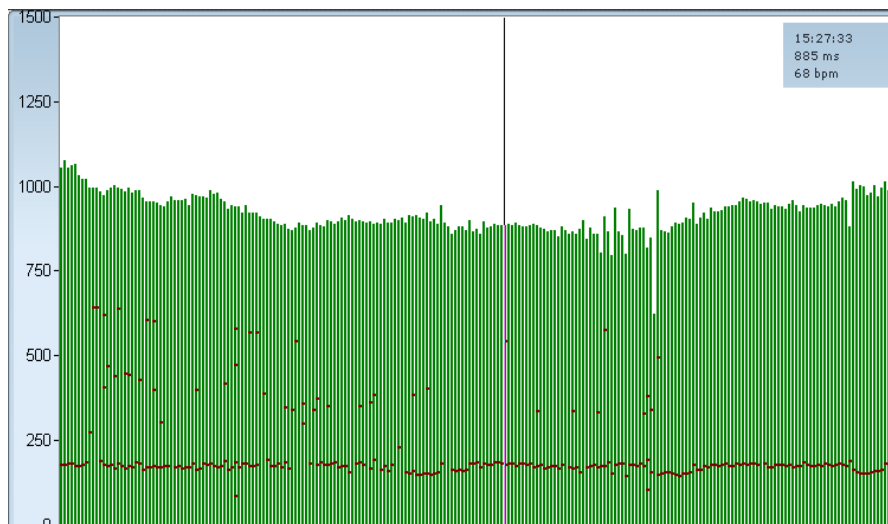
- Start/stop the reanalysis of the recording.
- Low amplitude ECG: this setting is only recommended for patients with low ECG signal amplitude. If this option is set and the signals are reanalysed. In that case, a more sensitive analysis algorithm is used to detect even low-amplitude QRS complexes, increasing 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.

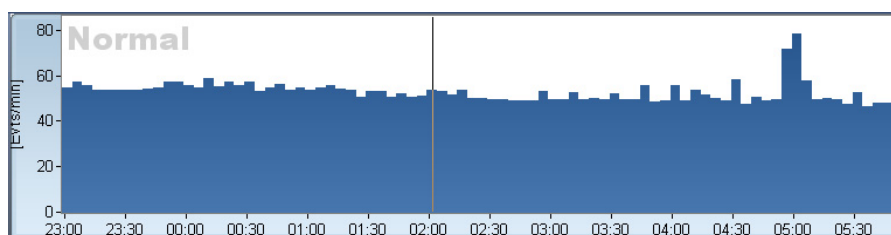
4.2.11 Tachogram

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:



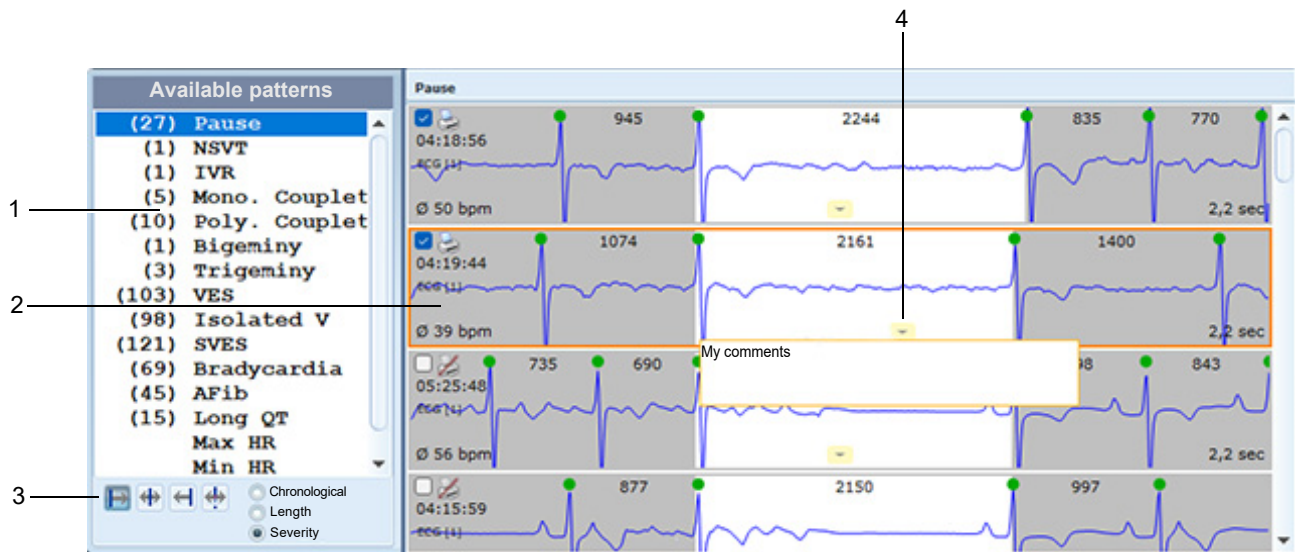
This example displays the trend for normal beats (unit: events per minute). Right-click to add the segment to the print queue (refer to [\(7\) Print queue, page 25](#)).

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.

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

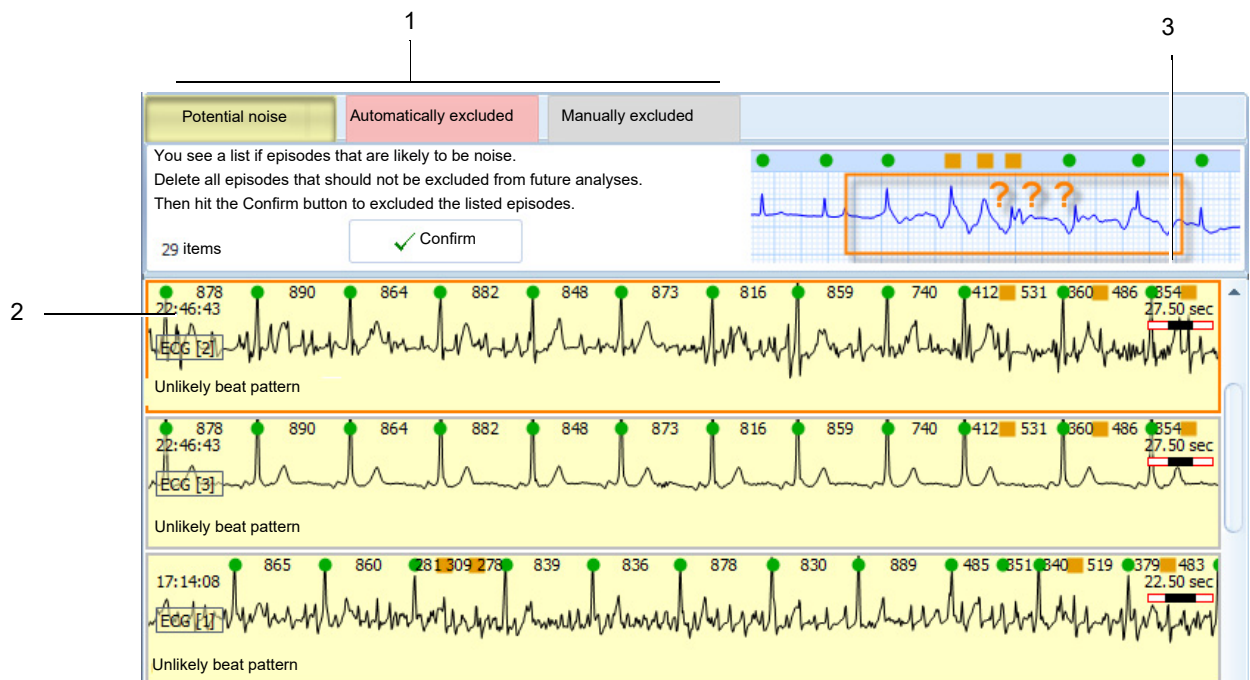
- Select the ECG channel to be displayed
- Define the speed and amplitude
- Activate/deactivate beat information
- Show only strips that are marked for printing
- Reanalyse arrhythmias
- Configure the arrhythmia settings (refer to [Arrhythmia Configuration, page 95](#))

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.

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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.

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.

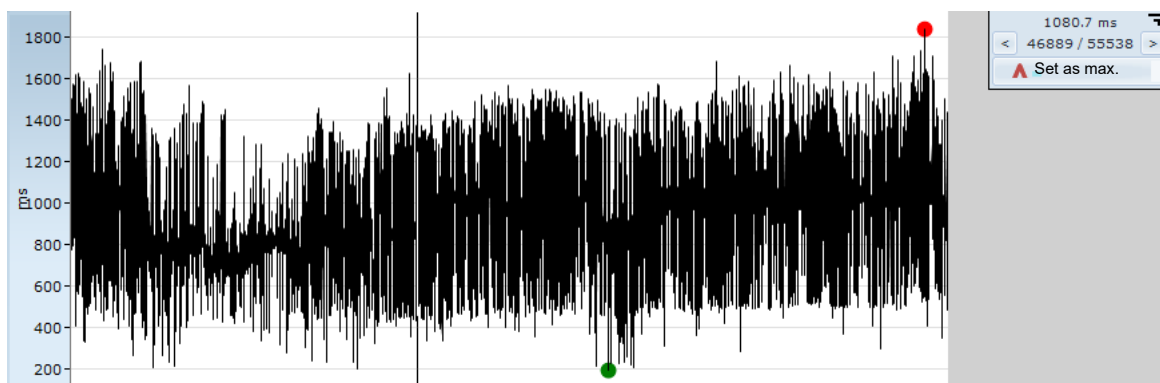
Review the list and delete any episodes that have been categorised incorrectly and are not noisy. Mark an episode and delete it. Episodes which are deleted from this category are included again in the analysis.

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)

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](#)).

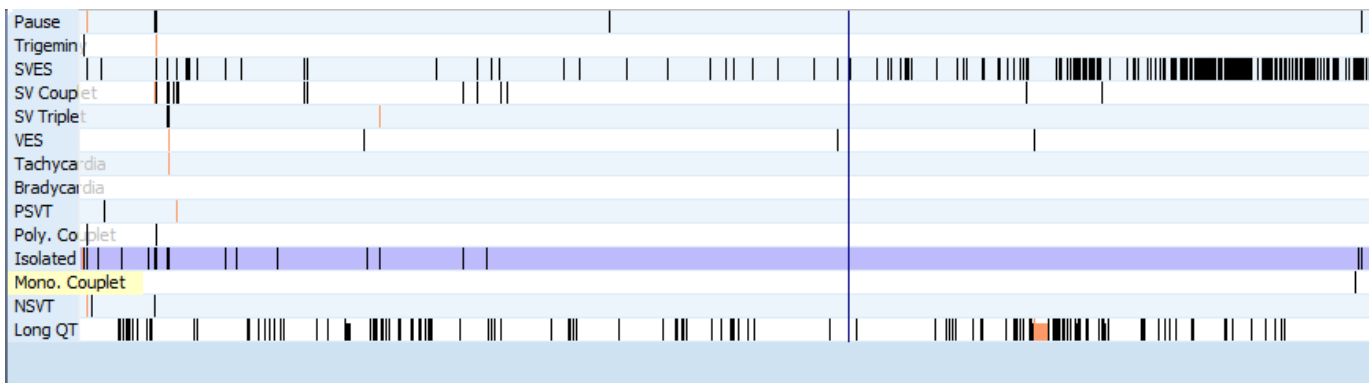
The longest interval, or the highest HR, is marked with a red dot, and the shortest with a green dot.

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](#)).

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.

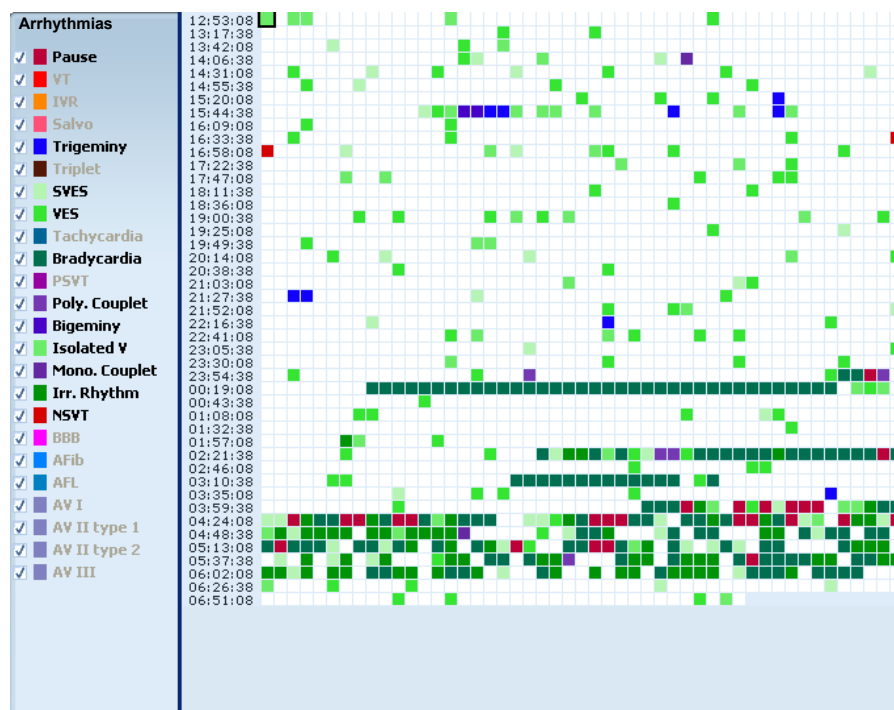
By pressing Ctrl + Page up/down, you can jump to the previous/next arrhythmia within the same category.

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.

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).

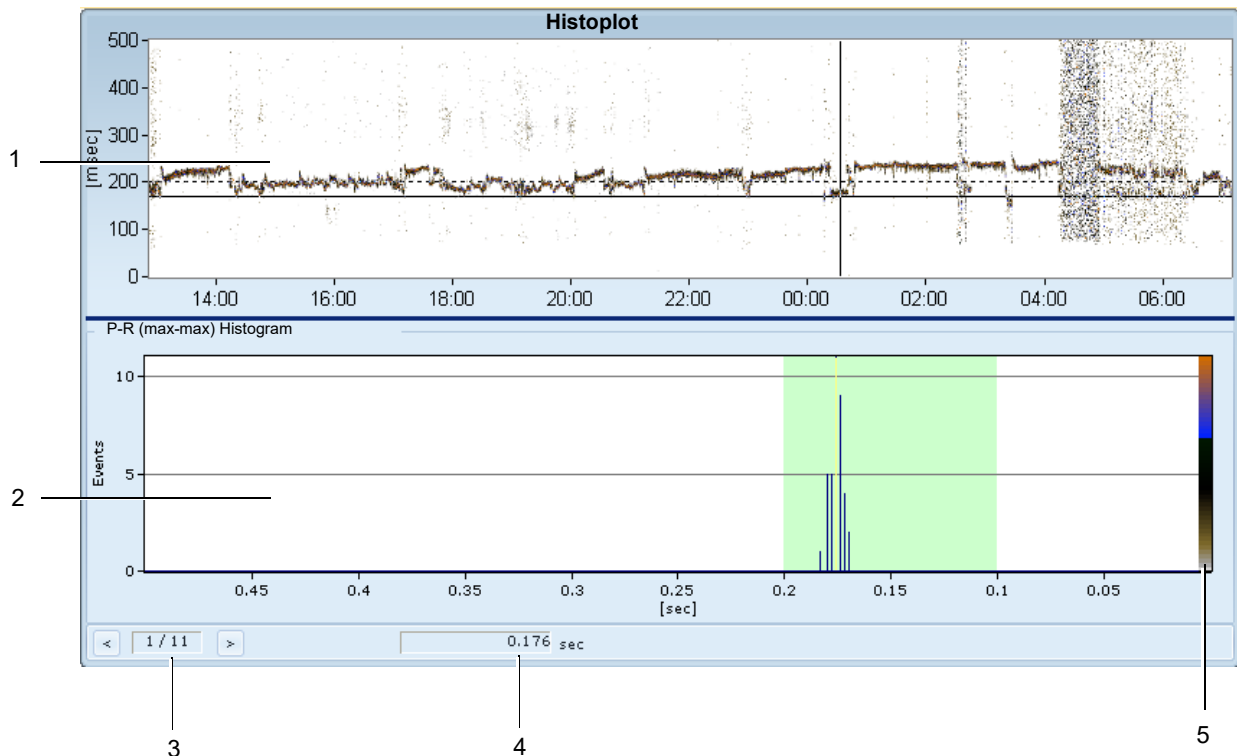
Settings

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.

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

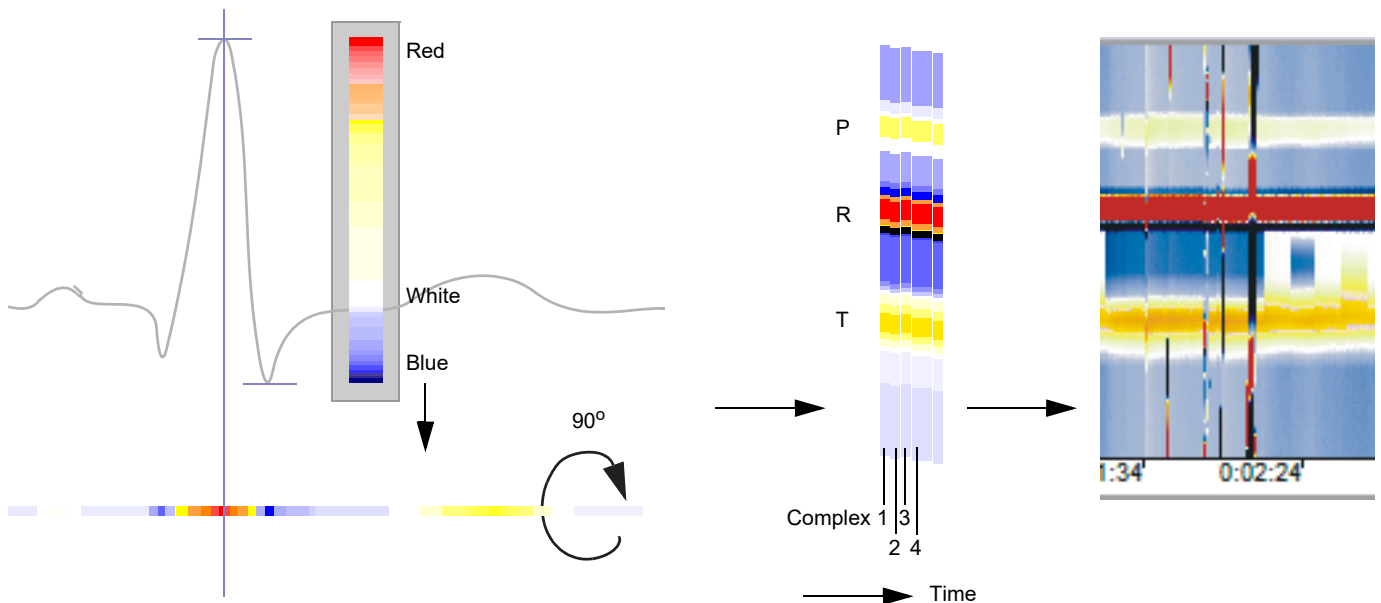
In the settings, you can select the resolution, maximum PR interval, and segment length, invert the colours and show AF episodes.

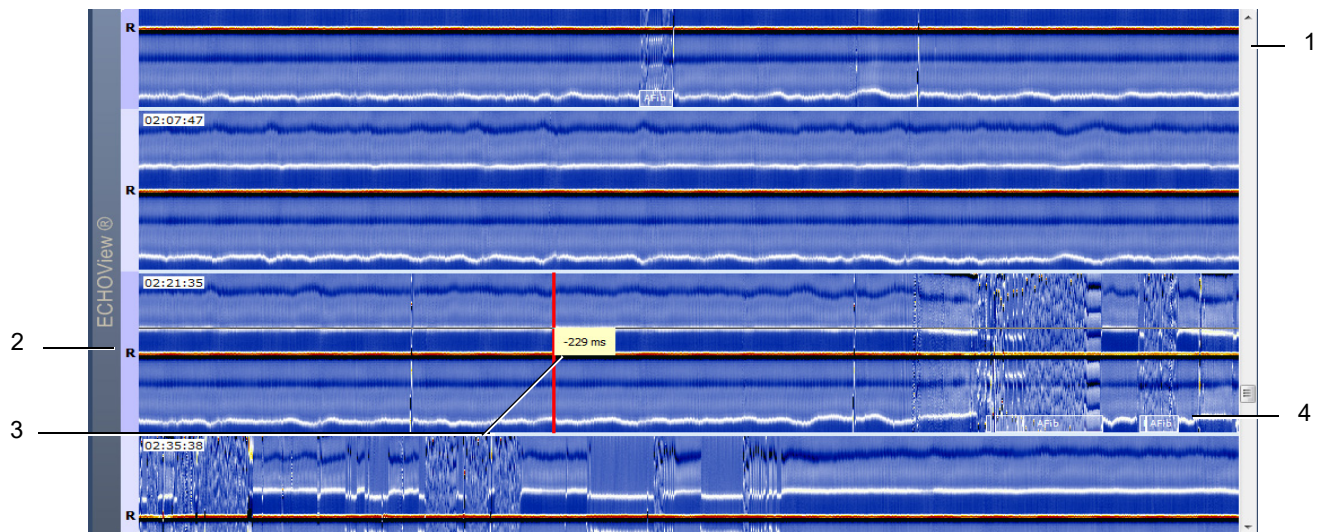
4.2.19 ECHOView

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

- 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)
- After the colour has been applied to the complex, the complex is converted to a single vertical coloured line.
- Each QRS complex is then ordered sequentially in real-time, resulting in a multi-colour Echo display stretching from left to right.
- 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.

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

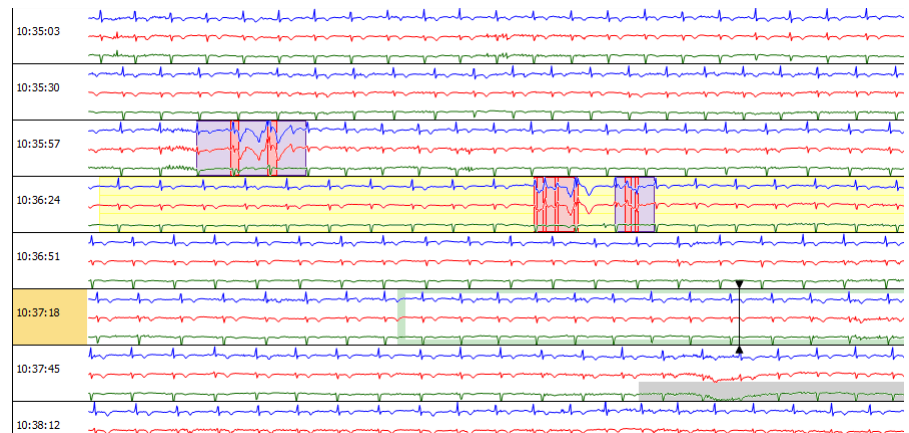
- Select the channels to be displayed:
 - HR
 - SV related (supraventricular)
 - AFib/AFL (atrial fibrillation/atrial flutter)
 - V related (ventricular)
 - Beats (number of supraventricular/N-SV/normal/ventricular beats, validity and the total number of beats).
 - **SV beats:** Beats covered by supraventricular 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.

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.

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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](#).

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.

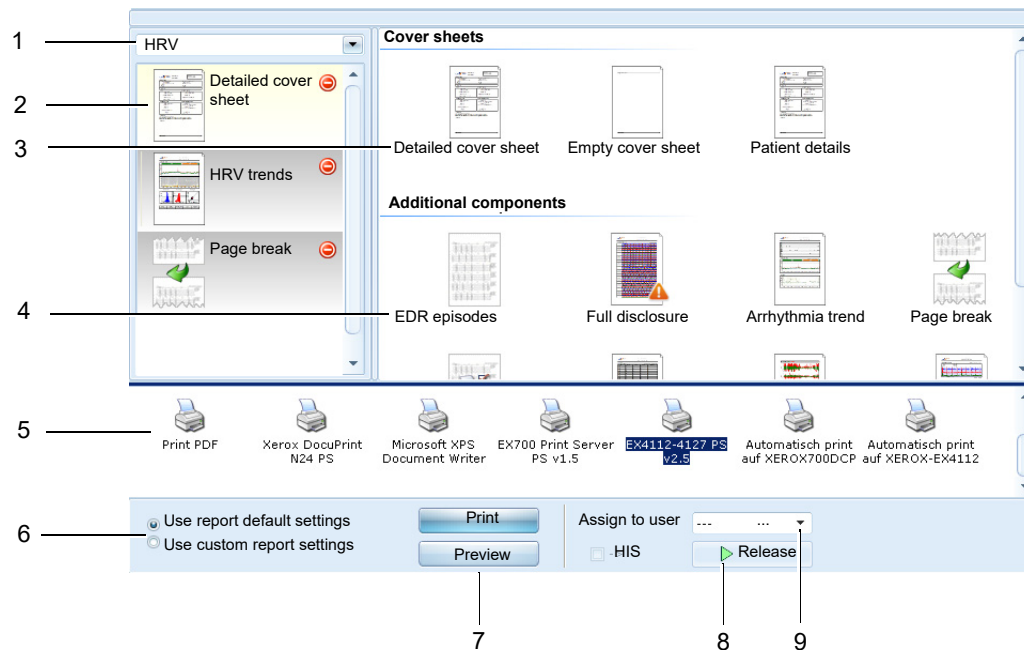
You can then edit the text and select the variables required. In this example, only variables concerning HR have been used.



- ▲ 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.



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:



Full Disclosure

- (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}■		



Copy plugin setting to clipboard

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.

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.

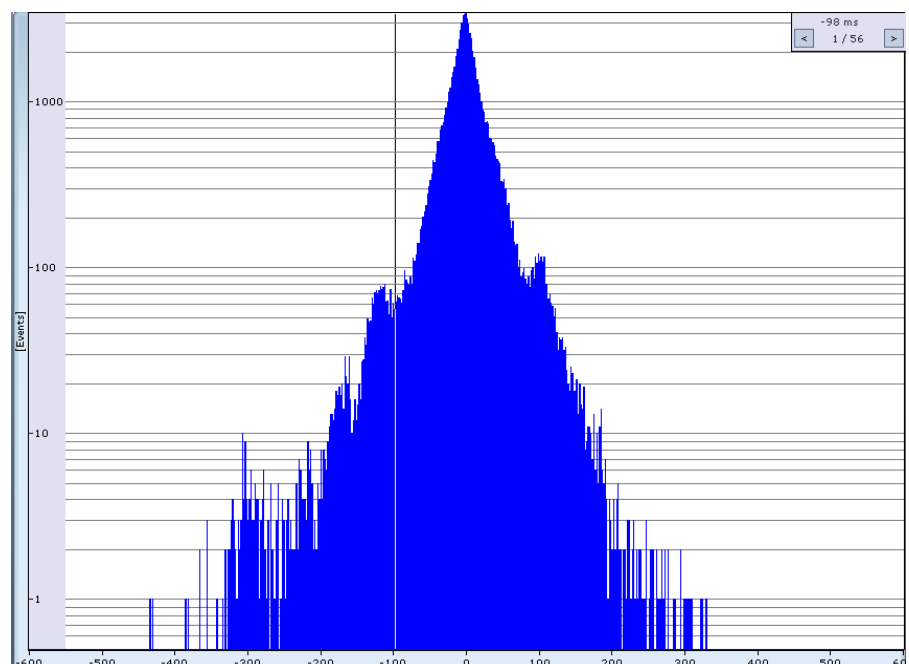
Decreased autonomic regulation is generally a sign of bad health. Using HRV analysis, it is also possible to validate the selected therapy. An increasing HRV (increasing autonomic regulation) shows that a therapy is effective.

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:



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.

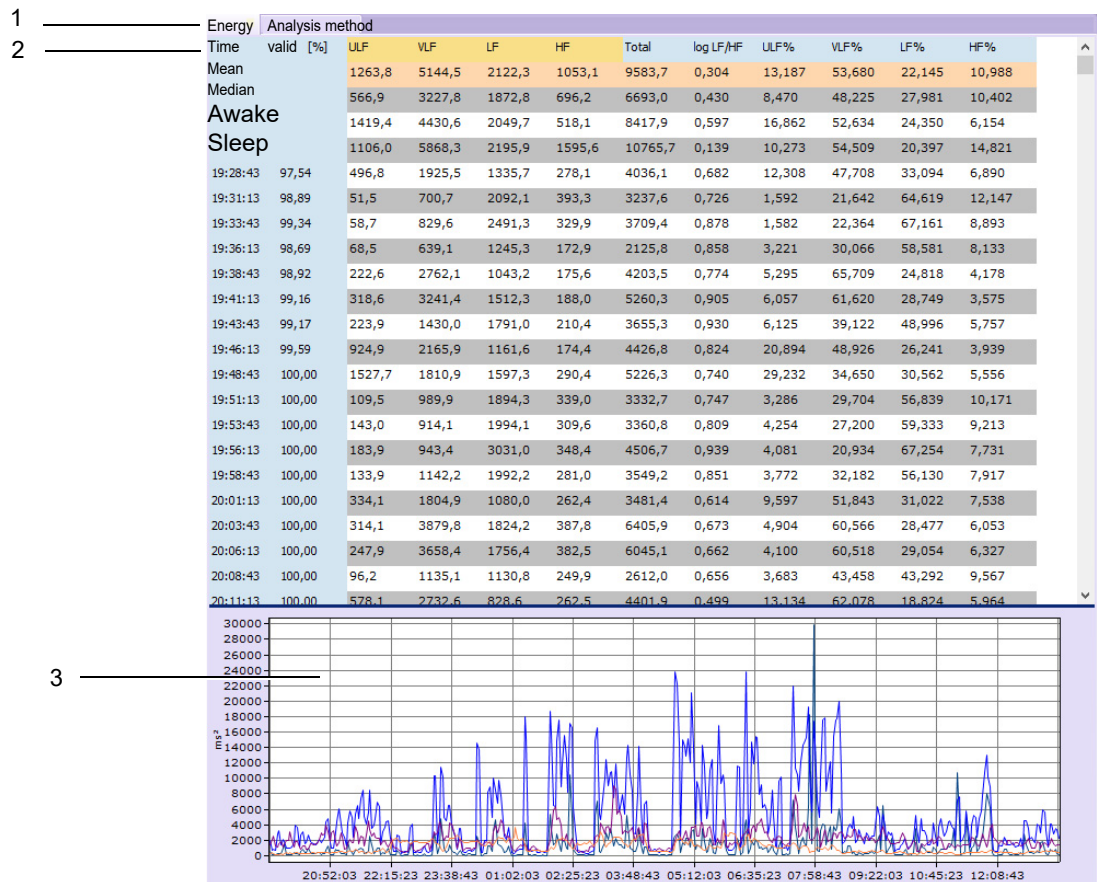
Settings

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

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.

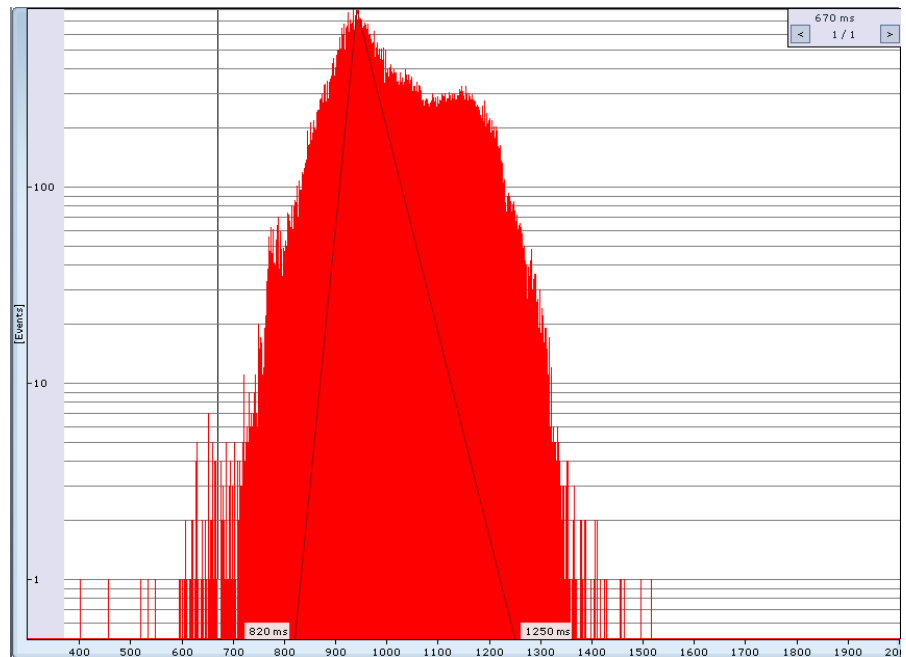
Settings

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.

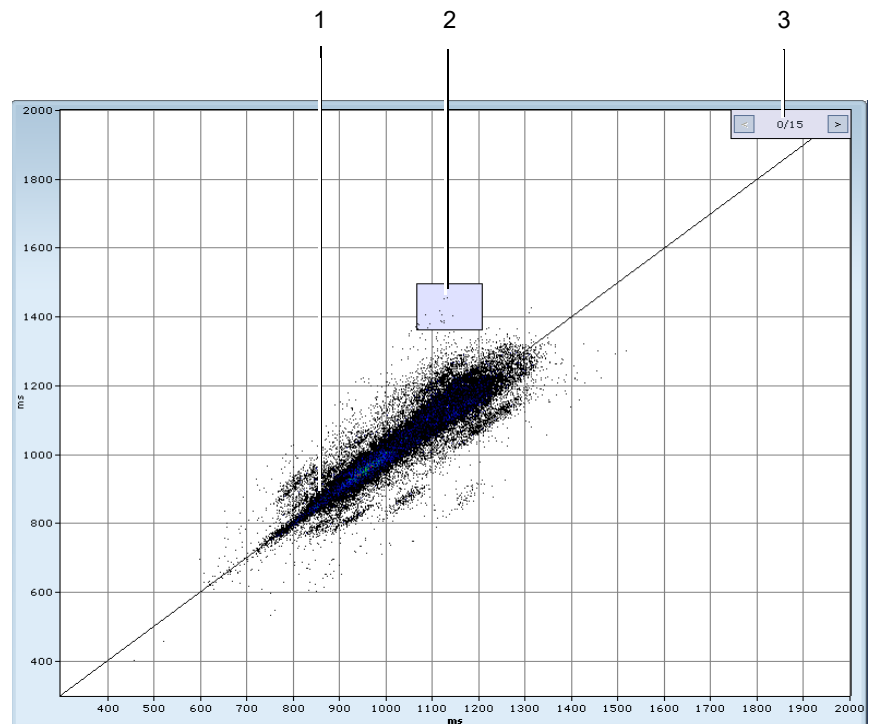
Settings

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](#)

HRV Scatterplot

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

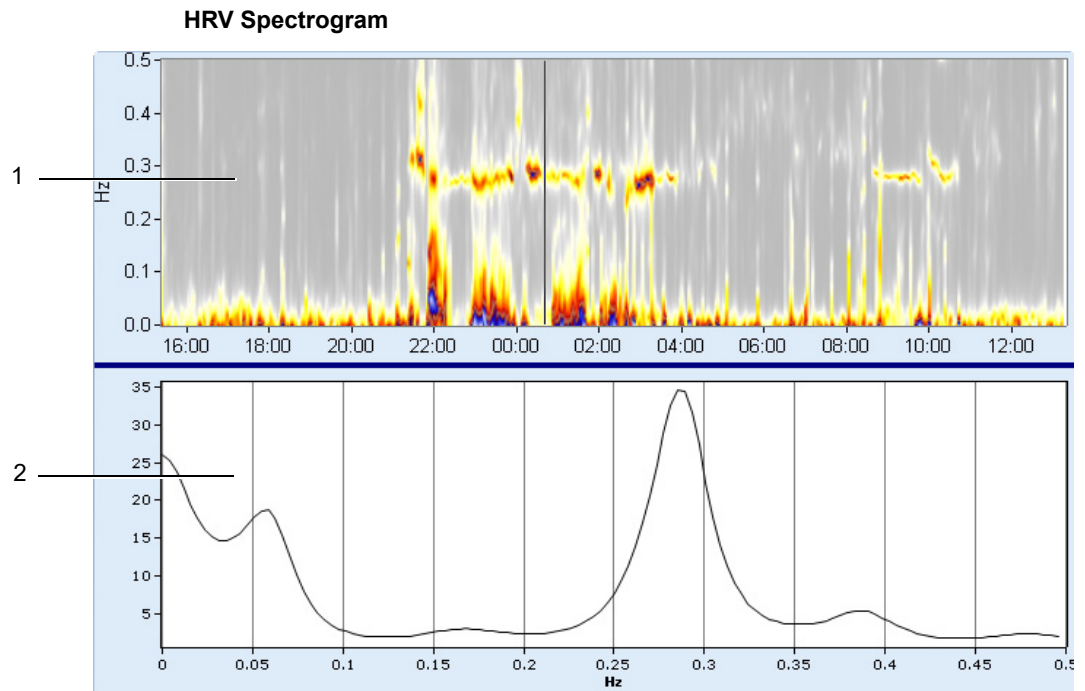


- (1) Each dot represents two consecutive RR intervals: the first interval determines the position on the X-axis (horizontal), and the second interval the position on the Y-axis (vertical). The lower the HRV, the narrower the shape of the diagonal pattern.
- (2) In this module, a magnifying lens is displayed 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:

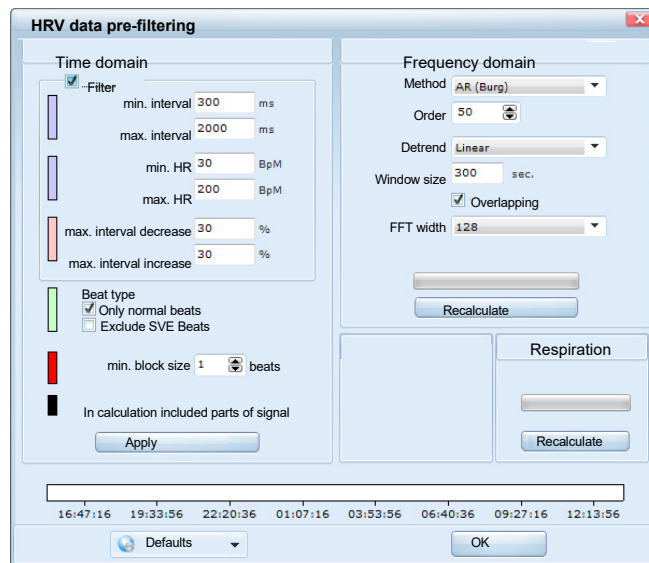
- Resolution setting
- Controls: jump to the previous/next selected interval



- (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 ms²) 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.

HRV Configure

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



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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).

HRV Tabular summary

SDNN-i 98,4ms		SDANN-i 199,2ms		Circadian index 1,44		HRV index 69,6		TINN 1117,2	
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	

Trend min [bpm]

Trend min [bpm]



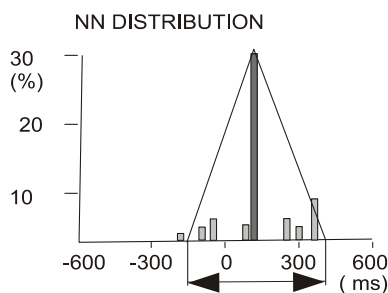
In this table, HRV parameters of the time domain analysis are displayed for each 5-minute time segment, as well as over the entire recording:

- 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.



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:

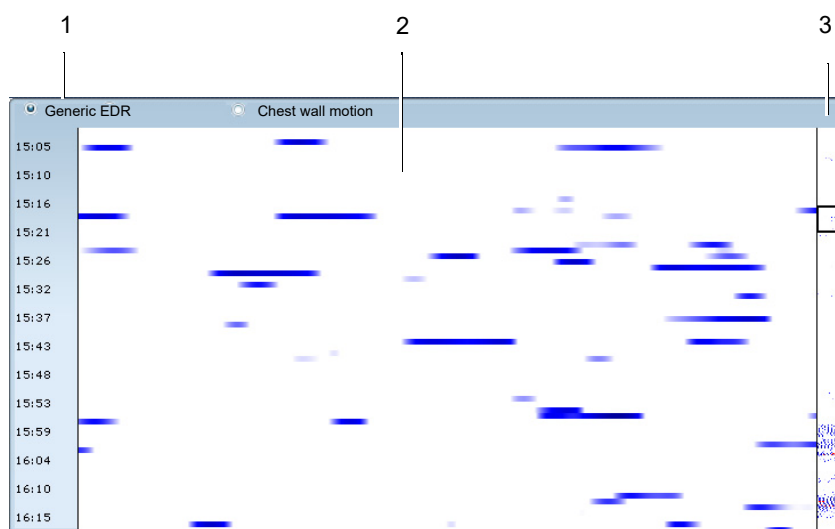
- $fn(\text{Mean}(x))$
- $\text{Mean}(fn(x))$

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

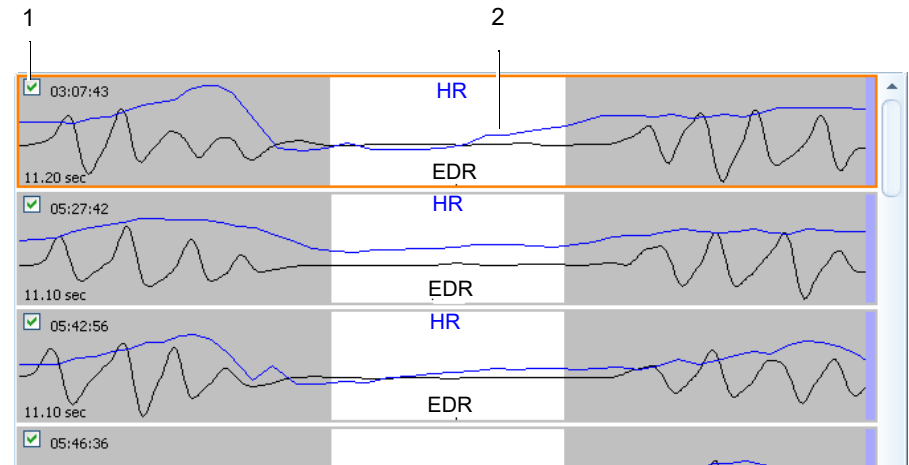
This module provides an overview of EDR episodes of the recording (EDR = ECG-derived respiration, that is, the change in amplitudes of R peak due to respiration activity)



- (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.

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 SpO₂ value is also given here (refer to SpO₂, page 91).

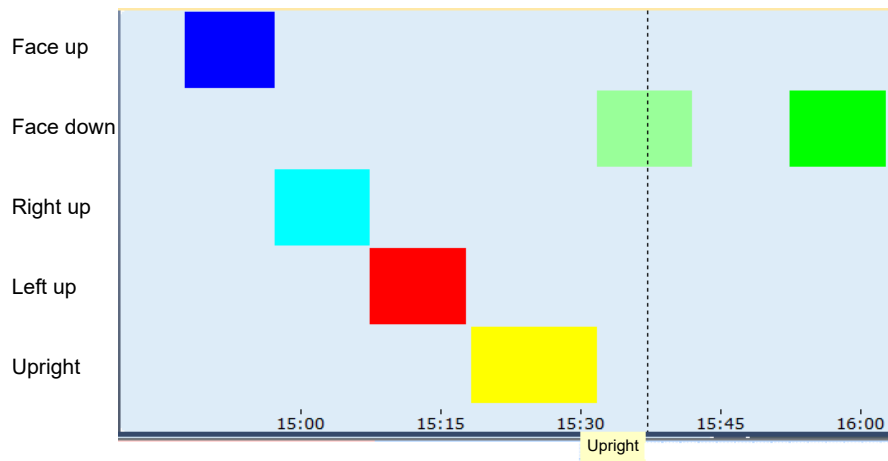
4.2.28 EDR Configuration

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.

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.

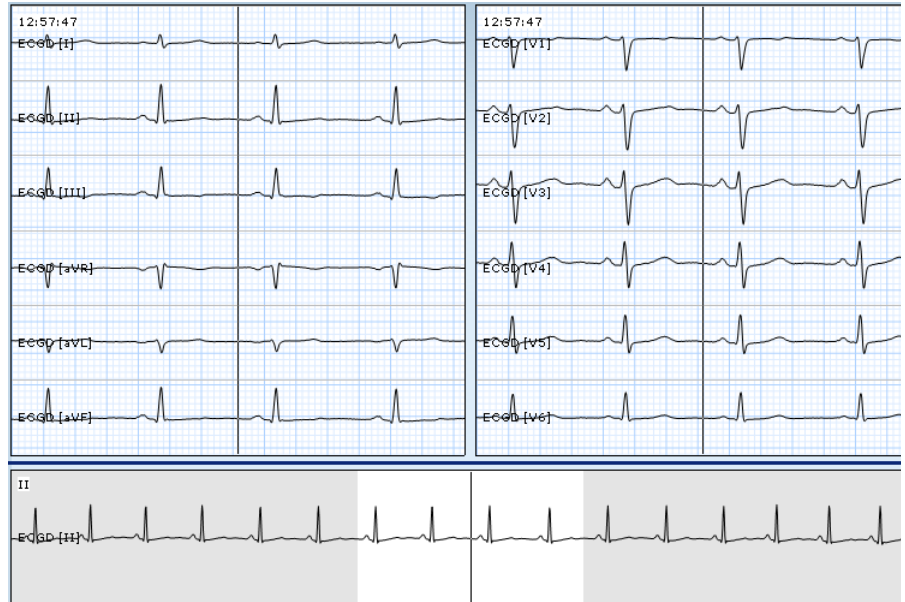
Available positions are Face down, Face up, Right up, Left up and Upright.

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:



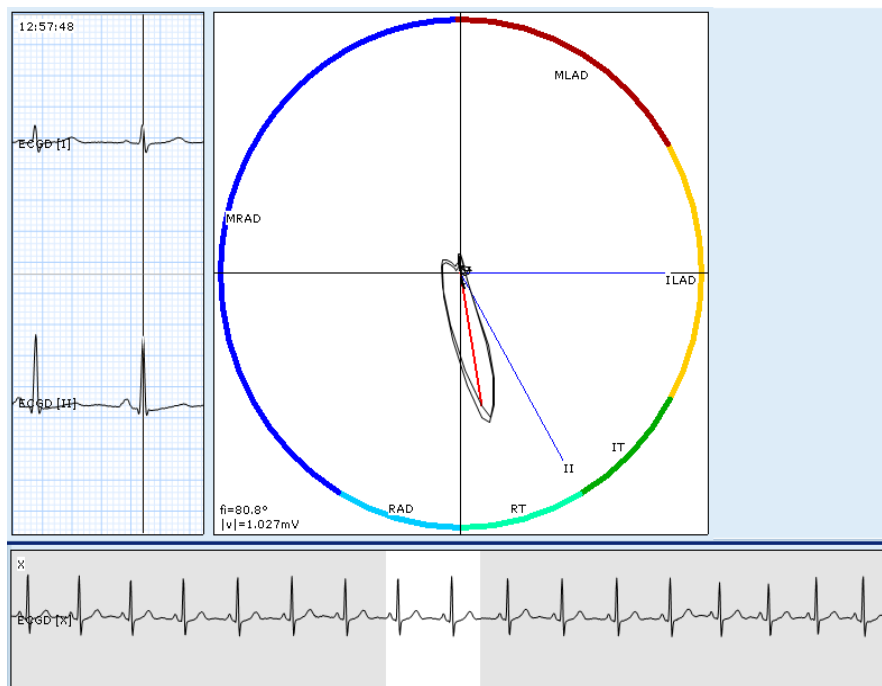
According to the settings, the ECG channels are displayed at the top. At the bottom, the overview strip is given.

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

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.



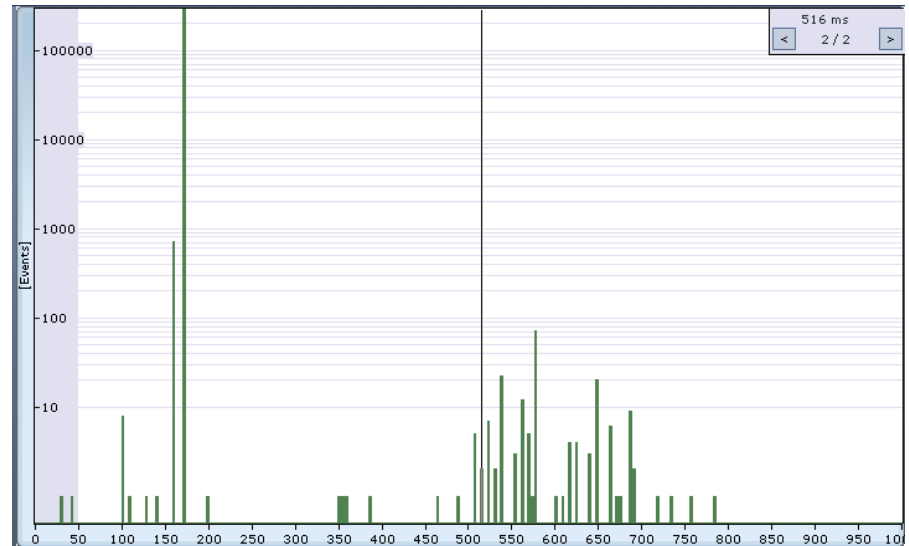
Settings

- 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

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.



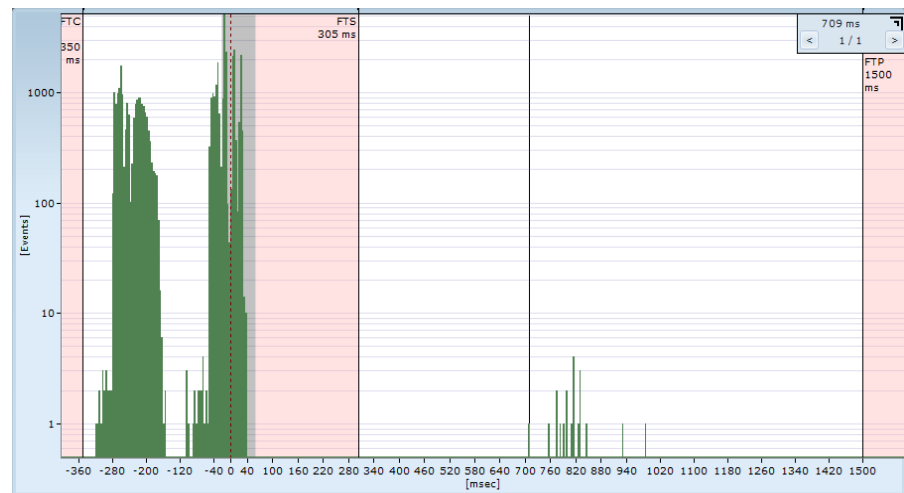
Click on a bar of the histogram and use the Arrow icons in the top right corner to jump to the previous/next event. The corresponding ECG complex is shown in the ECG detail viewer.

Settings

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

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

4.2.32 QT Summary table

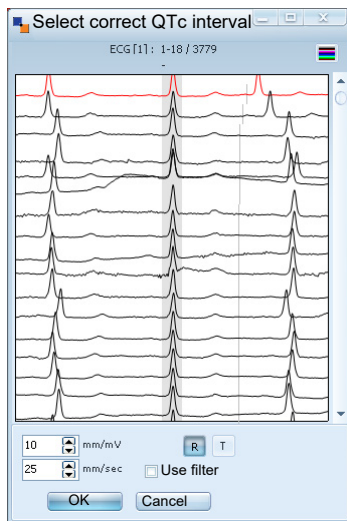
QT is the time between the beginning of the Q wave and the end of the T wave in the averaged ECG. The QT below table shows the measured and frequency-corrected maximum and minimum values per hour (QTc), the dispersion and the number of valid beats used for the calculation.

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:



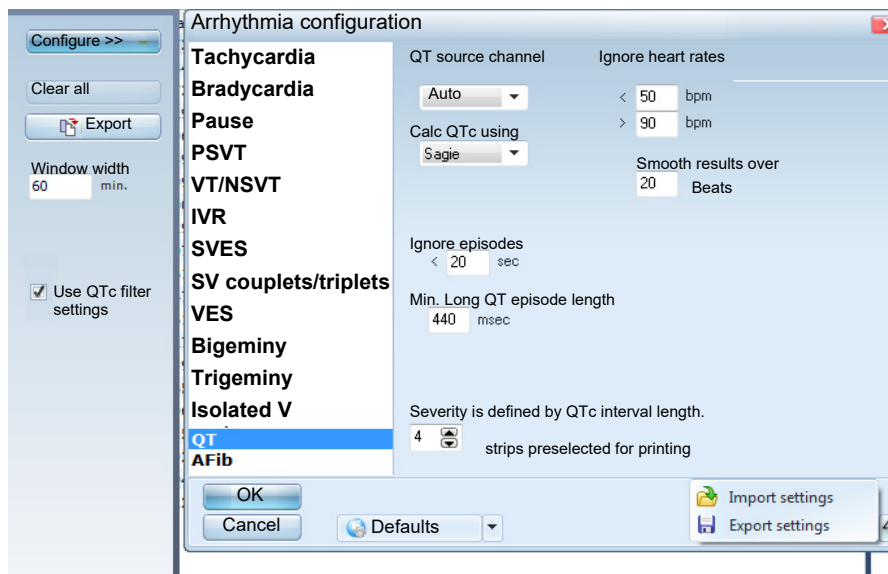
- All beats are displayed below each other with the R peak marked grey (if activated) and the end of the T wave indicated by a grey line. The beats are ordered according to QT interval length, with the shortest (for QTc Min) or the longest (for QTc Max) at the top, respectively.
- Use the scroll bar 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](#)).

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: $QTc = \frac{(QTtime)}{(\sqrt{RRinterval})}$
- 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](#)).

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](#)).

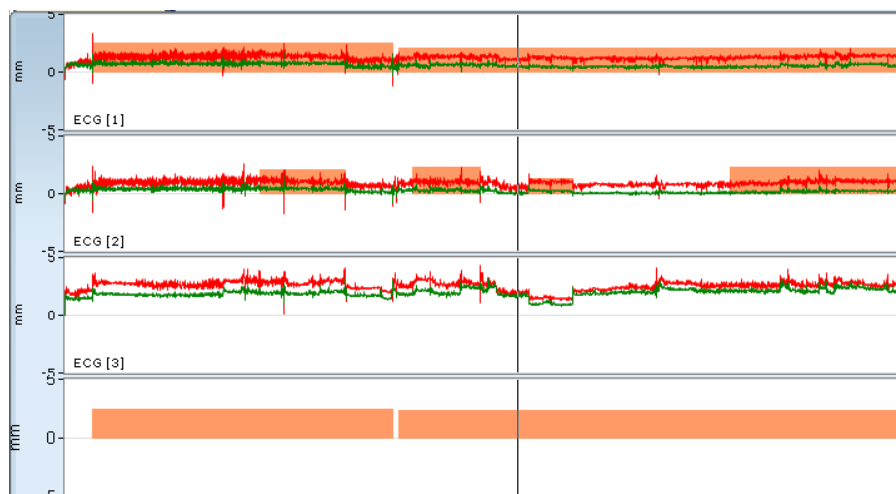
ST episodes are detailed individually with start time, duration, level in mV and channel. ST depressions are highlighted blue, and ST elevations are highlighted orange.

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.

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).

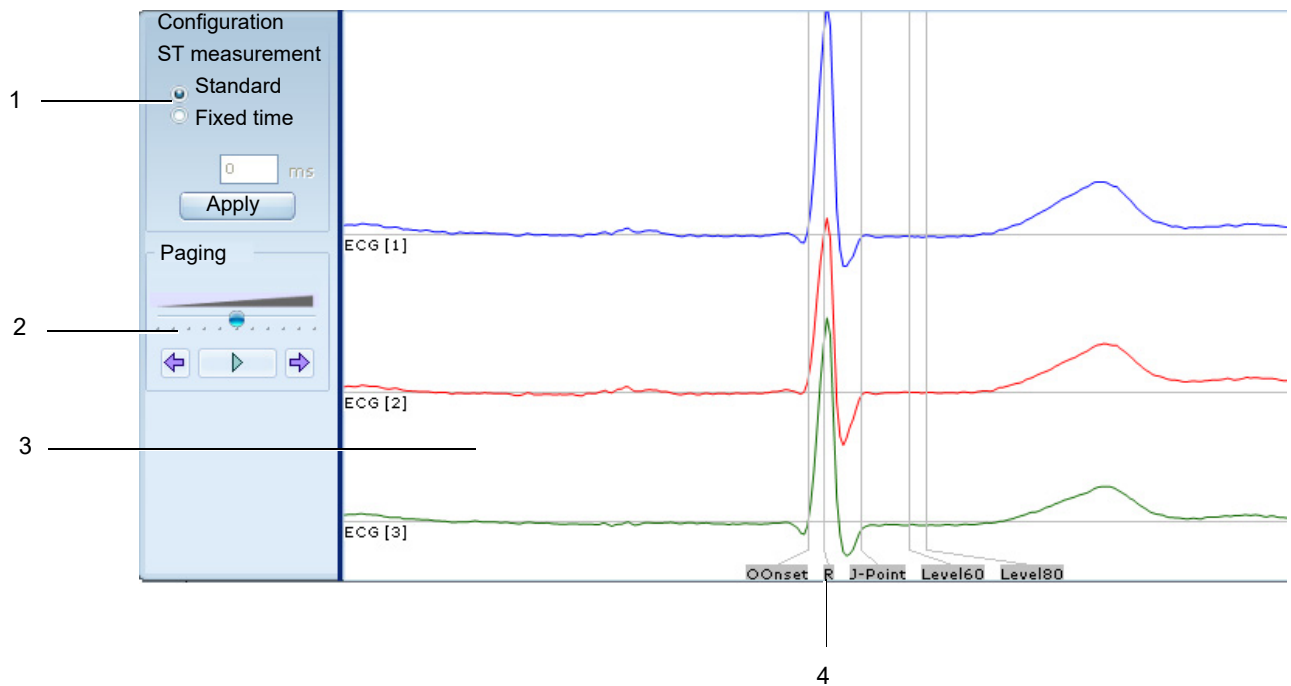
ST episodes (refer to [ST Table, page 73](#)) are highlighted blue (ST depression) or orange (ST elevation). At the bottom of the module, a strip summarises the ST episodes of all ECG channels.

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.

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.

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 (Alx) is often cited with gender, age and HR. Arterial stiffness is an important determinant of cardiovascular risk, and the Alx is a measure of wave reflection and, thus, systemic arterial stiffness derived from the ascending aortic pressure waveform. The Alx 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](#)).

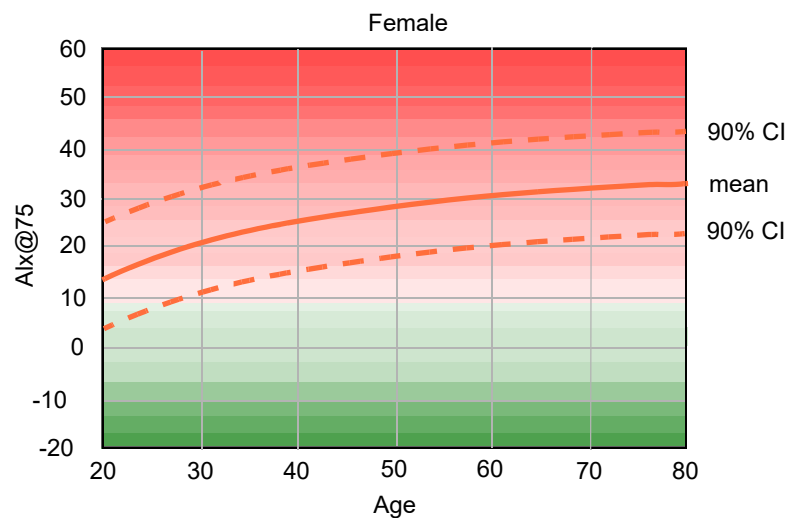
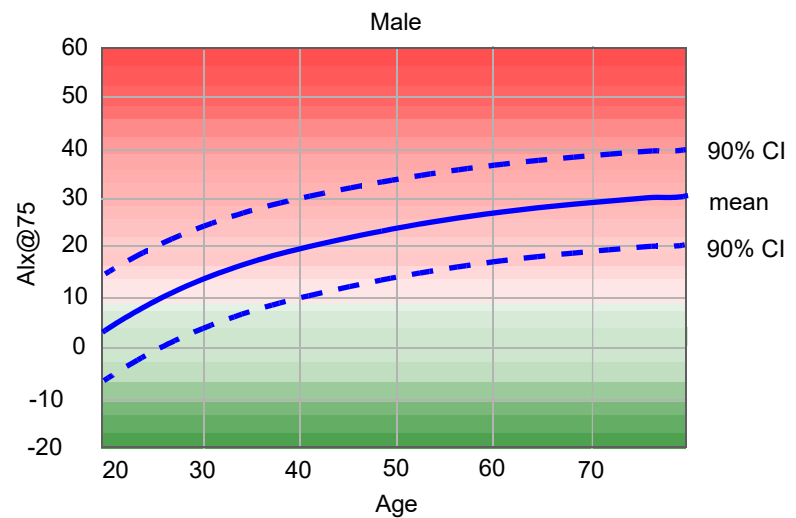
5.1.1 Overview method

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 Alx@75.

Alx@75 has been analysed in a representative cross-section of the population (see reference [2]), and an age-dependent estimate for the Alx@75 plus the respective confidence interval has been assessed. These relevant analyses have also shown a significant difference in the average Alx@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 Alx until the 55th year has been identified; after the 55th year, the increase slows for both sexes. The level difference of the Alx 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, Alx 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.



Average value and 90% confidence interval for the Alx@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.

5.2 Overview of Patient Details and Recording

The screenshot displays the 'medilog Darwin Enterprise V2.5.1 [Admin] [Steinhaeuser Ralf / 28.10.2012]' window. The interface is divided into several sections:

- Patient Data (top left):** Contains fields for ID (1327), Date of birth (23.08.1973), Age (39), Last name (Steinhaeuser), First name (Ralf), Gender (unknown), Height (0 cm), Weight (0 kg), BMI (---), Phone, Address, Prim. Ins. Nr., Sec. Ins. Nr., and Comments. It also shows '1 recordings' and buttons for 'Save' and 'Cancel'.
- Recording Data (bottom left):** Includes a 'History' section with a list of recording events, such as 'Converted with observer V 2.0.1.87', 'Import date: 29.10.2012 10:04:14', and 'Recording opened at 29.10.2012 10:04:40 by user Ralf'.
- Patient Diary (right):** A table showing event data with columns for Time, Event, Condition, and Comment. It lists events like 'Other activities' at 11:43:03 and 'Sleep: 22:30' at 22:00.
- Manual measurements (bottom right):** A section for manual BP measurements with fields for Time (11:43:03), Comment, Condition, and a 'Timepoint only' checkbox. It includes 'Add', 'Update', and 'Delete' buttons.

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).

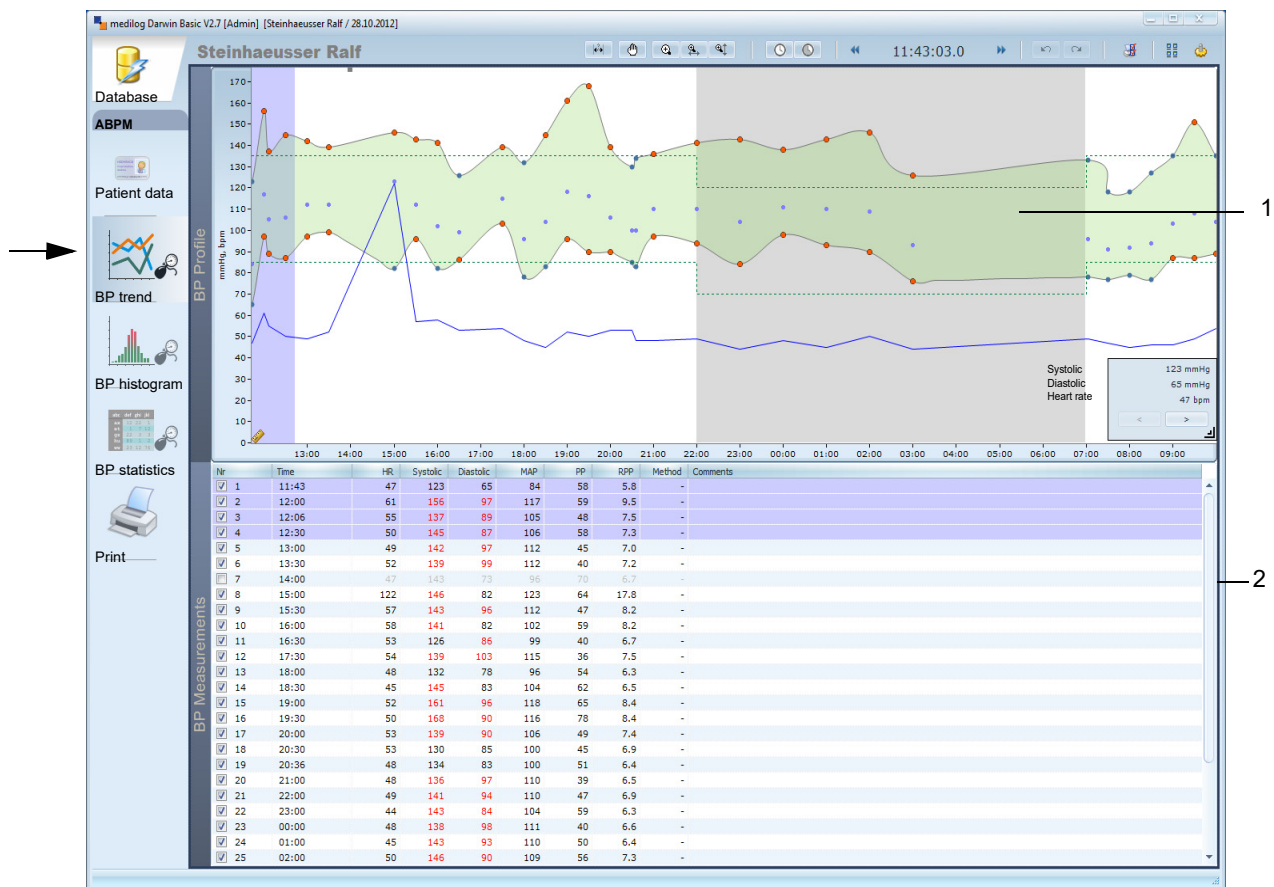
Manual measurements (bottom right)

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).

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.

5.3.1 BP Profile

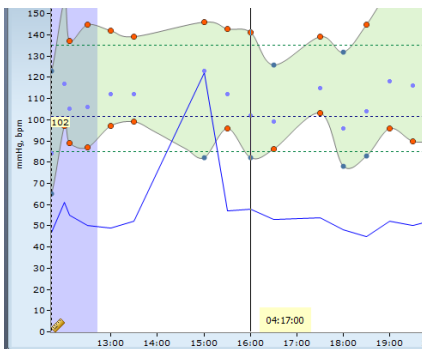
The trend graph displays the following data:

- 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)

	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 [bpm] x systolic BP [mmHg].

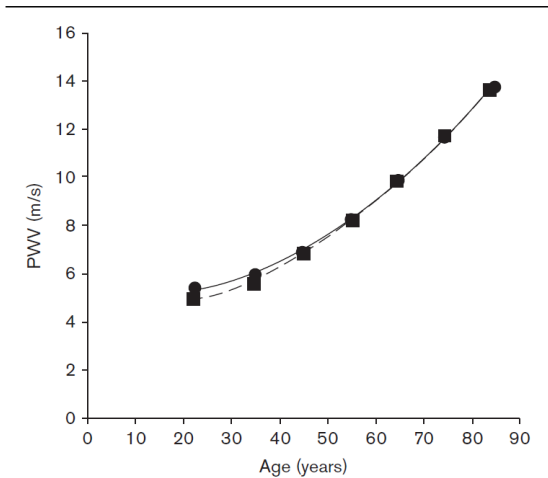
A blank triangle in the measurement table indicates manual measurements.

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.

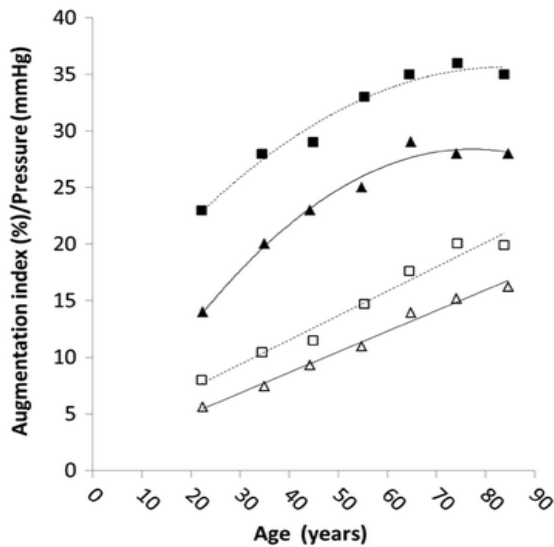
The following values are given:

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.



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).

Alx 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.).

Alx@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]

- 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

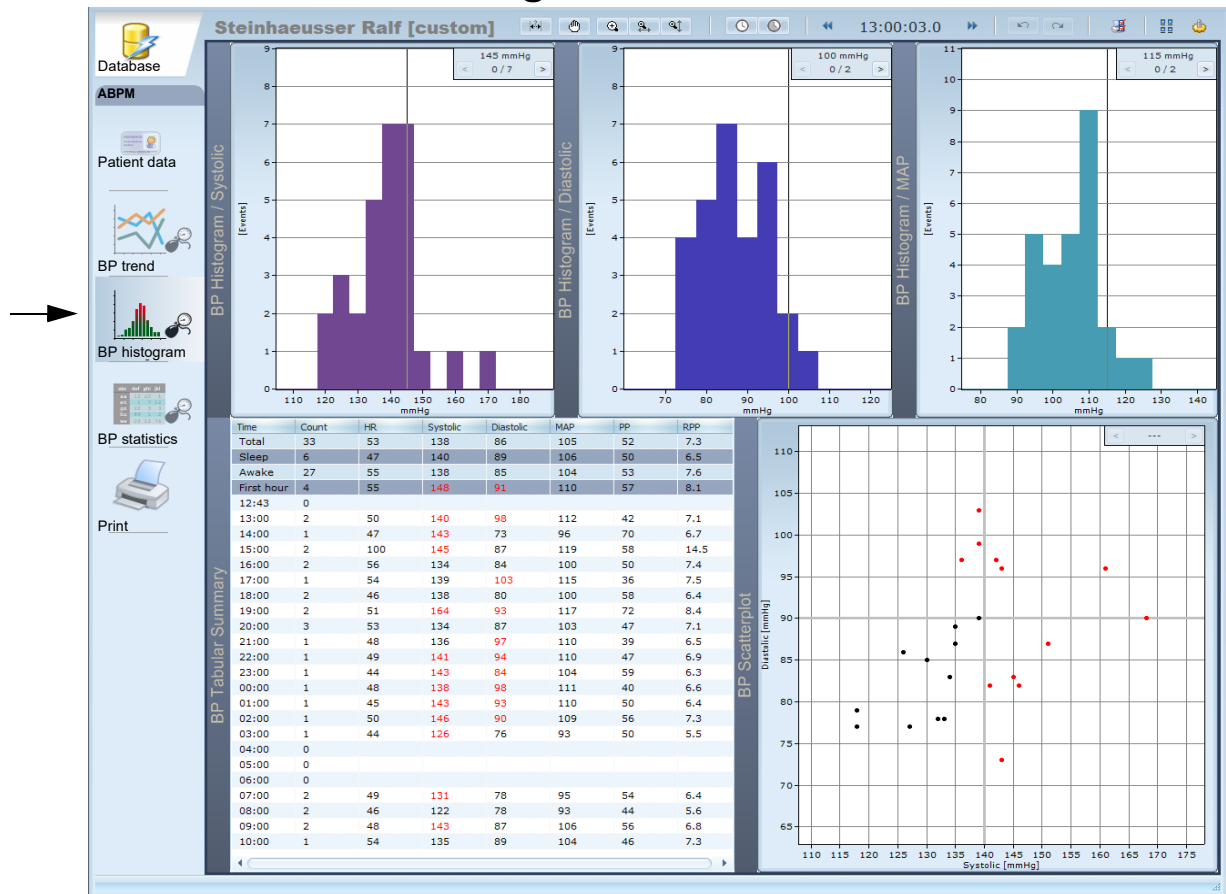
Clicking the grey settings bar on the left-hand side of the measurement table gives the following settings:

- 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.

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.

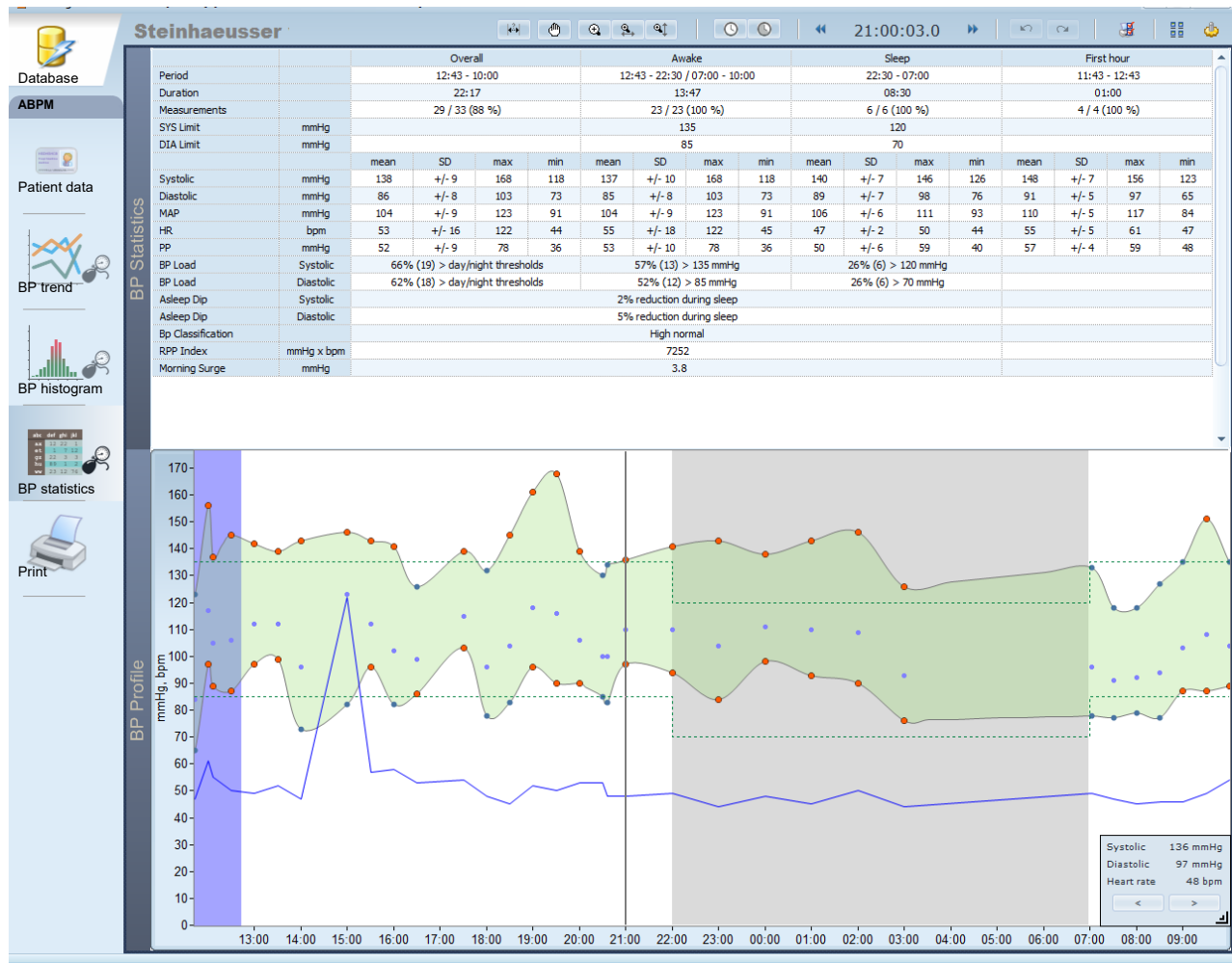
5.4.1 BP Scatterplot

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.

5.5 BP Statistics

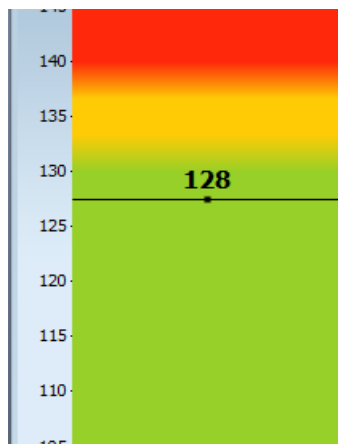


The statistics table provides the following values for the recording divided into the following periods: Overall, Awake period, Sleep period, and the First hour of the recording. For each period, the following information is calculated:

- 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).

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 [bpm]
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 • Alx@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).

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&recordId=1062922&fileId=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).

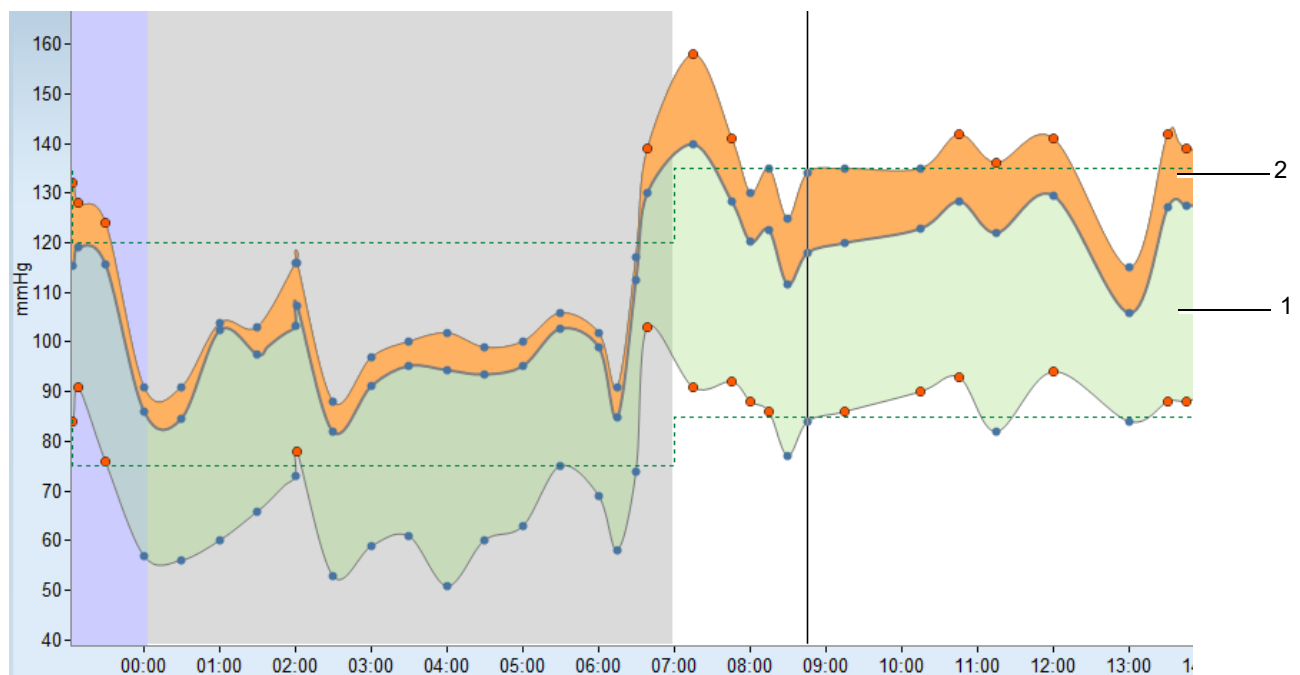
5.7 PWA Measurements (PWA recordings only)

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

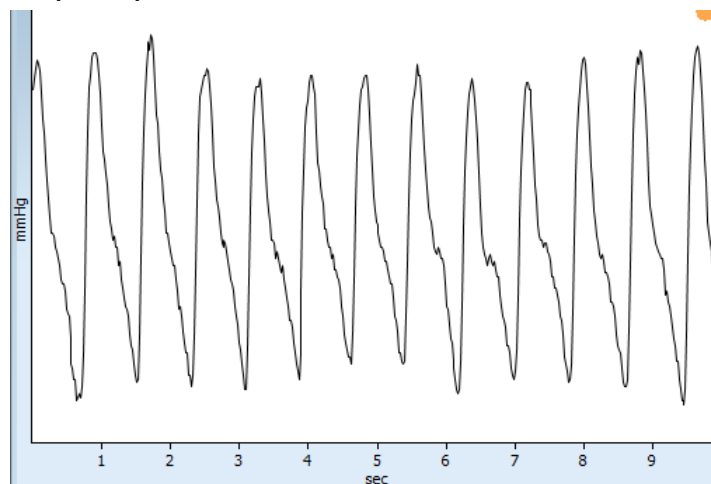


The central BP values are given in this view, framing the green area (1). In addition, the peripheral systolic BP is given, marking the border of the orange area (2). A large orange area (2) indicates high arterial stiffness, as the orange area shows the difference between the central and peripheral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

5.7.2 Pulse wave signal

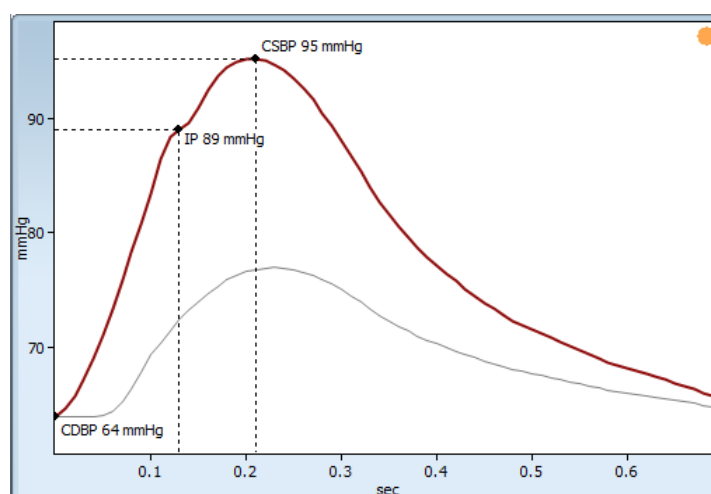
In this module, either the Peripheral pulse wave or the Central aortic wave is displayed (defined in the settings):

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.

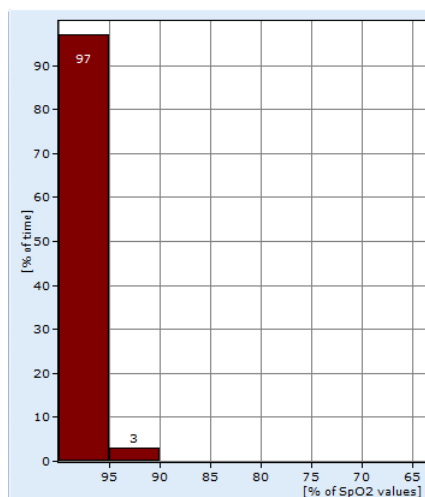
Also, this graph indicates the Augmentation pressure: the AugP is the difference between the pressure value at the IP and the CSBP (see above). It indicates arterial stiffness: the augmentation in pressure caused by the reflected wave is higher when arteries are stiffer.

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

6 SpO₂

SpO₂ measurements are only possible with AR12plus and FD12plus recorders equipped with a SpO₂ sensor.

6.1 SpO₂ Overview



This module provides graphical information on the distribution of SpO₂ values: the X-axis indicates the SpO₂ 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%

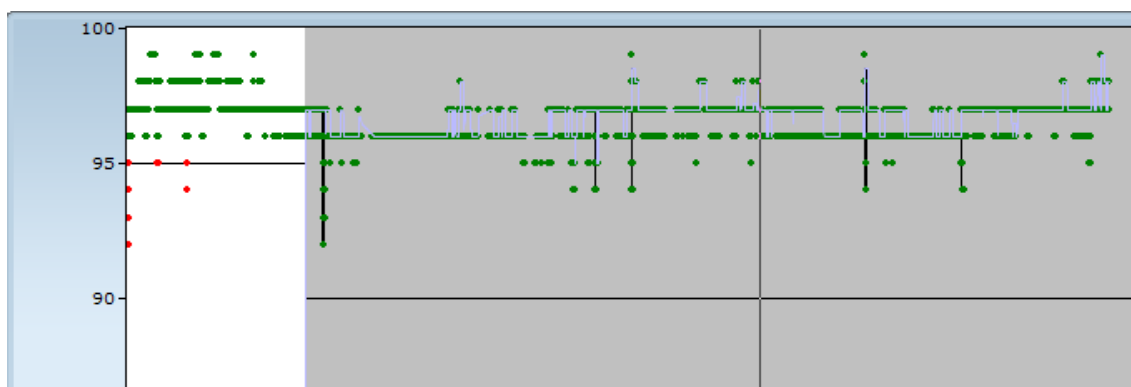
In the settings, you can set the threshold value for measurements that can be ignored, for example, below 70%. Also, you can set the threshold value for deviations that can be ignored, for example, more than 10%.

6.2 SpO₂ Trend

SpO₂ 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 SpO₂ 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 (SpO₂ trend, SpO₂ overview, EDR overview etc.).



Settings

- Select the threshold value for day and night.
- Basal SpO₂: average value of the last 40 seconds.
- SpO₂ episodes: desaturation episodes are displayed (refer to [SpO₂ Statistics](#), page 92).

6.3 SpO₂ Statistics

Time in bed	07:41:42	
Evaluable recording duration	03:03:53	11059
Desaturation index (ODI)	1.6 desat/h	
	92%	22:04:33
Min SpO ₂	0%	0
Mean SpO ₂	0%	0

	44 sec	23:10:05
	92%	22:04:13
Values < 90%	180 sec	
	0%	0
Values < 80%		
	41 sec	92%
	1/5	22:04:13
	◀ ▶	

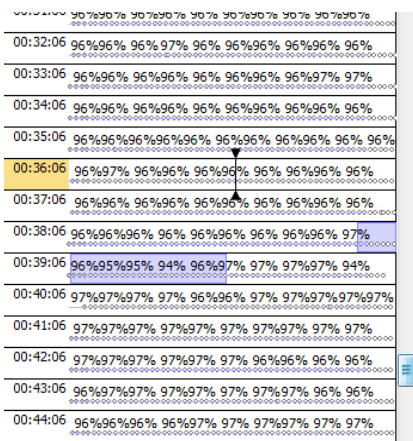
This module provides the following information:

- 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 SpO₂ 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 (SpO₂ trend, SpO₂ 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 SpO₂ Full disclosure



This module provides an overview of the entire recording.

SpO₂ 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 [SpO₂ 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 (SpO₂ trend, SpO₂ overview, EDR overview etc.).

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.

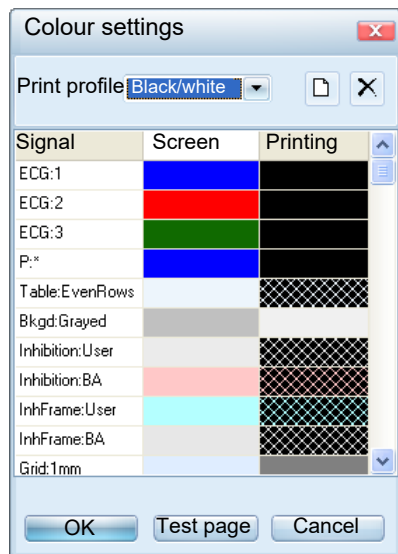
Full disclosure

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.

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.

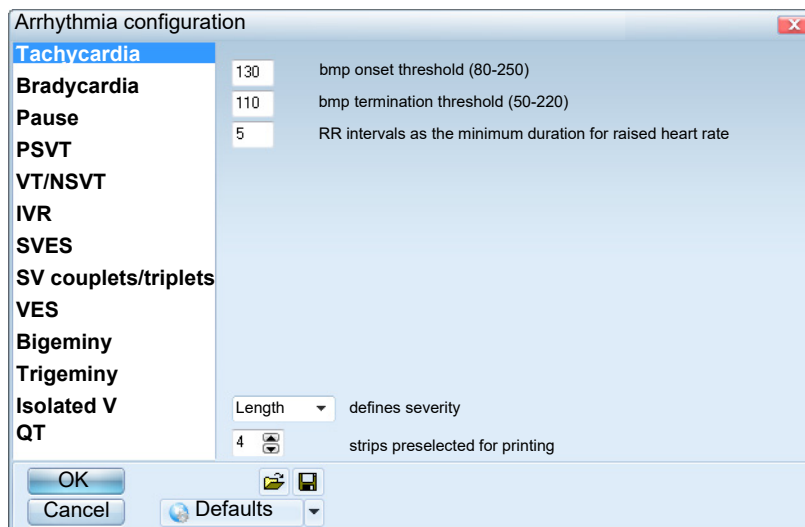
Note that this menu option might not be available depending on your user rights.



7.7 HRV Data Preparation

Refer to [HRV Configure](#), page 62.

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

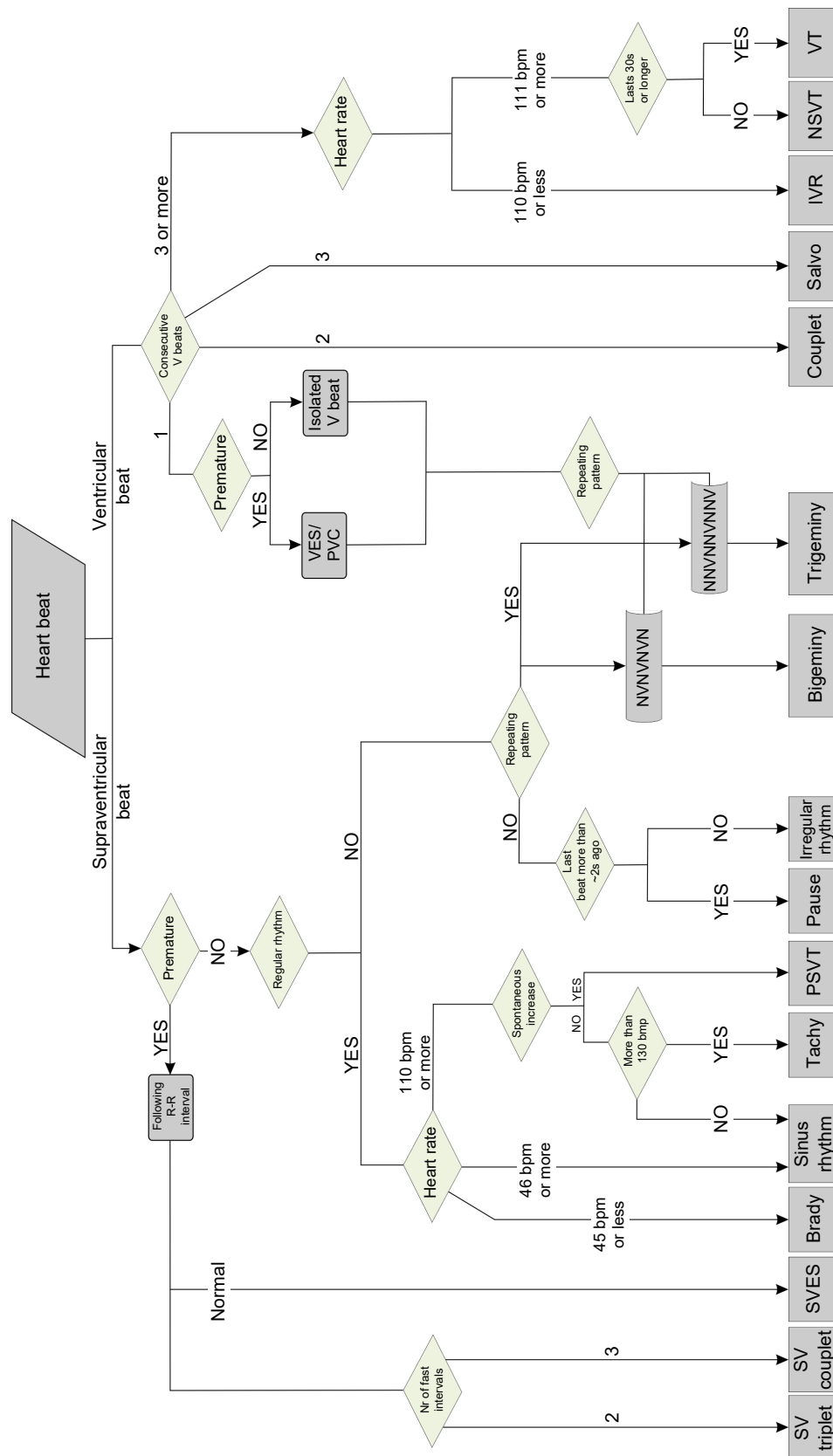
Also, select the number of strips automatically added to the report for printouts (refer to [General settings, page 93](#)).

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.

7.8.1 Information on arrhythmia definitions



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.

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.

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.

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, Server-Name), 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](#)).

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 myNewSysDbPass 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 myNewSysDbPass
// Create a new user:
gsec -user sysdba -password myNewSysDbPass -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 myNewSysDbPass "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"
```

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.

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.

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.



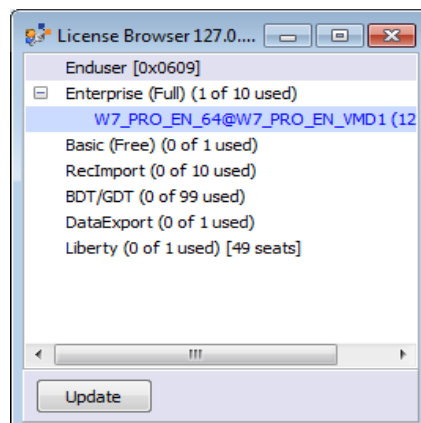
- ▲ The administrator must change the admin password when the Admin tool is used for the first time to prevent misuse.

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.

8.5 Database Setup

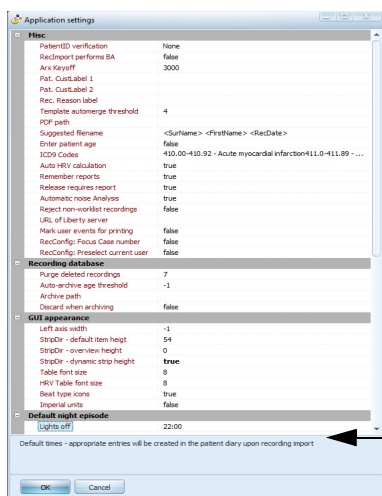
Using the Admin tool, you can set up the database location. Use the Pen icon to create a new database.

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.

8.7 User Setup and Authentication

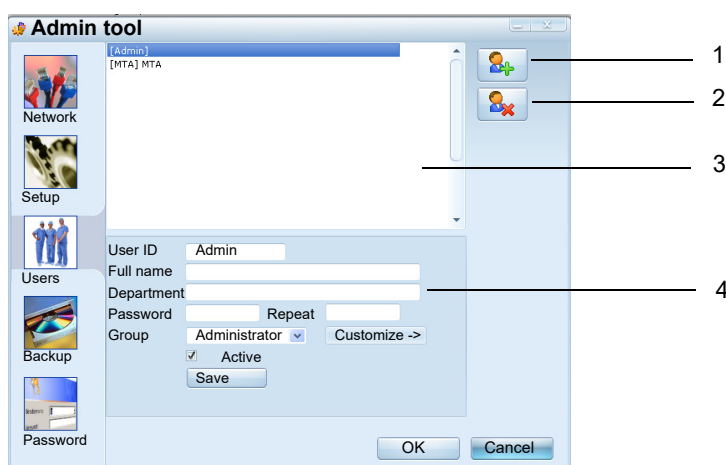
Different authentication methods are available; the method is selected in the Admin tool > Extended settings > User authentication > Authentication method.

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.

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.

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



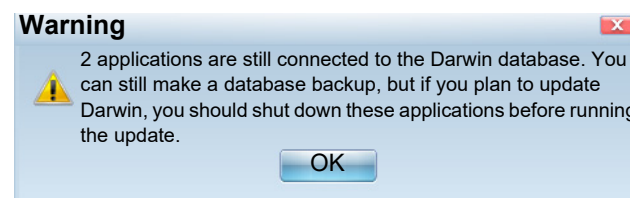
It is good practice to perform backups of the **medilog DARWIN2** database regularly. Back up the database before upgrading the **medilog DARWIN2** program to a newer version.

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.



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.

8.9 medilog Liberty Scanlab Installation and Settings

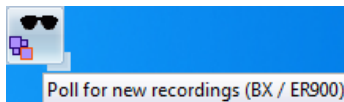
For installation procedures and necessary settings for medilog Liberty Scanlab, refer to the medilog Liberty Scanlab user guide (art. no. 2.511368).

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.

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
	Medical device
	Serial number
	Reference number
	Batch code
	Global Trade Item Number
	Catalogue number
	Quantity
	UDI: unique device identification as QR code machine readable and human readable as number (e.g.  (01) 0 761 3365 00210 2 (21)xxxx.xxxxxx)
	Number of pieces in the packaging
	Authorised European representative
	Notified body (e.g.  0123 marking notified body TÜV SÜD)

	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

	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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