Anexa 1

Specificație Tehnică Completată

Anexa 1 Monitor Holter ECG (caracteristici avansate)
Model: medilogFD Reg. SDM: DM000813791; DM000633964
Producător: SCHILLER AG
Țara: Elvetia

Specificarea tehnică deplină solicitată, Standarde de referință	Specificația tehnică propusă de ofertant
Monitor Holter ECG (caracteristici avansate)	Monitor Holter ECG **DA, model medilogFD pag.1 din medilog FD manual**
Cod 260270	Cod 260270
Descriere Dispozitivul înregistrează ECG in 12 derivații simultan, nictimeral monitorizind parametrii in timpul repaosului si la efort.	Descriere Dispozitivul înregistrează ECG in 12 derivații simultan, nictimeral monitorizind parametrii in timpul repaosului si la efort. **DA, pag.7-9 din medilog FD manual**
Parametrul Specificația	Parametrul Specificația
Tip pacient adult, pediatric	Tip pacient adult, pediatric **DA, pag.7 din medilog FD manual**
Numărul de canale de procesare 12	Numărul de canale de procesare 12 **DA, pag.12 din medilog FD manual**
Configurația Portabil obligatoriu	Configurația Portabil obligatoriu **DA, pag.12 din medilog FD manual**
Derivațiile Tip înregistrare automat	Derivațiile Tip înregistrare automat **DA, pag.40-41 din medilog FD manual**
Gama de frecvență De diagnostic 0.05-100 Hz	Gama de frecvență De diagnostic 0.05-150 Hz **DA, semnalul ECG înregistrat respectă standartul IEC 60601-2-25, pag.76 medilog FD IEC 60601-2-25: Gama de frecvență diagnostic: 0.05–150 Hz**
Impendanța de intrare ≥ 100 MOhm	Impendanța de intrare ≥ 100 Mohm **DA, conform scrisorii de confirmare din partea producătorului**
Gama de rejecție a modului comun la 50 Hz > 100 dB	Gama de rejecție a modului comun la 50 Hz > 100 dB **DA, conform scrisorii de confirmare din partea producătorului**
Detectare pacemaker obligatoriu	Detectare pacemaker obligatoriu **DA, pag.20 din medilog FD manual**
Frecvența maximă de eșantionare (sampling rate) de achiziție ≥ 1200 Hz Frecvența ajustabilă obligatoriu	Frecvența maximă de eșantionare (sampling rate) de achiziție 128 000 Hz **DA, pag.53 din medilog FD manual**
Rezoluția ADC (Convertor Analog/Digital) ≥ 14 bit	Frecvența ajustabilă obligatoriu **DA, pag.53 din medilog FD manual**
	Rezoluția ADC (Convertor Analog/Digital) 16bit **pag.5 din medilog FD brosura**
Ecran LCD obligatoriu	Ecran OLED obligatoriu **DA, pag.74 din medilog FD manual**

Anexa 1

lumină fundal obligatoriu	lumină fundal obligatoriu **DA, pag.32 din medilog FD manual, pag.3 din medilog FD brosura**
Date ecran ora obligatoriu	Date ecran ora obligatoriu **DA, pag.33 din medilog FD manual**
statut baterie obligatoriu	statut baterie obligatoriu **DA, pag.32 din medilog FD manual**
Indicator deconectare electrod acustic sau vizual obligatoriu	Indicator deconectare electrod acustic sau vizual obligatoriu **DA pag.3 din medilog FD brosura**
Buton evenimente obligatoriu	Buton evenimente obligatoriu **DA, pag.2 din medilog FD prezentare**
Buton navigare meniu obligatoriu	2 Butoane navigare meniu obligatoriu **DA, pag.2 din medilog FD prezentare**
Blocarea automată a butoanelor obligatoriu	Blocarea automată a butoanelor obligatoriu **DA, pag.46 din medilog FD manual**
Posibilitatea transmiterii datelor ECG la PC sau notebook USB / SD-Card / Wi-Fi / BT	Posibilitatea transmiterii datelor ECG la PC sau notebook USB / SD-Card /BT **DA, pag.23 din medilog FD manual**
Baterie reîncărcabilă obligatoriu	Baterie reîncărcabilă obligatoriu **DA, pag.74 din medilog FD manual**
tip baterie AA sau AAA	tip baterie AAA **DA, pag.74 din medilog FD manual**
Tip operare autonomă ≥ 72 ore	Tip operare autonomă ≥ 72 ore **DA, pag.53 din medilog FD manual**
Indicatori vizuali contact slab sau lipsă de contact	Indicatori vizuali contact slab sau lipsă de contact **DA pag.3 din medilog FD brosura**
status sistem	status sistem **DA pag.3 din medilog FD brosura**
deconectare alimentare	deconectare alimentare **DA, pag.73 din medilog FD manual**
baterie descărcată	baterie descărcată **DA, pag.73 din medilog FD manual**
Posibilități soft PC de interpretare	Posibilități soft PC de interpretare **DA, soft Darwin2, Medilog Darwin2_usermanual**
Introducere date pacient obligatoriu	Introducere date pacient obligatoriu **DA, pag. 36 din Medilog Darwin2_usermanual**
Adnotare eveniment ECG obligatoriu	Adnotare eveniment ECG obligatoriu **DA, pag.47 din medilog FD manual**
Clasificarea de evenimente obligatoriu	Clasificarea de evenimente obligatoriu **DA, pag.46 din medilog FD manual**
Analiza ST obligatoriu	Analiza ST obligatoriu **DA, Prezentare soft DARWIN**
Analiza QT obligatoriu	Analiza QT obligatoriu **DA, Prezentare soft DARWIN**
Analiza PQ obligatoriu	Analiza PQ obligatoriu **DA, Prezentare soft DARWIN**
Analiza PM obligatoriu	Analiza PM obligatoriu **DA, Prezentare soft DARWIN**
Analiza aretmiilor obligatoriu	Analiza aretmiilor obligatoriu **DA, Prezentare soft DARWIN**
Variabilitate ritm cardiac după timp obligatoriu	Variabilitate ritm cardiac după timp obligatoriu **DA, Prezentare soft DARWIN**
Variabilitate ritm cardiac după frecvență obligatoriu	Variabilitate ritm cardiac după frecvență obligatoriu **DA, Prezentare soft DARWIN**

Anexa 1

Reprezentarea grafică a datelor obligatoriu	Reprezentarea grafică a datelor obligatoriu **DA, Prezentare soft DARWIN**
Reprezentarea tabelară a datelor obligatoriu	Reprezentarea tabelară a datelor obligatoriu **DA, Prezentare soft DARWIN**
Raport presetabil de utilizator obligatoriu	Raport presetabil de utilizator obligatoriu **DA, Prezentare soft DARWIN**
Interfața presetabilă utilizator obligatoriu	Interfața presetabilă utilizator obligatoriu **DA, Prezentare soft DARWIN**
Posibilitate printare raport obligatoriu	Posibilitate printare raport obligatoriu **DA, Prezentare soft DARWIN**
Accesorii Nota: Modelele accesoriilor (coduri) sunt obligatorii a fi prezentate și ofertate de operatorul economic. Totodată operatorul economic are posibilitate de a ajusta/completa aceste coduri/modele ca urmare a clarificarilor fără ca această ajustare să fie considerată modificare a ofertei inițiale.	Accesorii Nota: Modelele accesoriilor (coduri) sunt obligatorii a fi prezentate și ofertate de operatorul economic. Totodată operatorul economic are posibilitate de a ajusta/completa aceste coduri/modele ca urmare a clarificarilor fără ca această ajustare să fie considerată modificare a ofertei inițiale.
Cablu ECG ≥ 3 unități, indicați modelul oferit	Cablu ECG 3 unități, **model 2.400183 din medilog FD manual**
Set de electrozi de unica folosinta adult ≥ 500 buc., indicați modelul oferit	Set de electrozi de unica folosinta adult 500 buc., model **Electrod de unica folosinta 50RLI, Ceracarta**
Set de electrozi de unica folosinta pediatric ≥ 500 buc., indicați modelul oferit	Set de electrozi de unica folosinta pediatric 500 buc., model **Electrod de unica folosinta 30RFI, Ceracarta**
Soft necesar pentru analiza Holter ECG pe PC inclus cu cheie de acces, licență cu un termen nelimitat de utilizare obligatoriu, indicați modelul oferit	Soft necesar pentru analiza Holter ECG pe PC inclus cu cheie de acces, licență cu un termen nelimitat de utilizare obligatoriu, **model DARWIN2 din medilog Darwin2_user manual**
Sursa de alimentare pentru reîncărcarea bateriilor obligatoriu, indicați modelul oferit	Sursa de alimentare pentru reîncărcarea bateriilor obligatoriu, indicați modelul oferit: acumulatorul intern se incarca prin cablu USB. **pag.70 din medilog FD manual**

SCHILLER'S MEDILOG HOLTER SYSTEM

Sophisticated and precise ECG analysis that meets the highest demands

SCHILLER
The Art of Diagnostics

SCHILLER'S MEDILOG HOLTER SYSTEM

Save time and uncover cardiovascular risks at a glance: with the medilog Holter system

The medilog Holter system offers unparalleled analysis advantages.

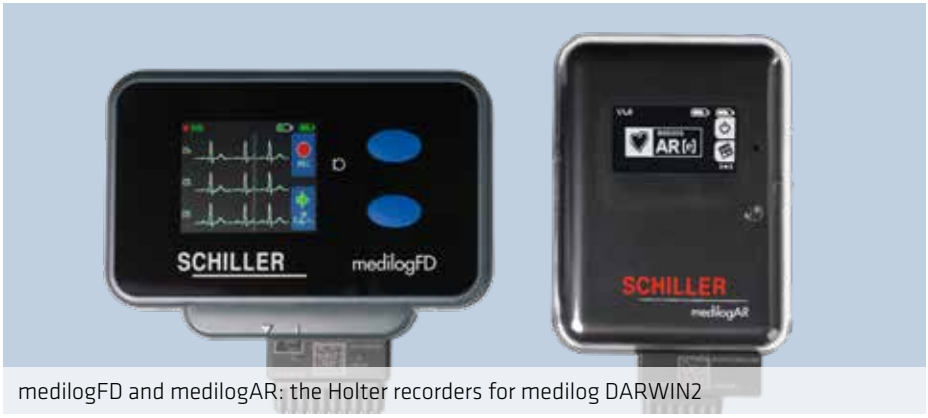
- Instantaneous atrial fibrillation detection
- Respiration analysis
- Recording upload from remote locations

SCHILLER's medilog Holter system offers much more than just arrhythmia detection: It provides a comprehensive analysis of the patient.

Atrial fibrillation detection in an extremely short time, respiration analysis and the assessment of the quality of life are just some of the exceptional features of the medilog Holter system.

A UNIQUE SET OF SOPHISTICATED TOOLS

- Real-time P-wave detection for accurate atrial fibrillation screening
- PureECG technology for superior signal quality
- ECHOView for instantaneous detection of atrial fibrillation onset
- Respiration analysis during sleep with synchronised ECG, respiration waveforms, and SpO_2 readings
- Fire of Life: a brilliant approach to Heart Rate Variability analysis



medilogFD and medilogAR: the Holter recorders for medilog DARWIN2

THREE DIFFERENT SOLUTIONS AVAILABLE

medilog DARWIN2 offers maximum flexibility with configurable reports, user-defined screen layout and workflows. Meets all requirements:

- medilog DARWIN2 Office: optimised for routine application in physicians' offices
- medilog DARWIN2 Professional: perfect for a small to mid-sized Holter scanning centre requiring fast atrial fibrillation detection
- medilog DARWIN2 Enterprise: for the most demanding research centres and high-volume hospitals. Includes atrial fibrillation, respiration analysis, SpO_2, and an option for scanlab web-service

All versions[1] provide floating licences, option for multi-tenancy, connectivity to HIS, and SCHILLER's data management solution SEMA.

1 All three medilog DARWIN2 versions are compatible with all SCHILLER medilog recorders since 2007: medilogFD, medilogAR, FD12plus, AR12plus, AR4plus, FD5plus, AR12, AR4, MT-101, BR-102 plus

MEDILOG RECORDER OPTIONS

FIND THE OPTION THAT SUITS YOUR REQUIREMENTS:

	medilogAR **Office**	medilogAR **Professional**	medilogAR **Enterprise**	**medilogFD**
ECG leads	3 leads (5 or 7 wires)	3 leads (5 or 7 wires)	3 leads (5 or 7 wires)	12 leads (10 wires)
Sampling rate	32,000 Hz	32,000 Hz	32,000 Hz	up to 128,000 Hz
Battery concept	rechargeable internal & AAA	rechargeable internal & AAA	rechargeable internal & AAA	rechargeable internal & AAA
Recording duration	14 days	14 days	14 days	120 hours/5 days
Bluetooth	x	x	x	x
P-wave detection		x	x	x
Respiration			x	x
SpO_2 (optional)			x	x

THREE MOUSE CLICKS TO A REPORT

medilog DARWIN2 is designed to maximise speed and ease of use. The automatic analysis of a 24-hour Holter recording takes less than 90 seconds, with extremely accurate results. Generate a comprehensive report with only three mouse clicks.

99.86 % ACCURACY WITH MEDILOG ADAPT

The medilog ADAPT algorithm has a 99.86% accuracy in beat detection.[2] All recorded channels are analysed and excessively noisy episodes are automatically excluded. As a result, the automatic analysis is greatly improved, saving time in the final report generation.

3-LEAD AND 12-LEAD RECORDERS

The medilogAR and medilogFD recorders are the solid basis for analysis, interpretation, and storage with medilog DARWIN2. They are equipped with the following features:

- Zero-second atrial fibrillation/atrial flutter detection based on true P-wave analysis
- Latest technology for a new standard of signal quality, artifact suppression, and motion detection
- Voice recording, allowing healthcare specialists to easily store patient information before starting the recording
- Robust, shock- and splash-proof as well as easy to clean
- Flexible dual-battery concept for more than 14 days (medilogAR) or up to 120 hours (medilogFD) of recording duration
- Removable patient cable with 5 wires for 3 channels, alternatively with 7 wires for enhanced reliability (medilogAR) and up to 10 wires for 12 leads (medilogFD)
- Bluetooth: Transfer patient data to the recorder, check the live ECG on the PC and connect the SpO_2 sensor (optional, medilogAR Enterprise and medilogFD only) via Bluetooth
- Delivered with a robust carrying case with various carrying options

2 Obtained in comparison with the MIT-BIH database using DARWIN2.10.1, released in December 2021 (QRS Se: 99.86%, QRS +P: 99.91%), according to IEC 60601-2-47:2012

ATRIAL FIBRILLATION

P-WAVE DETECTION AND ECHOVIEW

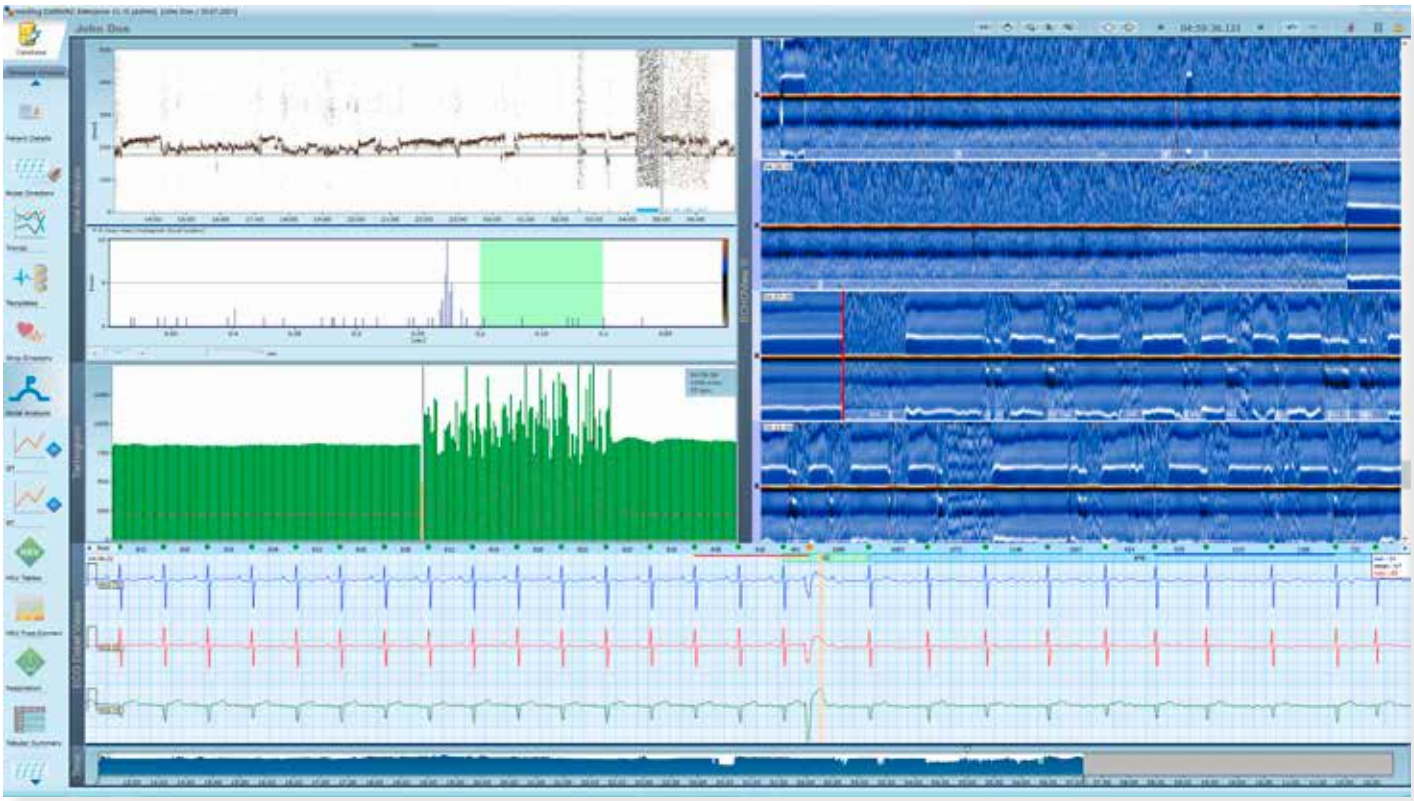
The high-end medilog recorders offer unparalleled signal quality in Holter recordings. Using state-of-the-art amplifiers with up to 32,000/128,000 Hz and advanced filter technology, the medilog recorders detect P waves in real time. When using medilogAR Professional, medilogAR Enterprise, or medilogFD, even very short episodes of atrial fibrillation are automatically detected and listed in the strip directory with their onset and offset.

This tool is invaluable in following the ESC's Clinical Guidelines[3] for classification. Distinguishing paroxysmal from persistent AF even in a recording of up to two weeks of the medilogAR or in a full 12-lead recording by medilogFD becomes a matter of seconds.

Without real-time P-wave detection, medilogAR Office analyses atrial fibrillation based on irregular rhythms.

ECHOView is a "bird's eye" view of the ECG, with clear representation of the P and T waves in each cycle. This innovative diagnostic tool makes it easy to identify patterns of irregular PR and QT intervals across 15,000 beats.

- Reduce cost and improve patient care with early detection of atrial fibrillation and atrial flutter
- Preliminary assessment of the need for invasive diagnosis, therapy, or surgery
- Effective patient monitoring following surgery or ablation



AV-block patterns and other critical anomalies are easily identified

3 2020 ESC Guidelines for Management of Atrial Fibrillation

RESPIRATION ANALYSIS

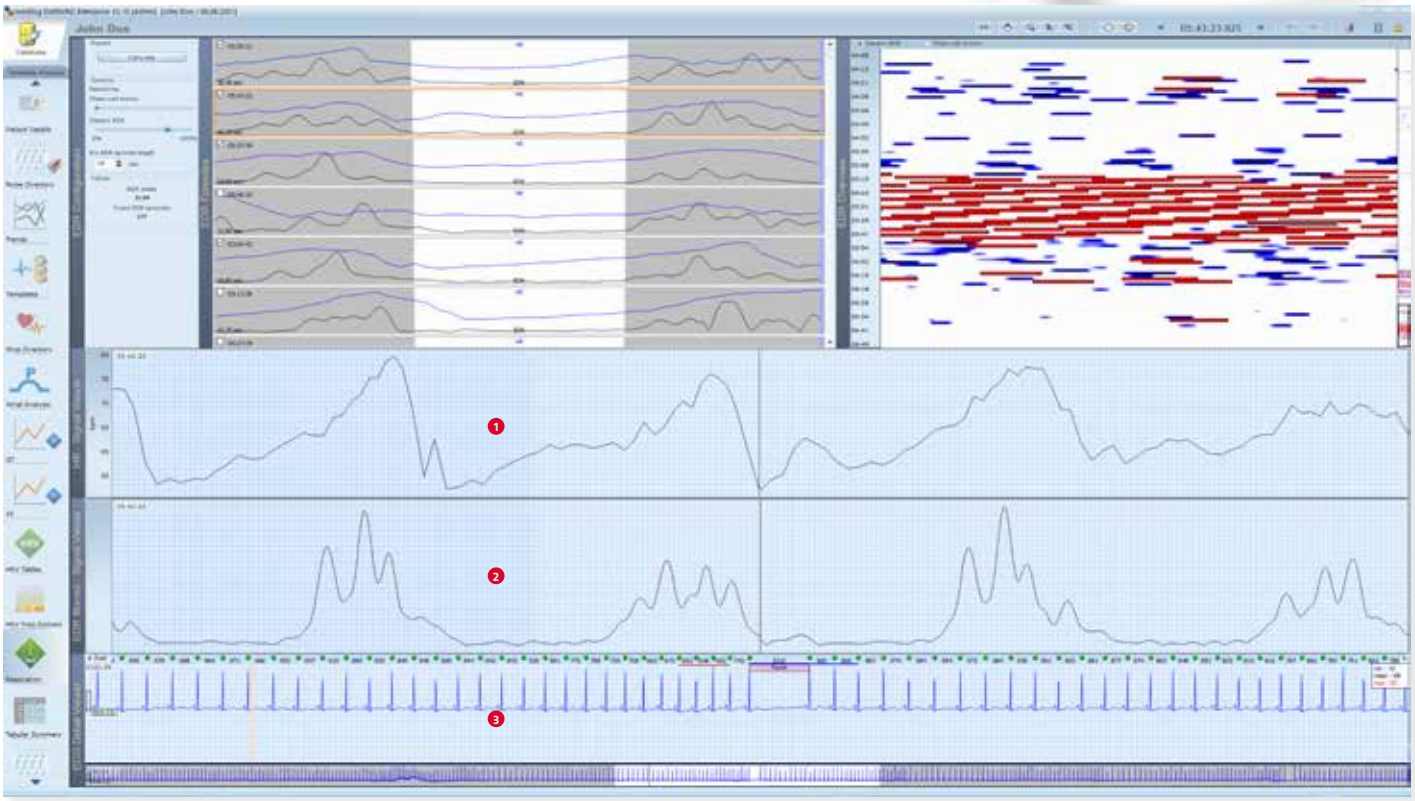
SYNCHRONISED ECG AND RESPIRATION CURVES

medilog DARWIN2 employs the method of ECG-derived respiration analysis. Thanks to the medilog recorder's high sampling rate and resolution, the results are highly accurate.

The synchronised display of ECG waveforms, heart rate trends, and respiration curves provides a valuable tool to thoroughly analyse the correlation between arrhythmias and respiratory episodes.

medilog DARWIN2 Enterprise offers a fast, reliable and inexpensive screening tool to exclude respiratory events in your patients.

- Early detection of respiratory episodes during sleep
- Low-cost, comfortable tool for tests at home
- Therapy assessment
- Review of sleep quality and evaluation of quality of life
- Optional SpO_2 sensor available, for the most comprehensive approach to respiration screening during sleep



Are arrhythmias caused by respiratory episodes? Synchronised ECG and respiration curves provide all the information at a glance.

1. Heart rate trend
2. Respiration curve
3. ECG

FIRE OF LIFE

A BRILLIANT, INTUITIVE APPROACH TO HRV ANALYSIS

Time-domain and frequency-domain Heart Rate Variability results are often difficult to interpret and traditionally require a time-consuming review.

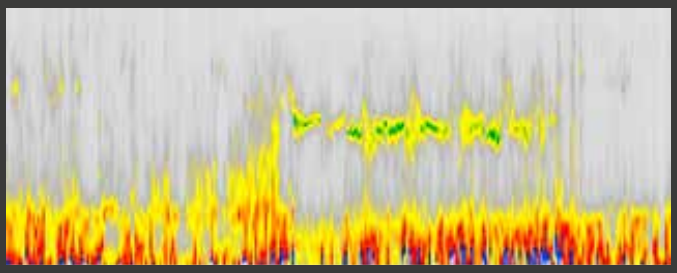
Fire of Life is a very intuitive visual presentation of frequency-domain HRV that makes the assessment of 24-hour results fast and simple.

Repeatable patterns of high- and low-frequency activity during day and night can be easily identified, providing information on sleep quality and stress level.

It can be used effectively in the occupational health sector to manage stress levels and sleep quality as well as in sports medicine to monitor the recovery process.

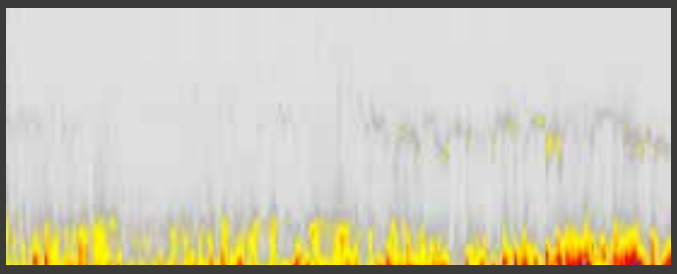
The Fire of Life evaluation is available with the recorders medilogAR Professional, medilogAR Enterprise and medilogFD and with the software versions medilog DARWIN2 Professional and medilog DARWIN2 Enterprise.

NORMAL REGULATION – and recovery during the night



Example 1: Swim trainer, woman, 23y, very good sleep quality, rhythmic sleep structure, very good capability for regeneration.

REDUCED REGULATION – overloaded, only little recovery at night



Example 2: 40-year-old manager, overloaded, stress-induced reduction of parasympathetic activation at night.

BLOOD PRESSURE ANALYSIS

USE ABPM-RECORDER AND EVALUATE WITH MEDILOG DARWIN2

medilog DARWIN2 software features the evaluation and reporting of ambulatory blood pressure measurements taken with BR-102 plus. For a well-founded cardiovascular risk assessment, pulse wave analysis is also available when using BR-102 plus PWA.

LIBERTY

UPLOAD YOUR RECORDINGS FROM ANYWHERE

medilog DARWIN2 Liberty is the perfect solution for Holter scanning service providers and hospitals with patients in remote locations. Fast turnaround will dramatically increase cost-effectiveness of the scanning service and improve patient care.

- Holter recordings can be uploaded from anywhere via a PC with an internet connection and a web browser: No need for dedicated client software at the remote location
- Patient data and waveforms can be displayed at the remote site for quality check
- The scanning service will review the Holter, analyse beat-templates and arrhythmias, and create the report
- An e-mail notification is sent, informing that the reports are available for review

Patients can easily and quickly maintain a diary of events that coincide with their ECG. To do this, they scan a QR code at the doctor's office, access the web application, and automatically save their data directly in their patient file.

PERSONALISE YOUR MEDILOG DARWIN2 REPORTS

- Brand your medilog DARWIN2 reports with your own logo
- Add or remove arrhythmia strips
- Add different trend views or diagrams for a specific recording
- If a patient shows very specific QT duration changes over time, just add this trend to your final report

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medilogFD

Instructions for Use (IFU)

Art. no. 2.511585 Rev. a

SCHILLER
The Art of Diagnostics

Sales and Service Information

The SCHILLER sales and service centre network is world-wide.

www.schiller.ch

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

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EC REP

Schiller Medizintechnik GmbH
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85622 Feldkirchen
Germany

CE 0123

The medilogFD bears a CE marking and an 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 complies with the EU MDR 2017/745.

Article no.: 2.511585 Rev. a
Issue date: 2024-10-30

SCHILLER
The Art of Diagnostics

Contents

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Art. no. 2.511585 Rev. a

Art. no. 2.511585 Rev. a

Art. no. 2.511585 Rev. a

1 Safety Notes

⚠ WARNING

▲ Read and follow these safety notes including the intended use and the information given in this instruction for use to prevent any injuries or damages.

1.1 Intended Purpose

▲ The medilogFD is an ambulatory ECG recorder intended to be used by or following instruction and under the direct supervision of a licensed physician in healthcare facilities or home environment to acquire, digitize, wirelessly transmit and store data of up to a 12 lead ECG for a measuring duration of an extended period of 24 hours or more including the detection of pacemaker pulses, presence of p-waves and R-peaks as well as the ECG derived respiration (EDR) to help user making a diagnosis in adult and paediatric patients above 2 years of age and with a body weight of over 10kg (22lbs).

▲ The ability to stream ECG with diagnostic bandwidth is intended to be used by or following instruction and under the direct supervision of a licensed physician in healthcare facilities to acquire ECG signals from body surface electrodes and wirelessly transmit ECG snapshots during an ambulatory ECG recording to a host device to help user in making a diagnosis in adult and paediatric patients above 2 years of age and with a body weight of over 10kg (22lbs).

▲ The medilogFD can be connected with other medical devices (e.g. SpO_2 sensor, blood pressure measurement devices) using the Bluetooth® module.

1.1.1 Indications ambulatory Holter ECG

The medilogFD is a Holter recorder that is indicated for patients who may benefit from a long-term continuous ECG recording, including, but not limited to, those with complaints of palpitations, syncope, chest pain, shortness of breath or those who need to be monitored to judge their current cardiac function or device functionality.

Holter is a diagnostic tool for use with the following applications:

- Cardiac arrhythmias
- Atrial fibrillation
- Atrial and ventricular tachyarrhyhthmias
- AV blocks
- Bradycardia
- Congenital heart disease
- Heart failure
- Ventricular arrhythmias
- Hypertrophic cardiomyopathy
- Stable coronary artery disease
- Superventricular arrhythmias
- ST-depression/elevation
- Long QT

Art. no. 2.511585 Rev. a

It can also be used to:

- Control of pacemaker therapy
- Screen for respiratory events
- Observe clinical research studies.

Art. no. 2.511585 Rev. a

1.1.2 Indications resting ECG

The medilogFD recorder is indicated for screening and assessment of cardiovascular diseases, including:

- Resting myocardial ischaemia
- Former myocardial infarction
- Conduction system abnormalities, including atrioventricular blocks, bundle branch blocks and pre-excitation syndromes
- Long QT syndromes
- Atrial abnormalities
- Ventricular hypertrophy and strain
- Pericarditis
- Secondary repolarisation abnormalities, such as electrolyte disturbances
- Drug-induced abnormalities.

1.1.3 Intended users

▲ The medilogFD is intended to be operated by or following instruction and under the direct supervision of a licensed physician.

▲ During the ambulatory holter recording, the device is worn and operated by an untrained patient.

1.1.4 Patient target group

▲ There are no restrictions regarding height, strength, gender, or ethnicity of the patients.

▲ In order to be eligible for the procedure, patients must have a body weight of over 10 kg (22 lbs).

▲ Patients in the following age groups may use the device: children, adolescents and adults.
The age ranges are defined by the FDA as follows:
- Child (from two years to 12 years of age)
- Adolescent (from 12 years to 21 years of age)
- Adults (21 years of age or older)

1.1.5 Affected body regions

Direct, prolonged contact with intact skin of the upper body.

1.1.6 Context of use

- The ambulatory holter recorder is designed for a measuring duration of more than 24 hours and less than 30 days and is therefore worn and operated by an untrained patient during day and night also in home environment. The recorder is fixed with a neck belt or similar.
- The preparation for the recording (attaching electrodes, transferring patient data, etc.) and operation in case of wirelessly transmitting ECG is performed by or following instruction and under the direct supervision of a licensed physician in a healthcare facility.
- In case of wirelessly transmitting ECG, the receiver is in immediate vicinity of the patient (less than 5 m / 16.4 feet).
- The device is designed to be used in conjunction with a compatible ambulatory ECG analysis software or a compatible ECG device or software to receive ECG.

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1.1.7 Contraindications

⚠ WARNING

Patients

- ▲ Patients below 2 years of age must not use the medilogFD recorder due to the risk of strangulation through the ECG cables or the neck strap of a carrying solution.
- ▲ If strangulation risk can not be ruled out, e.g. with children or patients impaired with a cognitive deficit, a caregiver must oversee the operation tasks and continuously monitor the recording.

1.1.8 Limitations and restrictions

⚠ WARNING

The medilogFD recorder is not:

- ▲ Capable of any diagnosis nor it is able to provide any interpretation of the recorded data.
- ▲ Intended for monitoring of vital physiological parameters.
- ▲ Intended to be used in life-sustaining, rescue or emergency context.
- ▲ Intended to be used for diagnosis in clinical situations where the patient is in immediate danger.
- ▲ To be used in areas where there is any danger of explosion or in the presence of flammable gases.
- ▲ Intended for sterile use.
- ▲ To be used in the vicinity of an MR scanner.
- ▲ Protected against the effects of defibrillation.

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1.2 User's Responsibility

⚠ WARNING

- Ensure the personnel have read and understood the Instructions for Use (IFU), especially these safety notes.
- The medilogFD recorder must not be used or charged if any damage to the medilogFD recorder, accessories or cables is visible.
- The owner is responsible for visually inspecting the medilogFD recorder, accessories or cables before use to determine if they are fit for purpose. If determined unfit, the medilogFD recorder, accessories or cables must not be used.
- Damaged or missing components must be replaced immediately.
- The numerical and graphical results and interpretation suggested by the medilogFD recorder must be examined along with the patient's overall clinical condition and the quality of the recorded data.
- Before each recording, check the battery compartment (isolation), the casing for cracks, damage, or melted areas and the ECG cable for damage. Even though the medilogFD recorder is drip-proof (IP22), prevent it from being exposed to liquids. Do not spray clean.
- It is the owner's responsibility that the valid regulations for safety and prevention of accidents are observed. Make sure to store the medilogFD recorder so that it is not accessible for children (to prevent inhalation/swallowing of small parts).
- Keep the battery cover fitted to ensure no direct access to the memory card.
- The safety, reliability and performance of the medilogFD recorder can only be guaranteed if the maintenance intervals, as stated in the maintenance section, are adhered to.

  9 Maintenance, page 69
- The medilogFD recorder is a medical device that protects it from unauthorised access.

1.3 Organisational Measures

- Keep the IFU accessible, and ensure it is always complete and legible.
- These operating instructions do not override statutory or local regulations or procedures for preventing accidents or environmental protection.

Packaging

- Do not use the medilogFD recorder or disposables if the packaging is damaged or has been unintentionally opened.
- Do not use the medilogFD recorder if the packaging is exposed to environmental conditions outside those specified.

  11.3 Ambient Conditions, page 77

Using the medilogFD recorder outside the conditions specified may cause a loss or reduced functionality of the medilogFD recorder.

11.3 Ambient Conditions, page 77

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1.4 Safety-Conscious Operation

⚠ CAUTION

- To avoid damaging the medilogFD recorder, do not expose the medilogFD recorder to any of the following as this may damage the medilogFD recorder:
  - Extreme heat or direct sunlight from a car dashboard, in a glasshouse, on a radiator or near a fireplace.
  - Very dusty, damp or moist environments, e.g. moisture from a nebuliser, or steam from a kettle.

⚠ WARNING

- This IFU, especially these safety notes, must be read and observed.
- Only operate the medilogFD recorder and the CS-3 in accordance with the specified technical data.
- Even though the medilogFD recorder meets IP22 standards, including protection from limited water spray, the medilogFD recorder is unsuitable for use while taking a bath or shower.
- It must be ensured that the electrodes do not come into contact with other conducting objects (even if these are earthed). Do not operate the medilogFD recorder near exposed live parts.
- Do not, under any circumstances, open the casing. The medilogFD recorder does not contain any serviceable parts.
- The medilogFD recorder power supply and patient circuit are not distinctly isolated. Only use batteries that are specified for the operation of this medilogFD recorder. Do not, under any circumstances, use a power supply unit; this could endanger the patient's life.
- Follow the instructions given in the electrode placement section. A recording can be started from DARWIN2 (medilogDARWIN2 version 2.11.2 or higher) or directly on the recorder. Following the procedural flow outlined below is important for patient safety and comfort. Not following these instructions can lead to incorrect measurements and an incorrect diagnosis.
- Do not, under any circumstances, insert objects into the microSD card slot, USB port or battery compartment other than the appropriate item, as it could damage the medilogFD recorder and endanger the patient.
- The medilogFD recorder is BF  classified and is not protected against the effects of defibrillation and/or shocks.
- When using the medilogFD recorder during sleep, note that this can cause sleep disturbances and a lack of concentration the following day.
- During operation, ensure that any moving parts of a machine or sports equipment do not catch the cable (especially the neck belt if used).
- Danger of strangulation from the patient cable and neck belt, especially at night. Take extra care in the vicinity of children to prevent strangulation.
- Ensure that children cannot swallow small parts (e.g. microSD card).
- When not in use, store the medilogFD recorder and the patient cable out of reach of children.
- If the patient falls while wearing the medilogFD recorder (e.g. during sports activities), there may be an increased risk of injury.
- No modifications to the medilogFD recorder are permitted.
- Operating conditions of the medilogFD recorder are up to 45°C, but the surface temperature must not exceed 43°C.
- The medilogFD recorder is not intended to be used in areas with any danger of explosion or in the presence of flammable gases such as anaesthetic agents.

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⚠ WARNING

- A small danger exists when using the medilogFD recorder for a patient with a pacemaker fitted. Data transmission modules could affect pacemaker functionality. To prevent a pacemaker malfunction, a distance of at least 20 cm (8 inches) must be kept between the medilogFD recorder and the pacemaker when the Bluetooth® module is active.
- Precautions for Bluetooth® pairing :
  - Ensure no two sensor pairing processes are started simultaneously to prevent incorrect pairing.
  - Ensure that only one medilogFD recorder is in range of the receiver during advertising/pairing.
- Only use accessories and other parts recommended or supplied by Schiller. Use of parts other than recommended or supplied may result in injury, inaccurate information and/or damage to the medilogFD recorder.
- Do not connect the medilogFD recorder with other equipment not described in this IFU (e.g. the USB socket must not be used to connect anything except a computer or wall charger (for data transfer/internal battery charging) to ensure no connection with any medical device.
- Any connected equipment must fulfil IEC 62368-1 Audio/Video, information and communication technology equipment.

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1.5 Operation with other Devices

⚠ WARNING

- Simultaneously using or connecting several devices on the same patient increases patient currents. Contact the device manufacturers to ensure that the simultaneous use/connection of the devices does not cause harm.
- The medilogFD recorder is designed for use in an electromagnetic environment with controlled HF interferences. Electromagnetic interferences can be avoided by observing the minimum distances between portable and mobile HF communication equipment (transmitter) and the Holter recorder, according to the communication equipment's maximum transmitting power.
  11.8.1 Measures to prevent electromagnetic interferences, page 81
- The device may be disturbed in electromagnetic environments. Patients should avoid environments with unusually high electromagnetic fields, e.g. train stations, electrical power plants, and steel production facilities.
- Portable communication devices, HF radios and devices labelled with the  symbol (non-ionising electromagnetic radiation) can affect the operation of the medilogFD recorder.
- It is highly recommended that both devices are kept close to each other to maintain a consistent Bluetooth® connection. Keeping the devices within the same room or at a distance of approximately 5 meters (16.4 feet) greatly improves the connection's reliability and prevents unexpected problems.

1.6 Networks and access security

- Connecting medilogFD via USB and/or Bluetooth to an IT network could result in previously unidentified risks to patient, operators or third parties. The responsible organisation needs to identify, analyse, evaluate and control any additional risks resulting from the medilogFD connected to IT networks including other equipment. Subsequent changes to the IT network might introduce new risks and require additional analysis.

1.7 Maintenance

- There are no serviceable parts inside. Do not open the casing of the medilogFD recorder.
- Do not use high-temperature sterilisation processes (such as autoclaving). Do not use E-beam or gamma radiation sterilisation.
- Do not use solvent or abrasive cleaners on the medilogFD recorder or cable assemblies.
- Do not, under any circumstances, immerse the medilogFD recorder or cable assemblies in liquid.

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1.8 Disposal

The medilogFD, accessories and batteries must be disposed of as follows:

⚠ CAUTION

- They must not be disposed of in the household waste.
- The recorder and accessories must be disposed of in a municipally approved collection point or recycling centre when no longer required.
- Improper disposal harms the environment and human health due to the presence of dangerous substances in electrical and electronic equipment.
- Disposal of the recorder per the EU Directive 2002/96/EC (WEEE).
- Batteries must be disposed of according to the national transposition of Directive 2006/66/EC of the European Parliament and of the Council of 6 September 2006 on batteries and accumulators.
- Only dispose of batteries in official recycling centres or municipally approved areas.

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1.9 Safety Symbols and Pictograms

1.9.1 Symbols used in this document

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

⚠ DANGER	For a direct danger which could lead to severe personal injury or death.
⚠ WARNING	For a possibly dangerous situation which could lead to severe personal injury or to death.
⚠ CAUTION	For a possibly dangerous situation which could lead to personal injury. This symbol is also used to indicate possible damage to property.


For general safety notes as listed in this section.


Especially important or helpful information


Reference to other guidelines.


Cross-reference

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1.9.2 medilogFD recorder and type label symbols

General used symbols

14 Appendix - Symbols, page 87

Not all of the symbols listed here are necessarily present on your medilogFD recorder.

Read the Instruction For Use (IFU) before using the medilogFD recorder.

IP22

According to IEC 60529. Protection against deposits of dust and protection against water. (The first digit indicates the protection of the equipment against ingress of solid foreign bodies and dust, and the second digit indicates the degree of protection of the equipment inside the enclosure from ingress of water).

The medilogFD recorder is rated IP22, meaning protection against solid objects over 12 mm, e.g. a person's fingers, and drip water protection (no harmful effect from vertically dripping water when the enclosure is tilted at an angle up to 15° from its normal position).

Applied part of type BF (device is not defibrillation protected)

The symbol for the recognition of electrical and electronic equipment.

Improper disposal harms the environment and human health due to the presence of dangerous substances in electrical and electronic equipment.

Bluetooth® symbol (transmission/reception)

The recorder is connected via Bluetooth®

Microphone symbol, recorder front panel

Non-ionising electromagnetic radiation. The device contains an RF transmitter.

The device is not intended to be operated in or near an MRI suite.

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1.9.3 Navigation and configuration symbols


Select/Confirm


Forward


Increase/Decrease


Cancel


Exit/Back


A green maker indicates an option is selected and active


High charging temperature


Low charging temperature


Power off


Configuration menu

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1.10 Additional Terms

1.10.1 Federal Communications Commission (FCC) Rules

This equipment has been tested and found to comply with the limits for a class B digital device, pursuant to Part 15 of the FCC rules and the Canadian Department of Communications radio interference regulations. These limits are designed to provide reasonable protection against harmful interference when the equipment is operated in a commercial environment. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with this IFU, may cause harmful interference to radio communications. The operation of this equipment in a residential area is likely to cause harmful interference; the user must correct the interference at his own expense.

1.10.2 Terms of warranty

The medilogFD recorder is warranted against material and manufacturing defects for one year (from the date of purchase). Excluded from this warranty is damage caused by an accident, water ingress, or as a result of improper handling. The warranty entitles free replacement of the defective part. Any liability for subsequent damage is excluded. The warranty is deemed void/invalid if unauthorised or unqualified persons attempt to make repairs.

In case of a defect, send the medilogFD recorder to your dealer or the manufacturer. The manufacturer can only be held responsible for the safety, reliability and performance of the medilogFD recorder and Schiller accessories:

- Assembly, extensions, adjustments, modifications or repairs are carried out by persons authorised by your dealer or manufacturer.
- All spare parts used during assembly, extensions, adjustments, modifications or repairs are recommended parts or supplied by Schiller.
- The medilogFD recorder and approved attached equipment are used in accordance with the manufacturer's instructions.
- The maintenance intervals, as stated in this manual, are observed.

8 Cleaning and Disinfecting, page 65

No express or implied warranties extend beyond the warranties hereinabove set forth. Schiller makes no warranty of merchantability or fitness for a particular purpose concerning the product or parts thereof.

Schiller is not liable for the loss of data saved on the PC or the medilogFD recorder. The user is solely responsible for the data backup.

1.10.3 Implied authorisation

Possession or purchase of this medilogFD recorder does not convey any express or implied license to use the medilogFD recorder with replacement parts which would alone, or in combination with the medilogFD recorder, fall within the scope of one or more patents relating to this device.

1.10.4 Serious incident

Where a serious incident has occurred concerning the medilogFD recorder, such an incident needs to be reported to Schiller and the competent national authority in the state where the user and/or patient is established.

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2 Introduction

The medilogFD recorder is used to record a 12-channel ECG. The medilogFD recorder is designed for measuring more than 24 hours and is worn by the patient throughout the day. The technician or doctor prepares the recording (attaching electrodes). During recording, the medilogFD recorder is hold in a carrying case. This case can also be worn with the neck strap.

The recorder offers the following features:

- Measuring the time intervals between consecutive R peaks
- Recording the occurrence of P waves
- Detecting pacemaker pulses
- Recording the ECG amplitude, due to the heart's connection to the rib cage, breathing causes the electrical heart vector to turn. This changes the amplitude of ECG-derived respiration (EDR).
- Bluetooth® module
  6.4 Bluetooth® Menu, page 56

The medilogFD recorder is powered by two separate batteries;.a replaceable AAA battery and an internal non-replaceable battery. The internal battery is the primary power source used for recordings. The replaceable AAA battery provides an extended recording capability when required.

The recording duration depends on the recording mode, settings, and battery condition.
6.1.1 Recording profiles, page 53

2.1 What's in the Package

The original package contains the following:

- medilogFD Holter recorder
- USB cable assembly
- microSD memory card and adapter
- Carrying case (for patient attachment)
- Instructions for Use (IFU)
- 10-wire patient cable
- Neck belt.

Options

- CS-3 Wireless charging station for wireless charging of internal battery.
- Power adaptor.
- USB cable

Details of parts and accessories are given in the back of this manual.
7 Accessories and Spare Parts, page 63

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3 Overview

The medilogFD recorder (hereafter referred to as the recorder) screen is not touch-sensitive. The recorder's physical UPPER (1) and LOWER (2) buttons are used to select/navigate through menus and select options. Key features include:

1. UPPER button (On/Off and function button)
2. LOWER button (function button)
3. Front panel LED
4. Microphone
5. Patient cable connection
6. CS-3 Wireless charging station (optional)
7. OLED display (not touch-sensitive)
8. Patient cable connector
9. USB-C port (data transmission and charging)
10. Battery compartment
11. External replaceable AAA Battery (optional)
12. microSD card slot
13. Type label including recorder serial number, etc.

1.9 Safety Symbols and Pictograms, page 16

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4 Operation

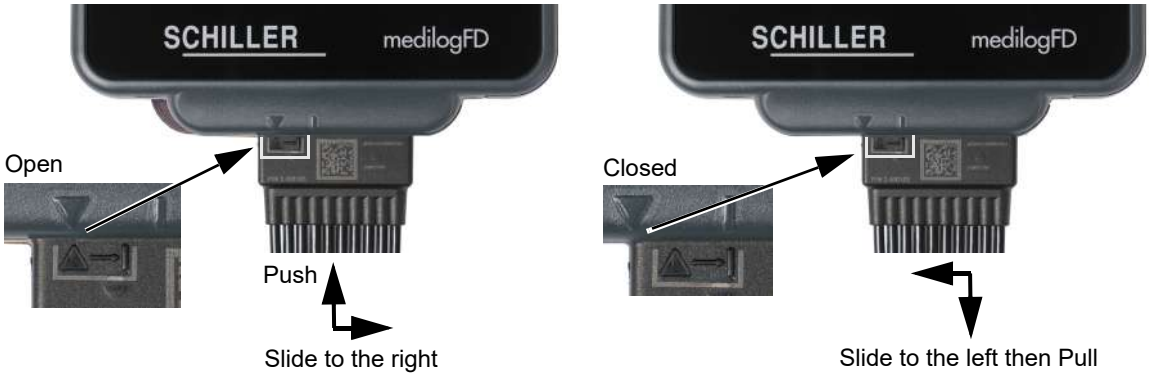
Only use the compatible patient cable supplied by Schiller.

4.1 Connecting the Patient Cable

The patient cable needs to be removed to access the USB port. Watch the how-to movie by scanning the QR code. Written instructions are provided below.

4.1.1 Connect the patient cable

1. Holding the patient cable connector (not the leads) position as shown below, gently push the cable connector into and slightly to the left of the recorder's cable interface so that the triangles align (see the Open graphic below).
2. Now, slide the patient cable connector to the right until the connector clicks into place.
3. The patient cable is now attached.



4.1.2 Disconnect the patient cable

1. Slide the patient cable to the left until it clicks away from the recorder cable interface.
2. Hold the patient cable connector (not the leads), and gently pull the cable away from the recorder.
3. With the patient cable removed, the USB-C port is accessible.

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4.2 USB Port Access

⚠ WARNING

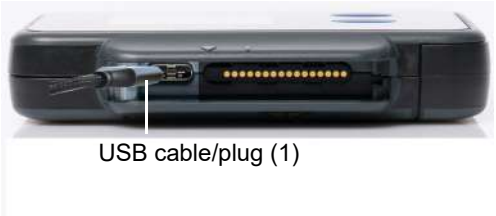
▲ Do not use the recorder or associated cables if any damage is apparent.

- Only USB-C-type cables are compatible.

The USB port is used to transfer data between the medilogDARWIN2 and PC and is used to charge the recorder's internal battery.

Connect the USB cable as follows:

1. Remove the patient cable to gain access to the recorder's USB port.
   4.1.2 Disconnect the patient cable, page 22
2. Connect the USB cable to a USB port on a PC (USB 2.0 or higher) or power adapter.
3. Connect the other end of the USB cable (1) to the USB port of the recorder.
4. When the recorder is successfully connected to a power source, the recorder switches on, and the battery charging screen is displayed.
   4.4.3 Charging the internal battery, page 27



USB cable/plug (1)

5. When the recorder is successfully connected to the PC, the following USB screen (left) is displayed on the recorder, including the recorder's serial number after the hash #. The recorder's serial number is also displayed on other medilogFD. screens, including in the recorder's Info menu.
   6.6 Info Menu, page 62
6. The internal battery begins charging as required. During charging, the internal battery State of Charge (SoC) symbol (top right) and the recorder's front panel LED flashes. The LED remains on without flashing when the internal battery is fully charged.

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4.3 Memory Card

The recorder's micoSD card stores all patient information and ECG recording data. The data can be analysed later using medilogDARWIN2. No patient data is stored on the recorder.The microSD card capacity limits patient recording duration/length.

- Only use microSD cards specified and approved by the manufacturer. Memory cards vary considerably in power consumption and read/write speed.
- Do not use the recorder's microSD card with any other devices or vice versa (digital cameras, MP3 players or similar devices), as it can lead to incorrect functioning and data loss.

Only compatible microSD cards with the following specifications should be used. Do not attempt to insert any non-compatible memory cards.

- Type: Secure Digital (microSD) or Secure Digital High Capacity (microSDHC)
- Capacity: 2 GB to 32 GB (FAT16/32)

4.3.1 Memory card access

⚠ WARNING

▲ Do not remove the memory card unnecessarily.
– Risk of patient data mix up, when removing the SD card and replacing it with an other used SD card with old data.
▲ Keep the memory card away from children at all times.

- The recorder is mechanically protected from inserting the microSD card incorrectly. Do not force the card into the slot.
- When the microSD card is positioned slightly below the slot's inner casing, the microSD card is correctly inserted.

First, remove the recorder's battery cover to access the microSD card.

1. Remove the battery cover by applying pressure until it slides/pulls away from the recorder. The microSD card slot is at the side of the recorder, as shown on the left.
2. /Insert or remove the microSD card by gently pushing it 1 to 2 mm until it locks into position or is raised to allow removal.

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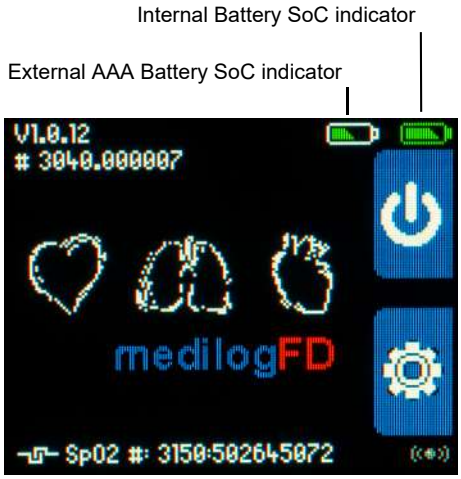
4.4 Power Supply

The recorder is battery-powered for mobility. The primary power source is the non-replaceable internal rechargeable battery; a secondary standard replaceable AAA battery is incorporated to increase the recording duration if required.

- Both battery State of Charge levels are displayed in the top right of the recorder as shown below.
- Replace the AAA battery and recharge the internal battery as required.

4.4.1 Battery indicators and State of Charge (SoC)



- The recorder must be turned on to view the battery's SoC. The battery indicators display the SoC of the inserted battery  . When the battery is full, the symbol is filled.
- The 

icon indicates low SoC. Note that the use of partly discharged batteries can lead to premature termination of the recording when the batteries are exhausted and the recording stops.If the low SoC icon is displayed after switch-on, the external battery must be replaced/internal battery charged to ensure regular operation.
- When the external battery is not installed, it is indicated by a grey outline  .
- If the recorder display is off but the recorder itself is not switched off, press the UPPER or LOWER button to turn on the display.

The recorder is powered by the internal battery only. In case the SoC of the internal battery is too low to complete the planned recording, it is still possible to do a recording by inserting a AAA battery as long as the SoC of the internal battery is > 10%.

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4.4.2 AAA Replaceable battery

- Only compatible AAA batteries with the following specifications should be used. Do not attempt to insert any non-compatible batteries.
  - Type/size: AAA/LR03, 1.5V
- Operation with rechargeable NiMH batteries (at least 800 mAh) is possible. Note that the recorder's running period can be reduced depending on the state and age of a rechargeable battery. The battery type must be defined in the system settings.
  6.5 Battery Type Menu, page 61
  - **Note:** The device does not charge the rechargeable battery.
- If the external battery's depletes during a recording, the recorder automatically switches to the internal Li-Ion battery.
- If the internal battery is > 10% charged, the external removable AAA battery may be replaced during a recording without disruption. However, you must disconnect the recorder from the patient before replacement.
  4.4.2 AAA Replaceable battery, page 26

⚠ WARNING

▲ Check that the recorder's battery cover is always fitted correctly, specifically following battery replacement or after accessing the memory card.

Remove/replace the external battery as follows:

1. Remove the battery cover by sliding/pulling it away from the recorder; see left.
2. Remove the battery by pushing the negative end until the positive end lifts, as shown below, and remove the battery. Under no circumstances should you use a tool to remove the battery.
3. Insert a new, fully charged compatible battery, negative end first, then press the positive end until the battery is installed correctly.
4. Replace the battery cover and check that the cover is fitted correctly.

⚠ CAUTION

▲ Observe the correct polarity when inserting a new battery. Follow the instructions in the battery compartment. Batteries that are inserted incorrectly can damage the recorder.

▲ Only use batteries specified and approved by the manufacturer. The mechanical manufacturing tolerance for batteries is often considerable and can lead to problems with the battery contacts in the worst case. In addition, the energy density of different batteries can vary significantly.

▲ Do not change the battery while the recorder is connected to the patient. Always change the battery before connecting to the patient. Do not touch the patient when changing the battery. Disconnect the patient cable.

▲ Ensure the battery compartment is closed.

▲ Remove the AAA battery after use. The battery must be removed from the recorder when not used for a long time. Failure to remove the battery may lead to battery leakage and toxic fumes.

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4.4.3 Charging the internal battery

⚠ WARNING

▲ Use only USB chargers or other USB power sources which meet IEC 62368-1 requirements.

▲ Check that used power adapter/source or USB connector/cable is not damaged.

- 500 mA minimum charging current is required by the USB power source. A higher wattage does not decrease the charging time.
- Ensure that the power adaptor or the USB cable can be quickly and easily disconnected from the mains or PC.
- The use environment for charging the internal battery is limited to healthcare facilities.

The internal battery is automatically charged in the following ways:

1 

- The recorder is connected to a PC USB port using the USB cable (1).
  4.2 USB Port Access, page 23

2 

- The recorder is connected to a power adaptor (2) (optional accessory) using the USB cable.

3 

- The recorder is placed in a CS-3 (3) (optional accessory).
  4.5 CS-3 Wireless Charging Station, page 29

Internal battery state of charge indicator

Wireless charging symbol

USB charging symbol

High-temperature symbol

Low-temperature symbol

During internal battery charging, the recorder:

- Displays a charging symbol indicating the battery state of charge and that the device is recharging the recorder's internal battery. Here, the symbol shows the battery recharging wirelessly.
- The internal battery charging status indicator (top right) flashes until the battery is full.
- The recorder's front panel orange LED flashes (very one second) until the battery is full.
- If the recorder reaches a critical temperature for any reason, charging is halted until the recorder's temperature is back to normal.
- After charging, the screen switches off.

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4.4.4 Internal battery storage

- For battery longevity, it is recommended that the recorder is stored with the battery approximately 70% charged.
- Normally, the internal battery loses its charging state over time. When the recorder is not used for long periods, the internal battery must be recharged every 8 weeks.

Important

The internal battery must be checked every year.

9.3.1 Internal Li-Ion battery check, page 70

⚠ WARNING

▲ **Danger of Explosion:** Do not dispose of batteries by fire or incinerator.

▲ The life of the batteries is defined in the maintenance section.

9.3 Battery Maintenance, page 70

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4.5 CS-3 Wireless Charging Station

The CS-3 wireless charging station is an optional accessory for recharging the recorder's internal battery.

⚠ WARNING

- ▲ Charge only compatible SCHILLER devices.
- ▲ Do not place any metal parts on the CS-3.
- ▲ Before use check CS-3 and accessories for damages.
- ▲ Do not use a defective or damaged CS-3, power adaptor, or USB cable.
- ▲ Danger of electric shock. Do not open the device. No modifications are allowed. Maintenance work may only be completed by a qualified technician authorised by Schiller.
- ▲ Risk of fire or electric shock. Protect connection of the CS-3 and power adapter against ingress of solid parts or liquids.
- ▲ Power supply connected to the CS-3 need to be certified according to the respective IEC standards (e.g. IEC 62368-1 for audio/video, information and communication technology equipment, and IEC 60601-1 for medical electrical equipment.

- Schiller CS-3 is the only compatible wireless charging station for the recorder. Do not use any other wireless charging device.
- The use environment for charging the internal battery is limited to healthcare facilities.
- Wireless charging halts an ongoing recording until the recorder is removed from the charger.
- At maximum charging time, the temperature of the CS-3 housing may exceed 48°C. Avoid prolonged contact with the housing.
- No ECG-related functions or ECG-quality screens are available while charging wirelessly.
- If the medilogFD is USB-powered when placed in a CS-3, then the medilogFD is charged via the USB.
- Disconnect the CS-3 from its power source when charging is complete or not in use.
- Ensure that the power adaptor or the USB cable can be quickly and easily disconnected from the mains or PC.
- Clean the CS-3
  See:
  8 Cleaning and Disinfecting, page 65
  8.2 Cleaning Procedure, page 66

According to radio frequency exposure regulations, the user must not be closer than 10 cm (3.9 inches) from the device.

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4.5.1 Wireless charging of the internal battery

1. Connect the CS-3 to a suitable USB output of at least 10W **(1)**, e.g. using a power adaptor (optional accessory).
2. Place the recorder into the CS-3 **(2/3)**. Refer to the CS-3 IFU.
3. Check that the recorder is fully touching the CS-3 housing.
4. When the recorder is detected, the recorder switches on, and the charging status is displayed
   4.4.3 Charging the internal battery, page 27
5. Disconnect the CS-3 from its power source when charging is complete or not in use.

Removing the recorder from the CS-3

1. Holding the recorder body, gently lift the recorder from the CS-3 **(2)**. Do not hold or remove the recorder by the patient cable (3) if attached.
2. Disconnect the CS-3 from its power source when charging is complete or not in use.

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4.6 Front Panel LED

The functionality of the LED (1) is as follows:

LED always ON

The LED (1) remains ON when the internal battery is fully charged while the USB cable is connected or the recorder is placed in the CS-3.

LED flashing

The recorder front panel LED flashes at the following two different rates:

- At approximately every 1 second:
  - while the internal battery is being charged via the USB or wirelessly
  - if the charging is completed the LED is continuously on.
- At approximately 4 times every second:
  - When basic patient data has been received and displayed on the recorder screen, it allows verification of correct recorder-to-patient matching.

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4.7 Switching the Recorder On

Switch on the recorder by pressing the UPPER button for 1 second. The recorder's front panel LED illuminates briefly, followed by the initial screen (left).

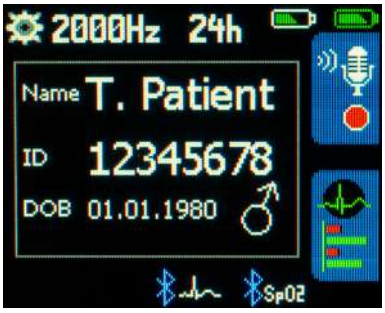
In addition, the recorder can be switched on:

- By connecting the recorder to the USB
- By placing the recorder in the charging station.

The following information applies only to recorders not being charged (no connection to USB or wireless charger).

When the recorder is switched on with no patient cable connected or no memory card inserted and while not being charged (no connection USB or wireless charger) and no patient data has yet been added, the Start screen (left) is displayed following the initial screen. Access to the recorder Configuration menu (pressing the LOWER front panel button) is possible from this screen.

6 Configuration, page 52



Patient data added with DARWIN2

When the recorder is switched on after patient data has been added, the recorder displays basic patient data as shown on the screen left following the initial screen.

After configuring a recording using medilogDarwin2, the screen shows the associated patient data and the planned recording settings.

The following information applies only to recorders not being charged (no connection to USB or wireless charger).

When the recorder is switched on with no patient cable connected or no memory card inserted and while not being charged (no connection USB or wireless charger) and no patient data has yet been added, the Start screen (left) is displayed following the initial screen. Access to the recorder Configuration menu (pressing the LOWER front panel button) is possible from this screen.

6 Configuration, page 52

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4.8 Switching the Recorder Off

The recorder switches off automatically:

- If no front panel button has been pressed for 5 minutes (when not in recording mode), the recorder switches off to save battery power.
- When the set recording duration has been reached
- If no free space is left on the microSD memory card
- When both batteries' are depleted during recording. The recording ends automatically before the recorder is switched off to prevent data loss.

Switching off at the Start screen

When the Start screen (below) is displayed, a short press of the UPPER button switches off the recorder.

Switching off during recording

➜ Press and hold the UPPER and LOWER buttons for several seconds to stop a recording. A progress bar shows how long both buttons must be pressed to stop the recorder.
– The process is stopped by releasing one or both buttons while the progress bar is displayed; the recording then continues.

Note: During a recording, the display switches off after approximately 45 seconds to save battery power. Pressing any front panel button, the display switches on for approximately 45 seconds before switching back off.

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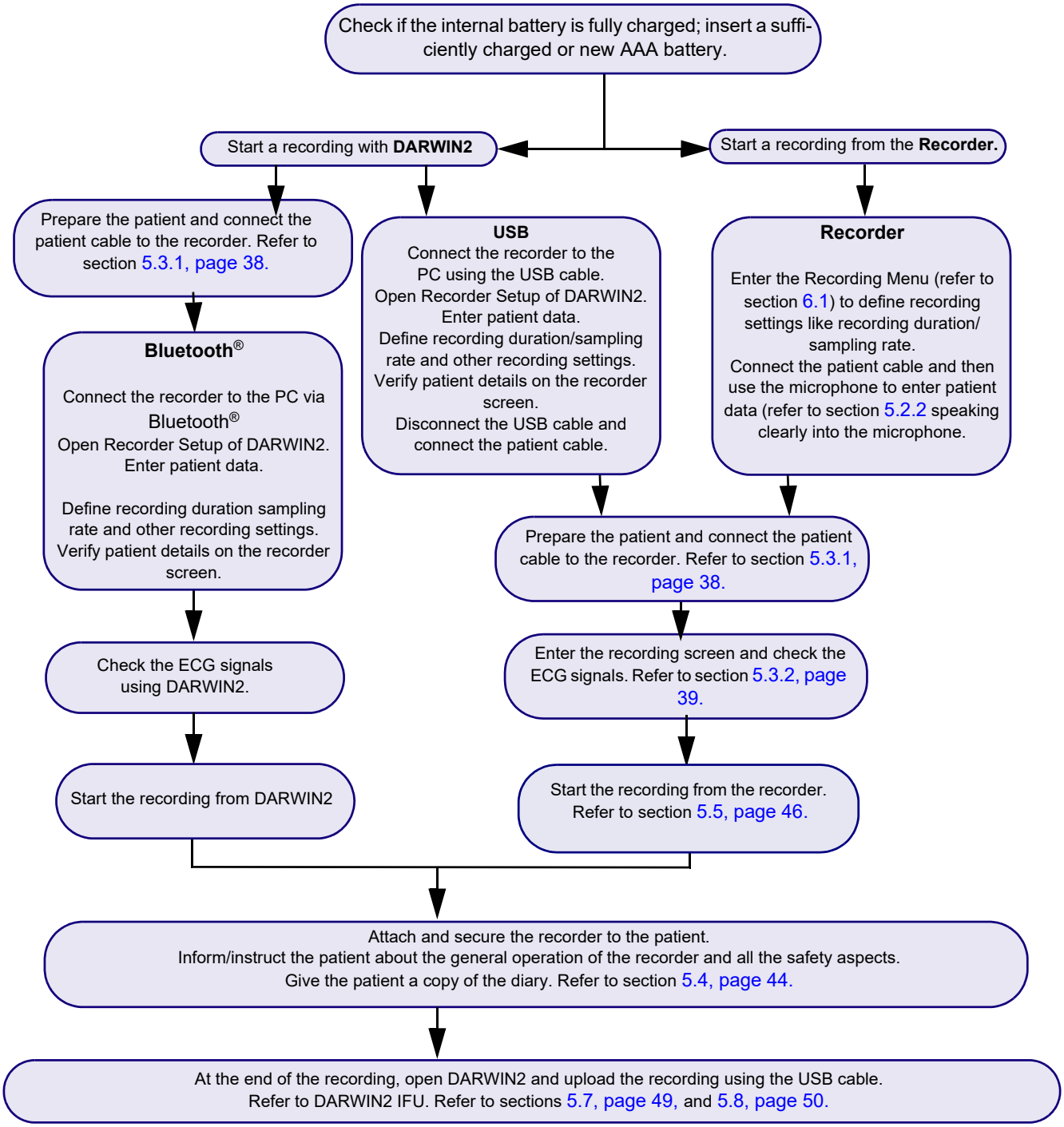
5 Recording

A recording can be started from DARWIN2 (medilogDARWIN2 version 2.11.2 or higher) or directly on the recorder. Following the procedural flow outlined below is important for patient safety and comfort.

Procedural Flow



➜ When using Bluetooth®, the patient/patient cable shall be connected before.

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5.1 Initial Steps before starting a recording

Before starting a recording

- Check that the replaceable AAA battery has a sufficient charge level, or insert a new AAA battery in the battery compartment. Recording is also possible without a AAA battery.
- Check that the internal battery state of charge is sufficiently charged (> 80% without an external AAA battery, > 10% if an external AAA battery is inserted).
  4.4.3 Charging the internal battery, page 27

- Note that settings made in the medilog DARWIN2 software overrule settings made on the recorder.
- Depending on the configuration, the storing rate is 250 Hz or 2000 Hz before starting a recording.
  6.1.3 Recorder modes, page 53
- If the Bluetooth® symbol is displayed, the Bluetooth® module is activated.
- When the charging state of the internal battery is very low (< 10%), it is necessary to charge the recorder > 10% before a recording can be started using an external AAA battery.

5.1.1 Initial steps

Either set up and start a recording directly via the recorder or use DARWIN2 (version 2.11.2 or higher).
6.1 Recording Menu, page 52
To use DARWIN2, use one of the following methods to connect the recorder to DARWIN2:

- **USB Cable**: Connect the recorder to the PC using the USB cable.
  4.2 USB Port Access, page 23
- Bluetooth®: Activate and connect the recorder to the PC using the Bluetooth® function.
  6.4 Bluetooth® Menu, page 56

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5.2 Enter Patient Data

Important patient data is at the start of the recording setup process using DARWIN2. The recorder's screen displays basic patient data, including Patient ID (see below). A patient data recording feature (microphone symbol) is active on the recorder to allow the recording of patient data. Voice recordings can be played back, and the details can be entered using DARWIN2 later. Voice message recording is always possible.

⚠ WARNING

- ▲ If patient data is not entered using DARWIN2, it is mandatory to record patient data using the microphone, otherwise it is not possible to start a recording.
- ▲ If it is not possible to link a voice recording to a patient recording, the recording must not be used.
- ▲ The recording must not be used if patient data cannot be verified.

5.2.1 Using DARWIN2

The recorder must be connected to the PC (USB or Bluetooth®).

1. Open DARWIN2 and select **Recorder Setup.**
2. Enter patient data (1), patient ID and case details as required.
3. Select the recorder type medilogFD
4. If the recorder is connected via USB to the PC, the recorder configuration screen directly opens in DARWIN2. Otherwise, (for Bluetooth® connection), select the connection type Bluetooth® by clicking on the Bluetooth® symbol and then selecting the recorder (identified by its serial number). Note: The serial number is also written on the recorder label.
5. Patient data (1) is displayed on the recorder screen as soon as the following icon is clicked on in DARWIN2:
   - The green triangle (Save settings) when connected via USB
   - Respectively, the magnifier symbol (Prepare recording) when connected via Bluetooth®.
6. Verify patient details on the recorder screen. If patient data is not correct repeat step 1.

⚠ WARNING

- ▲ A unique patient ID must be used to ensure that all recordings are linked with the correct patient. Check that all patient data on-screen is correct and linked with the correct patient ID (1). If the patient data is not correct, repeat the configuration with DARWIN2 with the correct data.
- ▲ Before streaming ECG data via Bluetooth®, patient details must be checked.

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5.2.2 Using the microphone

A patient data recording feature (microphone symbol) is active on the recorder to allow a voice recording of patient data. Voice recordings can be played back within DARWIN2, and the details can be typed in using DARWIN2 later.

Before you start, ensure you have the patient ID, and other patient details should be available. Always speak in a normal voice/volume with the recorder's microphone close to the mouth.

3 Overview, page 21

Be ready to start speaking/recording.

1. Press the UPPER button to start the voice recording.
2. Voice record the patient's details. The recording length is up to 40 seconds, as indicated by the on-screen progress bar (left). Press the microphone symbol to pause the recording if necessary.
3. The recording is saved to the recorder's memory card.
4. The voice recording process is complete.

1

2

Note

➜ Enabling pacemaker detection is shown with the pacemaker symbol **(2)**

➜ If no patient data have been entered via DARWIN2, the following screen appears to complete a voice recording of the patient name, DOB and the patient ID:

▲ To confirm if a voice recording has been made, a symbol and time stamp is displayed at the bottom left of the recorder screen:

– A symbol and the duration time 

are displayed in the bottom left of the recorder screen **(1)** to confirm that a voice recording has been made.

▲ A voice recording should be of good quality to identify the patient. Always speak clearly into the microphone located on the front of the recorder.

3 Overview, page 21

▲ Voice recordings do not replace/supersede any written or stored patient data.

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5.3 Patient and Electrodes

5.3.1 Preparing the patient

Careful application of the electrodes is essential for electrode security and to ensure good recording quality and patient comfort.

Good adhesion and minimal resistance between skin and electrode are required to ensure the highest quality ECG recording. Therefore, note the following:

- Ensure that the patient is warm and relaxed.
- Shave the electrode area before cleaning.
- Thoroughly clean the area with alcohol.
- When applying the electrodes, ensure that a gel layer is between the electrode and the skin.
- It is recommended that the cable is connected to the electrode before attaching the electrode to the patient.
- Form a stress loop in the electrode cable and secure it with tape.
- Inform the patient about the use of the recorder.
  12 Patient Information, page 82
- Patient events can be registered during a recording to mark any particular event during use. A physician defines and informs the patient what events should be marked.
  5.6.2 Registering patient events, page 47

i

- Many ECG adhesive electrodes are suitable for use. As ECG electrodes from different manufacturers have different electrical properties, the choice of ECG electrodes can considerably affect the measurement results and quality. Ensure that only high-quality electrodes are used.
- Electrodes must have snap connectors and be certified for long-term use according to the planned recording duration.

We recommend electrodes manufactured by Ambu GmbH (61231 Germany), suited for ambulatory use.

⚠ WARNING

▲ Never use patient cables that show damage of any sort. Damaged cables can lead to increased patient currents.

i

▲ If you take the electrodes from a package with several electrodes, ensure the package is air-tight so the electrodes do not dry out. Do not use out-of-date electrodes (see use by date), as the gel can dry out.

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5.3.2 Connecting the electrodes

Attach the electrodes to the patient. The following positions according to Mason-Likar are recommended[1].

R/RA Electrode Placement:

1. Identify the right infraclavicular fossa (the hollow area just below the collarbone).
2. Find the spot just inside (medial to) the edge of the deltoid muscle.
3. Place the electrode about 2 cm (0.8 inches) below the lower edge of the collarbone.

This position minimizes muscle noise during exercise and provides recordings similar to standard Leads I and II.

L/LA Electrode Placement:

1. Identify the left infraclavicular fossa (the hollow area just below the collarbone).
2. Find the spot just inside (medial to) the edge of the deltoid muscle.
3. Place the electrode about 2 cm (0.8 inches) below the lower edge of the collarbone.

This position minimizes muscle noise during exercise and provides recordings similar to standard Leads I and III.

F/LL Electrode Placement:

1. Locate the left side of the body, in line with the front of the armpit (anterior axillary line).
2. Position the electrode halfway between the lower edge of the rib cage and the top of the hip bone.

This placement can be adjusted for a few centimeters (up to 1 inch) to avoid skin folds or clothing interference. Be sure not to place the electrode too close to the leg, as it may pick up extra muscle noise and won't improve R-wave detection.

N/RL Electrode Placement:

1. Locate the right side of the body, in line with the front of the armpit (anterior axillary line).
2. Position the electrode halfway between the lower edge of the rib cage and the top of the hip bone.

This placement can be adjusted for a few centimeters (up to 1 inch) to avoid skin folds or clothing interference. Be sure not to place the electrode too close to the leg, as it may pick up extra muscle noise and won't improve R-wave detection.

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1. Mason RE, Likar I. A new system of multiple-lead exercise electrocardiography. Am Heart J. 1966;71(2):196-205. doi:10.1016/0002-8703(66)90182-7

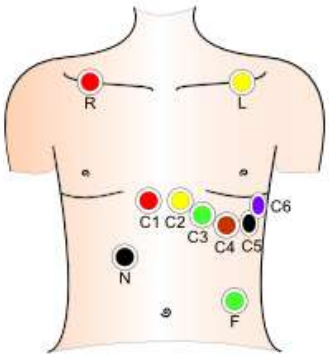
Precordial Electrodes

1. Place these electrodes in their standard placement guidelines:

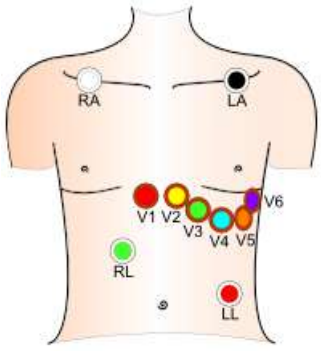
IEC Label	AHA Label		Electrode Placement
C1 white / red	V1 brown / red	➜	Fourth intercostal space at the right sternal border
C2 white / yellow	V2 brown / yellow	➜	Fourth intercostal space at the left sternal border
C3 white / green	V3 brown / green	➜	Midway between C2 and C4
C4 white / brown	V4 brown / blue	➜	Left mid-clavicular line in the fifth intercostal space
C5 white / black	V5 brown / orange	➜	Left anterior axillary line on the same horizontal level as C4
C6 white / violet	V6 brown / violet	➜	Left mid-axillary line on the same horizontal level as C4
L yellow	LA black	➜	Left arm
R red	RA white	➜	Right arm
F green	LL red	➜	Left foot
N black	RL green	➜	Right foot

These positions are illustrated in the provided diagram for reference.

10-lead cable: ECG label		10-lead cable: AHA label	
Position	**Colour**	**Position**	**Colour**



C1 - red
C2 - yellow
C3 - green
C4 - brown
C5 - black
C6 - purple
R - red
L - yellow
N - black
F - green



V1 - red
V2 - yellow
V3 - green
V4 - blue
V5 - orange
V6 - purple
RA - white
LA - black
RL - green
LL - red

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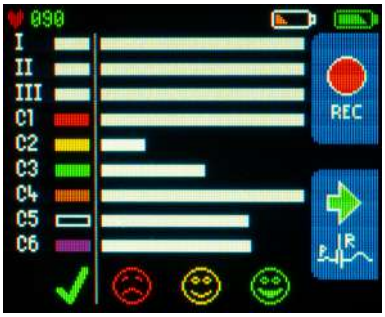
5.3.3 Lead test and ECG signal checks

The recorder's ECG signal quality and lead tests can be checked. To complete the checks within DARWIN2, refer to the DARWIN2 IFU.

- For most, connecting and disconnecting snap electrodes is self-evident. Pushing the lead connector onto the pad nipple secures the lead to the pad. Use the lead-off detection facility (see below) to check that the leads are connected correctly.
- To detach the lead, gently pull the lead end away from the pad nipple.



True ECG signal check

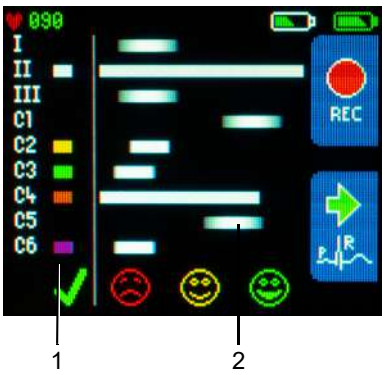
The lead test/signal quality evaluation screen (left) indicates lead connectivity, channel quality, lead and electrode resistance, and the first screen the user sees while attaching the electrodes to the patient. For precise signal quality evaluation, patients must be at rest and relaxed.

From the screen left, the electrode, skin contact, and the signal quality of attached electrodes I, II, III, C1, and C4 have been evaluated as excellent, i.e. maximum, long white bars. However, electrodes C2, C3, C5, and C6, connected with excellent skin contact, have less-than-perfect signal quality and should be checked. The following three on-screen smilies also provide an indication/feedback as to signal quality:

-  Signal quality is too low to ensure a good recording; the electrode must be replaced.
-  Signal quality is good and ensures a good recording.
-  Signal quality resistance is excellent.

Lead-off detection

From this screen, electrodes C1 and C5 are either disconnected or faulty, resulting in no or very low signal quality; therefore, the bars to the left (1) disappear (lead-off detection), and a moving bar (2) replaces the normal static signal quality bar. A moving bar essentially indicates it is searching for an electrode signal.



Skin contact quality

The lead-off bars (1) from this screen are smaller/reduced in width, indicating that the skin contact is critically weak or the electrodes are not connected properly and must be checked.

ECG signal quality is calculated, i.e. the length of bars, by analysing the signal amplitude, high-frequency noise, R-peak detection quality and the skin/electrode contact quality.

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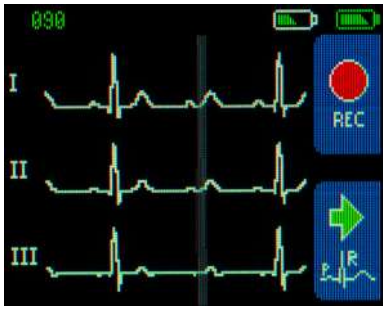

ECG signals

From the quality screen above, press the lower button to check leads C1...C3 and C4...C6 for lead reversal or other signal quality problems.

➜ Pressing the upper button will start the recording.

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5.3.4 Consequences of weak signals

Bad signal quality can lead to:

- Significantly more review/editing effort in DARWIN2.
- The whole recording can be unusable (from the moment of disconnection) if one of the peripheral electrodes (R, L, F, N and RA, LA, LL, RL respectively) is disconnected because the Wilson point is no longer defined. These electrodes are very important for making a usable recording.
- V1 to V6 are less critical because these leads do not affect the quality of other leads.

  5.3.2 Connecting the electrodes, page 39

  However, good signal quality equals less editing work later.

Proper skin preparation is essential, combined with high-quality Holter ECG electrodes suited for ambulatory use e.g. manufactured by Ambu GmbH.

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5.4 Attaching the Recorder to the Patient

⚠ WARNING

▲ To help keep the electrode leads in position and prevent strangulation, a T-shirt or outer clothing must remain on at night or be replaced by the patient's normal nightwear over the electrodes.

5.4.1 Electrode cable

Form a stress loop in every cable and secure them in position with adhesive strips to relieve electrode strain.

5.4.2 Recorder carrying solution

The recorder-carrying solution consists of a carrying case and an adjustable neck belt.

5.4.3 Securing the recorder to the patient

Select a suitable recorder securing method, considering patient preferences and conditions.

Currently, there are two possibilities as follows:

- Using the neck belt and carrier.
  5.4.4 Assemble the carrying solution, page 45

Neck belt

⚠ WARNING

▲ **Danger of Strangulation:** The neck belt or electrode cable can become entangled around the patient's neck, leading to strangulation. The danger increases at night. Ensure the patient is aware of the danger.

▲ This method of attachment is not suitable for children or frail patients.

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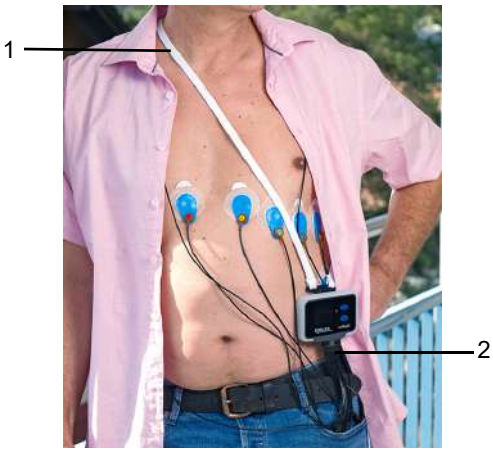
5.4.4 Assemble the carrying solution

1. Insert the neck belt strap through an opening of the rear of the carrying case (1)
2. Secure/snap the neck belt strap together (2)
3. Insert the recorder into the carrying case (3), then press the recorder down (4) fully into the carrying case.

Patient and carrying solution

1. The neck belt (1) should be positioned around the patient, as shown below.
2. Adjust the position of the recorder and patient cable appropriately for the patient. The patient cable (2) can face up or downwards for comfort/ease-of-use.



3. Check that the neck belt is not tight or looped around the patient's neck.
4. Check that the electrodes and patient cable are not under strain or looped, which may cause injury to the patient or damage to the cables.
5. Once the patient is wearing the recorder, check that the front panel of the recorder is facing outwards and not in contact with the patient's skin.

Art. no. 2.511585 Rev. a

5.5 Starting the Recording

/To start a recording using DARWIN2, refer to the DARWIN2 IFU. To start a recording directly from the recorder, proceed as follows:

1. Select **REC** using the UPPER button from the lead test screen to start the recording. An hourglass is displayed while the recording process initialises.
2. After a few seconds, the time is displayed for a short period, the screen goes blank, and the recording continues. The recorder's orange LED flashes approximately every 5 seconds during the recording.
   5.5 Starting the Recording, page 46

If all leads are connected, patient data is available, and the screen shows ECG signals or the true signal check screen and no action is selected for 2 minutes, the recorder automatically starts recording.

Art. no. 2.511585 Rev. a

5.6 During the Recording

⚠ WARNING

▲ Do not open the battery compartment while the recorder is attached to a patient and recording.

5.6.1 Indicators during a recording

If not disabled in the configuration, the recorder's orange LED (1) flashes every 5 seconds, indicating the unit is in recording mode.
See:

6.1.4 LED Indicator, page 53
4.6 Front Panel LED, page 31

During a recording, if the screen goes blank after a short period, press any front panel button to turn the screen on again.

5.6.2 Registering patient events

To register an important patient event:

1. Press any front panel buttons to register an event during the recording. This action sets a time-stamped event marker (1) in the recording for later analysis with DARWIN2 by a physician. The physician will advise what type of patient events should be recorded, e.g. going to bed, waking up, feeling dizzy, and taking medication.
   – When an event is registered, the time is displayed for a short period (1).
   – An event with the corresponding time stamp and the notes made in the patient's diary support the physician.
2. If the screen goes blank after a short period, press any front panel button to turn the screen on again.

The Triple Clap feature

- The triple clap feature allows patients to register events by clapping on the recorder 3 times within 1 to 2 seconds.
- This feature can be activated or deactivated using DARWIN2 Recorder Setup. If activated the recording data file size increases slightly.

Art. no. 2.511585 Rev. a

5.6.3 Heart Rate (HR)

1

The lead test screens displayed during the connection process show the HR (1).
The calculation of the HR and related analysis is completed in DARWIN2.

Art. no. 2.511585 Rev. a

5.7 Stopping the Recording

The recording stops automatically when:

- The set recording duration has been reached
- The microSD card is full
- Both batteries are low
- A recording can also be stopped using DARWIN2 when connected via USB or Bluetooth®.

5.7.1 Manually stopping a recording

The recording can be stopped by:

- Pressing and holding the UPPER and LOWER buttons for approximately 5 seconds. A progress bar is displayed during the switch-off process.
- Removing the patient cable and connecting the recorder via the USB port to a PC (with DARWIN2 installed).

⚠ WARNING

▲ Do not take out the memory card during a recording.

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5.8 Analysing the Recording

⚠ WARNING

▲ Patient details must be checked before analysing patient ECG data with any application or device. Care must be taken to safe-guard patient data/ recordings.

Recordings can be viewed and analysed using DARWIN2 version 2.11.2 or higher. Refer to the DARWIN2 IFU.

5.9 Deleting a Recording from the Memory Card

If the recorder detects a recording saved on the memory card that has not yet been read by the PC (not transferred to DARWIN2, false start, mistake), the recording information is displayed when the memory card is inserted as shown. The recording can be deleted by pressing both recorder front panel buttons for several seconds until the full progress bar indicates the recording has been deleted.

⚠ WARNING

▲ If a recording is resumed, ensure that the correct patient is displayed. It is very important to avoid any confusion or incorrect recording assignments.

Art. no. 2.511585 Rev. a

5.10 Trigger Resting ECG Snapshot Streaming

This feature is not available with standard recorders; it is optional.

⚠ WARNING

- ▲ Before streaming ECG data via Bluetooth®, patient details must be checked.
- ▲ To prevent the recording device from being assigned to another patient in the vicinity during ECG data transmission via Bluetooth®, always check the following on the device and software for identification:
  - – Patient name and patient ID are always sent to the PC host system for verification when available on the recorder.
  - – Otherwise, the device's serial number is shown in the PC host system and needs to be checked against the serial number shown on the display of the re- corder. The serial number is also written on the recorder label.
  - – If the ECG sent cannot be assigned to a patient on the host system, the ECG must not be used for diagnostic purposes.

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6 Configuration

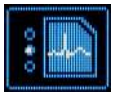
Navigation and configuration symbols used within the configuration menus are generally self-explanatory.

1.9.3 Navigation and configuration symbols, page 18

Entry to the Configuration menus is via the recorder Start screen (upper left). To display the Start screen, complete the following:

1. If Start screen is not displayed recording is still pending or waiting to be uploaded.
   – In this case stop recording/upload recording or remove memory card.
2. Remove the patient cable. Removing the patient cable while the recorder is switched on forces the recorder to display the Start screen.
3. Switch On the recorder if switched Off.
4. Press the LOWER button to display the recorder Configuration menu (lower left).

6.1 Recording Menu

Select  to configure the recording setup.

Multiple options are available within the recorder menu; each is described below. A green marker in the top left of an option confirms the selection.

Art. no. 2.511585 Rev. a

6.1.1 Recording profiles

Select this menu item to define the recording duration. When 24, 48 or 72 hours have been selected, the recorder switches off automatically at the end of the selected recording period.

Scientific mode: The recording rate is set to 2000 Hz in this mode. This mode ensures full diagnostic bandwidth. The recording duration is set to 24 hours is this mode.

6.1.2 Recording continuation

When selected, the recorder switches off automatically when the defined recording duration (see above) has been reached. When this option is deactivated, the recording continues until the external and internal batteries are empty, the memory card is full, or the user stops the recording by pressing and holding both front panel buttons for several seconds.

⚠ CAUTION

▲ Danger of incorrect patient registration. Always check the patient's name and patient ID on-screen if a recording is interrupted and the recording continues. It is very important to avoid confusion or incorrect assignment of the recording data. The displayed patient data is saved with the recording.

6.1.3 Recorder modes

	24 hours	48 hours	72 hours	Scientific mode
Sampling rate	128000 Hz	64000 Hz	32000 Hz	128000 Hz
Storing rate	250 Hz	250 Hz	250 Hz	2000 Hz
p-wave detection	250 µs	500 µs	1000 µs	31.25 µs
r-peak/EDR detection resolution	31.2 µs	62.5 µs	125 µs	31.25 µs
Pacemaker Pulse detection resolution	31.25 µs	62.5 µs	125 µs	31.25 µs
Internal Battery lifetime without AAA battery (@ a status of 100% charged)	> 72 hours	> 96 hours	> 120 hours	> 60 hours
Battery lifetime with AAA battery inserted	+26 hours	+34 hours	+42 hours	+24 hours

6.1.4 LED Indicator

Select to enable/disable the five-second LED indicator flash when recording an ECG.

Note: Disable the LED if patient gets disturbed by the flashing LED during the night.

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6.2 Contrast Menu

Select  to adjust the display contrast.

6.2.1 Adjusting contrast

1. Press the LOWER button repeatedly to adjust the Contrast. The test pattern helps to judge the selected contrast setting.
2. Press the UPPER button to save the setting.

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6.3 Time and Date Menu

Select  to set up the Time and Date.

6.3.1 Set the time and date

1. Press the LOWER button to navigate to the digits to be adjusted (Highlighted).
2. Press the UPPER button to change/increase the value.

3. After completing the last adjustment, press the UPPER button to Save or the LOWER button to Cancel.

Note that the date and time set here are displayed on the screen.

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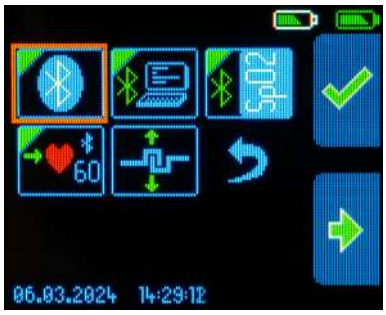
6.4 Bluetooth® Menu

Select  to configure Bluetooth® connectivity.



Multiple options and sub-menus are available within the Bluetooth menu; each is described in more detail below.

6.4.1 PC Mode

Use this mode so that the recorder can send acquired data to a paired PC. The advantage of using this mode is that signal quality can be checked during the connection process and patient recording. Signal analysis can be carried out using DARWIN2.

PC Mode sub-menu

 Used to start the recorder-to-PC pairing process.

 Used to disconnect/unpair a recorder with a PC.

6.4.2 Bluetooth® pairing and data transfer

⚠ WARNING

- ▲ Before streaming any patient ECG data via Bluetooth to DARWIN2 or any other application or device, the patient's details must be checked.
- ▲ Data transmission modules could affect pacemaker functionality. To prevent a pacemaker malfunction, a distance of at least 20 cm (8 inches) must be kept between the recorder and any pacemaker after the Bluetooth® module is activated.

- The recorder must be within approximately 5 meters (16.4 feet) of the paired device to establish a stable transmission. Check that there are no obstacles between the recorder and the paired device.
- All secondary devices must support trusted pairing via code handshake. This is a 6-digit pairing code displayed on the recorder during the pairing process.
- The recorder can be paired with up to 7 PCs/HR profile-capable devices to analyse recording data using DARWIN2, paired with one SpO_2 device.

Familiarise yourself with how to pair devices on a PC (Windows settings) before attempting to pair the recorder.

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1. Navigate to the Bluetooth® menu and press the UPPER button, and a sub-menu appears.

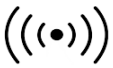
2. Press the LOWER button to select the PC Mode symbol (left) if not already selected. Now press the UPPER button, a sub-menu appears.

3. With the symbol left selected, press the UPPER button again. A dialogue now occurs between the recorder and the PC. A 6-digit pairing code is displayed on the recorder.

4. Press the UPPER button to accept/confirm the pairing code.
   – The recorder is now paired with the PC. A green marker is now visible on the Bluetooth® symbol (left).

-Checking the list of paired devices on the PC (Windows settings), it should now show the recorder (medilogFD + Serial Number + Battery status) as paired.

5. Start DARWIN2 and select Recorder Setup.
6. Select the Recorder and Connection type. In this case, select the Bluetooth® symbol.
7. Now select the recorder by serial number from the list displayed.



8. The recorder is now connected via Bluetooth® to DARWIN2.
   – A transmission symbol is displayed at the bottom right of the recorder screen. It is now possible to set up, start a recording and import previous recordings from DARWIN2.
   – For all further DARWIN2 operations, refer to the DARWIN2 IFU.

If Bluetooth® becomes troublesome, connect the recorder to the PC with the USB cable, restart DARWIN2, select Recorder Setup, and then select Recorder and Connection type. In this case, select the USB symbol.

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6.4.3 Disconnecting Bluetooth®

Disconnecting the Bluetooth in this menu unpairs ALL paired devices (including a SpO2 sensor). To unpair all PCs only the user must use unpair option within the PC submenu.

1. Navigate to the Bluetooth menu, press the UPPER button, and a sub-menu appears.

2. Press the LOWER button to select the Disconnect symbol (left).
3. Press the UPPER button. An hourglass appears while the recorder disconnects the Bluetooth connection with all paired devices.

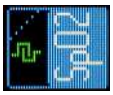
4. All devices are now disconnected. The green marker on the Bluetooth symbol (left) is removed.

6.4.4 SpO_2 devices

- Only use the compatible SpO_2 devices supplied by Schiller.
  7.2 Accessories, page 63
- Only one SpO_2 Bluetooth® device can be paired/connected to the recorder.
- To connect a different SpO_2 sensor, delete/disconnect any other sensor from within the SpO_2 Bluetooth® configuration menu.
  6.4.6 Disconnecting a SpO_2 Bluetooth® device, page 59
- When a SpO_2 device is connected, a SpO_2 symbol and its serial number are displayed on the screen. The SpO_2 serial number is also displayed in the recorder's Info menu.
  6.6 Info Menu, page 62
- The user must check that the serial number displayed on-screen is that of the connected SpO_2 device.

Use this function to receive SpO_2 data from a paired/connected SpO_2 device (the Bluetooth® SpO_2 function is receive mode only). The signal is received from the connected SpO_2 sensor, stored, and synchronised with the ECG on the microSD card. An analysis is carried out using DARWIN2. Refer to the DARWIN2 IFU for details.

SpO_2 sub-menu



Used to start the recorder-to-SpO_2 pairing process.

Used to disconnect/unpair a recorder with a SpO_2 device.

Art. no. 2.511585 Rev. a

6.4.5 SpO_2 Bluetooth® pairing and data transfer

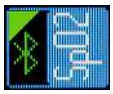
Sensor pairing:

1. Connect the SpO_2 probe.
2. Remove the batteries of the SpO_2 sensor
3. Re-insert the batteries

4. Start the pairing process on the medilogFD by selecting the pairing option within the SpO_2 Bluetooth® sub-menu.

5. Insert a finger into the probe to switch on the SpO_2 sensor.
6. As soon the serial number of the SpO_2 sensor is shown on the display of the medilogFD, check it for correctness and confirm if the serial number is correct.

The serial number of the paired sensor is shown on the Start-Up Screen, the Charging Screens, and the Recording Screen.



During a recording, the SpO_2 values are recorded fully automatically as soon as a paired SpO_2 sensor has been switched on. The Recording Screen shows the transmitted SpO_2 values.

6.4.6 Disconnecting a SpO_2 Bluetooth® device

Disconnecting the Bluetooth in this menu unpairs ALL paired devices (including a PCs). To unpair all SpO_2only the user must use unpair option within the SpO_2 submenu.

1. Navigate to the Bluetooth® menu, press the UPPER button, and a sub-menu appears.

2. Press the LOWER button to select the SpO_2 symbol (left). Now press the UPPER button, and a sub-menu appears.

3. Press the LOWER button to select the Disconnect symbol (left).
4. Press the UPPER button. An hourglass appears while the recorder disconnects the Bluetooth® connection with the SpO_2 device.

5. The SpO_2 sensor is now disconnected. The green marker on the SpO_2 Bluetooth® symbol (left) is removed.

6.4.7 Heart Rate (HR)

The recorder can be paired with a Bluetooth® BLE client supporting the BLE HR profile. When paired, the BLE HR client shows the patient's HR.

5.6.3 Heart Rate (HR), page 48

If a paired device supports the BLE Heart Rate profile, it will receive heart rate information from the recorder as soon this option is activated and a BLE connection has been established.

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6.4.8 Disabling the Bluetooth® module

To disable the Bluetooth function, it is sufficient to deselect the Bluetooth option (press the UPPER button while the Bluetooth symbol of the Top Level Bluetooth menu is selected).

Selecting the unpair button within the Top Level Bluetooth® menu deletes all 'trusted devices' (PC and SpO_2). Deleting all trusted devices deactivates Bluetooth®.

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6.5 Battery Type Menu

Select 

to select the external battery type.

This setting is required for the correct display of the battery charging level.

6.5.1 Battery type

Two types of external replaceable AAA batteries can be selected: a 1.5V alkaline or a 1.2V NiMH rechargeable battery. Only use batteries or rechargeable batteries that have been approved for this recorder.

1. Press the UPPER button to select/toggle between the two types of batteries.

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6.6 Info Menu

Select  to display specific recorder information.

This menu displays specific recorder information, including the version and serial numbers of the recorder and other attached Bluetooth® devices/accessories. This information must be available when contacting Schiller service departments for help and troubleshooting.

1. Press the UPPER button to return to the Configuration menu.

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7 Accessories and Spare Parts

⚠ WARNING

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

Your local representative stocks all the disposables and accessories available for the recorder. A full list of all Schiller representatives can be found on the Schiller website (www.schiller.ch).

7.1 Device

Part Number	Description	Applied parts	optional skin contact
3.900491	medilogFD Holter Recorder (Device)	☒	☒
2.400183	10-wire patient cable IEC snap-button 0.8 meters (2.6 feet), medilogFD	☒	☒
2.400189	10-wire patient cable AHA snap-button 0.8 meters (2.6 feet), medilogFD	☒	☒

7.2 Accessories

Part Number	Description	Applied parts	optional skin contact
3.900100	CS-3 Wireless charging station	-	-
2.100939	Model 3150 WRIST-OX2, BLE (SpO_2 sensor)	☒	☒
2.155054	Ambu BlueSensor VL (VL-00-S/25), ECG electrodes (Clip) set of 25	☒	☒
2.310428	USB cable, USB Type-A to USB-C	-	-
2.100850	Alkaline battery LR03, type AAA, 1.5V	-	-
2.610078	microSDHC card with Adapter	-	-
2.200133	Power adaptor (5V/12W, USB Type-A)	-	-
2.156096	Neck belt	-	☒
2.156086	Holter pouch single use	-	☒

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7.3 Spare Parts

Part Number	Description	Applied parts	optional skin contact
4.435414	Carrying case (for patient attachment)	-	☒
4.310735	Battery compartment cover	☒	☒

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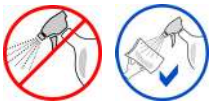
8 Cleaning and Disinfecting

Observe the following safety notes when cleaning/disinfecting the medilogFD recorder, patient cable or CS-3.

⚠ WARNING



- ▲ Danger of electric shock due to ingress of liquid:
  - – Do not disconnect the patient cable
  - – Do not remove battery cover
  - – Do not immerse the device or accessories in liquid
  - – Do not spray detergent/disinfectant onto the device or accessories
  - – Moisten the cloth with detergent/disinfectant (do not let it soak up too much liquid)
  - – If liquid does penetrate the unit send it to Schiller for testing
- ▲ Do not sterilise with steam or autoclave the device or accessories
- ▲ Only use the detergents/disinfectants listed.
  8.5 Approved Cleaning Materials, page 67
- ▲ Observe the manufacturer's instructions on using the detergent/disinfectant
- ▲ The device and accessories may become less resistant if an alkaline detergent or a detergent with a high alcohol concentration is left for a long time, or if a warm detergent/disinfectant is used:
  - – Only use the detergents/disinfectants listed in this chapter at room temperature
  - – Observe the manufacturer's instructions on using the detergent/disinfectant
- ▲ Damage to the cable due to mechanical stress:
  - – Do not stretch patient cable (insulation) while cleaning
- ▲ Some patients have intolerances (e.g. allergies) to disinfectants or their components. If you have such a patient or are unsure, remove possible residues with careful washing.
- ▲ After cleaning, check the casing and the ECG patient cable for damages. Do not use the recorder if you detect cracks, melted areas or any other signs of damage to the cable or casing.

8.1 Cleaning/disinfection Interval

⚠ WARNING

- ▲ The user should clean and disinfect the cables, recorder and carrying solution before every use.

All parts that come into contact with the patient, that is, the patient cable, recorder, carrying case, and CS-3 (due to recorder charging), must be cleaned and disinfected after each use, especially when contaminated with potentially infectious material (especially contamination with blood or other bodily fluids). Visible soiling needs to be removed, and the equipment disinfected immediately.

i

Always clean the device before disinfection and let it dry.

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8.2 Cleaning Procedure

Before cleaning:

- Check that the patient cable and the battery cover is fitted correctly to avoid ingress of liquid.
- Inspect device and accessories for any signs of damage or improper mechanical function of buttons or connectors.
- Switch off the recorder before cleaning.

▲ Do not spray the recorder or CS-3 directly.

▲ Make sure that no liquid penetrates the recorder or CS-3.

▲ Clean the recorder and CS-3 with a damp cloth, slightly moistened (not wet) on the surface. Use cleaning agents that are mild and diluted with water that are suitable for PC polycarbonate.
8.5 Approved Cleaning Materials, page 67

Use a clean, lint-free cloth moistened with detergent and wipe the unit to clean. Leave to dry in the air for at least 30 minutes.

Ensure liquid does not get into any connectors. If liquid should get into connectors, dry the area with warm air, and then check the equipment to confirm that it operates properly.

Wipe off any excess cleaning solution. Do not let the cleaning solution run into or accumulate in connector openings, latches, or crevices.

➜ If liquid penetrates the recorder or CS-3, remove the patient cable, the memory card, the battery and/or the CS-3 power and do not use the recorder. The manufacturer should now inspect the recorder.

➜ Ensure the contacts of the patient cable or CS-3 power cable are completely dry before use.

Observe the additional instruction for following accessories:

Patient cable

➜ Hold the cable in the centre and clean it towards the connector and the electrodes.

➜ Do not clean the whole length in one single action, as this may cause bunching of the sheathing. Only clean one section of the cable at a time (maximum 20 cm /8 inches) using the moistened cloth. Then, hold the next section and clean it. In this way, the cable (insulation) is not being stretched, and premature ageing can be prevented.

➜ Wipe off any excess cleaning solution. Do not let the cleaning solution run into or accumulate in connector openings, latches, or crevices

Neckbelt

➜ Hand wash only using a mild washing powder and allow to dry naturally.

Carrying case

➜ Hand wash only using soapy water and allow to dry naturally before disinfecting with a lint-free cloth moistened with disinfection.

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8.3 Disinfection

Use commercially available disinfectants for clinics, hospitals and practices to disinfect the recorder. Disinfect the unit in the same way as described.

8.2 Cleaning Procedure, page 66

8.4 Manufacturing Materials

The following material is used in the construction of the recorder and case. Only use compatible cleaning materials.

Component	Material
Recorder housing	PC/ABS/Styrene-Block-Copolymere
Patient cable	M-PUR/PUR/PA6/PBT
Button	Silicon
Carrying case	Silicon
Neck belt	POM/PP

Over time, the recorder casing may become less resistant for the following reasons:

- If an alkaline cleaner or a cleaner with a high alcohol concentration is left for a long time on the surface.
- If a warm disinfectant or detergent is used.

For this reason, Schiller recommends using only cleaning agents with alcohol content that are adequate for sensitive materials, such as Polycarbonate (PC/ABS), at room temperature (approximately 20°C). Let the recorder and accessories dry in the open air without heat exposure.

The recorder is not made with natural rubber latex

8.5 Approved Cleaning Materials

Please refer to the manufacturer's information regarding the detergents.

- Propan-2-ol/isopropyl alcohol (maximum 50%)
- Propan-1-ol/propanol (35%)
- Neutral mild detergents
- Soapy water
- All products that are suitable for Polycarbonate PC plastic (PC, PP (M)PUR)

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8.6 Approved Disinfectants

- Propan-2-ol/isopropyl alcohol (maximum 50%)
- Propan-1-ol/propanol (35%)
- Aldehyde (2 to 4%)
- Ethanol (50%)
- All products that are suitable for Polycarbonate PC plastic PC, PP, (M)PUR)

8.6.1 Recommended disinfectants

- Bacillol 30 foam/Bacillol 30 Tissues (10% Propanol-1, 15% Propanol-2, 20% Ethanol)
- Mikrozid AF (25 Ethanol, 35% 1 Propanol-1)

8.6.2 Disinfectants that are not approved

Never use products containing the following:

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

i Using these products or products containing similar components can cause discolouration, corrosion, and reduction of the product's life, which may render the warranty invalid.

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9 Maintenance

9.1 Maintenance Intervals

⚠ WARNING

▲ All maintenance work must be carried out by a qualified authorised technician. The user may carry out only the “Before every use” (see below) maintenance procedures given in this IFU.

▲ The recorder must be serviced regularly, and the test results must be documented.

The following table gives information about the interval and competence required for maintenance.

Interval	Maintenance	Responsible
Before every use	• Visual inspection of the recorder 9.2 Visual Inspection and Functional Check, page 70 • Clean and disinfect the cable and recorder as appropriate, i.e. before using it for another person 8 Cleaning and Disinfecting, page 65	→ The User/Nurse or equivalent
Every 12 months	• Internal battery check 9.3 Battery Maintenance, page 70	→ User or qualified service technician
	• Recurrent test and test after repair according to IEC/EN 62353 • Signal calibration and firmware updates according repair guide	→ Qualified service technician

9.1.1 Recurrent test

Simulator recording using the following settings:

- 24 hours mode
- Tap detection: On
- Automatic power down: Off
- 100% SoC of internal battery

Expected results

- Recording time > 72 hours
- Correct ECG amplitudes (± 5%)

9.1.2 Shelf life

Recorder 9.3 Battery Maintenance, page 70 (without patient cable)

Accessories shelf life See the expiration date on the battery or electrode packaging.

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9.2 Visual Inspection and Functional Check

Visual inspection

⚠ WARNING

▲ Before each recording and before attaching electrodes to the patient, check the casing and the ECG patient cable for damages. Do not use the recorder if you detect cracks, melted areas or any other signs of damage to the cable or casing.

Visually inspect the recorder and cable assemblies for the following:

- The recorder casing is not broken or cracked.
- The OLED screen is not broken or cracked.
- Electrode cable sheathing and connectors are undamaged. No kinks in the cable.
- USB cable sheathing and connectors are undamaged. No kinks in the cable.
- Input/output connector undamaged.
- Battery cover not closed or missing

➜ Defective units or damaged cables must be replaced immediately.

9.3 Battery Maintenance

9.3.1 Internal Li-Ion battery check

The internal battery is charged via the USB-C connector or wirelessly using CS-3.
4.4.3 Charging the internal battery, page 27

The internal battery must be checked annually by either Schiller or the user.

1. Fully charge the internal battery.
   4.4.3 Charging the internal battery, page 27
2. Remove the external battery if present.
   4.4.2 AAA Replaceable battery, page 26
3. Start a recording.
   Procedural Flow, page 34
4. After 72 hours, if the recorder is still operating by either:
   – Checking if the recording is still ongoing or
   – Importing the recording in medilog DARWIN2 and checking the recording duration.
5. The internal battery must be replaced if the recorder turns off due to a depleted battery before 65 hours.

- The internal battery must only be replaced by Schiller.
- **Shelf life:** Storing the recorder for long periods with the battery completely discharged or 100% charged reduces the battery life. Ensure that the battery is around 50% charged if the recorder is not used for a long time.

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9.3.2 Using external and rechargeable NiMH AAA batteries

- This section only applies when AAA, 1.2V rechargeable NiMH batteries are used.
- The battery is not charged from the medilog FD recorder.
- The batteries require no maintenance during their life.
- Refer to the manufacturer's documentation for the batteries' life cycle.
- Always remove the batteries from the recorder when not used for prolonged periods to prevent leakage.

Charging external batteries

- Full capacity of new NiMH batteries is only reached after three charge/discharge cycles.
- Refer to the battery and charger user information for charge times.
- Charged batteries lose their charge when removed from the charger unit. To ensure fully charged batteries, only remove the batteries from the charger immediately before recording.
- The batteries are not harmed by leaving them in the charger unit.

Remove the battery from the recorder and place it in the battery charger unit.
4.4.2 AAA Replaceable battery, page 26
Leave the battery in the charger until fully charged (refer to the battery charger operating instructions).

Batteries

⚠ WARNING

- ▲ **Danger of Explosion:** Batteries must not be burned or disposed of in domestic rubbish.
- ▲ **Danger of Acid Burns:** Do not open the batteries.

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10 Errors and Trouble Shooting

10.1 Error Messages

10.1.1 microSD card errors

microSD cards are constantly used during recording, and although industrial-grade microSD cards are durable, all microSD cards have a limited life and occasionally need replacing.

Remove the memory card and re-initialise it with the medilog DARWIN2 Recorder Setup program. If the error remains, proceed as follows:

- Perform a hardware reset (see next page)
- Replace the microSD card
- If the problem persists, contact a service partner.

10.1.2 General error message

This screen indicates an error. Perform a hardware reset (see next page). If the error persists, note the error number and contact the service department.

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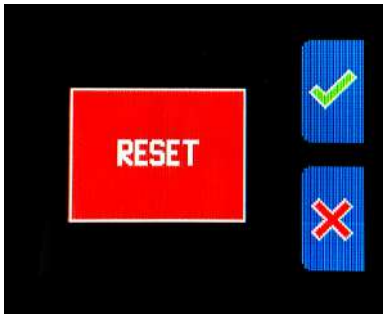
10.2 Trouble Shooting

Error	Possible cause	Remedy
The recorder cannot be switched On	• The internal battery is < 10% charged. It is not possible to switch on the recorder as soon the charging state of the internal battery is < 10%, even if an external battery has been inserted.	➜ Recharge via USB or CS-3
The recorder cannot be switched Off by pressing and holding the front panel buttons.	• The recorder is already switched off (the recorder switches itself off automatically as soon as the recording is finished (automatic switch-off activated). • The recorder is displaying an error due to unknown reasons.	➜ Normal operation ➜ See Error messages above
The recorder switches off prematurely	• The battery is empty • The battery is faulty • The memory card is defective. • When error messages 211, 212 or 213 are displayed.	➜ Recharge battery ➜ Replace external battery ➜ Replace memory card¨ ➜ Contact SCHILLER
Recording hangs up/screen locked	• Software	➜ Press the upper button for >10sec until the screen goes blank. After this reset the recorder should work as expected again.
The recorder is not working as expected	• Software	➜ Reset recorder see see section 10.3, p. 73

10.3 Reset the Recorder

If the recorder hangs/screen locks up, reset the recorder as follows:

1. Switch off the recorder. If it is not possible to navigate to the Switch off symbol (left), then:



2. Press and hold the LOWER button, then press and hold the UPPER button. Keep both front panel buttons pressed for approximately 7 seconds until the recorder screen goes blank.
3. The recorder is switched off.
4. Now press and hold the LOWER button.
5. Press and hold the UPPER button, and release the buttons when the hourglass appears. The RESET screen (left) appears.
6. Press the UPPER button to RESET the recorder
7. The recorder has been RESET.

Note: The RESET procedure above clears the recorder list of all trusted/paired devices, i.e. PCs and/or SpO_2. Once cleared, individual devices must be reconnected/ paired.

8. If the recorder is not reacting to user input, switch off the recorder by pressing the UPPER button for > 10 seconds.

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11 Technical Data

11.1 medilogFD Holter Recorder

Manufacturer	Schiller AG
Device name	medilogFD
Dimensions	101 x 70 x 19 mm (3.9 x 2.7 x 0.74 inches) without cable
Weight	Approximately 125 g (without AAA battery)
Protection against water ingress	IP22
Interface	
Protocol	• Mass storage device profile (read-only)
Transfer Speed (USB-C 3.0)	• Approximately 20 seconds/24 hours
Voice Recording	Up to 40 seconds
Buttons for operation	Two, multi-functional
Screen	Colour OLED 36 x 26.9 mm (1.4 x 1.0 inches) with 160*128 pixels
Memory	4 GB SDHC microSD
Storage	
Type	• microSDHC card, 4 to 32 GB
Typical recording size	• < 350 MB/24 hours with a 250 Hz storing rate and accelerometer enabled.
Acceleration sensor	
Channels	• 3
Sensitivity	• ± 2g to ± 8g
Secondary Power supply (internal battery)	
Vin (supply voltage)	• 1 x 3.7V, 1000 mAh internal rechargeable Lithium Ion battery
Internally occurring voltage	• Maximum 12V, typically 2.7V, < 40V during wireless charging
Charging USB	• Charged via PC to USB-C port of the device. Alternatively, an external USB power supply (5V, 500 mA minimum) can be used.
Charging Time	– 10 to 100% - approximately 3 hours – 10 to 80% - approximately 2 hours – 10 to 60% - approximately 1.5 hours
Charging wirelessly	• Charged via CS-3. Supplied with an external USB power supply (5V, 2A).
Charging Time	– 10 to 80% maximum 4 hours
Battery Life	• > 500 charge/discharge cycles (100%) • The battery must be checked every year. 9.3.1 Internal Li-Ion battery check, page 70

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Primary Power supply (external battery) Vin (supply voltage)	• 1 x 1.5V AAA battery alkaline or lithium, or 1 x 1.2V rechargeable NiMH battery
Operating duration without AAA battery *	• Up to 72 hours (128 kHz sampling rate, 250 Hz storing rate) • Up to 60 hours (128 kHz sampling rate, 2000 Hz storing rate)
Operating duration with AAA battery **	• Up to 98 hours (128 kHz sampling rate, 250 Hz storing rate) • Up to 84 hours (128 kHz sampling rate, 2000 Hz storing rate)
Maximum operation duration ***	> 12 days (repeatedly replacing the AAA battery)
Bluetooth® **module 5.0**	PAN1780
FCC ID	• T7V1780
IC	• nRF52840
Bluetooth® Standards	• 5, supporting high-speed and long-range modes
Output power	• -40 to +8 dBm
Receiving sensitivity	• -103 dBm (125 kbps Bluetooth® LE Mode, -95 dBm (1 Mbps), -92 dBm (2 Mbps)
Hopping frequency	• 2402 to 2480 MHz

Power consumption and operation duration were measured with a Cactus Industrial Grade 4 GB microSD card (KS4GRT-803M). The power consumption varies depending on the microSD card and the selected settings. In addition, the operation duration varies depending on the battery type used. The recorder is operated with a 1.5V AAA battery. The recorder is equipped with a mechanical protective mechanism against the reverse connection of the battery. The permitted supply voltage range Vin of 1.0 to 2.7V permits using 1.2V NiMH rechargeable batteries.

Note:

- If activated, the Bluetooth® module reduces battery life by approximately 10%
- The internal rechargeable Lithium Ion battery capacity decreases over the lifespan (with a maximum of 500 charge cycles of approximately 20%)

* 100% charge of the internal battery (in perfect condition), Cactus 4 GB industrial grade SLC microSD card (KS4GRT-803M).

** 100% charge of the internal battery, AAA battery Panasonic industrial grade, Cactus 4 GB industrial grade SLC microSD card (KS4GRT-803M).

*** 100% charge of the internal battery (in perfect condition), AAA battery Energizer Ultimate Lithium, Cactus 4 GB industrial grade SLC microSD card (KS4GRT-803M).

Note that the Bluetooth® and SpO_2 connectivity features are unavailable in the USA market.

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11.2 Standards

Standards	medilogFD complies with IEC standard 60601-1
Other standards	• IEC 60601-1-11: Requirements for medical devices used in the home healthcare environment • 60601-2-47 Particular requirements for the basic safety and essential performance of ambulatory ECG systems – The recorded ECG signal complies with the standard IEC 60601-2-47. – For the required statements IEC 60601-2-47, section 201.7.9.2.101: f), g), 2), 3) and 4. Refer to the DARWIN2 IFU. • 60601-2-25 for diagnostic bandwidth-related parts
EMC	• IEC 60601-1-2 • CISPR 11 class B The device can be exposed in a professional healthcare facility or home healthcare electromagnetic environment to the following interferences without any impairment: • Static discharges up to 15 kV • Field strength up to 10 V/m in the radio frequency range of (80 to 2700 MHz, 5 Hz modulated) • Magnetic fields of 30 A/m, 50 Hz
Compliance	The device complies with the EU MDR 2017/745, Annex VIII Class IIa.
Conformity	• Hereby, Schiller declares that the radio equipment type medilogFD complies with Directive 2014/53/EU. The full text of the EU Declaration of Conformity is available at the following internet address: https://www.schiller.ch/en/conformity
Lifetime	The medilogFD has a lifetime of 5 years with respect to the Council Regulation EU 2017/745 Annex I, Requirement 6.

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11.3 Ambient Conditions

The recorder, cable, and accessories reach the ambient temperature over time from storage or transport.

Ambient conditions (operation)	
Temperature	• 5 to 45°C/41°F to 113°F (surface temperature must not exceed 43°C/109.4°F).
Humidity, non-condensing	• 10 to 95% relative humidity
Atmospheric pressure	• 700 to 1060 hPa
Ambient conditions for storage and transport	
Temperature	• -25 to 70°C/-13°F to 158°F
Humidity, non-condensing	• 10 to 90% relative humidity
Atmospheric pressure	• 700 to 1060 hPa
Conditions between uses	
Temperature	• -25 to 70°C/-13°F to 158°F
Humidity, non-condensing	• 10 to 90% relative humidity
Atmospheric pressure	• 700 to 1060 hPa
Warmup times	• < 2 hours for Min/Max storage temperature to mean operating temperature

11.4 Recorded ECG Signal

The recorded ECG signal complies with the standard IEC 60601-2-47. For the required statements IEC 60601-2-47, section 201.7.9.2.101: f), g), 2), 3) and 4, consult the analysing software DARWIN2 IFU.

ECG resolution	• Up to 16.5 bit used for SNR improvement up to 27 dB (recording and streaming 12 bit)
Oversampling	Up to 512x
ECG Amplifier	
Dynamic bandwidth	• 12 to 14 mV, typically 13.65 mV
Patient cable	• 10-lead interchangeable, automatic detection of cable type
Analogue bandwidth	• > 1.0 kHz
Lower cut-off frequency	• 0.05 Hz
Channels	• 9
Signal Check	True signal quality check with amplitude indication
HR Calculation	Refer to the DARWIN2 IFU.

	24h mode	48h mode	72h mode	Scientific mode
Sampling rate [Hz]	128000	64000	128000	128000
Storing rate [Hz]	250	250	250	2000
P wave detection resolution	250 µs	500 µs	1000 µs	31.25 µs
R peak/EDR detection resolution	31,25 µs	62,5 µs	125 µs	31.2,5 µs
Pacemaker detection	31,25 µs	62,5 µs	125 µs	31.2,5 µs

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11.5 CS-3 Wireless Charging Station (option)

Type name	CS-3
Dimensions and weight	
Height/Width//Depth	• 34 x 107 x 69 mm
Weight	• 140 g, including USB cable 1.0 m
Power supply	5 VDC via PC USB or power adaptor minimum 2 A (10 W)
Connection	USB-C
Operating frequency	103 kHz
Operating temperature	10 to 40 °C
Ambient humidity	30 to 75%
Atmospheric pressure	700 to 1060 hPa
Storage/Transport	• 5 to 50 °C /-10 to 50 °C • 500 to 1060 hPa • 10 to 95% rel. humidity
Ingress Protection	IP20 for indoor use only
Safety standard	IEC 60601-1
EMC	IEC 60601-1-2 The device can be exposed in a professional healthcare facility or home healthcare electromagnetic environment to the following interferences without any impairment: • Static discharges up to 15 kV • Field strength up to 10 V/m in the frequency range of 80 to 6000 MHz • Magnetic fields 80 A/m, 50/60 Hz • Proximity magnetic fields not closer than 50 mm to any part of this device including cables. – 30 kHz - 8 A/m, 134.2 Khz - 65 A/m, 13.56 Mhz - 7.5 A/m
Lifetime	The CS-3 has a lifetime of 5 years with respect to the Council Regulation EU 2017/745 Annex I, Requirement 6.

11.6 Power Supply (option)

USB power supply for internal battery charge.

Type	• MEAN WELL GSM12E05-USB (Medical Adaptor)
Output	• USB socket type A • 5 V • 2.4 A
Input	• 100 to 240 VAC, 0.4 to 0.2A, 50/60 Hz
Ambient conditions (operation)	
Temperature	• 0 to 40 °C/32 °F to 104 °F
Humidity, non-condensing	• 0 to 95% RH non-condensing
Ambient conditions (storage)	• -20 to 85°C/-4°F to 185°F, 0 to 95%, RH non-condensing
Protection class	• For indoor use only.

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11.7 PC Specification

Type	• Windows-based PC
64-bit OS	• Windows 10 or higher
I/O	• Minimum 1 x USB socket
Bluetooth® **(optional feature)**	• 5.0

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11.8 Preventing Electromagnetic Interferences

Non-ionising electromagnetic radiation

The user can help avoid electromagnetic disturbances by keeping the minimum distance between portable and mobile HF telecommunication devices (transmitters) and the recorder. The distance depends on the output performance of the communication device, as indicated below. The recorder is designed to meet the IEC60601-1-2 requirements.

HF source Wireless communications devices	Transmitter frequency [MHz]	Testing frequency [MHz]	Maximum power P [W]	Distance d [m]
Various radio services (TETRA 400)	380-390	385	1.8	0.3
– Walkie-talkies (FRS) – Rescue service, police, fire brigade, servicing (GMRS)	430-470	450	2	0.3
LTE band 13/17	704-787	710/745/780	0.2	0.3
– GSM800/900 – LTE band 5 – Radiotelephone (microcellular) CT1+, CT2, CT3	800-960	810/870/930	2	0.3
– GSM1800/1900 – DECT (radio telephone) – LTE Band 1/3/4/25 – UMTS	1700-1990	1720/1845/ 1970	2	0.3
– Bluetooth®, WLAN 802.11b/g/n – LTE Band 7 – RFID 2450 (active and passive transponders and reading devices)	2400-2570	2450	2	0.3
WLAN 802.11a/n	5100-5800	5240/5500/ 5785	0.2	0.3

⚠ WARNING

- ▲ Portable HF telecommunication devices must not be used within a radius of 0.3 meters from the recorder and its cables.
- ▲ Do not place the recorder on top of other electric/electronic devices, i.e. maintain a sufficient distance from other devices (this includes the patient cables).

For permanent high-frequency telecommunication devices (e. g. radio and TV), the minimum distance can be calculated as follows:

$$d = 0.6 \times \sqrt{P}$$

where:
d = minimum distance in meters
P = transmitted power in Watts

The formula is based on the max. immunity level of 10 V/m in the frequency domain of 80 MHz to 3000 MHz.

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11.8.1 Measures to prevent electromagnetic interferences

The user can take the following measures to solve this problem:

- During use/recording, the user should avoid being near any high electromagnetic radiation for prolonged periods (hours), for example, at a train station or power plant.
- Increase distance to the source of interference.
- Immediately replace defective cables, especially patient cables, with defective sheathing.
- Make sure the patient cable is securely applied
- Observe the maintenance intervals as defined.
  9 Maintenance, page 69

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12 Patient Information

12.1 Inform the Patient or Caregiver

- Pay attention to the intended purpose, especially observe contraindications.
- Inform the patient or caregiver about the use of the recorder and instruct the patient or caregiver about all the following points:

⚠ WARNING

- ▲ Do not open the recorder or take out the memory card.
- ▲ Do not use the recorder when the housing or cables are damaged, e.g. cracks, torn cables, insulation damage, exposed wires or melted plastics. In such cases, do not use/remove the equipment from the patient.
- ▲ The device is not waterproof and unsuitable for use while taking a shower or a bath.
- ▲ Always avoid contact with liquids.
- ▲ When using the medilogFD recorder during sleep, note that this can cause sleep disturbances and a lack of concentration the following day.

Danger of Strangulation

- ▲ The neck belt or electrode cable can become entangled around the patient's neck, leading to strangulation. The danger increases at night. Ensure the patient is aware of the danger.
- ▲ Cable (e.g. patient cable) must not be worn outside the outerwear/clothing.
- ▲ Be careful while moving around; turning or rotating the body or moving parts cables (e.g. patient cable) could become trapped in door handles and armrests.
- ▲ If the patient is a child, a frail or disabled adult, or not fully competent, the recorder must be worn only under the supervision of a caregiver who oversees the operation tasks and continuously monitors the recording.

⚠ CAUTION

- ▲ Keep the recorder away from direct sunlight or heat sources to prevent overheating.

i

- ▲ Do not remove the recorder from its carrying case
- ▲ Do not disconnect the patient cable
- ▲ Do not use the recorder in extreme conditions, e.g. in very high or low temperatures, very high or low humidity, 3000 meters (9842 feet) above sea level.
- ▲ To prevent the device from malfunctioning, keep a sufficient distance (at least 30 cm / 12 inches) to other electrical / electronic devices (eg Smart Phone) and other electromagnetic sources (eg working at train station, electrical power plant, steel production, MRI)
- ▲ If the connection of the electrode wire and skin electrode becomes detached:
  - Try to reconnect it.
  - Make a note in your patient diary or register a patient event by pressing any front panel button on the recorder.
  - When returning to your physician, inform the physician that the electrode was detached and reconnected.

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- If the patient cable connector detaches from the recorder device or the cable is torn, inform your physician.
- The patient cable and connector must not be strained, pulled, kinked or torn. Be careful not to pinch the cable in a door when closing it.
- The best time to attach the SpO_2 sensor is before going to sleep. The best place to mount the SpO_2 sensor is on the wrist. Switching the sensor on is unnecessary; you must only place a finger in the probe.
- When to register a patient event, e.g. waking up, going to bed, feeling dizzy, palpitations, or medication intake.
- The triple clap feature allows patients to register events by clapping on the recorder 3 times within 1 to 2 seconds.Ways to register a patient event:
  - Press any recorder front panel button
  - Lightly clap on the device 3 times while counting one, two, three.
  - Make a written note in your patient diary along with the time shown on the recorder. Press any recorder front panel button to turn on the screen to view the time.
  - The recorder should not be turned off; the recorder stops automatically at the end of the recording.

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14 Appendix - Symbols

This appendix lists all general symbols that may be present on the device, label and accessories. Not all of those symbols are necessarily present on your device.

This appendix has its own article number, which is independent of the user guide's article number.

	Identification of the manufacturer
	Identification of the manufacturing date
	Identification of the distributor
	Identification of the importer
MD	Medical device
SN	Serial number
REF	Reference number
LOT	Batch code
GTIN	Global Trade Item Number
CAT	Catalogue number
QTY	Quantity
UDI	UDI: unique device identification as QR code machine readable and human readable as number (e.g. (01) 0 7613365 00210 2 (21)xxxx.xxxxxx)
	Number of pieces in the packaging
EC REP	Authorised European representative
CE XXXX	Notified body (e.g. CE 0123 marking notified body TÜV SÜD)

	UKCA marking (UK Conformity Assessed)
	CE marking, affirms its conformity with European standards
	NRTL symbol (Nationally Recognised Testing Laboratory) TÜV SÜD as accredited NRTL certification provider
	Regulatory Compliance Mark for the Australian standards
	The device is recyclable
	Symbol for the recognition of electrical and electronic equipment. Device must not be disposed of in the household waste.
	Symbol for the recognition of a battery. Battery must not be disposed of in the household waste.
	The packaging is made in low density polyethylene and can be recycled.
	Federal law (USA) restricts this device to sale by or on the order of a physician
	Non ionising electromagnetic radiation. To indicate that the device contains a Radio Frequency (RF) transmitter to transmit data (e.g Bluetooth or WiFi)
	Contains a Bluetooth module
	Do not reuse
	Latex-free
	Use-by date (expiry date of battery, electrodes or other consumables)
	Temperature range for storage or transport, respectively
	Pressure range for storage or transport, respectively
	Humidity range for storage or transport, respectively

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	Consult instruction for use (indicates the need for the user to consult the instructions for use)
	Use within X days after opening (electrodes or other consumables)
	Keep dry (store in a dry location)
	Keep away from sunlight (protect from direct sunlight)
	Fragile, handle with care
	Transport upwards (this way up)
	Do not use hooks
	EIP = electronic information product (does not contain any toxic and hazardous substances or elements above the maximum concentration values (product can be recycled and re-used)).

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medilogFD

The 12-lead Holter ECG for a spatial heart health analysis

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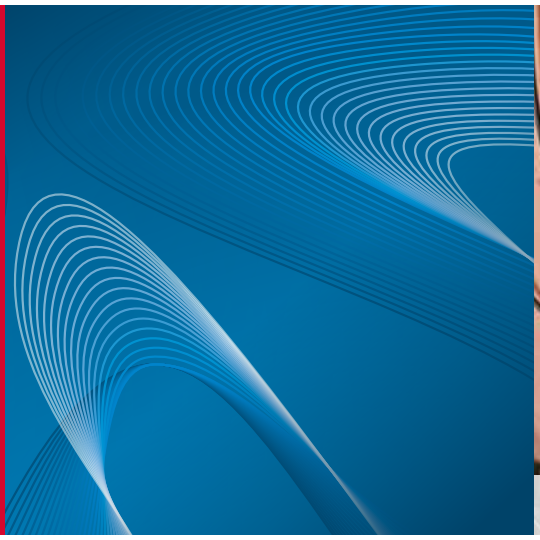
medilogFD

The Holter recorder that complements your medilog portfolio:

- 12-lead Holter ECG allows assessing the full spectrum of cardiac ECG conditions
- Instantaneous atrial fibrillation/atrial flutter detection based on true P-wave analysis
- Optional SpO_2 sensor for additional respiratory information



Easy-to-clean carrying case

12-LEAD HOLTER ECG FOR A SPATIAL ANALYSIS

The 12-lead Holter ECG is preferred for detailed and spatial heart analysis. Physicians, cardiologists, and electrophysiologists find great value in industry-leading technology:

- Regional assessment of myocardial ischemia. Distinguish anterior, septal, lateral, inferior region in the dynamic setting of everyday life.
- Identify the origin of ectopic beats, whether they are from the left or right ventricle.

Superior in identifying abnormal heartbeats that start in the right or left atrium.

MADE TO SUPPRESS ARTIFACTS

The medilogFD Holter recorder features a superior resting ECG-grade 128,000Hz sampling rate on 12 leads. This is used for real-time P-wave analysis, sophisticated artifact suppression, and motion detection, enabling a speedy evaluation.

HOLISTIC APPROACH

Instantaneous detection of atrial fibrillation onset, analysis of respiratory episodes, and high-resolution HRV are just some of the exceptional features of the medilogFD.

DUAL-BATTERY CONCEPT

The high-quality internal battery is recharged via USB or wirelessly on an optional charging station. Moreover, easily available standard AAA batteries can be used. This allows patients to be screened for up to five days on a single charge.

COMPLETES THE MEDILOG PORTFOLIO

medilogFD completes your medilog line-up with medilogAR (3-lead Holter ECG, up to 14 days runtime) and medilog DARWIN2 (high-end ECG analysis software).

High-contrast colour display for easy operation. Live ECG preview: 3 channels shown at a time, all 12 can be scrolled through

Multifactor signal check based on:

- Impedance
- Amplitude
- Amount of noise

Microphone to record patient ID. In an anonymous start, a voice recording is a must to prevent patient mix-up.

Shock-proof thanks to its robust design

Large and easy-to-operate buttons

Eco-friendly: runs on an internal recharge-able battery, or, if needed, on normal AAA batteries for fast turnaround times

Visible and tactile position markers for easy patient cable connection

Data exchange via USB with robust state-of-the-art USB-C connector

Removeable patient cable with 10 wires, tested for more than 4000 connection cycles

Wireless SpO_2 sensor, attached for the night

SCREEN FOR RESPIRATION EPISODES

Thanks to ECG-derived respiration recording (EDR), the medilogFD can screen for potential respiratory episodes during sleep. The optional SpO_2 sensor, connected via Blue-tooth, allows for additional respira-tory information.

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SCHILLER reserves the right to make changes in design, specifications and features shown, or discontinue the product described at any time without notice or obligation. Images may be representative. The illustration of patient cables and screen contents show the system using an IEC cable. Depending on your region, the unit is supplied with an AHA patient cable. Some products may not be regulatory cleared or released for sale in all markets. Contact your SCHILLER representative for the most current information and availability.

DESIGNED AND MANUFACTURED IN SWITZERLAND

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The Art of Diagnostics

Technical Data

medilogFD Holter recorder

medilogFD

Device
Dimensions: 101 x 70 x 19 mm
Weight: approx. 125 g without AAA battery
Protection against ingress of water: IP22
Keyboard: 2 Buttons for operation and patient event marking
USB connector: USB-C for charging or data transfer

Electrical data
Power: – 1 x AAA 1.5 V single use or 1.2 V NiMH rechargeable battery – 1 x Li-Ion 3.7 V 1000 mAh (internal battery)
Charging current: USB max. 400 mA; wireless max 325mA
Charging voltage: 5 V min 500mA (via PC-USB or USB power supply)
Charging time: 10 to 80 %: approx. 2 h with USB; 3 h wireless.

Interface Bluetooth®
Type: Low Energy 5.0
Receiving range: 5 m
Supported profiles: PLX for SpO2 sensor, battery service, device information service, heart rate and proprietary streaming
Safety: White list management bonding to ensure data transfer to the correct address with man-in-the-middle protection

Interface USB-C
Protocol: Mass storage device
Transfer speed: approx. 20 seconds for a 24 h recording

Display
OLED color
Resolution: 160 x 128 px
Dimension: 33.6 x 26.9 mm
Signal check: True signal quality with lead off detection

Storage micro SD card (SDHC)
Capacity: 4GB (up to 32 GB supported)
Typical recording size: 350MB/24 hours

Recording duration[1]
Recording duration only internal / + with AAA battery inserted – 24 h mode > 72 h / +26 h – 48 h mode > 96 h / +34 h – 72 h mode > 120 h / +42 h – Scientific mode > 60 h / +24 h
Maximum operation duration: 12 days (repeatedly replacing the AAA battery)

Voice recording
1 x 40 s (for patient identification)

Accelerometer
For recording patient movements and optionally for marking patient events using clap detection if enabled
Axes: 3
Range: ±2 g
Recording frequency: 25 - 100 Hz

ECG

ECG amplifier
Physical ECG channels: 9 (I,II,III, and V1...V6)
ECG resolution: Up to 16.5 bit used for SNR improvement up to 27 dB (recording and streaming 12 bit)
Sampling rate: 32000 up to 128000 Hz (mode depending)
Oversampling: max. 512x
Recording/streaming rate: 250 Hz
Recording/streaming rate scientific mode: 2000 Hz
Lower filter frequency: 0.05 Hz
Digital bandwidth at 250Hz clinical mode: >55Hz
Digital bandwidth at 2000Hz scientific mode: >150Hz
Analogue bandwidth: >1.0 kHz
Dynamic bandwidth: 12 - 14 mV, typically 13.65 mV
Resolution real time analysis R peak: up to 31.25 µs
Resolution real time analysis P peak: up to 250 µs
Resolution real time analysis pacemaker: up to 31.25 µs
ECG derived respiration signal recording

Patient Cable IEC and AHA
Leads: 10
Length: 0.80 m
Connectors: Snap
Automatic cable type detection
Lead off detection and true signal check with quality indication during hook-up

Software

Software
medilogDARWIN2 version 2.11.2 or higher

Environmental Conditions

Operation
Temperature: 5 to 45 °C
Humidity: 10 to 95 % non-condensing
Pressure: 700 to 1060 hPa

Transport and storage
Temperature: –25 to 70 °C
Humidity: 10 to 90 % non-condensing
Pressure: 700 to 1060 hPa

Charging Station

CS-3
Wireless charging device compatible with the medilogFD
Power: 5 VDC via PC-USB or USB power adaptor min. 10 Watt
Connection: USB-C

Standards

Classification
Safety and performance standard: Conforms with IEC/EN 60601-1-11, IEC/EN 60601-2-47 and 60601-2-25 for the diagnostic bandwidth related parts.
Protection class according 60601-1: internally powered
Applied Part according 60601-1: BF
Compliance: The device complies with the EU MDR 2017/745, Annex VIII Class IIa.
Electromagnetic radiation: CISPR 11, class B
Notified body: CE 0123

1) Recording duration may vary depending on the battery or SD card used.

Technical datasheet for Part no.: 2.500876 10/24, EN

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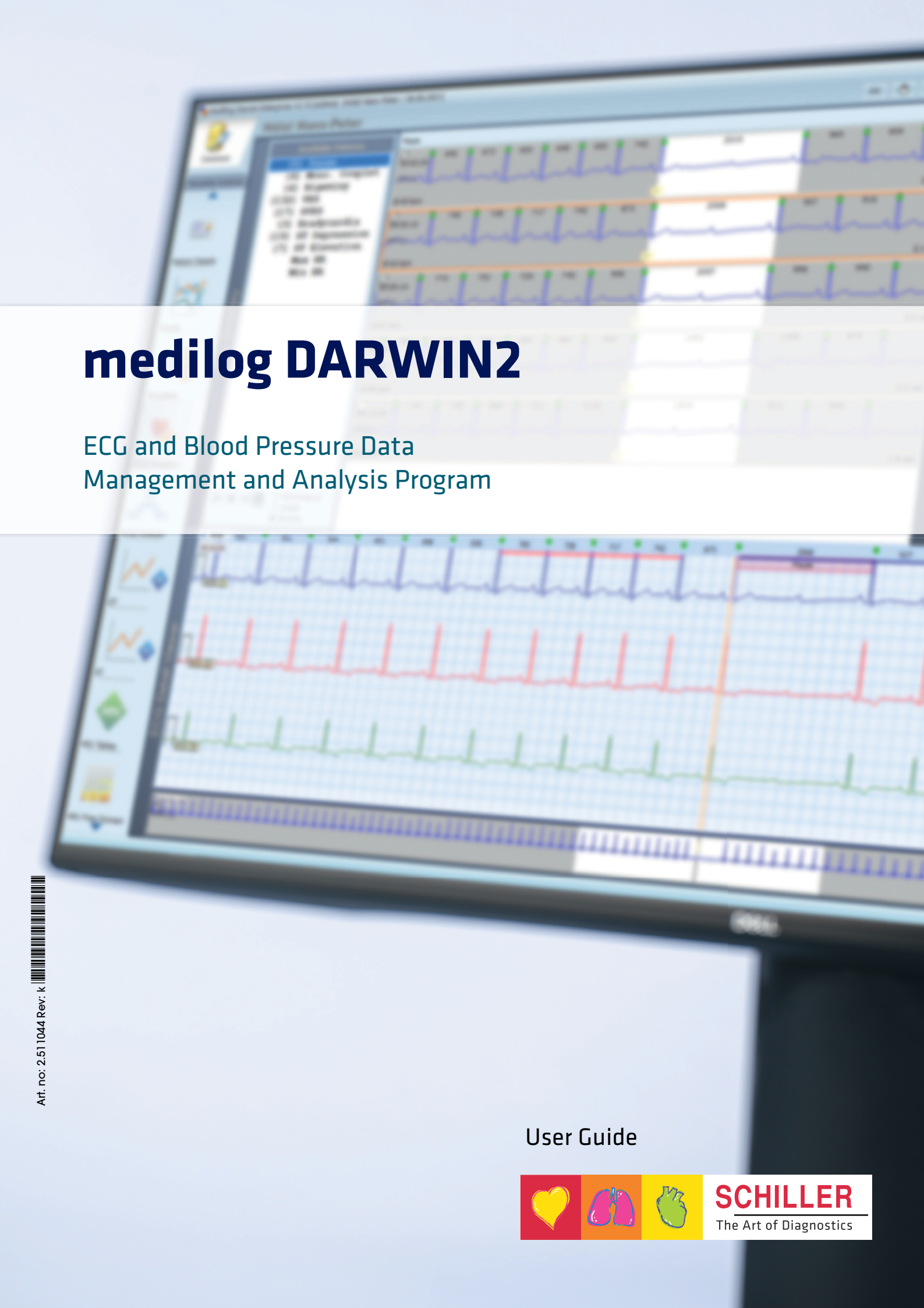

medilog DARWIN2

ECG and Blood Pressure Data Management and Analysis Program

Art. no: 2.511044 Rev: k

User Guide

SCHILLER
The Art of Diagnostics

Sales and Service Information

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

www.schiller.ch

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

Address Headquarters

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E-mail: sales@schiller.ch
Web:www.schiller.ch

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

EC REP

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

CE 0123

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

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

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SCHILLER
The Art of Diagnostics

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1 Safety Notes

1.1 Intended Purpose

medilog DARWIN2

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

The **medilog DARWIN2** software functions include:

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

1.2 Limitations and Restrictions

The software is NOT intended to be used:

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

1.3 Indications

1.3.1 Indications for a long-term continuous ambulatory Holter ECG

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

Holter is a diagnostic tool used in the following applications:

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

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- Long QT syndrome

and for:

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

1.3.2 Indications for an ambulatory blood pressure monitoring

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

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

1.3.3 Indications for a Pulse wave analysis

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

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

1.3.4 Indications for a SpO_2 analysis

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

1.4 Intended Users

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

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1.5 Patient Target Group

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

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

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

1.6 Context of Use

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

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

1.7 Responsibility of the User

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

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1.8 Organisational Measures

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

1.9 Networks and Internet

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

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1.10 Safety Symbols and Pictograms

1.10.1 Symbols used in this document

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

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

For general safety notes as listed in this chapter.

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

Reference to other guidelines

1.10.2 Symbols used on the label

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

Consulting the user guide is mandatory before using the program.

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2 Introduction

2.1 What is medilog DARWIN2

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

Holter ECG recordings

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

Long-term BP measurements (ABPM)

- Pulse wave analysis

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

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

2.1.1 medilog DARWIN2 versions

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

medilog DARWIN2 Basic

The free Basic version includes the following features:

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

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medilog DARWIN2 Office

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

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

medilog DARWIN2 Professional

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

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

medilog DARWIN2 Enterprise

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

- EDR analysis
- SpO_2 values
- medilog Liberty Scanlab software

2.1.2 Overview of recording formats

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

SCHILLER medilog Holter recorders

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

SCHILLER blood pressure recorders

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

SCHILLER Holter ECG recorders

- SCHILLER MT-101

DARWIN exported data

- Recordings from the DARWIN program (.daw files)

MIT recordings

- Refer to physionet.org

Miscellaneous

- ER900

2.1.3 medilog Liberty Scanlab

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

2.1.4 Method for HR calculation

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

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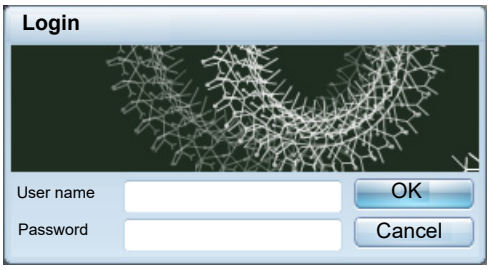
3 medilog DARWIN2 Program Overview

3.1 Login

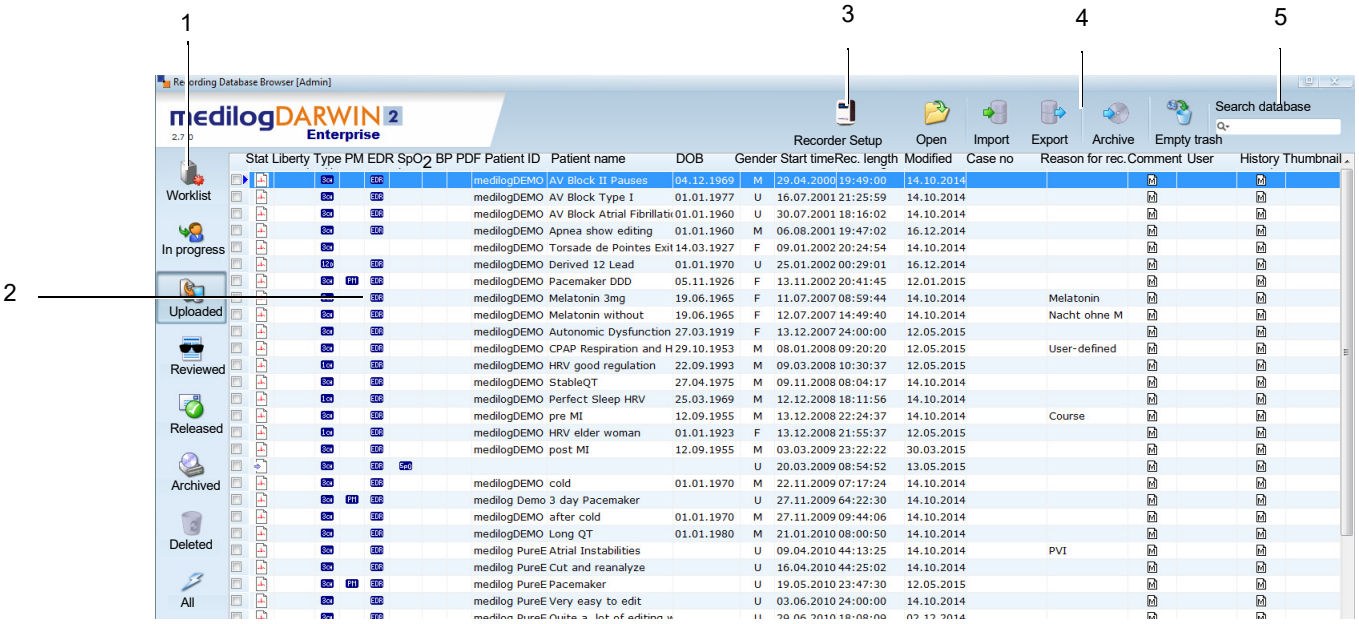
Double-click on the Program icon and enter the user name and password to log in:



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

3.2 Database Screen

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



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

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

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

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

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

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3.3 Starting a Recording

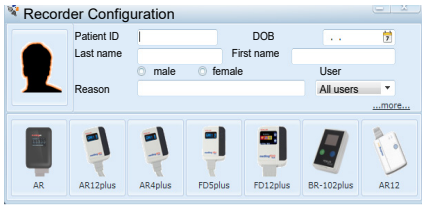
There are three possibilities for starting a recording:

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

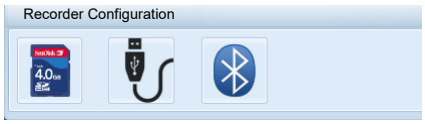
Below, only initiation via the **medilog DARWIN2** is described. For information on how to start a recording from the recorder, refer to the recorder's user guide.

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

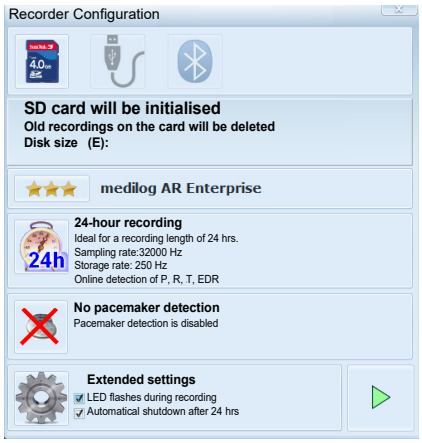
3.3.1 Configuration of medilog AR recorders



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



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



Configuration with a memory card

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

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

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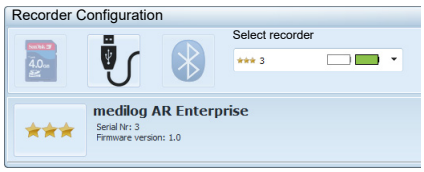


Configuration via USB

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

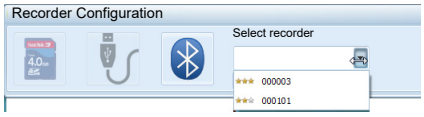
Click the Star icon to start the configuration of the selected recorder.

Click on the recorder name to perform the settings:

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

Configuration via Bluetooth

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



Select the recorder from the drop-down list.

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

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

Perform the settings:

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

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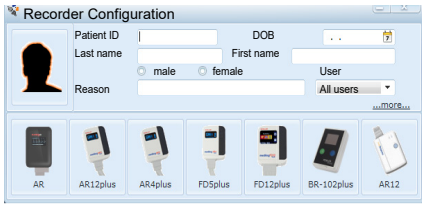
During a recording, checking the live ECG via Bluetooth connection is possible by opening the Recorder setup and double-clicking on the recorder in the list.

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

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

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

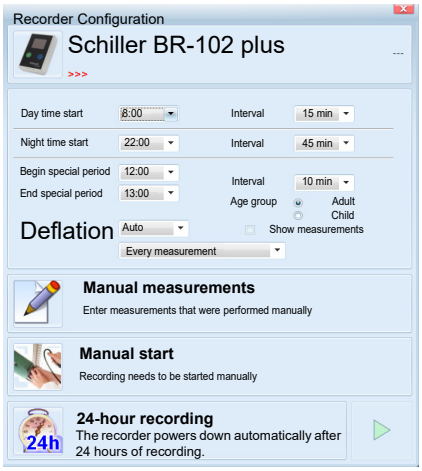
3.3.2 Configuration of BR-102 plus recorders (ABPM)



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

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

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



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

The following settings can be made:

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

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

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

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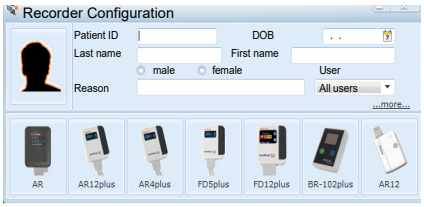
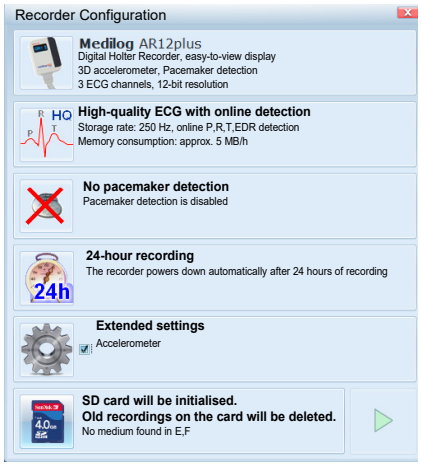
3.3.3 Configuration of all other recorders



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



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

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

Configuration via a memory card

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

Configuration via Bluetooth

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

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

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

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3.4 Receiving a Recording

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

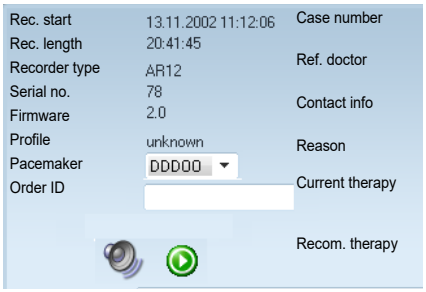
Usually, recordings are received by reading the recorder's memory card on the PC; however, some recorders offer the possibility to directly connect the recorder to the PC (for example, via a USB cable) to download the data (BR-102 plus, medilog AR).

3.4.1 Receiving a recording via a memory card

1. Insert the memory card into the PC.

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

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



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

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

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

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

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

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

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

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

3.5 medilog Liberty Scanlab Integration

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

3.5.1 Uploader

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

The procedure for the uploader is as follows:

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

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

3.5.2 Analyst (editor)

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

The procedure for the analyst is as follows:

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

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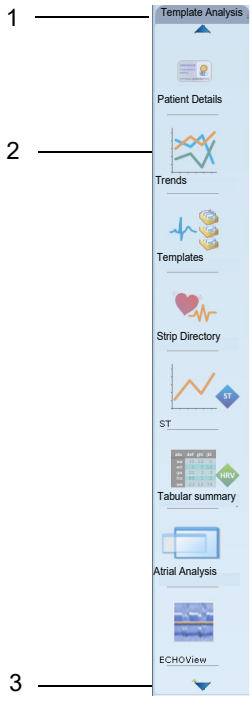
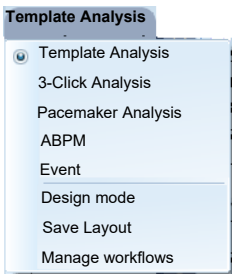
3.6 Controls

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

3.6.1 General workflow



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



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

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

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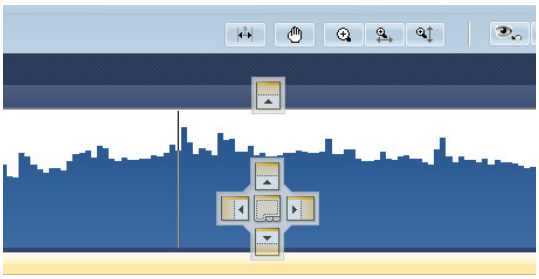
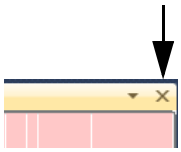
3.6.2 Workflow settings

Design mode

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



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



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

Save layout

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

Manage workflows

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

Icon modules

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

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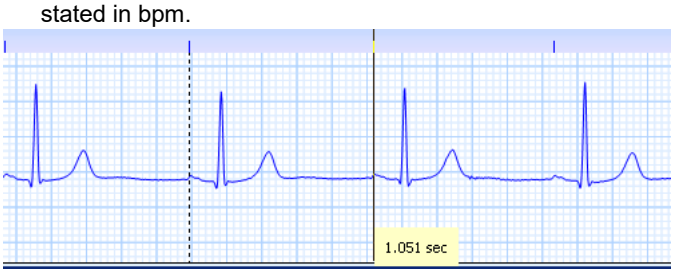
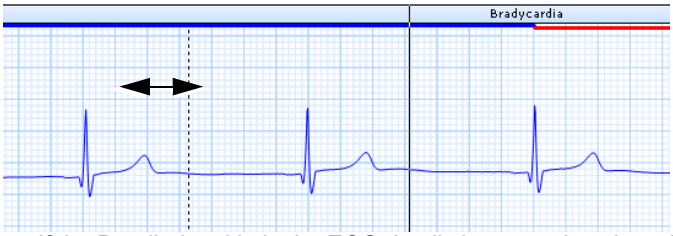
3.6.3 Toolbar

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

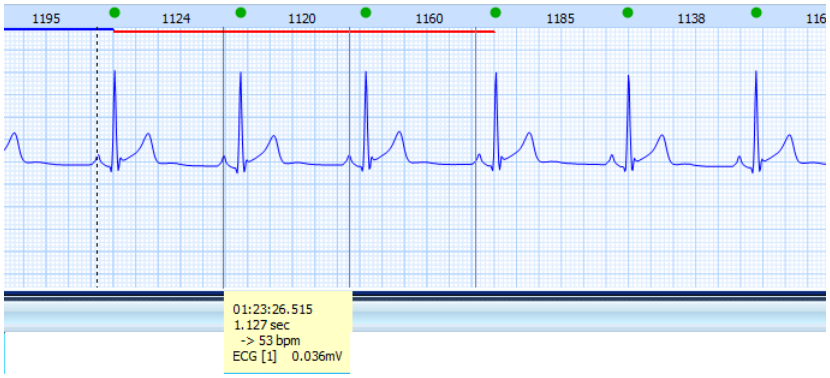
(1) **Measure tool:** Select this tool to measure distances in the ECG detail viewer (refer to HRV, page 56) and any other modules. To do so, click on the start point of the measurement and drag the mouse to the end point. A dashed line indicates the start of the measurement and the end point by a solid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



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



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



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

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

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

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

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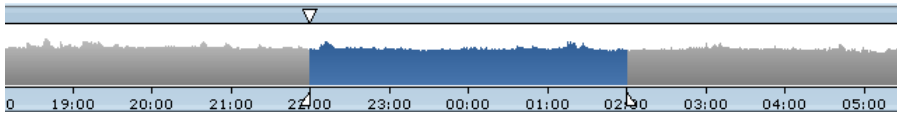
the segment with the mouse to zoom. This feature is only available in some modules, such as ECG detail and signal viewer.

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

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

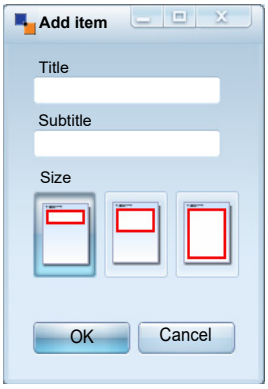


Click the Show entire recording icon in the toolbar to display the entire recording.

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

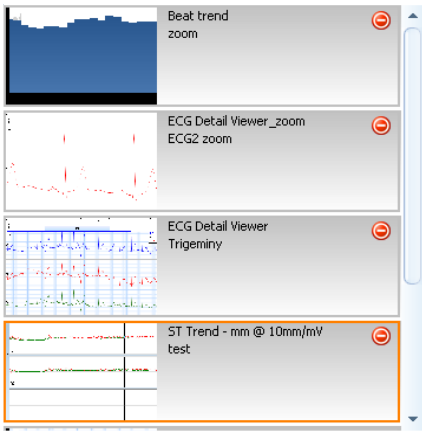
(6) **Undo/Redo:** Use these icons to undo/redo an editing action.

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



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

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



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

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

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

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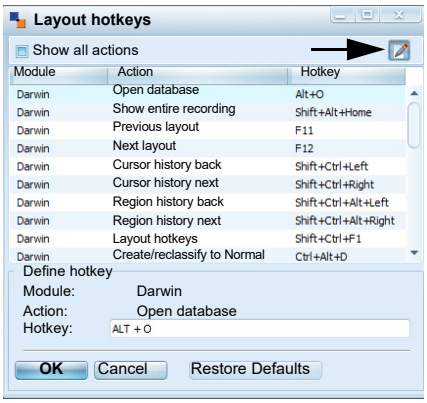
3.6.4 Selection tools

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

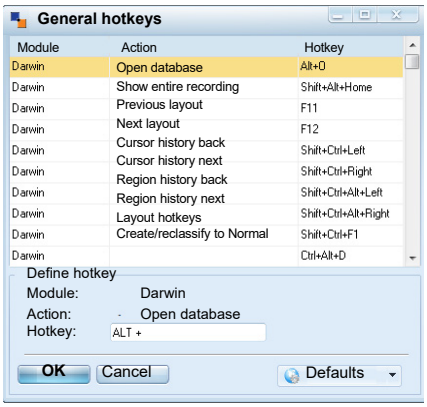
- Press and hold the Ctrl key and simultaneously mark the segment with the mouse; the segment is highlighted and selected. A menu has several options: exclude channel, set arrhythmia type, delete pacemaker spikes, etc. The menu options depend on the module.
- In the ECG detail viewer, set a marker by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

3.6.5 Shortcuts



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

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



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

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

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

3.7 Log Off

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

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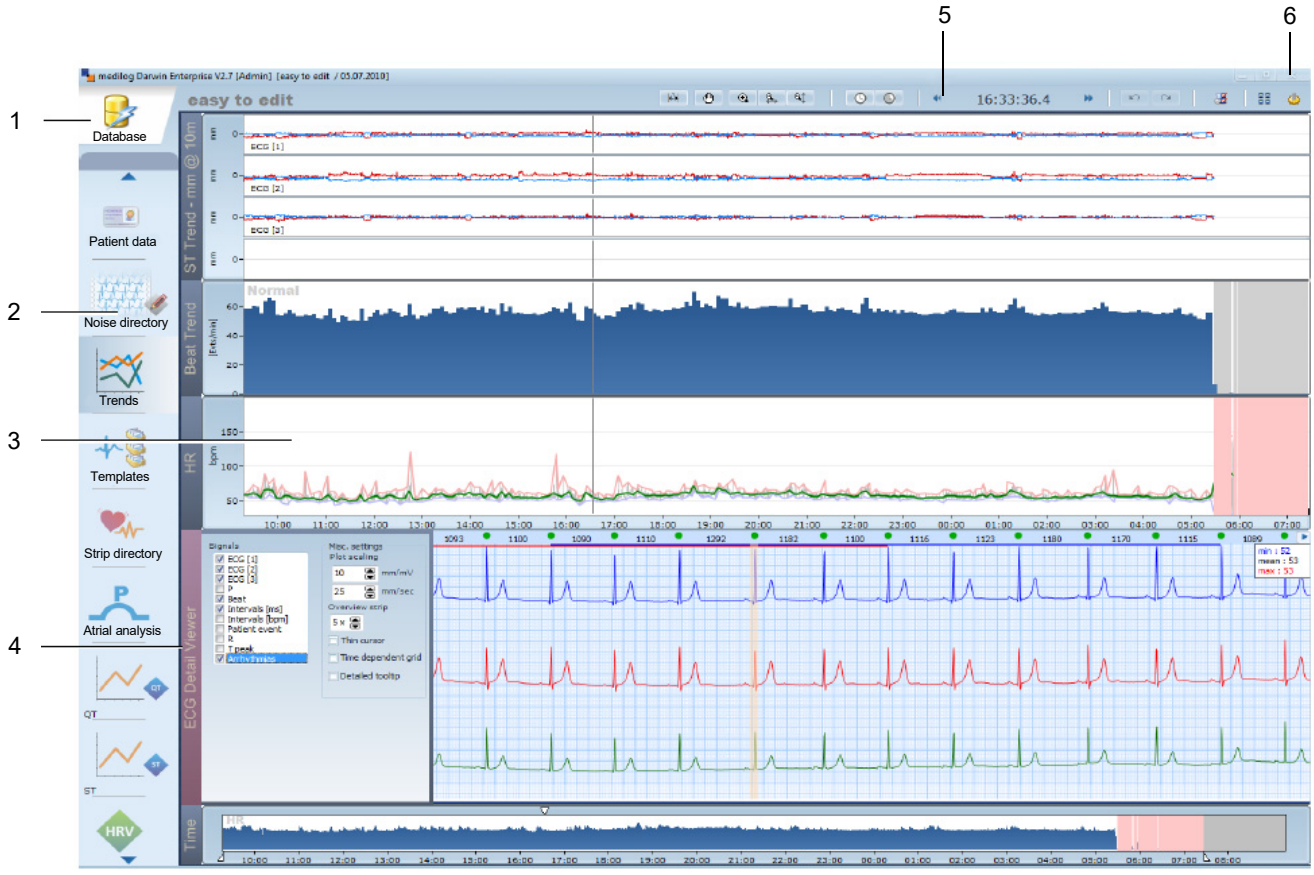
4 ECG Analysis

4.1 Example Screen

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



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

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

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

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

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

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

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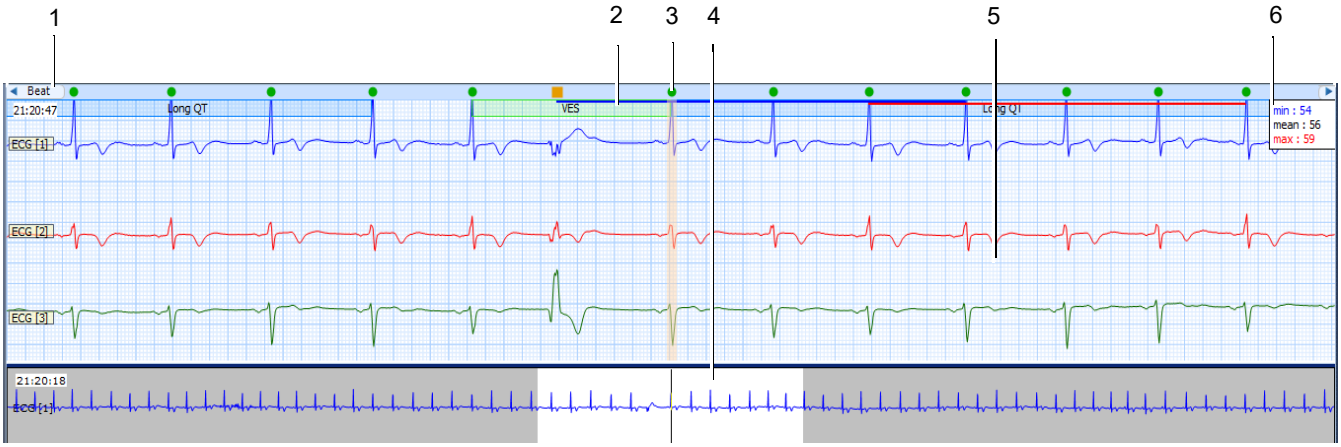
4.2 Modules

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

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

4.2.1 ECG Detail viewer

This module shows the ECG curves in detail.



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

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

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

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

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

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

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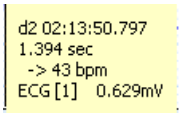
Settings

Perform the following settings:

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



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

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

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Right-click menu options

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

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

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

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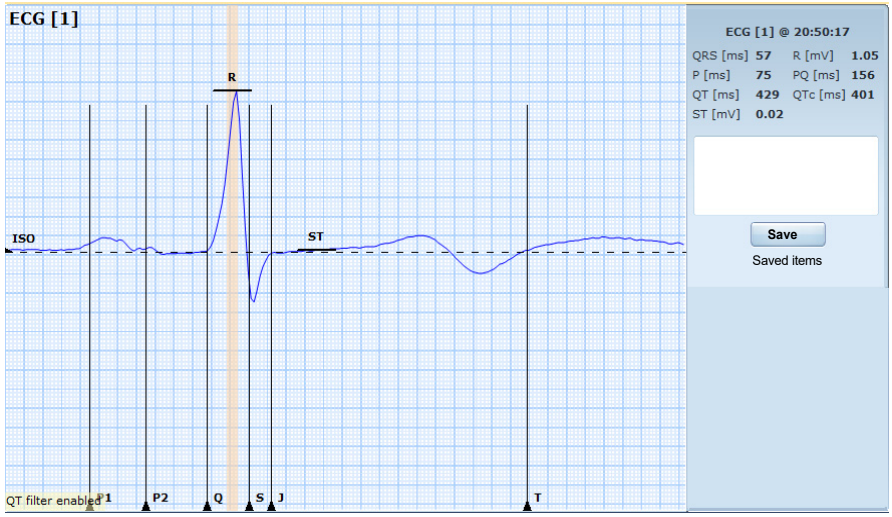
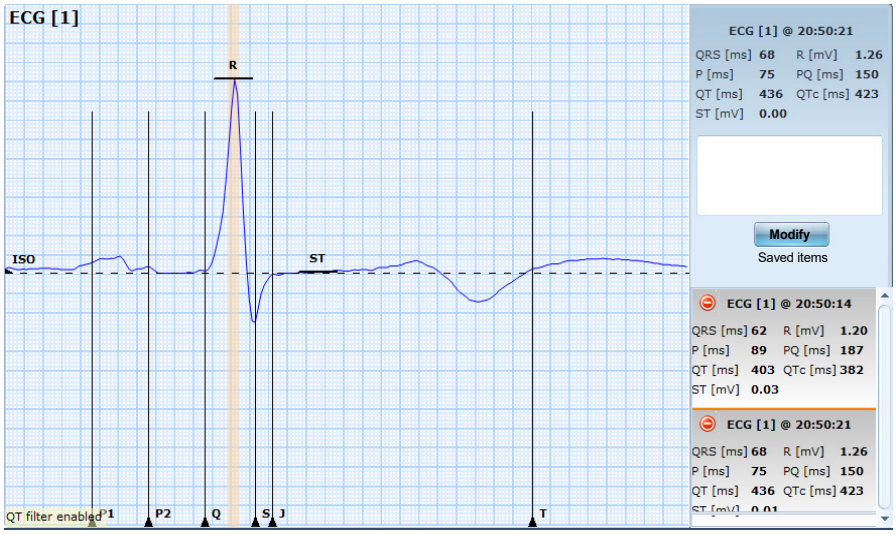
4.2.2 Beat meter

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



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



Settings

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

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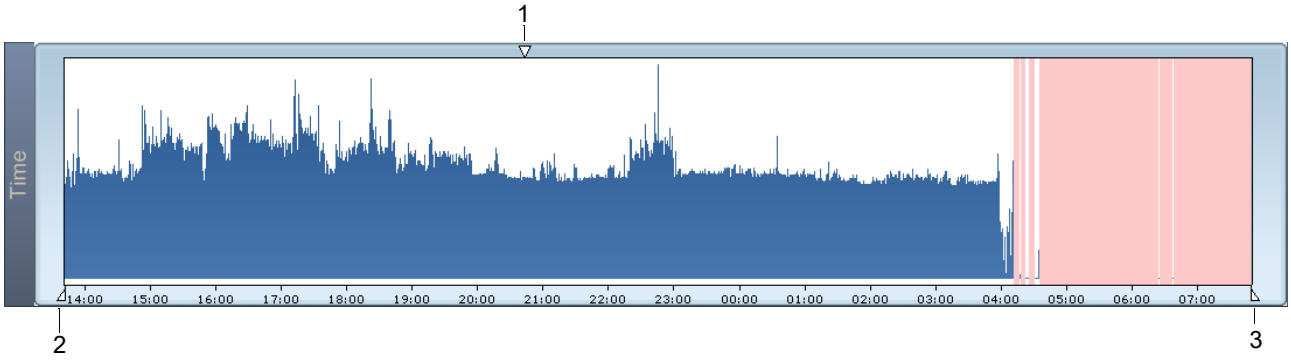
4.2.3 Time navigator



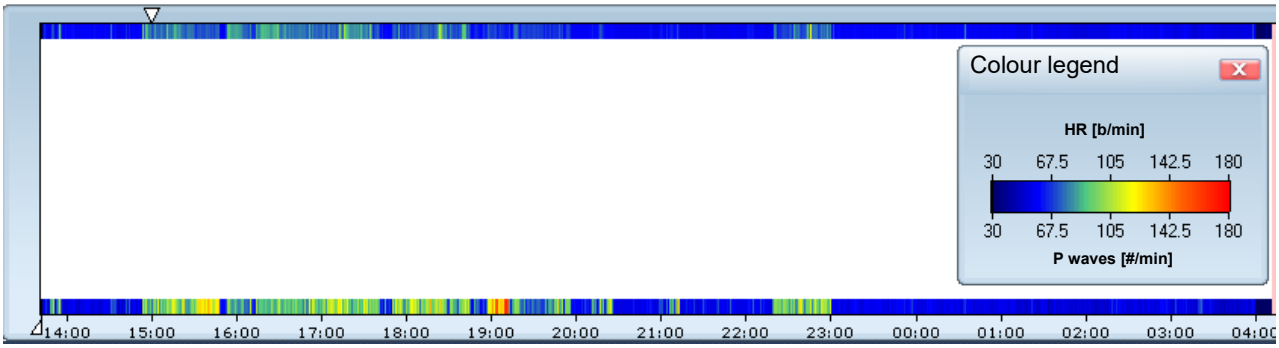
The time navigator provides an overview of the recording and shows either HR, P waves or PM events (this is defined in the settings and depends on the recorder used).
Excluded sections are displayed in light pink (see the example above, right-hand side).
The Arrow icon at the top indicates the current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

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

The right-click menu has the following menu options:

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

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



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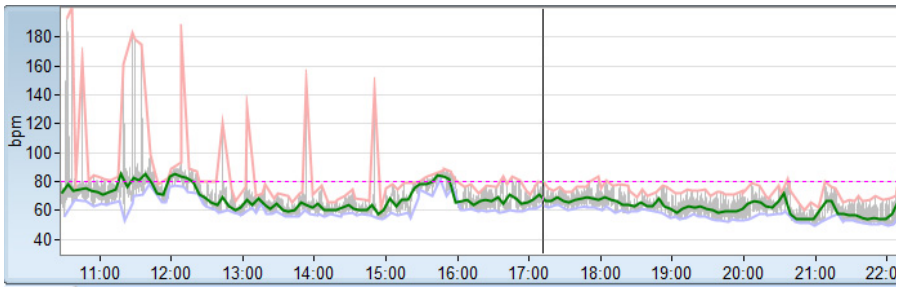
4.2.4 Range viewer

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



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

Settings

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

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

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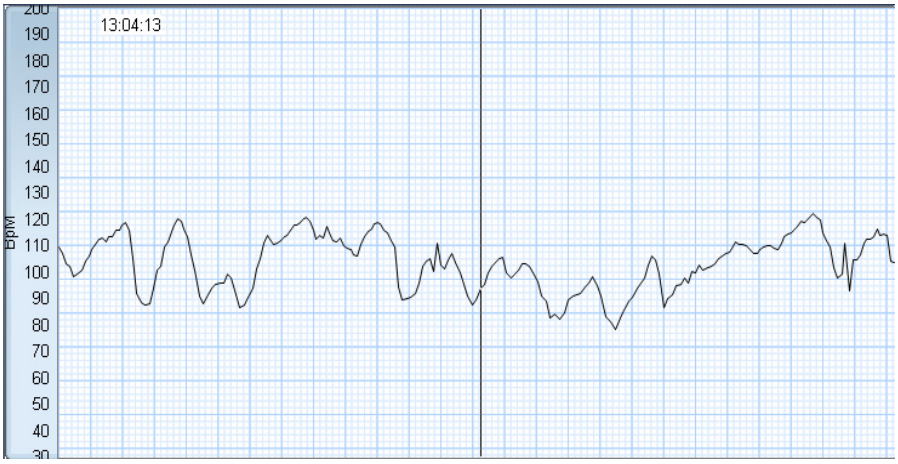
4.2.5 Signal viewer

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



Settings

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

Note that these settings vary depending on the selected signal.

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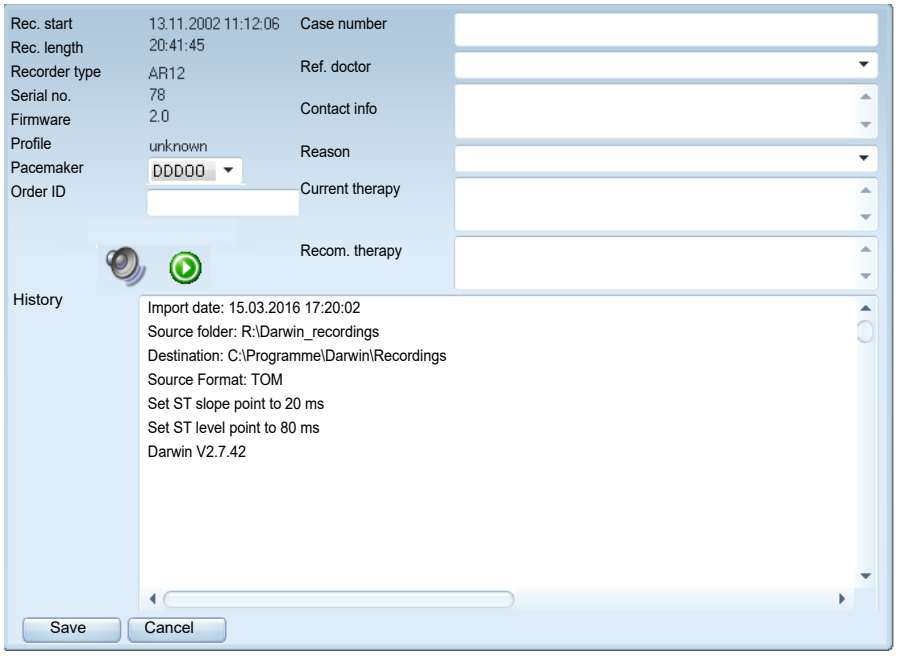
4.2.6 Recording information



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

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

⚠ CAUTION

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

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

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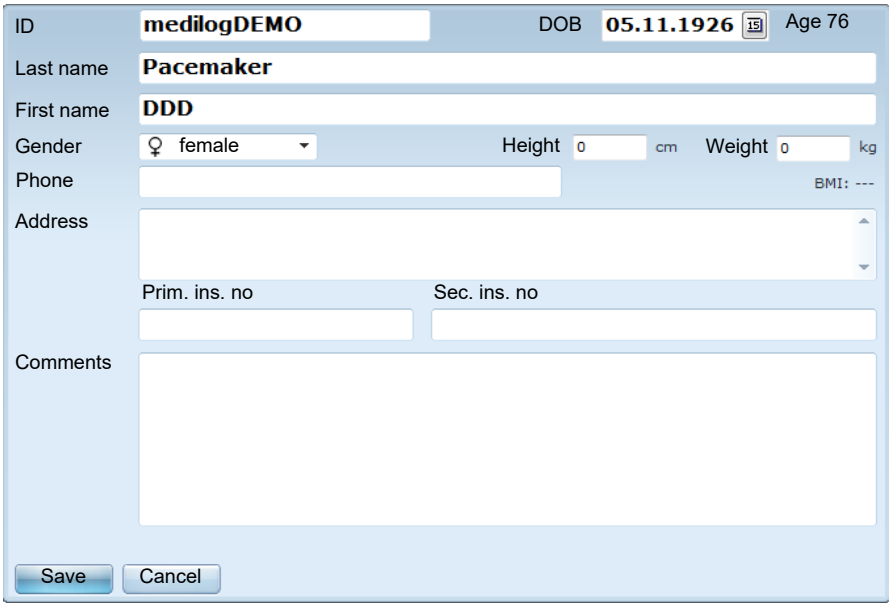
4.2.7 Patient data

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



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

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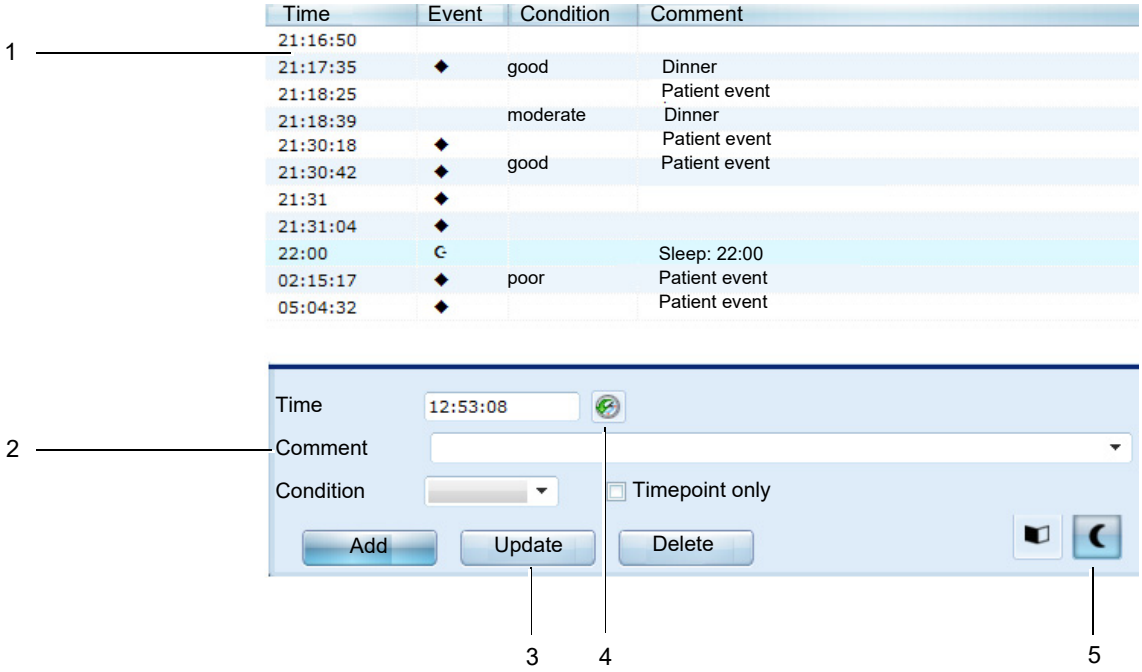
4.2.8 Patient diary

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

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



(1) List of all diary entries.

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

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

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

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

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

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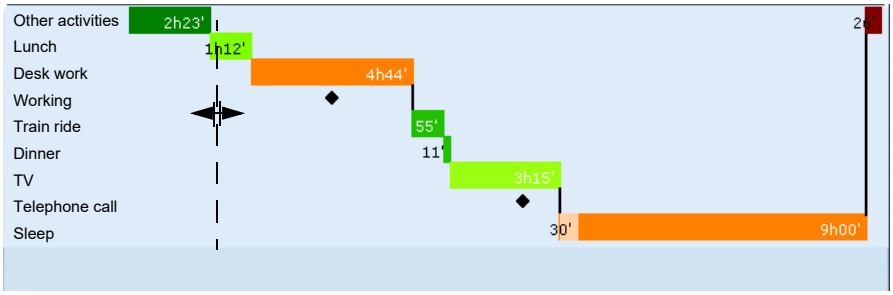
4.2.9 Patient diary graph

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



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

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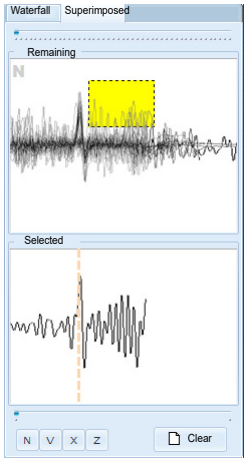
4.2.10 Template editor

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

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

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



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

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

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

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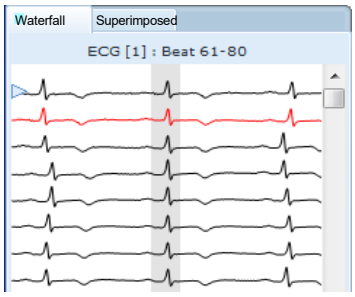
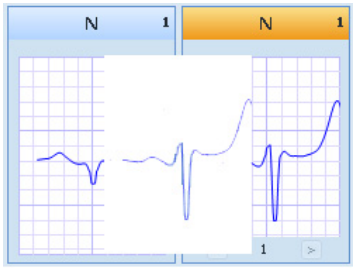


Waterfall: all beats are displayed below each other, showing one second before and after the complex.
Highlighted beats are marked red, press Ctrl or Shift to highlight several beats simultaneously. Use the scroll bar or the mouse wheel to scroll through the beats. This way, you can quickly check that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

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



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

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

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

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

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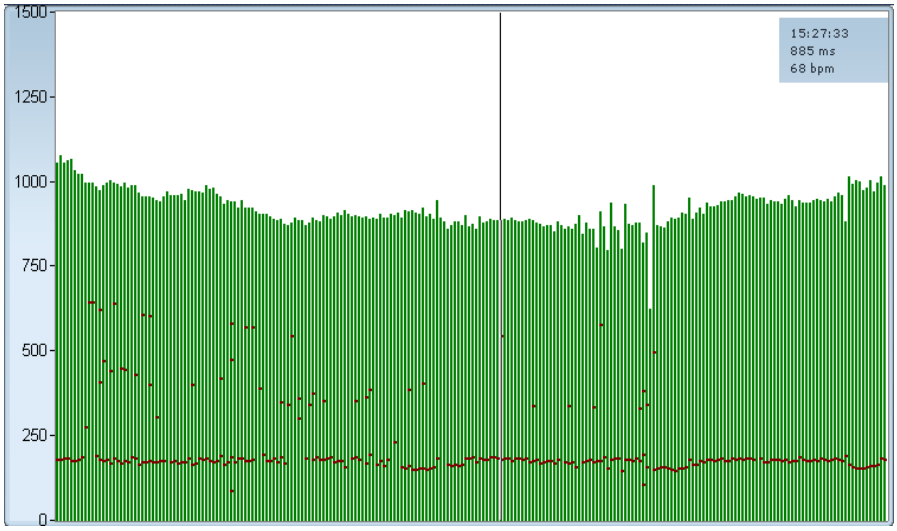
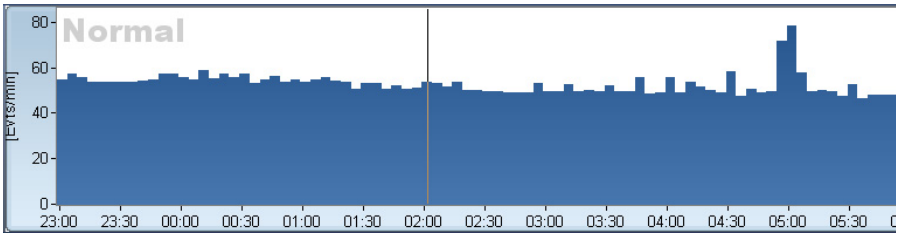
4.2.11 Tachogram

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



4.2.12 Beat trend

This module provides an overview of different beat trends:



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

Settings

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

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4.2.13 Strip directory

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

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

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

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

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

Settings

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

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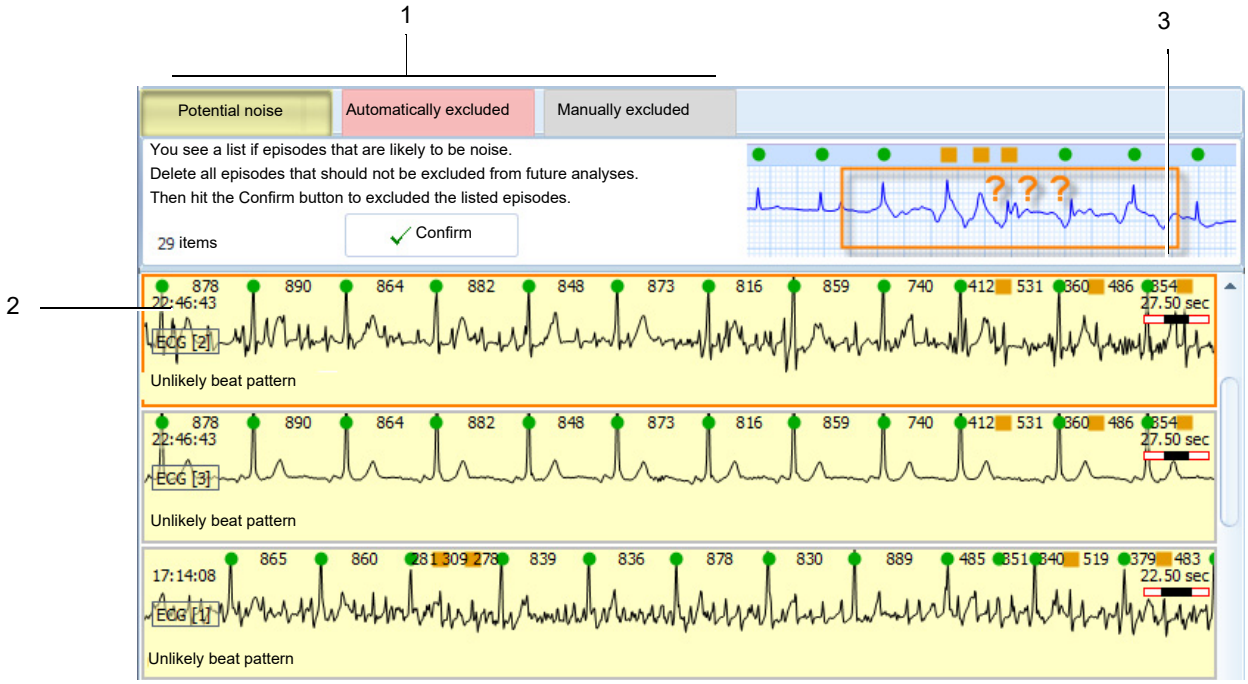
4.2.14 Noise directory

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

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



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

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

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

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

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Potential noise

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

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

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

Automatically excluded

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

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

Manually excluded

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

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

Settings

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

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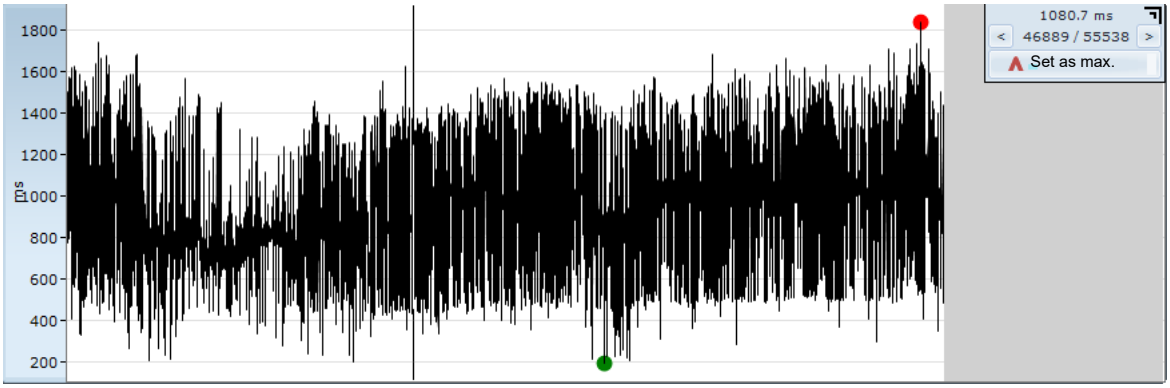
4.2.15 Minimum and maximum scanner

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



In the fold-out menu, you can select:

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

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

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

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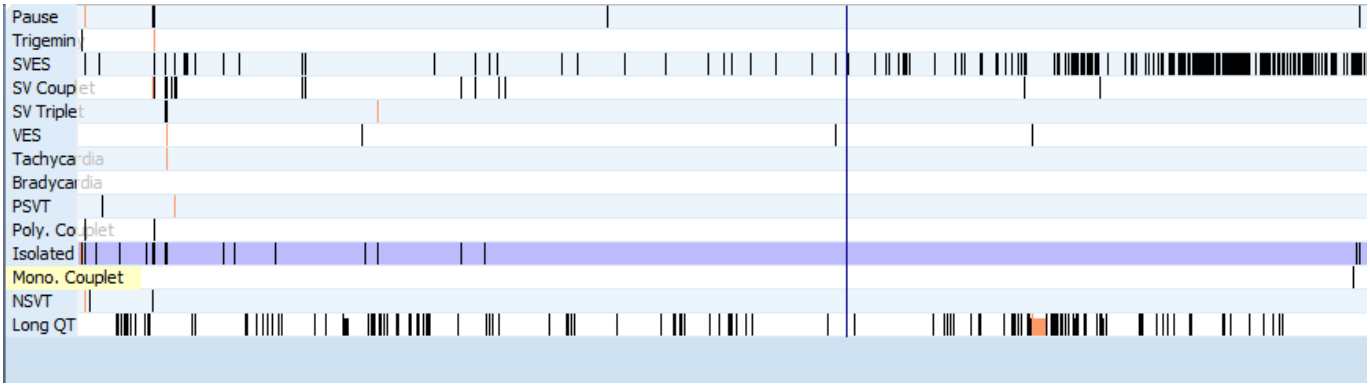
4.2.16 Arrhythmia trends

This module provides an overview of all arrhythmia events.



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

Settings

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

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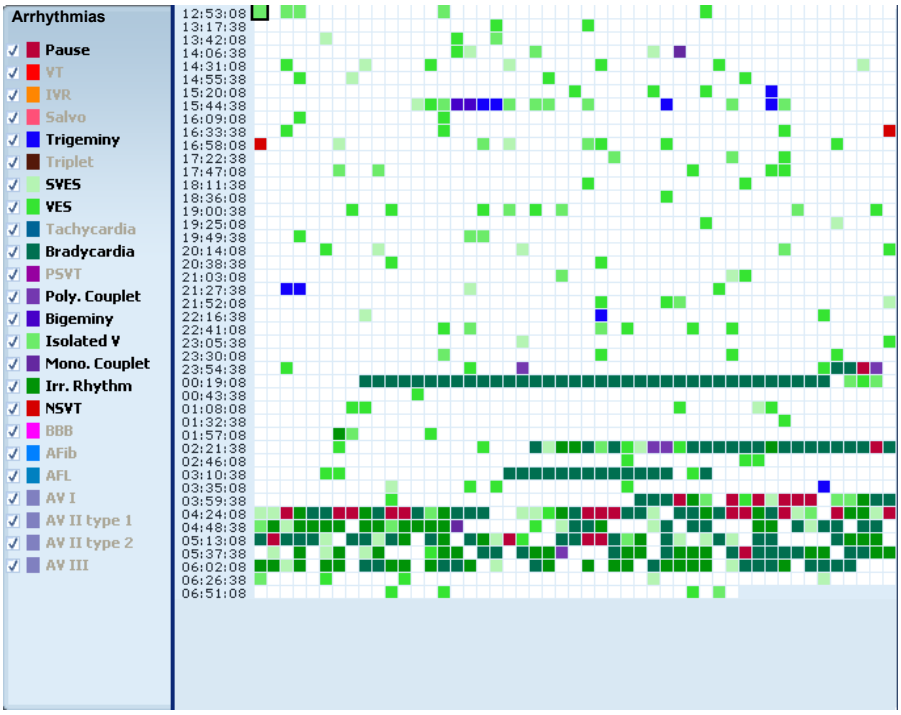
4.2.17 Arrhythmia overview

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



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

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

Settings

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

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

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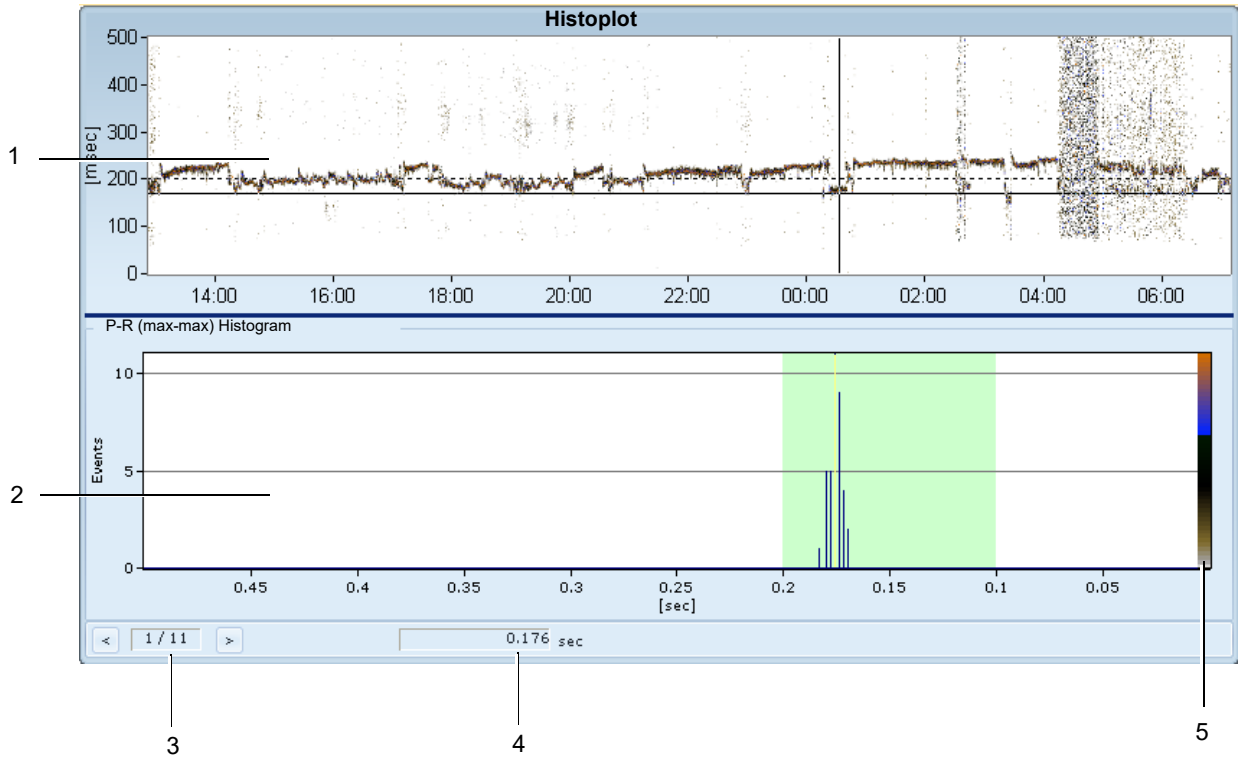
4.2.18 Atrial analysis

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



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

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

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

(4) The interval duration is given in seconds.

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

Settings

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

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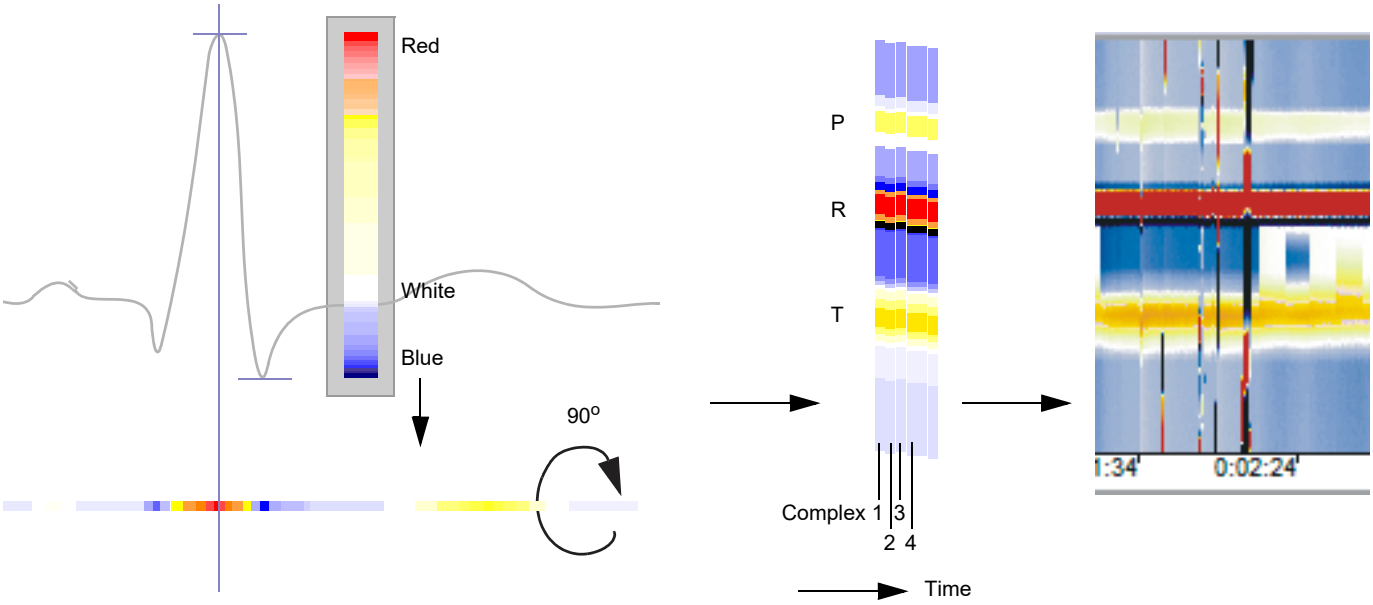
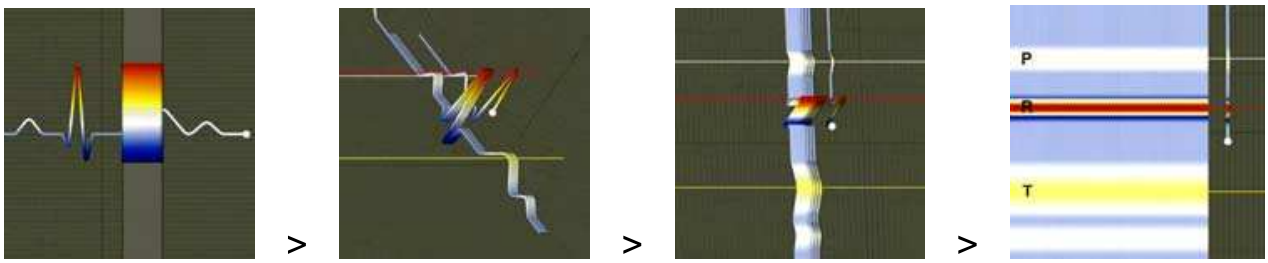
4.2.19 ECHOView

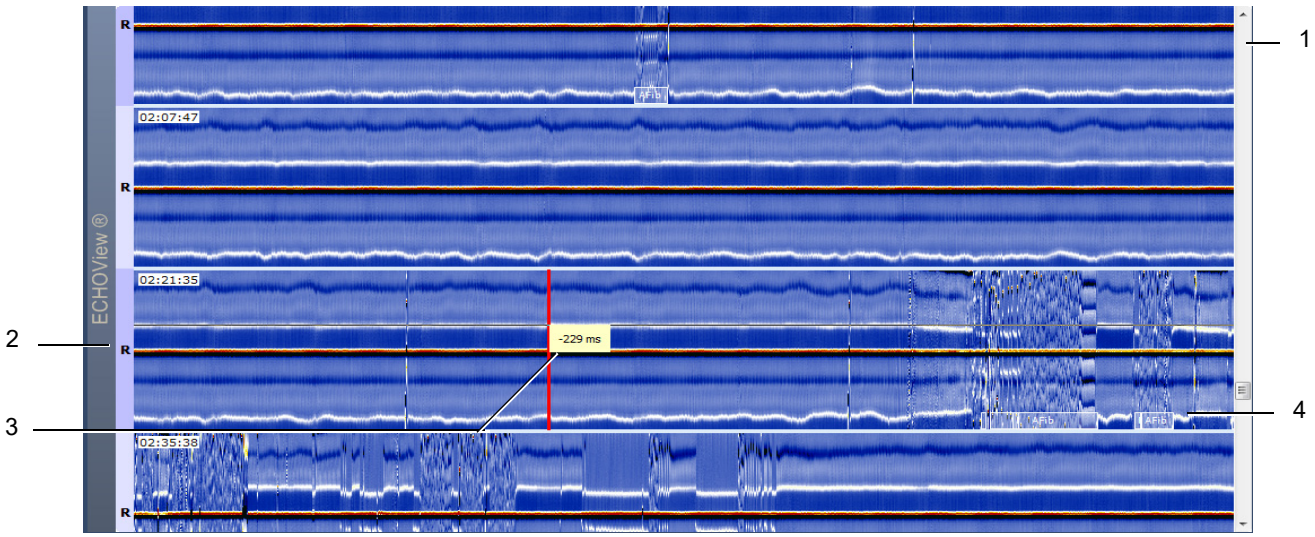
The ECHOView module provides an instant display of ECG changes during the recording. The program converts the QRS complexes to colour. It transforms the ECG data so that the user can summarise the ECG data and easily identify changes in QT intervals, PR intervals, arrhythmias and ST segments. This means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

Method and analysis

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







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

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

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

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

Settings

Access the settings and set the following:

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

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

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4.2.20 Tabular summary

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

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

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

Settings

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

Method for determining a pause

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

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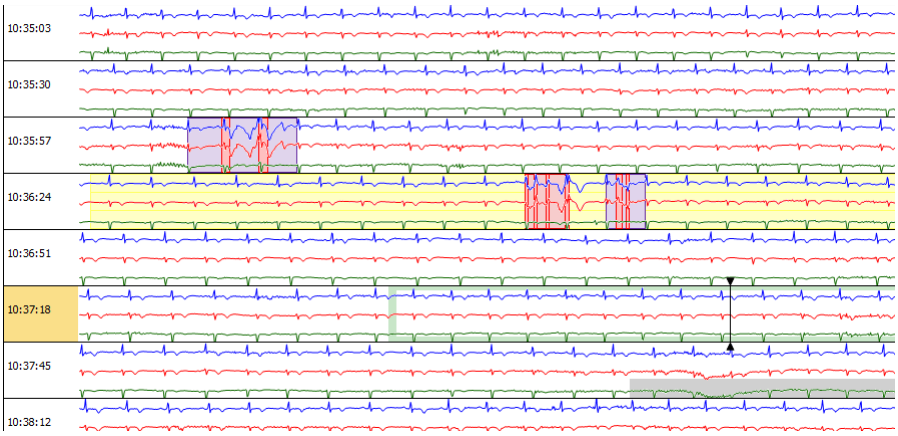
4.2.21 Full disclosure

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



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

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

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

Settings

Open the settings menu to select the following:

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

4.2.22 Print queue

Refer to (7) Print queue, page 25.

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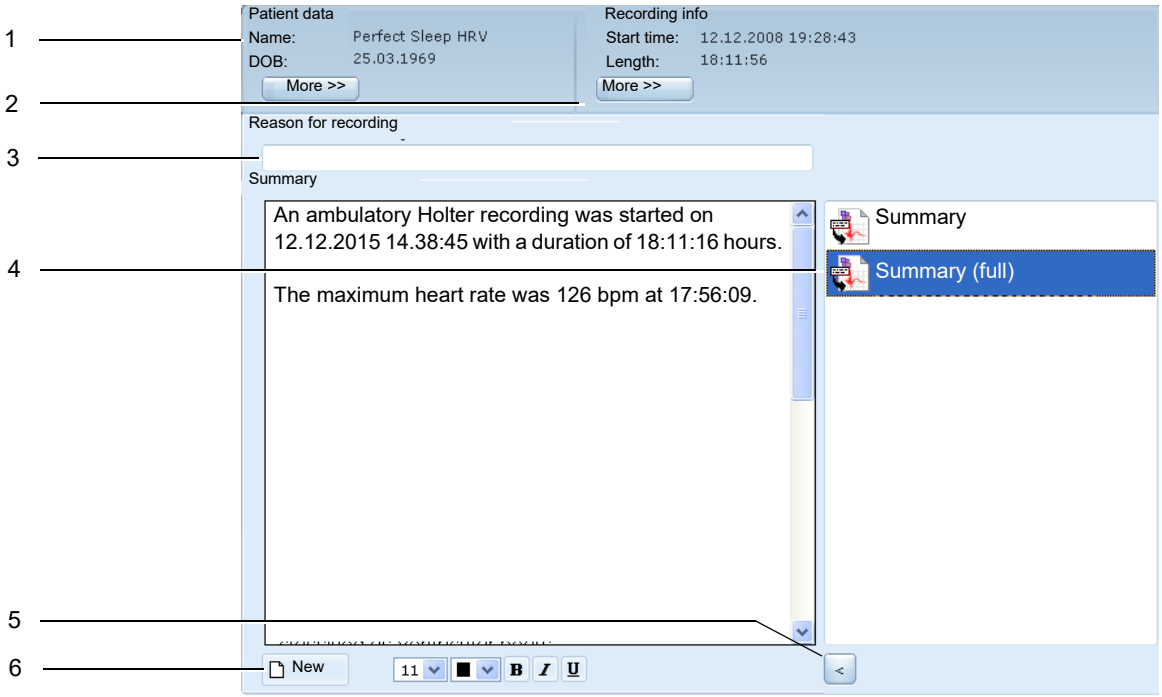
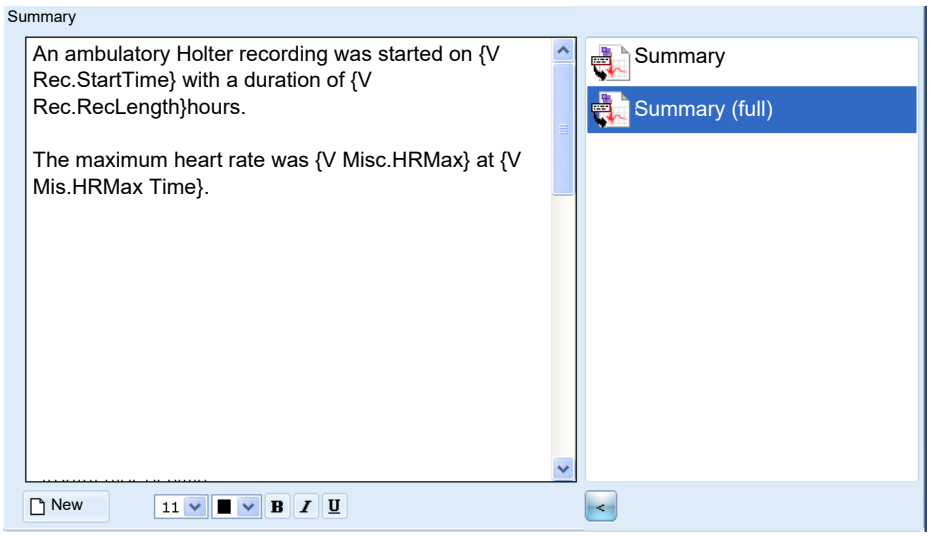
4.2.23 Narrative summary

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



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

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

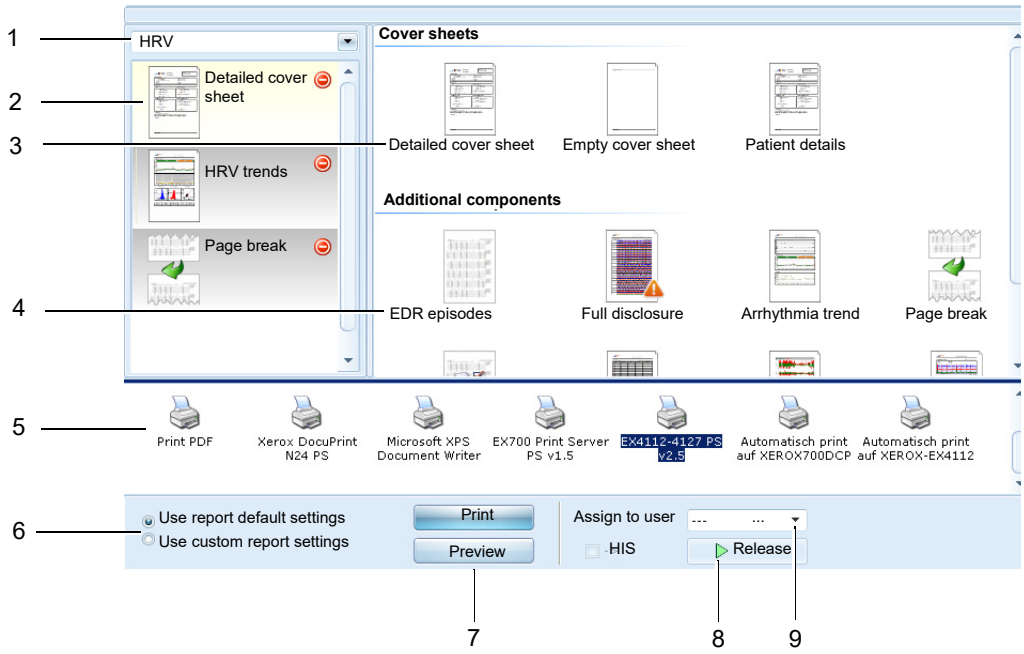


You can then edit the text and select the variables required. In this example, only variables concerning HR have been used.

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

4.2.24 Print reports

This module is used to compose reports for a recording:



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

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

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

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

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Choose a Cover sheet before selecting Additional components.

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

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

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

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.

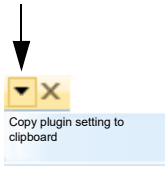
(9) **Assign** the recording to another user.

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}¤



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

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4.2.25 HRV

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

The autonomic nervous system consists of two parts:

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

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

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

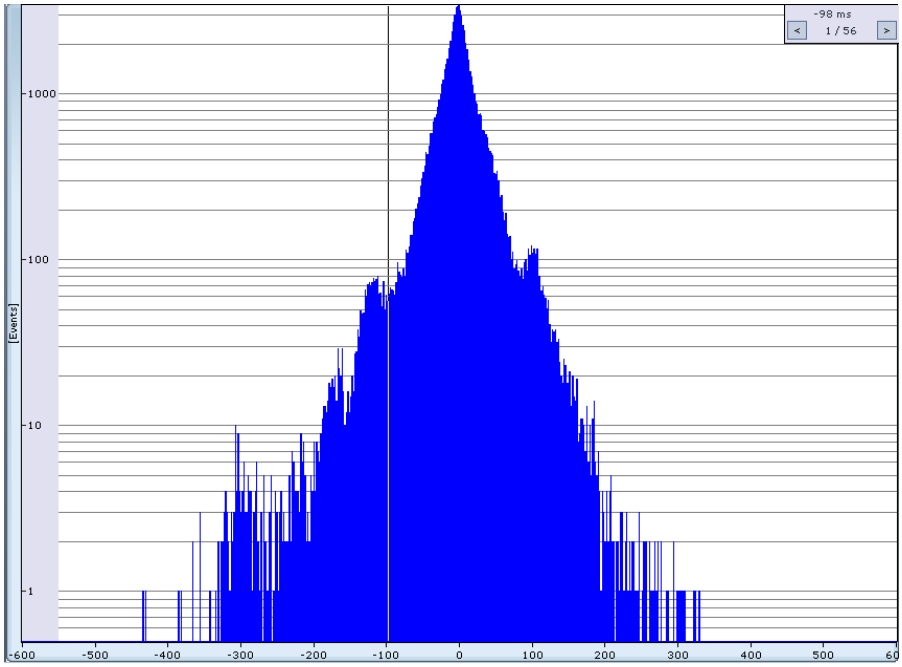
Decreased autonomic regulation is generally a sign of bad health. Using HRV analysis, it is also possible to validate the selected therapy. An increasing HRV (increasing autonomic regulation) shows that a therapy is effective.

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

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

HRV Differential histogram

This histogram shows the RR interval differences:



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

The smaller the blue area, the smaller the HRV.

Settings

Open this menu to perform the following settings:

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

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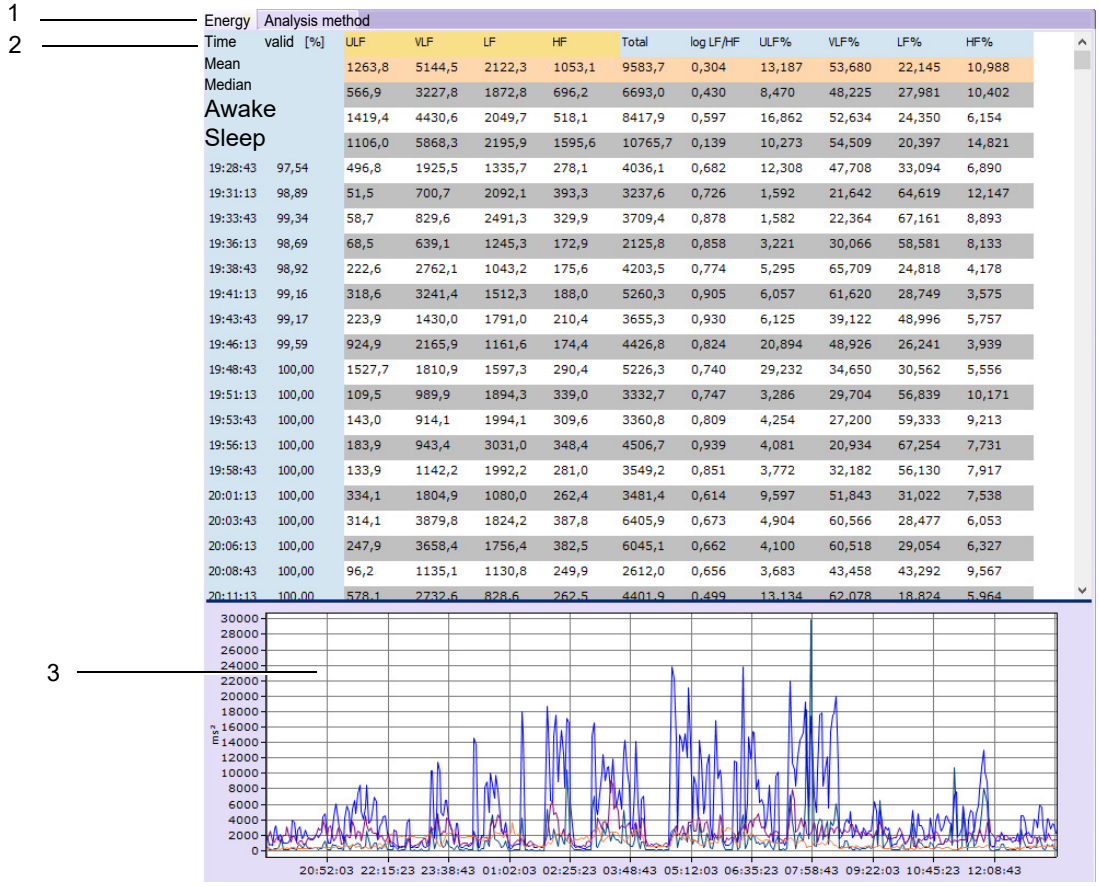
HRV Parameters and frequency domain

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



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

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

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

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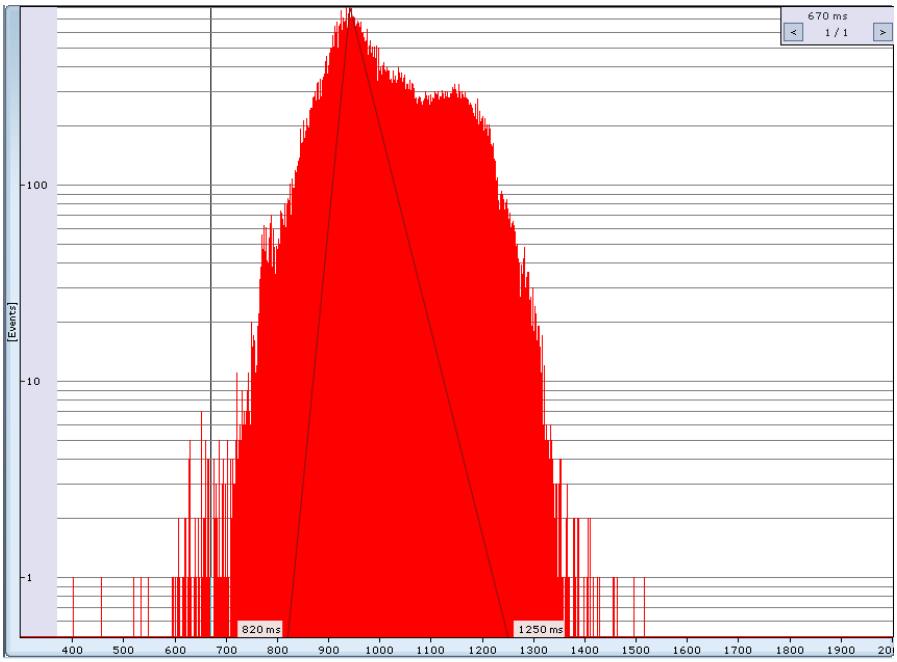
Settings

Configure the following settings:

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

HRV Histogram

In this histogram, the RR intervals are displayed.



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

Settings

In the settings menu, you can configure the following:

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

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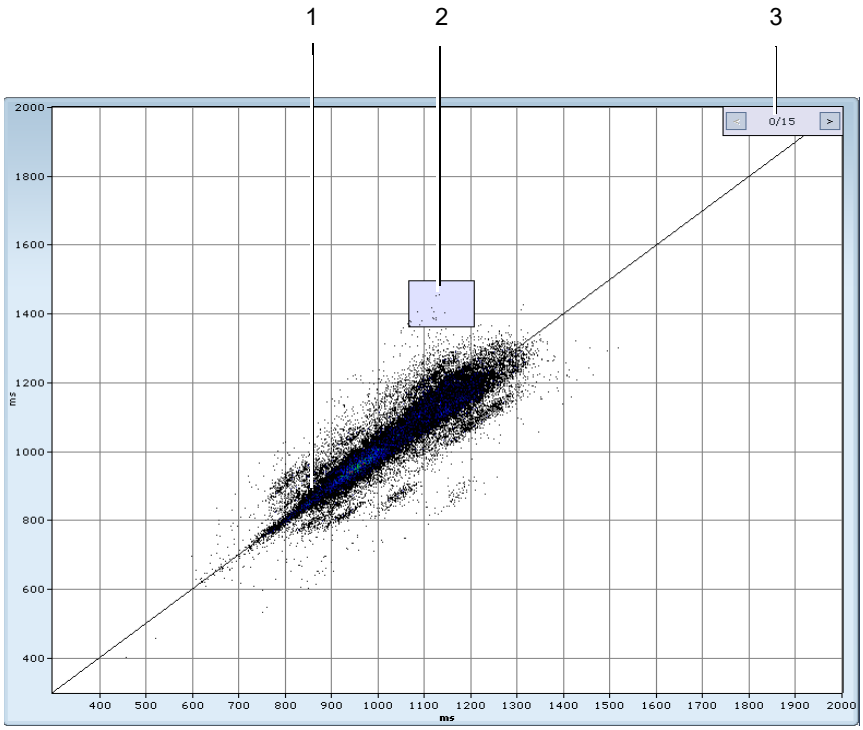
HRV Scatterplot

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



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

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

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

Settings

The following settings are available:

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

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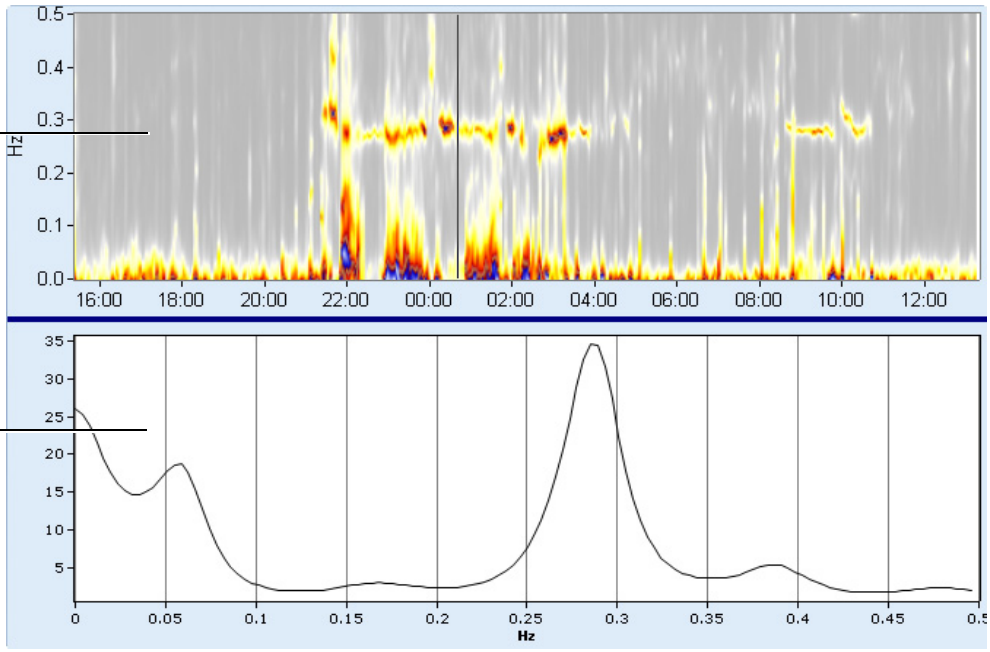
HRV Spectrogram



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

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

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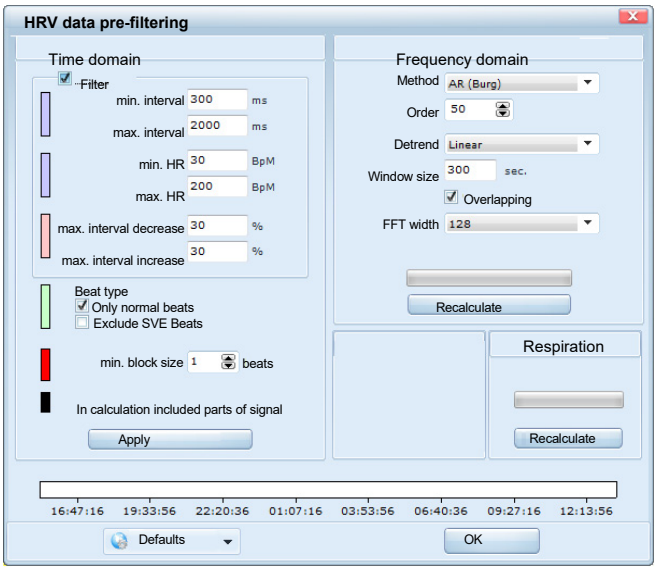
HRV Configure

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



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

Perform the following settings, if necessary:

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

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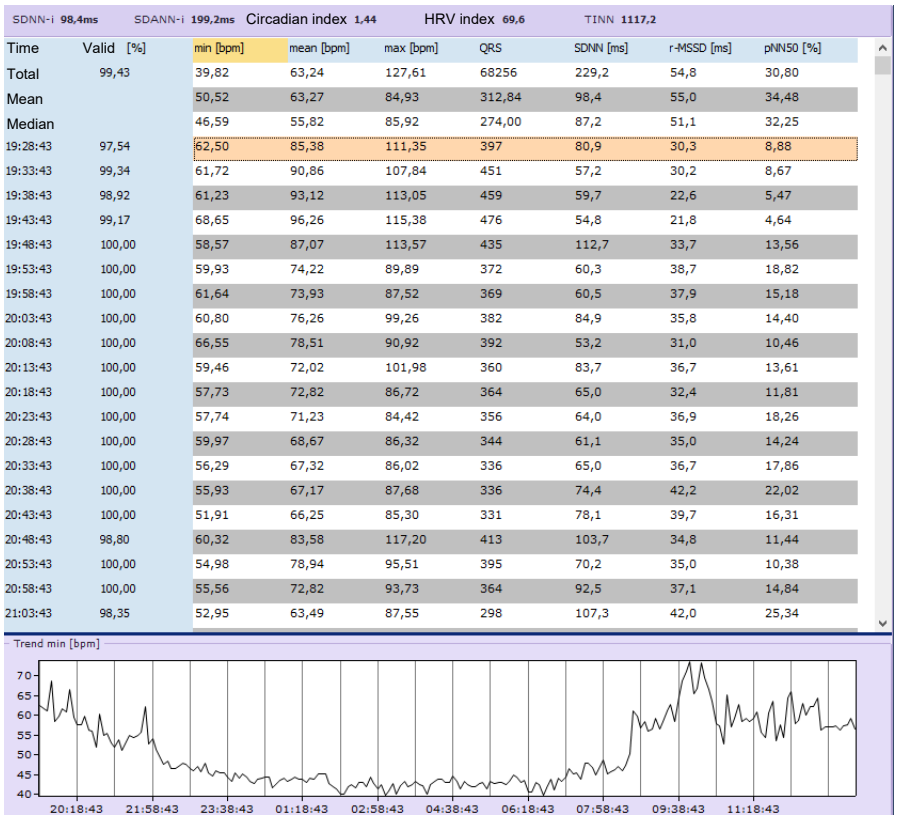
HRV Tabular summary



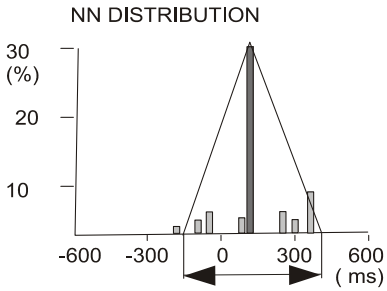
Time	Valid [%]	min [bpm]	mean [bpm]	max [bpm]	QRS	SDNN [ms]	r-MSSD [ms]	pNN50 [%]
Total	99,43	39,82	63,24	127,61	68256	229,2	54,8	30,80
Mean		50,52	63,27	84,93	312,84	98,4	55,0	34,48
Median		46,59	55,82	85,92	274,00	87,2	51,1	32,25
19:28:43	97,54	62,50	85,38	111,35	397	80,9	30,3	8,88
19:33:43	99,34	61,72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

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

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

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

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



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

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Settings

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

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

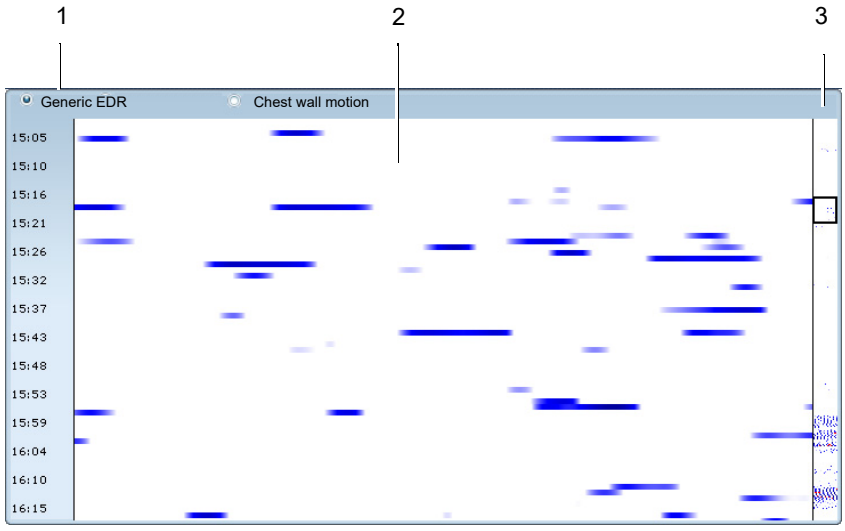
- fn(Mean(x))
- Mean(fn(x))

HRV Diary summary

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

4.2.26 EDR Overview

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



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

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

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

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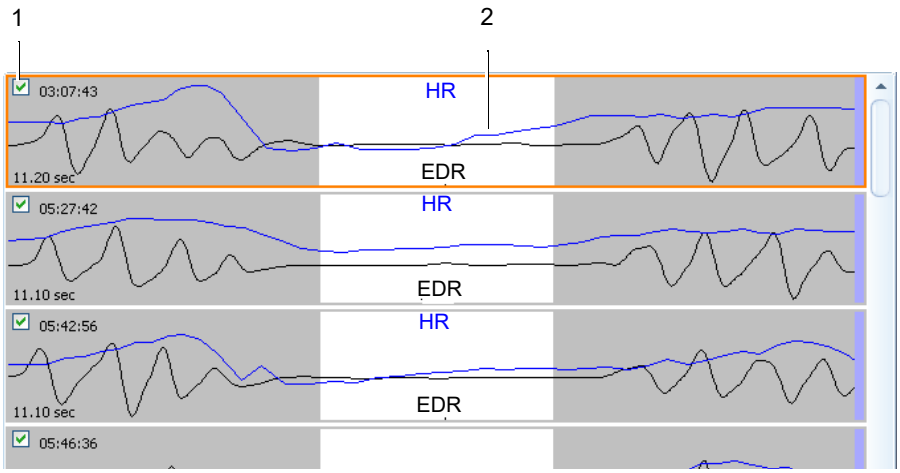
4.2.27 EDR Episodes

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



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

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

4.2.28 EDR Configuration

The following settings are available:

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

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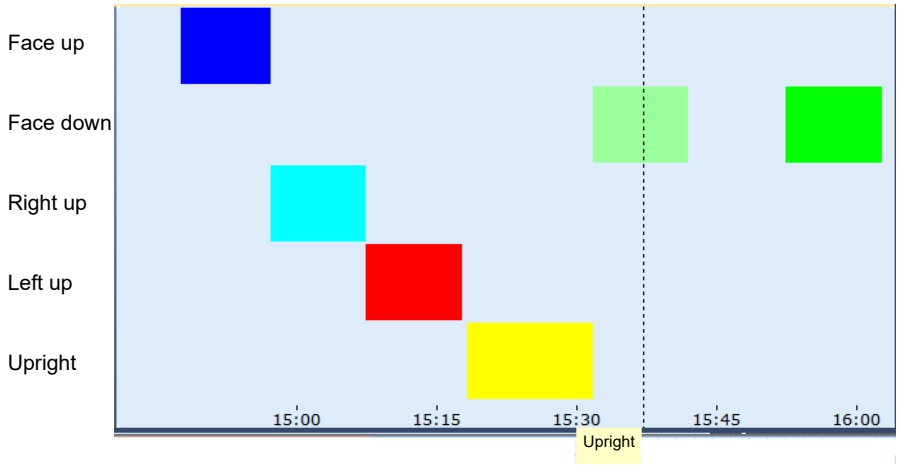
4.2.29 Body position graph

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



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

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

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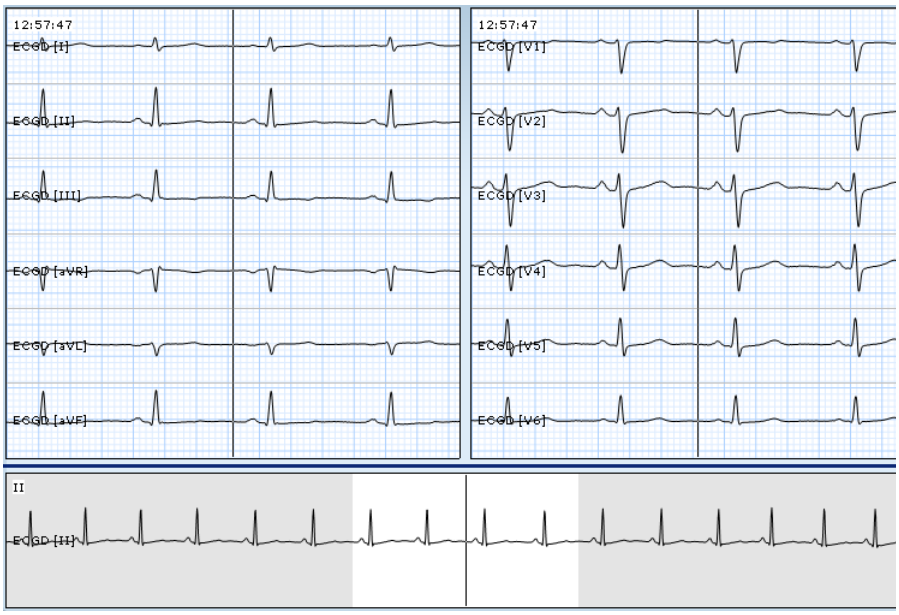
4.2.30 12-channel ECG

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

Strip view

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



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

Settings

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

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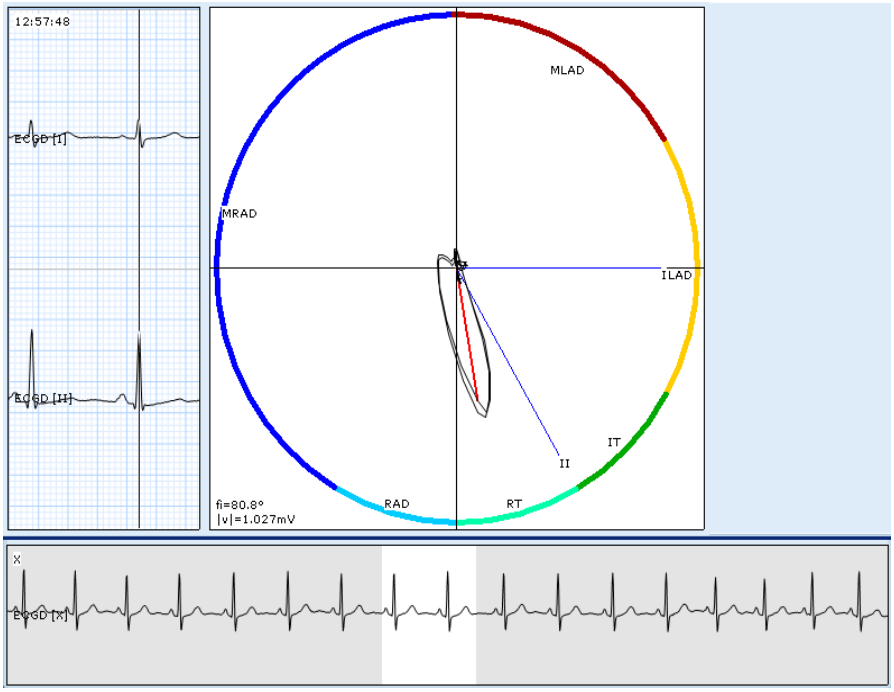
Cabrera circle

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



Settings

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

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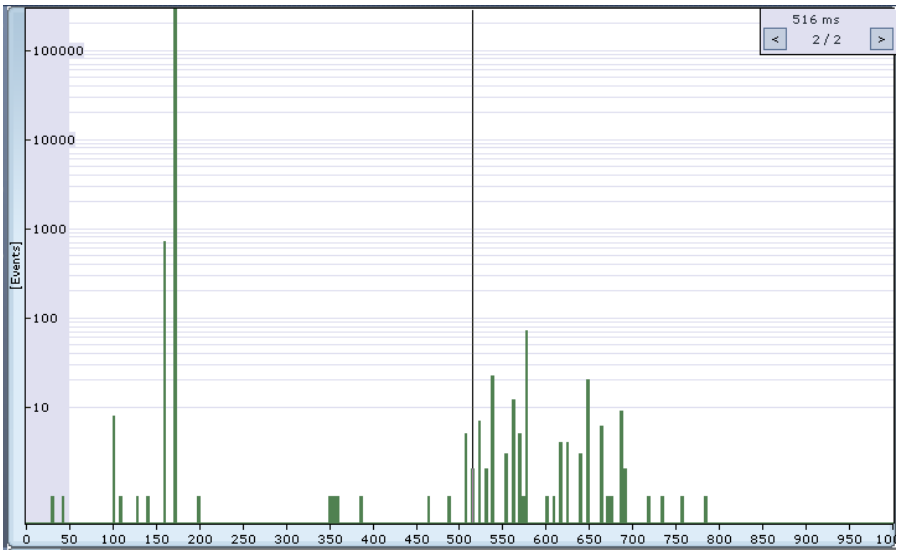
4.2.31 Pacemaker

PM-PM Histogram

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



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

Settings

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

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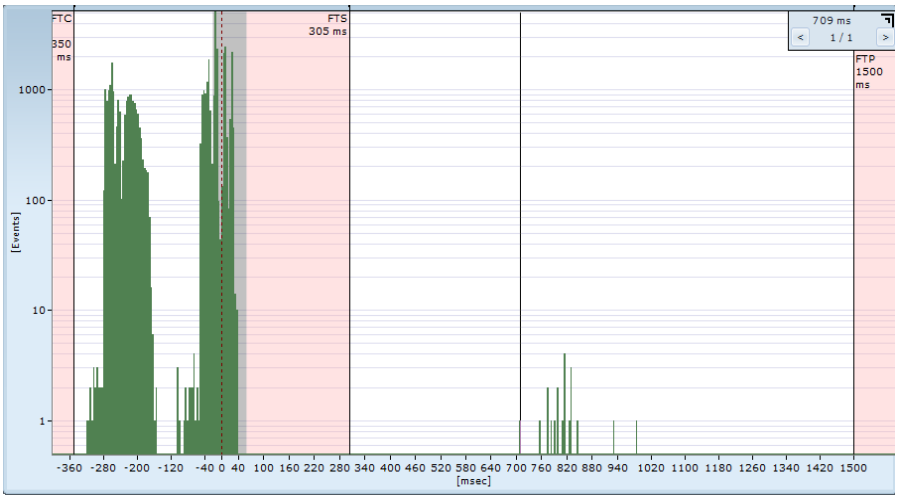
PM-R Histogram

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



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

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

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

Settings

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

Tabular summary

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

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

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4.2.32 QT Summary table

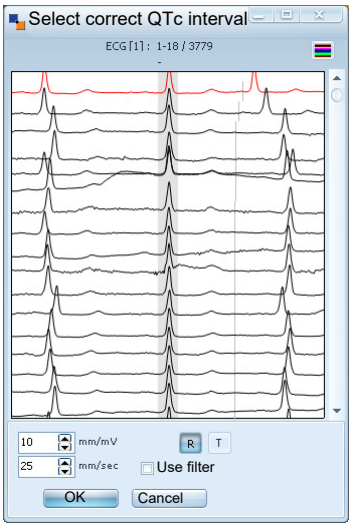
QT is the time between the beginning of the Q wave and the end of the T wave in the averaged ECG. The QT below table shows the measured and frequency-corrected maximum and minimum values per hour (QTc), the dispersion and the number of valid beats used for the calculation.

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

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

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

The following dialogue is displayed:



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

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

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

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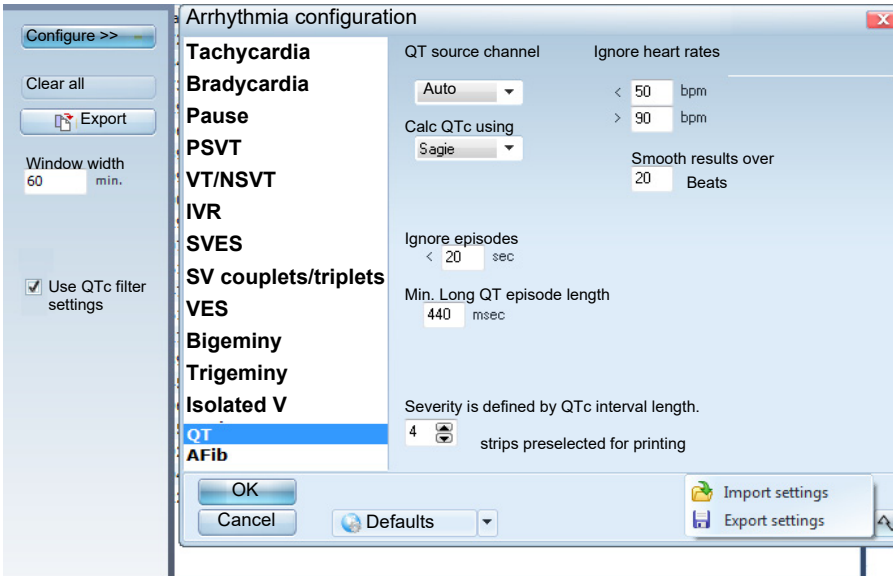
Settings

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



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

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

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

– Pfeufer: the following formulas are applied:

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

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

– Sagie: the following formula is applied:

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

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

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4.2.33 ST Analysis

Notes

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

4.2.34 ST Table

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

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

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

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

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

Settings

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

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

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4.2.35 ST Trend

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

Settings

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

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

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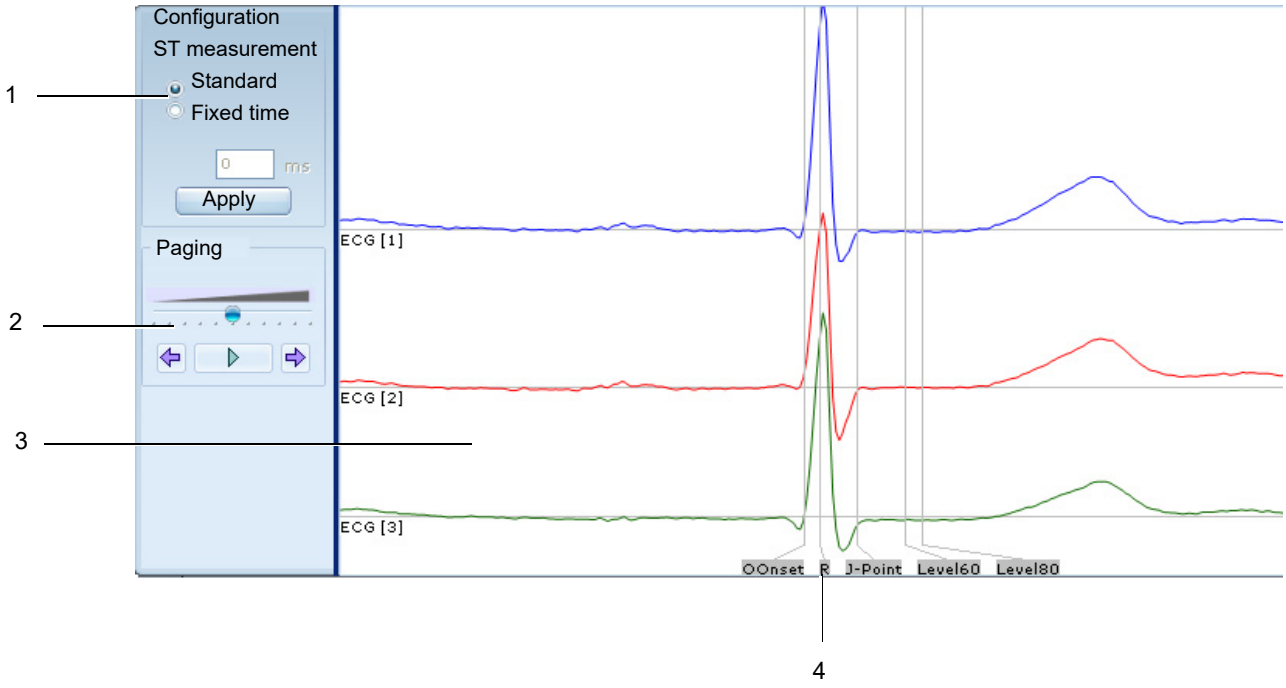
4.2.36 ST Meter



Define the settings for the ST analysis as follows:

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

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

(3) All available ECG channels are displayed.

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

Settings

Set the speed and amplitude.

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5 Blood Pressure Analysis

5.1 Overview of Pulse Wave Analysis

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

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

5.1.1 Overview method

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

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

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

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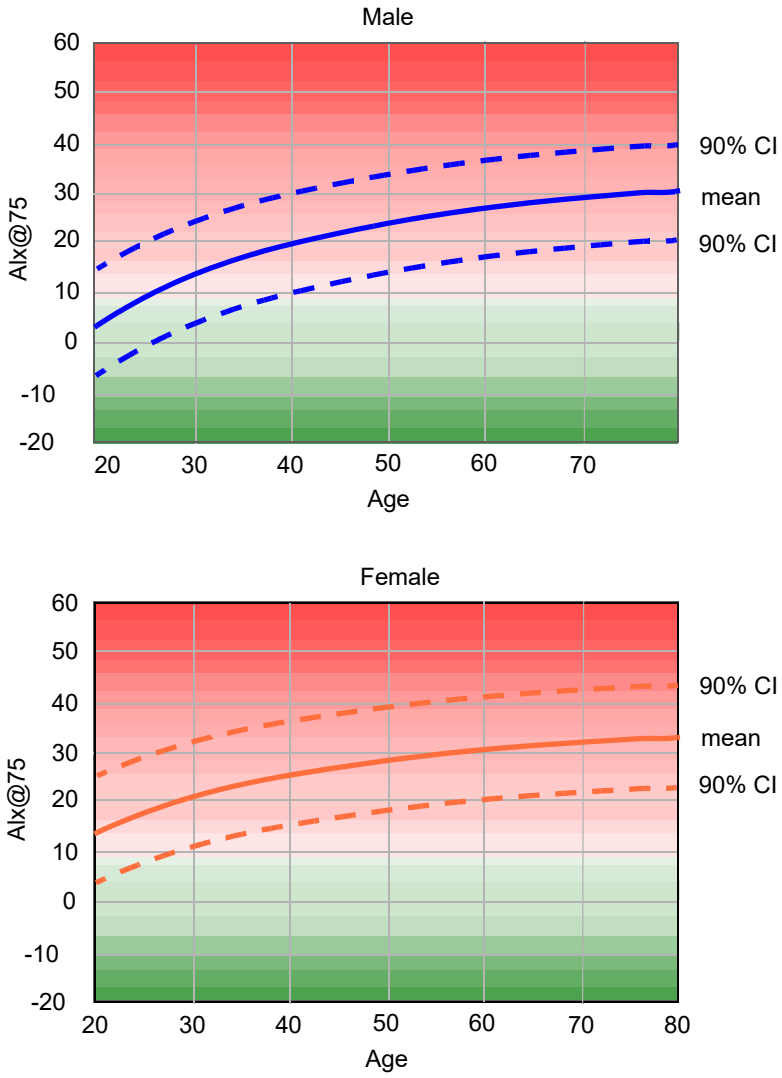

Average value and 90% confidence interval for the AIx@75

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

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

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

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

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

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

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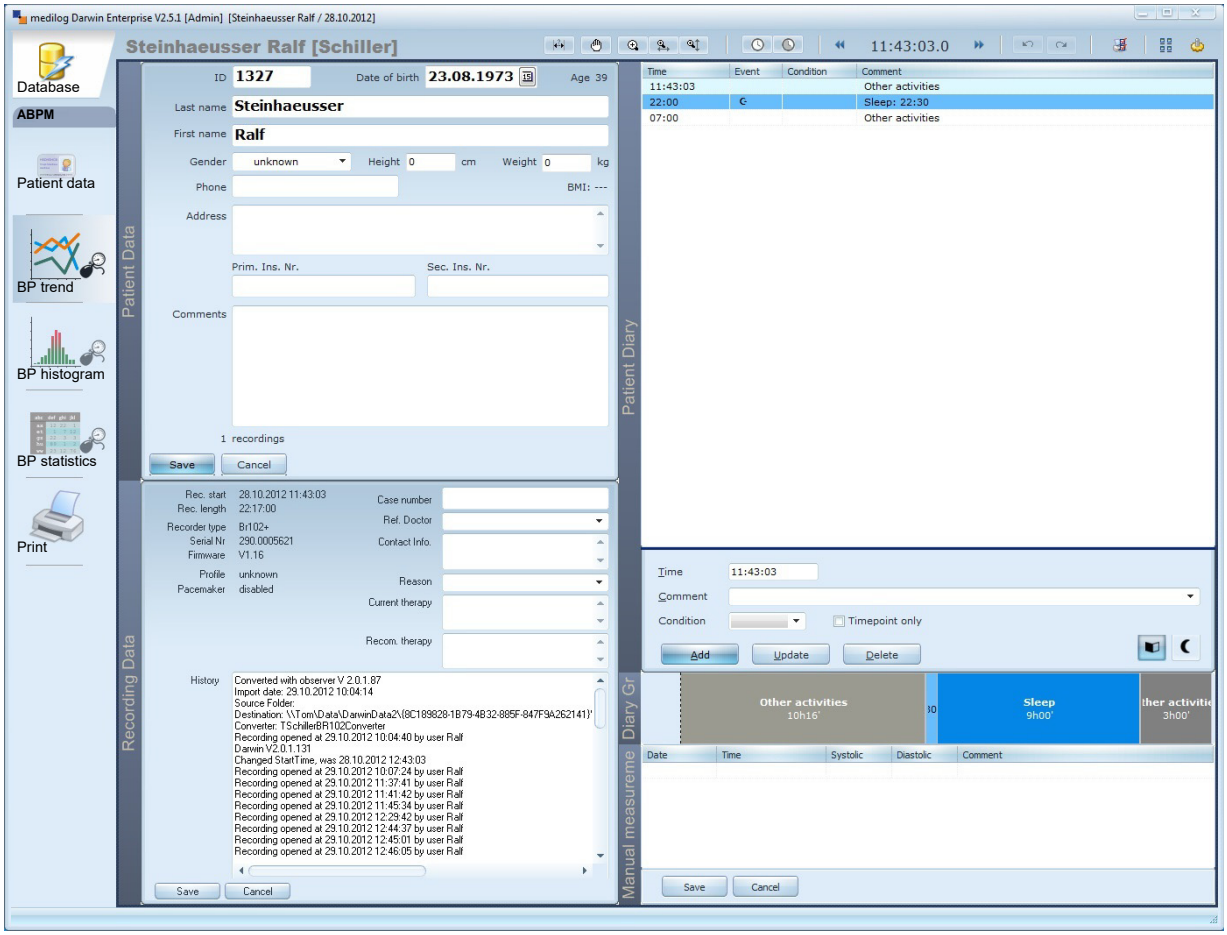
5.2 Overview of Patient Details and Recording



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

Patient Data (top left)

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

Patient Diary (right)

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

Manual measurements (bottom right)

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

Recording Data (bottom left)

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

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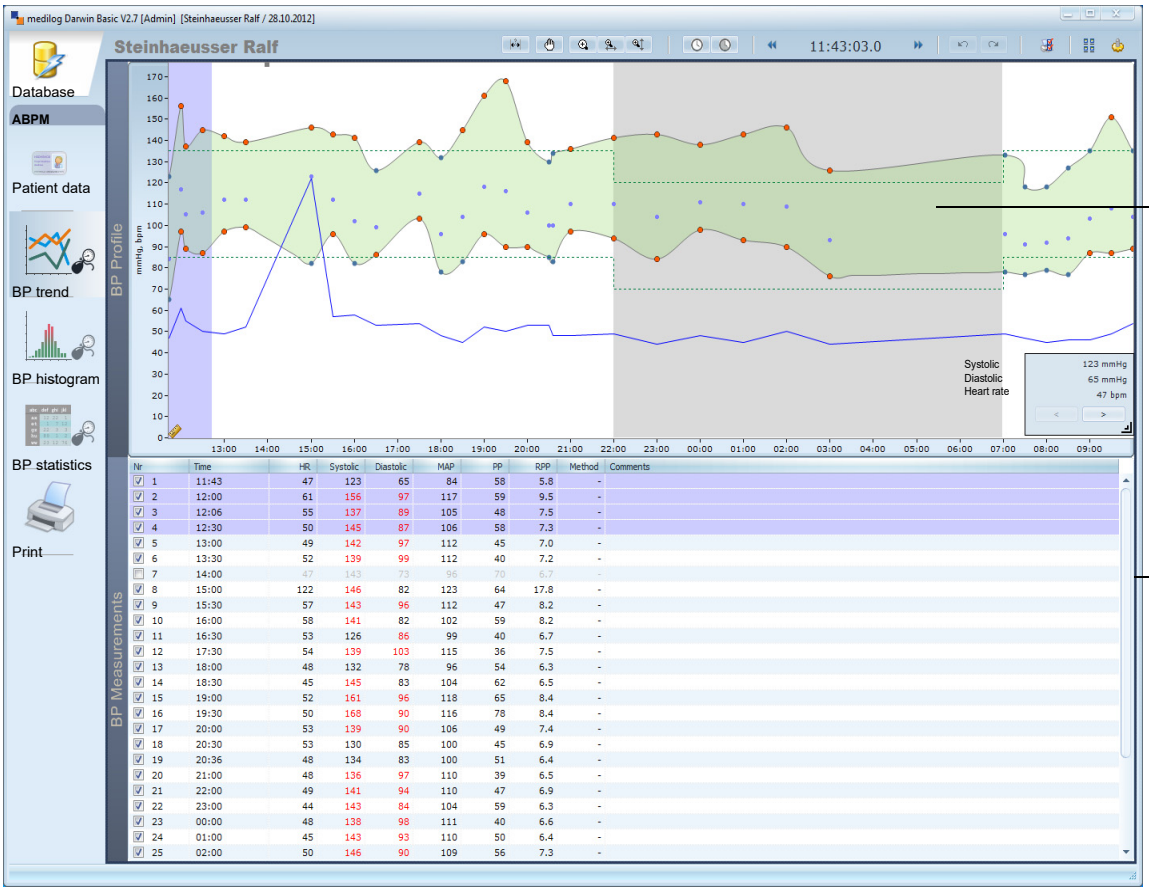
5.3 BP Trend



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

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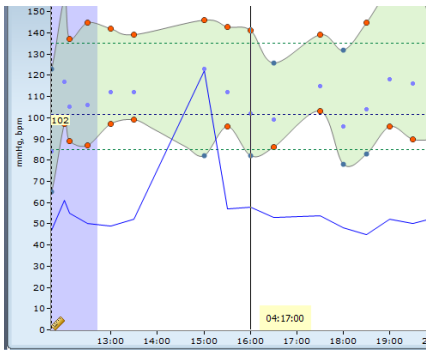
5.3.1 BP Profile

The trend graph displays the following data:

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

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



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

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

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

Settings

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

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

Setting the threshold and classification

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

Load profile

Select between:

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

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- Schiller

Settings

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

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

White-coat analysis

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

Classification

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

Defaults

Select Save as system defaults or Restore to factory defaults.

5.3.2 BP Measurements

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

A blank triangle in the measurement table indicates manual measurements.

Pulse wave analysis measurements (PWA recordings only)

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

The following values are given:

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

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

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

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

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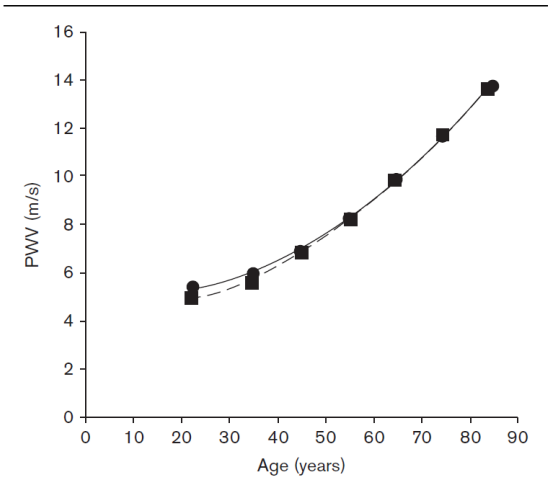
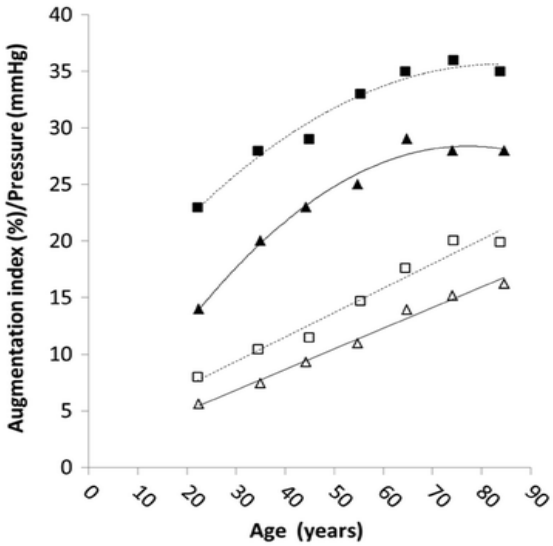


The regression curve represents age's effect on pulse wave velocity in the total sample population. Symbols represent male individuals (● - solid line) and female individuals (■ - dashed lines) (see Nunan et al. Performance of pulse wave velocity measured using a brachial cuff in a community setting.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

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



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

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

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

PRes Peripheral resistance: [mmHg*s/ml]

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

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

Method Cuff-based auscultatory or oscillometric measurement.

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

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

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

Settings

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

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

Exporting measurement summary

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

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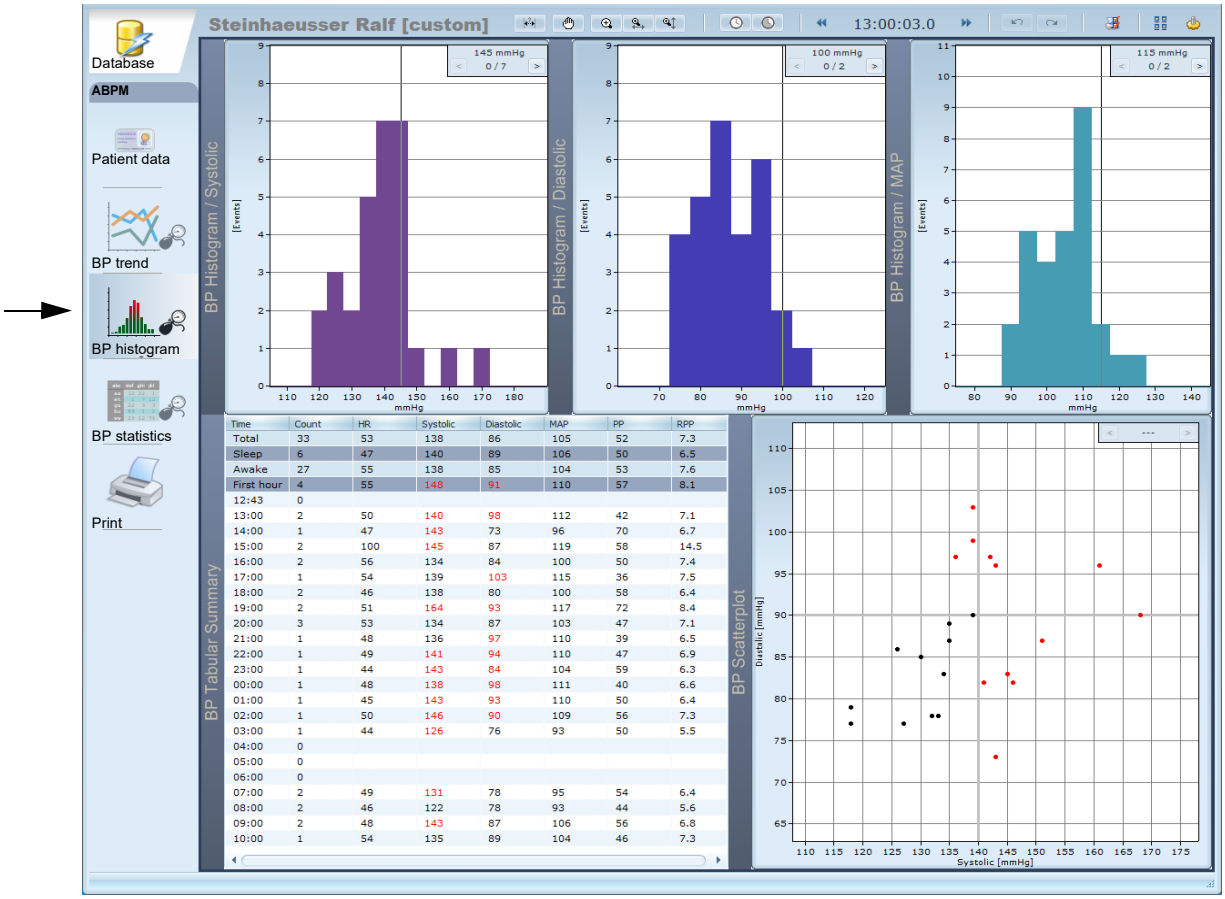
5.4 BP Histogram



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

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

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

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

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

Art. no: 2.511044 Rev: k

5.4.1 BP Scatterplot

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

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

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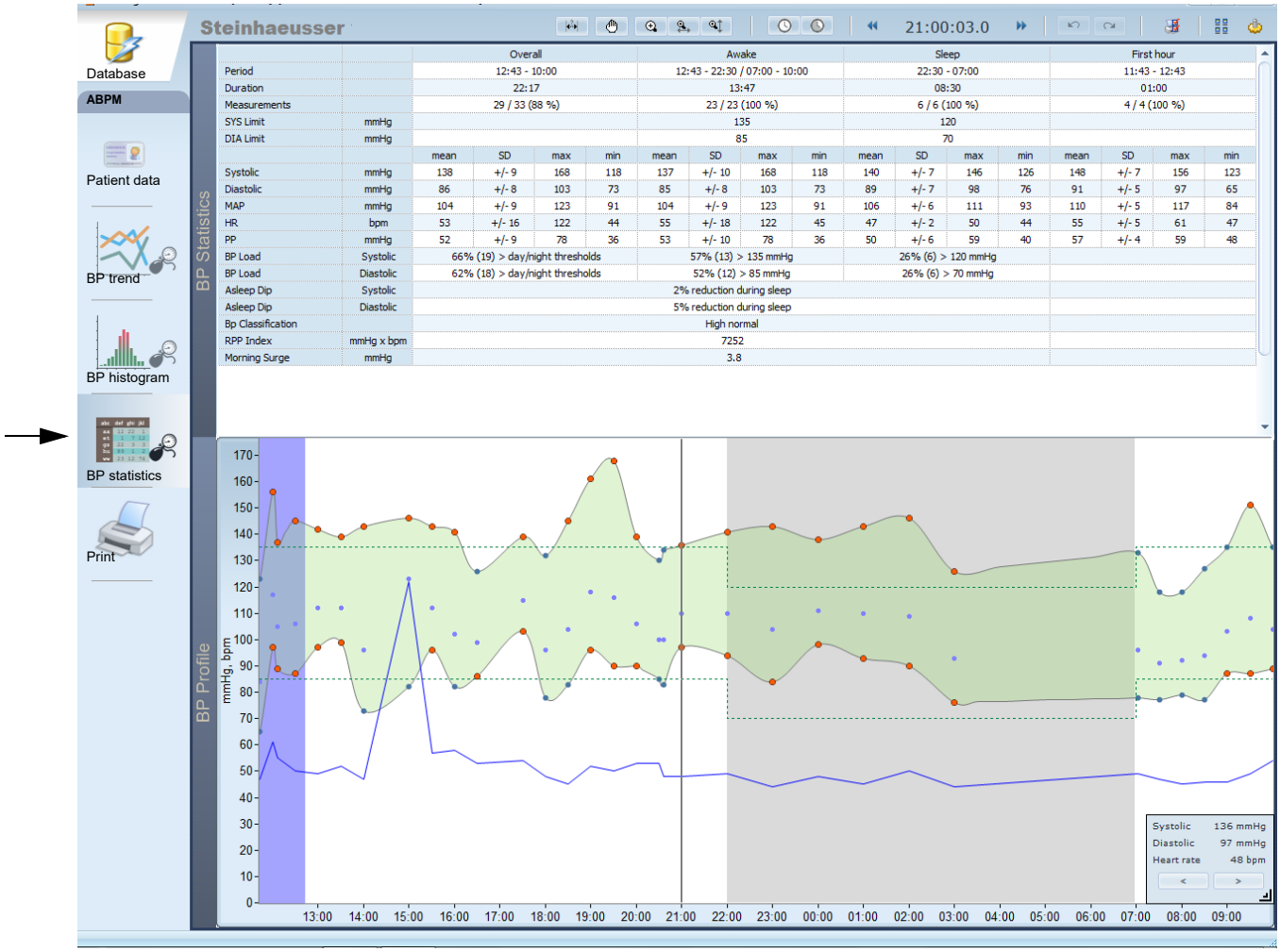
5.5 BP Statistics



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

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

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

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

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

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

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

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BP Load

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

Asleep Dip

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

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

BP Classification

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

RPP Index

The Rate Pressure product is as follows:

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

Morning Surge

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

Time index (systolic/diastolic)

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

Area index (systolic/diastolic)

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

Standardised area index (systolic/diastolic)

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

PWA Recordings only

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

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

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

Settings

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

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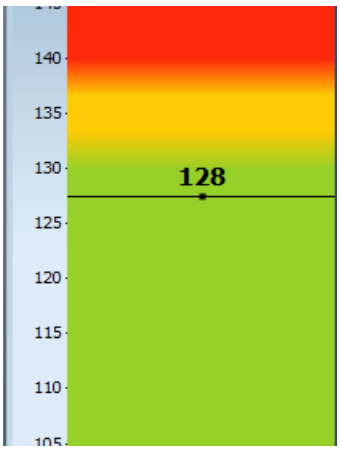
5.6 BP Rating



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

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

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

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

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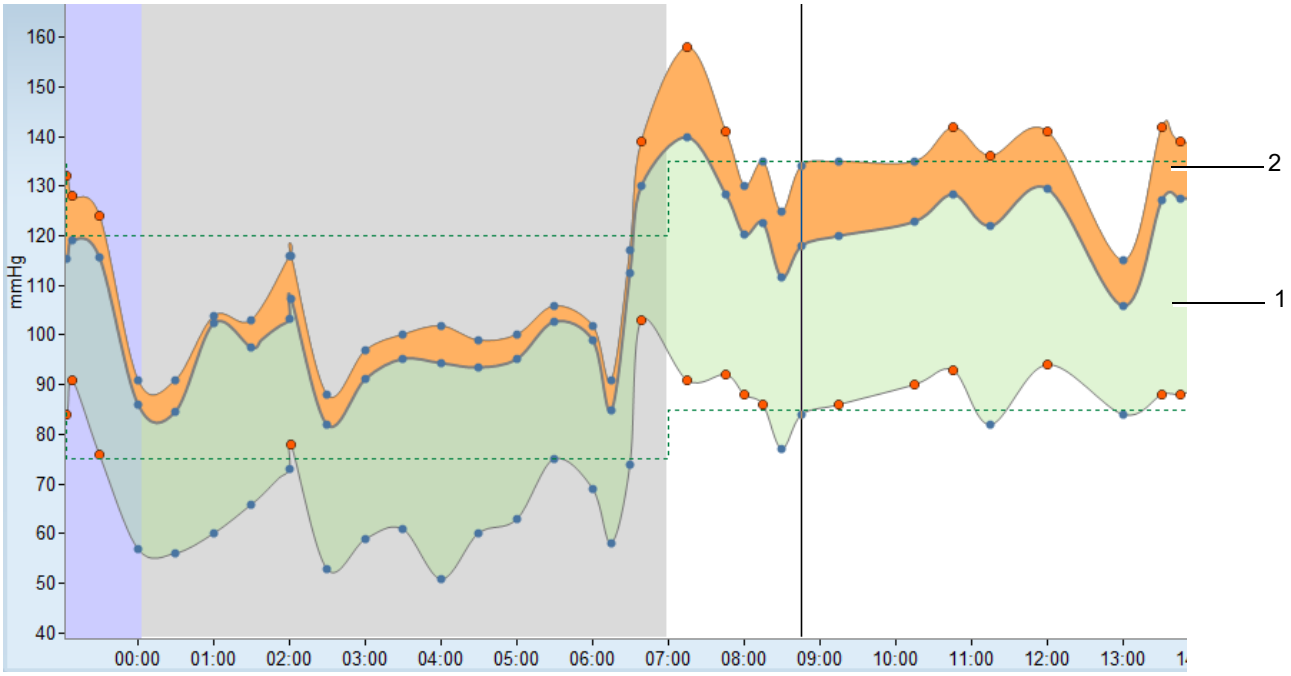
5.7 PWA Measurements (PWA recordings only)

5.7.1 Central BP profile

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

In the settings, select the values to be displayed:

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



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

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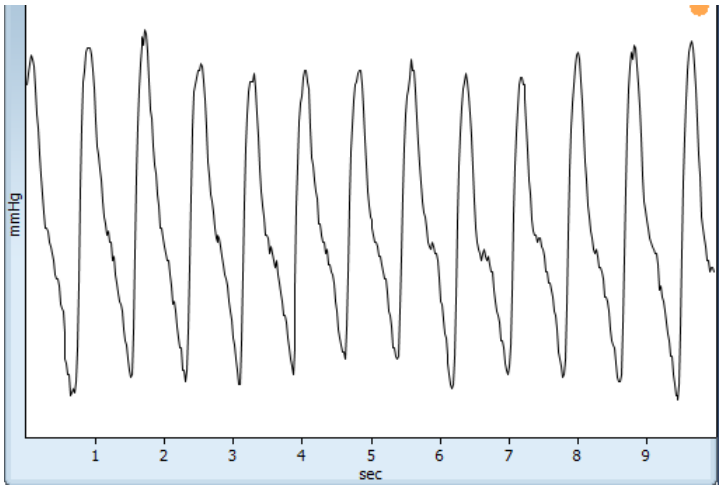
5.7.2 Pulse wave signal

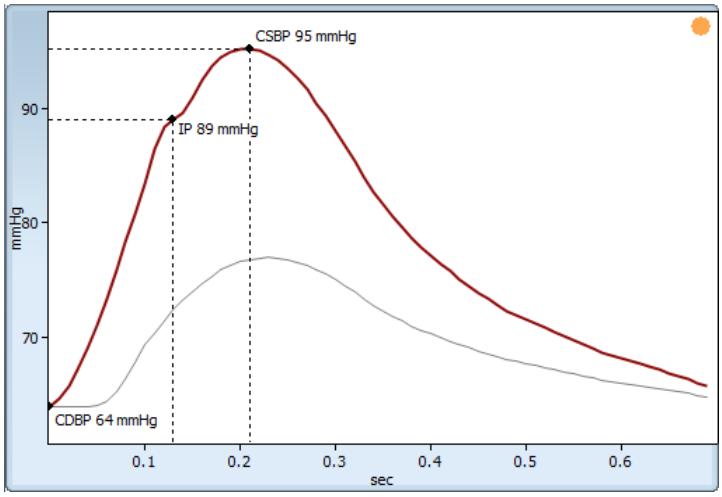
In this module, either the Peripheral pulse wave or the Central aortic wave is displayed (defined in the settings):

Peripheral pulse wave



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

Central aortic wave



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

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

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

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

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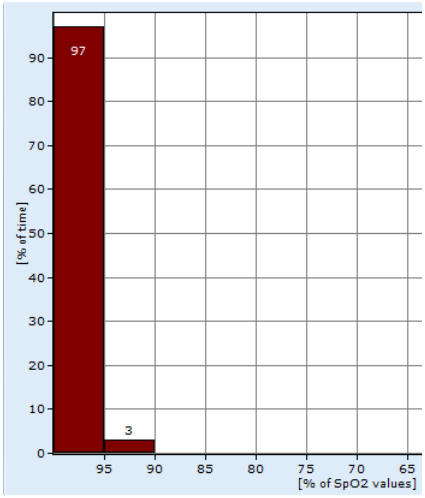
6 SpO_2

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

6.1 SpO_2 Overview



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

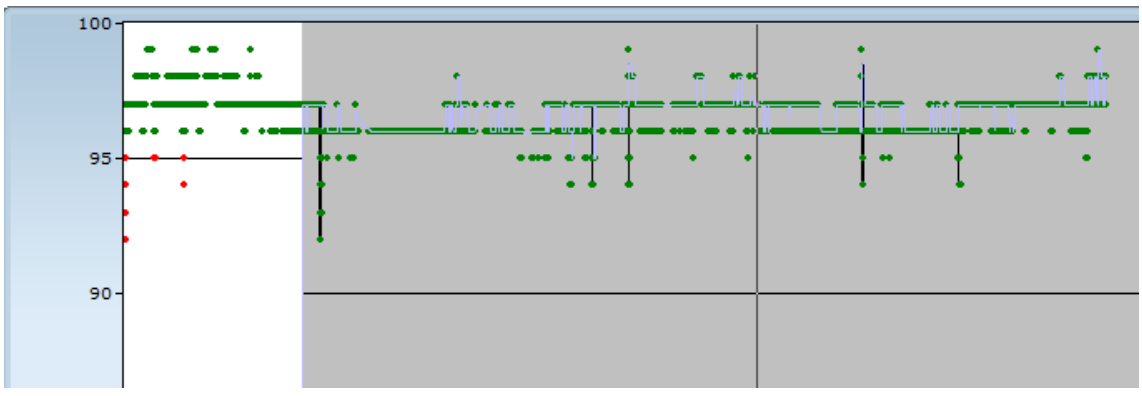
In the settings, you can set the threshold value for measurements that can be ignored, for example, below 70%. Also, you can set the threshold value for deviations that can be ignored, for example, more than 10%.

6.2 SpO_2 Trend

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

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

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



Settings

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

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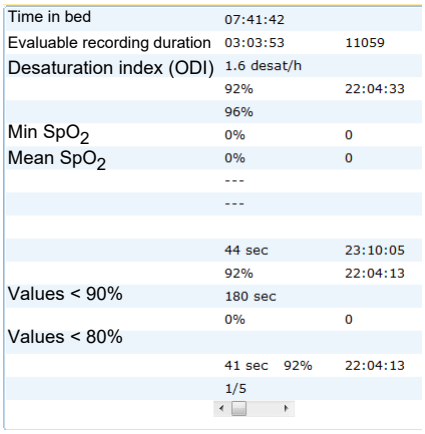
6.3 SpO_2 Statistics



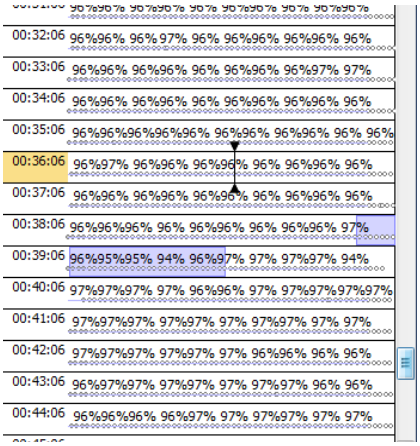
This module provides the following information:

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

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

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

6.4 SpO_2 Full disclosure



This module provides an overview of the entire recording.

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

Settings:

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

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

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7 General settings

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

7.1 Miscellaneous Settings

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

7.2 Report Settings

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

Strip directory

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

Full disclosure

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

7.3 Calibrate Display Resolution

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

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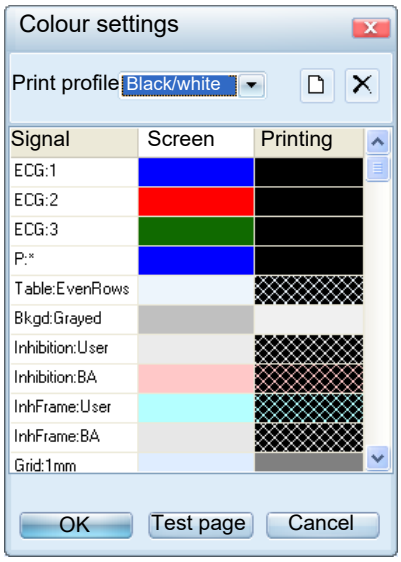
7.4 Colour Settings



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

7.5 Configure Hotkeys and Layout

Refer to Shortcuts, page 26.

7.6 Change Password

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

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

7.7 HRV Data Preparation

Refer to HRV Configure, page 62.

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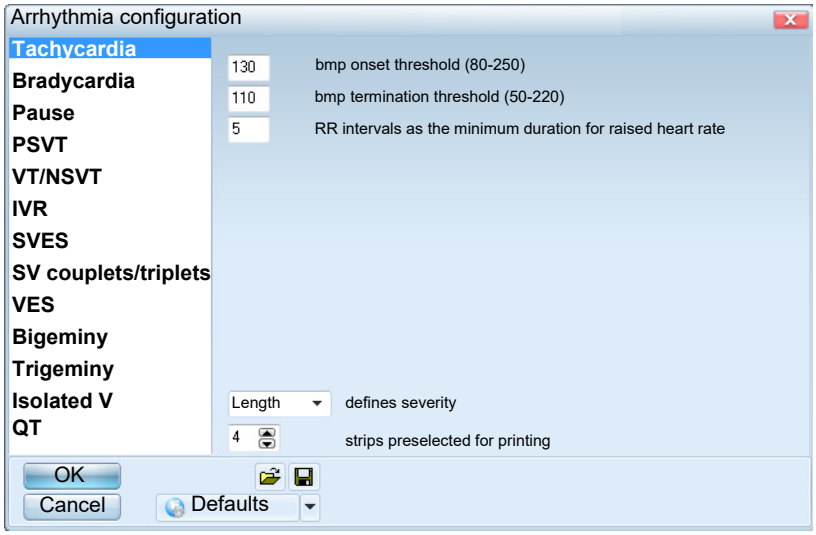
7.8 Arrhythmia Configuration



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

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

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

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

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

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

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

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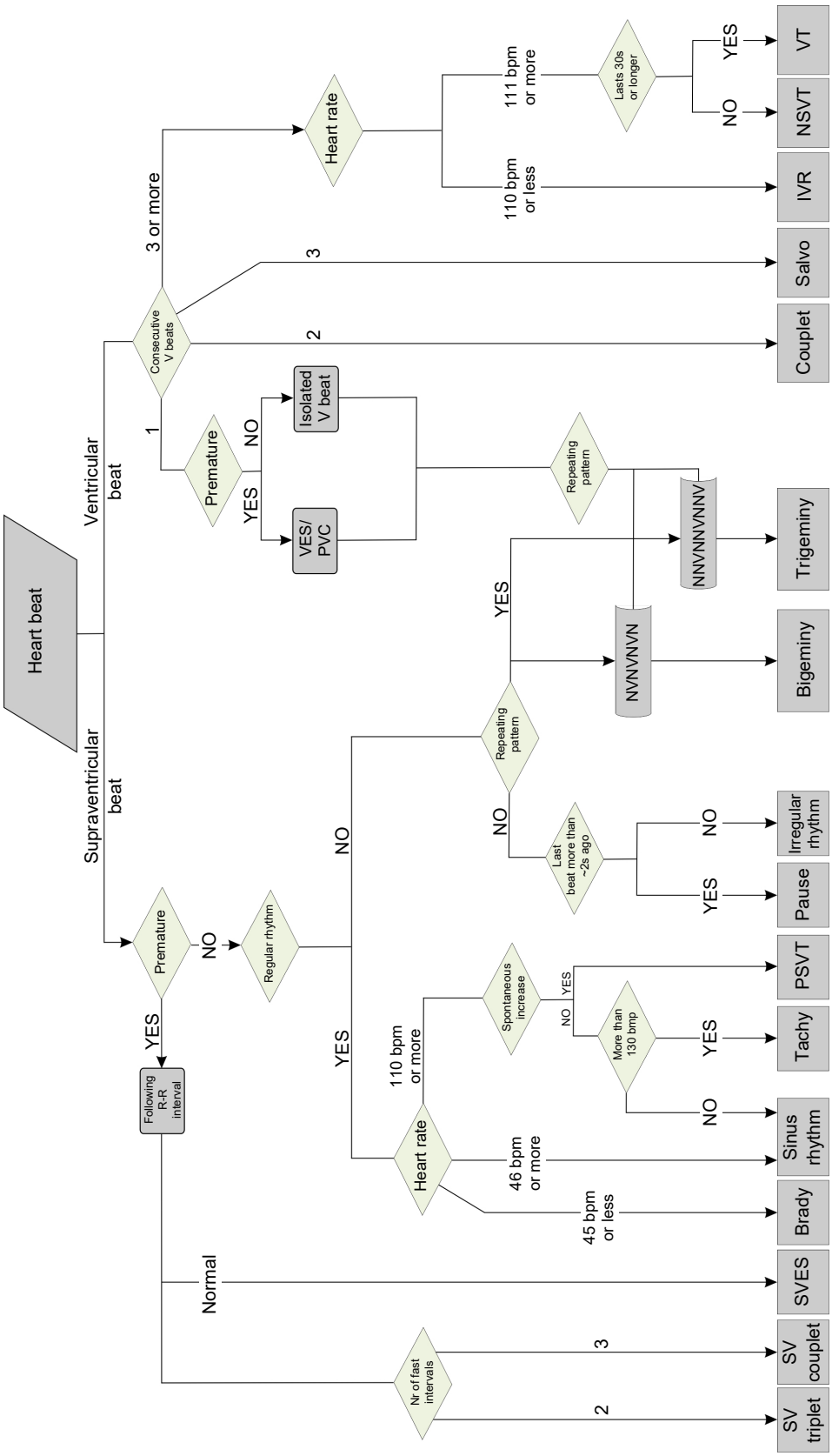
7.8.1 Information on arrhythmia definitions



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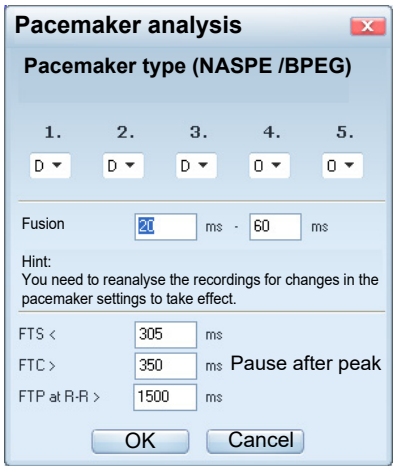
7.9 Pacemaker Analysis



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

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

7.10 Blood Pressure Settings

Refer to Setting the threshold and classification, page 80.

7.11 Reanalyse

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

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

7.12 Info

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

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8 Installation and Administrator Settings

8.1 Minimum Specification for the Computer System

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

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

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

8.2 Scope of Delivery

The **medilog DARWIN2** software pack includes:

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

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

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8.3 Installation

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

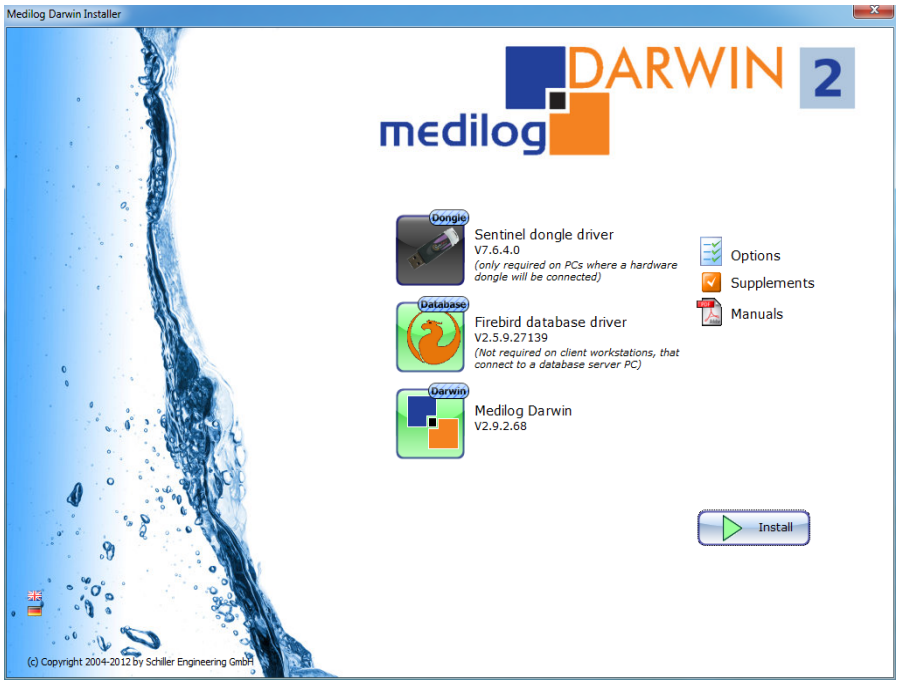
8.3.1 Scripted installation

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

8.3.2 Installation on a single workstation

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

The following dialogue is displayed:



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

To start the installation:

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

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

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8.3.3 Client/server installation

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

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

Installation on the server

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

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

On the clients

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

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8.3.4 Firebird user and password

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

Securing Firebird database access

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

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

- Open a command shell (click Start/run and enter cmd)
- Navigate to the Firebird installation path (enter cd \program files\Firebird\Firebird_2_5\bin)
- Enter the following commands:

// Change the password of the firebird superuser:
gsec -user SYSDBA -password masterkey -modify sysdba -pw myNewSysDbaPass
// Create a new user:
gsec -user sysdba -password myNewSysDbaPass -add MyDarwinUser -pw MyDarwinPassword

Setting custom database user name/ password in medilog DARWIN2

For the **medilog DARWIN2** to use a designated database user name/password, proceed as follows:

- Open the Admin tool
- Click the icon in the right corner of the DB name field to open the DB connection dialogue.
- Click the check box; Use a custom database user.
- Enter the desired values (for example, MyDarwinUser/MyDarwinPassword)

Making an old database accessible to a new user

If you created a database before setting up the new user, the new user has no rights to access this database. (In **medilog DARWIN2**, the error message, Could not determine the database version is displayed.)
The easiest way to grant access rights to the new user is to make a backup of the old database using the old user and restore it using the new user. The new user is now be the database owner.

To do so, enter the following commands:

// Back up the database:
gbak -B -USER sysdba -PASSWORD myNewSysDbaPass "C:\ProgramData\Darwin2\Evolution2.fdb" "C:\ProgramData\Darwin2\Evolution2.fbk"
// Move the old database out of the way (ATT: requires admin rights):
rename "C:\ProgramData\Darwin2\Evolution2.fdb" Evolution2_OldOwner.fdb
// restore database with new user:
gbak -R -USER MyDarwinUser -PASSWORD MyDarwinPassword "C:\ProgramData\Darwin2\Evolution2.fbk" "C:\ProgramData\Darwin2\Evolution2.fdb"

Art. no: 2.511044 Rev: k

8.3.5 Securing the system

Network security

Connections to the **medilog DARWIN2** database and HIS connection (if used) via HL7 or similar use network communication.

Some communication standards, like HL7, do not offer encryption. If software connects to the **medilog DARWIN2** using such a standard, communication is in plain text over the network. Also, communication with the Firebird database is unencrypted.

The network needs to be secured to prevent attackers from accessing sensitive data.

Recommended measures are:

- Restrict physical access to the network.
- Use a firewall so only the **medilog DARWIN2** workstations can connect to the firebird database.
- If you cannot restrict physical access to the network, you may want to use encryption/tunnelling for potential communication paths.

Explanation: An attacker who plugs into your network can use network sniffing software to listen to all network traffic and find unencrypted HL7 messages containing sensitive patient data. By setting up a secure tunnel, you can establish an encrypted communication path between two fixed points in the network. Communication between these points (for example, the HL7 caller on one side and **medilog DARWIN2** on the other) is secure and cannot be intercepted.

Restricting access to the PC

Attackers may try to install malicious software on servers/workstations to gain access to passwords or other sensitive data. To prevent this, restrict normal users from installing software.

Attackers may try copying the Firebird database file to access the stored information. To prevent this, restrict access to the database file's location. (You can remove read-access-permissions for all users for the folder where the Firebird database is stored as **medilog DARWIN2** accesses the database through a system service).

Audit log

From version 2.10, the **medilog DARWIN2** logs various events (failed login attempts, deleting a recording, report generation) in the Windows event service (Event source: MedilogDarwin). The **medilog DARWIN2** can be configured so that all workstations send these messages to a central event server (see AdminTool/Extended settings/ Misc/Audit log server). Specialised IDS/IPS HIDS software systems (for example, SIEM https://www.solarwinds.com/en/security-event-manager) that monitor these logs can be used to detect potential cyber attacks automatically.

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8.3.6 Installing medilog DARWIN2 updates

The update is first installed on the server, then on the workstations.
For installation on a single workstation (No client-server setup), only perform the steps listed under “On the server”.

On the server:

1. Make sure all instances of **medilog DARWIN2** applications (for example, **medilog DARWIN2**, Observer, DConnect) are closed, even on network connected workstations.
2. Back up the recordings database; refer to Backup database, page 108.
3. Install the new version of **medilog DARWIN2** as follows:
4. Insert an installation medium with the new version of **medilog DARWIN2**. The installation program should automatically start. If nothing happens, manually start the application "Autorun.exe" in the root folder of the installation medium. The installer automatically detects which parts of your installation can be updated to a newer version. The appropriate buttons are highlighted green, indicating that these parts are to be installed. You can overrule the selection by clicking on the appropriate buttons.
5. To start the installation process, click **Install**.
6. Test **medilog DARWIN2**: Open **medilog DARWIN2**, then open a recording. Verify the application starts and loads as expected.
7. Optional: Once the installation is finished, update the medilog Liberty Scanlab.

On workstations:

On workstations, you only need to install the new version of **medilog DARWIN2** without removing the old one. You do not need to update/install database drivers or perform backups.

8.3.7 Uninstall medilog DARWIN2

To remove **medilog DARWIN2** from a PC, use the Windows uninstall feature (Control panel) to remove all program parts; however, the recording database and raw data remain on the PC.

To remove the remaining data:

1. Delete the recording database (Evolution2.fdb)
2. Delete the raw data folder.

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8.4 Software Setup

There are other settings to be made to adapt the **medilog DARWIN2** software to the IT environment and the particular user requirements. A separate application has been programmed for those settings, allowing quick and easy setup. The Admin tool is automatically copied to the computer during the software installation.
After installation, the Admin tool is automatically started to perform the software's initial setup. You can run the Admin tool anytime by selecting the application from the Windows Start menu (All programs > DARWIN2 > Admin tool.exe).
When starting the Admin tool, you are asked to enter a password. At the time of installation, the password is: admin.

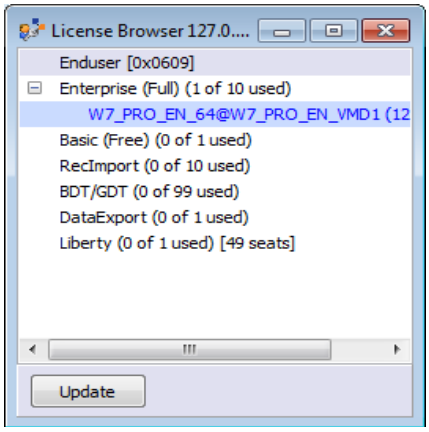
▲ The administrator must change the admin password when the Admin tool is used for the first time to prevent misuse.

8.4.1 Soft licences

1. The location of the licences server can be specified on the first page of the Admin tool.
2. After the correct licence server location is entered, click the Connect button. A window presents the Host ID, a value uniquely identifying the licence server PC.
3. Send this Host ID to your Schiller representative. One or more licence codes are returned to you.
4. For each licence code: Enter the licence code into the appropriate field and click Add licence. The window displays the number of licence files registered on your server; licences are available immediately.
5. Clicking the blue info icon starts the licence browser, which can be used to verify the correct operation.

8.4.2 Licence browser

For an overview of how many licences are in use, open the Licence browser application: DARWIN2 > LicSvrInfo.exe.



8.4.3 Automatic log off

After a certain period of inactivity (default value: 20 minutes), the user is logged off from the **medilog DARWIN2** and the licence is released. When the user moves the mouse again, **medilog DARWIN2** tries to get a licence, if available.

- Open the Admin tool > Settings > Extended settings > Licence hold duration to activate this setting and change the default value.

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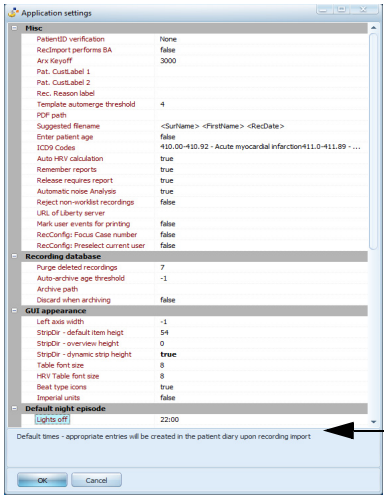
8.5 Database Setup

Using the Admin tool, you can set up the database location. Use the Pen icon to create a new database.
To connect to an existing database, enter the name and path to the database and the database user name and password as described above; refer to Firebird user and password, page 101.

8.6 Local Component Setup

In the **Setup** tab**,** you can adjust several parameters:

- Drive letters/drive types: enter any drives used to download recordings (for example, FlashCard drive F). Separate the drive letters with a comma but no extra spaces. This information is used for the DARWIN Observer (refer to DARWIN Observer, page 110). On how to receive a recording, refer to Controls, page 22.
- Look and feel: select the language and set the edition (refer to User Setup and Authentication, page 106, for more detailed information):
  - Full version
  - Professional
  - Office
  - Basic
- Report design items: enter the address of your hospital/private clinic in the text boxes. On the right side, use the Load Image button to upload your logo, which is printed in each report's report header.
- Recorder support: select all recorders that need to be supported by the software (refer to Software Setup, page 104)



- Extended settings: set options like Patient ID verification, Archive path, PDF path, default night settings, SEMA import path, and imperial units. Click an option to display additional information at the bottom of the window (see the arrow on the left).

- Reset to factory defaults: select the settings that need to be reset to the factory defaults. Note that greyed-out items have not been changed and still correspond to the factory defaults.

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8.7 User Setup and Authentication

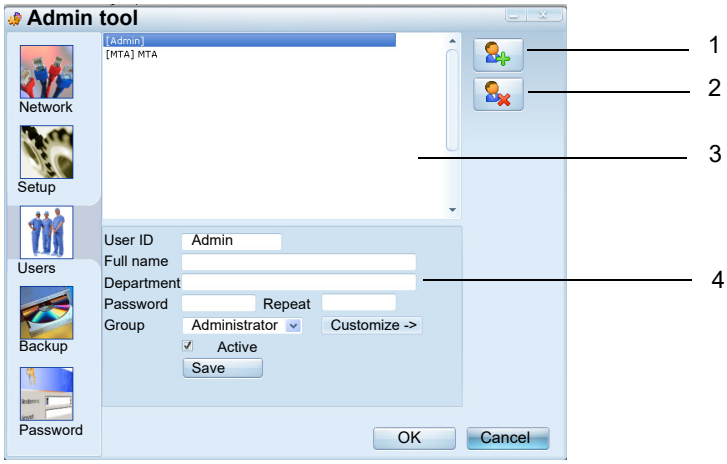
Different authentication methods are available; the method is selected in the Admin tool > Extended settings > User authentication > Authentication method.

In the Admin tool, you can also enable Two-factor authentication. If this option is activated, the **medilog DARWIN2** displays a QR code to each user at the next login. To set up the 2FA account, the code must be scanned with Windows authenticator, Google authenticator or similar. Then the **medilog DARWIN2** asks for a 2FA key which the authenticator app provides.

8.7.1 User setup in the admin tool

Before any users can access **medilog DARWIN2**, the administrator has to set up the database access and the relevant access rights for those users.

In the User tab, you can create users with the necessary access rights:



1. Add a new user.
2. Delete the highlighted user.
3. List of all users
4. User data:
   - User ID: enter a unique short name to identify the user. The User ID has to be entered together with the password at login.
   - Full name: this entry is optional; you can enter the user's full name for identification.
   - Department: this entry is optional. You can allocate the users here if several departments (for example, paediatrics and internal medicine) work with the medilog DARWIN2.
   - Password: enter a password for the user. There is no minimum length or other limitation, but using capitals, small letters, numbers and special characters in a password makes sense.
   - Repeat: for safety reasons, the password has to be entered again. It is not possible to copy and paste the password using the clipboard.
   - Group: with this setting, you select the user's access rights. Click Customize to view and edit access rights. Click an option to display additional information.

The following groups are available:

Default: users in this group have no restrictions (for example, they may delete recordings, change system default settings etc.). This template defines the standard values used by all other templates.

Administrator: full access to all functions of the **medilog DARWIN2**, like the Default group, and access to some special maintenance features.

Maintenance: like the Administrator group, this group has access to maintenance functions, but the user does not see the patient demographic data.

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Technician: The medical assistant can analyse recordings and mark them as “reviewed”. However, a user with more rights must release the recording.

– Active: this box must be activated for the user to log in to the program.

8.7.2 Single sign-on and Darwin user groups

When the **medilog DARWIN2** is started, it uses the same user name currently used as Windows login to identify itself in **medilog DARWIN2**.
If a user with that name does not yet exist in the **medilog DARWIN2** database, it is automatically created and assigned to the user group; Default. You can change the user group later in the Admin tool.

8.7.3 Windows users and Darwin groups

The **medilog DARWIN2** asks for a username/password upon startup. It then checks with Windows if this is a valid combination for a Windows user. If it is, the user may log in.
If a user with that name does not yet exist in the **medilog DARWIN2** database, it is automatically created and assigned to the user group "Default". You can change the user group later in the Admin tool.

8.7.4 Single sign-on and LDAP groups

LDAP offers the possibility of having a central server that manages all user accounts for a set of PCs. So if a new employee starts in a company, the admin only needs to set up an account on the central server, allowing the user to log on to all (or a defined number of) computers. The **medilog DARWIN2** can use this mechanism to check whether or not a user may use **medilog DARWIN2**.
With a single sign-on, the **medilog DARWIN2** uses the current Windows user name for authentication.
Using LDAP groups, it then checks the LDAP groups assigned to the user; for example, if Windows returns "medilogDarwin.Limited", the user is assigned to the user group, Limited, if available, and logged in with the privileges assigned to this group.

8.7.5 Windows users and LDAP groups

Ask for a username/password and check if this is a valid Windows user. Then get the user rights (=user group) from LDAP.

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8.8 Backup and Restore

8.8.1 Backup and restore system settings

Many settings in the **medilog DARWIN2** can be saved in a file for future maintenance and restore issues. This allows you to turn back to the previous settings. The following settings can be saved:

- Screen layouts and workflows
- Shortcuts for quick access
- Default arrhythmia settings (definitions which are used by the analysis module)
- Colour profiles for screen and printer
- Summary templates (text blocks which are used as a summary in the report)
- In-depth customisation: settings completed in the Admin tool, tab Setup, Extended settings

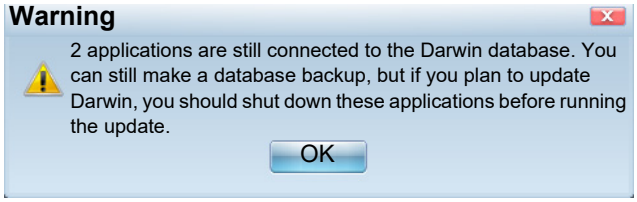
1. To back up the settings, press Backup, select the options and enter a file name and storage location.
2. To restore saved settings, press Restore, select the file and press OK.

8.8.2 Backup database

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

On the installation medium, a backup script can create a scheduled backup (\Admin\Backup\rotatingbackup.bat).
The script needs to be adapted to your system. The database path, firebird path and target path need to be defined. You can use the Windows task scheduler to generate an automated backup and store the backup data in a location accessible to authorised users only. Contact SCHILLER medilog for more information.

If an application is still running when you press Backup, the following warning is issued:



Press Backup in the Recording database section and specify the folder where the DB backup is to be stored.

Reports: If this box is ticked, the **medilog DARWIN2** creates a backup copy of all generated PDF reports. If you are creating the backup because you are about to update the **medilog DARWIN2**, you can untick this option. The reports are not stored in the database or modified during an update, and Unticking this option speeds up the backup.
Raw data: Tick this box to back up the ECG raw data. Backing up raw data requires a large amount of free disk space and can take a long period of time. Usually, it is unnecessary to back up raw data; when a later version of **medilog DARWIN2** is installed, the raw data is not modified at all.

Note that database backup is only possible to an empty target folder. If a file already exists in the target folder or the target folder does not exist, the backup process does not start.

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Start the backup by pressing OK. A copy of the current database and (if selected) the ECG raw data is saved in the target folder. Later, you can copy the created file(s) onto a separate backup medium.

Note that the current Administrator password is backed up together with the database. If the database is restored later, the password valid during the backup is restored automatically. If the ECG raw data and the database are to be restored, ensure that the database and the raw data are from an identical backup.

8.8.3 Restore database

Restoring the database must only be completed if no user is logged on. If need be, disconnect the network to avoid any unwanted login by other users.
During the database restore process, ensure the Observer application is not running as a background process. The Observer icon is shown in the Windows taskbar if the application is running. If necessary, close the application with a right-click on the icon. Then select the option Close from the context menu.

Press Restore in the Recording database section, enter the backup database's path and file name, and click OK to start the restore process.

8.8.4 Automatic archiving

The **medilog DARWIN2** offers a method to automatically archive recordings that have been released and not accessed for a specified period of time.
In the Admin tool, in the extended settings section Recording database, the following settings are available:

- Auto-archive age threshold
- Archive path
- Discard when archiving (optional)
- Delete .daw files after x days
- Permanently delete recordings after x days

Process:

- **Auto-archive age threshold:** All recordings marked as released and not opened for more than the specified number of days are archived to the path given in the Archive path. When archiving, if Discard is set, those recordings are not archived, but only the raw data is deleted, and the PDF remains.
- **Delete .daw files after x days:** archived recordings are deleted after the specified number of days. The database entries and the associated PDFs remain available.
- **Permanently delete recordings after x days:** database entries and the PDFs are deleted after the specified threshold.

To ensure that auto-archiving is possible, the application; ArchiveDaemon.exe must occasionally run on one of the workstations. This application can be put into the Start menu. Launching it from a Windows scheduler is recommended, ideally directly on the server and during nighttime when network usage is not an issue. To run the application manually, type; ArchiveDaemon into the Search field of

the Windows Start menu.

Attention new in V2.11.0:
When started without any parameter, ArchiveDaemon only lists all actions it would have performed using the current configuration and does not undertake any actual actions. This way, you can test your configuration. To tell ArchiveDaemon to perform the actions, call it with the command line parameter; -Execute.

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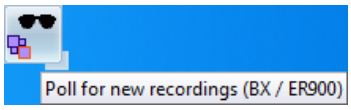
8.9 medilog Liberty Scanlab Installation and Settings

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

8.10 DARWIN Observer

The Observer is an auto-run program that permanently searches the indicated drive(s) (usually the memory card reader drive) for new recordings that have not yet been imported to **medilog DARWIN2** (refer to Local Component Setup, page 105). When a recording is found, the patient data dialogue is displayed; if you click OK, the recording is imported and analysed in the medilog DARWIN2. When the program is opened later, the recording is listed in the database view as an Uploaded recording (refer to Database Screen, page 14). This tool is therefore required for the automatic import of ECG recordings.

If a new card reader is connected to the PC and a new card reader drive is detected, Observer asks the user if this drive should as well be monitored.



The Observer must be opened for the BX and ER900 recorders; the search starts manually (see left).

8.11 Changing Administrator Password

The password for access to the Admin tool software is changed in the Password tab. Enter the current password in the text field Old password (after the initial installation: admin). Enter the new password in the text field New password and again in Retype password. It is not possible to use the clipboard to copy and paste passwords.

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

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8.12 Worklist with SCHILLER Server

For worklists via SCHILLER Server, items can be requested to be recorded by the **medilog DARWIN2**. SCHILLER Server uses device IDs to transmit such worklist items.

This applies to Holter ECG and BP recordings, including PWA. Once the recording is finished in **medilog DARWIN2**, it is transferred back to the SCHILLER Server as a PDF. When a recording is accessed in the SCHILLER Server, **medilog DARWIN2** is used to open, view and edit the recording.

For more information on SCHILLER Server integration, contact SCHILLER medilog.

8.13 Licence upgrade for medilog AR recorders

The medilog AR recorder is available in different versions, Office, Professional and Enterprise (for more information, refer to the medilog AR recorder's user guide, art. no. 2.511 345 EN).

Upgrading a recorder can be upgraded by purchasing a licence and utilizing the **medilog DARWIN2** program. To transfer the licence to the recorder, you must proceed as follows:

1. Connect the recorder via a USB port to the PC where the **medilog DARWIN2** is installed
2. Start the recorder configuration tool (refer to Configuration of medilog AR recorders, page 16)
3. Select medilog AR recorder
4. Make sure that the recorder you want to upgrade is selected
5. Right-click on the Star icon (that is, the button that shows the recorder's current version)
6. Select Install recorder licence from the popup menu. The recorder ID (unique identifier) is shown in a window:

7. Send the recorder ID to your Schiller representative. A licence code is then returned to you.
8. Enter the licence code into the appropriate field and click the green arrow. The recorder is updated immediately.

The licence is permanently valid and tied to a specific recorder, and it is not dependent on the **medilog DARWIN2** or the database.

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10 Appendix - Symbols

This appendix lists all general symbols that may be present on the device, label and accessories. Not all of those symbols are necessarily present on your device.

This appendix has its own article number, which is independent of the user guide's article number.

	Identification of the manufacturer
	Identification of the manufacturing date
	Identification of the distributor
	Identification of the importer
MD	Medical device
SN	Serial number
REF	Reference number
LOT	Batch code
GTIN	Global Trade Item Number
CAT	Catalogue number
QTY	Quantity
UDI	UDI: unique device identification as QR code machine readable and human readable as number (e.g. (01) 0 7613365 00210 2 (21)xxxx.xxxxxx)
	Number of pieces in the packaging
EC REP	Authorised European representative
CE XXXX	Notified body (e.g. CE 0123 marking notified body TÜV SÜD)

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	UKCA marking (UK Conformity Assessed)
	CE marking, affirms its conformity with European standards
	NRTL symbol (Nationally Recognised Testing Laboratory) TÜV SÜD as accredited NRTL certification provider
	Regulatory Compliance Mark for the Australian standards
	The device is recyclable
	Symbol for the recognition of electrical and electronic equipment. Device must not be disposed of in the household waste.
	Symbol for the recognition of a battery. Battery must not be disposed of in the household waste.
	The packaging is made in low density polyethylene and can be recycled.
	Federal law (USA) restricts this device to sale by or on the order of a physician
	Non ionising electromagnetic radiation. To indicate that the device contains a Radio Frequency (RF) transmitter to transmit data (e.g Bluetooth or WiFi)
	Contains a Bluetooth module
	Do not reuse
	Latex-free
	Use-by date (expiry date of battery, electrodes or other consumables)
	Temperature range for storage or transport, respectively
	Pressure range for storage or transport, respectively
	Humidity range for storage or transport, respectively

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	Consult instruction for use (indicates the need for the user to consult the instructions for use)
	Use within X days after opening (electrodes or other consumables)
	Keep dry (store in a dry location)
	Keep away from sunlight (protect from direct sunlight)
	Fragile, handle with care
	Transport upwards (this way up)
	Do not use hooks
	EIP = electronic information product (does not contain any toxic and hazardous substances or elements above the maximum concentration values (product can be recycled and re-used)).

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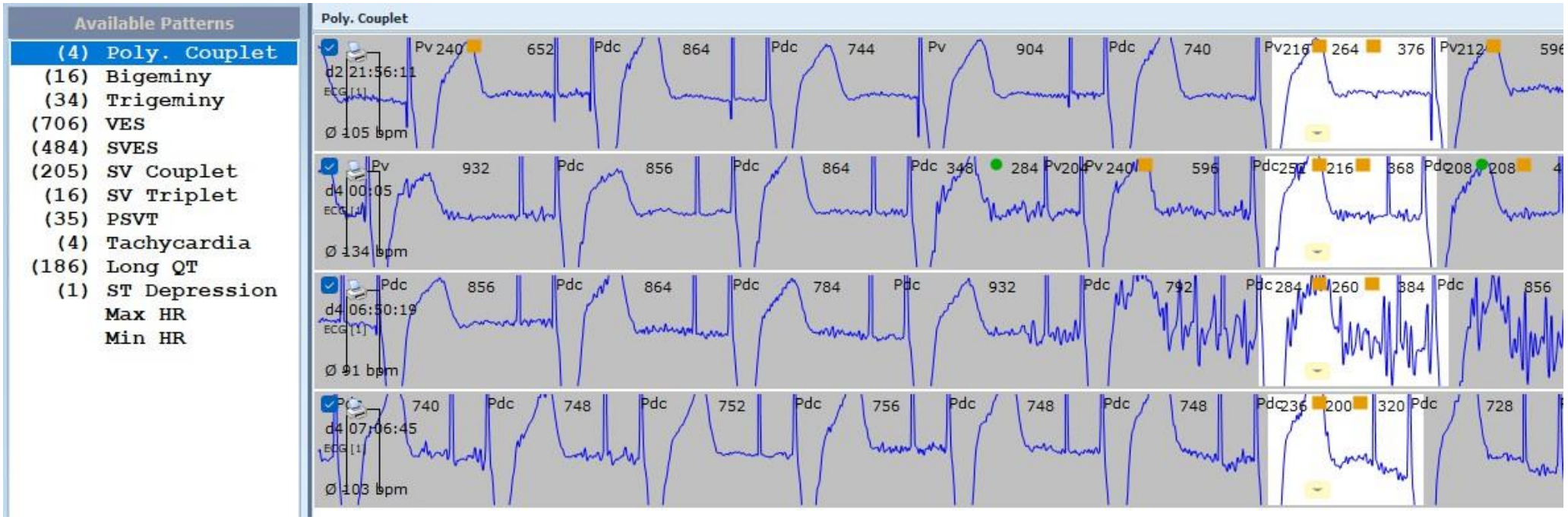
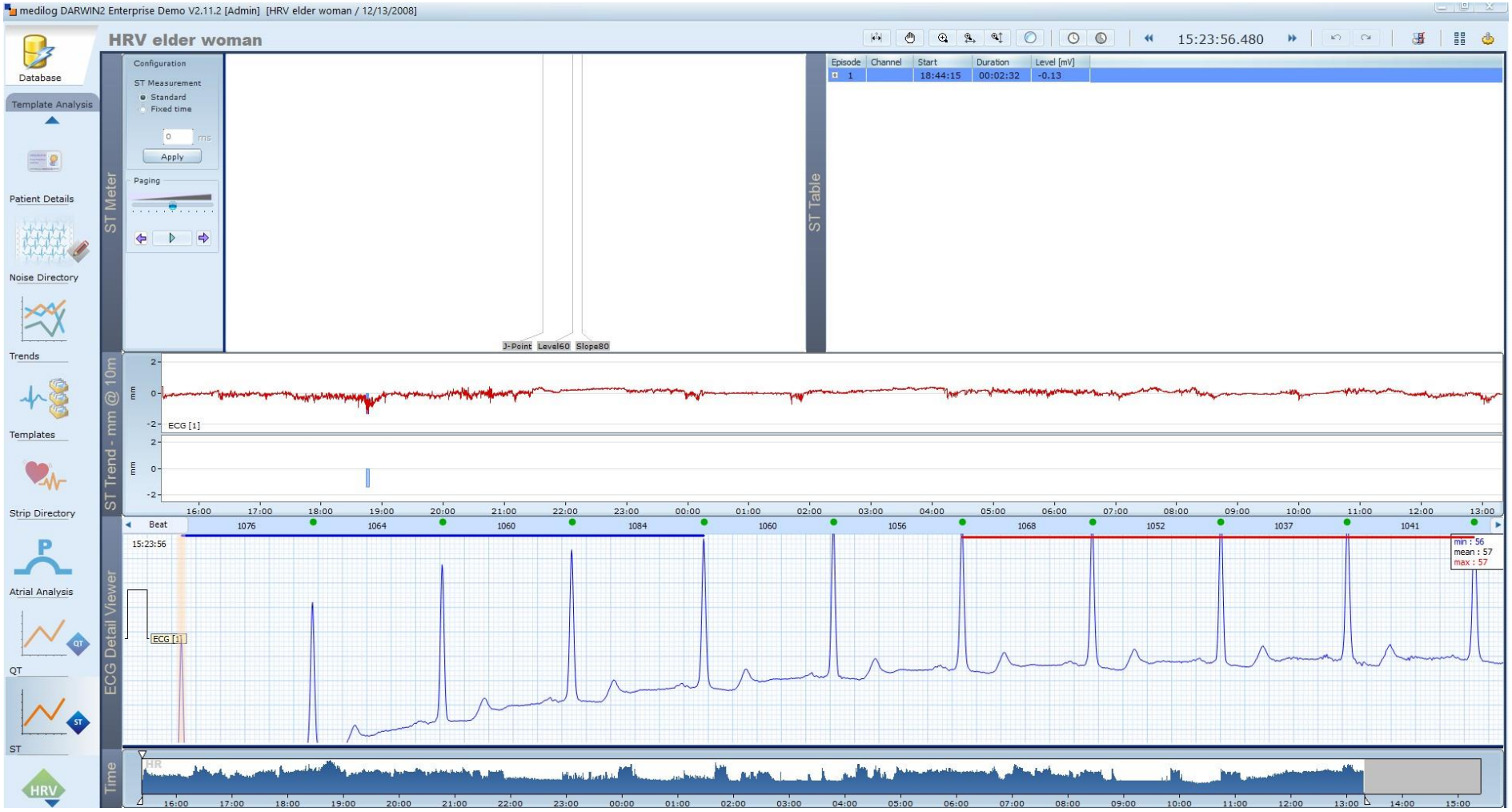
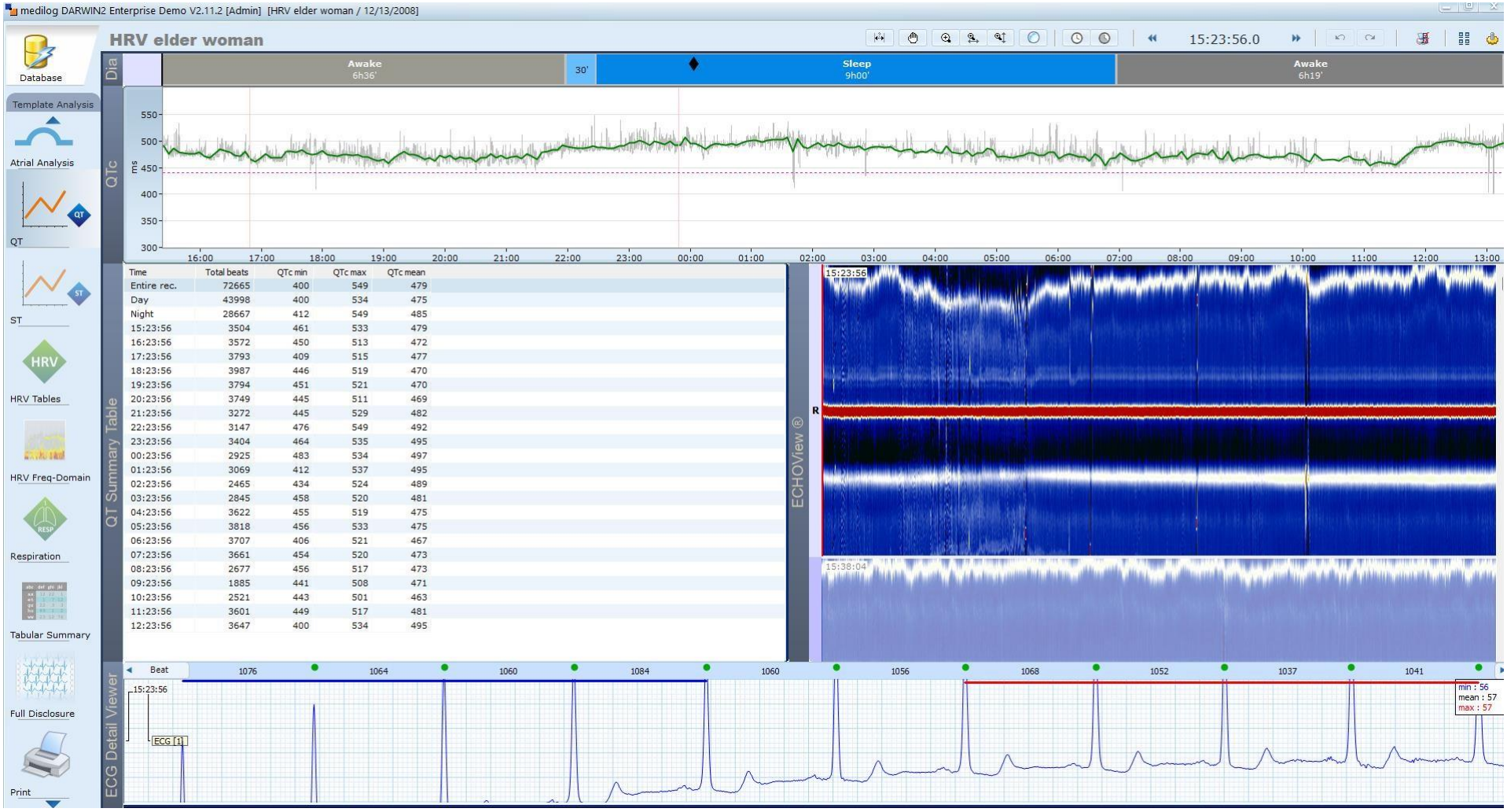
Clasificare de evenimente obligatoriu



Analiza ST


medilog DARWIN2 Enterprise Demo V2.11.2 [Admin] [HRV elder woman / 12/13/2008]
HRV elder woman
15:23:56.480
Database
Template Analysis
Patient Details
Noise Directory
Trends
Templates
Strip Directory
Atrial Analysis
QT
ST
HRV
ST Meter
Configuration
ST Measurement
Standard
Fixed time
Apply
Paging
J-Point
Level60
Slope80
ST Table
Episode
Channel
Start
Duration
Level [mV]
1
18:44:15
00:02:32
-0.13
ST Trend - mm @ 10m
ECG [1]
ECG Detail Viewer
Beat
1076
1064
1060
1084
1060
1056
1068
1052
1037
1041
15:23:56
min : 56
mean : 57
max : 57
Time
HR

Analiza QT


medilog DARWIN2 Enterprise Demo V2.11.2 [Admin] [HRV elder woman / 12/13/2008]
HRV elder woman
15:23:56.0
Database
Template Analysis
Atrial Analysis
QT
ST
HRV Tables
HRV Freq-Domain
Respiration
Tabular Summary
Full Disclosure
Print
Dia
Awake 6h36'
30'
Sleep 9h00'
Awake 6h19'
QTc
ms
550
500
450
400
350
300
16:00 17:00 18:00 19:00 20:00 21:00 22:00 23:00 00:00 01:00 02:00 03:00 04:00 05:00 06:00 07:00 08:00 09:00 10:00 11:00 12:00 13:00
QT Summary Table
Time Total beats QTc min QTc max QTc mean
Entire rec. 72665 400 549 479
Day 43998 400 534 475
Night 28667 412 549 485
15:23:56 3504 461 533 479
16:23:56 3572 450 513 472
17:23:56 3793 409 515 477
18:23:56 3987 446 519 470
19:23:56 3794 451 521 470
20:23:56 3749 445 511 469
21:23:56 3272 445 529 482
22:23:56 3147 476 549 492
23:23:56 3404 464 535 495
00:23:56 2925 483 534 497
01:23:56 3069 412 537 495
02:23:56 2465 434 524 489
03:23:56 2845 458 520 481
04:23:56 3622 455 519 475
05:23:56 3818 456 533 475
06:23:56 3707 406 521 467
07:23:56 3661 454 520 473
08:23:56 2677 456 517 473
09:23:56 1885 441 508 471
10:23:56 2521 443 501 463
11:23:56 3601 449 517 481
12:23:56 3647 400 534 495
ECHOView ®
15:23:56
R
15:38:04
ECG Detail Viewer
Beat
1076 1064 1060 1084 1060 1056 1068 1052 1037 1041
15:23:56
ECG [1]
min : 56
mean : 57
max : 57

Analiza PM

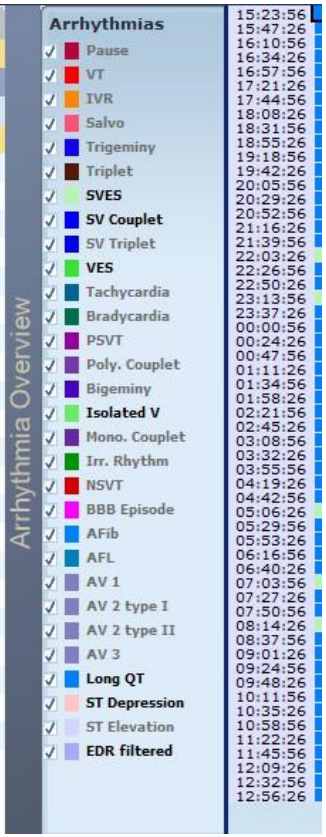
Pacemaker Events

max HR: **104bpm @ d4 06:59:50**

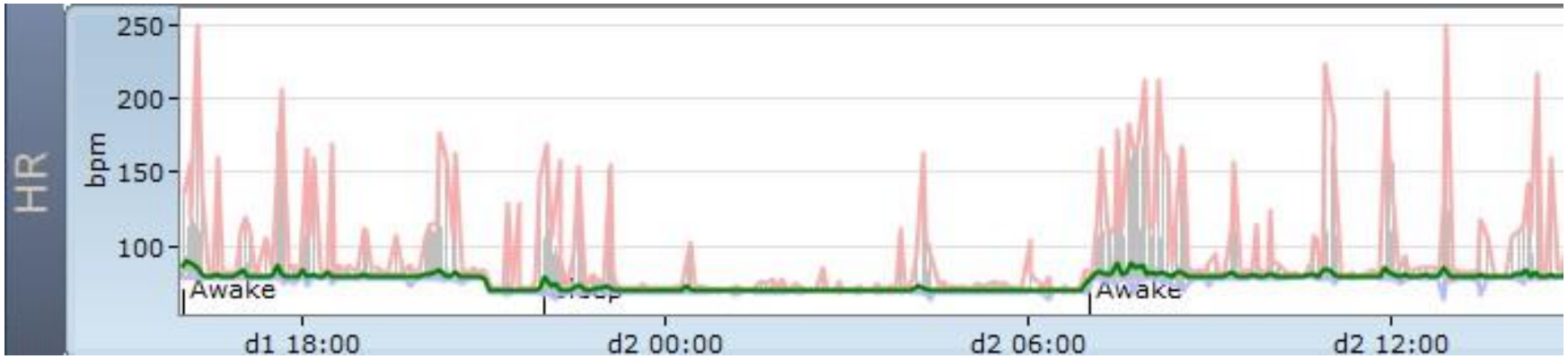
Time	Min HR	Mean HR	Max HR	Tachycardia	PS VT	SV ES	SV Couplet	SV Triplet	Poly. Couplet	Bigeminy	Trigeminy	VES	SV beats	N - SV beats	total N	total V	Validity [%]	Total beats	Undef. paced	Fusion	Pa	Pv	Pdc	PM [FTC]	PM [FTS]	Total paced
Entire rec.	68	76	104	4	35	484	205	16	4	16	34	706	94	88	182	837	100	293617	3	405	30	3307	288853	22	1342	292598
Sleep	68	70	104		8	232	23	7	2	3		93	32	21	53	107	100	113751	1	128	5	2055	111402	4	143	113591
Awake	69	80	103		27	252	182	9	2	13	34	613	62	67	129	730	100	179866	2	277	25	1252	177451	18	1199	179007
d1 15:59	79	80	81										0	0	0	0	100	30	0	0	0	0	30	0	0	30
d1 16:00	79	82	99			14	4	1			5	29	1	1	2	40	100	4961	0	11	0	460	4448	0	46	4919
d1 17:00	79	80	91		1	8	6					26	4	1	5	26	100	4867	0	6	1	7	4822	1	42	4836
d1 18:00	79	80	86		1	5	1			1		22	1	1	2	25	100	4842	0	2	0	10	4803	0	31	4815
d1 19:00	79	80	86			4	3					2	0	0	0	2	100	4809	0	3	1	10	4793	0	6	4807

Analiza aretmiilor obligatoriu

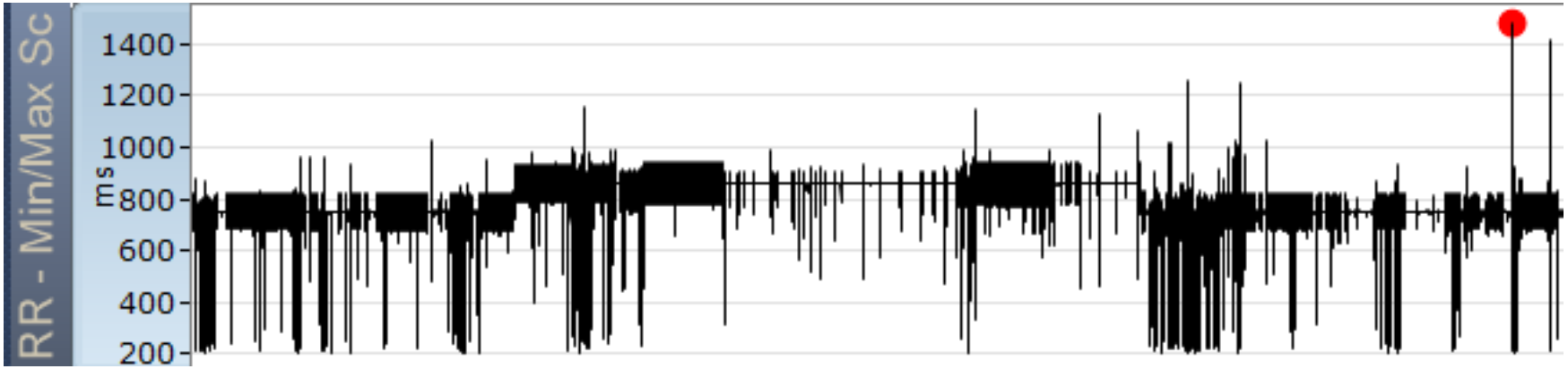
Time	Min HR	Mean HR	Max HR	SVES	SV Couplet	VES	Isolated V	SV beats	N - SV beats	total N	total V	User	Validity [%]	Total beats
Entire rec.	44	59	97	218	1	2	9	220	77726	77946	11	1	100	77957
Sleep	44	58	90	110		1	5	110	30995	31105	6	1	100	31111
Awake	45	60	97	108	1	1	4	110	46731	46841	5		100	46846
15:23	54	59	71	3				3	2116	2119	0		100	2119
16:00	51	60	74	6				6	3598	3604	0		100	3604
17:00	51	61	81	4		1		4	3647	3651	1		100	3652
18:00	54	68	90	10				10	4061	4071	0		100	4071
19:00	54	62	71	1				1	3735	3736	0		100	3736
20:00	54	63	77	4				4	3788	3792	0		100	3792
21:00	45	61	95	34				34	3631	3665	0		100	3665
22:00	46	53	72	34			1	34	3191	3225	1		100	3226
23:00	44	56	81	29				29	3355	3384	0		100	3384
00:00	45	56	76	6				6	3379	3385	0	1	100	3385
01:00	44	58	78	7				7	3489	3496	0		100	3496
02:00	45	56	76	15			1	15	3339	3354	1		100	3355
03:00	46	52	74	2			1	2	3117	3119	1		100	3120
04:00	50	60	78	3				3	3626	3629	0		100	3629
05:00	58	64	90	6		1	1	6	3826	3832	2		100	3834
06:00	51	61	87	8			1	8	3673	3681	1		100	3682
07:00	55	63	97	7				7	3783	3790	0		100	3790
08:00	48	58	77	17	1		1	19	3478	3497	1		100	3498
09:00	47	53	73	8				8	3161	3169	0		100	3169
10:00	45	53	72	7			2	7	3148	3155	2		100	3157
11:00	50	57	69	3			1	3	3434	3437	1		100	3438
12:00	57	64	77	3				3	3852	3855	0		100	3855
13:00	62	67	76	1				1	1299	1300	0		100	1300



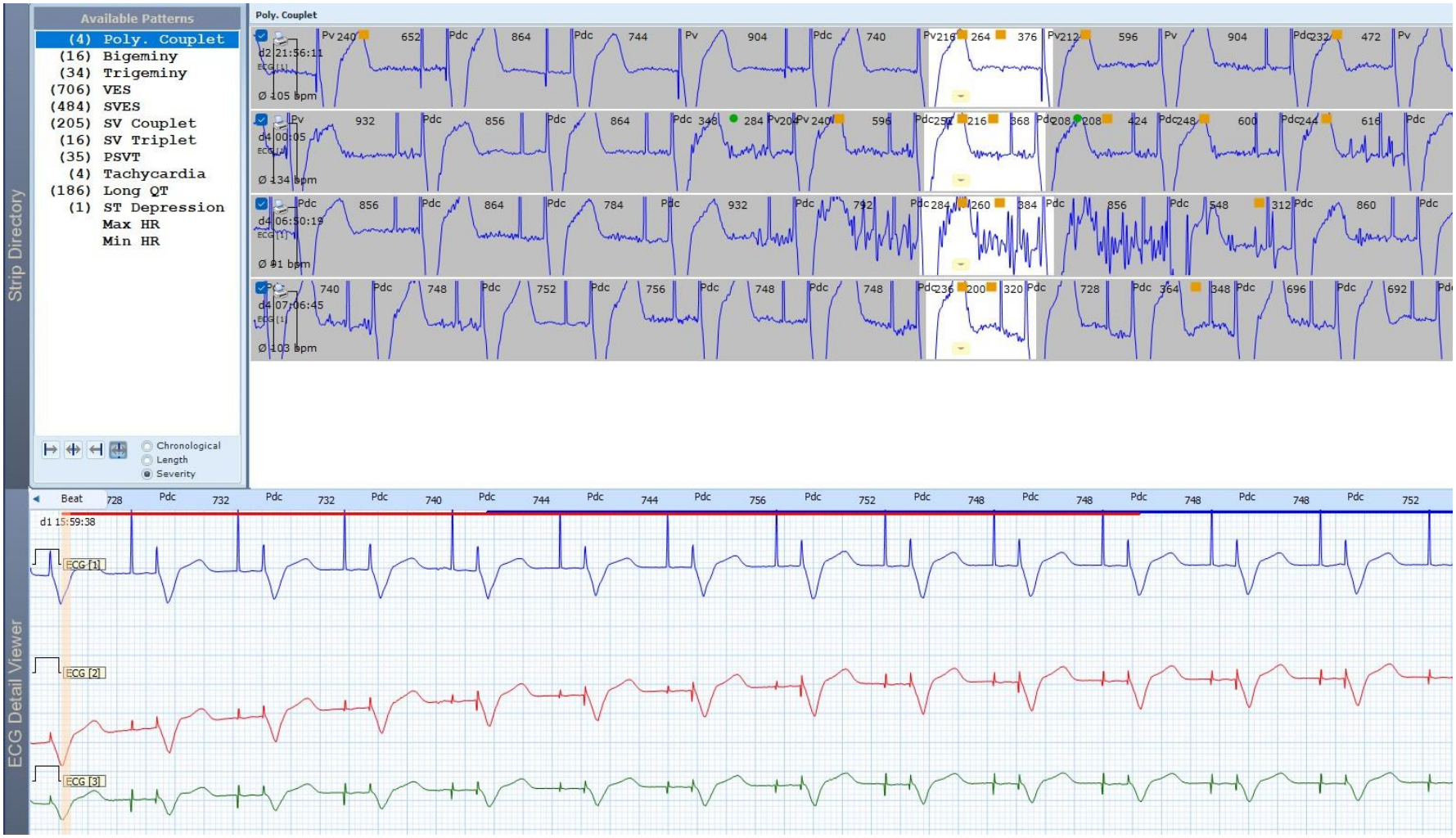
Variabilitatea ritm cardiac dupa timp



Variabilitatea ritm cardiac dupa frecventa



Reprezentarea grafica a datelor



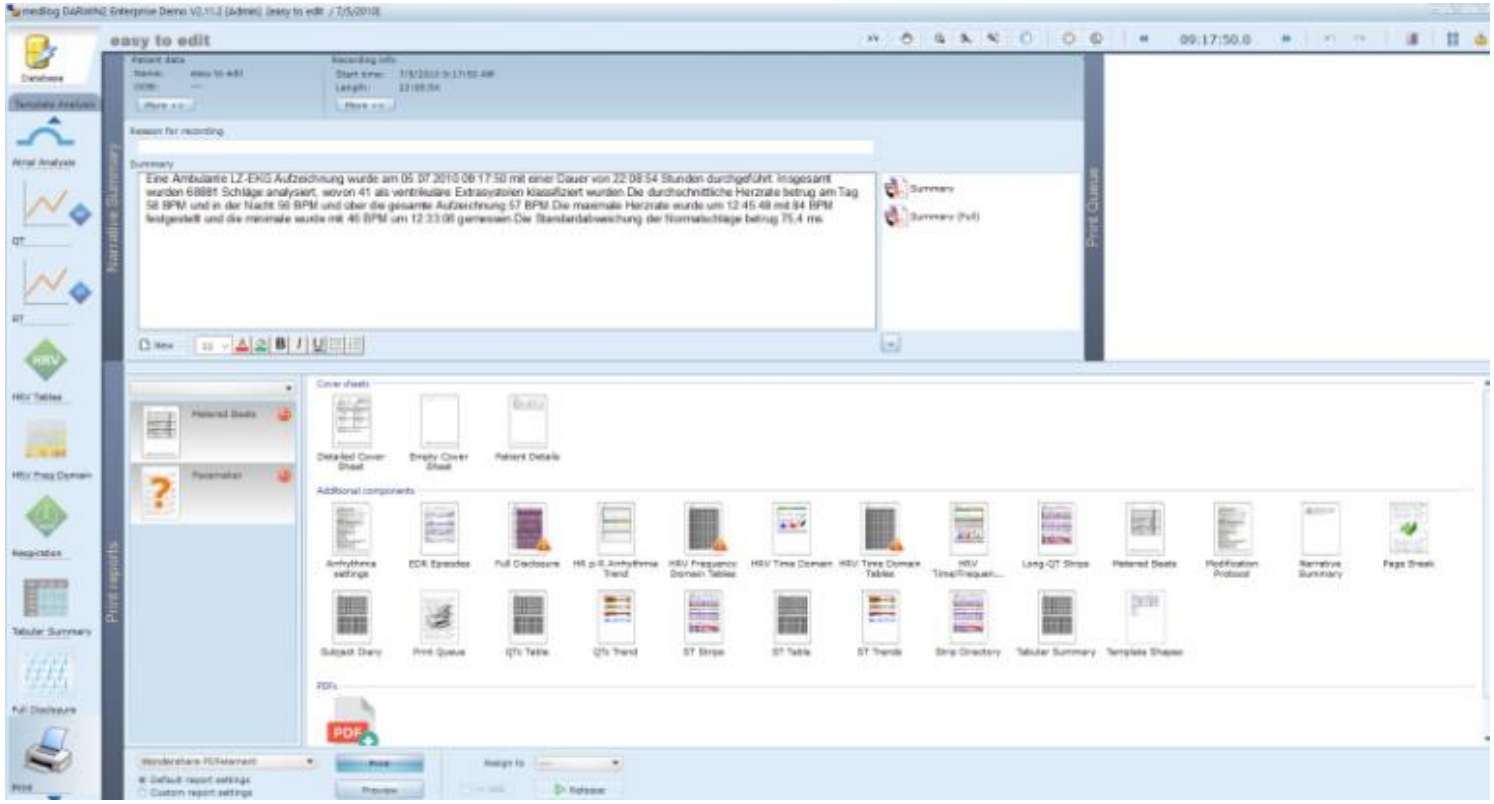
Reprezentarea tabelAra a datelor

Tabular Summary

Time	Min HR	Mean HR	Max HR	Tachycardia	PSVT	SVES	SV Couplet	SV Triplet	Poly. Couplet	Bigeminy	Trigeminy	VES	SV beats	N - SV be
Entire rec.	68	76	104	4	35	484	205	16	4	16	34	706	94	88
Sleep	68	70	104		8	232	23	7	2	3		93	32	21
Awake	69	80	103		27	252	182	9	2	13	34	613	62	67
d1 15:59	79	80	81										0	0
d1 16:00	79	82	99			14	4	1			5	29	1	1
d1 17:00	79	80	91		1	8	6					26	4	1
d1 18:00	79	80	86		1	5	1			1		22	1	1
d1 19:00	79	80	86			4	3					2	0	0
d1 20:00	79	80	91			9	2				1	29	1	2
d1 21:00	69	71	81		2	7						2	0	0
d1 22:00	69	72	84		2	47	3	3				21	11	4
d1 23:00	69	70	83			13						4	0	4
d2 00:00	69	70	92			1						1	0	0
d2 01:00	69	70	72			8							0	0
d2 02:00	69	70	75			3						1	0	0
d2 03:00	69	70	71			6							0	0
d2 04:00	69	70	80			21	3	1				12	2	1
d2 05:00	69	70	71			12							0	0
d2 06:00	69	70	81			3		1				2	1	0
d2 07:00	79	81	99			12	23	1		2	4	91	3	13
d2 08:00	78	81	91		2	17	2					16	4	3
d2 09:00	79	80	92		1	3	2					9	0	1
d2 10:00	79	80	90			3	4					13	1	3
d2 11:00	79	80	88			5	2			2	2	16	0	2
d2 12:00	73	81	95		2	6	2				1	6	4	1
d2 13:00	79	80	85			3	4					2	1	0
d2 14:00	79	81	89		1	2	6				1	19	2	0

JKJ

Raport presetabil de utilizator/Interfata presetabila utilizator



Electrozi adulti-50RLI

Electrozi pediatrici-30RFI

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CH-6341 Baar, 18.06.2025

To: Center for Centralized Public Procurement in Health

For tender nr: 21396977

Date of tender 08.04.2025

CONFIRMATION LETTER

The company Schiller AG confirms, that the 12- lead ECG Holter, model medilog FD fits and complies with the requirements of the public tender.

Requested technical specification	Confirmation of the requested technical specification
Frequency range Diagnostic 0.05-100 Hz	YES
Input impedance ≥ 100 Mohm	YES
Common mode rejection range at 50 Hz > 100 dB	YES
Automatic button lock required	YES, after the recording starts, the device screen turns off and stopping the recording is only possible if both buttons are pressed at the same time, for no less than 5 seconds. The unintentional disconnection of the device is impossible.

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Yours sincerely,

Mircea Dumitrescu

International Sales Manager.