Anexa 1

Specificație Tehnică Completată

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

Specificarea tehnică deplină solicitată, Standarde de referință	Specificația tehnică propusă de ofertant
Monitor Holter ECG (caracteristici avansate) Cod 260270 Descriere Dispozitivul înregistrează ECG in 12 derivații simultan, nictimeral monitorizind parametrii in timpul repaosului si la efort. Parametrul Specificația Tip pacient adult, pediatric Numărul de canale de procesare 12 Configurația Portabil obligatoriu Derivațiile Tip înregistrare automat Gama de frecvență De diagnostic 0.05-100 Hz Impendanța de intrare ≥ 100 MOhm Gama de rejecție a modului comun la 50 Hz > 100 dB Detectare pacemaker obligatoriu Frecvența maximă de eșantionare (sampling rate) de achiziție ≥ 1200 Hz Frecvența ajustabilă obligatoriu Rezoluția ADC (Convertor Analog/Digital) ≥ 14 bit Ecran LCD obligatoriu lumină fundal opțional Date ecran ora obligatoriu statut baterie obligatoriu Indicator deconectare electrod acustic sau vizual obligatoriu Buton evenimente obligatoriu Buton navigare meniu ≥1	Monitor Holter ECG (caracteristici avansate) Cod 260270 Descriere Dispozitivul înregistrează ECG in 12 derivații simultan, nictimeral monitorizind parametrii in timpul repaosului si la efort. **DA, pag.2 din medilog FD brosura** Parametrul Specificația Tip pacient adult, pediatric **DA, pag.9 din medilog FD manual** Numărul de canale de procesare 12 **DA, pag.1 din medilog FD brosura** Configurația Portabil obligatoriu **DA, pag.2 din medilog FD brosura** Derivațiile Tip înregistrare automat **DA, pag.2 din medilog FD brosura** Gama de frecvență De diagnostic 0.05-100 Hz **DA** Impendanța de intrare ≥ 100 MOhm **DA** Gama de rejecție a modului comun la 50 Hz > 100 dB **DA** Detectare pacemaker obligatoriu **DA, pag.5 din medilog FD brosura** Frecvența maximă de eșantionare (sampling rate) de achiziție **DA 32000 Hz, pînă la 128000 în scientific mode** Frecvența ajustabilă obligatoriu **DA, pag.5 din medilog FD brosura** Rezoluția ADC (Convertor Analog/Digital) **16.5 bit, pag.5 din medilog FD brosura** Ecran **OLED 36 x 26.9 mm (1.4 x 1.0 inches) with 160*128 pixels DA, pag.74 din medilog FD manual** lumină fundal **DA, pag. 32 din medilog FD manual** Date ecran ora obligatoriu **DA, pag. 33 din medilog FD manual** statut baterie obligatoriu **DA, pag. 32 din medilog FD manual** Indicator deconectare electrod acustic sau vizual obligatoriu **DA, pag. 3 din medilog FD brosura** Buton evenimente obligatoriu **DA, pag. 2 din medilog FD prezentare** Buton navigare meniu 2 **DA, pag. 2 din medilog FD prezentare**

Anexa 1

Blocarea automată a butoanelor obligatoriu	Blocarea automată a butoanelor obligatoriu **DA**
Posibilitatea transmiterii datelor ECG la PC sau notebook USB / SD-Card / Wi-Fi / BT	Posibilitatea transmiterii datelor ECG la PC **DA, pag.5 din medilog FD prezentare**
Baterie reîncărcabilă obligatoriu	Baterie reîncărcabilă obligatoriu **DA, pag.5 din medilog FD brosura**
tip baterie AA sau AAA	tip baterie AAA **DA, pag.5 din medilog FD brosura**
Tip operare autonomă ≥ 72 ore	Tip operare autonomă **≥ 120 ore DA, pag.5 din medilog FD brosura**
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**
Introducere date pacient obligatoriu	Introducere date pacient obligatoriu **DA, pag.36 din medilog FD manual**
Adnotare eveniment ECG obligatoriu	Adnotare eveniment ECG obligatoriu **DA, pag.47 din medilog FD manual**
Clasificarea de evenimente obligatoriu	Clasificarea de evenimente obligatoriu **DA, Prezentare soft DARWIN**
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**
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 Cablu ECG ≥ 3 unități	Accesorii Cablu ECG ≥ 3 unități **DA**
Set de electrozi de unica folosinta adult ≥ 500 buc.	Set de electrozi de unica folosinta adult 500 buc. **DA**
Set de electrozi de unica folosinta pediatric ≥ 500 buc.	Set de electrozi de unica folosinta pediatric 500 buc. **DA**
Soft necesar pentru analiza Holter ECG pe PC inclus cu cheie de acces, licență cu un termen nelimitat de utilizare obligatoriu	Soft necesar pentru analiza Holter ECG pe PC inclus cu cheie de acces, licență cu un termen nelimitat de utilizare obligatoriu **DA**
Sursa de alimentare pentru reîncărcarea bateriilor obligatoriu	Sursa de alimentare pentru reîncărcarea bateriilor obligatoriu **DA**

medilogFD

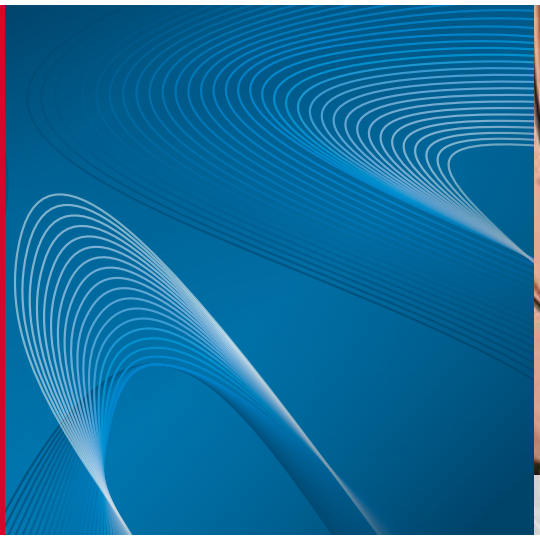
The 12-lead Holter ECG for a spatial heart health analysis

SCHILLER
The Art of Diagnostics

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.

Americas
SCHILLER Americas Inc.
Doral, Florida 33172

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

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

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

Austria
SCHILLER Handelsgesellschaft m.b.H.
A-4040 Linz
Phone +43 732 70 99 0
sales@schiller.at
www.schiller.at

China
Alfred Schiller (Beijing) Medical Technology Co., Ltd.
100102 Beijing, China
Phone +86 10 84565453
info@schillerchina.com
www.schillermedical.cn

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

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

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

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

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

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

Russia & C.I.S.
AO SCHILLER.RU
119049 Moscow, Russia
Phone +7 (495) 970 11 33
mail@schiller.ru
www.schiller.ru

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

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

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

Switzerland
SCHILLER Schweiz AG
CH-8912 Obfelden
Phone +41 44 744 30 00
sales@schiller-schweiz.ch
www.schiller-schweiz.ch

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

United Kingdom
SCHILLER UK Ltd.
Anstruther, Fife KY10 3H
Phone +44 1333 312150
sales@schilleruk.com
www.schilleruk.com

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

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

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.

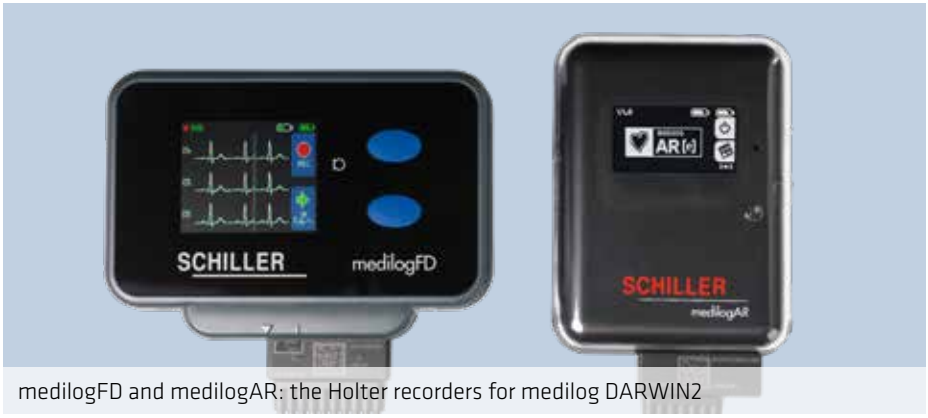
- Instantaneous atrial fibrillation detection
- Respiration analysis
- Recording upload from remote locations

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

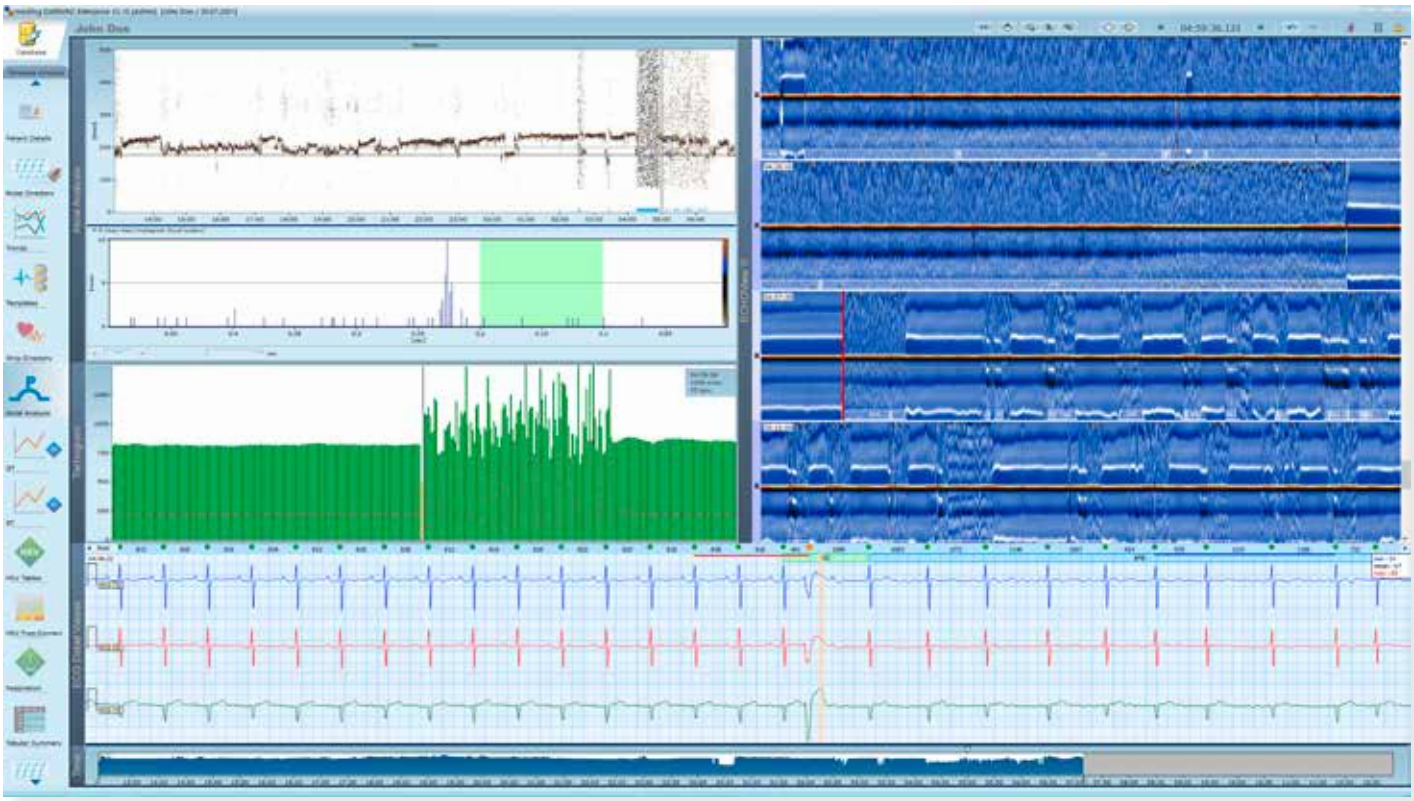
The high-end medilog recorders offer unparalleled signal quality in Holter recordings. Using state-of-the-art amplifiers with up to 32,000/128,000 Hz and advanced filter technology, the medilog recorders detect P waves in real time. When using medilogAR Professional, medilogAR Enterprise, or medilogFD, 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

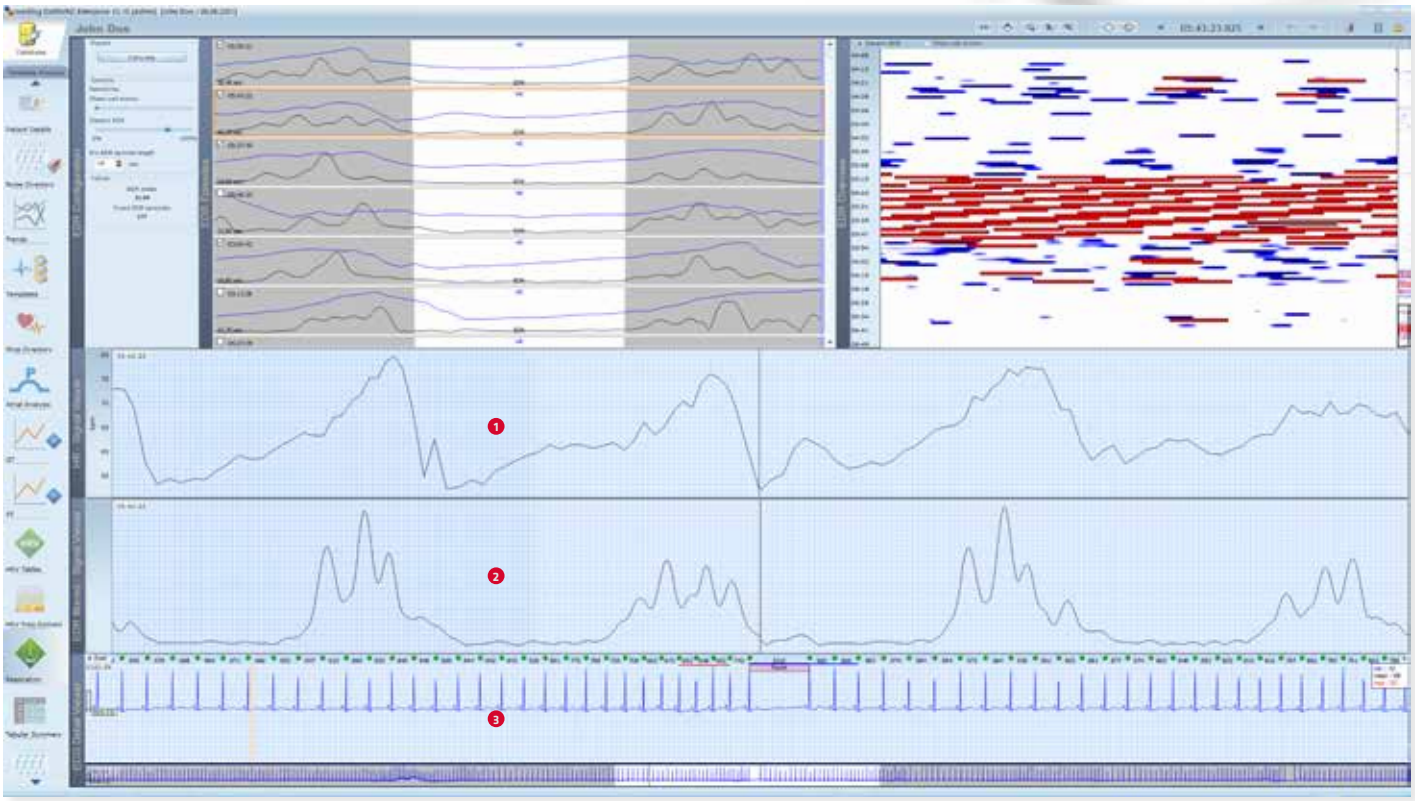
SYNCHRONISED ECG AND RESPIRATION CURVES

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.

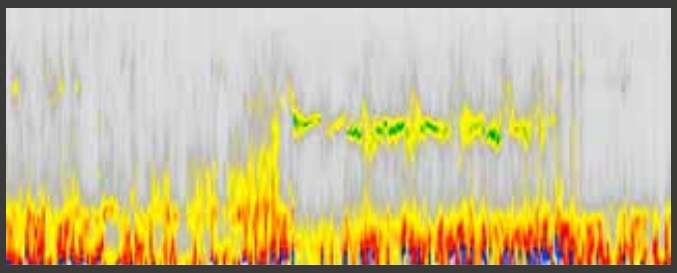
Fire of Life is a very intuitive visual presentation of frequency-domain HRV that makes the assessment of 24-hour results fast and simple.

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.

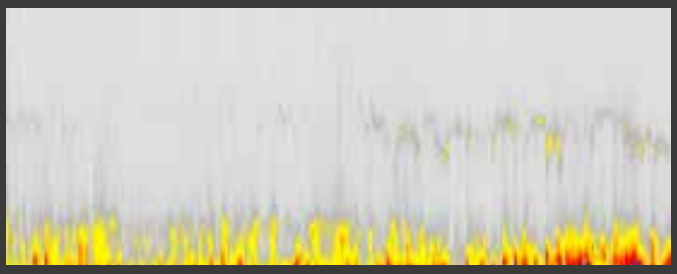
The Fire of Life evaluation is available with the recorders medilogAR Professional, medilogAR Enterprise and medilogFD and with the software versions medilog DARWIN2 Professional and medilog DARWIN2 Enterprise.

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

Americas
SCHILLER Americas Inc.
Doral, Florida 33172

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

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

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

Austria
SCHILLER Handelsgesellschaft m.b.H.
A-4040 Linz
Phone +43 732 70 99 0
sales@schiller.at
www.schiller.at

China
Alfred Schiller (Beijing) Medical Technology Co., Ltd.
100102 Beijing, China
Phone +86 10 84565453
info@schillerchina.com
www.schillermedical.cn

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

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

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

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

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

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

Russia & C.I.S.
AO SCHILLER.RU
119049 Moscow, Russia
Phone +7 (495) 970 11 33
mail@schiller.ru
www.schiller.ru

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

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

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

Switzerland
SCHILLER Schweiz AG
CH-8912 Obfelden
Phone +41 44 744 30 00
sales@schiller-schweiz.ch
www.schiller-schweiz.ch

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

United Kingdom
SCHILLER UK Ltd.
Anstruther, Fife KY10 3H
Phone +44 1333 312150
sales@schilleruk.com
www.schilleruk.com

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DESIGNED AND MANUFACTURED IN EUROPE

SCHILLER
The Art of Diagnostics

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

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

SCHILLER AG
Altgasse 68
CH-6341 Baar, Switzerland

Phone: +41 (0) 41 766 42 42
Fax: +41 (0) 41 761 08 80
E-mail: sales@schiller.ch
Web: www.schiller.ch

EC REP

Schiller Medizintechnik GmbH
Otto-Lilienthal-Ring 4
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.

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The Art of Diagnostics

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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

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It can also be used to:

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

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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

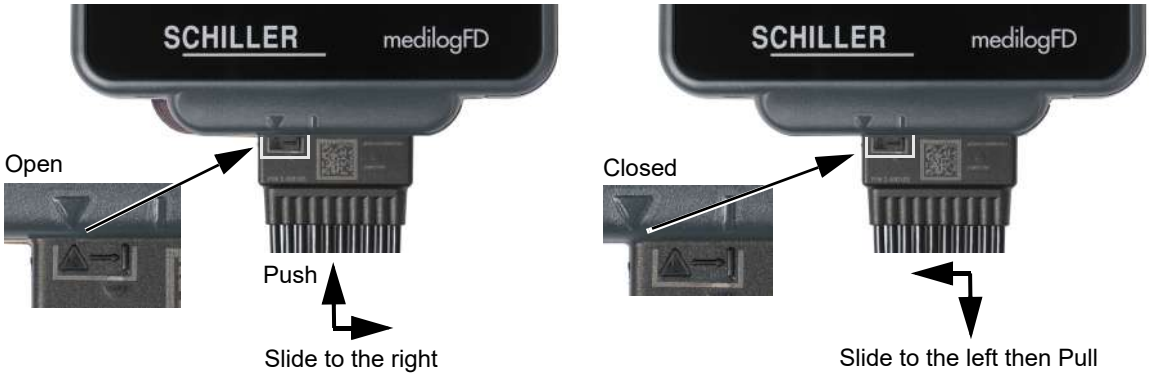
Only use the compatible patient cable supplied by Schiller.

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

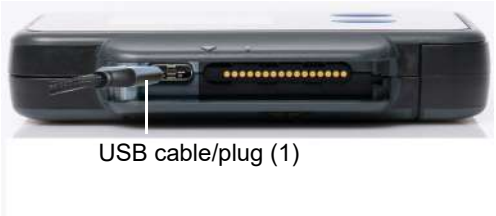
▲ Do not use the recorder or associated cables if any damage is apparent.

- 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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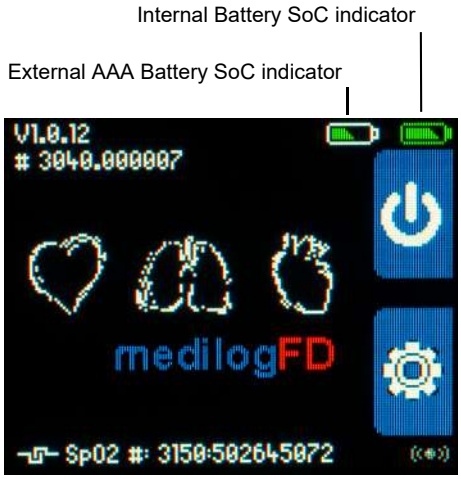
4.4 Power Supply

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.

Art. no. 2.511585 Rev. a

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).

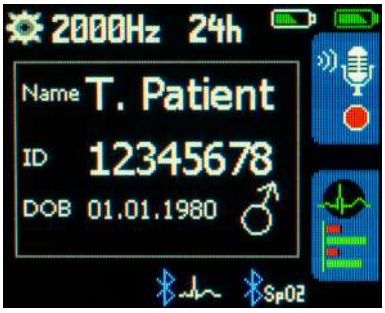
In addition, the recorder can be switched on:

- 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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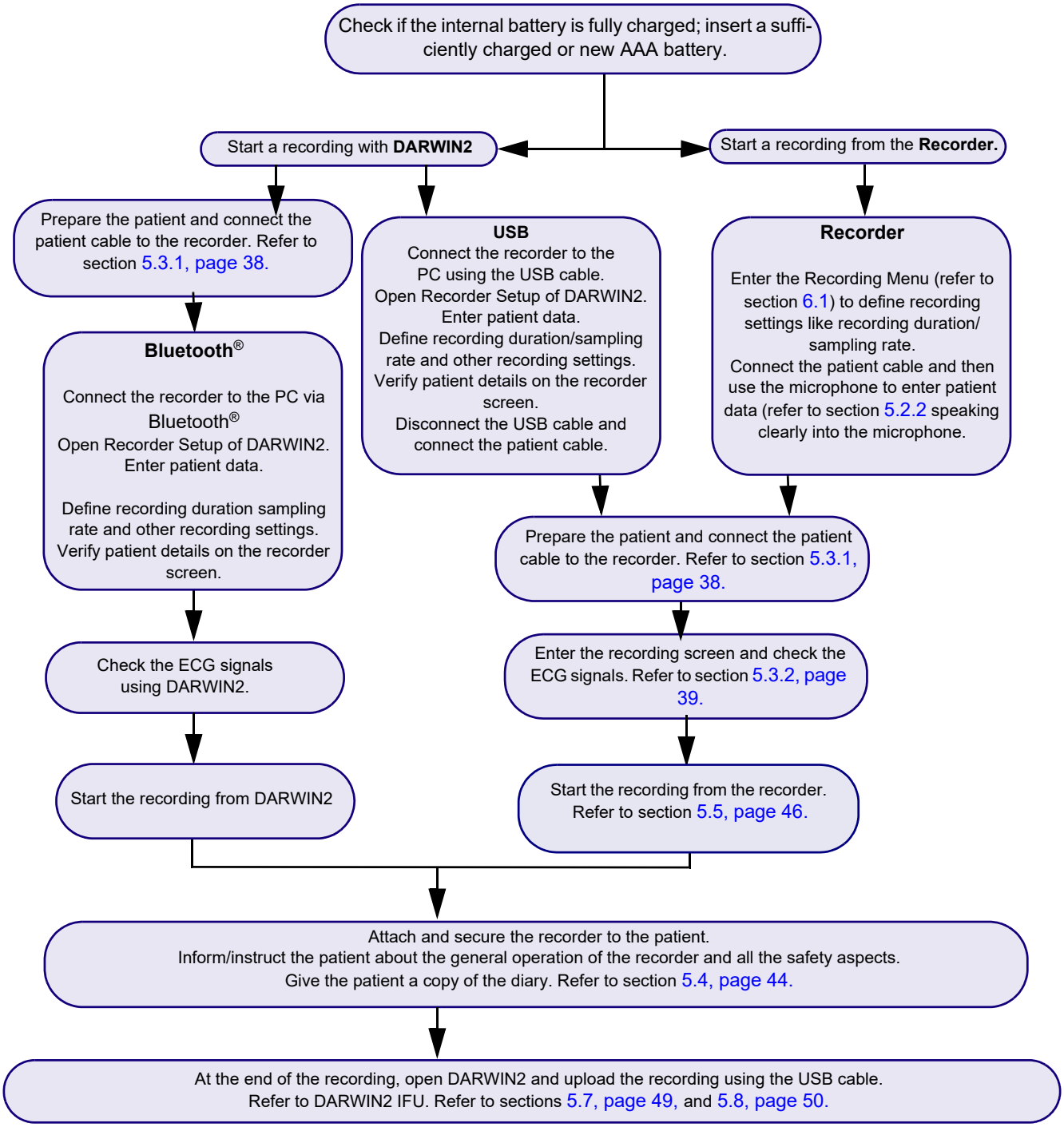
5 Recording

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.

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▲ 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

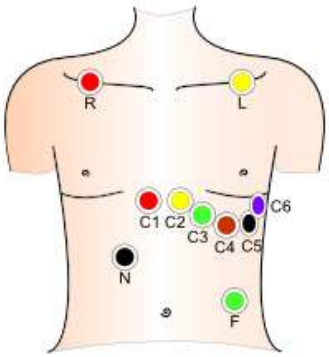
Precordial Electrodes

1. Place these electrodes in their standard placement guidelines:

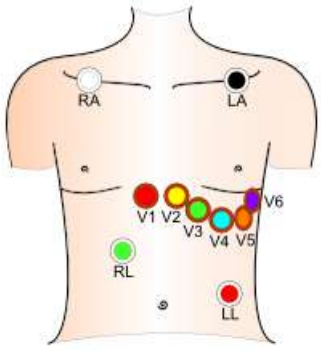
IEC Label	AHA Label		Electrode Placement
C1 white / red	V1 brown / red	➜	Fourth intercostal space at the right sternal border
C2 white / yellow	V2 brown / yellow	➜	Fourth intercostal space at the left sternal border
C3 white / green	V3 brown / green	➜	Midway between C2 and C4
C4 white / brown	V4 brown / 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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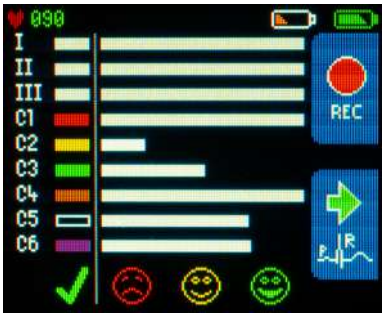
5.3.3 Lead test and ECG signal checks

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

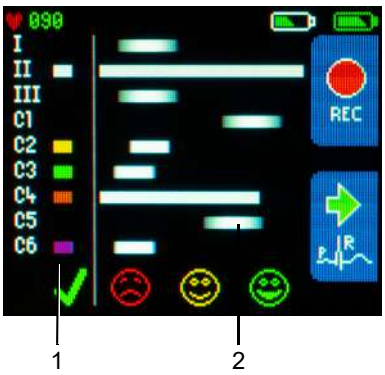
The lead test/signal quality evaluation screen (left) indicates lead connectivity, channel quality, lead and electrode resistance, and the first screen the user sees while attaching the electrodes to the patient. For precise signal quality evaluation, patients must be at rest and relaxed.

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.

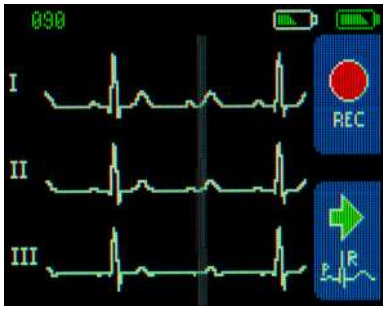


Skin contact quality

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.

Art. no. 2.511585 Rev. a



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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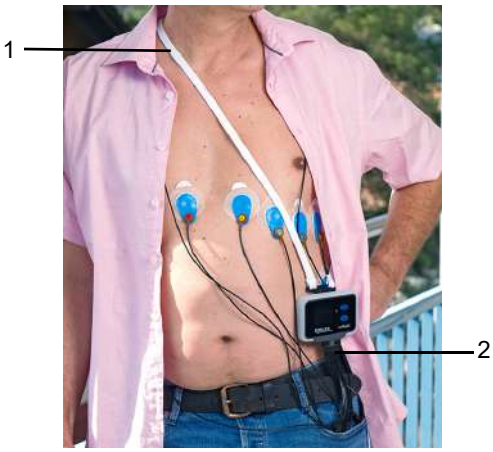
5.4.4 Assemble the carrying solution

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

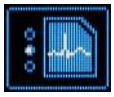
Navigation and configuration symbols used within the configuration menus are generally self-explanatory.

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.

Art. no. 2.511585 Rev. a

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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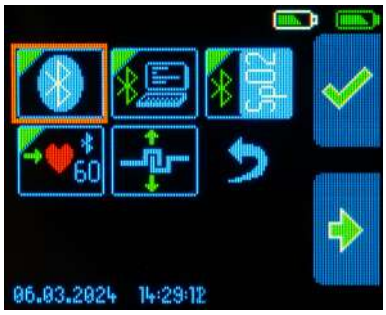
6.4 Bluetooth® Menu

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.

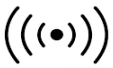
2. Press the LOWER button to select the PC Mode symbol (left) if not already selected. Now press the UPPER button, a sub-menu appears.

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.

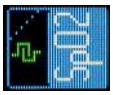
4. All devices are now disconnected. The green marker on the Bluetooth symbol (left) is removed.

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

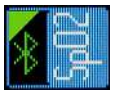
Sensor pairing:

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.

Art. no. 2.511585 Rev. a

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	-	☒

Art. no. 2.511585 Rev. a

7.3 Spare Parts

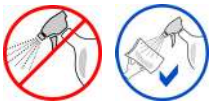
Part Number	Description	Applied parts	optional skin contact
4.435414	Carrying case (for patient attachment)	-	☒
4.310735	Battery compartment cover	☒	☒

Art. no. 2.511585 Rev. a

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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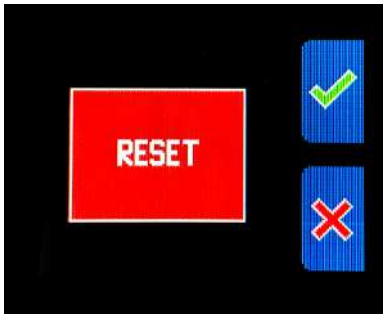
10.2 Trouble Shooting

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.

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- ▲ 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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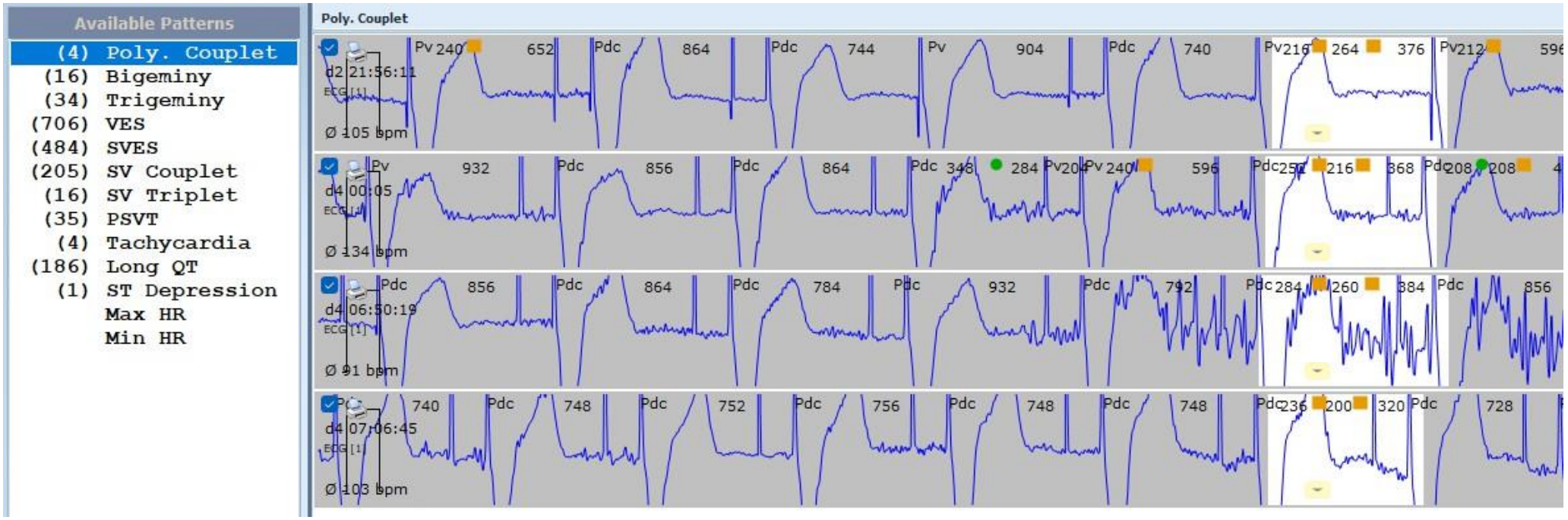
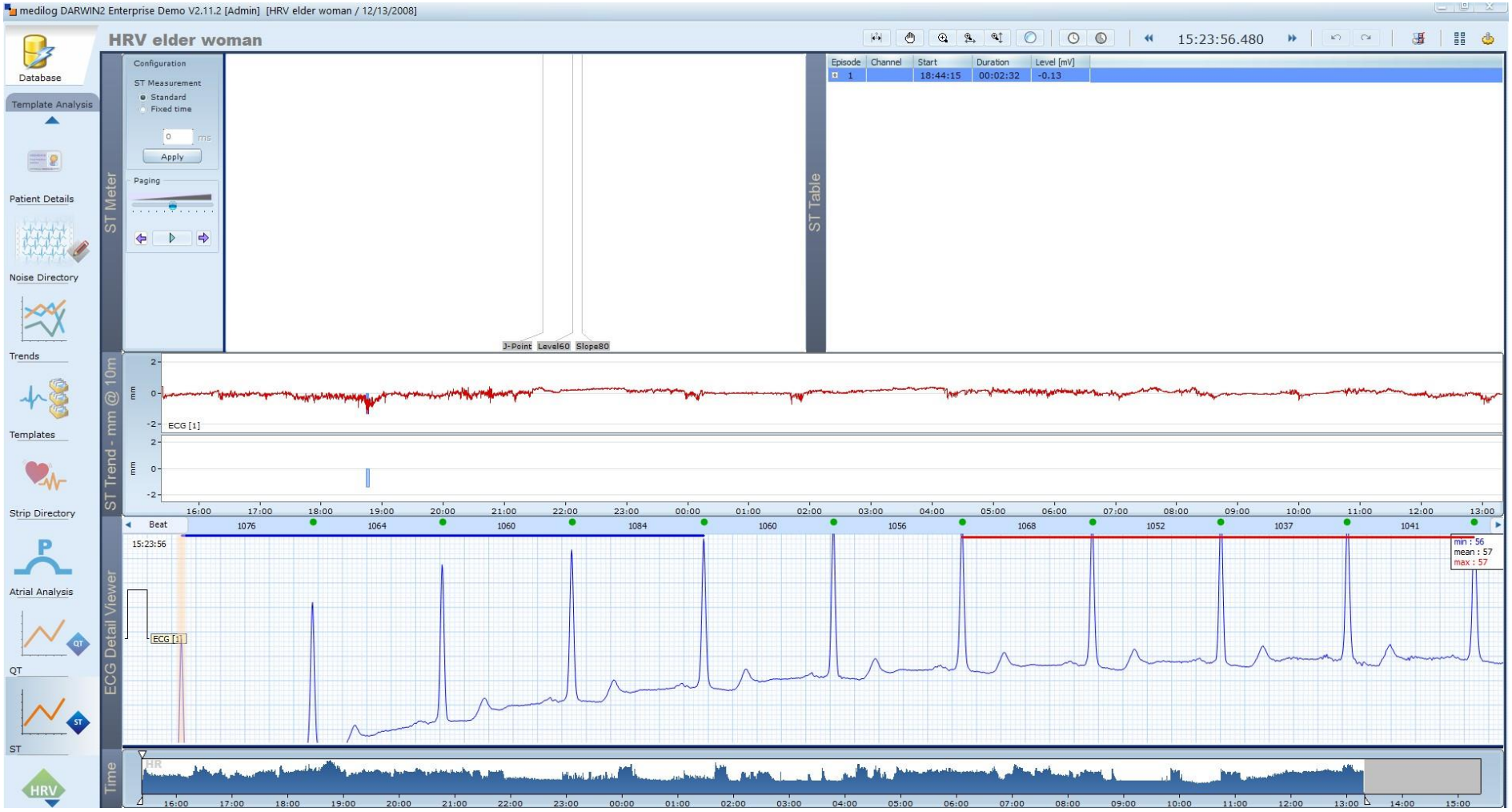
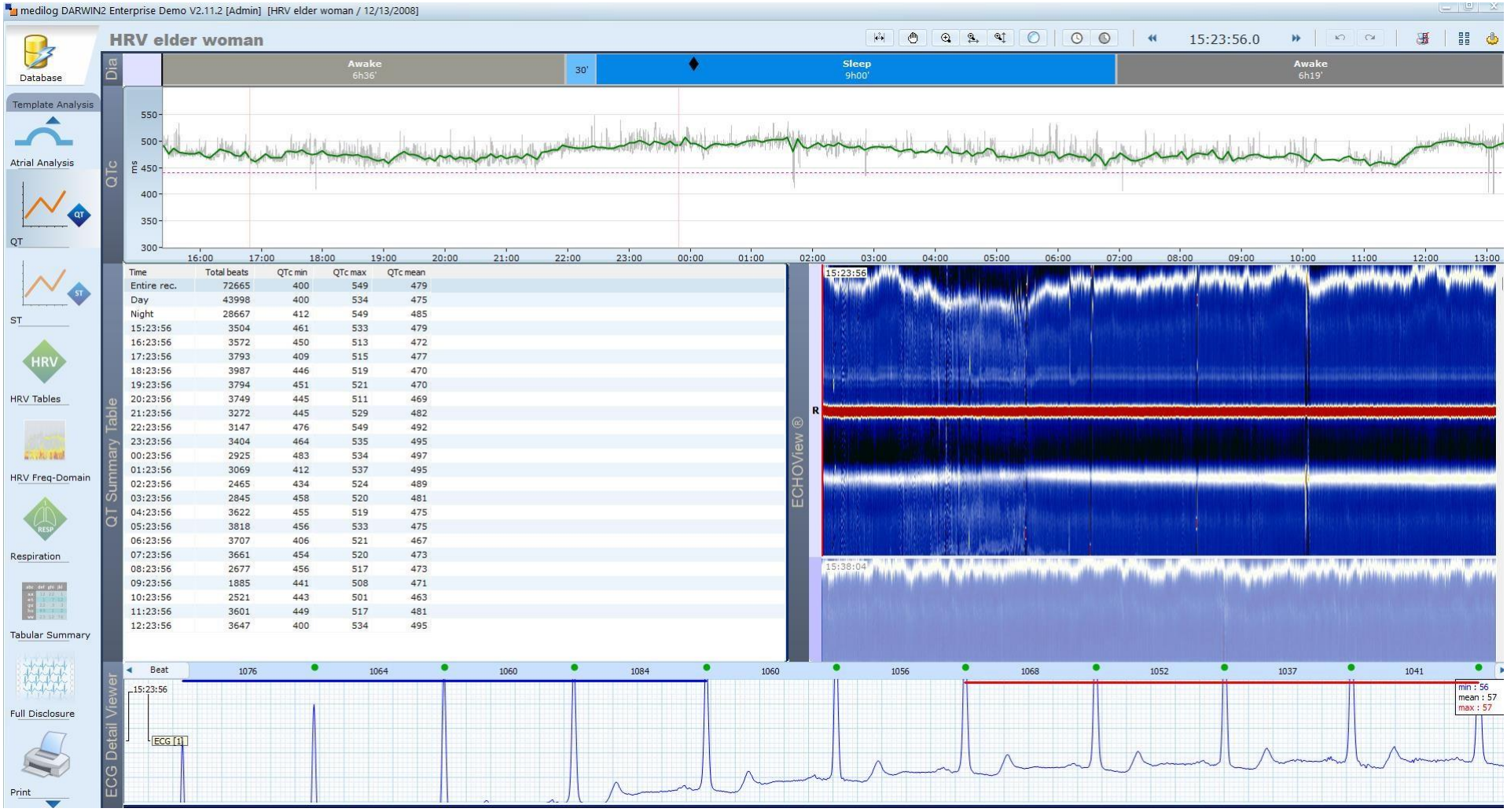
Clasificare de evenimente obligatoriu



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

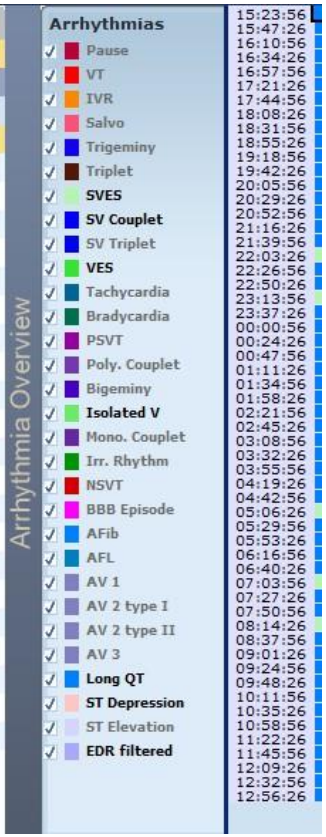
Pacemaker Events

max HR: **104bpm @ d4 06:59:50**

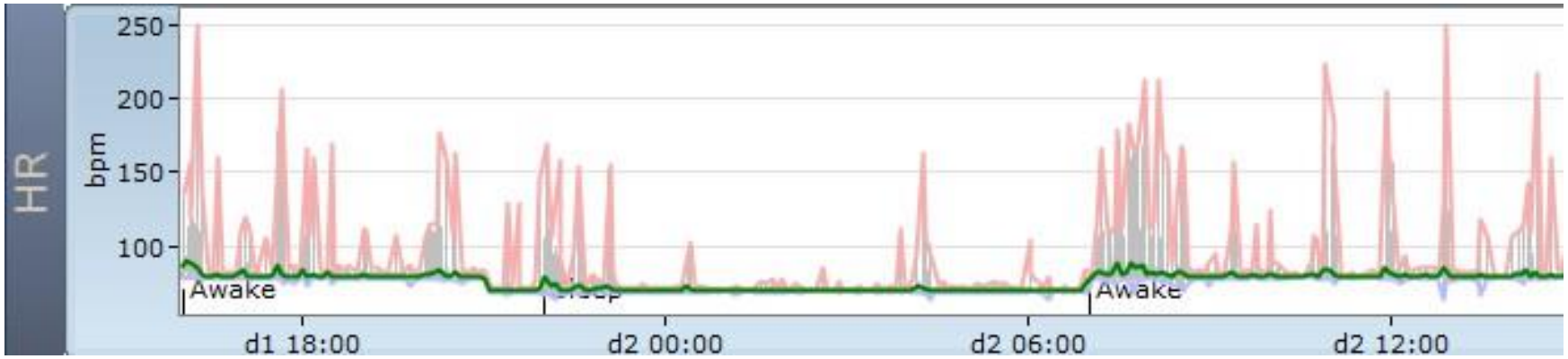
Time	Min HR	Mean HR	Max HR	Tachycardia	PS VT	SV ES	SV Couplet	SV Triplet	Poly. Couplet	Bigeminy	Trigeminy	VES	SV beats	N - SV beats	total N	total V	Validity [%]	Total beats	Undef. paced	Fusion	Pa	Pv	Pdc	PM [FTC]	PM [FTS]	Total paced
Entire rec.	68	76	104	4	35	484	205	16	4	16	34	706	94	88	182	837	100	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

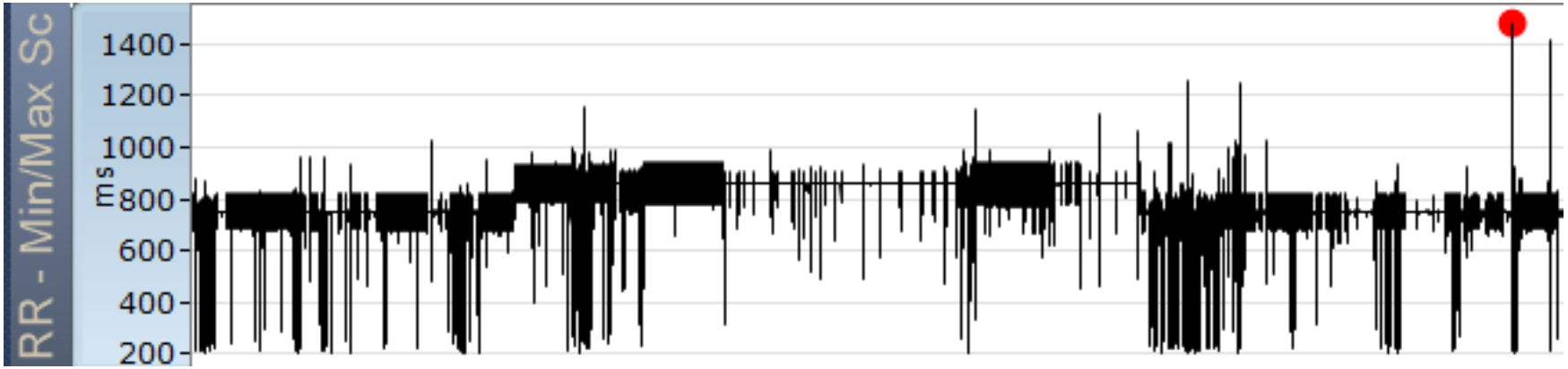
Time	Min HR	Mean HR	Max HR	SVES	SV Couplet	VES	Isolated V	SV beats	N - SV beats	total N	total V	User	Validity [%]	Total beats
Entire rec.	44	59	97	218	1	2	9	220	77726	77946	11	1	100	77957
Sleep	44	58	90	110		1	5	110	30995	31105	6	1	100	31111
Awake	45	60	97	108	1	1	4	110	46731	46841	5		100	46846
15:23	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



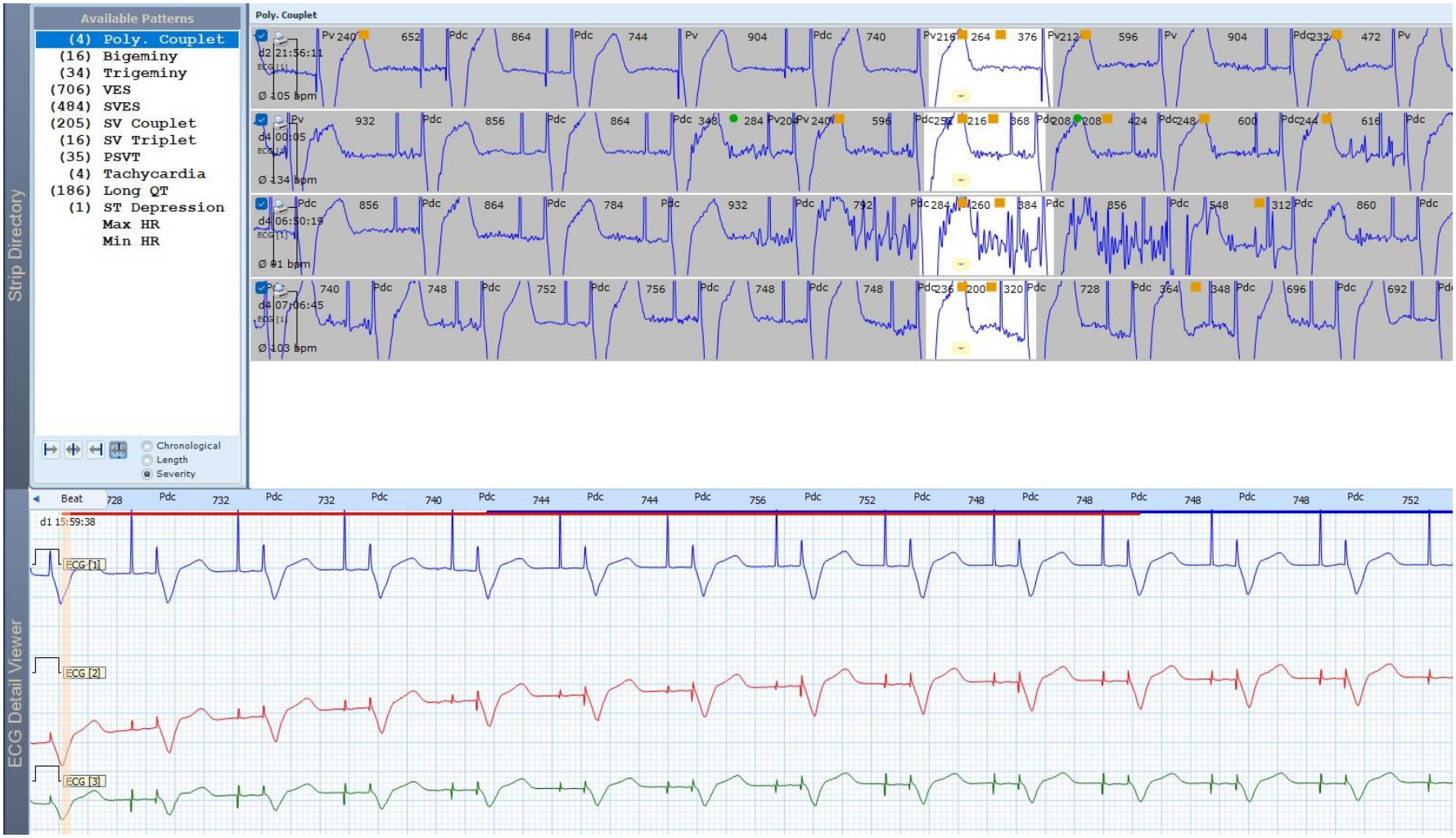
Variabilitatea ritm cardiac dupa timp



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