medilog®AR

Instructions for Use

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Art. no. 2.511345 Rev. d

SCHILLER
The Art of Diagnostics

Sales and Service Information

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

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EC REP

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CE 0123

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

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1 Safety Notes

1.1 Intended purpose

▲ The medilog®AR is used to record a 3-channel ECG. The recorder is designed for a measuring duration of more than 24 hours and is therefore worn by the patient throughout the day. The preparation for the recording (attaching electrodes, etc.) is performed by the technician or doctor.

Indications

▲ A Holter recording/analysis is indicated if the patient is suspected to suffer from:

- Cardiac arrhythmias (VT, SVT, blocks, tachycardia, bradycardia,…)
- ST-depression/elevation
- Long QT
- Pacemaker failure
- Respiratory events

Intended users

▲ The medilog®AR is intended to be used by:

- Experienced users with previous experience with the device (physician assistants, doctors and cardiologists with basic ECG experience)
- Patients (adults and paediatric) that are capable to handle the device in a proper way

Patient target group

▲ The medilog®AR is intended to be used for the following patients:

- Infants (29 days of age to less than 2 years of age, >=10kg, healthy or not)
- Children (two years of age to less than 12 years of age, >=10kg, healthy or not)
- Adolescents (12 years of age through 21 years of age (up to, but not including, the twenty-second birthday), healthy or not)
- Adults (greater than 21 years of age, healthy or not)

Affected body regions

▲ The medilog®AR is used to record a 3-channel ECG. This requires up to 7 ECG electrodes to be placed on the chest.

Context of use

▲ The medilog®AR is used in home healthcare environment and therefore extended requirements regarding environmental conditions.

▲ The medilog®AR needs to be operated according to the technical data (see Ambient Conditions, page 57).

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1.2 Contraindications

System

- The device is not protected against the effects of defibrillation.
- This device is not designed for emergency monitoring purposes. It is only designed to record the ECG and/or heart rate. It is not to be used for any life sustaining or life supporting, monitoring, treatment or alleviation of disease.

- The device is not intended to be used in MRI environments.
- The device is not designed for direct cardiac application.

Patient

- The recorder is not suitable for measurements conducted on infants/children weighing less than 10 kg (formation of loops in the patient cable that can lead to the danger of strangulation).
- The device is not suitable for disabled patients
- With children, elderly, and disabled patients, a caregiver must oversee the operation tasks and monitor the recording.

1.3 User's Responsibility

- The numerical and graphical results as well as any interpretation suggested by the device must be examined with respect to the patient's overall clinical condition and the quality of the recorded data.
- Make sure that the personnel have read and understood the user guide, and especially these safety notes.
- Before each recording, check the battery compartment (isolation), casing and ECG cable for damages. Do not use the device or cable if there are any signs of damages.
- Damaged or missing components must be replaced immediately.
- Even though the device is drip-proof (IP22), prevent it from being exposed to liquids. The recorder is not suitable for use in the bath tub or shower. 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 device so that it is not accessible for children (to prevent inhalation/swallowing of small parts).
- The safety, reliability and performance of the device can only be guaranteed if the maintenance intervals as stated in the maintenance section are adhered to (see Maintenance, page 48).
- The medilog®AR recorder is a medical device, protect from unauthorised access.

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1.4 Organizational Measures

- ▲ Before using the unit, ensure that an introduction regarding the unit functions and the safety precautions have been provided by a medical product representative.
- ▲ Keep the user guide accessible. Make sure that it is always complete and legible.
- ▲ These operating instructions do not override any statutory or local regulations, procedures for the prevention of accidents or environmental protection.

Packaging

- ▲ Do not use the device and disposables if the packaging is damaged or has been unintentionally opened before.
- ▲ Do not use the device if the packaging is exposed to environmental conditions outside of those specified (see Ambient Conditions, page 57) and contact SCHILLER.

1.5 Safety-Conscious Operation

- ▲ This user guide, and especially these safety notes, must be read and observed.
- ▲ Only operate the device in accordance with the specified technical data.
- ▲ Always use the protective carrying case when the recorder is attached to the patient.
- ▲ 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 recorder near exposed live parts.
- ▲ Do not, under any circumstances, open the casing. The device does not contain any serviceable parts.
- ▲ The recorder's power supply and patient circuit are not distinctly isolated. Only use batteries that are specified for the operation of this recorder. Do not, under any circumstances, use a power supply unit - this could threaten the patient's life.
- ▲ Follow all instructions given in the electrode placement section (see Electrode Placement, page 29). Not following these instructions can lead to incorrect measurements and possibly, as a consequence, to incorrect diagnosis.
- ▲ Do not, under any circumstances, insert objects in the SD card slot, USB connector or the battery compartment other than SD or SDHC memory cards, micro USB plug, or appropriate batteries, respectively (see Operation, page 17). This could damage the recorder and endanger the patient.
- ▲  The recorder is BF classified and is not protected against the effects of defibrillation.
- ▲ When using the instrument during sleep, please note that this can cause sleep disturbances; a lack of concentration can therefore occur the following day.
- ▲ During operation, make sure that the cable (and especially neck belt if used), is not caught by the moving parts of a machine or sport equipment.
- ▲ Danger of strangulation from the patient cable and neck belt, especially at night. Take extra care in the vicinity of children to prevent strangulation.
- ▲ Make sure that no smalls parts (e.g. SD card) can be swallowed by children.
- ▲ When not in use, store the device and the patient cable in a location that is inaccessible for children.
- ▲ If the patient falls when wearing the recorder (e.g. during sports activities), be aware that there maybe an increased risk of injury.

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- ▲ Pulling on electrode cables (for example during sports, by children or pets, by infants while breastfeeding etc.) will degrade performance. Where possible ensure that no strain is placed on the electrode cables.
- ▲ No modification of the device is permitted.
- ▲ The unit is classified IP22. When in use, ensure the protective case is always used.
- ▲ Operating conditions of the unit are up to 45 °C, but the surface temperature should not exceed 43 °C.
- ▲ Do not expose the device to any of the following as this may lead to damage of the recorder:
  - extreme heat or direct sunlight, e.g. dashboard of a car, glasshouse, radiator, fireplace.
  - very dusty environments.
  - damp or moist environments, e.g. moisture from a nebulizer, steam from a kettle.
- ▲ The device is not intended to be used in areas where there is any danger of explosion or in the presence of flammable gases such as anaesthetic agents.
- ▲ The electrodes may cause a slightly itchy sensation. Inform the patient according to the information in the patient diary (see Patient Information and Patient Diary, page 59). It is possible that skin irritation could occur through contact with the cables and the protective case.
- ▲ There is no danger when using the device for a patient with a pacemaker fitted. However, data transmission modules could affect the pacemaker functionality. To prevent a pacemaker malfunction, a distance of at least 25 cm must be kept between the device and the pacemaker when the Bluetooth module is active.
- ▲  Precautions for Bluetooth pairing:
  - ensure that no two sensor pairing processes are started simultaneously to prevent incorrect pairing, and
  - ensure that only one recorder is in range of the receiver during advertising/pairing.
- ▲ Only use accessories and other parts recommended or supplied by SCHILLER AG. Use of other than recommended or supplied parts may result in injury, inaccurate information and/or damage to the unit.

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1.6 Operation with other Devices

- Do not connect the medilog®AR with other equipment not described in this IFU (e.g. the USB socket must not be used to connect anything except a computer (for data transfer) to ensure no connection with any medical device.
- Simultaneously using or connecting several devices on the same patient can lead to increased patient currents. Contact the device manufacturers to ensure that the simultaneous use/connection of the devices does not cause harm.
- The 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 (see Preventing Electromagnetic Interferences, page 58).
- Patients should avoid environments with unusually high electromagnetic fields.
- Portable communication devices, HF radios and devices labelled with the  symbol (non-ionic electromagnetic radiation) can affect the operation of this device.
- Any connected equipment must fulfil IEC 62368-1 Audio/Video, information and communication technology equipment - Part 1: Safety requirements

1.7 Maintenance

- No serviceable parts inside, do not open the casing of the unit.
- Do not use high-temperature sterilization processes (such as autoclaving). Do not use E-beam or gamma radiation sterilization.
- Do not use solvent or abrasive cleaners on either the unit or cable assemblies.
- Do not, under any circumstances, immerse the unit or cable assemblies in liquid.

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1.8 Safety Symbols and Pictograms

1.8.1 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.

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

For a possibly dangerous situation which could lead to serious bodily injury or to death.

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

For general safety notes as listed in this chapter.

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

Reference to other guidelines.

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1.8.2 Symbols Used on the Device and the Type Label

For general symbols, see para. 13, Appendix - Symbols, page 67

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

Consulting the user guide is mandatory before using the medilog®AR.

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 medilog®AR is rated IP22 meaning protection against solid objects over 12 mm, e.g. persons fingers, and drip water protected (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

Symbol for the recognition of electrical and electronic equipment. Do not dispose the battery or the unit in household waste.

Equipment/components and accessories no longer required must be disposed of in a municipally approved collection point or recycling centre. Alternatively, you can return the equipment to your supplier or SCHILLER for disposal. Improper disposal can harm the environment and human health. Disposal of the device in accordance with the EU Directive 2002/96/EC (WEEE).

General symbol Bluetooth (transmission / reception)

General Microphone symbol

May cause or be susceptible to electromagnetic disturbances (see para. 10.5, Preventing Electromagnetic Interferences, page 58).

The device is not intended to be operated in or in the vicinity of an MRI suite.

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1.9 Additional Terms

1.9.1 FCC rules

This equipment has been tested and found to comply with the limits for a class A digital device, pursuant to both Part 15 of the FCC (Federal Communications Commission) rules and the radio interference regulations of the Canadian Department of Communications. 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 instruction user guide, may cause harmful interference to radio communications. Operation of this equipment in a residential area is likely to cause harmful interference in which case the user will be required to correct the interference at his own expense.

1.9.2 Terms of warranty

Your medilog®AR is warranted against defects in material and manufacture for the duration of one year (as from 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 void if unauthorised or unqualified persons attempt to make repairs.

In case of a defect, send the device to your dealer or directly to the manufacturer. The manufacturer can only be held responsible for the safety, reliability and performance of the apparatus if:

- assembly operations, extensions, readjustments, modifications or repairs are carried out by persons authorized by him,
- spare parts used for assembly operations, extensions, readjustments, modifications or repairs are recommended or supplied by SCHILLER,
- the medilog®AR and approved attached equipment is used in accordance with the manufacturer's instructions, and
- the maintenance intervals as stated in this handbook are observed (see Cleaning and Disinfecting, page 44).

There are no express or implied warranties which extend beyond the warranties hereinabove set forth. SCHILLER makes no warranty of merchantability or fitness for a particular purpose with respect to the product or parts thereof.

SCHILLER is not liable for the loss of data saved on the PC or device. The user is solely responsible for the data backup.

1.9.3 Implied Authorization

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

1.9.4 Serious incident

In case a serious incident has occurred in relation to the device, such incident needs to be reported to SCHILLER and the competent national authority in the state in which the user and/or patient is established.

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2 Introduction

The medilog®AR is used to record a 3-channel ECG. The recorder is designed for a measuring duration of more than 24 hours and is therefore worn by the patient throughout the day. The preparation for the recording (attaching electrodes, etc.) is performed by the technician or doctor. During the recording, it is carried in a protective case that can be attached to a belt or a neck strap.

The medilog®AR recorder offers the following features:

- 3 bipolar ECG channels
- measuring the time intervals between consecutive R peaks
- recording the occurrence of P waves
- detecting pacemaker pulses
- recording the device's acceleration in all three dimensions
- recording the ECG amplitude – due to the heart's mechanical connection to the rib cage, breathing causes the electrical heart vector to turn and therefore changes the ECG amplitude (EDR - ECG-derived respiration).
- Bluetooth module (see Bluetooth, page 38)

The medilog®AR is powered by two separate batteries. A replaceable AAA battery and an internal non-replaceable battery. The replaceable AAA battery is the primary power source used for standard recordings. The internal battery is used to give a extended recording capability when required. Operation without the AAA battery and with only the internal battery is also possible.

The recording duration available depends on recording mode, settings, battery condition, etc. (see Storing Rate, page 40).

Please note that the Bluetooth and SpO2 connectivity features are not yet available in the USA market.

2.1 What's in the Package

The original package contains the following:

- medilog®AR Holter recorder
- USB cable assembly
- AAA High energy battery
- 2GB SD memory card
- Protective rubber case with belt clip (for unit protection and patient attachment)
- Instructions for use
- Patient cable (delivered separately): Applied part. Two patient cables are available in accordance with the specified channel configuration:
  - 7-wire patient cable, or
  - 5- wire patient cable

Option

Power supply for internal battery charging.

Details of parts and accessories are given in the back of this book (see Accessories and spare parts, page 43).

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2.2 Device Options

The medilog®AR is available in four versions designated medilog®AR Office U, Office, Professional and Enterprise. The features of each option are shown in the following table.

2.2.1 Features Chart

Feature	medilog®AR version			
	medilog®AR Office U	Office	Professional	Enterprise
P-wave analysis for fully automated Atrial Fibrillation screening	no	no	yes	yes
Basic Atrial Fibrillation screening based on RR interval analysis	yes	yes	-	-
ECG derived respiration recording (EDR)	no	no	no	yes
14 days recording time	yes	yes	yes	yes
SpO_2 sensor	no	no	no	optional
HRV time domain	yes (limited)	yes (limited)	yes	yes
HRV Fire of Life and HRV frequency domain[a]	yes (limited)	yes (limited)	yes	yes
Accelerometer[b]	no	no	yes	yes
Scientific mode with 1000Hz storing rate	no	no	yes	yes
Bluetooth	no	yes	yes	yes

a. HRV Fire of Life and HRV frequency domain is analysed in medilog®DARWIN2, see user guide.

b. The accelerometer senses the patient's movement and the data is sent to medilog®DARWIN2 for analysis. This can help the cardiologist to judge for example, if a tachycardia is of concern or not. (140 HR during exercise, and therefore a lot of movement, is judged differently to 140 HR with zero movement).

Sampling and storing rate options are given in settings (see Storing Rate, page 40).

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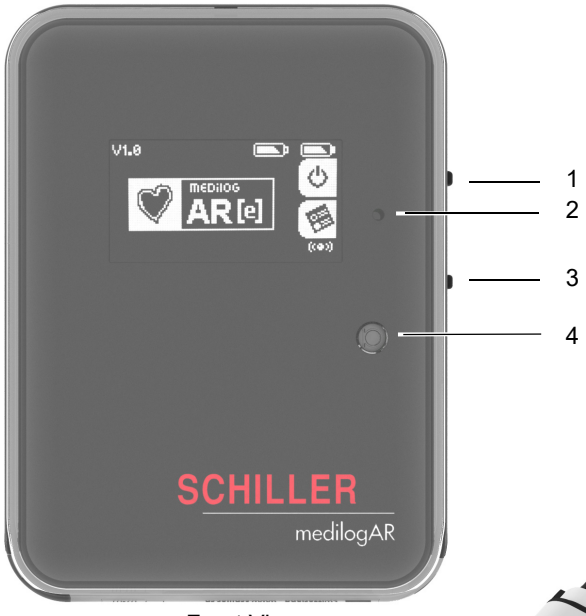
3 Operation

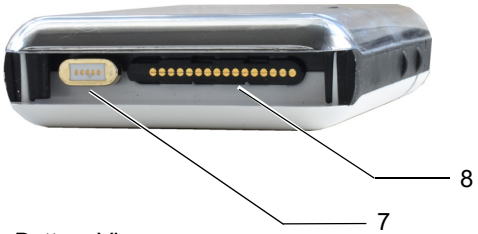
3.1 Operating Elements

1. Upper button
2. LED Function Indicator:
   – lights for three seconds when switching on
   – blinks every 5 seconds when in recording mode
   – blinks every two seconds when the internal battery is charging
   – remains lit when the internal battery fully charged (and unit not switched on)
   – blinks rapidly when the recorder is configured by Darwin, patient data has been uploaded and the device is ready to be disconnected from the USB plug.
3. Lower button
4. Microphone
5. Battery compartment
6. Micro SD Card
7. USB connector with magnetic adapter
8. Patient cable connector



Front View

Back View



Bottom View
(Patient cable removed)

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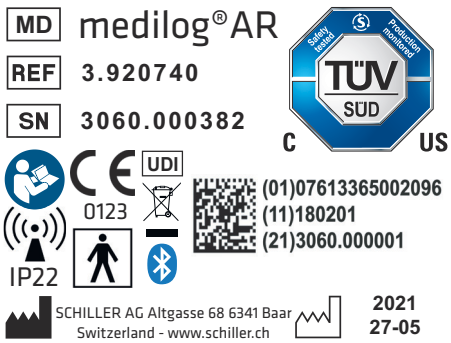
3.2 Type Label

Type reference and serial number

Manufacturer, date of manufacture, transmission and other regulatory and general and safety relevant information (see Safety Symbols and Pictograms, page 12).



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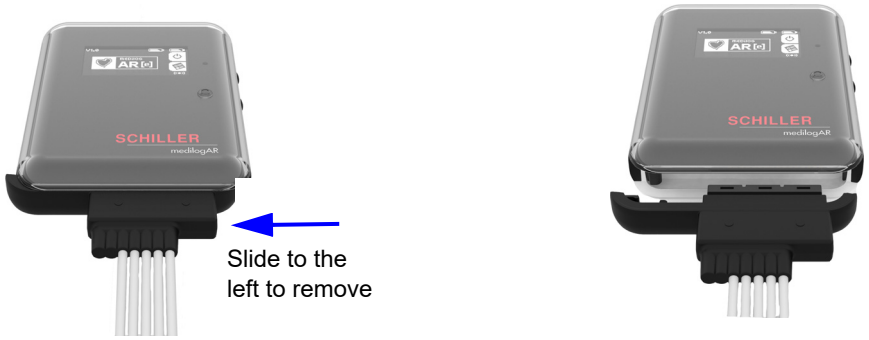
3.3 Removing and re-connecting the patient cable

The patient cable needs to be removed to access the USB port.

Remove the patient cable by gently sliding the patient cable connector to the left (as viewed from the front), until it clicks away from the unit. The patient cable can be completely detached from the recorder.

To connect the patient cable, follow the above instructions in reverse. Position the patient cable connector slightly to the left of the body of the unit, position and gently slide to the right until it clicks in place.



From May 2022, the USB port is equipped with a magnetic adapter. As a consequence, the patient cable was modified to accommodate the adapter.

When connecting the patient cable, make sure to use the correct patient cable as shown below:

medilog®AR with micro USB port

medilog®AR with magnetic USB adapter

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3.4 USB port

The patient cable needs to be removed to access the USB port (see previous).

For data transfer to a PC, and/or, to charge the battery, connect the USB connector to a free USB connector of the computer using the supplied magnetic USB cable assembly.

USB port (accessible with patient cable removed)

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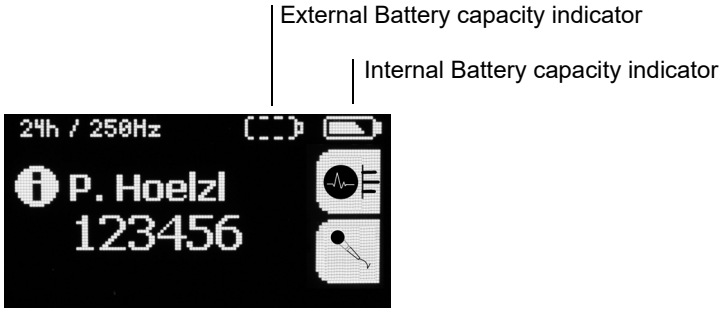
3.5 Power Supply

The unit is battery powered. The primary power source is a replaceable AAA battery. A secondary non-replaceable rechargeable battery is additionally incorporated to increase the recording duration if required. Operation without AAA battery and with only the internal battery is also possible.

3.5.1 Battery Symbols and Charge State

The battery indicators are given in the top right of the display.




Full


Half full

Low capacity

The battery indicators display the charge state of the inserted battery  . When the battery is full the symbol is filled.

Low capacity is indicated by the icon 

. Please note that the use of partly discharged batteries can lead to a premature termination of the recording - when the batteries are exhausted, recording stops. If the low capacity 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 dashed outline  .

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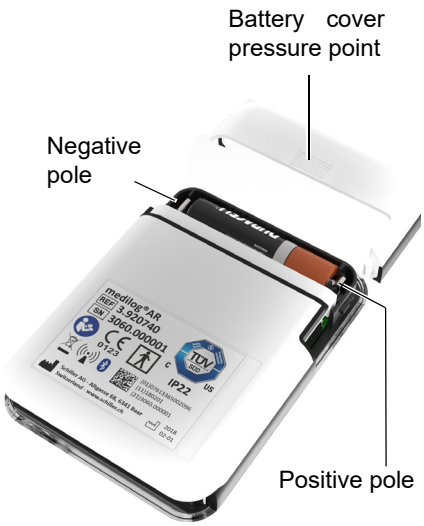
3.5.2 External Replaceable Battery



Remove the battery cover by applying pressure and gently pushing the cover until it clicks away from the device.

Insert the battery with the negative pole first and then press the positive side until the battery is in position. Make sure you position the battery correctly.

Remove the battery by pushing one end of the battery (negative end) until the positive end lifts and gently lift the battery away from the housing. Do not, under any circumstances, use a tool to remove the battery.

A battery with the following specifications is required:

Type/size: AAA/L03, 1.5 V

Operation with rechargeable NiMH batteries (at least 800 mAh) is possible. Please 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 system settings (see Battery Type, page 38).

⚠ CAUTION

- ▲ Observe correct polarity when inserting a new battery. Follow the instructions given in the battery compartment. Incorrectly inserted batteries can damage the recorder.
- ▲ Only use batteries specified and approved by the manufacturer. The mechanical manufacturing tolerance for batteries is often considerable and can in the worst case lead to problems with the battery contacts. Moreover, the energy density (capacity) of different batteries can vary significantly.
- ▲ Do not change the battery when the recorder is hooked up to the patient, change the battery before patient hookup. Do not touch the patient when changing the battery.
- ▲ Make sure the battery compartment is closed during hookup and recording.

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If the battery capacity becomes depleted during the recording, the device switches to the internal Li-Ion battery automatically.

Remove the AAA battery after use - the battery must be removed from the recorder when not used for a long period of time.

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3.5.3 Internal Battery

In addition to the AAA battery, the medilog®AR incorporates an internal battery to increase the recording duration if required. Operation without AAA battery and with only the internal battery is also possible.

3.5.4 Charging the Internal Battery

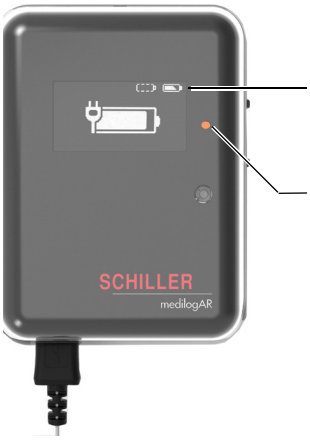
The battery is charged from the micro USB connector accessible when the patient cable is removed.

Accessing the USB Port

Access the USB by removing the patient cable (see Removing and re-connecting the patient cable, page 19).

Charging the Internal Battery

To charge the battery, connect the USB connector to a free USB connector of the computer using the supplied USB cable assembly



During Charging

During charging the following happens:

- the orange LED indicator blinks every two seconds
- the charging symbol shows the level of charge and blinks synchronously with the LED

Charging Complete

When the internal battery is fully charged:

- the orange LED remains lit and does not blink
- the internal battery symbol indicates full

3.5.5 Internal Battery Storage

- For battery longevity it is recommended that the recorder is stored with the battery charged to approximately 50%.
- It is normal that the internal battery loses capacity over time when the recorder is not used for a long period, the internal battery must be recharged periodically (every 8 weeks).

▲ The internal battery must be checked every year (see Internal Li-Ion Battery Check, page 50).

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3.5.6 USB Power Supply for Internal Battery Charging

A USB power supply is available as an option to charge the internal battery via the USB port of the unit (see previous page). USB power supply operation is detailed in the accompanying documents. Details of the power supply are given in the technical data (see Power Supply (Option), page 57).

3.5.7 Isolating from the Mains

To isolate the device from the mains supply, remove the mains plug from the external power supply unit or from the PC, or unplug the USB cable from the recorder.

3.5.8 Disposal

⚠WARNING

- ▲ **Danger of explosion** Do not dispose of batteries by fire or incinerator.
- ▲ Do not short circuit
- ▲ **Attention - danger of acid burn** Do not open the battery casing

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.

Within the EU, this product, at the end of its life, must be disposed of via a government-approved collection scheme or treatment facility. If in doubt, contact your local medilog representative.

Disposal of the device in accordance with the EU Directive 2002/96/EC (WEEE).

Note: The medilog®AR has an internal Li-Ion battery. The U.S. Environmental Protection Agency (EPA) does not regulate the disposal of batteries in small quantities and Lithium batteries are not currently being collected by manufacturers for recycling. While there are no federal regulations for disposal of lithium batteries, individual states or localities can establish their own guidelines for battery disposal, and should be contacted for any disposal guidelines that they may have.

The life of the batteries are defined in the maintenance section (see Battery Maintenance, page 50).

3.6 The medilog®DARWIN2 Program

The medilog®DARWIN2 program is used to display, save, edit, analyse and print recordings. Details of the program are given in the medilog®DARWIN2 user guide (see para. 6.1, Device, page 43)

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3.7 Memory Cards

A memory card with the following specifications is required:

– Type: SD (Secure Digital) or SDHC (Secure Digital High Capacity)
– Capacity: 128 MB - 32 GB (FAT16/32)

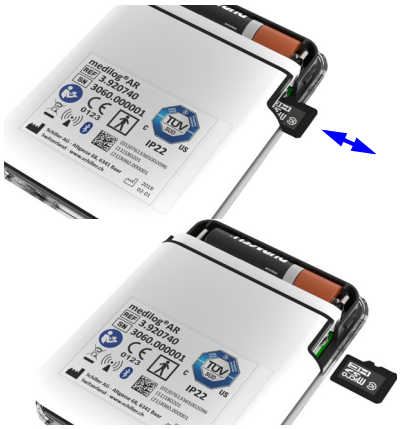
Use the medilog setup software (medilog®DARWIN2) to initialize the memory card and enter patient details. Connection with the medilog®DARWIN2 can be as follows:

- **USB Cable**: Connect the unit to the PC and open the medilog®DARWIN2 program. Fill in the information and click on Save. Patient data is saved onto the memory card.
- **Bluetooth**: Activate the Bluetooth function (see Configuring the Bluetooth Module, page 41) and open the medilog®DARWIN2 program. Fill in the information and click on Save. Patient data is saved onto the memory card.
- **Card reader**: Insert the memory card in the card reader and start the program. Enter required information and click on Save. Patient data is saved onto the memory card. Insert the memory card in the recorder.

⚠ CAUTION

▲ Only use memory cards specified and approved by the manufacturer. Memory cards vary considerably with respect to their power consumption and read/write speed.

▲ Using the memory cards with other instruments (digital cameras, MP3 players, etc.) can lead to incorrect functioning and/or data loss.



To access the micro SD card slot, the battery cover must be removed (see External Replaceable Battery, page 22)

The memory card slot is a ‘push-push slot. Insert the memory card into the device and push the card into the slot until it locks in place.

To remove the memory card, push the card 1 - 2 mm into the slot to release the locking catch.

The data is stored digitally on the memory card. After removing the memory card, the data can be read by an appropriate card reader. The data can then be viewed and analysed using the analysis software (for further information, see user guide for the medilog®DARWIN2 analysis software).

The recorder is mechanically protected from an incorrect insertion of the memory card. Do not force the card into the slot.

If the storage space runs out during a recording, the recording is stopped automatically and the device switches off.

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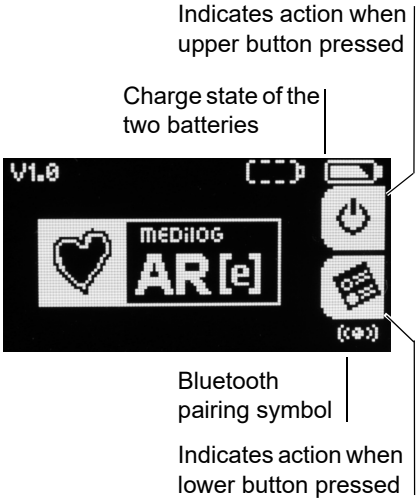
3.8 Basic Recorder Operation

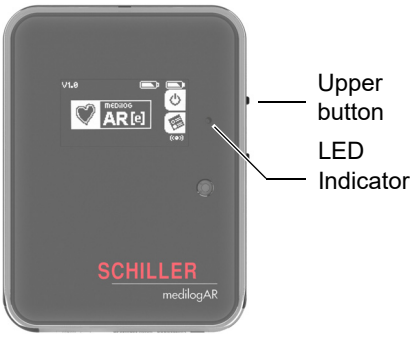


The recorder is operated by means of two buttons (see Operating Elements, page 17). The symbols on the display indicates the respective function of the buttons.

In the example shown here:

- the upper button switches off the recorder
- the lower button enters the settings menu.
- in the top right-hand corner the capacities of the internal and the external batteries are indicated. The left battery symbol displays the capacity of the external battery, right symbol the capacity of the internal battery (see Battery Symbols and Charge State, page 21).
- The transmission symbol indicated Bluetooth pairing (see Configuring the Bluetooth Module, page 41).
- Time and date are generally displayed at the bottom.

3.8.1 Switching on the Recorder



Switch on the recorder by pressing the upper button. If the patient cable is not connected, the start screen is displayed.

When the device is switched on, the LED indicator lights for approximately three seconds and the on switch symbol is displayed on the screen.

This is then followed by the initial screen, the initial screen will depend on the state of the recorder (SD card inserted, patient cable connected, UBS cable, etc.)

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3.8.2 Switching off the Recorder

General

If no button has been pressed for some time (when not in recording mode), the recorder switches off to save energy.

Switching off when the start screen is displayed

When the start screen is displayed press the upper button to switch off the recorder.

Switching off when an information screen is displayed

When the information screen is displayed or a recording is currently in progress the memory card must be removed before the recorder can be switched off.

The recorder switches off automatically if no button has been pressed for some time (when not in record mode).

Switching off During a Recording

If you wish to stop a recording and switch off the device, press and hold both buttons for several seconds. A progress bar shows how long both buttons must be pressed to switch off the recorder.

The switch off process is stopped by releasing one or both buttons when the progress bar is still displayed, and recording will continue.

The recorder will switch off automatically:

- When the set recording duration has been reached
- If no free space is left on the SD card
- The battery capacity is depleted - if the battery becomes depleted during recording the recording is first ended automatically before the device is switched off to prevent any data loss.

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4 Performing a Recording

4.1 Basics

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

Good adhesion and a minimal resistance between skin and electrode is required to ensure the highest quality ECG recording. Therefore please note the following points:

- Ensure that the patient is warm and relaxed.
- Shave electrode area before cleaning.
- Thoroughly clean the area with alcohol.
- When applying the electrodes, ensure that a layer of gel is between the electrode and the skin.
- It is recommended to connect the cable to the electrode before attaching the electrode to the patient.
- Form a stress loop in the electrode cable and secure with tape.
- Inform the patient about the use of the recorder (see Patient Information and Patient Diary, page 59).

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. We recommend electrodes manufactured by **Ambu GmbH (61231 Germany**):

- Ambu® Blue Sensor L
- Ambu® Blue Sensor VL
- Ambu® Blue Sensor VLC

The main channel (channel I, electrodes A and B) is used for various real-time evaluations (e.g. detection of R wave and P wave). The positioning of these electrodes is therefore important. Ensure in particular that there is no strain on the electrodes.

⚠WARNING

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

▲ Even though the device is protected against ingress of liquids (IP22), prevent it from being exposed to liquids. The recorder is not suitable for use in the bath tub or shower.

i

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

Before starting a recording, inform the patient about the recording procedure, event recording and safety: refer to the patient information and patient diary provided at the back of this user guide (see Patient Information and Patient Diary, page 59).

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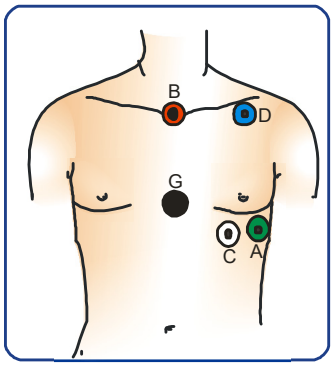
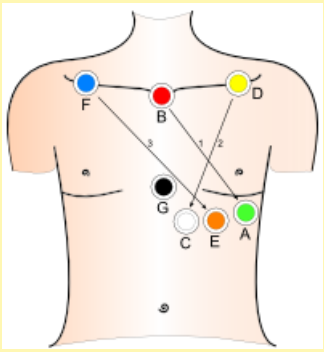
4.2 Electrode Placement

The following electrode positions are recommended:

Position	Patient cable - colours	Channels
	**5-lead cable:** • A - green • B - red • C - white • D - blue • G - black	➜ Channel I: A - B ➜ Channel II: B - C ➜ Channel III: A - D ➜ Neutral: G
	**7-lead cable:** • A - green • B - red • C - white • D - yellow • E - orange • F - blue • G - black	➜ Channel 1: A - B ➜ Channel 2: C - D ➜ Channel 3: E - F ➜ Neutral: G

To avoid artifacts in female patients, the lower electrodes can be positioned further down on the torso if necessary.

SCHILLER has prepared a video with a 7-lead patient cable to help with electrode preparation and placement, and how to incorporate stress loops in the leads and Holter placement. This is found at https://www.youtube.com/watch?v=vlH5psSPoYc

4.3 Preparing a Recording

Before starting a recording, settings must be defined or checked to ensure correct operation, these include selection of the recording quality, recording duration, etc.

There are two ways of performing these settings:

– use the medilog®AR analysis software. For more details, see the medilog®DARWIN2 user guide; or
– perform the settings directly on the recorder. For more information (see Configuration, page 37).

Please note that settings made in the medilog®DARWIN2 software overrule settings made on the recorder.

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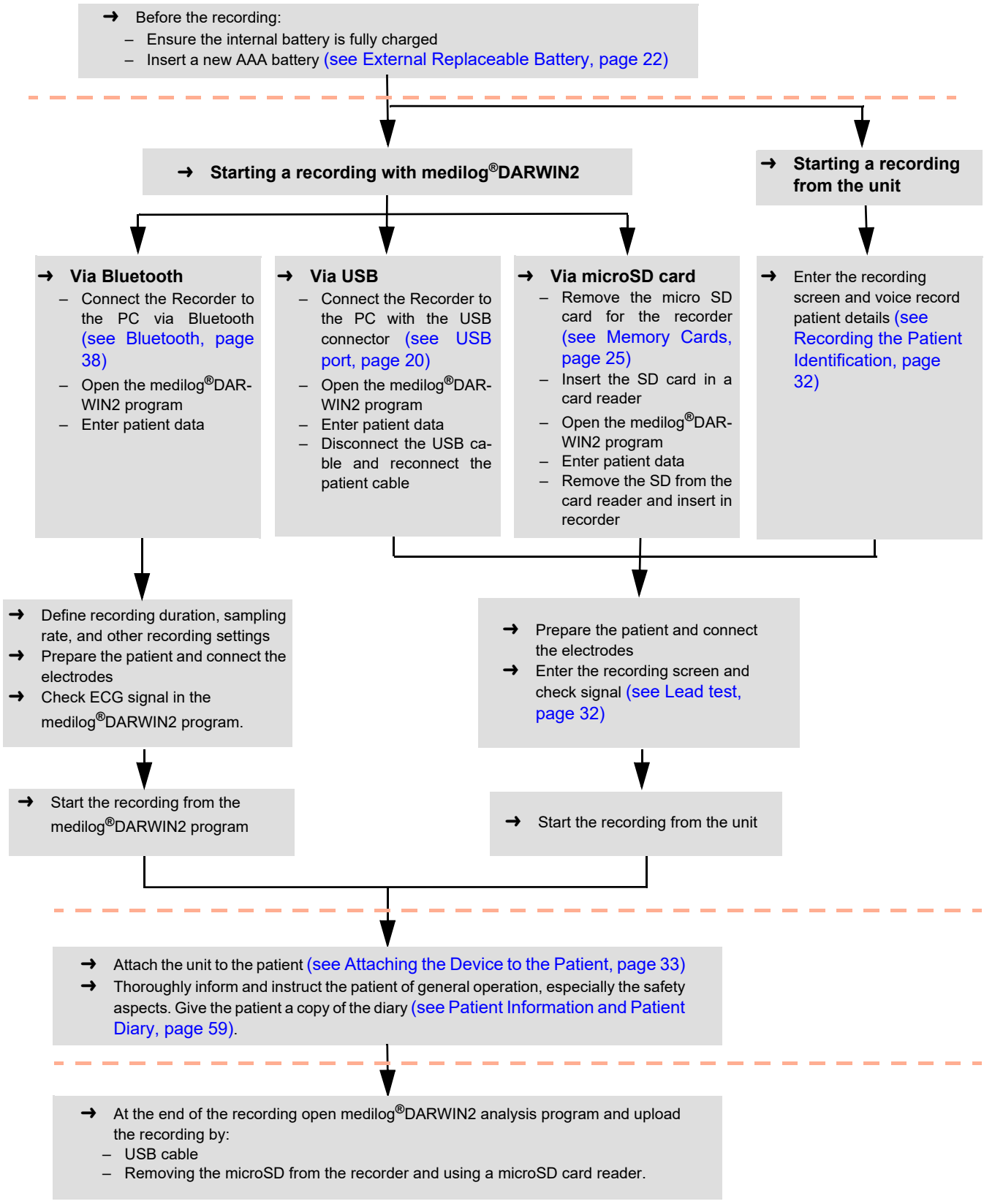
4.4 Procedural Flow Overview



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4.5 Starting a Recording

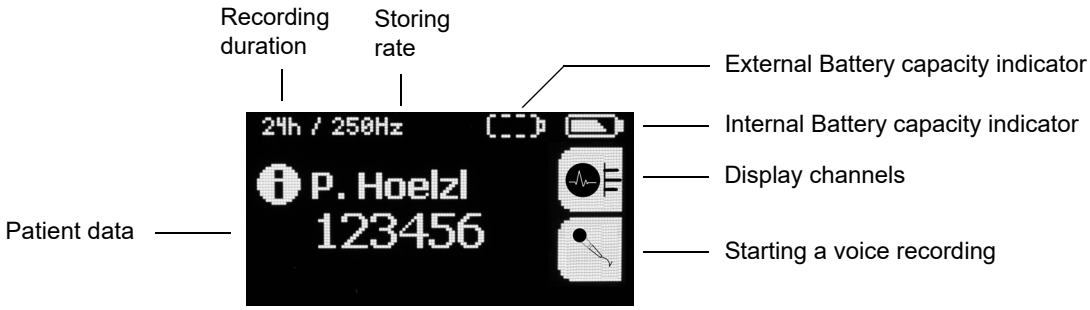
If the memory card has been initialized with the medilog® Setup PC program, the entered patient data is displayed on the screen. The icons in the top row give information on the selected recording mode and the capacities of the two batteries.

⚠ CAUTION

▲ Before the start of the recording:

- **Ensure that the patient data is correct**. A unique patient ID must be used to ensure that the recording made is associated with the specific patient.
- Ensure a new full battery is inserted in the battery compartment.
- Ensure the internal battery is fully charged (see Internal Battery, page 23).

If the charge state of the internal battery is not sufficient for the selected recording duration (see Storing Rate, page 40), ensure a fully charged new 1.5V AAA battery is inserted. If still insufficient, recharge the internal battery. In any case the state of charge of the internal battery should not be lower than 20% before a recording is started to ensure stable operation under all possible conditions.



The storing rate is either 250 Hz or 1000 Hz, depending on the configuration (see Storing Rate, page 40).

If the Bluetooth icon is displayed, the Bluetooth module is activated.

Battery Indicators and Capacity

The internal and external battery symbols are displayed in the top right of the screen. The symbols indicate the charge state of the batteries (see Battery Symbols and Charge State, page 21).

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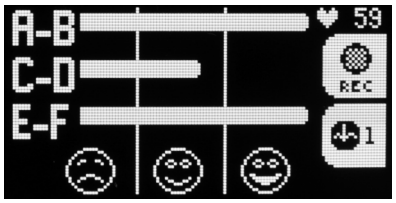
4.5.1 Recording the Patient Identification

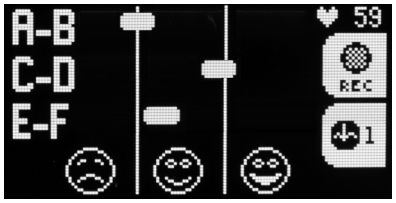
The patient data recording feature is active if patient data has been entered or not, but can be useful to identify the patient if no patient data has been stored on the memory card. Press the microphone icon to activate. Recording is possible for up to 30 seconds. Make sure that the microphone is close to your mouth when recording and that you speak at a normal volume. The voice recording can be played back in the analysis software; for more information, see the medilog®DARWIN2 user guide.

4.5.2 Lead test

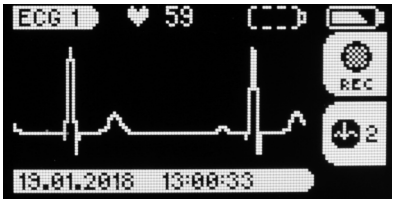


The lead test gives an indication of channel quality and cable and electrode resistance. If high resistance is detected, because of for example, kinked cables, or dried out or high resistance electrode contact, this is indicated as described below. Exchange the faulty electrodes. If the error remains, exchange the cable. Three indications are given as follows:

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



If electrodes are not connected or there is no signal no bar graph is displayed and a truncated bar line moves across the screen.



When the electrode test screen is displayed, press the lower button to view the first set of ECG channels. In this way, you can check the signal quality and polarity and correct it by repositioning the electrodes, if necessary.

The other ECG channels can be checked in the same way.

4.5.3 Starting the Recording

From the Lead test screen, select Rec (upper button) to start the recording. An hourglass is displayed while the recording process initializes.

After a few moments, the time is displayed for a short period and then the screen goes blank and recording continues. The unit LED blinks approximately every 5 seconds during the recording (see During the Recording, page 35).

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4.6 Attaching the Device to the Patient

⚠ CAUTION

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

4.6.1 Electrode Cable

- Form a stress loop in every cable and secure them with adhesive strips to provide electrode strain relief.

SCHILLER has prepared a video of electrode placement to help with electrode preparation and placement and how to incorporate stress loops in the leads. This is found at https://www.youtube.com/watch?v=vlH5psSPoYc

4.6.2 Securing the Device to the Patient

Select the most suitable device securing method for preference and with regard to the patient and condition of the patient.

A number of possibilities to attach the device to the patient are available, for example:

- Belt clip to attach the device to the patient's belt
- Placing the device in a suitable pocket
- Using a neck belt

▲ For protection and to maintain IP rating, it is important that the device is always placed in the device case when attached to the patient.

Belt Clip

Position the medilog®AR device in the protective case and attach the case to the patient's belt with the belt clip.

Position in the most appropriate and comfortable way for the patient.

The medilog®AR can be placed on the left or right of the body. Position in the most comfortable way for the patient with respect to, for example left / right handed, predominant sleeping position, etc.

It is recommended that the patient wears a t-shirt over the electrode cables to help hold the cables in place. This can be covered with for example, a loose fitting shirt.

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In a Pocket

Position the medilog®AR device in the protective case and place in a convenient pocket. Position in the most appropriate and comfortable way for the patient.

Neck Belt

⚠WARNING

▲ Danger of strangulation. The neck belt or electrode cable can become entangled around the patient's neck and lead to strangulation. The danger increases at night. Ensure the patient is aware of the danger.

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

The neck belt is positioned around the patient's neck and can be adjusted for height with the patient cable facing upward or downward for comfort.

- For preference of the patient cable facing upward or downward, insert the neck belt clip in the case from the left or right.
- Bend and click the fastener to secure.

Clip positioned for patient cable facing upwards

Clip positioned for patient cable facing downwards

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4.7 During the Recording

4.7.1 Indicators During the Recording

If not disabled manually (see System Settings, page 37), the orange LED blinks every 5 seconds indicating the unit is in recording mode.

4.7.2 Registering an Event

Press any of the two buttons to register an event during the recording. This sets an event marker in the recording for later analysis by medilog®DARWIN2. When an event is registered, the time is indicated on the display for a short period. This can be used for recording the time of any event /note entered in the patient diary.

The screen goes blank after a short period.

4.7.3 Heart Rate

The lead test screens displayed during the hook up process show the heart rate (see Lead test, page 32). The calculation of the heart rate and related analysis is done in the medilog®DARWIN2 analysis program.

4.8 Stopping a Recording

The recording stop automatically when:

- the set recording duration has been reached
- the SD card is full
- battery capacity is low

4.8.1 Manually Stopping a Recording

The recording can be stopped at any time by pressing and holding both buttons for several seconds. A progress bar is displayed during switch off.

▲ It is important that a recording is stopped correctly. Ensure the recorder is switched off correctly before removing the memory card.

▲ If the memory card is removed during a recording the recording mode continues when the memory card is reinserted (see Deleting a Recording from the Memory Card, page 36). If this is intentional, ensure that the correct patient is displayed. This is very important to avoid any confusion or incorrect recording assignment.

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4.9 Analyzing a Recording

Once the recording has been performed, it can be viewed and analyzed using the medilog®DARWIN2 analysis software (see Memory Cards, page 25).

4.10 Deleting a Recording from the Memory Card

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

- If the recorder is in the endless mode and the recording is not deleted by pressing the two buttons, the recording is resumed automatically after 15 seconds.
- If a recording is resumed, ensure that the correct patient is displayed. This is very important to avoid any confusion or incorrect recording assignment.

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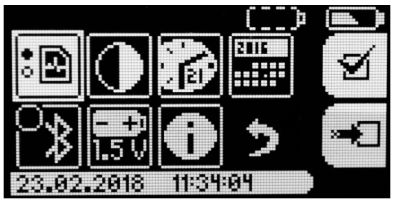
5 Configuration

To enter the configuration menus, switch on the recorder (upper button) when the SD card is empty or removed and the patient cable disconnected, the start screen is displayed.

➜ The start screen is only displayed when the SD card is empty or removed and the patient cable is not connected (see Removing and re-connecting the patient cable, page 19). Access the SD card by removing the battery cover (see Memory Cards, page 25).



Press the lower button to enter the main configuration menu. Select a menu item by means of the lower button and enter the menu by pressing the upper button.

When the exit / settings menu option is selected  the second menu is displayed.

5.1 System Settings

5.1.1 Recording Settings

Select the menu option 

(see Recording Settings, page 39).

5.1.2 Contrast

Select the menu option 

Adjust the contrast by repeatedly pressing the lower button; to save the setting, press the upper button. The test pattern helps you to judge the selected contrast setting.

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5.1.3 Time

Select the menu option 

Use the lower button to adjust the setting and the upper button to confirm the entry and enter next field (highlighted).

After the last setting has been made (minutes setting), confirm with the upper button.

5.1.4 Date

Select the menu option 

Use the lower button to adjust the setting and the upper button to confirm the entry and enter next field (highlighted).

The last setting shows how the date is displayed, select between:

- 11/27/2018 or
- 27.11.2018.

After the last setting has been made, confirm with the upper button.

5.1.5 Bluetooth

Select the menu option 

Bluetooth options and pairing procedures are detailed later in this section (see Configuring the Bluetooth Module, page 41).

Please note that the Bluetooth and SpO2 connectivity features are not yet available in the USA market.

5.1.6 Battery Type

Select the battery type. This refers to the replaceable AAA battery only. Select 1.5 V for alkaline batteries and 1.2 V for NiMh rechargeable batteries. Only use batteries and rechargeable batteries that have been approved for this recorder.

5.1.7 Recorder Serial number and Software version

This menu gives you recorder-specific information, including version and serial number. Please have this information when contacting our service department to help troubleshooting.

Exit

Exit the menu.

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5.2 Recording Settings

Select the menu option  .

Select one of the available recording options. The activated option is highlighted.

5.2.1 Duration

Select this menu item to define the recording duration. When 24, 48 or 72 hours has been selected, the recorder switches off automatically at the end of the recording period. When continuous is selected the recorder does not switch off automatically but continues recording until:

- the user stops the recording by pressing and holding both buttons for several seconds.
- the battery is empty.
- the memory card is full.

5.2.2 Recording Continuation

When this is active the recorder switches off automatically when the defined recording duration has been reached. When this option is deactivated the recording will continue until the battery or batteries are depleted.

⚠ CAUTION

▲ Danger of incorrect patient registration. Always check name and ID on screen if a recording is interrupted and it is decided to continue the recording. This is very important to avoid confusion or incorrect assignment of the recording data. The displayed patient data is saved with the recording.

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5.2.3 Storing Rate

Select to set a 1000 Hz storing rate. When not selected, the storing rate is set at the default 250 Hz.

- The 1000Hz mode not available in the medilog®AR Office U and Office versions.
- We recommend that the 1k mode setting is applied only when ECG signals with high temporal resolutions are required. The data volume for this setting is considerable and therefore more time for reading and analysis of the measurements is required.
- **250 Hz (default setting)** means that the ECG signal recorded 250 times per second. In addition, the position of distinctive signal sections (e.g. p wave, R wave) as well as the **EDR** (ECG-derived respiration) signals are recorded; the EDR signals serve as basis for the analysis of respiratory results. For these signals, a significantly higher internal sampling frequency is used.

Recorder Modes

	24 hours	48 hours	72 hours	Infinity mode	1k
Sampling rate	32000	32000	16000	8000	32000
Storing rate	250	250	250	250	1000[a]
P wave detection[b]	yes	yes	yes	yes	yes
R peak resolution	62,5µs	62,5µs	128µs	250µs	62,5µs
EDR (Enterprise only)	yes	yes	yes	yes	yes
File size	75MB/24h	75MB/24h	75MB/24h	75MB/24h	300MB/24h
Recording duration with AAA battery	>72h	>72h	>100h	>14 days	>48h
Recording duration without AAA battery	>48h	>48h	>80h	>7 days	>24h
Accelerometer[c]	yes	yes	yes	yes	yes
Pacemaker detection	62,5µs	62,5µs	128µs	250µs	62,5µs

a. 1k storing rate not available in versions medilog®AR Office U and Office

b. P wave detection not available in versions medilog®AR Office U and Office

c. Accelerometer not available in versions medilog®AR Office U and Office

5.2.4 LED Indicator

LED indicator: Enable / disable 5 second LED indicator flash when recording an ECG

5.2.5 Exit

Exit the menu.

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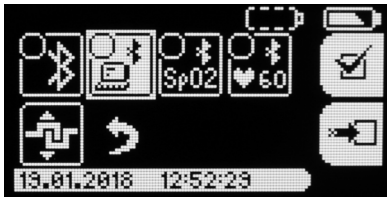
5.3 Configuring the Bluetooth Module

The built-in Bluetooth module is a Class II module. The recorder must be within a radius of approx. 5 m of the paired device to establish a stable transmission. Make sure that there are no obstacles between the recorder and the paired device.

Please note that the Bluetooth and SpO2 connectivity features are not yet available in the USA market.

WARNING

▲ Data transmission modules could affect the pacemaker functionality. To prevent a pacemaker malfunction, a distance of at least 25 cm must be kept between the device and the pacemaker as soon as the Bluetooth module is activated.



Select the menu option  .

When the Bluetooth module is active, a transmission symbol is displayed on the screen.

5.3.1 Pairing and Data Transfer

Pairing and data transfer is possible between PC, SpO_2 device, and Heart Rate profile capable device.

Choose this option to pair the recorder with a PC  .

When this option is selected, three further options are given  .

The second icon pairs the device with an available PC. As soon the pairing process is started, the user can add the recorder as new Bluetooth device (the Bluetooth name of the Recorder is AR[t] xxxxxx where ‘t’ is the recorder type and ‘xxxxxx’ is the recorder serial number). The recorder can be paired with up to 8 different PCs.

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5.3.2 PC Mode

PC mode: in this mode, the recorder sends the acquired signals to a PC. In this way, the signal quality can be checked at any time during the hook-up process or during the recording. This may be used with the medilog®DARWIN2 analysis software. See medilog®DARWIN2 user guide for details.

5.3.3 SpO_2

Use this function to receive SpO_2 data from an SpO_2 device (the Bluetooth SpO2 function is receive mode only). The signal is received from the connected/paired SpO2 sensor and stored and synchronized with the ECG on the SD card. Analysis is carried out in medilogDARWIN2.

Before initiating the SpO2 sensor must be switched on and the probe connected.

The medilog®AR is compatible with SpO2 sensor, article number 2.100939.

Please note that the Bluetooth and SpO2 connectivity features are not yet available in the USA market.

5.3.4 Heart Rate

The medilog®AR can be paired with a Bluetooth BLE client supporting the BLE Heart Rate profile. When paired correctly the BLE Heart rate client will show the heart rate of the patient.

5.3.5 Disabling the Bluetooth Module

Selecting this option to delete the recorder's list of paired devices deactivate the Bluetooth module. Wireless connection is not possible anymore.

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6 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 medilog®AR. A full list of all SCHILLER representatives can be found on the SCHILLER website (www.schiller.ch).

6.1 Device

Part Number	Description
3.920740	medilog®AR Holter Recorder (Device)
1A.306000	medilog®AR Holter Recorder (Kit)

6.2 Spare parts

Part Number	Description
2.400176	5-wire patient cable push-button 82cm, medilog®AR
2.400177	7-wire patient cable push-button 82cm, medilog®AR
2.100850	Alkaline battery LR03, type AAA, 1.5V
2.610066	Micro USB cable assembly (medilog®AR - PC)
2.610067	MicroSD card with Adapter
2.310426	USB cable 2.0 high speed, magnetic adapter, 1.0 m
2.310427	USB cable 2.0 high speed, magnetic adapter, 0.3 m
2.610063	Protective case (for unit protection and patient attachment)
2.610064	Battery compartment cover
2.610065	Transparent front cover
2.156096	Neck belt (compatible with 2.610063)

6.3 Accessories

Part Number	Description
2.155054	Blue sensor disposable Holter ECG electrodes (Clip) set of 25
2.100939	SpO2 sensor, medilog®AR

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7 Cleaning and Disinfecting

⚠ CAUTION

- ▲ Do not autoclave the unit or any accessories.
- ▲ Never use any of the following solutions or similar products to clean the equipment: ethyl alcohol, acetone, hexane, abrasive or scouring powder or material, any cleaning material that damages plastic.
- ▲ Unit connectors, and battery and electrode cable contacts, must not come in contact with soap or water. Do not immerse in liquid when cleaning. Do not spray the unit directly. Only clean the device and cable with a damp cloth **slightly moistened (not wet)** on the surface only. If liquid does penetrate the unit, switch it off immediately and send it to SCHILLER for testing
- ▲ The recorder and patient cables must not be autoclaved or sterilized with steam.
- ▲ Always follow the diluting instructions provided by the manufacturer of the cleaning solution.
- ▲ When cleaning, ensure that all labels and safety statements, whether etched, printed or stuck to the unit, remain in place and remain readable.
- ▲ The patient cable must not be exposed to excessive mechanical stress. Whenever disconnecting, slide the plug/connector and not the cable.
- ▲ Some patients have intolerances (e.g. allergies) to disinfectants or their components. If you have such a patient or you are not sure, remove possible residues with careful washing.

7.1 Manufacturing Materials

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

Component	Material
Recorder housing	PC polycarbonate
Patient cable	M-PUR
Case	THERMOLAST®M - cleaning material compatibility, behaves as PC polycarbonate

All materials according to EN ISO 10993-1 / -5 / 10 are tested on the finished product.

With time, the device 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, or
- if a warm disinfectant or detergent is used.

For this reason, Schiller AG recommends using only cleaning agents with alcohol content that are adequate for sensitive materials such as polycarbonate (PC), at room temperature (approx. 20°C).

Let the device and its accessories dry in open air and without heat exposure.

i Not made with natural rubber latex.

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7.2 Cleaning Interval

All parts that come into contact with the patient, that is patient cable, device, case, need to be cleaned and disinfected after each use especially when contaminated with potentially infectious material (especially contamination with blood or other body fluids). Visible soiling needs to be removed and the equipment disinfected immediately.

7.3 Cleaning / Disinfecting

⚠ CAUTION

▲ Observe the following safety notes when cleaning/disinfecting the device or patient cable:
- If removing the patient cable before cleaning the device, always remove by sliding the plug, not the cord
- Never immerse the device or patient cable in liquid
- Never pour or spray liquid directly onto the unit patient cable
- Make sure that no liquid penetrates the connections or openings
- The device and / or patient cable must not be autoclaved or sterilised with steam

Before cleaning/disinfecting the unit thoroughly inspect for any signs of damage and any improper mechanical function of buttons or connectors. Switch off the recorder before cleaning. The patient cable can be removed of required.

▲ Do not spray the device directly.

▲ Make sure that no liquid penetrates the device.

▲ Clean the recorder with a damp cloth **slightly moistened (not wet)** on the surface only. Use cleaning agents that are mild and diluted with water that are suitable for PC polycarbonate (see Approved Cleaning Materials, page 46).

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 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 device or into the connectors this may interfere with correct functioning. Remove the patient cable, the memory card and the battery. Leave the recorder in a warm, dry room with the battery chamber open for 48 hours and then check the equipment to confirm that it operates properly. If the functioning is still affected, contact the manufacturer.

Ensure the contacts of the patient cable are completely dry before reassembling.

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Patient Cable

For the patient cable observe the following:

➜ Hold the cable in the **centre** and clean it towards the connector and the electrodes, respectively.
➜ 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 (max. 20 cm) using the moistened cloth. Then hold the next section and clean it. In this way, the cable (insulation) is not being stretched and premature aging 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. If liquid gets into connectors, dry the area with warm air.

7.4 Disinfection

The user (doctor) decides, whether and when disinfection is necessary for reasons of hygiene. Use commercially available disinfectants intended for clinics, hospitals and practices to disinfect the device. Disinfect the unit in the same way as described for cleaning.

7.5 Approved Cleaning Materials

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

- Propan-2-ol/isopropyl alcohol (max. 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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7.6 Approved Disinfectants

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

7.6.1 Recommended Disinfectants

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

7.6.2 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® etc.)
- Conductive solution
- Solutions or products containing the following ingredients:
  - Ammonium chloride compound
  - Betadine
  - Chlorine, wax or wax compound
  - Ketone (acetone)

Using these products or products containing similar components can cause discoloration of the product, corrosion and reduction of the product life, and may render the warranty invalid.

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8 Maintenance

8.1 Maintenance Intervals

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

For maintenance work that is carried out by a qualified authorised technician, more details are given in the service manual.

The device must be serviced at regular intervals and the test results documented (see Check List, page 51).

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

Interval	Maintenance	Responsible
Before every use	• Visual inspection of the recorder • Clean the cable and recorder before using it for another person	➜ User
Every 6 months	• Functional check according to the instructions – visual inspection of the device and cable assembly – functional check of the OLED display and control buttons	➜ User
Every 12 months	• Internal battery check	➜ User or qualified service technician
Every 12 months	• Recurrent test and test after repair according to IEC/EN 62353	➜ Qualified service technician

8.1.1 Service/Shelf life

Device and electrode cables

The device and electrode cables do not have a defined service life. The life of the device and accessories is defined by the service technician during the yearly Recurrent test according IEC/EN 62353.

Accessories shelf life

See expiry date on the battery or electrode packaging; shelf life for electrodes approx. 2 years.

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8.2 Visual Inspection and Functional Check

Visual inspection

⚠ CAUTION

▲ 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 unit and cable assemblies for the following:

- ➜ Device casing not broken or cracked.
- ➜ OLED screen not broken or cracked.
- ➜ Electrode cable sheathing and connectors undamaged. No kinks in the cable.
- ➜ USB cable sheathing and connectors undamaged. No kinks in the cable.
- ➜ Input/output connector undamaged.

Functional, OLED Screen, and Control Keys Check

This procedure provides a basic software integrity check, ensures that the OLED screen is usable, and checks the function of the two control keys. Proceed as follows:

1. Switch on the unit.
2. Check the OLED screen - ensure the display is clear and readable. Look for missing pixels.
3. Scroll through the menu and select some items.
4. Ensure correct operation of the two control keys during scrolling and menu selection.

➜ Defective units or damaged cables must be replaced immediately.

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8.3 Battery Maintenance

8.3.1 Internal Li-Ion Battery Check

The expected life of the battery is >500 charge / discharge cycles (0 to 100%). The internal battery is charged via the USB connector (see Charging the Internal Battery, page 23).

The internal battery needs to be checked every year, either by SCHILLER AG or by the user.

1. Fully charge the internal battery (see Charging the Internal Battery, page 23).
2. Set the recorder mode to Scientific/1k (storing rate 1000 Hz) with Bluetooth switched off (see Storing Rate, page 40).
3. Remove the external batteries, if present (see External Replaceable Battery, page 22).
4. Start a recording (see Starting a Recording, page 31).
5. After 56 hours, check 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.
6. If the recorder has turned off due to a depleted battery before 56 hours have elapsed, the internal battery needs to be replaced.

The internal battery must only be replaced by SCHILLER AG.

Storing the recorder for long periods with the battery completely discharged or 100% charged, reduces battery life. Make sure that if the recorder is not used for a long time, the state of charge is approximately 50%.

8.3.2 Using External AAA, 1.2 V Rechargeable NiMh Batteries

This section is only applicable when AAA, 1.2 V rechargeable NiMh batteries are used.

- The batteries require no maintenance during their life.
- For the life cycle of the batteries see manufacturers documentation.
- To prevent the possibility of battery leakage, always remove the batteries from the device when not used for prolonged periods.

Charging External Batteries

- Full capacity of new NiMh batteries are only reached after three charge/discharge cycles.
- See battery and charger user information for charge times.
- Charged batteries lose their charge when removed from the charger unit. Therefore to ensure full capacity only remove the batteries from the charger immediately before taking a recording.
- No harm will be done to the batteries by leaving them in the charger unit.

Remove the battery from the medilog®AR (see para. 3.5.2, External Replaceable Battery, page 22), and place in the battery charger unit. Leave in the charger unit until fully charged (see battery charger operating instructions).

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Battery Disposal

⚠WARNING

- ▲ Danger of explosion! Batteries must not be burned or disposed of in domestic rubbish.
- ▲ Danger of acid burns! Do not open the batteries.

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

8.4 Packaging and Transport

The transport case should be used to prevent damage during transport.

8.5 Check List

8.5.1 Every 6 Months

Visual inspection and functional check (user)

Maintenance	Inspection																							
Visual inspection																								
➜ Visual inspection of the device and cable assembly: casing, cables and connections in good condition.	❒	❒	❒	❒	❒	❒	❒	❒	❒	❒	❒	❒	❒	❒	❒	❒	❒	❒	❒	❒	❒	❒	❒	❒
➜ Expired date of electrodes	❒	❒	❒	❒	❒	❒	❒	❒	❒	❒	❒	❒	❒	❒	❒	❒	❒	❒	❒	❒	❒	❒	❒	❒
Functional check of the OLED display and control buttons																								
➜ Check of the OLED display and control buttons. OLED is readable, control buttons are working.	❒	❒	❒	❒	❒	❒	❒	❒	❒	❒	❒	❒	❒	❒	❒	❒	❒	❒	❒	❒	❒	❒	❒	❒
Date:																								
Inspector																								

8.5.2 Every 12 months

Internal battery check (see Internal Li-Ion Battery Check, page 50), performed either by SCHILLER AG or by the user.

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9 Errors and Trouble Shooting

9.1 Error Messages

9.1.1 SD Card Error

SD cards are under heavy and constant use during recording and although industrial grade SD cards are standard, all SD card have a limited life and will need replacing from time to time.

This screen indicates that the information saved on the memory card is incorrect or that the card is faulty. 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 SD card
- if the problem persists, contact a service partner

9.1.2 General Error Message

This screen indicates an error. Perform a hardware reset. If the error persists, make a note of the error number and contact the service department.

9.2 Trouble Shooting

Error	Possible cause	Remedy
The recorder cannot be switched on	• The recorder is displaying an error due to unknown reasons	→ See Error messages above
	• The battery has been inserted incorrectly	→ Check the battery polarity and change the battery position, if necessary.
The device cannot be switched off by pressing and holding the button	• The recorder is already switched off (the recorder switches itself off automatically as soon as the recording is finished (automatic switch-off activated).	→ Normal operation
	• The recorder is displaying an error due to unknown reasons	→ See Error messages above
The device switches off prematurely	• The battery is empty. The battery is faulty • The memory card is defective.	→ Use a new memory card.

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9.3 Hardware Reset

If the recorder ‘hangs, a unit reset is available as follows:

1. Connect the recorder via USB to the PC or the battery charger (see USB port, page 20)
2. Press the lower button of the recorder. A hardware reset is initiated.

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10 Technical Data

10.1 Holter Recorder

Manufacturer	SCHILLER AG
Device name	medilog®AR
Dimensions	83 x 60 x 18 mm (without cable)
Weight	approx. 125 g (without AAA battery)
Protection against water ingress	IP22
Interface	
Protocol	• mass storage device profile (read only)
Transfer Speed	• approx. 150sec /24h
Voice Recording	Up to 30 seconds
Buttons for operation	2, also used for patient marker
Screen	128 x 64 OLED
Memory	up to 32GB SDHC microSD
Signal Check	True signal quality check with amplitude indication
Real-time analysis (temporal resolution)	
R peak	• up to 62.5 µs
P wave	• up to 500 µs
Pacemaker	• up to 62.5 µs
ECG derived respiration (EDR)	• up to 62.5 µs
ECG Amplifier	
Dynamic bandwidth	• 12 - 14 mV, typically 13 mV
Patient Cable	• 5 or 7 lead interchangeable, automatic detection of cable type
Analogue bandwidth	• >1.0 kHz
Lower cut-off frequency	• 0.05 Hz
Channels	• 3 bipolar
Sampling Rate	Up to 32000 Hz
24h mode	• 32000 Hz
48h mode	• 32000 Hz
72h mode	• 16000 Hz
Infinity mode	• 8000 Hz
Scientific mode	• 32000 Hz

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Recording Rate	Up to 1000 Hz
24h mode	• 250 Hz
48h mode	• 250 Hz
72h mode	• 250 Hz
Infinity mode	• 250 Hz
Scientific mode	• 1000 Hz
Oversampling	• max. 128 x
Amplitude resolution	max. 15.5 bit (up to 3.5 bit used for denoising)
Amplitude storing resolution	12 bit
HR Calculation	refer to medilog®DARWIN2 User Guide
Storage	
Type	• micro SD card, 2 GB to 32 GB
Max. Recording Length	• 14 days
Typical recoding size	• <100MB / 24hrs.
Primary Power supply (external battery)	
Vin (supply voltage)	• 1 x 1.5 V AAA battery alkaline or lithium, or 1 x 1.2 V rechargeable NiMH battery
Internally occurring voltage	• max. 12 V, typically 2.7 V
Secondary Power supply (internal battery)	
Vin (supply voltage)	• 1 x 3.7 V, 1000 mAh internal rechargeable Lithium Ion battery
Internally occurring voltage	• max. 12 V, typically 2.7 V
Charging	• Charged via PC USB port. Alternatively an external USB power supply can be used (5 V, 500 mA minimum).
Charging Time	• 0% to 100% - appox. 3 h • 0% to 80% - appox. 2 h • 0% to 60% - appox. 1.5 h
Battery Life	• > 500 charge / discharge cycles (100%)
Maintenance	• The battery must be checked every year (by SCHILLER AG or by the user). • Note: Storing the recorder with the battery completely discharged or 100% charged will reduce the battery life. Make sure that the SoC (state of charge) is around 50% if the recorder is not used for a long time.
Operating duration without AAA battery *	
24 h mode	• >48 h
48 h mode	• >48 h
72 h mode	• >80 h
infinity mode	• >7 days
scientific mode	• >24 h
Operating duration with AAA battery **	
24 h mode	• >72 h
48 h mode	• >72 h
72 h mode	• >100 h
infinity mode	• >14 days
scientific mode	• >48 h
Maximum operation duration ***	>14 days

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Warmup times	
Minimum storage temperature to mean operating temperature	<2 h
Maximum storage temperature to mean operating temperature	<2 h
Electromagnetic radiation	CISPR 11, class B
Conformity	• According to 93/42/EEC appendix IX: Class IIa • Hereby, SCHILLER AG declares that the radio equipment type medilogAR is in compliance 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
Safety and performance standard	IEC 60601-1-11
Bluetooth module	PAN1780
FCC ID	• T7V1780
IC	• 216Q-1780
Power level	• Class II
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 2 GB microSD Card (K2GRT-803M) - power consumption varies depending on the SD card and the selected settings. Moreover, the operation duration varies depending on the battery type used. The recorder is operated with a 1.5V AA battery. The recorder is equipped with a mechanical protective mechanism against the reverse connection of the battery. The permitted supply voltage range Vin of 1.0-2.7V permits the use of 1.2V NiMH rechargeable batteries.

Please note that if activated, the Bluetooth module reduces battery life by approx. 10 %

* 100% charge of internal battery (in mint condition), Cactus 2GB industrial grade SLC microSD card (KS2GRT-803M).

** 100% charge of internal battery, AAA battery Panasonic industrial grade, Cactus 2GB industrial grade SLC microSD card (KS2GRT-803M).

*** 100% charge of internal battery (in mint condition), AAA battery Energizer Ultimate Lithium, Cactus 2GB industrial grade SLC microSD card (KS2GRT-803M)

Please note that the Bluetooth and SpO2 connectivity features are not yet available in the USA market.

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10.2 Ambient Conditions

From storage or transport the recorder, cable and accessories will reach the ambient temperature over time.

Ambient conditions (operation)	
Temperature	• 5 to 45° C (surface temperature must not exceed 43° C).
Humidity, non condensing	• 10 to 95 % RH
Atmospheric pressure	• 700 to 1060 hPa
Ambient conditions (storage/transport)	
Temperature	• -25 to 70° C
Humidity, non condensing	• 10 to 90 % relative humidity
Atmospheric pressure	• 700 to 1060 hPa

10.3 Power Supply (Option)

USB Power supply for internal battery charge.

Type	• FRIWO FW8005/EU • FRIWO FW8005/US
Output	• USB socket type A • 5V ±2 % • 1000 mA
Input	• EURO, US/JP • 100 - 240 V, 50/60 Hz ±10 %
Ambient conditions (operation)	
Temperature	• 0 to 40° C
Humidity, non condensing	• 10 to 95 %RH
Ambient conditions (storage)	• -40 to 70° C
Standards	• IEC 62368-1, IEC60065, IEC60335
Protection class	• II
Mean time before failure	• 200.000h according Mil217F (based on calculations at 120Vac/60Hz & 230Vac/50Hz, ambient 25°C and 100% load). The MTBF are theoretically determined values, which does not guarantee the lifetime of the product or of the electrolytic)

10.4 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 medilog®DARWIN2 user guide.

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10.5 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 medilog®AR. The distance depends on the output performance of the communication device as indicated below.

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

⚠ CAUTION

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

For permanent HF telecommunication devices (e.g. radio and TV), the recommended distance can be calculated using the following formula: $d = 1.2 \times \sqrt{P}$ for 150 kHz to 800 MHz and $d = 2.3 \times \sqrt{P}$ for 800 MHz to 2.5 GHz

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

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11 Patient Information and Patient Diary

11.1 Patient Information

⚠WARNING

▲ Danger of strangulation. The neck belt or electrode cable can become entangled around the patient's neck and lead to strangulation. The danger increases at night. Ensure the patient is aware of the danger. The doctor should draw the patient's attention to the fact that care must always be taken to ensure that neither the electrode cable nor the shoulder strap ever become wrapped around the neck.

▲ If the patient is a child, a frail adult or not fully competent, the equipment should be worn only under supervision.

▲ Tell the patient not to get the unit wet - the unit is not waterproof and must remain dry.

11.1.1 General

Inform the patient about the use of the medilog®AR and instruct the patient on the following points:

- Patients should avoid environments with unusually high electromagnetic fields. The equipment must not be used in the vicinity of an MRI scanner.
- The performance of the medilog®AR can be affected by extremes of temperature and humidity. Keep away from direct sunlight.
- There is the potential of allergic reactions to accessible materials used in the device. The electrodes especially can cause a slightly itchy sensation in some patients. If skin irritations are noticed at any location where the device comes in contact with the skin check for allergy.
- Tell the patient that event markers can be set in the recordings by pressing any of the two buttons. When an event is registered the time is displayed for a short time This can be used for reference when making an entry in the patient diary.
- Tell the patient that during the measurement:
  - Not to place any strain on the electrode cable or electrodes. The electrode cable must not be knotted or stretched or subject to stress or restriction.
  - It must be ensured that the electrodes do not come into contact with any other conducting objects
  - Entries must be made in the patient diary on a regular basis during the long-term measurement and for physical activity and any events that occur.
- The recorder should not be turned off and will stop automatically at the end of the recording

11.2 Patient diary

A copy of the Holter patient diary is available as a word file and a PDF file and is given on the following pages where it may be copied. The patient should fill in the diary with all details as required.

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Patient information and diary

medilog®AR

First name: ..... Last name: .....

Date: ..... Start time: .....

Please read the information below carefully before the start of this ECG recording.

Warning

- **Danger** of **strangulation** from the patient cable and neck belt due to length of the cable and belt, especially at night. Beware of this risk. Take extra care for children and frail or vulnerable adults.
- It must be ensured that the electrodes do not come into contact with any other conducting objects.
- If you have a **pacemaker**, make sure that the distance between the pacemaker and the device is always more than 30 cm.

Caution

- The electrodes may cause a slightly itchy sensation - this is normal. If **skin irritations** are noticed at any location where the device comes in contact with the skin (e.g. rashes or any change in colour, appearance or texture of the skin), **please contact your physician**.
- **Do not expose the device to extreme heat or direct sunlight**, e.g. dashboard of a car, glasshouse, radiator, fireplace, etc., as this may lead to damage of the recorder.
- **Avoid contact with liquids. Do not take a shower or bath while wearing the device**. Wipe excessive sweat away from electrode contact areas.
- If the device or the cables are damaged (e.g. cuts or excessive abrasion on the cable, broken device casing etc.), remove all cables and contact your physician.
- To prevent the device from malfunctioning, keep a sufficient distance (at least 30 cm) to other electrical / electronic devices (eg Smart Phone)

General information

- This device measures the electrical activity of your heart. Performing this recording does not have a direct physiological impact.
- Your physician has set up and placed this device in a way so that no changes need to be performed. Therefore, carry the device in the protective case. Do not remove the electrodes or any cables and do not open the device.
- Pulling on electrode cables (for example during sports or physical activity, by children or pets, by infants while breastfeeding etc.) can affect the recording. Where possible **ensure that no strain is placed on the electrode cables during the recording**.
- **In case of dizziness, palpitations etc., register an event in the recording by pressing one of the buttons on the side of the recorder**. Enter the event in the diary (please see below for more information).
- If you have any questions, contact your physician.

Indicators and registering an event during the recording

The orange LED blinks every 5 seconds indicating the unit is in recording mode. Assurance that the measurement is running is also given when the measurement duration is displayed after pressing one of the buttons.

Press either of the two buttons during the recording to register an event, the time is indicated on the display when an event is registered and displayed for a short time. This can be used for recording the time of any event /note entered in the patient diary.

The screen goes blank after a short period.

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Patient information and diary

When to make diary entries

Use the diary provided here. For every entry note the time of the event, the activity being carried out, the symptoms and any extra comments that you may have. Be brief but use extra sheets if required.

- Make a routine diary entry approximately every two hours when awake. Enter sleeping, resting and waking times.
- Make a diary entry for every event. Press any of the two buttons on the recorder to register an event in the recording at any time. Events should be registered when you experience pain, dizziness, light-headedness, palpitations, etc. Also for any activities, especially stressful activities such as going up stairs, carrying heavy objects, bicycling, etc.

Patient diary during the recording

Time	Activity	Symptoms / comments

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Patient information and diary

Time	Activity	Symptoms / comments

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Patient information and diary

Time	Activity	Symptoms / comments

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13 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)

CE	CE marking, affirms its conformity with European standards
	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.
4 LDPE	The packaging is made in low density polyethylene and can be recycled.
Rx Only	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	Latex-free
	Use-by date (expiry date of battery, electrodes or other consumables)
	Temperature range for storage or transport, respectively
	Pressure range for storage or transport, respectively
%	Humidity range for storage or transport, respectively
	Consult instruction for use (indicates the need for the user to consult the instructions for use)
xd MAX	Use within X days after opening (electrodes or other consumables)

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	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 (dos 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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EN: European Authorised Representative, **DE:** Europäischer Bevollmächtigter, **CZ:** Evropský zmocněný zástupce, **ES:** Representante Europea Autorizada, **FR:** Représentant autorisé européen, **HU:** Meghatalmazott európai képviselő, **HR:** Europski ovlašteni predstavnik, **IT:** Rappresentante autorizzato per l'Europa, **LT:** Europos įgaliotasis atstovas, **LV:** Eiropas pilnvarotais pārstāvis, **NL:** Gemachtigde Europese vertegenwoordiger, **NO:** Europeisk autorisert representant, **PL:** Autoryzowany przedstawiciel w Europie, **PT:** Representante Autorizado Europeu, **RO:** Reprezentant autorizat European, **SR:** Evropski ovlašćeni predstavnik, **SV:** Europeiska auktoriserade representanten, **SK:** Európsky splnomocnený zástupca, **SL:** Evropski pooblaščeni zastopnik, **FI:** Euroopan valtuutettu edustaja, zastopnik, **BG:** Европейски оторизиран представител **EL:** Ευρωπαίος Εξουσιοδοτημένος Αντιπρόσωπος, **DA:** Europæisk autoriseret repræsentant, **ET:** Euroopa volitatud esindaja

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Device availability in your market is subject to regulatory approval.

SCHILLER
The Art of Diagnostics

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