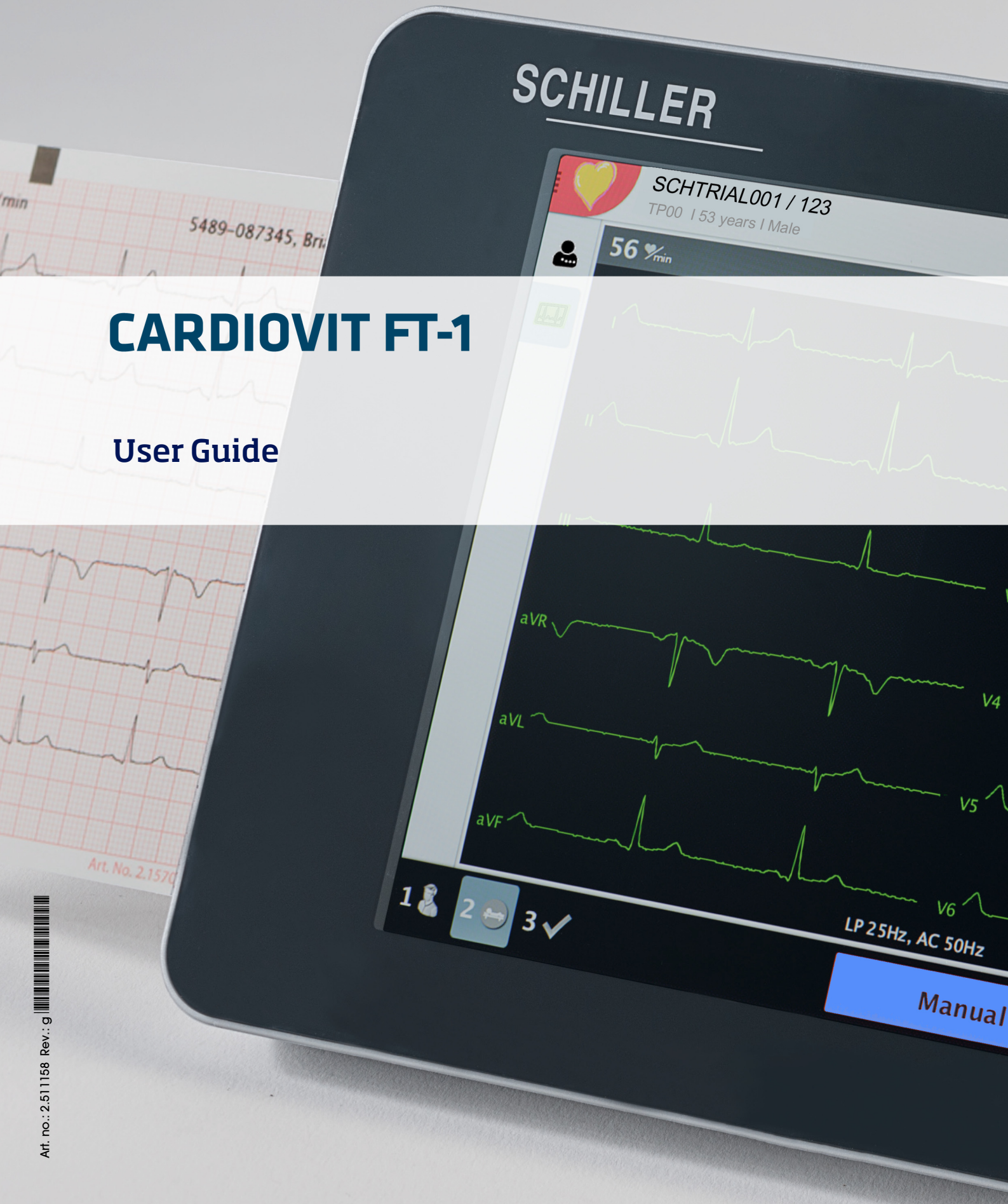
CARDIOVIT FT-1

User Guide



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SCHILLER
The Art of Diagnostics

Sales and Service Information

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

www.schiller.ch

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Java POWERED

CE 0123

The CARDIOVIT FT-1 bears the CE-0123 mark (Notified Body TÜV-SÜD Produkte Service GmbH, Ridlerstr. 65, 80339 Munich, Germany), indicating its compliance with the essential requirements of the Annex I of the Medical Device Directive 93/42/EE regarding safety, functionality and labelling. The requirements apply to patients, users and third persons who come into contact with this device within the scope of its intended use.

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1 Safety Notes

▲ Read and follow these safety notes to prevent any injuries or damages.

1.1 Intended purpose

▲ The CARDIOVIT FT-1 is a 12-lead electrocardiograph device intended to be used by or under the direct supervision of a licensed healthcare practitioner in healthcare facilities to acquire ECG signals from body surface electrodes, record, analyse, display and print ECGs for diagnosis in adult and paediatric patients.

Indications

▲ The CARDIOVIT FT-1 is indicated for screening and assessment of cardiovascular diseases including:

- Resting myocardial ischaemia
- Myocardial infarction (acute and former)
- Conduction system abnormalities including atrio-ventricular blocks, bundle branch block and pre-excitation syndromes
- Long QT syndromes
- Atrial abnormalities
- Ventricular hypertrophy and strain
- Pericarditis
- Secondary repolarisation abnormalities such as electrolytes disturbances
- Drug-induced abnormalities

Intended users

▲ The CARDIOVIT FT-1 is intended to be used by trained operators under supervision of a licensed healthcare practitioner.

Patient target group

▲ The CARDIOVIT FT-1 is intended to be used for adult and paediatric patients.

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

▲ Paediatric patients are defined as follows:

- Neonates: from birth through the first 28 days of life
- Infants: 29 days of age to less than two years of age
- Children: Two years of age to less than 12 years of age
- Adolescents: 12 years of age through 21 years of age (up to, but not including, the twenty-second birthday)

• Subgroups:

- Transitional Adolescent B: 18 through 21 years of age BUT no special considerations compared to adults

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Affected body regions

▲ The CARDIOVIT FT-1 is not in direct contact with the patient.

Context of use

▲ The CARDIOVIT FT-1 is intended for indoor use in healthcare facilities.

▲ The CARDIOVIT FT-1 needs to be operated according to the technical data (see section 13 Technical data).

▲ The CARDIOVIT FT-1 is portable. The CARDIOVIT FT-1 is transportable by means of a trolley (optional).

1.2 Contraindications

System

▲ The CARDIOVIT FT-1 is not indicated:

- for sterile use
- for use in areas where there is any danger of explosion or in the presence of flammable gases such as anaesthetic agents
- for direct cardiac application
- for use in an MRI suite
- for outdoor use
- for use as a vital signs physiological monitor
- for use with high frequency surgical units

Patient

▲ No known contraindications for resting ECG.

1.3 Responsibility of the User

▲ The CARDIOVIT FT-1 must only be used by qualified physicians or trained medical personnel.

▲ The numerical and graphical results as well as any interpretation suggested by the device must be examined with respect to the patient's overall clinical condition and the quality of the recorded data.

▲ The responsibilities of the personnel for the operation and maintenance of the device must be specified.

▲ Ensure that the personnel have read and understood this user guide, in particular this section **Safety Notes**.

▲ Damaged or missing components must be replaced immediately.

▲ The safety, reliability and performance of the device can only be guaranteed when the maintenance intervals as stated in section 11 Maintenance are observed.

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1.4 Organisational Measures

- ▲ Before using the device, ensure that a medical product representative has explained its functions as well as the safety requirements.
- ▲ Keep this user guide in an accessible place for reference purposes. Make sure that it is always complete and legible.
- ▲ Observe the operating and maintenance instructions.
- ▲ In addition to this user guide, legal and other binding regulations for the prevention of accidents and for environment protection must be observed.

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 (section 13.1 Device) and contact SCHILLER.

1.5 Safety-Conscious Operation

- ▲ Make sure that the staff have read and understood the operating instructions, in particular this section Safety Notes.
- ▲ Only operate the device in accordance with the specified technical data.
- ▲ The device is CF classified. It is defibrillation protected only when the SCHILLER original patient cable is used. However, as a safety precaution, remove the electrodes before defibrillation, if possible.
- ▲ Do not touch the unit casing during defibrillation.
- ▲ To ensure patient safety, none of the electrodes, including the neutral electrode, nor the patient or any person with simultaneous patient contact, must come in contact with conductive parts, even when these are earthed.
- ▲ Immediately report any changes that impair safety (including operating behaviour) to the person responsible.
- ▲ Do not place any liquids on the unit. If liquid is spilled on the device, immediately disconnect the device from the mains and wipe it. The device must be serviced before reusing.
- ▲ Only connect the original SCHILLER patient cable to the patient socket.
- ▲ If the patient cable should become defective after defibrillation, an electrode becomes displaced, or an electrode resistance is too high, a lead-off indication is displayed in the upper right part of the screen.
- ▲ Only use accessories and disposables recommended or supplied by SCHILLER. Use of other than recommended or supplied parts may result in injury, inaccurate information and/or damage to the unit.
- ▲ To prevent pacemaker malfunction, a distance of at least 20 cm must be observed between the device and the pacemaker as soon as the Wi-Fi (wireless LAN) module is switched on.

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1.6 Safety facilities

▲ Operating the device without the correctly rated fuse or with defective cables constitutes a danger to life! Therefore:

– Do not operate the unit if the earth connection is suspect or if the mains lead, the power supply unit or the device is damaged or suspected of being damaged.
– Damaged cable connections and connectors must be replaced immediately.
– The electrical safety devices, such as fuses, must not be altered.
– Ruptured fuses must only be replaced with the same type and rating as the original.

1.7 Operation with other Devices

▲ The CARDIOVIT FT-1 may be connected/combined with other medical devices such as:

- ECG:
  – Patient cables and electrodes
  – ECG suction pump
- Thermal paper
- CARDIOVIT CS-104
- Trolley

▲ Accessory equipment connected to the analogue and digital interfaces must be certified according to the respective IEC standards (e.g. IEC/EN 60950 for data processing equipment and IEC/EN 60601-1 for medical equipment). Furthermore, all configurations shall comply with the valid version of IEC/EN 60601-1. Everybody who connects additional equipment to the signal input part or signal output part configures a medical system and is therefore responsible that the system complies with the requirements of the valid version of IEC/EN 60601-1. If in doubt, contact the technical service department or your local representative.

▲ Any other equipment used with the patient must use the same common earth as the CARDIOVIT FT-1.

▲ Special care must be exercised when the unit is used with high-frequency equipment. Use the special high-frequency SCHILLER patient cable to avoid possible signal interference during ECG acquisition and to reduce the risk of burns in case of a lack of potential equalisation. However, the stimulation units should only be used at a sufficient distance from the electrodes and both devices must be connected to the same potential equalisation. If in doubt, the patient should be disconnected from the device.

▲ This device can safely be used with pacemaker patients.

▲ There is no danger when using this device simultaneously with electrical stimulation equipment.

▲ If the device is part of a medical system, only the original SCHILLER patient cable must be used with, and connected to, the CARDIOVIT FT-1.

▲ If the patient cable should become defective after defibrillation, a lead-off indication is displayed on the screen (see page 39).

▲ Portable communication devices, HF radios and devices labelled with the  symbol (non-ionic electromagnetic radiation) can affect the operation of this device (page 105).

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1.8 Network safety

▲ When the FT-1 is part of a *network (LAN, WLAN, HIS, etc.),* the operator of the network/data coupling must take appropriate security measures to protect the transmission of data. Networks that are not protected and maintained can lead to failure of the data transmission or to incorrect transmission of data, which in turn can result in danger to the patient. For further safety notes, see chapter 10.

1.9 Maintenance

▲ Danger of electric shock! Do not open the device. There are no serviceable parts inside. Refer servicing to qualified technicians authorised by SCHILLER only.

▲ Before cleaning and to isolate the mains power supply, switch the unit off and disconnect it from the mains by removing the plug.

▲ Do not use high-temperature sterilisation processes (such as autoclaving). Do not use E-beam or gamma radiation sterilisation.

▲ Do not use aggressive or abrasive cleaners.

▲ Do not, under any circumstances, immerse the device or cable assemblies in liquid.

1.10 Serious incidents

▲ If any serious incident occurs in relation to the CARDIOVIT FT-1, such incident needs to be reported to SCHILLER as well as the competent national authority of the country in which the user and/or patient is established.

1.11 Terms of Warranty

Your SCHILLER CARDIOVIT FT-1 is warranted against defects in material and manufacture, as stated in the Terms and Conditions. Excluded from this warranty is damage caused by an accident or as a result of improper handling. The warranty entitles to 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 the device is defective, send it to your local SCHILLER representative or directly to the manufacturer. The manufacturer can only be held responsible for the safety, reliability and performance of the device if:

- assembly operations, extensions, readjustments, modifications or repairs are carried out by persons authorised by him, and
- the SCHILLER device and approved attached equipment is used in accordance with the manufacturer's instructions, and
- the maintenance intervals as stated in the section section 11 Maintenance are observed.

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 assumes no liability for the loss of data saved on the computer or on the device. The owner is solely responsible for the data backup.

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1.12 Safety Symbols and Pictograms

1.12.1 Symbols used in this document

The safety level is classified according to ISO 3864-2. The following overview shows the safety symbols and pictograms used in this manual.

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

⚠WARNING For a possibly dangerous situation which could lead to severe personal injury or to death.

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


For general safety notes as listed in this chapter.


For electrical hazards, warnings or precautionary measures when dealing with electricity.


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


Reference to other instructions.

Touch-sensitive areas

This symbol is used to designate touch-sensitive areas that might not be self-evident.


Touch (to open/close menus and perform functions)


Move up or down.


Move to the right or left


Scroll up or down using two fingers

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1.12.2 Symbols used on the device

For general symbols, see section 15 Appendix - Symbols

Potential equalisation.

CF symbol. The device is classified safe for internal and external use. However, it is only defibrillation protected when used with the original SCHILLER patient cable.

Symbol for the recognition of electrical and electronic equipment

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 the manufacturer for disposal. Improper disposal can harm the environment and human health.

Attention: consult accompanying documents.

Consult the user guide.

Attention: non ionising electromagnetic radiation. The device contains an HF transmitter (Wi-Fi).

The CARDIOVIT FT-1 radiates high-frequency electromagnetic energy and can disturb other devices if not installed and operated in accordance with the user guide. CARDIOVIT FT-1 However, there is no guarantee that no interference can occur in certain installations. If the CARDIOVIT FT-1 causes interferences, these can be determined by switching the device off/on or by transmitting/not transmitting ECG data. The user can take the following measures to solve this problem:

- Increase the distance between the disturbed device and the CARDIOVIT FT-1. A minimum distance of 20 cm must be kept between the device and a pacemaker.
- Turn the device to change the angle of radiation.
- Connect the device to a different mains connector.

For more details, see page 103.

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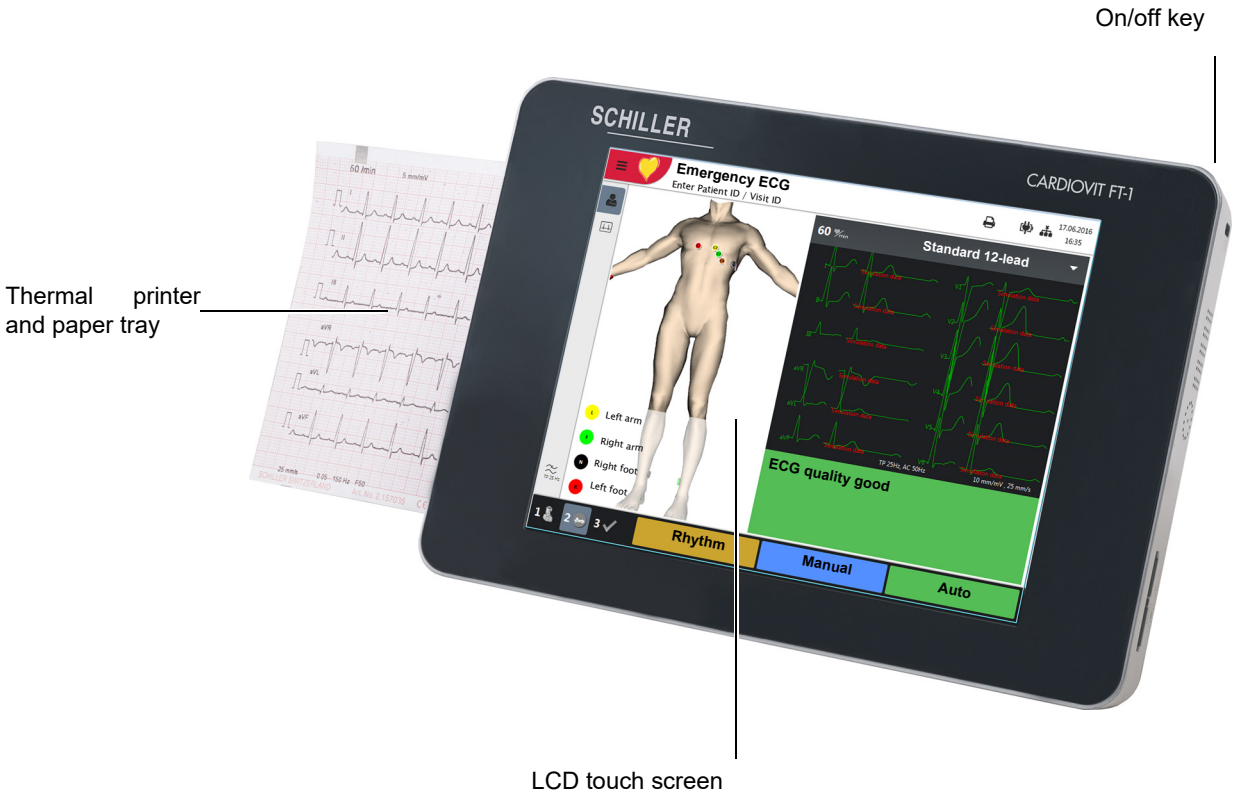
2 Introduction

The SCHILLER CARDIOVIT FT-1 is a 12-channel ECG unit designed to record, display, and measure resting ECGs. The multi-touch screen allows easy and intuitive operation to efficiently enter patient data, record ECGs and adjust device settings.

The CARDIOVIT FT-1 has the following features:

2.1 Main components of the CARDIOVIT FT-1



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2.1.1 Standard

- Pacemaker detection
- Manual rhythm printout in real time (leads, speed and amplitude can be changed)
- Auto mode recording (10 seconds) with user-defined layout
- Rhythm
- Measurements
- Full disclosure of all 12 channels
- Display of reversed electrodes
- Recording review
- Connectivity
  - Wi-Fi
  - LAN
- Schiller Link
- PDF export to USB

2.1.2 Options

- Interpretation with ETM Sport
- Barcode reader - to read a patient‘s ID and retrieve patient data from a database
- Culprit Coronary Artery Algorithm (CCAA)
- Worklist

2.2 Connections

- RJ-45 Ethernet connector (network)
- 2 USB interfaces for software updates with a USB stick and connection of a bar-code reader.
- 1 USB connection type B for streaming to CS-104 application
- Kensington lock

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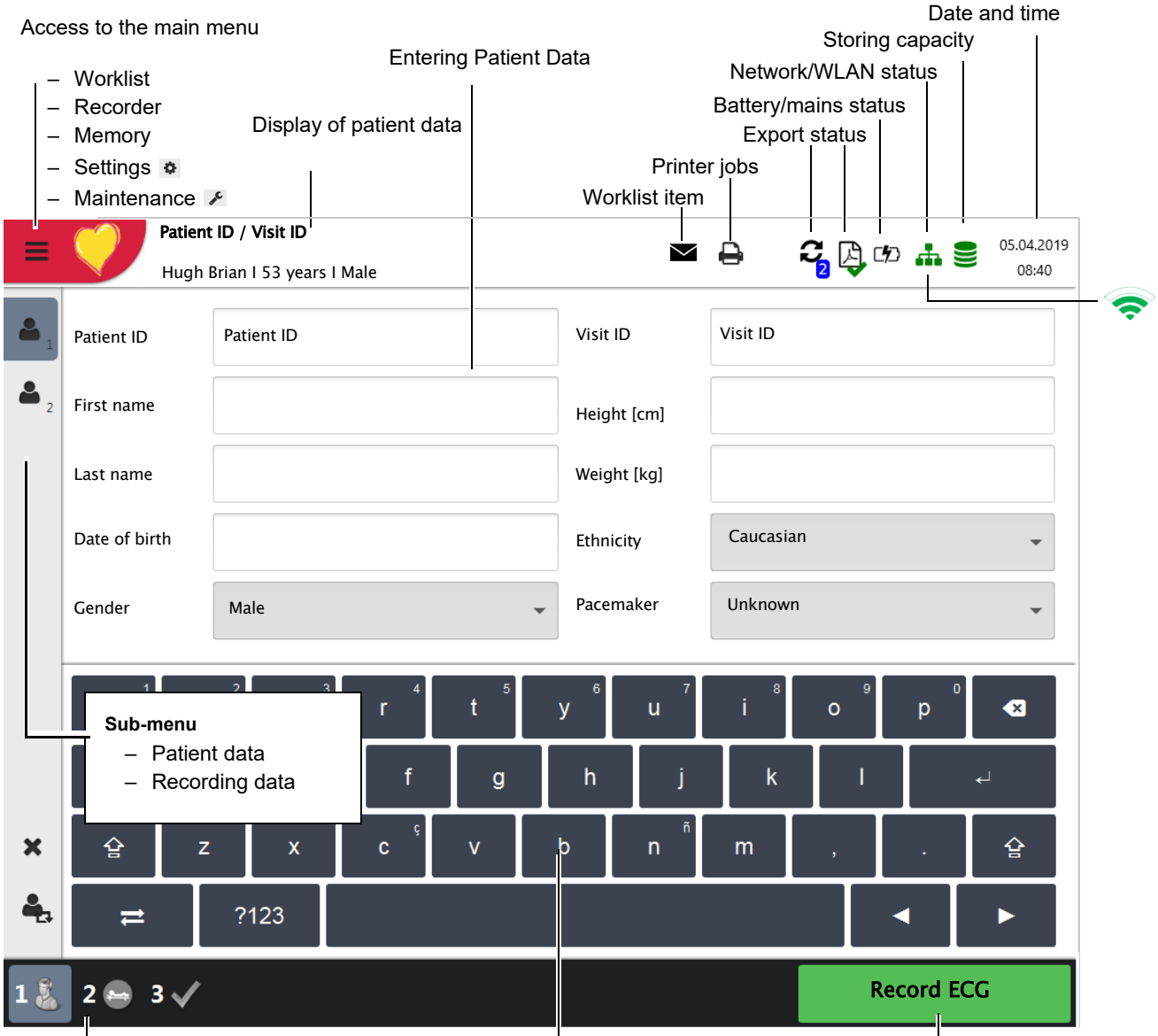
2.3 Display

The display will vary according to the task being carried out. In all screens, however, the top, bottom and right areas always display the same category of information. Example for a typical patient data view:



Access to process steps

- 1 Enter patient data
- 2 Apply electrodes, check and record resting ECG, CCAA or ETM Sport
- 3 Check and save recording

Alphanumeric or just numeric virtual keyboard

Function key, go to the next step. The function keys change their function depending on the selected view.

Review

Function key to return to the review screen; this is only available when the recording has not yet been accepted.

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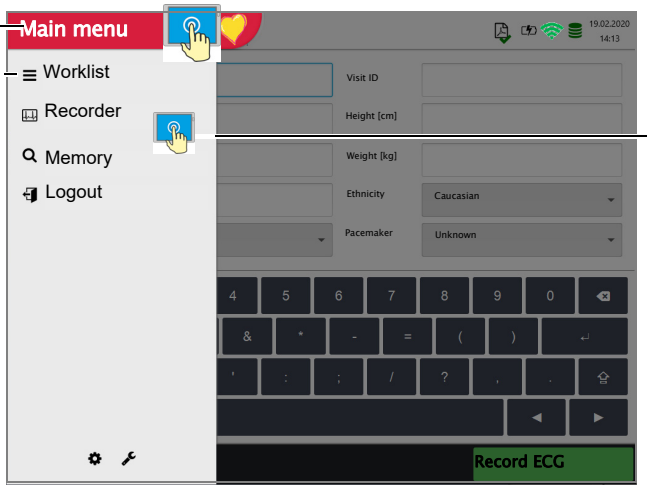
2.4 Multi-touch screen operation

The touch-sensitive areas of the screen are located as follows:

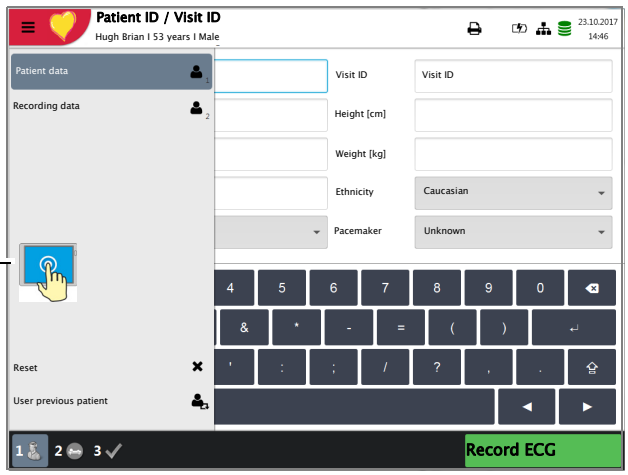
→ Open/close the main menu

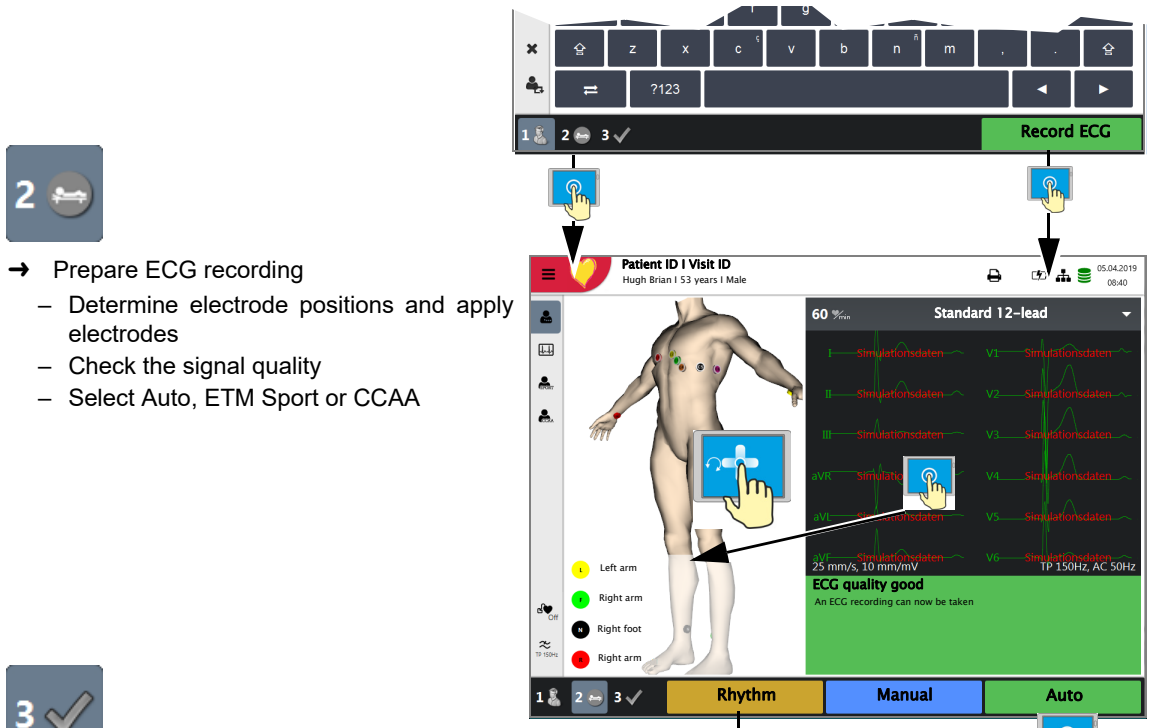
→ Enter patient and recording data, or import patient and recording data from an EMR system using the symbol ✉

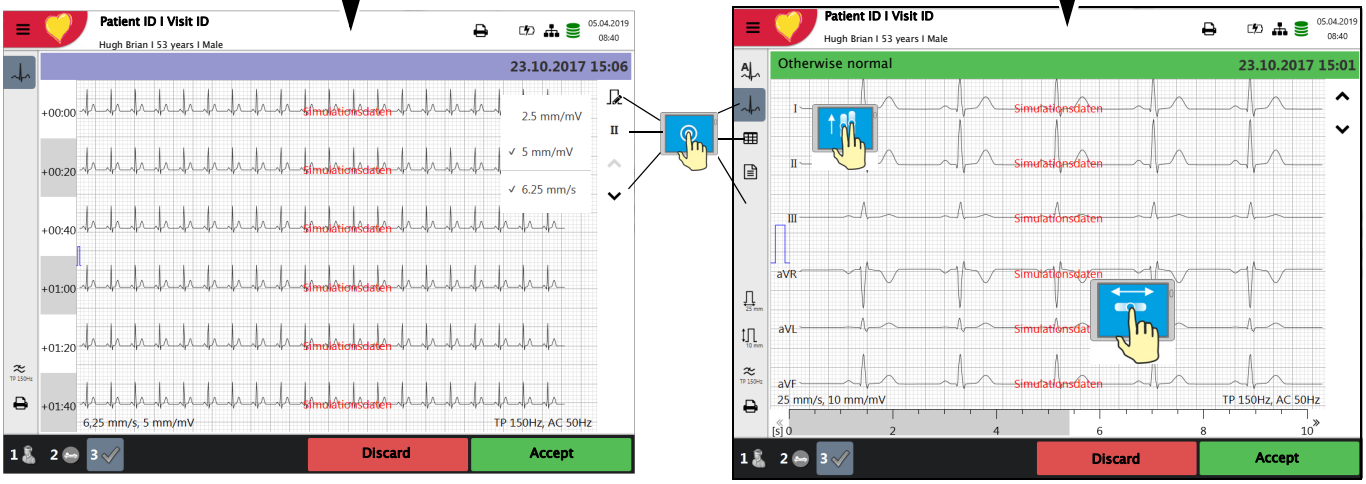


→ Select a menu option

→ Show/hide menu texts







→ Prepare ECG recording
  – Determine electrode positions and apply electrodes
  – Check the signal quality
  – Select Auto, ETM Sport or CCAA

→ To edit patient data or record an emergency ECG, press the key 1 before accepting the recording, and edit/enter the patient data. Press Review to return to the review screen.

→ The recorded ECG is displayed and can be reviewed.

→ Rotate leads I...V6: scroll up or down and along the time axis.

→ Display average values, results and measurements.

→ Set the speed with , and the amplitude with .

→ Set filter for display to 25/40/150 Hz or Off.

→ Accept the ECG (i.e. save), print, or discard.

Rhythm ECG

→ Press to set the amplitude, press II to select the lead and to move along the time axis.

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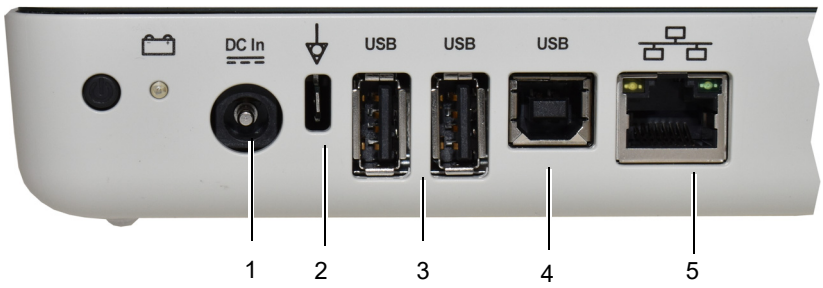
2.5 Connection panel

⚠ CAUTION

▲ All externally connected hardware must be approved by SCHILLER. Connection of any hardware not approved by SCHILLER is at the owner's risk. Moreover, the unit's warranty may become invalid.

2.5.1 Back panel



(1) Power input 15 VDC

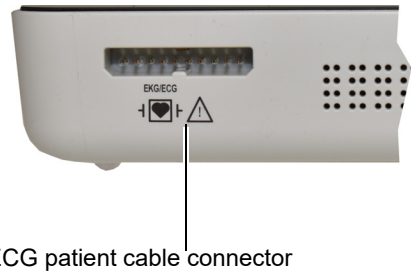
(2) Potential equalisation stud. The potential equalisation stud is used to equalise the ground potential of the unit to that of any nearby mains-powered equipment. Use the hospital or building common ground for all mains-powered units.

(3) 2x USB interfaces for the barcode scanner and USB sticks.

(4) 1x USB interfaces type B for ECG streaming to CS-104 application

(5) RJ-45 Ethernet LAN connection (Local Area Network)

2.5.2 Right hand side panel



⚠ CAUTION

▲ The patient cable as well as the connector comply with the safety standard CF, e.g. they are fully floating and isolated and defibrillation protected.

▲ The unit is only CF rated and defibrillation protected if used with the original SCHILER patient cable.

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3 Operation

3.1 Start-up and Preparation

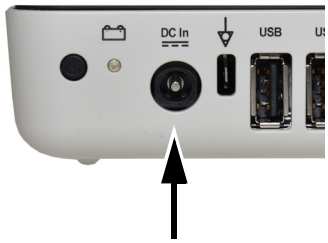
⚠ DANGER

▲ Danger of electrical shock. Do not operate the unit if the earth connection is suspect or if the power supply unit/mains lead is damaged or suspected of being damaged.

3.1.1 Location

- Do not keep or operate the unit in a wet, moist or dusty environment. Avoid exposure to direct sunlight or heat from other sources.
- Do not allow the unit to come into contact with acidic vapours or liquids.
- The CARDIOVIT FT-1 must not be placed in the vicinity of X-ray or diathermy units, large transformers or electric motors.

3.1.2 Connection of external cable assemblies and ancillary equipment



1. Connect the external power supply unit to the mains.
2. Connect the external power supply unit's output to the back panel. The mains indicator lamp is lit.
3. Leave the CARDIOVIT FT-1 connected to the mains for 8 hours to fully charge the battery (see page 22).
4. Connect the potential equalisation cable.
5. Connect the patient cable (side panel).
6. Connect any ancillary and optional equipment (see page 19). These may include the following:
   – Network cable
   – USB barcode reader

3.1.3 Potential equalisation

The potential equalisation stud at the back of the unit is used to equalise the ground potential of the CARDIOVIT FT-1 to that of all mains-powered equipment in the vicinity. Use the hospital or building common ground. A yellow/green ground cable is supplied as an option (article number 2.310320).

⚠ WARNING

▲ Danger of triggering ventricular fibrillation! If the CARDIOVIT FT-1 is used together with devices that are designed for direct cardiac application, both devices must be connected to the hospital/building common ground (potential equalisation) to prevent equalising currents between different device potentials.

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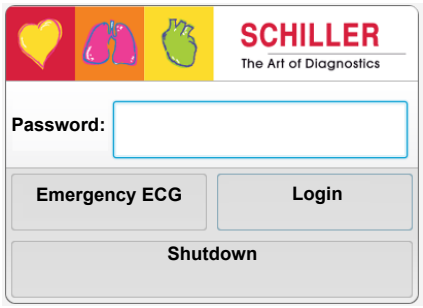
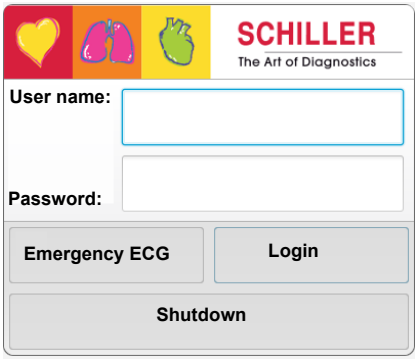
3.2 Switching on / off

➜ The unit is switched on and off with the **On / Off** key.

3.2.1 Login and Logout / Emergency ECG

If Access control is activated, the following dialogues are displayed:





Login

➜ Enter the password and press **"Login"** to log in.

In addition, for access control modes "Local" or "Schiller Server", a user name is required.

Emergency ECG

➜ Select **"Emergency ECG"** to bypass the login procedure and to perform an emergency ECG.

➜ You are automatically logged off when the ECG recording is accepted.

Logout

➜ Open the main menu  and select Logout .

- In the system settings (Section Access control, page 87), the following Access control settings are available:
  - **None**: no user name or password is required, the program is opened directly when the device is switched on.
  - **Basic**: two access levels with a separate password for the device (recording) and/or the settings.
  - **Local**: the user and password are defined locally in the settings. Three different privileges can be defined.
  - **SCHILLER Server**: user, password and access privileges are defined on the SCHILLER Server.
- The user roles and privileges are individually assigned to the users, defining access to different workflows and functions. If a function is not available, it means that the logged in user does not have the necessary privileges for this function. Individual users and their user groups and privileges are defined on the **SCHILLER Server**, or **locally** if the system is not networked
- If **Emergency ECG** is selected, the login procedure is bypassed and the patient data view is displayed directly. Once the emergency ECG has been accepted, the login dialogue is displayed again. Access to other functions is not possible.

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3.3 Power supply

3.3.1 Mains and battery indicators

The unit can either be operated from the mains supply or from the built-in rechargeable battery. Battery charging is indicated by the LED below the battery symbol.

The current power source is displayed in the top right corner of the screen when the unit is switched on:

- Mains via external power supply unit , battery is being charged
- Internal rechargeable battery ( )
- When running on battery power and the battery capacity is limited, the battery symbol is flashing.
- When mains is connected and the battery is charging, the battery symbol is displayed 'filling'.

Full

Half full

Almost

Empty

Battery capacity

The internal battery provides power for up to four hours. When the unit is running on battery power (mains not connected), the battery symbol indicates the battery status. When the battery is full, the symbol is solid.

When running on battery power and the battery capacity is low, the battery symbol turns red.

Battery charging

The battery is charged when the unit is connected to the mains supply. The unit can remain connected to the mains supply without damage to either the battery or the unit.

When the battery is not fully charged and the mains supply is connected, the battery LED is blinking, indicating that the battery is being charged.

3.3.2 Isolating the device from the mains supply

To isolate the device from the mains supply, remove the mains plug from the external power supply unit.

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3.4 System and ECG settings

- The system settings (time, date, device ID etc.) and other general settings are described on page 77.
- Resting ECG settings (auto format, user defined leads, print options, interpretation, rhythm lead definition, etc.) are described on page 52.

Overview **Menu > Settings**

Menu Settings	Sub-menu
ECG (Page 77)	• Leads & cable • Filters & formulas • Views & layouts • Additional leads • Interpretation • Rhythm ECG
Reports (Page 80)	• General • Manual printout • Resting ECG • Rhythm ECG
Connectivity (Page 83)	• EMR integration • Update server • Ethernet • WLAN
Regional (Page 84)	• Date & time • Keyboard • Language • Units • Patient ID system
General (Page 85)	• Info • Power management • Station • Update • Manage licenses • Mandatory fields • Workflow • Access control • Printer

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3.5 Changing the printing paper

Important

The device is delivered without printing paper inserted. The thermal paper is sensitive to heat, humidity and chemical vapours. The following points apply to both paper storage and archiving of recordings:

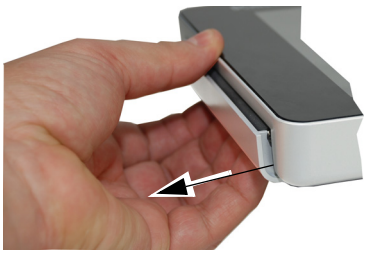
- Before use, keep the paper in its original cardboard cover. Do not remove the cardboard cover until the paper is to be used.
- Store the paper in a cool, dark and dry location.
- Do not store near chemicals, e.g. sterilisation liquids.
- Do not store in a plastic cover.
- Certain glues can react with the paper. Therefore, do not use glue to attach the printout onto a mounting sheet.

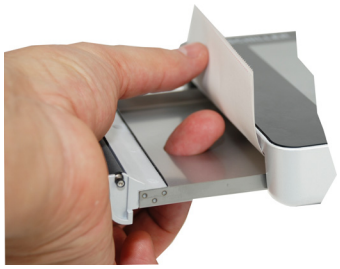
SCHILLER can only guarantee perfect printouts when original SCHILLER chart paper or chart paper of the same quality is used.

If different paper is used:

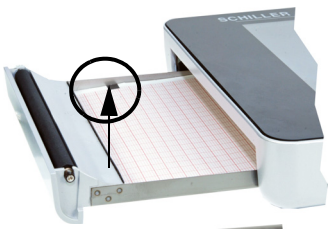
- The operator is solely responsible for making sure that the printing quality is flawless.
- The printing quality needs to be checked before the device is used for patient recordings

1. Pull out the paper tray.





2. Remove the remaining paper.



3. Place a new paper pack into the paper tray with the printed (grid) side facing upwards and the black paper mark facing the top of the unit.

4. Pull out the first page as shown on the left.
5. Push the paper tray home until it locks into place.

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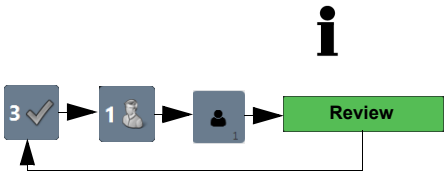
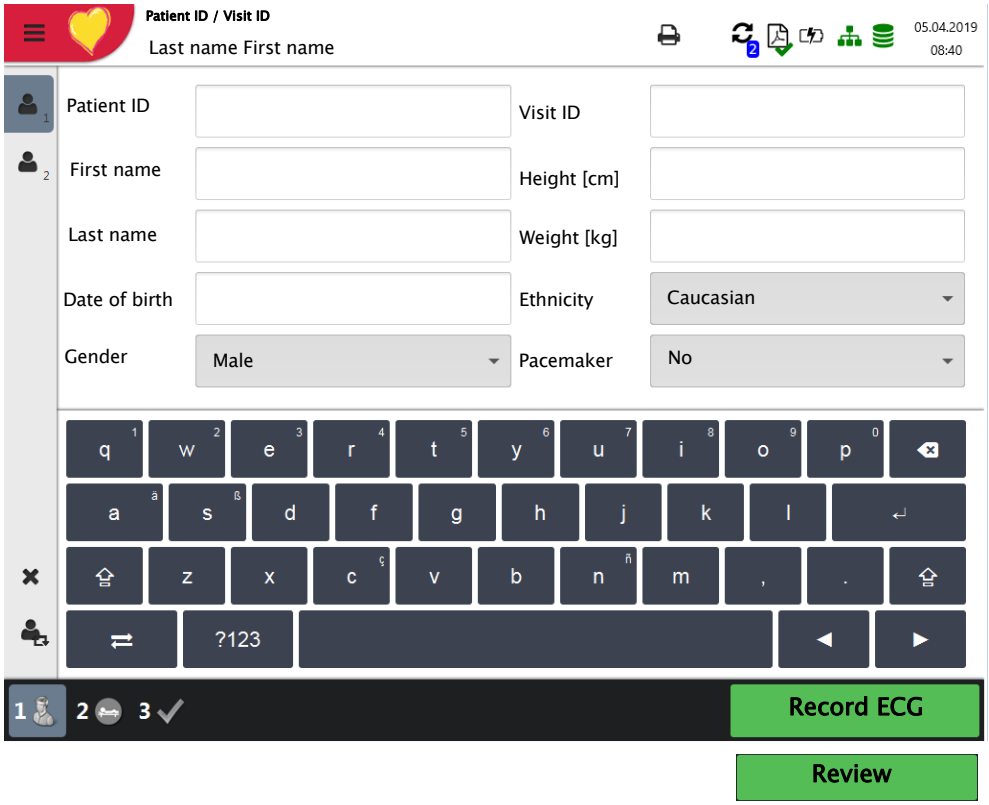
3.6 Patient / recording data

In the patient data screen, new patients can be entered and previously stored patient data can be edited.



If a recording is performed without having entered a patient or visit ID, a UUID is generated instead of a patient ID, "Emergency ECG" is given instead of a last name, and the date and time are given instead of a first name. If you want to enter patient data once the recording has been performed (and before it has been accepted), you can jump to the Patient data screen, enter the data and use the Review key to jump back to Step 3 to accept (save) the recording.



With the data of the current patient, you can:

- edit it directly in the entry fields
- obtain the data from the server by entering the Patient or Visit ID (configuration: see page 83)
- press **X** to reset the data and enter a new patient
- press to use the previous patient data
- read the Patient ID with a barcode scanner.
  - Use the alphanumeric keyboard (shown) to enter the patient data.
  - For numeric entry fields, only the numeric keypad is displayed.
  - Press the key **?123/ABC** to display special characters.
  - Use the **Shift** key to switch the keyboard to capitals.
  - To select special characters from the keyboard, **press and hold the key and select the special character**.

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Patient data - left entry fields

Patient ID Enter the patient's identification number.

Last name Enter patient's name (maximum 50 characters).

First name Enter patient's first name (maximum 50 characters).

Date of birth Enter the patient‘s date of birth in the format dd-mm-yyyy or yyyy.mm.dd.

Gender Enter the patient‘s gender - Male or Female or Undefined.

Patient data - right entry fields

⚠ CAUTION

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

Visit ID An additional field for visit ID can be entered if required. The maximum number of characters is 50.

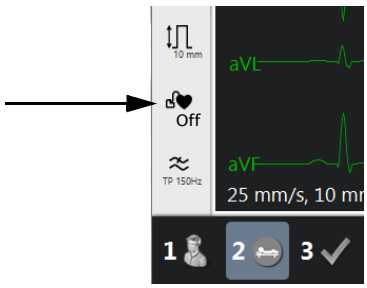
Height Enter the patient's height.

Weight Enter the patient's weight.

Ethnicity Select one of the following:

- Undefined
- Caucasian
- Asian
- Black / African American
- American Indian / Alaska Native
- Native Hawaiian / Pacific Islander
- Hispanic
- Oriental
- Other

Pacemaker Select if the patient has a pacemaker (Yes/No/Unknown).



Regardless of this setting, detected pacemaker pulses are indicated in blue and the interpretation states that it is a pacemaker ECG. Visual indication of pacemaker pulses is switched off and needs to be manually activated in the ECG preview.

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Recording data - left side

Room Examination room

Medication ☐ Digitalis

Indication Reason for medication

Recording data - right side

Referring physician Referring physician

Attending physician Attending physician

Remark Remarks about the patient/recording

Deleting entered patient data.

The previous patient data is entered again.

All fields (except for Medication) can be set as Mandatory fields: **Menu** > **Settings > General > Mandatory fields**, see Section 9.5 General, page 85. For worklist recordings, defined mandatory fields are not taken into account.

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3.6.1 Patient data query (PDQ)

When the unit is connected to SEMA or another hospital patient database (via network or WLAN), patient data can be filled in automatically when the **Patient ID** or **Visit ID** is entered. This is called **Patient Data Query** or **PDQ**.

Patient data query is possible as follows:

- The patient data is filled in automatically after the Pat ID/visit ID has been entered by the user or read with a barcode reader (confirm by pressing Enter) (see following).

The PDQ settings are defined in **Menu** > **Settings > General > Workflow** - the following options are available:

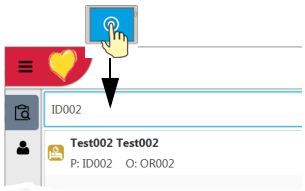
- **Patient data query (PDQ mode)** - select one of the following:
  - Patient ID
  - Visit ID

These settings along with other transmission settings are detailed in the system settings (see page 74).

PDQ with barcode reader

If a barcode reader is attached (see next page), scan the barcode to enter the **Patient ID** / **Visit** ID. Patient data is filled in automatically when the **Patient ID**/**Visit ID** is read with a barcode reader.

3.6.2 PDQ in the worklist



If you use the "Worklist" workflow, you can search/enter patient data in the same way (see page 69).

Tap the Search field and read the **Patient ID** or **Visit ID** using the barcode reader. The corresponding work item is shown in the worklist.

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3.6.3 Barcode reader

Barcode scanner configuration: see document 2.510721.

Country-specific character sets can be defined in **Menu** > **Settings > Regional > Keyboard > External keyboard layout**.

A barcode reader can be attached to the USB port on the back panel to read the Patient ID / Visit ID. SCHILLER has tested the following barcode reader:

➜ Symbol Model LS 2208, from Symbol Tech N.Y.

When a barcode reader is connected, the patient data is read from the barcode (generated by the hospital system). If an external hospital patient database is available, all patient data is entered in the patient data fields of the FT-1 as described on the previous page.

A worklist can also be downloaded from a hospital patient database giving patient data and specifying the type of recording to be carried out. The worklist is described on page 69.

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4 Placing the electrodes

⚠WARNING

▲ Ensure that neither the patient nor the leading parts of the patient connection nor the electrodes (including the neutral electrodes) come in contact with other persons or conductive objects, even when these are earthed.

4.1 Basics

Careful application of the electrodes and good electrode contact is important for a good recording (see electrode positioning on pages 32 - 39).

A minimal resistance between skin and electrode is required to obtain the best ECG signal and ensure the highest quality ECG recording. Therefore, please note the following points:

1. Only use electrodes that are recommended by Schiller AG (see accessories)
2. Before using disposable electrodes, check that the expiration date has not yet passed.
3. To increase the electrode's conductivity and adherence:
   – Shave the areas where the electrodes are to be placed, if necessary.
   – Thoroughly clean the areas with alcohol or soapy water.
   – Let the skin dry before applying the electrodes.
   – [1]When applying the electrodes, ensure that a layer of gel is between the electrode and the skin.
4. Check the electrode resistance as described in the section 4.10.
5. If the electrode resistance is higher than the acceptable level:
   – Remove the electrode and use an abrasive cleaning pad or abrasive cleaning gel [2] to remove the uppermost layer of epidermis.
   – Apply the electrode. Always use a new disposable electrode.
6. Ensure that the patient is warm and relaxed before you start the recording.
7. After the recording, remove the electrodes. Clean the suction or vacuum electrodes according to the manufacturer's instructions.

1. Electrode gel is integral with single-use electrodes and extra gel does not need to be applied when single-use electrodes are used. For biotab electrodes, solid conductive gel is incorporated in the adhesive.
2. Dedicated abrasive cleaning gel gives very good results in reducing the skin-electrode resistance.

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4.2 Electrode Identification and Colour Code

The electrode colour codes in the following sections correspond to Code 1 (IEC) for the graphics and to Code 2 (AHA) in the tables

	IEC		AHA	
	IEC label	Colour	AHA label	Colour
Limb	R	Red	RA	White
	L	Yellow	LA	Black
	F	Green	LL	Red
Chest according to Wilson	C1	White/red	V1	Brown/red
	C2	White/yellow	V2	Brown/yellow
	C3	White/green	V3	Brown/green
	C4	White/brown	V4	Brown/blue
	C5	White/black	V5	Brown/orange
	C6	White/violet	V6	Brown/violet
Neutral	N	Black	RL	Green

The patient cable (type IEC or AHA) is set in the menu section 5.6.1 Leads & cable, see chapter 5.6.1.

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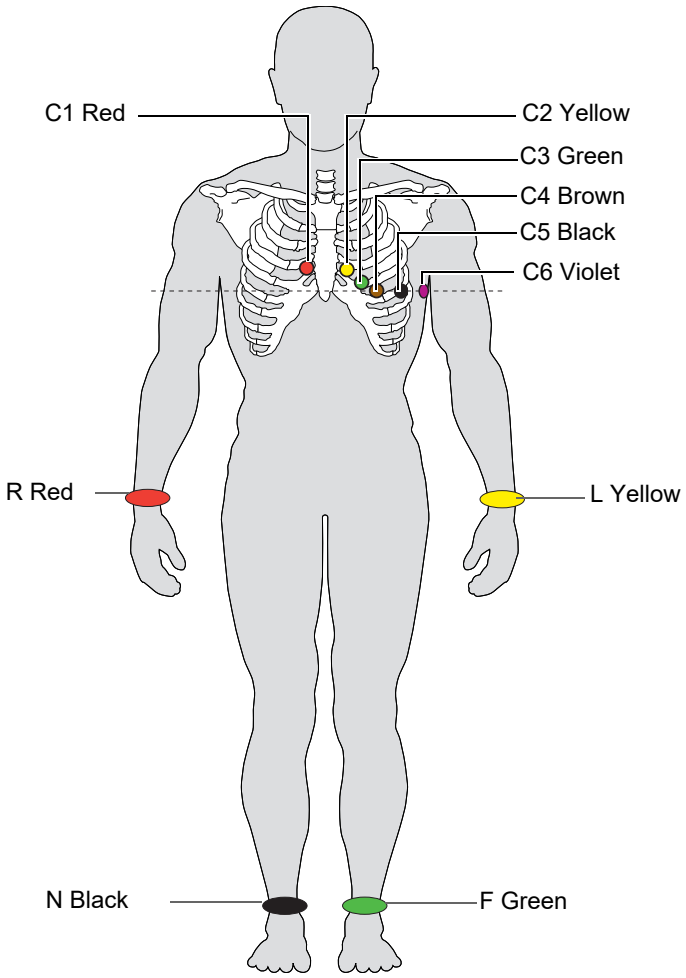
4.3 Standard 10-lead resting ECG



4.3.1 Electrode placement for standard leads

IEC label	AHA label	Electrode placement
C1 red	V1 red	→ Fourth intercostal space at the right sternal border
C2 yellow	V2 yellow	→ Fourth intercostal space at the left sternal border
C3 green	V3 green	→ Midway between C2 and C4
C4 brown	V4 blue	→ Fifth intercostal space on the mid-clavicular line
C5 black	V5 orange	→ Anterior axillary line on the same horizontal level as C4
C6 purple	V6 purple	→ Mid-axillary line on the same horizontal level as C4
L yellow	LA black	→ Left arm (resting ECG)
R red	RA white	→ Right arm (resting ECG)
F green	LL red	→ Left foot (resting ECG)
N black	RL green	→ Right foot (resting ECG)

The electrode resistance can be checked in the electrode test screen (see page 39).

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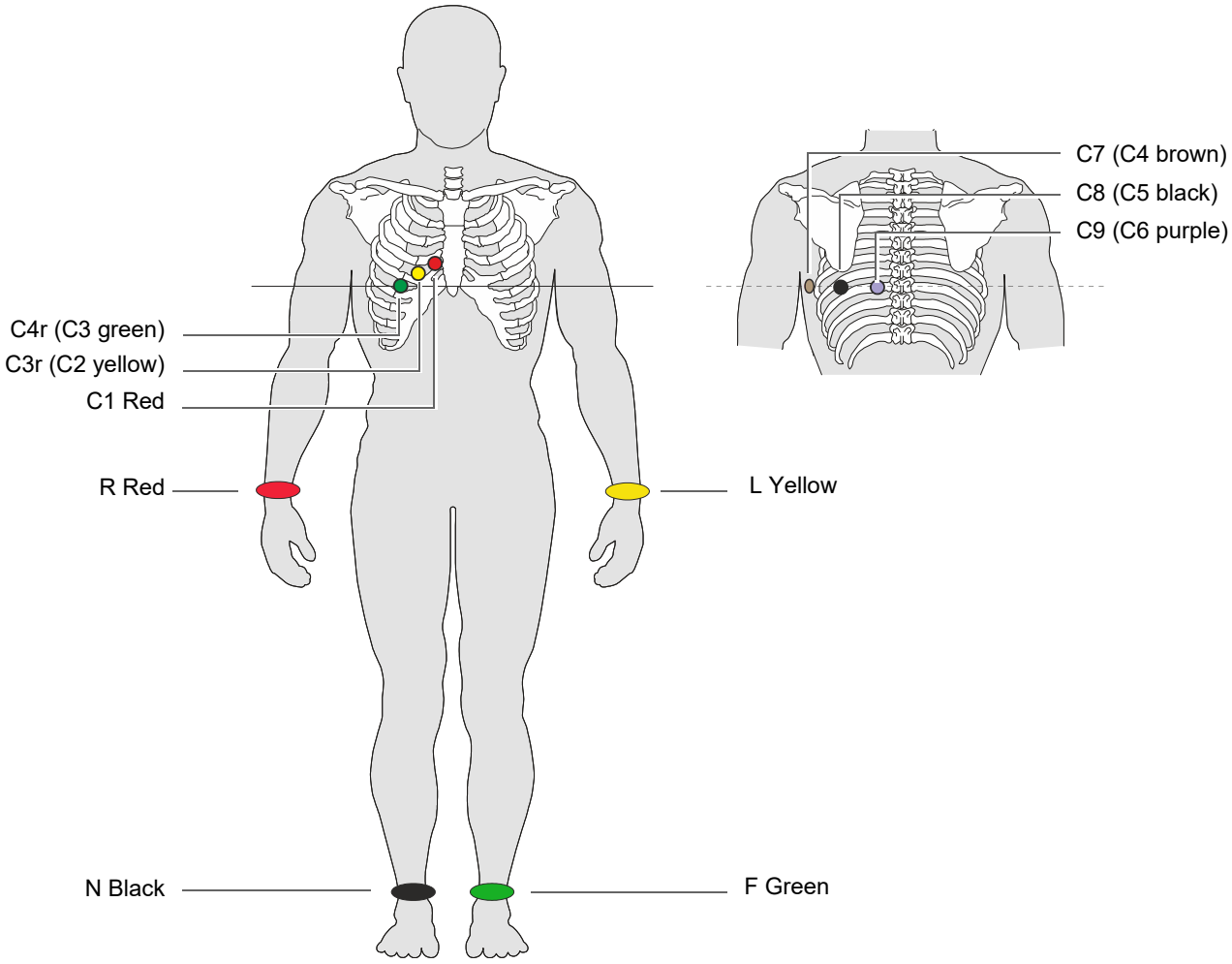
4.4 Balanced



Balanced, 10-wire cable

IEC label	AHA label	Electrode placement
C1 white / red	V1 brown / red	→ Fourth intercostal space at the right sternal border.
C3r white / yellow	V3r brown / yellow	→ Left of the mid-scapular line at the level of C3
C4r white / green	V4r brown / green	→ Left of the mid-scapular line at the level of C4
C7 white / brown	V7 brown / blue	→ Left axillary line at the level of C4.
C8 white / black	V8 brown / orange	→ left posterior axillary line opposite C4
C9 white /violet	V9 brown / violet	→ Left axillary line at the level of C4, opposite C3
L Yellow	LA Black	→ Left arm
R Red	RA White	→ Right arm
F Green	LL Red	→ Left foot
N Black	RL Green	→ Right foot

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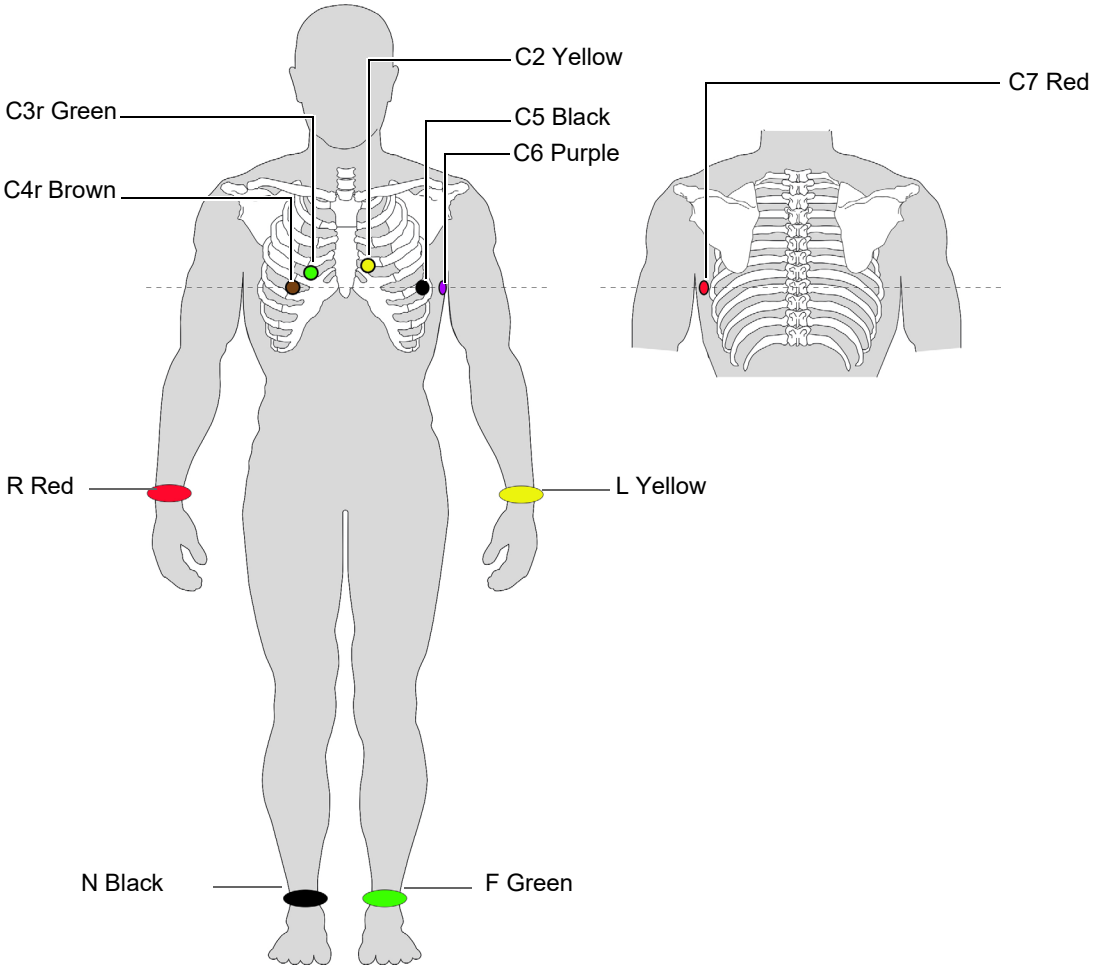
4.5 Paediatric



IEC label	AHA label	Electrode placement
C4r white / brown	V4 brown / blue	→ Fifth intercostal space on the mid-clavicular line.
C3r white / green	V3 brown / green	→ Fourth intercostal space, above C4r
C2 white / yellow	V2 brown / yellow	→ Fourth intercostal space at the left sternal border
C5 white / black	V5 brown / orange	→ Anterior axillary line on the same horizontal level as C4
C6 white /violet	V6 brown / violet	→ Mid-axillary line on the same horizontal level as C4
C7 (C1 white /red)	V7 (V1 brown / red)	→ Left posterior axillary line at the level of C4.
L yellow	LA black	→ Left arm (resting ECG)
R red	RA white	→ Right arm (resting ECG)
F green	LL red	→ Left foot (resting ECG)
N black	RL green	→ Right foot (resting ECG)

For paediatric patients, we recommend setting the myogram filter to Off = 250 Hz.

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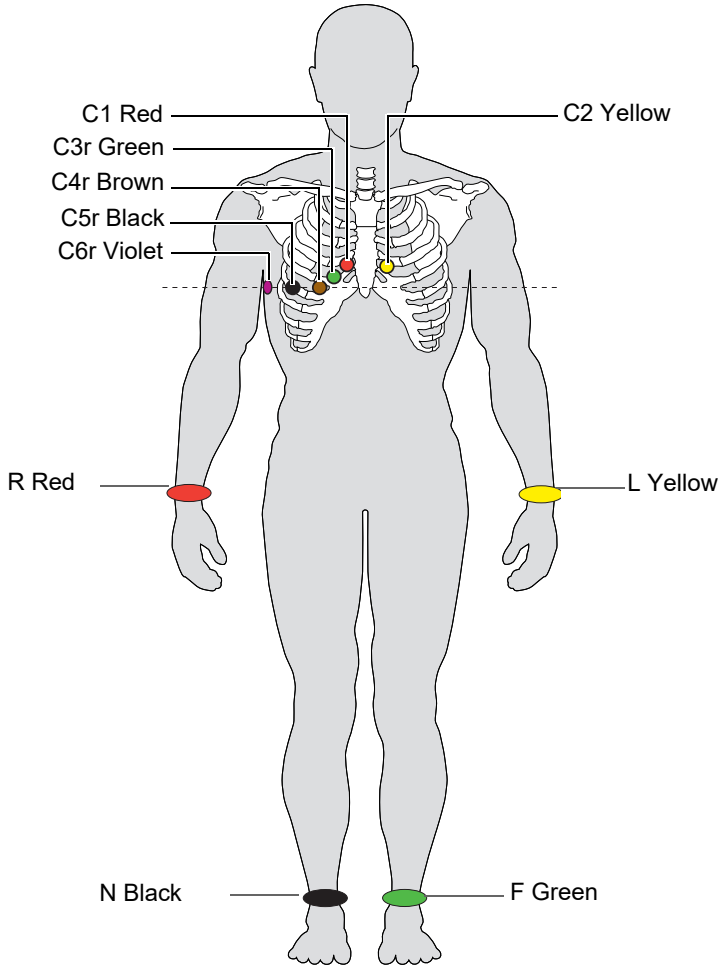
4.6 Right precordials (C3r-C6r)

Since the treatment of an infarction might depend on the influence of the right ventricle, it is suggested to perform additional recordings with right precordial leads in the case of an acute infarction of the right ventricle's inferior wall (Circulation 2007).



IEC label	AHA label		Positioning
C1 white / red	V1 brown / red	→	Fourth intercostal space at the right sternal border.
C2 white / yellow	V2 brown / yellow	→	Fourth intercostal space at the left sternal border.
C3r white / green	V3 brown / green	→	Designated point halfway between C1 and C4r.
C4r white / brown	V4 brown / blue	→	Fifth intercostal space on the mid-clavicular line.
C5r white / black	V5 brown / orange	→	Anterior axillary line on the same horizontal level as C4r.
C6r white / violet	V6 brown / violet	→	Mid-axillary line on the same horizontal level as C4r.
L Yellow	LA Black	→	Left arm
R Red	RA White	→	Right arm
F Green	LL Red	→	Left foot
N Black	RL Green	→	Right foot

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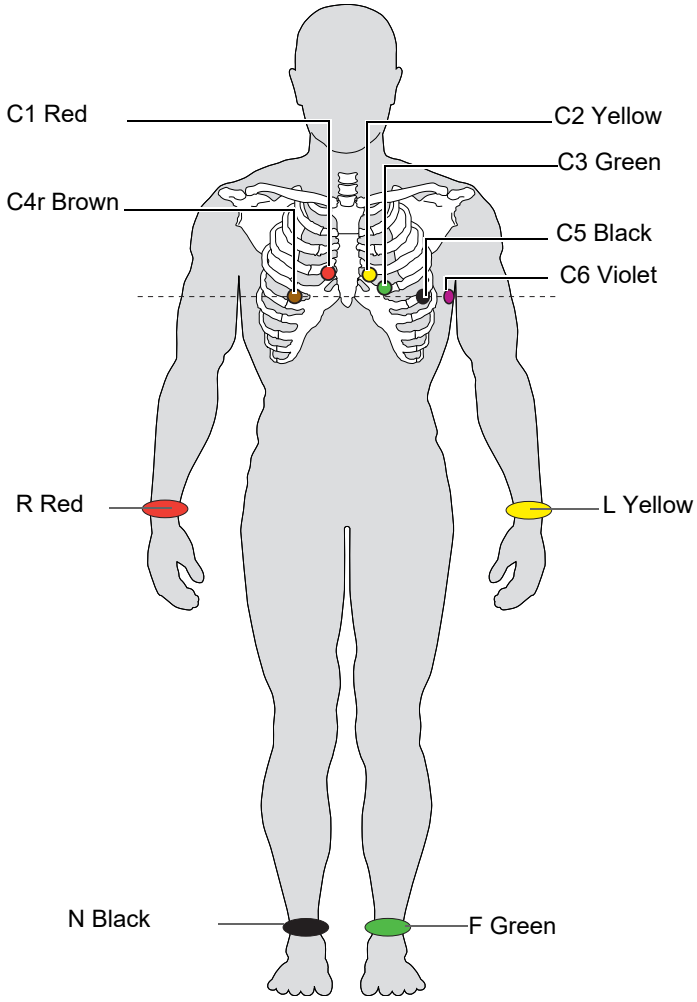
4.7 Standard with C4r

ACC/AHA guidelines recommend examining patients suffering from a myocardial infarction with inferior ST elevation for possible RV ischaemia or RV infarction; this examination should be performed with a right precordial C4r lead.



IEC Label	AHA Label		Electrode placement
C1 white / red	V1 brown / red	→	Fourth intercostal space at the right sternal border.
C2 white / yellow	V2 brown / yellow	→	Fourth intercostal space at the left sternal border.
C3 white / green	V3 brown / green	→	Midway between C2 and C4.
C4r white / brown	V4 brown / blue	→	Fifth intercostal space on the mid-clavicular line.
C5 white / black	V5 brown / orange	→	Anterior axillary line on the same horizontal level as C4.
C6 white /violet	V6 brown / violet	→	Mid-axillary line on the same horizontal level as C4.
L Yellow	LA Black	→	Left arm
R Red	RA White	→	Right arm
F Green	LL Red	→	Left foot
N Black	RL Green	→	Right foot

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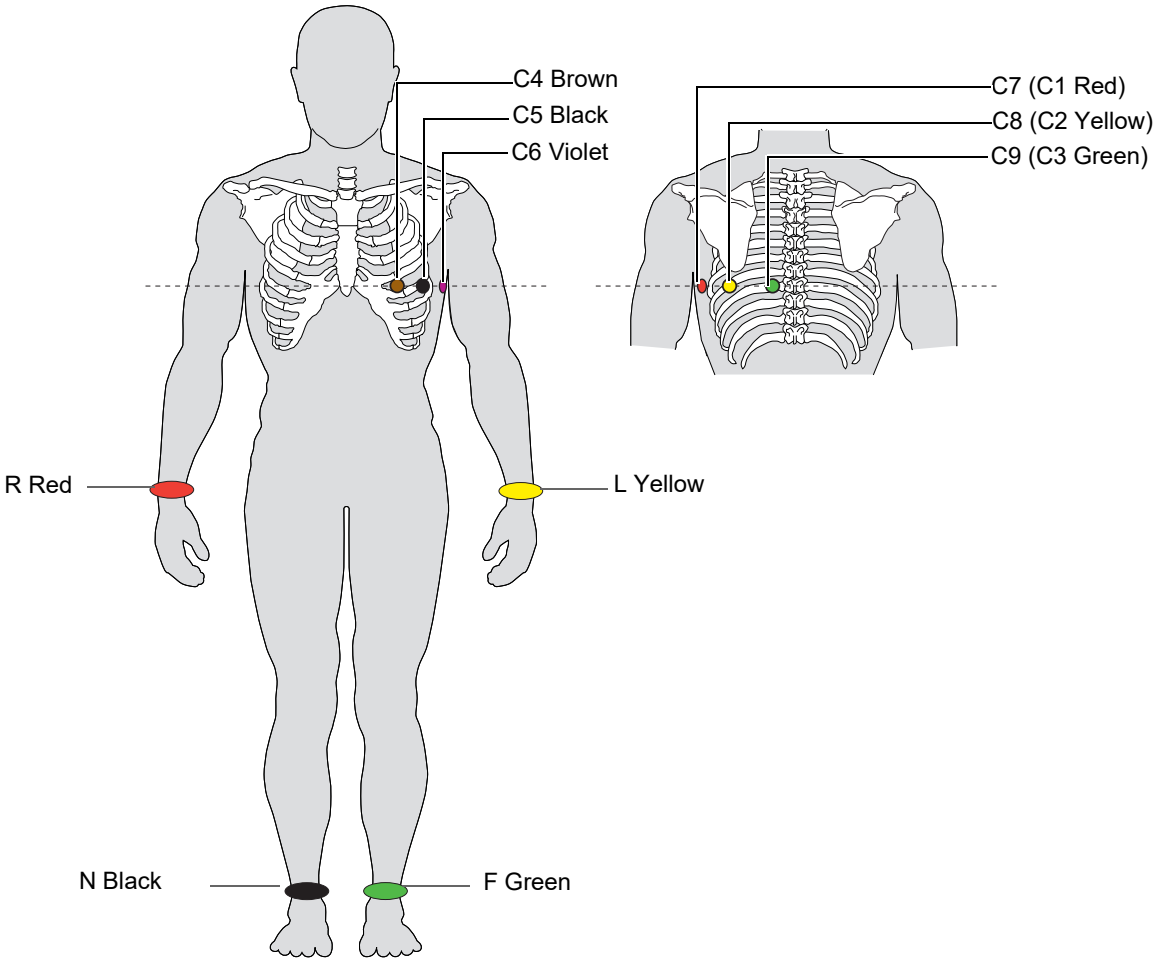
4.8 Left posterior C7-C9

If an acute coronary occlusion is strongly suspected, it is recommended to also register posterior chest wall leads (C7–C9)



IEC label	AHA label		Positioning
C7 (C1 white /red)	V7 (V1 brown / red)	→	Left posterior axillary line at the level of C4.
C8 (C2 white /yellow)	V8 (V2 brown / yellow)	→	Left of the mid-scapular line at the level of C4.
C9 (C3 white /green)	V9 (V3 brown / green)	→	Left paravertebral line at the level of C4.
C4 white / brown	V4 brown / blue	→	Fifth intercostal space on the mid-clavicular line.
C5 white / black	V5 brown / orange	→	Anterior axillary line on the same horizontal level as C4.
C6 white /violet	V6 brown / violet	→	Mid-axillary line on the same horizontal level as C4.
L Yellow	LA Black	→	Left arm
R Red	RA White	→	Right arm
F Green	LL Red	→	Left foot
N Black	RL Green	→	Right foot

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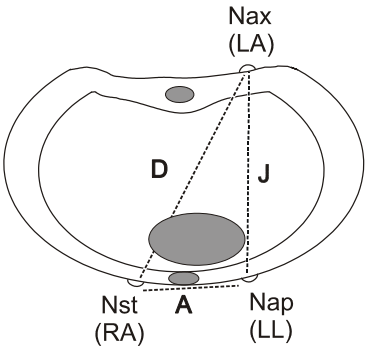
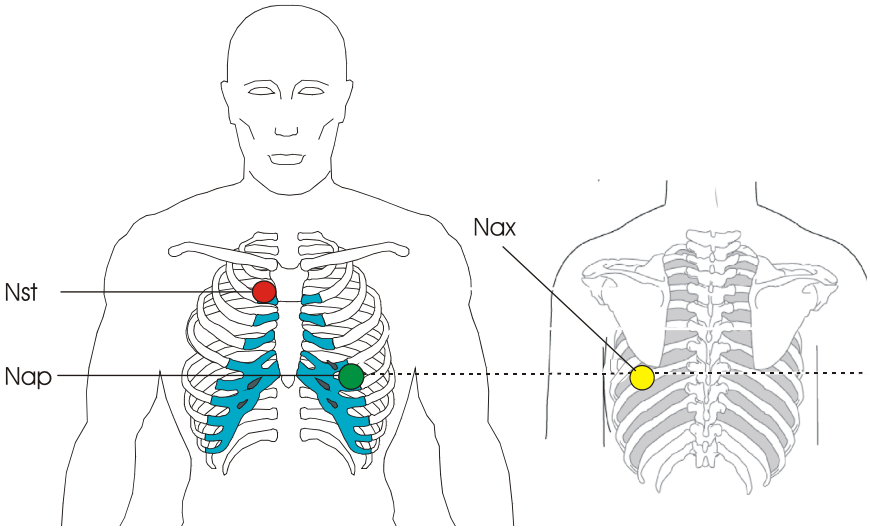
4.9 Nehb leads



The Nehb leads are bipolar chest leads. They are of special interest for the diagnosis of changes in the posterior ventricle wall. Three leads are arranged in the form of a triangle, also called the “small cardiac triangle”. Nehb dorsal (D) is measured between the electrode positions Nax and Nst; Nehb anterior (A) between Nap and Nst, and Nehb inferior (J) between Nap and Nax.



Place the electrodes as follows:

IEC label	AHA label		Electrode placement
C1 white / red	V1 brown / red	➜	**Nst**: 2nd rib at the right sternal border.
C2 white / yellow	V2 brown / yellow	➜	**Nax**: left posterior axillary line (on the back), directly opposite Nap.
C4 white / brown	V4 brown / blue	➜	**Nap**: 5th intercostal space, midclavicular line (cardiac apex).

Place all other electrodes in the normal positions (page 32).

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4.10 Skin/Electrode Resistance

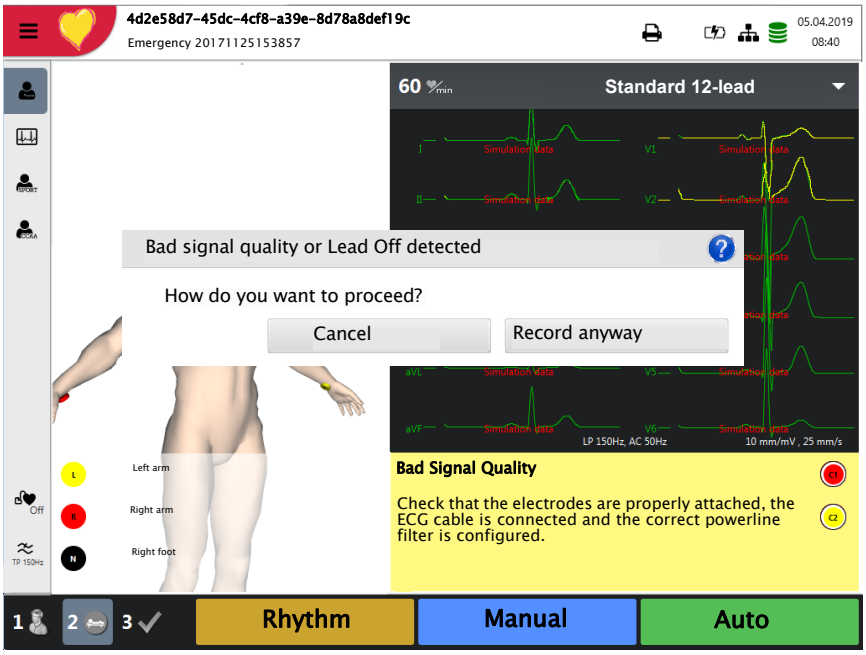
4.10.1 Electrode and patient cable check

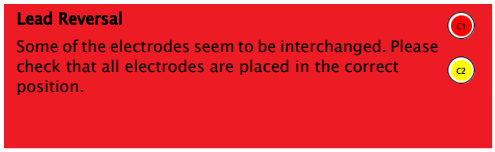
The electrode check is part of step 2 before the start of an ECG recording. The following is checked and displayed:

- Excessive noise (signal noise too high)
  - Due to poor electrode contact
  - Mains interferences (mains filter not activated)
- Electrodes reversed
- Electrodes have come off

The electrode status is shown in the bottom right information field of the screen. If an electrode is displayed red, the suspected cause is displayed. Reapply the electrode.

- If F (LL) or N is not connected or has come off, the electrode resistance cannot be measured and all leads are marked red.





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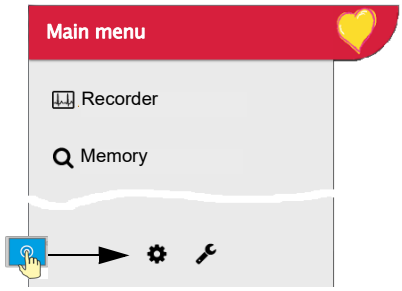
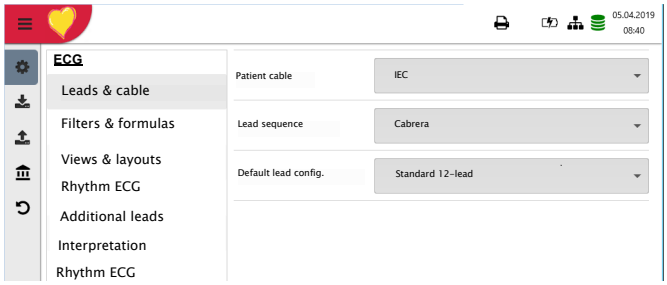
4.11 Lead sequence/lead view

4.11.1 Setting Standard or Cabrera lead sequence

➜ The lead sequence is defined in the settings.
(**Menu > Settings > ECG > Leads & cable**).

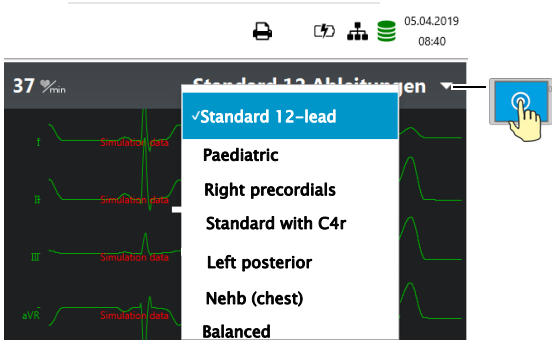
➜ In the Lead menu, select between Standard and Cabrera.





4.11.2 Select the lead view (Standard or other settings)

The lead display can be set directly in the electrode screen in Step 2.



The lead labels on the display and on printouts change accordingly.

Important

Automatic interpretation is only possible when **Standard 12 lead** is set.

For ETM Sport recordings, lead configuration Standard 12 lead is selected automatically.

For CCAA recordings, lead configuration Standard with C4r is selected automatically.

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5 Resting ECG

WARNING

▲ After heavy artefacts or lead off, the displayed heart rate may not be reliable.

CAUTION

▲ The safety notes at the beginning of this book must be read and fully understood before taking an ECG recording.

▲ The CARDIOVIT FT-1 device is CF classified ⊣♥⊢. The patient connection is fully isolated. During the ECG recording, ensure that neither the patient nor the leading parts of the patient connection nor the electrodes (including the neutral electrodes) come in contact with other persons or conductive objects, even when these are earthed.

▲ Do not operate the unit if the earth connection is suspect or if the mains lead is damaged or suspected of being damaged.

▲ If an external electronic device (e.g. a PC) is connected to the CARDIOVIT FT-1, use the potential equalisation stud for earth protection.

If another format than the default format is set for the automatic printout, the printout can differ from the format displayed on the screen.

The displayed lead sequence (Standard or Cabrera) can be selected (see 5.6.1 section 5.6.1 Leads & cable page 52). Amplitude and speed can be defined in the menu 5.6.3 section 5.6.3 Views & layouts, page 54.

For the preview, the following parameters can be freely programmed (before start of the recording):

- Lead configuration
- Filter

Saved recordings can be displayed and printed in another format at any time. For further information on how to define the format, see 5.6.7section 5.6.7 Reportspage 58.

CAUTION

▲ When using the 25 Hz or 40 Hz filter, the displayed or printed ECG may not always fulfil the requirements for a diagnostic ECG.

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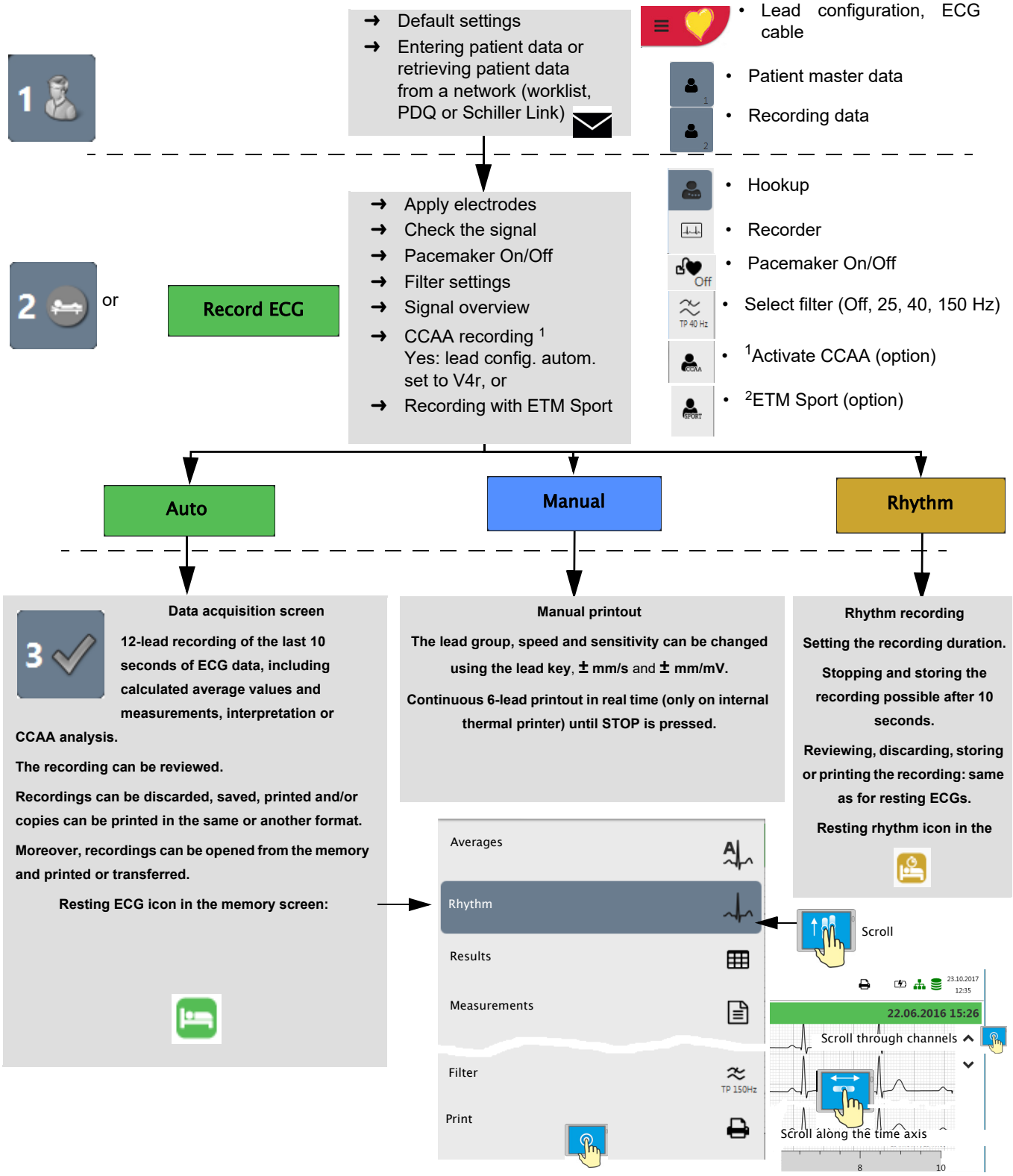
5.1 Resting ECG - procedural flow diagram



1. The dialogue CCAA is only displayed if this option is installed (Section 6.1.2 Starting the CCAA analysis, page 64).
2. The dialogue ETM Sport is only displayed if the Interpretation option is installed.

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5.1.1 Printing, saving and transferring automatically

Menu > Settings > General > **Workflow**

Activate **Print after acquisition**, **Transmit after acquisition** and **Delete after transmission** to automatically print and transmit a saved recording or to delete recordings after transmission.

- The transmission settings are detailed in the section Settings (see page 83).
- Further ECG settings are described later in this section (see page 52).
- Printing and transfer from the memory is described in the section Memory (see page 66).
- The settings are saved automatically. The settings can be exported (see page 76).

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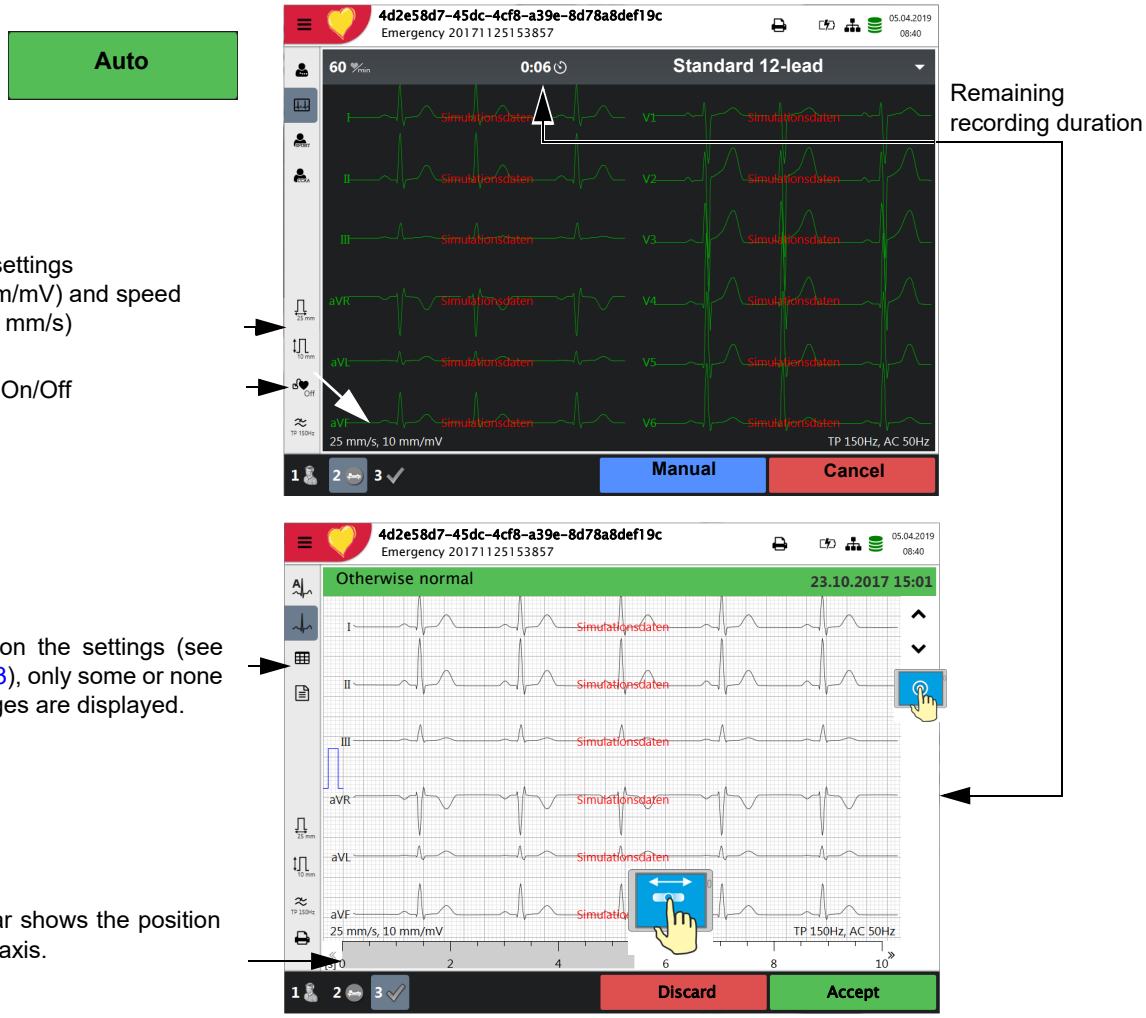
5.2 Automatic resting ECG recording

To take an automatic ECG recording, press the **Auto** key. After approx. 10 seconds, the recording is analysed and the result displayed. The recording can be checked and saved and further printouts can be obtained in different formats. Depending on the setting, the recording is deleted automatically as soon as it has been transmitted, or it remains stored in the memory.



Check the recording using (time axis) and (select channels).

➜ Select the amplitude and speed for the display .

➜ Select filter (Off = 250 Hz, 25, 40 or 150 Hz) .

➜ **Accept** the recording.

➜ Print the recording .

➜ Press **Discard** to exit the preview without storing the ECG.

➜ Select a recording for review and printout via the **Memory** menu.

➜ Open the menu **Memory** to delete a recording from memory.

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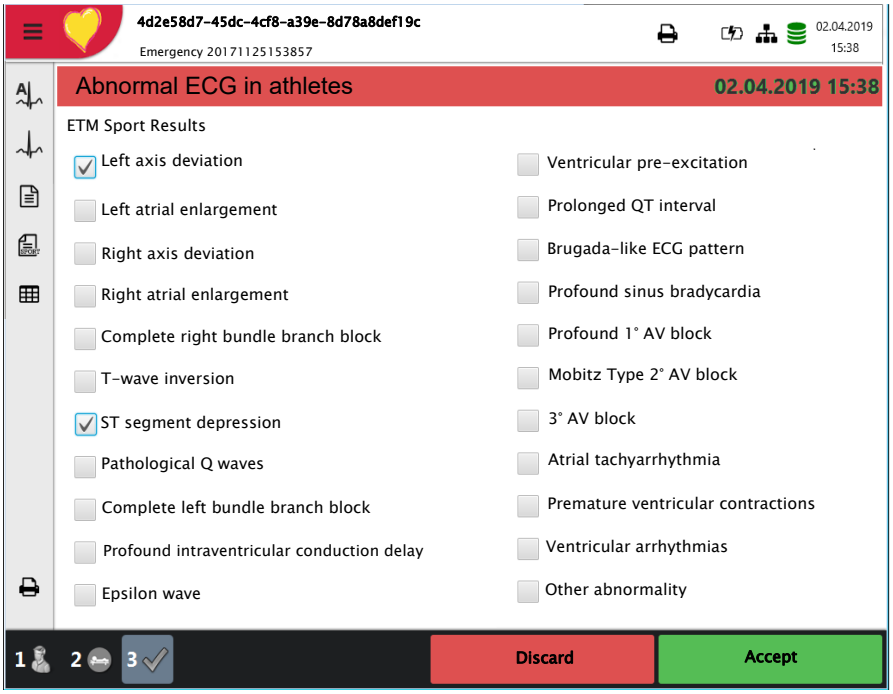
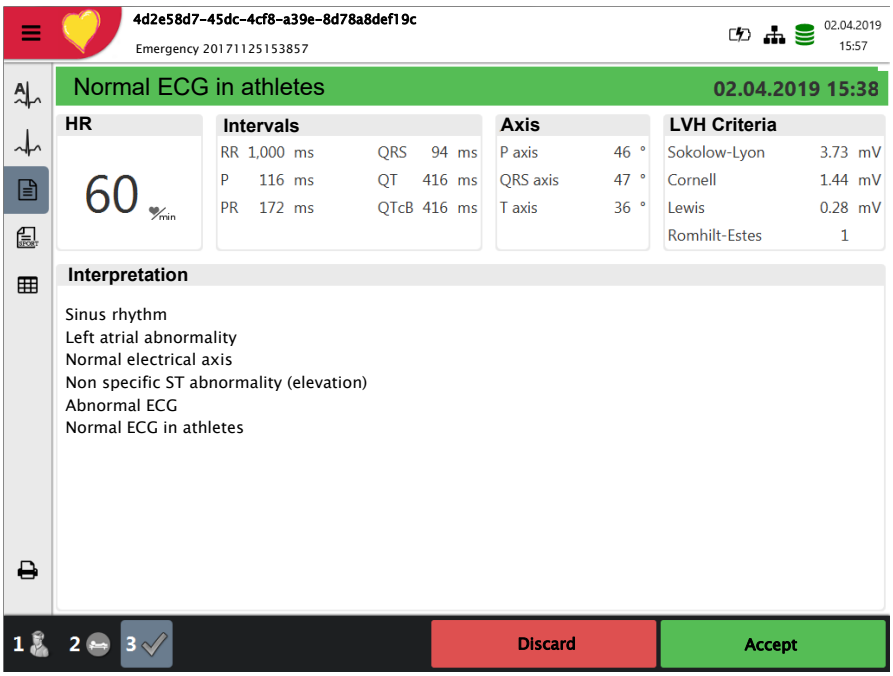
5.2.1 ETM Sport

When ETM Sport interpretation is selected before the start of a recording, the additional criteria for an athlete's ECG are analysed and displayed.

Activate ETM Sport



Example of an ECG rated normal for athletes, but rated abnormal when the standard interpretation is used.



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5.2.2 Automatic printout

The printout gives the following:

- Heart rate
- Patient ID or Visit ID
- Time and date
- Speed
- Sensitivity
- Filter
- Device ID
- Serial number
- Software version
- Technician

And any combination of the following (for printout settings, see page 58):

Patient data
- All patient data according to Section 3.6 Patient / recording data, page 25

Result
- Interpretation (can be deactivated in **Menu > Settings > ECG > Interpretation** , see Section 5.6.5 Interpretation, page 57).
- Intervals & axis

Measurements
- Detailed measurement table

Rhythm
- ECG recording of all 12 leads in either Standard or Cabrera format (according to selection)

Averages
- Averaged cycles with markings

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5.3 Manual rhythm printout

Use this function to print a real-time ECG. The print parameters such as lead sequence, print speed and sensitivity can be changed by the user during the printout.

The real-time ECG is not saved. The chosen settings only apply to the printout.

5.3.1 Starting manual printout

Manual

➜ To start a manual real-time printout, press the **Manual** key.

The default printout settings are **25 mm/s** and **10 mm/mV.** These settings can be changed, see Section 5.6.7 Reports, page 58

Select lead sequence

➜ To change the lead sequence for the printout (Standard I, II, III, aVR, aVL, aVF), press the key **- I - aVF +**.

The Standard and Cabrera lead sequences are as follows:

Lead sequence	Lead group 1	Lead group 2
Standard	I, II, III, aVR, aVL, aVF	V1, V2, V3, V4, V5, V6
Cabrera	aVL, I, -aVR, II, aVF, III	V1, V2, V3, V4, V5, V6

The lead group is selected in the ECG settings (see page 52).

Select speed

➜ To change the printout speed (5, 12.5, **25** and 50 mm/s), press the key **"- mm/s +".**

Select sensitivity

➜ To change the printout sensitivity (5, **10** and 20 mm/mV), press the key **"- mm/mV +".**

Stopping the printout

➜ To stop the manual recording (printout), press the **Stop** key.

The printout provides the following information:

- Selected leads
- Heart rate, averaged over four beats
- Patient ID or Visit ID
- Time and date
- Speed
- Sensitivity
- Filter
- Device ID
- Serial number
- Software version

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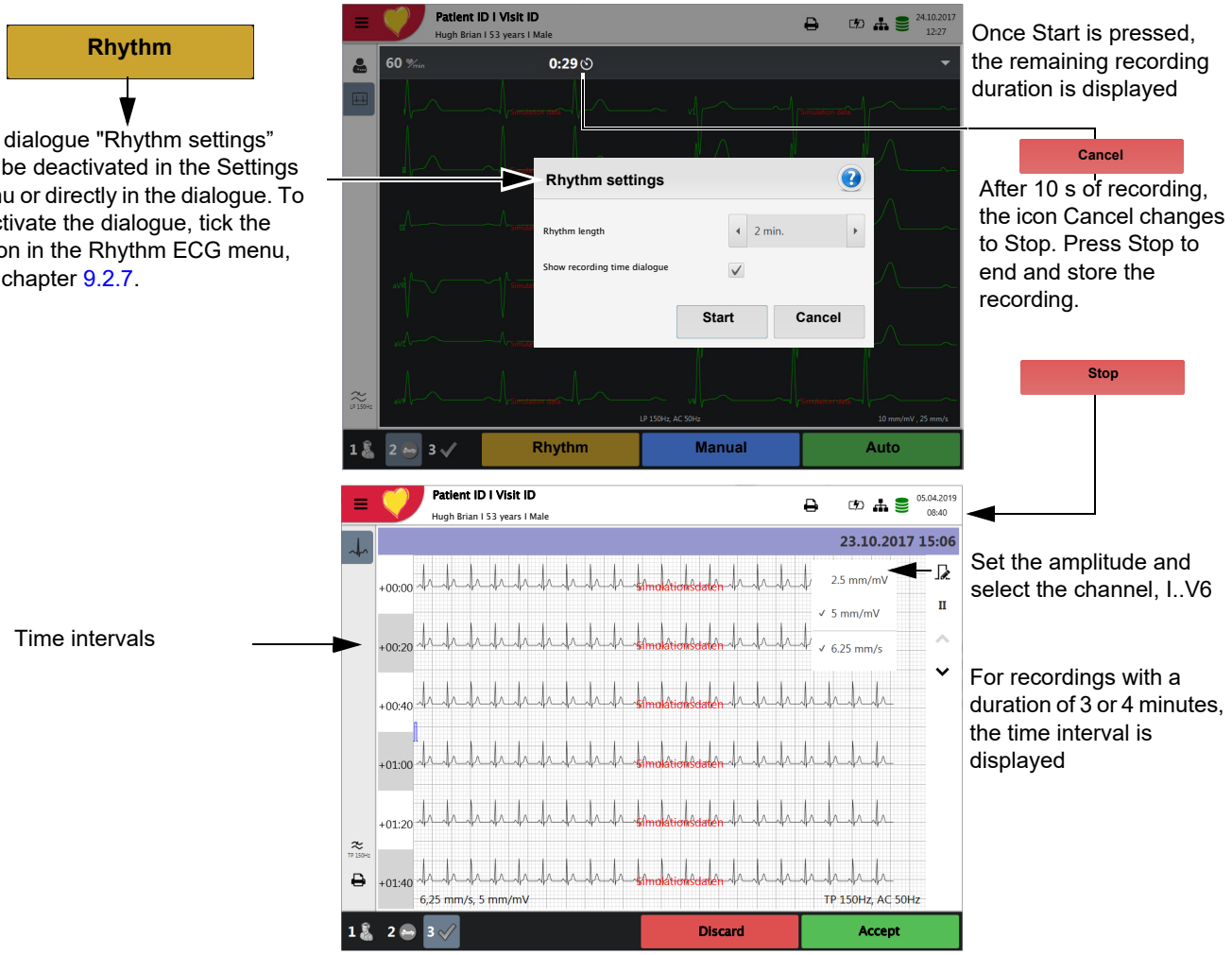
5.4 Rhythm recording

Press **Rhythm** to perform a rhythm recording. Select the recording duration in the dialogue that pops up. If a recording is cancelled after more than 10 seconds, it can still be stored. The recording can be checked and saved and further printouts can be obtained in different formats. Depending on the setting, the recording is deleted automatically as soon as it has been transmitted, or it remains stored in the memory.



Check the recording using II (select channel) and ⌃⌄ (time axis).

- ➜ Select filter (Off = 250 Hz, 25, 40 or 150 Hz)
- ➜ **Accept** the recording
- ➜ Print the recording
- ➜ Press **Discard** to exit the preview without storing the ECG
- ➜ Select a recording for review and printout via the **Memory** menu .
- ➜ Open the menu **Memory** to delete a recording from memory.

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5.4.1 Automatic printout

The printout gives the following:

- Heart rate
- Patient ID or Visit ID
- Time and date
- Speed
- Sensitivity
- Filter
- Device ID
- Serial number
- Software version
- Technician
- Resting rhythm curves, see page 61.

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5.5 Changing the ECG preview layout

The ECG preview is optimised for 2 columns with 6 leads each, or for 3 columns with 4 leads each. The amplitude and speed can be set to 5, **10** or 20 mm/mV, and to 12.5, **25** or 50 mm/s. For the settings, see Section 5.6.3 Views & layouts, page 54.

The hookup preview layout is always set to 2 columns with 6 leads each.

5.5.1 Display

Leads

➜ The following presentation can be selected in **Menu > Settings > ECG > Leads & cable**:

The Standard and Cabrera lead sequences are as follows:

Lead sequence	Lead group 1	Lead group 2
Standard	I, II, III, aVR, aVL, aVF	V1, V2, V3, V4, V5, V6
Cabrera	aVL, I, -aVR, II, aVF, III	V1, V2, V3, V4, V5, V6

The factory setting for the Default lead configuration is Standard 12 lead. The following settings can be made:

- Standard 12-lead
- Paediatric
- Right precordials
- Standard C4r
- Left posterior
- Nebh (chest)
- Balanced

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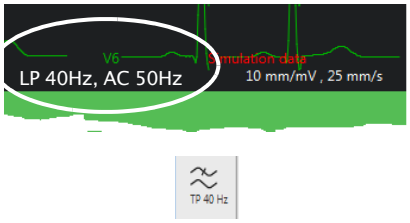
5.5.2 Myogram filter

The myogram filter suppresses disturbances caused by strong muscle tremor. In **Menu > Settings > ECG > Filters & formulas,** the **myogram filter is** defined.



In the information field, **LP 25 Hz, LP 40 Hz** or **LP 150 Hz** is displayed.

- The **default** cut-off frequency is user-defined at LP 25 Hz, 40 Hz,**150** Hz or 250 Hz (Filter Off) (see chapter 5.5.2, page 53).
- An ECG recorded in auto mode is stored unfiltered. It is therefore possible to print the stored ECG either with or without applying the myogram filter.
- For paediatric patients, we recommend setting the myogram filter to Off = 250 Hz.

⚠ CAUTION

▲ When using the 25 Hz or 40 Hz filter, the displayed or printed ECG may not always fulfil the requirements for a diagnostic ECG.

5.5.3 Other filters

The following additional filters are available:

Baseline filter

The cut-off frequency for the baseline filter is based on IEC 60601-2-25 and cannot be changed.

Notch filter

This filter prevents recording interference due to mains frequency oscillation. If the filter is active, "AC 50 Hz" or "AC 60 Hz" is displayed.

- The filters are activated/deactivated or changed in the ECG settings (see following description).

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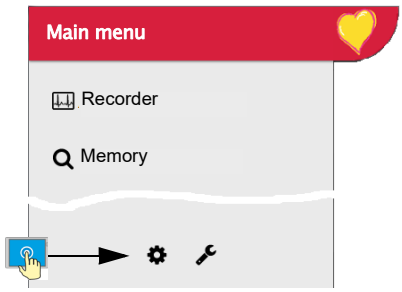
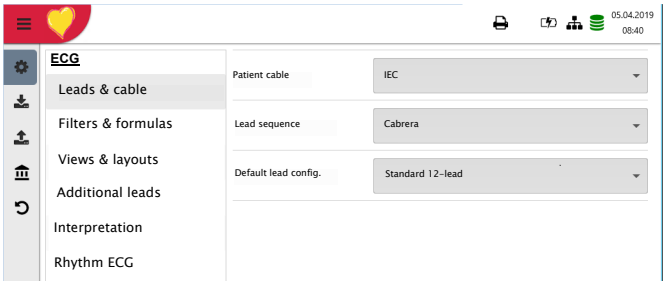
5.6 ECG settings

When pressing the Menu key , the option **Settings** is displayed. The following table gives an overview of all the settings concerning the ECG acquisition:





Overview **Menu > Settings**

Menu Settings	Sub-menu
ECG (Page 52)	• Leads & cable • Filters & formulas • Views & layouts • Additional leads • Interpretation • Rhythm ECG

Changed settings are saved automatically. In **Menu > Import**, settings from another device can be imported, or a backup of the settings can be restored (see page 76).

5.6.1 Leads & cable

Menu	Parameter	Description / selection
Leads & cable	Patient cable	IEC or AHA
	Lead sequence	Standard or Cabrera
	Default lead config.	• Standard 12-lead • Paediatric • Right precordials • Standard C4r • Left posterior • Nebh (chest) • Balanced

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5.6.2 Filters & formulas

Menu	Parameter	Description / selection
Filters & formulas	Notch filter	Off/ AC 50/AC 60 Hz
	Myogram filter	Off = 250 Hz/LP25/LP40/LP150 Hz
	Default QTc calculation	Bazett, Fridericia, Framingham, Hodges

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5.6.3 Views & layouts

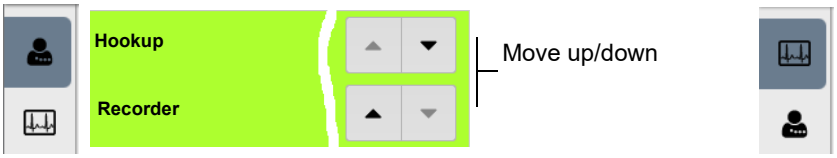
In this menu, the views and layouts for the **Preview, RECG review** and **Resting rhythms** are defined.

Preview

Menu	Parameter	Description
Preview	Preview view order	Select whether **Hookup** or **Recorder** is shown at the top
	9 lead layout	**6/3** for Nebh Chest
	12 lead layout	**2x6** / 4x3
	Speed/Amplitude	Speed 12.5/**25**/50 mm/s Amplitude 5/**10**/20 mm/mV

Order of preview views in Step 2

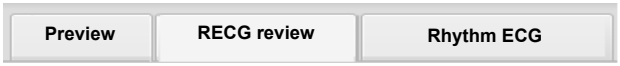
View in Step 2: either Hookup or Recorder is shown at the top



Art. no.: 2.511158 Rev.: g

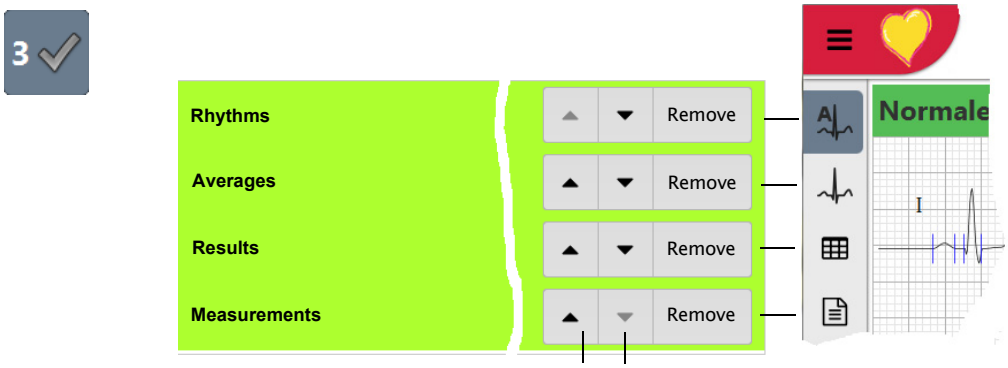
RECG review

These settings apply to current resting ECG recordings and recordings from the memory. Therefore, saved ECGs can be displayed with different settings at any time.



Menu	Parameter	Description
RECG Review	Review views and order	Adding/removing views, and defining their order: rhythms, averages, results and measurements. Settings see below.
	Rhythm 12 lead layout	**1x6** / 1x12
	Rhythm Speed/Amplitude	Speed 12.5/**25**/50 mm/s Amplitude 5/**10**/20 mm/mV
	Avg. Speed/Amplitude	Speed **25**/50 mm/s Amplitude **10**/20 mm/mV

View and order in Step 3 of the Review



Move up/down

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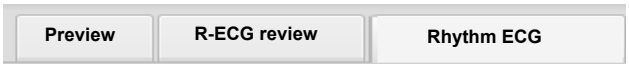
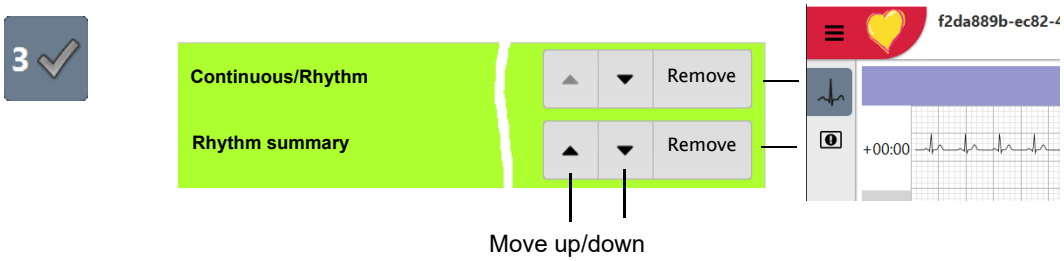
Rhythm ECG

These settings apply to current resting rhythm recordings and recordings from the memory. Therefore, saved ECGs can be displayed with different settings at any time.



Menu	Parameter	Description
Rhythm ECG	Review views and order	Adding/removing views, and defining their order: Continuous/Rhythm and Rhythm summary. Settings see below.
	Amplitude	2.5/**5** mm/mV
	Speed	Speed **6.25**/12.5mm/s

View and order in Step 3 of the Review



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5.6.4 Additional leads

Default leads per lead configuration

These settings apply to the current resting rhythm recording, recordings from the memory, and the printout. Therefore, saved ECGs can be displayed or printed with different settings at any time.

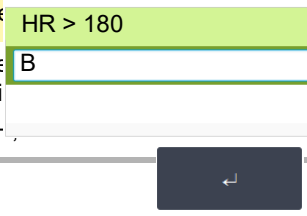
Menu	Parameter	Description / selection
Additional leads	Standard 12-lead	I/ II / III aVR / aVL / aVF / V1 / V2 / V3 / V4 / V5 / V6 / -aVR Rhythm 1 **II**, Rhythm 2 **V2**, Rhythm 3 **V5**
	Paediatric	I/ II / III aVR / aVL / aVF / V7 / V2 / V3r / V4r / V5 / V6 / -aVR Rhythm 1 **V7**, Rhythm 2 **V4r**, Rhythm 3 **II**
	Right precordials	I/ II / III aVR / aVL / aVF / V1 / V2 / V3r / V4r / V5r / V6r / -aVR Rhythm 1 **V3r**, Rhythm 2 **V5r**, Rhythm 3 **II**
	Standard C4r	I/ II / III aVR / aVL / aVF / V1 / V2 / V3 / V4r / V5 / V6 / -aVR Rhythm 1 **V4r**, Rhythm 2 **V2**, Rhythm 3 **II**
	Left posterior	I/ II / III aVR / aVL / aVF / V4 / V5 / V6 / V7 / V8 / V9 / -aVR Rhythm 1 **V8**, Rhythm 2 **V5**, Rhythm 3 **II**
	Nehb (chest)	I/ II / III / aVR / aVL / aVF / D / A / J / -aVR Rhythm 1 **D**, Rhythm 2 **A**, Rhythm 3 **J**
	Balanced	I/ II / III aVR / aVL / aVF / V4r / V3r / V1 / V7/ V8 /V9 /-aVR Rhythm 1 **V7**, Rhythm 2 **V4r**, Rhythm 3 **II**

5.6.5 Interpretation

Menu	Parameter	Description / selection
Interpretation	Print interpretation	**Yes**/No
	Display interpretation	**Yes**/No

5.6.6 Resting rhythm

Parameter	Description / selection
Rhythm length	**30 s**, 1, 2, 3 or 4 minutes Setting the recording duration.
Show recording time dialogue	☑ Yes. The dialog and can be
Predefined event texts	Enter (dele lected duri ➜ Press



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5.6.7 Reports

In this menu, the **Print layout** is defined.

General

Parameter	Description
Rhythm mode	**Sequential** or Simultaneous. When Sequential is selected, the individual lead groups show consecutive time segments (applies to the printout). When Simultaneous is selected, all lead groups show the same time segment (applies to the printout). If a format including a rhythm lead is defined for printout, Sequential is always used, even if you have selected Simultaneous.
PDF paper format	**A4** or Letter
PDF conformance	**None**, PDF/A-1a, PDF/A-1b
Company info 1, 2, 3	Enter company information on PDF rows 1, 2 and 3.

Manual printout

In this menu, the default settings for manual printouts are defined.

Parameter	Description
Lead group	Select the lead group **Limb** or Precordials
Speed [mm/s]	5, 12.5, **25** or 50 mm/s
Amplitude [mm/mV]	5, **10**, 50 mm/mV

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Resting ECG

These settings apply to current resting ECG recordings and recordings from the memory. Therefore, saved ECGs can be printed with different settings at any time.

- The order listed below can vary.

Menu	Description / selection
12 Lead	Selection and order of the following printout formats: • **Patient data** • **Rhythm 2x6, 25 mm/s, 1 page** • **Averages 4x3+1, 50/25 mm/s, 1 page** • **Results** • Rhythm 2x6, 25 mm/s, 2 page • Rhythm 2x6, 50 mm/s, 2 page • Rhythm 4x3+1, 25 mm/s, 1 page • Averages 4x3+1, 25/25 mm/s, 1 page • Averages 6x2+2, 50/25 mm/s, 1 page • Measurement Table
12 Lead (PDF)	• **Rhythms 10s, 25 mm/s, 2p** • Measurements • Averages Grid, 25/25 mm/s • Averages Grid, 50/25 mm/s • Averages Wide, 25/25 mm/s • Panorama • Rhythms 10s, 25 mm/s • Rhythms 5s, 25 mm/s • Rhythms 5s, 50 mm/s, 2p • Rhythms Grid, 25 mm/s
9 Lead	• **Patient data** • **Rhythm 6/3, 25 mm/s, 1 page** • **Averages 3x3+1, 50/25 mm/s, 1 page** • **Results** • Rhythm 6/3, 50 mm/s, 2 pages • Rhythm 6/3, 50 mm/s, 2 pages • Averages 6/3+2, 50/25 mm/s, 1 page • Measurement Table
9 Lead (PDF)	• **Rhythms 10s, 25 mm/s, 2p** • Measurements • Averages Grid, 50/25 mm/s • Averages Wide, 50/25 mm/s • Rhythms 5s, 25 mm/s • Rhythms 5s, 50 mm/s, 2p

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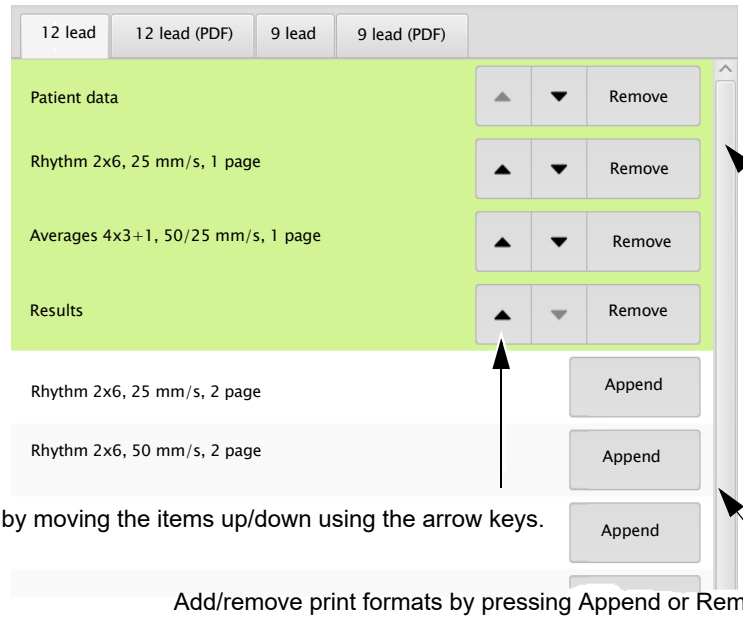
Printout formats highlighted in green are printed.



Change the order by moving the items up/down using the arrow keys.

Add/remove print formats by pressing Append or Remove.

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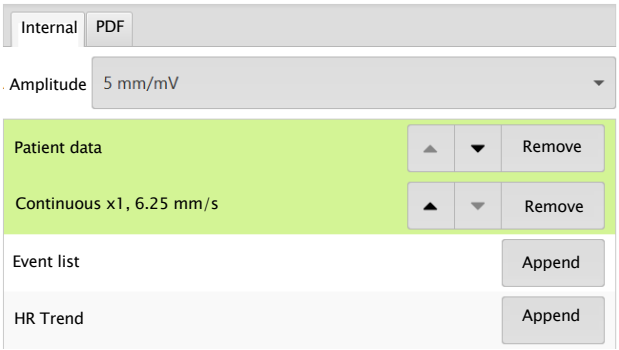
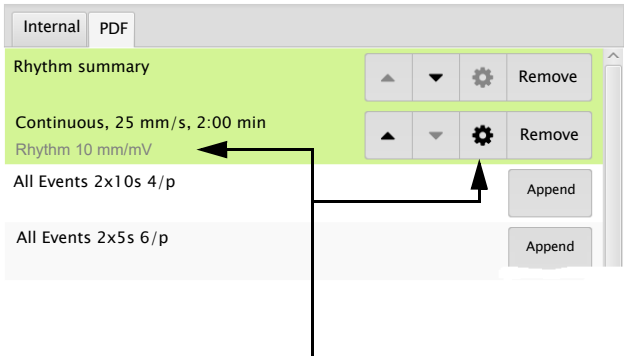
Rhythm ECG

These settings apply to current resting rhythm recordings, resting rhythm recordings from the memory (Internal, display and printout), as well as PDF. Therefore, saved resting rhythm ECGs can be printed with different settings at any time.

Menu	Description / selection
Internal	• Amplitude **5** or 2.5 mm/mV • **Patient data** • **Continuous x1, 6.25 mm/s** • Event list • HR trend
PDF	• **Rhythm summary** • **Continuous 25 mm/s, 2:00 min** Rhythm 5, **10**, 20 mm/mV • All events 2x10s, 6 pages Rhythm 5, **10**, 20 mm/mV • All events 2x5s, 6 pages Rhythm 5, **10**, 20 mm/mV • Continuous 12.5 mm/s, 5:20 min Rhythm 5, **10**, 20 mm/mV • Continuous 6.25 mm/s, 10:40 min Rhythm 5, **10**, 20 mm/mV • Manual events 10s,1/2 page Rhythm 5, **10**, 20 mm/mV • Manual events 10s, 1 page Rhythm 5, **10**, 20 mm/mV • Rhythm 10s/page Rhythm 5, **10**, 20 mm/mV • Rhythm 20s/page Rhythm 5, **10**, 20 mm/mV





Setting the rhythm amplitude
5, 1**0**, 20 mm/mV

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6 Culprit Coronary Artery Algorithm

6.1 Introduction

The Culprit Coronary Artery Algorithm developed by Professor Hein Wellens is designed to determine the size of the cardiac area at risk by localising the occlusion site in the coronary artery and to provide clinical data to shorten the time interval between the onset of chest pain and restoration of myocardial blood flow, as well as to ensure that the patient is assigned to the most suitable hospital. The algorithm uses the ST segment deviation of 12 ECG leads to indicate the site of occlusion in the culprit artery.

The closer the occlusion site to the origin of the coronary artery, the larger the size of the area at risk. The algorithm indicates the location of the occlusion site and issues a recommendation based on the ECG data and patient history. The recommendation is based on the following:

- **Prior Bypass/ Stent.** This data is entered before the ECG recording is taken (see Section 5.1 Resting ECG - procedural flow diagram, page 42). If the patient has had prior bypass or stent, the ECG is not analysed further and the advice **Go to PCI centre (P**ercutaneous **C**oronary **I**ntervention) is given.
- **ST Score**. The sum of the absolute ST deviations in mm in 12 leads (excluding V4r). That is the total ST deviation (mm) of all leads (I, II, III, aVR, aVL, aVF, and all leads V1 to V6).
- **Occlusion Site.** The calculated occlusion site.

The site of occlusion is determined by the following:

1. The number of leads indicating a occlusion are counted (= sum)
2. The occlusion site with the highest number is chosen as the occluded location.
3. If two locations have an equal value, then the more critical occlusion site (highest in the artery) is selected.

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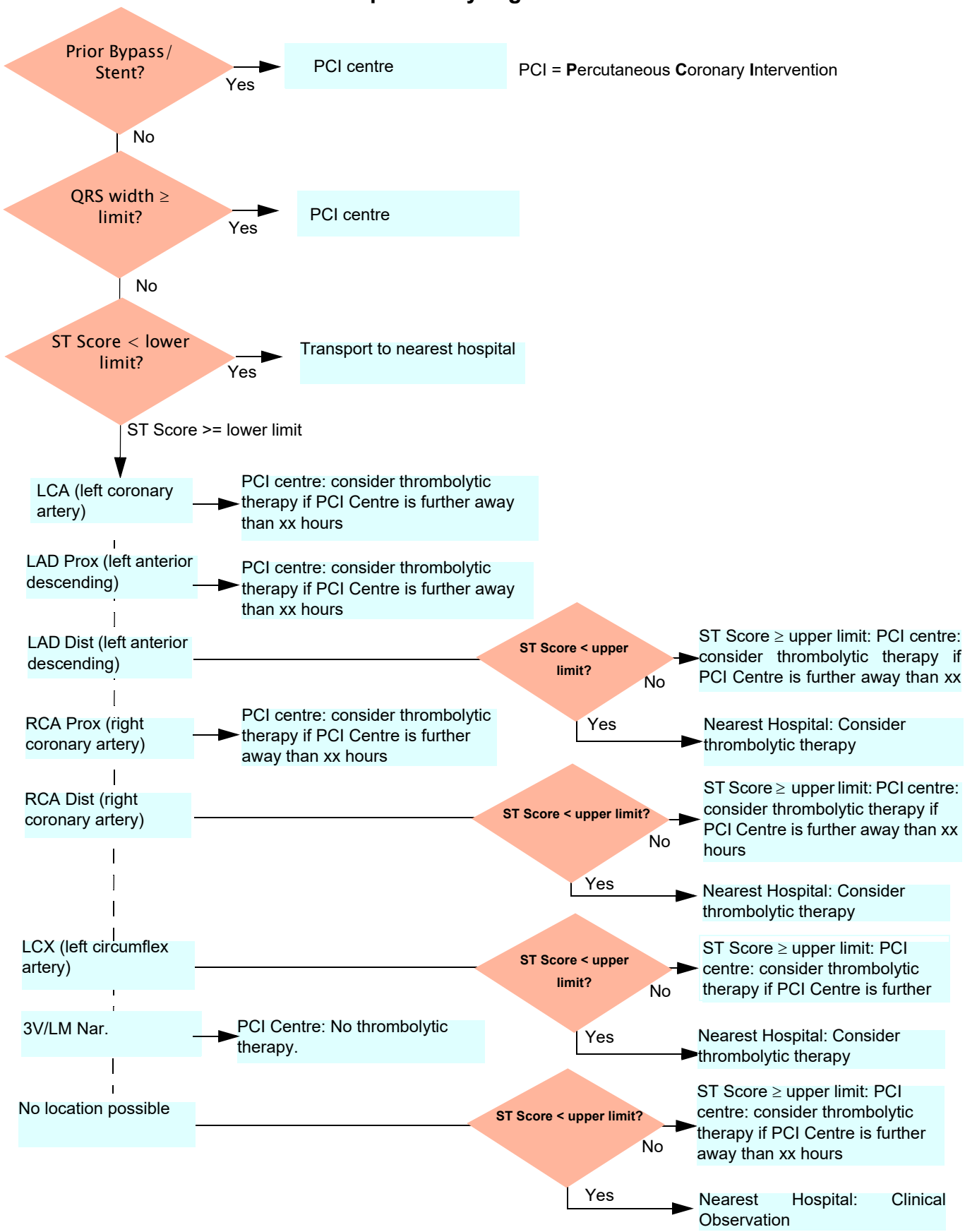
6.1.1 Culprit Artery Algorithm Decision Overview



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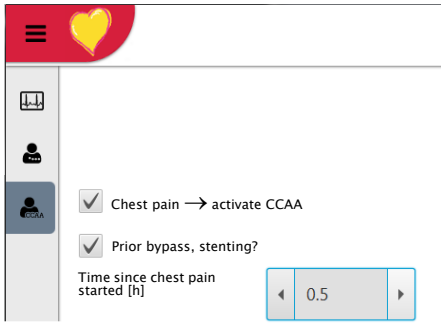
6.1.2 Starting the CCAA analysis

When CCAA analysis is set, the following applies:

- The lead setting is automatically set to Right Precordial (V4r). Ensure that the C4 electrode is placed in the C4r (precordial) position.

Procedure

1. Enter the patient data.
2. Press Record ECG to proceed to the next dialogue.
3. To take an automatic ECG recording including CCAA analysis, press **CCAA**.
4. Activate the CCAA analysis: parameter Chest pain "✓".



5. Enter the additional parameters Bypass, stenting and time since chest pain started.
6. Check the electrode placement (V4r) and record the ECG.

The data is shown in the print preview. The recording can be checked, accepted and further printouts obtained in different formats.

All other settings and features (saving, printing etc.) are the same as described in Section 5.2 Automatic resting ECG recording, page 44.

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6.1.3 CCAA information on print preview/printout

Information on LAD (left anterior descending)

▲ For men under the age of 40 showing early repolarisation in the anterior leads, false LAD diagnoses may occur.

The following CCAA information is given on the print preview/printout:

Manual entry before the start of the recording:

– Previous bypass or stenting (Yes/No)
– Time since chest pain started, in hours

Measured values:

- QRS width (averaged) [ms]
- ST score (averaged) [mm]

Assessed area of an occlusion:

– LCA (left coronary artery)
– LAD Prox (left anterior descending)
– LAD Dist (left anterior descending)
– RCA Prox (right coronary artery)
– RCA Dist (right coronary artery)
– LCX (left circumflex artery)
– 3V/LM narrowing (all three vessels or left main is affected)

Advice:

Recommendations based on the ST score and additional information:

- Transport to PCI centre
- Transport to nearest hospital
- Consider thrombolytic therapy if PCI centre is further away than 1.5 hours.
- Consider thrombolytic therapy
- No thrombolytic therapy

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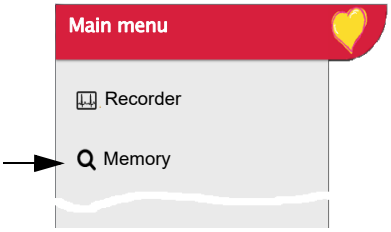
7 Memory

Recordings can be stored locally and transmitted automatically to Schiller Link or SEMA. Recordings stored in the memory can be viewed, printed, transmitted or deleted at any time.

Approx. 350 resting ECGs and 100 resting rhythms can be stored on the CARDIOVIT FT-1. Recordings are stored manually after completion of the acquisition.

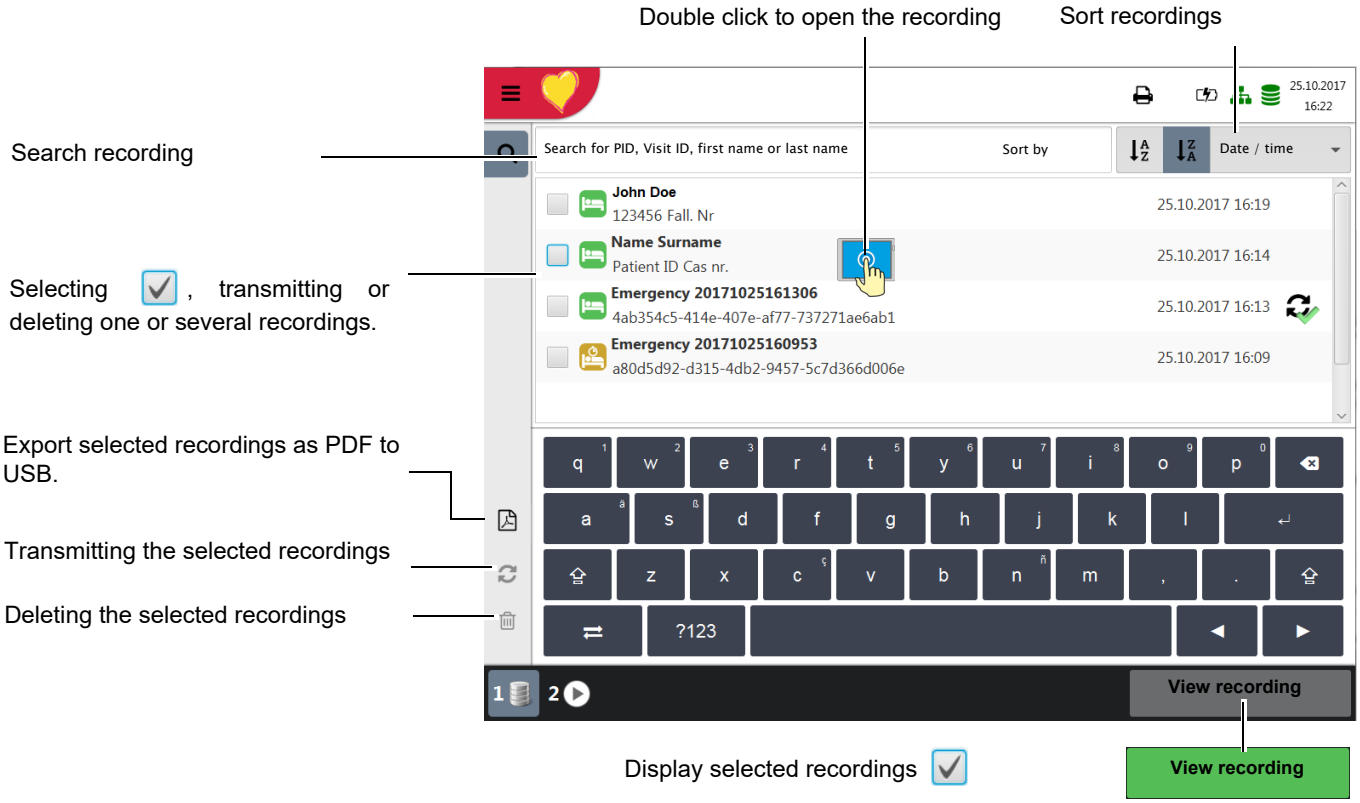
Memory capacity is indicated by the icon . A green icon means Memory OK, a yellow icon means Memory almost full, a red icon means Memory full, no recording possible. Chapter 7.1.2 describes how to delete recordings.

7.1 Editing the memory



➜ When **Menu > Memory** is selected, stored recordings are displayed

- The recordings are listed by date/time; however, different listing criteria can be selected and recordings can also be searched via the search function.



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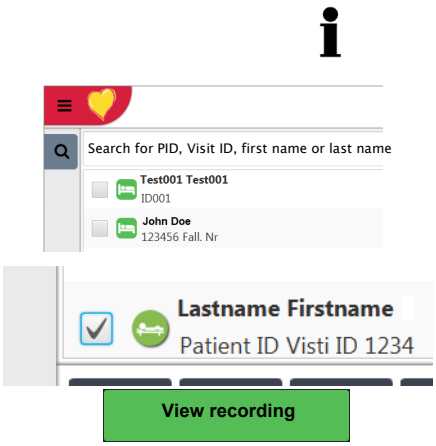
7.1.1 Opening the print preview from the memory and printing a recording

If the recording cannot be printed (e.g. no paper), the printout can be generated again by pressing the icon **(1)** Print jobs in the status bar at the top.



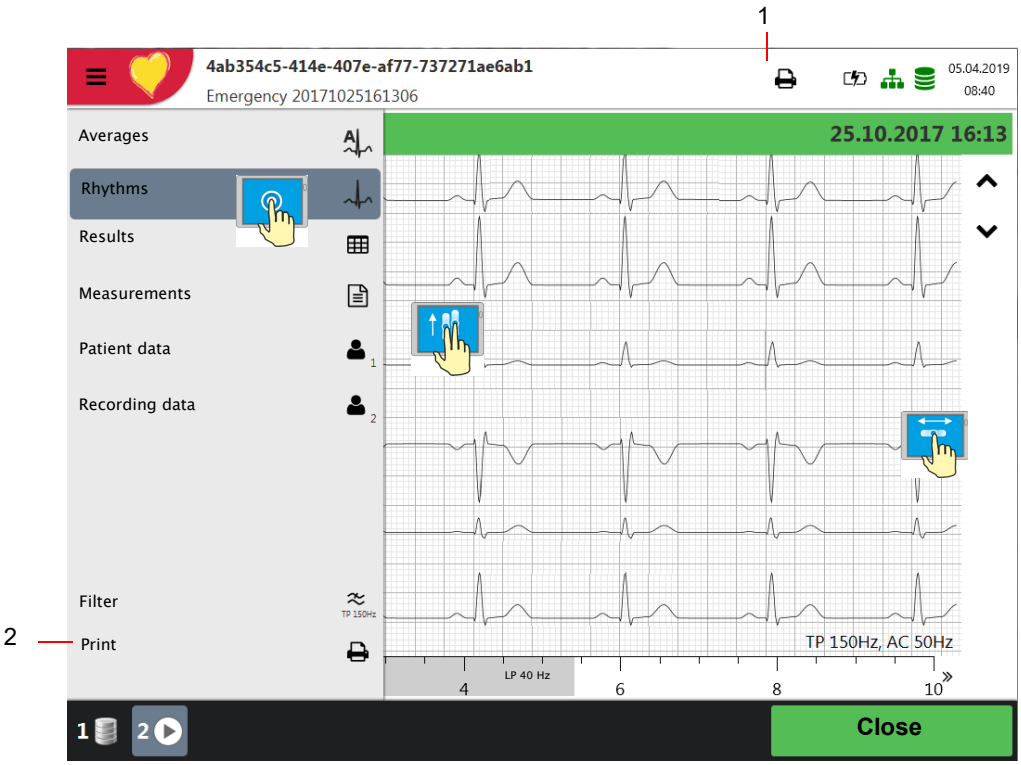
Recordings can be searched using the Patient ID, Visit ID or first/last name. Enter the search term via keyboard or via barcode reader.

1. Search and select the desired recording.
2. Press the key View recording.

→ The recording is displayed according to the settings in **Menu > Settings > Resting ECG > Vies & layouts > RECG Review**, and the layout can be changed for the displayed recording at any time.

3. Press **(2)** to print the recording in the selected format, see Section 9.2.7 Reports, page 80.

Example: resting ECG



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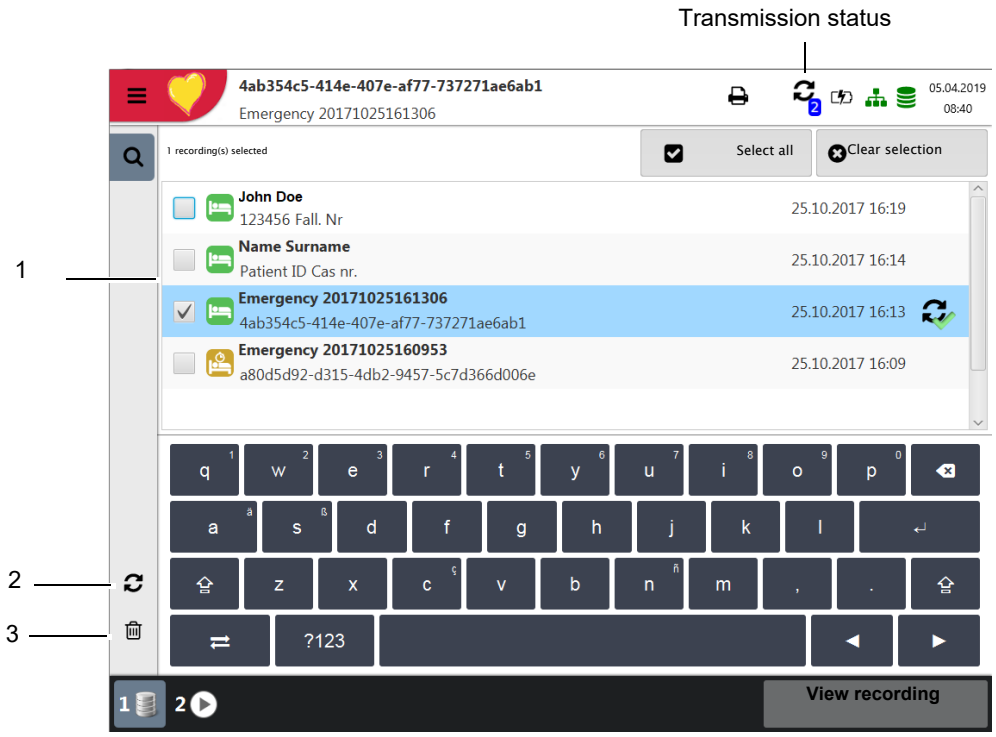
7.1.2 Transmitting and deleting stored recordings

Depending on the settings in **Menu > Settings > General > Workflow**, the recording is transmitted and deleted automatically as soon as it has been recorded. If automatic transmission is not activated, recordings can be transmitted as follows.



1. Select one or more recordings directly on the screen **(1)**.
2. To select all recordings, press the key **Select all**.
3. Select one of the following options:
   – Export **(2)**
   – Delete **(3)** (automatic deletion after transmission can be set in **Settings > General > Workflow**).

If the selected operation cannot be carried out due to an error, an error message is issued (see page 92) and the following symbols/buttons are displayed for each recording:

Indicates faulty recordings or recordings that have not been transmitted.

Indicates recordings that have not been transmitted.

Exported recordings.

The transmitting options are detailed in the section System settings (see page 88).

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8 Worklist (Option)

8.1 General information

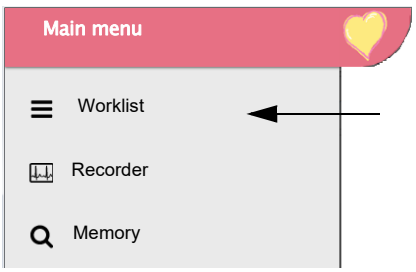
The Worklist function enables a doctor / administrator to define a worklist of patients that require recordings to be made. The doctor can define the patient, room / department, and specify the type of recording to be made. The worklist is defined directly from the Hospital information system (HIS) (e.g. SEMA or GDT) and after the recording has been made by the CARDIOVIT FT-1, the recordings are sent back to the HIS for analysis, examination and storage.

Instead of the type of recording, "Undefined" can be set. When this is the case, only the patient demographics are sent to the unit.

- To be able to use the worklist function, the unit must be set up to communicate with SEMA (see page 83).
- The SEMA user guides describes how to define worklists from SEMA.

SEMA has options to send a worklist to a specific unit or to all units on the system. To receive a specific worklist from SEMA, the unit identification of the CARDIOVIT FT-1 (device ID in the system) must be the same as the one defined for SEMA. This is usually set when the unit is first commissioned. The Device ID is shown in **Menu** > **Settings > General > Station**.

8.1.1 Worklist settings



If worklists are to be used, the workflow can be adapted accordingly. To do so, set the Default workflow in **Menu** > **Settings > General > Workflow** to Record from worklist (Section 9.5 General, page 85). In this way, the worklist is shown directly after power-up. However, worklist can also be selected manually from the menu.

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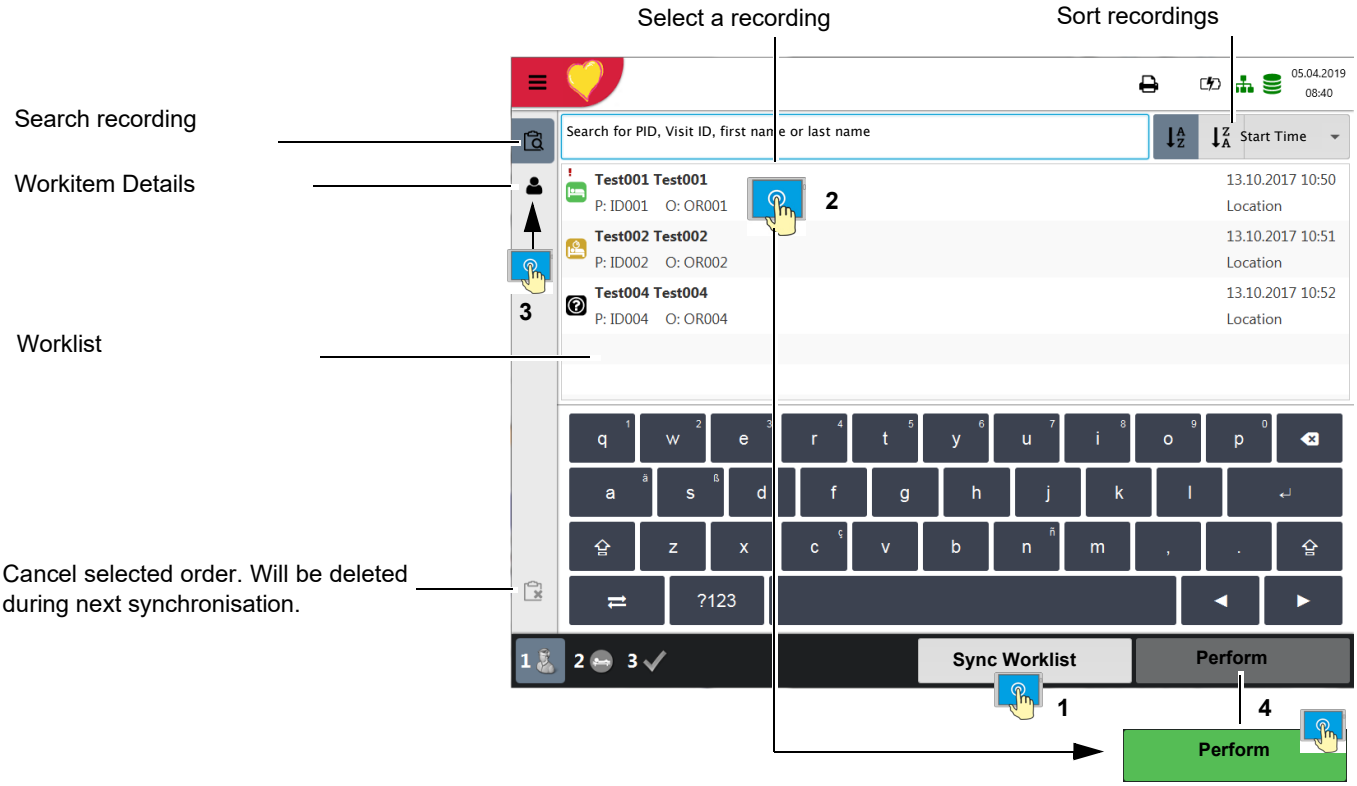
8.2 Receiving a worklist

To open the worklist proceed as follows:

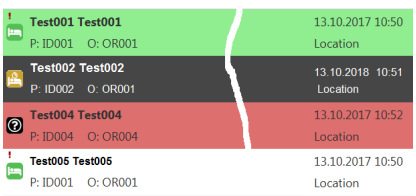
1. Press **Menu** > **Worklist**.



If **Menu** > **Settings** > **General** > **Workflow** Auto sync worklist is activated, the list is updated every minute and the time for the next update is shown on the key.

2. To receive a worklist from a HIS, press the **Sync worklist (1)** key to download the worklist from the server. Wait (up to a few minutes) for the worklist to be populated. Select a work item **(2)**. You can check the work item by pressing **(3)**, return to the worklist and/or perform the work item **(4)**.
3. All patients given in the worklist are displayed with their last/first name, patient ID, order ID and room number. The following recording types are available:

- Resting ECG
- Resting rhythm
- Undefined recording type. The recording type is assigned when the recording is performed.



Recording status:

- White background = recording to be performed.
- Blue or grey background = selected recording.
- Green background = already performed recording. This work item will be deleted from the device during the next synchronisation.
- Red background = recording was cancelled. Will be deleted during next synchronisation.

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8.2.1 Taking a Worklist Recording

- This procedure corresponds with the worklist mode “Record from worklist”, see setting Section 9.5 General, page 85, workflow.
- Patient data provided by the HIS cannot be edited (except for height and weight).
- If you have selected an incorrect work item, press the key , but **not** the key (Cancel order). Select the new work item from the list, or use the Search field.

1. Prepare the patient and select a work item.
2. Select **Work item details** to check the work order or to complement patient data.
3. Press the Perform key.
4. The corresponding recording acquisition screen (resting ECG or resting rhythm) is opened. If no recording type has been defined, both options are available.

Press to return to the worklist without performing the recording (last chance to do so).

5. Take the recording:
   – Resting ECG (see page 44)
   – Resting rhythm (see page 48)

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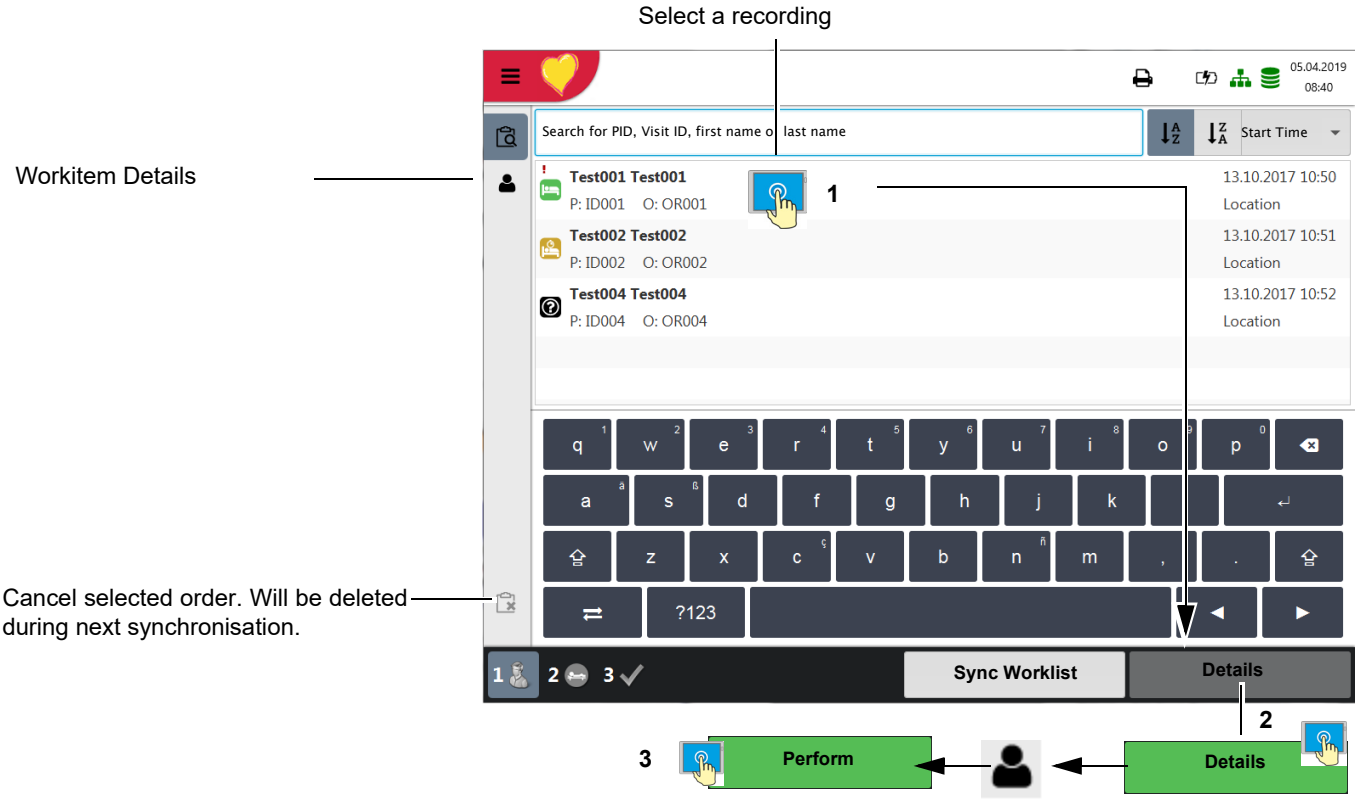
8.2.2 Performing a recording from work order details

- This procedure corresponds with the worklist mode “Record from work order details”, see setting Section 9.5 General, page 85, workflow.
- Patient data provided by the HIS cannot be edited (except for height and weight).
- If you have selected an incorrect work item, press the key , but **not** the key (Cancel order). Select the new work item from the list, or use the Search field.

1. Prepare the patient and select a work item.



2. Select **Details (2)** to check the work order or to complement patient data.
3. Press **Perform (3)** in the “Work item details" view .
4. The corresponding recording acquisition screen (resting ECG or resting rhythm) is opened. If no recording type has been defined, both options are available.

Press to return to the worklist without performing the recording (last chance to do so).

5. Take the recording:
   - Resting ECG (see page 44)
   - Resting rhythm (see page 48)

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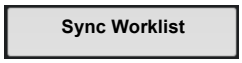
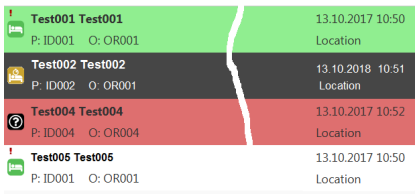
8.2.3 Sending worklist recordings to the HIS

- It is possible to automatically send performed worklist recordings; alternatively, you can have the unit prompt you to manually send worklist items. This is defined in system settings (**Menu** > **Settings > General > Workflow** page 85).



→ In order to manually transmit recordings to SEMA, press **Sync worklist.** Wait (up to a few minutes) while the recordings are sent - the Worklist will go blank after the files have been sent.



Pending work items are indicated by a white background and selected work items by a blue or grey background. Already performed recordings (green background) can be sent at any time without losing pending work items.

Cancelled work items (red background) are deleted from the worklist during the next synchronisation.

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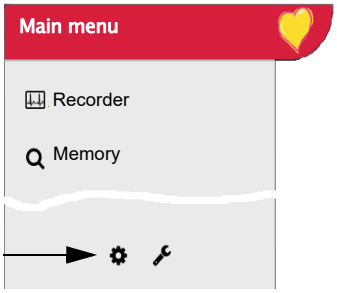
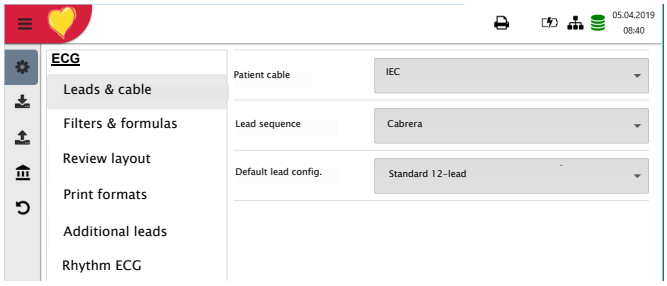
9 General and system settings

9.1 System settings

When pressing the Menu key, the options Settings and Memory are displayed. The following table gives an overview of all the settings available.





Overview **Menu > Settings**

Menu Settings	Sub-menu
ECG (Page 77)	• Leads & cable • Filters & formulas • Views & layouts • Additional leads • Interpretation • Rhythm ECG
Reports (Page 80)	• General • Manual printout • Resting ECG • Rhythm ECG
Connectivity (Page 83)	• EMR integration • Update server • Ethernet • WLAN
Regional (Page 84)	• Date & time • Keyboard • Language • Units • Patient ID system

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Menu Settings	Sub-menu
General (Page 85)	• Info • Power management • Station • Update • Manage licenses • Mandatory fields • Workflow • Access control • Printer

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9.1.1 Saving and restoring settings

The settings are saved automatically.

Import settings Select Import and Import target USB and enter the desired file name to load the stored settings (e.g. default settings) from the USB to the device.

Export settings Select Export and Export target USB and enter a file name to save the settings.

Export audit log Select Export target and enter the file name to export the Audit Log

Reset to factory settings All settings are reset to the factory defaults. If the network settings are to be reset as well, untick the check box.

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9.2 ECG

The default settings are printed **bold**

9.2.1 Leads & cable

Menu	Parameter	Description / selection
Leads & cable	Patient cable	IEC or AHA
	Lead sequence	Standard or Cabrera
	Default lead config.	• Standard 12-lead • Paediatric • Right precordials • Standard C4r • Left posterior • Nebh (chest) • Balanced

9.2.2 Filters & formulas

Menu	Parameter	Description / selection
Filters & formulas	Notch filter	Off/ AC 50/AC 60 Hz
	Myogram filter	Off = 250 Hz/LP25/LP40/LP150 Hz
	Default QTc calculation	Bazett, Fridericia, Framingham, Hodges

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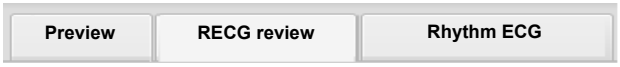
9.2.3 Views & layouts

In this menu, the views and layouts for the **Preview, RECG review** and **Resting rhythms** are defined.

Preview

Menu	Parameter	Description
Preview	Preview view order	Select whether **Hookup** or **Recorder** is shown at the top
	9 lead layout	**6/3** for Nebh Chest
	12 lead layout	**2x6 /** 4x3
	Speed/Amplitude	Speed 12.5/**25**/50 mm/s Amplitude 5/**10** /20 mm/mV

RECG Review

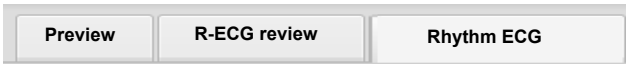


These settings apply to current resting ECG recordings and recordings from the memory. Therefore, saved ECGs can be displayed with different settings at any time.

Menu	Parameter	Description
RECG Review	Review views and order	Adding/removing views, and defining their order: rhythms, averages, results and measurements.
	Rhythm 12 lead layout	**1x6** / 1x12
	Rhythm Speed/Amplitude	Speed 12.5/**25**/50 mm/s Amplitude 5/**10** /20 mm/mV
	Avg. Speed/Amplitude	Speed **25**/50 mm/s Amplitude **10**/20 mm/mV

Rhythm ECG

These settings apply to current resting rhythm recordings and recordings from the memory. Therefore, saved ECGs can be displayed with different settings at any time.



Menu	Parameter	Description
Rhythm ECG	Review views and order	Adding/removing views, and defining their order: Continuous/Rhythm and Rhythm summary. Settings see below.
	Amplitude	2.5/**5** mm/mV
	Speed	Speed **6.25**/12.5mm/s

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9.2.4 Additional leads

Default leads per lead configuration

These settings apply to the current resting rhythm recording, recordings from the memory, and the printout. Therefore, saved ECGs can be displayed or printed with different settings at any time.

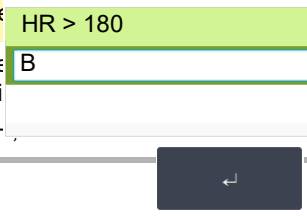
Menu	Parameter	Description / selection
Additional leads	Standard 12-lead	I/ II / III aVR / aVL / aVF / V1 / V2 / V3 / V4 / V5 / V6 / -aVR Rhythm 1 **II**, Rhythm 2 **V2**, Rhythm 3 **V5**
	Paediatric	I/ II / III aVR / aVL / aVF / V7 / V2 / V3r / V4r / V5 / V6 / -aVR Rhythm 1 **V7**, Rhythm 2 **V4r**, Rhythm 3 **II**
	Right precordials	I/ II / III aVR / aVL / aVF / V1 / V2 / V3r / V4r / V5r / V6r / -aVR Rhythm 1 **V3r**, Rhythm 2 **V5r**, Rhythm 3 **II**
	Standard C4r	I/ II / III aVR / aVL / aVF / V1 / V2 / V3 / V4r / V5 / V6 / -aVR Rhythm 1 **V4r**, Rhythm 2 **V2**, Rhythm 3 **II**
	Left posterior	I/ II / III aVR / aVL / aVF / V4 / V5 / V6 / V7 / V8 / V9 / -aVR Rhythm 1 **V8**, Rhythm 2 **V5**, Rhythm 3 **II**
	Nehb (chest)	I/ II / III / aVR / aVL / aVF / D / A / J / -aVR Rhythm 1 **D**, Rhythm 2 **A**, Rhythm 3 **J**
	Balanced	I/ II / III aVR / aVL / aVF / V4r / V3r / V1 / V7/ V8 /V9 /-aVR Rhythm 1 **V7**, Rhythm 2 **V4r**, Rhythm 3 **II**

9.2.5 Interpretation

Menu	Parameter	Description / selection
Interpretation	Print interpretation	**Yes**/No
	Display interpretation	**Yes**/No

9.2.6 Resting rhythm

Parameter	Description / selection
Rhythm length	**30 s**, 1, 2, 3 or 4 minutes Setting the recording duration.
Show recording time dialogue	☑ Yes. The dialog and can be
Predefined event texts	Enter (dele lected duri ➜ Press



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9.2.7 Reports

In this menu, the **Print layout** is defined.

General

Parameter	Description
Rhythm mode	**Sequential** or Simultaneous. When Sequential is selected, the individual lead groups show consecutive time segments (applies to the printout). When Simultaneous is selected, all lead groups show the same time segment (applies to the printout). If a format including a rhythm lead is defined for printout, Sequential is always used, even if you have selected Simultaneous.
PDF paper format	**A4** or Letter
PDF conformance	**None**, PDF/A-1a, PDF/A-1b
Company info 1, 2, 3	Enter company information on PDF rows 1, 2 and 3.

Manual printout

In this menu, the default settings for manual printouts are defined.

Parameter	Description
Lead group	Select the lead group **Limb** or Precordials
Speed [mm/s]	5, 12.5, **25** or 50 mm/s
Amplitude [mm/mV]	5, **10**, 50 mm/mV

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Resting ECG

These settings apply to current resting ECG recordings and recordings from the memory. Therefore, saved ECGs can be printed with different settings at any time.

- The order listed below can vary.

Menu	Description / selection
12 Lead	Selection and order of the following printout formats: • **Patient data** • **Rhythm 2x6, 25 mm/s, 1 page** • **Averages 4x3+1, 50/25 mm/s, 1 page** • **Results** • Rhythm 2x6, 25 mm/s, 2 page • Rhythm 2x6, 50 mm/s, 2 page • Rhythm 4x3+1, 25 mm/s, 1 page • Averages 4x3+1, 25/25 mm/s, 1 page • Averages 6x2+2, 50/25 mm/s, 1 page • Measurement Table
12 Lead (PDF)	• **Rhythms 10s, 25 mm/s, 2p** • Measurements • Averages Grid, 25/25 mm/s • Averages Grid, 50/25 mm/s • Averages Wide, 25/25 mm/s • Panorama • Rhythms 10s, 25 mm/s • Rhythms 5s, 25 mm/s • Rhythms 5s, 50 mm/s, 2p • Rhythms Grid, 25 mm/s
9 Lead	• **Patient data** • **Rhythm 6/3, 25 mm/s, 1 page** • **Averages 3x3+1, 50/25 mm/s, 1 page** • **Results** • Rhythm 6/3, 50 mm/s, 2 pages • Rhythm 6/3, 50 mm/s, 2 pages • Averages 6/3+2, 50/25 mm/s, 1 page • Measurement Table
9 Lead (PDF)	• **Rhythms 10s, 25 mm/s, 2p** • Measurements • Averages Grid, 50/25 mm/s • Averages Wide, 50/25 mm/s • Rhythms 5s, 25 mm/s • Rhythms 5s, 50 mm/s, 2p

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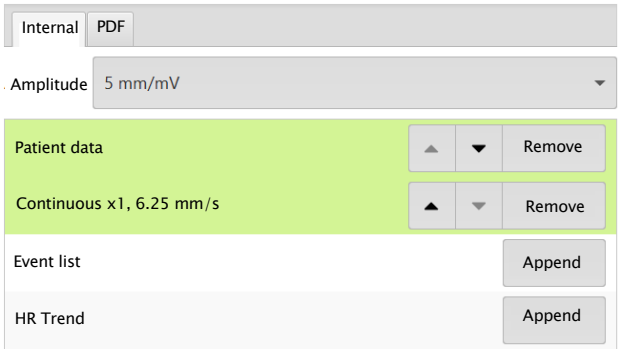
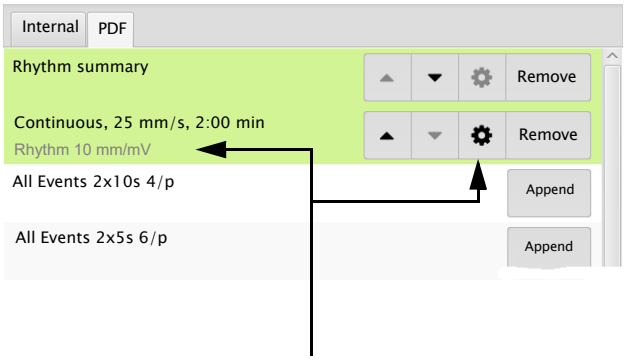
Rhythm ECG

These settings apply to current resting rhythm recordings, resting rhythm recordings from the memory (Internal, display and printout), as well as PDF. Therefore, saved resting rhythm ECGs can be printed with different settings at any time.

Menu	Description / selection
Internal	• Amplitude **5** or 2.5 mm/mV • **Patient data** • **Continuous x1, 6.25 mm/s** • Event list • HR trend
PDF	• **Rhythm summary** • **Continuous 25 mm/s, 2:00 min** Rhythm 5, **10**, 20 mm/mV • All events 2x10s, 6 pages Rhythm 5, **10**, 20 mm/mV • All events 2x5s, 6 pages Rhythm 5, **10**, 20 mm/mV • Continuous 12.5 mm/s, 5:20 min Rhythm 5, **10**, 20 mm/mV • Continuous 6.25 mm/s, 10:40 min Rhythm 5, **10**, 20 mm/mV • Manual events 10s,1/2 page Rhythm 5, **10**, 20 mm/mV • Manual events 10s, 1 page Rhythm 5, **10**, 20 mm/mV • Rhythm 10s/page Rhythm 5, **10**, 20 mm/mV • Rhythm 20s/page Rhythm 5, **10**, 20 mm/mV





Setting the rhythm amplitude
5, 1**0**, 20 mm/mV

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9.3 Connectivity

Menu	Parameter	Description / selection
EMR integration Server settings	EMR integration (EMR = electronic medical record system)	**None** – No input field displayed Schiller Link – Device ID is displayed Schiller Server – Host, port, user and password input fields are displayed. (See following)
	Host	Name of the server
	SSL cert. validation	**No**/Yes ☑
	Port	Port address
	User	User name
	Password	Password
Update server	Host	Schiller Update server
	Port	Port address and key Test connection
Ethernet	Use DHCP	☑ **Active** or ☐ Not active. If this is not activated, the following parameters need to be entered:
	IP address	Identifier address of the device in the TCP/IP network.
	Subnet mask	E.g.: 255.255.255.0
	Standard Gateway	Gateway IP address.
	DNS server	Domain name of the server
WLAN general	Wi-Fi enabled	☑ Active ☐ **Not active**
	SSID..... ☐ Hidden	SSID = Enter network name. Check box “Hidden” = if the SSID is configured as hidden in the Wi-Fi network, the check box "SSID Hidden" needs to be activated.
	Wi-Fi security	Selection of the encryption protocol • WPA/WPA2 personal SSID + key + (encryption = AES + authentication) • WPA2 enterprise / ieee802.1 (*additional settings see* *) SSID + certificate + (encryption = AES + authentication) SSID + user name & password + (encryption = AES + authentication)
WLAN security (for WPA/WPA2 personal)	Password	Enter password for WPA/WPA2 protocol

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Menu	Parameter	Description / selection
WLAN security (for WPA2 enterprise / ieee802.1)	Authentication protocol	Select the authentication protocol: **PEAP**, EAP-TLS or EPA-TTLS
	User	Definition of the user name
	Password	Definition of the password
	Client certificate and CA certificate	Download the certificate via USB port of the device when **EAP-TLS** is selected ➜ Connect USB stick to the device and press Load . Certificate structure: a single file in pem. format contains client certificate, of origin, private key. The private key may or may not be encrypted. If it is encrypted, the user name and password need to be entered.
Advanced	☐ Hidden	Check box “Hidden” = if the SSID is configured as hidden in the Wi-Fi network, the check box "SSID Hidden" needs to be activated.
	Anonymous identity	Enter an anonymous identity (name)
WLAN network	see Ethernet parameters	Settings network parameters

9.4 Regional settings

Sub-menu	Parameter	Description / selection
Date/time	Various	Date and time format Time zone Date and time setting ➜ Key Sync time with server. Time and date on the device are updated. The device needs to be restarted.
Keyboard	Keyboard layout	Select a language
	External keyboard layout (bar-code scanner layout)	Selecting the character set for the external barcode scanner.
Language	Language	Select a language
Units	Weight	Units available are g, **kg** and lb
	Length	**cm**, m, inch
	Temperature	**C**elsius or Fahrenheit
Patient ID system	None Swedish Danish Finnish Norwegian	Using country-specific patient IDs.

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9.5 General

Menu	Parameter	Description / selection
Info	Various parameters	Software and hardware versions are displayed.
	Write info to USB	A diagnostic file (.nfo) is written to the connected USB USB memory stick.
Power management	**Battery operation** Dim backlight [s]	120 seconds (2 min.). If set to 0, this function is deactivated.
	Shut down device [s]	600 seconds (5 min.). If set to 0, this function is deactivated.
	Mains operation Dim backlight [s]	0 seconds (0 min.). If set to 0, this function is deactivated.
	Shut down device [s]	3600 seconds (1 hour). If set to 0, this function is deactivated.
Station	Device ID	Device identification
	Institute	Name of the institute
	Department	Name of the department
	Technician	Technician
	Network host name	Host name of the device (e.g. ft1) displayed in the network.
Update	Check Schiller update server	Update software The check is performed on the Schiller update server. Therefore, an Ethernet/WLAN connection is required, including the necessary network settings for this connection
	Check USB device for update file	The Update is performed via the connected USB stick.
Manage licenses	Available options	Automatic interpretation Worklist ETM Sport CCAA
	Activate license	Enter the licence key and activate
	Import licence from USB	Activation via USB stick (.lic file)
Mandatory fields	Defining the mandatory fields	Following fields must be filled before a recording can be taken. Mandatory fields for exercise ECG which cannot be deactivated: Gender, height, weight, date of birth.

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Menu	Parameter	Description / selection
Workflow	Transmit after acquisition	ECG data is transmitted after acquisition and storage of the recording
	PDF to USB after save	Yes, **No**. After saving, the PDF is automatically exported to the USB stick
	Delete after transmission	ECG data is deleted once it has been successfully transmitted from the memory.
	Print after acquisition	ECG data is printed once it has been stored.
	PDQ mode	PDQ by **Patient ID** PDQ by Visit ID None (PDQ is not started, even if **EPA integration** has been selected)
	Default workflow	**Worklist** Recorder
	Worklist mode (only if option has been activated)	Record from worklist Record from work order details
	Auto sync worklist	☑ Yes, **No**. Worklist is synchronised every minute.

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Menu	Parameter	Description / selection
Access control (automatic logout when access control is activated, see menu “Automatic logout” next page) Important! These settings must only be performed by trained personnel.	Access control mode	• None No access control • **Basic** Login when switching on the device and/or accessing the Settings menu requires a password • **Local** Defining users, passwords and privileges locally on the device • **Schiller Server** Access control is defined via the Schiller Server.
	Basic	
	Device login active	☑ If activated, the login dialogue is displayed at switch-on.
	Device password	Defining the password (default)
	Settings Login Active	☑ If this is activated, the login dialogue is displayed when the settings are opened ⚙
	Settings Password	Defining the password (admin)
	Local	
	User name	Administrator (additional users can be created)
	Password	Enter the password (“administrator” is used as password if no other password is entered)
	Retype Password	Confirm password
	Privileges	Selecting the privileges: Adjust system settings; Analyse recordings (from memory); Create recordings.
	Schiller Server	This requires a working EMR connection and Schiller Server administrator rights. Access control is defined on the Schiller Server.
Automatic logout (Is only displayed if Access control is activated)	**Automatic logout enabled**	☑ **Yes**/No
	Logout timeout [s]	**300**
Print setting	**Contrast**	1-10 **(5)**
	Line width	Thin, **normal**, thick

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10 Transmission - Overview

⚠ CAUTION

- ▲ Security of the network is the sole responsibility of the network operator.
- ▲ SCHILLER AG takes no responsibility for the configuration of Windows.
- ▲ In order to guarantee the security of the network, Schiller AG recommends the following:
  - – isolating the FT-1 network from other networks
  - – defining access authorisation for the configuration of the host system, incl. FT-1, so that no unauthorised alterations of the system are possible
  - – limiting the data transmission between the host and other systems/networks to a minimum
  - – installing the latest antivirus/firewall programs on the host in order to prevent malware from affecting the system
  - – regularly installing security updates on the host
  - – installing software updates that increase the FT-1's security
  - – taking the appropriate measures to check the system's security and ensure safe operation when changing the network configuration, installing security updates and adding/removing devices.

10.1 Transmission Options

With the FT-1, transmission is possible via a network or Wi-Fi. The transmission options are as follows:

⚠ WARNING

- ▲ When a non-medical device is connected to the interface, ensure that both units are securely connected to the same earth potential.
- ▲ An external device must only be connected using the original interface cable assembly.
- ▲ The transmission of ECG data via WLAN can disturb other devices, including pacemakers. Therefore, keep a distance of at least 20 cm from the patient while an ECG is transmitted.


Notactive


Network connected


Connection to the server OK


Connection to the server interrupted

LAN

data transmission via local LAN network (Ethernet) to the EMR system. For an Ethernet (network) connection, connect the cable assembly to the RJ-45 connector.

LAN or WLAN not active/active

The network symbol in the status bar at the top right indicates with a square ■ that the connection (WLAN or LAN) is active.

Green = connection to network/server established

Black = no connection to network/server

Wifi

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If Wifi is activated, the following symbols are displayed

- Green symbol: connected to the Wifi network and the SCHILLER Server.
- Black Symbol: connected to the network but no connection to the SCHILLER Server
- Signal strength is displayed with bars.

Schiller Link

Schiller Link offers easy communication with an EMR system within the same network. This communication comprises the following: import (GDT) of examination requests including patient data and recording type from an EMR system, export of recordings to an EMR system in the formats GDT, Sema2 or PDF. To activate this communication, set **Schiller Link** in the menu Connectivity > EMR integration (see page 83).

The transmitted patient data is displayed automatically when the patient data screen is open, if it does not contain any entries and is not in review mode after a recording.

SEMA

For patient data queries from the EMR system, the SCHILLER SEMA Server is required. A more detailed description of the transmission settings are given in the SCHILLER Communication Handbook 2.520036.

PDF export

Simple export of a recording as PDF to a memory stick

10.1.1 Automatic transmission

The automatic transmission setting is defined in Settings:

Menu > Settings > General - Workflow- Transmit after acquisition (Yes/No - see page 85).

When auto transmission is defined, a recording is transmitted automatically after it has been saved.

10.1.2 Manual transmission

To transmit a recording, select the recording in the **Memory** and press **Export** (see page 68)

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10.1.3 PDF export

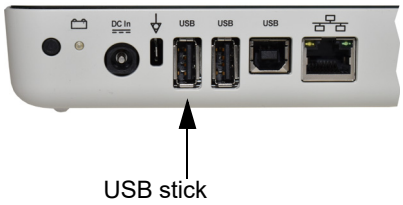
Data integrity

⚠ CAUTION

▲ When exporting patient data to a memory stick, the responsible user needs to protect the data with appropriate security measures:
- Make sure that only authorised people have access to the memory stick.
- Once the data has been transmitted from the memory stick to a secure system, delete all data from the memory stick.
- Deactivate the PDF export function if it is not used.

Settings

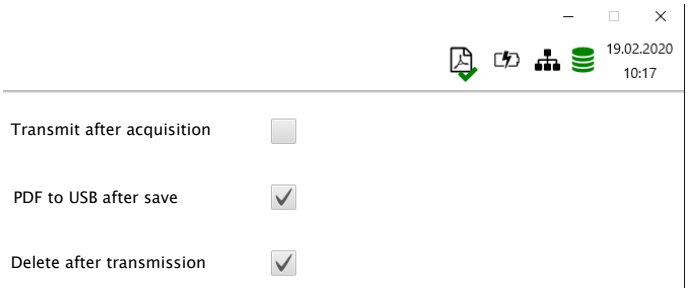
Activate **PDF export** in the **Menu > Settings > Workflow > PDF to USB after save**. If **PDF export** is active, the recordings from the memory are transmitted as soon as a USB stick is connected. The symbol PDF export is displayed when data has successfully been transferred to the memory stick.



USB stick

Caution

If **"Delete after transmission"** is activated in the same menu, the recordings are deleted from the memory.



Manual PDF export from memory

An individual recording can be exported to a USB stick from the memory if the setting above "Delete after transmission" has been selected.

➜ Open the Memory, select the recording and export with the key. Storage progress is shown in the status bar with the PDF symbol.

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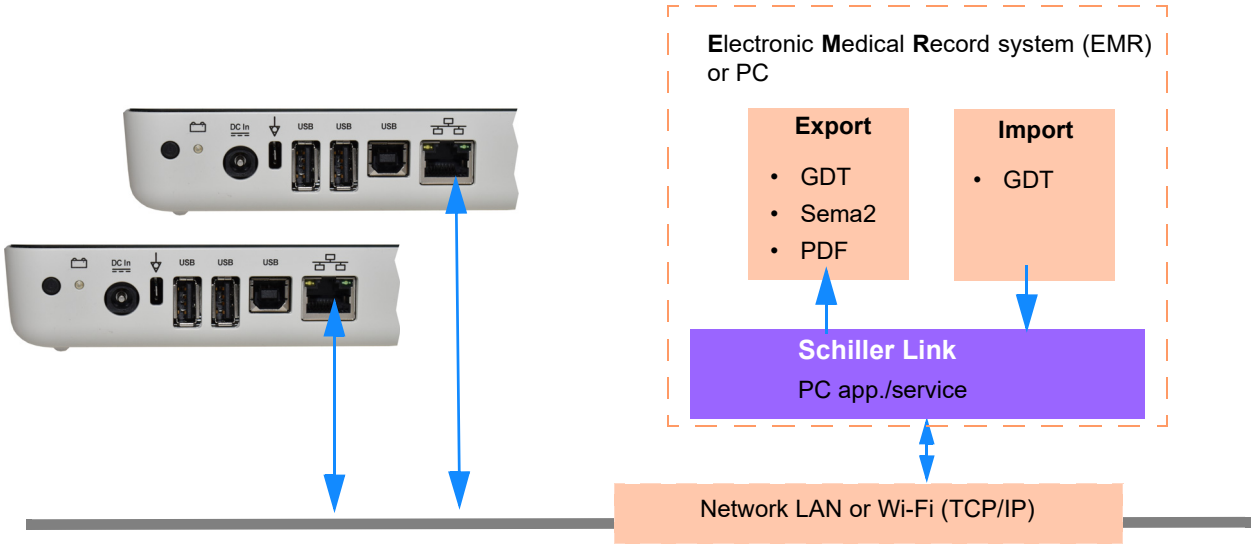
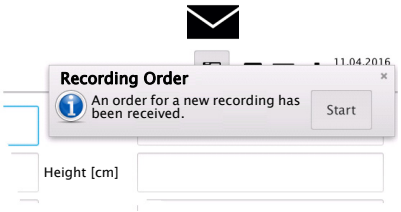
10.1.4 Schiller Link

Schiller Link is a PC application/service which communicates between the EMR system and the FT-1.

➜ To activate this communication, set Schiller Link in the menu **Connectivity > EMR integration** (see page 83).

➜ Integration in the network is automatic, provided the FT-1 is part of the same network





Procedure with EMR system

1. Enter/select a patient in the EMR system
2. Generate a new order for this patient
3. Upload the GDT file into the import folder of the Schiller Link service
4. Start and check the order incl. patient data on the FT-1.
5. Perform the recording on the FT-1.
6. Store the recording and export it automatically or manually to the export folder.
7. The EMR system imports the recording for review in the EMR system.

Procedure without EMR system

1. Manually enter the patient data on the FT-1 (via keyboard or barcode reader).
2. Perform the recording on the FT-1.
3. Store the recording and export it automatically or manually to the export folder.
4. Review the recording (PDF) on the PC and print or transmit it via e-mail.

If necessary, successfully exported recordings can be exported again. This feature is not available for the Schiller Server.

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10.1.5 Receiving data from SEMA

Patient data can be received from a Schiller SEMA server and automatically entered on the CARDIOVIT FT-1. This is called patient data query (PDQ). To do this, the Patient or Visit ID is entered in the patient data screen manually or via a barcode reader (see page 29).

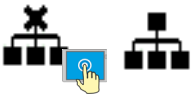
- Patient data query requires the Schiller SEMA Server being available via network.
- The server name, URL, TCP/IP address etc. as well as all other transmission settings are defined in the system settings (see page 83).
- A communication overview is given in the SCHILLER Communication Handbook (Art. No. 2.520036).

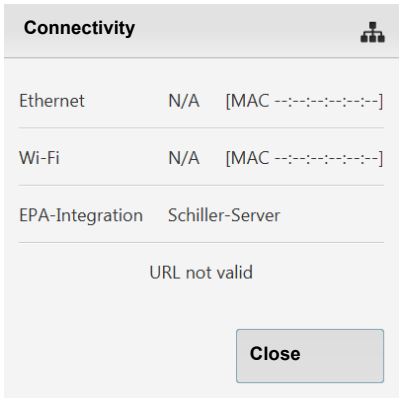
10.1.6 Failed data transmission

Failed transmission of data is indicated with the symbol  in the status bar.

1. The blue figure indicates the number of failed transmissions.
2. Data that was not transmitted can be resent from the memory. See Section 7.1.2 Transmitting and deleting stored recordings, page 68.

If no data can be transmitted, check the following:





- ➜ Network settings (see page 83)
- ➜ Network connection WLAN or LAN
- ➜ Encryption settings on the server
- ➜ Settings in the Schiller Link App.

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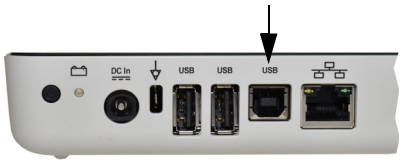
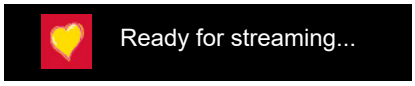
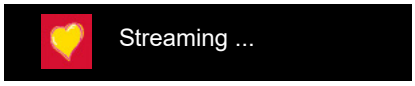
10.2 FT-1 streaming







As soon as the switched on FT-1 is connected to a PC via the USB interface type B, the device indicates "Ready for streaming".

As soon as a recording is started with the CS-104 application on the PC, the FT-1 indicates "Streaming.." and transmits the ECG raw data to the PC where the data is displayed online in the CS-104 application. In addition to the raw data, the lead-off status and detected pacemaker pulses are transmitted.

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11 Maintenance

The regular system maintenance must include a software check according to the manufacturer's instructions. The test results must be recorded and compared to the values in the accompanying documents.

Maintenance work not described in this section may only be accomplished by a qualified technician authorised by SCHILLER AG.

The following table indicates the intervals and responsibilities of the maintenance work required. Local regulations in your country may stipulate additional or different inspection intervals and tests.

Interval	Maintenance step	Responsible
Before each use	• Visual inspection of the device and ECG electrodes	➜ User
Every 6 months	• Visual inspection of the device (see page 99, 11.6 section 11.6 Inspection report) – Touch screen test – Cables and accessories – Power supply unit and mains cable • Functional tests according to the instructions (see page 99, 11.6 section 11.6 Inspection report)	➜ User
Every 12 months	• Safety test according to IEC/EN 62353	➜ Qualified service personnel

11.1 Visual Inspection

Visual inspection of the unit and the cable assembly for the following:

➜ Device casing and power supply unit not broken or cracked
➜ LCD screen not broken or cracked
➜ Electrode cable sheathing and connectors not damaged
➜ No kinks, abrasion or wear in any cable assembly.
➜ Input/output connectors not damaged.

In addition to the visual inspection, switch on the CARDIOVIT FT-1, toggle through the menu and check some functions randomly. In this way, you can check that:

- the device performs faultlessly
- the display works
- the touch screen works

WARNING

▲ Defective units or damaged cables must be replaced immediately.

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11.2 Cleaning the casing and cables

⚠WARNING

▲ Switch the device off before cleaning and disconnect it from the mains by removing the plug. Do not, under any circumstances, immerse the device in cleaning liquid and do not sterilise it with hot water, steam or air.

⚠ CAUTION

▲ Do not autoclave the device and accessories.

▲ Do not immerse the device in liquid.

▲ Do not spray liquid onto the device/cable.

▲ The use of detergents with a high acid content or detergents that are otherwise unsuitable can damage the device (i.e. cracks and wear of the plastic casing).

▲ Always follow the usage instructions provided by the manufacturer of the cleaning solution.

▲ With time, the casing may become less resistant:

– if an alcaline 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. Schiller AG therefore recommends using only cleaning agents that are adequate for sensitive materials such as plastics, and using them at room temperature (approx. 20°C).

▲ 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.

▲ The patient cable and other cable assemblies must not be exposed to excessive mechanical stress. Whenever disconnecting the leads, hold the plugs and not the cables. Store the leads in such a way as to prevent anyone stumbling over them or any damage being caused by the wheels of instrument trolleys.

▲ When cleaning, ensure that all labels and safety statements, whether etched, printed or stuck to the device, remain in place and remain readable.

Thoroughly inspect the device and the accessories before cleaning.

- Look for any signs of damage and make sure that the keys and connectors work correctly.
- Gently bend and flex cables, inspecting them for damage or extreme wear, exposed wires, and bent connectors.
- Confirm that all connectors engage securely.

The casing of the CARDIOVIT FT-1 and the cable assemblies can be cleaned with a cloth slightly moistened (not wet) on the surface only. If necessary, a domestic non-caustic cleaner or a 50 % alcohol solution can be used to remove grease stains and finger prints. Wipe the equipment with a cloth slightly moistened (not wet) with one of the approved cleaning solutions (see section 11.2.2). Thoroughly wipe off any excess cleaning solution. Do not let the cleaning solution run into or accumulate in connector openings, switches, or gaps. If liquid gets into connectors, dry the area with warm air and check that the device operates properly.

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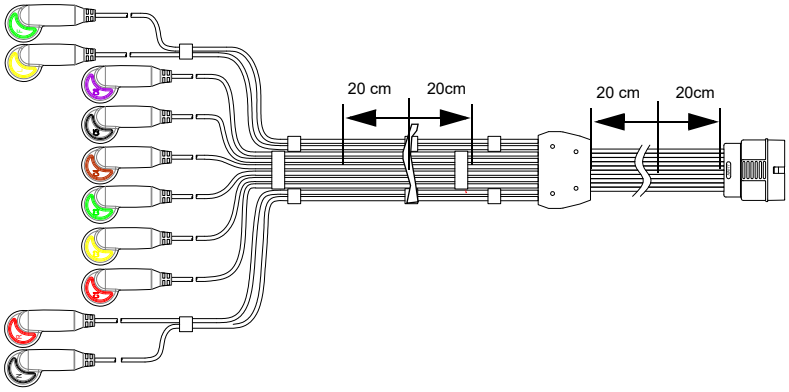
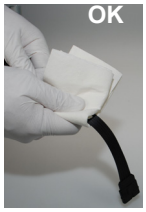
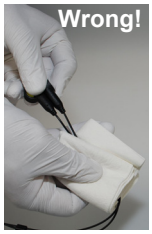
11.2.1 Cleaning the cable assembly

1. Before cleaning, inspect the cable for damage. Gently bend and flex all parts of the cable. Inspect for splits in the sheathing, damage or extreme wear, exposed wires or bent connectors.
2. Wipe the cable with a cloth slightly moistened (not wet) with one of the approved cleaning solutions listed below.
3. Gently grip the cable with the damp cloth in the centre of the cable and slide the cable through the cloth 20 cm at a time until clean. Do not clean the whole length in one single action as this may cause ‘bunching‘ of the insulation sheathing.



4. Thoroughly wipe off any excess cleaning solution. Do not let the cleaning solution run into or accumulate in connector openings, switches, or gaps. If liquid gets into connectors, dry the area with warm air.





11.2.2 Approved cleaning solutions

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

11.2.3 Non-admissible detergents

Never use products containing the following:

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

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11.3 Disinfection

Disinfection removes certain bacteria and viruses. Please refer to the manufacturer's information. Use commercially available disinfectants intended for clinics, hospitals and medical practices.

Disinfect the units in the same way as described for cleaning the units (previous page).

11.3.1 Approved disinfectants

- Isopropyl alcohol 50%
- Propanol (35%)
- Aldehyde (2-4 %)
- Ethanol (50%)
- all products that are suitable for sensitive surfaces, such as:
  - Bacillol® 30 foam/ Bacillol® 30 Tissues
  - Mikrozid® AF

11.3.2 Non-admissible disinfectants

Never use products containing the following:

- Organic solvents
- Ammonia-based detergent
- Abrasive cleaning agents
- 100 % alcohol
- Conductive solution
- Solutions or products with the following ingredients:
  - Ketone (Acetone)
  - Quaternary ammonium compound
  - Betadine
  - Chlorine, wax or wax compound
  - Sodium salt

11.4 Cleaning the thermal print head

Over a period of time, the printing ink from the grid on the paper can form a film on the thermal print head. This can cause the print quality to deteriorate. We recommend therefore that the print head is cleaned with alcohol every month. This is done as follows:

1. Open the paper tray and remove the paper. The thermal print head is located directly above the pressure roller (when the paper tray is closed).
2. With a tissue dampened in alcohol, gently rub the printhead to remove the ink residue. If the print head is badly soiled, the colour of the paper grid ink will show on the tissue.

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11.5 Battery

- No maintenance is required for the lithium-ion polymer batteries.
- Replace the battery approx. every 4 years (depending on the application) when the battery running time falls substantially under one hour.
- Storage and operation conditions outside the temperature range of 15-25 °C will reduce the service life of the battery!
- Make sure that the batteries remain charged during storage. If the device is not used for more than 3 to 4 months, the battery needs to be protected from deep discharge by recharging it; the ideal capacity is 50-80%. If a fully charged battery is stored for a long period of time, this may reduce its service life.

11.5.1 Charging the battery

A totally discharged battery requires approximately 3 hours to be 100% charged (when the unit is switched off). It is possible to use the unit when the battery is being charged; however, the charging time may be longer.

No harm will be done to the battery by leaving the unit connected to the mains supply.

1. Connect the device to the mains supply.
2. Mains via external power supply unit .
3. The blinking battery LED indicates that the battery is being charged.
4. Charge the battery for at least 3 hours.

11.5.2 Battery disposal

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

⚠WARNING

▲ Explosion hazard! The battery must not be burned or disposed of in domestic waste.

▲ Acid burn hazard! Do not open the battery.

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11.6 Inspection report

▲ The user guide, especially chapter 11, must be read before the inspection.
▲ **Recommended inspection interval:** Every 6 months

Serial no.: _____

Test	Results	Date				
Visual inspection 11.1	• Casing not damaged	❒	❒	❒	❒	❒
➜ External condition						
	• Electrode connector port not damaged	❒	❒	❒	❒	❒
➜ Availability and condition of accessories	• ECG Electrodes (expiration date and compatibility)	❒	❒	❒	❒	❒
	• User Guide	❒	❒	❒	❒	❒
	• Mains and patient cable	❒	❒	❒	❒	❒
Functional test 2.3	• No error message shown in the standard display	❒	❒	❒	❒	❒
➜ ECG test						
➜ Multi-touch screen test	• Touch screen works	❒	❒	❒	❒	❒
➜ Check the battery	• Battery OK	❒	❒	❒	❒	❒
➜ Printer	• Contrast and line strength	❒	❒	❒	❒	❒
	• Cleaning the thermal print head	❒	❒	❒	❒	❒
Remarks						
➜ Recurrent test conducted (every 12 months)			❒		❒	
Inspection carried out by:						

In case of a defect, please contact the service department of your hospital r, your SCHILLER representative r or the local after-sales service r.

Name: .....
Phone: .....

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11.6.1 Lifed-item replacement every 3 - 5 years

Inspection	Results	Replacement				
Internal battery						
➜ Replace internal battery if operation falls substantially under one hour.	• Unit sent to SCHILLER service centre for accumulator replacement.	❒	❒	❒	❒	❒
	Date of replacement:					
	Inspector:					

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12 Trouble shooting

12.1 Possible problems

Error	Possible causes and indicators	Error localisation and troubleshooting
Unit does not switch on; blank screen	• No mains supply; green mains indicator on the power supply unit is off.	→ Check the power supply unit and fuses. → If the mains indicator is lit, it indicates that power is reaching the unit and the internal power supply should be OK. Press and hold the On/Off key for 10 seconds. Wait a few seconds and switch the device on again.
	• Mains connection OK, but indicator and LED are not lit.	→ Check / change the battery. If the battery is faulty, it is possible that the unit cannot be switched on even if the mains supply is connected. → If the screen is still not lit, it indicates a software fault, monitor problem or internal power supply. Call your local SCHILLER representative.
QRS traces overlap	• Incorrect settings for patient. • Bad electrode contact.	→ Change sensitivity setting. → Check electrode contact and reposition the electrodes. → If the problem persists, call your local SCHILLER representative. → Note: Some patients have very high amplitudes and even on the lowest sensitivity settings, the QRS traces can overlap.
"Noisy" traces	• High resistance between skin and electrodes • Patient not relaxed • Incorrect settings	→ Check the electrode resistance (all leads need to be shown in green) → Re-apply electrodes. → Ensure that the patient is warm and relaxed. → Check all filter settings (**Menu > Settings > ECG > Filters & formulas**). → Activate the myogram filter and change the cut-off frequency. → Ensure mains filter is correct for mains supply. → If the problem persists, call your local SCHILLER representative.
No printout obtained after an auto mode recording.	• No paper • Paper incorrectly loaded. • Incorrect settings	→ Ensure that paper is loaded. → Reload paper. → Ensure that the paper has been inserted correctly with the black mark at the top. → Check that the printout is activated for at least one setting, and that Print after acquisition is activated (see page 58 and 85) → If the problem persists, call your local SCHILLER representative.
Printout fades, is not clear or the printout is 'patchy'.	• Old paper inserted. • Dirty print head • Line width/contrast setting incorrect • Print-head out of adjustment.	→ Ensure that new SCHILLER paper is inserted. → Note that the CARDIOVIT FT-1 thermal paper is heat- and light-sensitive. If it is not stored in its original seal, stored in high temperatures or is simply old, print quality can deteriorate. → Over a period of time, the printing ink from the grid on the paper can form a film on the thermal print head. Clean the thermal print head. → Set the line width, contrast, printer, see page 87. → If the problem persists, call your local SCHILLER representative.

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Error	Possible causes and indicators	Error localisation and troubleshooting
No printout of interpretation statement, average cycles or measurements	• Incorrect settings	➜ Check that the interpretation and measurement options are enabled for the printout and that the lead sequence is set to Normal (see page 58 section 5.6.7 and page 40 section 4.11.2,
Multi-touch screen is blocked	• Software hangs up	➜ Switch off and on again after a few seconds. ➜ Press and hold the On/Off button for 10 seconds to force the device to switch off. Reconnect mains and switch on. ➜ If the problem persists, call your local SCHILLER representative.
Multi-touch screen responds in an irregular way	• Excessive EMC interferences	➜ Check for sources of excessive EMC interferences.
Not able to start ECG recording	Memory full 	➜ Delete old ECG recordings, see page 66.

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12.2 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 **FT-1**. 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 **FT-1** and its cables.
- ▲ Do not place the **FT-1** on top of other electric/electronic devices - i.e. maintain a sufficient distance to other devices (this includes the patient cables).

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

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

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

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12.2.1 Measures to prevent electromagnetic interferences

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

- Increase distance to the source of interference.
- Turn the device to change the angle of radiation.
- Connect the potential equalisation cable.
- Connect the device to a different mains connector.
- Only use original accessories (especially patient cables).
- Immediately replace defective cables, especially patient cables with defective sheathing.
- Make sure the patient cable is securely screwed on.
- Observe the maintenance intervals as stated in Section 11 Maintenance, page 94 .

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12.3 Accessories and disposables

WARNING

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

Your local representative stocks all the disposables and accessories available for the CARDIOVIT FT-1. A comprehensive list of all SCHILLER representatives can be found on the SCHILLER website (www.schiller.ch). In case of difficulty, contact our head office in Switzerland. Our staff will be pleased to help process your order or to provide information on all SCHILLER products.

12.3.1 Patient cables

Art. no.	Label	Description
2.400175	ECG D-SUB C 4.6/4.25 x10 IEC	10-wire patient cable IEC, clip type, 4.6/4.25 m
2.400178	ECG D-SUB C 4.6/4.25 x10 AHA	10-wire patient cable AHA, clip type, 4.6/4.25 m
2.400179	ECG D-SUB B 3.1/2.55 x10 AHA	10-wire patient cable AHA, banana plug, 3.1/2.55 m
2.400180	ECG D-SUB B 3.1/2.55 x10 IEC	10-wire patient cable IEC, banana plug, 3.1/2.55 m
2.400226	ECG FS P 2.1/1.6 x10 IEC	10-wire patient cable, IEC, push-button, 2.1/1.6 m
2.400227	ECG FS P 2.1/1.6 x10 AHA	10-wire patient cable, AHA, push-button, 2.1/1.6 m
2.400330	ECG FS B 2.1/1.6 x10 IEC	10-wire patient cable, IEC, banana plug, 2.1/1.6 m
2.400331	ECG FS B 2.1/1.6 x10 AHA	10-wire patient cable, AHA, banana plug, 2.1/1.6 m

12.3.2 Electrodes and ECG consumables

Art. no.	Label	Description
2.000041	ECG KIT	Electrode kit for adults (metal) including electrode gel
2.000052	ECG KIT	Electrode kit for children (metal) including electrode gel
2.155020	Set of 4 clamp electrodes	Limb electrodes, adults (metal)
2.155000	Suction chest electrode	Suction electrodes chest, 24 mm, set of 6 pieces
2.310317	ECG FS D-SUB 0.25 x10 AC	Suction pump adaptor
2.155025	Ambu® BlueSensor R	Blue Sensor electrodes for exercise ECG (500 pieces)
2.155032	Ambu® Snap Clip	Adapter for banana plugs (10 pieces)
2.155034	Ambu® WhiteSensor 0415M	White Sensor electrodes for resting ECG (500 pieces)
2.157055	ECG Recording Paper Fanfold	Thermal chart paper, box of 10 (60 sheets each)

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12.3.3 Mains leads

Art. no.:	Article
2.310320	Earth cable for the potential equalisation stud
2.300000	Mains cable Switzerland
2.300002	Mains cable Schuko Europe
2.300011	Mains cable UK
2.300012	Mains cable (medical grade) USA
2.300014	Mains cable China
2.300016	Mains cable Japan
2.300025	Mains cable Brazil
2.300003	Mains cable Switzerland, angled
2.300005	Mains cable Europe, angled
2.300024	Mains cable (medical grade) USA, angled
2.300004	Mains cable UK, angled

12.3.4 Spare parts

Art. no.:	Article
4.410300	Pressure roller for printer
2.200136	Power supply unit, 15 V/30 W

12.3.5 Accessories

Art. no.:	Article
2.000147	Barcode scanner set including barcode scanner (2.200208 //LS2208-SR20001R-UR) and SCHILLER User guide “Barcode scanner for use with SCHILLER units” (2.510721)

12.3.6 Trolley

Art. no.:	Label	Article
2.101126	Trolley X1 with console for FT-1	Trolley X1 incl. basket and mounting bracket for CARDIOVIT FT-1
2.101118	Drawer for trolleys X1, X2, X3, X4	Drawer
2.101119	Basket translucent for trolleys X1, X2, X3, X4, X5	Transparent basket
2.101121	Holder barcode scanner for trolleys X1, X2, X3, X4, X5	Barcode scanner holder
2.101130	ECG patient cable support for trolleys X1, X3	ECG patient cable support
2.101181	Holder Strässle for DT-80 for X1	Holder for Strässle suction pump DT-80
2.101184	Holder Strässle for DT-100 for X1	Holder for Strässle suction pump DT-100
2.101143	Kit screws for trolley X1	Replacement screw kit for trolley
2.101163	HOLDER FOR X1 TROLLEY	Holder for accessories
2.101174	Wheel with braking function for X1	Wheel with brake

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13 Technical data

13.1 Device

Dimensions	230 x 160 x 33 mm, approx. 1.1 kg incl. thermal paper
Display	• Multi-touch backlit LCD screen for graphic and alphanumeric representation • Resolution: 1024 x 768 dots, 8 “
Power supply with: • **external power supply unit**	Medical grade switching power supply, protection class I (Note: because the protective earth (PE) ends in the power supply, the protective earth test does not need to be performed.)
Input	100 - 240 VAC, max. 1.0 A (100 V) - 0.6 A (240V), 50-60 Hz
Output to FT-1	15 VDC, max. 2 A
• **Battery**	Operation with built-in rechargeable battery
Power supply device	15 VDC 30 VA
Battery	
Capacity	• Lithium-ion polymer 11.1 V, 2.4 Ah • 4 hours normal use without printing and WLAN
Battery life	Under normal operating conditions, 4 years
Charging time	100 %: approx. 3 hours when the device is switched off
Printer	High-resolution thermal head printer; 8 dots/mm (amplitude axis); 20 dots/mm (time axis) @ 25 mm/s
Frequency range	0 to 250 Hz (IEC/AHA)
Chart paper	Thermo-reactive, Z-fold, 114 mm wide, optimal positioning on 150 mm
Speed	• 5/12.5/ 25/ 50 mm/s (5 /12.5 mm/s only available for manual printouts), for resting rhythm: 6.25 mm/s
Sensitivity	• 5 /10 / 20 mm/mV, for resting rhythm: 2.5/5 mm/mV
ECG review	Display of the ECG on an area of 118 x 192 mm with different layouts.
Speed	• 12.5 / 25 / 50 mm/s, for resting rhythm: 6.25 mm/s
Sensitivity	• 5 /10 / 20 mm/mV, for resting rhythm: 2.5/5 mm/mV
Interfaces	• ECG cable connection • Potential equalisation • Network connection (1Gbit) • 2x USB type A • 1x USB type B
Memory	Memory for at least 350 ECG recordings and 100 resting rhythm recordings

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Ambient conditions	
Operating temperature	• 10 to 40 °C
Relative humidity	• 15 to 95% (non-condensing)
Pressure during operation	• 700 to 1060 hPa
Storage temperature	• 5 to 50 °C
Transport temperature	• -10 to 50 °C
Humidity during storage/ transport	• 10 to 95% (non-condensing)
Pressure during storage/ transport	• 500 to 1060 hPa

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13.2 ECG

Patient input	Fully floating and isolated, defibrillation protected (only with original SCHILLER patient cable)
Lead configurations	• Standard 12-lead • Paediatric • Right precordials • Standard C4r • Left posterior • Nehb • Balanced
Display	
Leads	• Display of the selected leads, 2x6 or **4x3** leads (configurable) – Chart speed **12.5**, 25 or 55 mm/s (configurable) – Amplitude 5, **10** or 20 mm/V (configurable)
Status	• Filter status • Power source • Leads • Electrode contact status • Heart rate (HR) • Date and time • Patient name and number • WLAN transmission
Filter	
Myogram filter (muscle tremor)	Set to 25, 40, 150, 250 Hz (250 Hz = Filter Off)
Notch filter	Distortion-free suppression of superimposed AC 50 or AC 60 Hz sinusoidal interferences by means of adaptive digital filtering
Data record	• Patient data (name, age, height, weight, BP, device ID, MTA ID) • Listing of all ECG recording conditions (date, time, filter) • ECG measurement results (intervals, amplitudes, electrical axes) • Average complexes • Guidance on interpreting adult and paediatric ECGs
With optional interpretation (C) program	
ECG amplifier	Complies with IEC 60601-2-25 and ANSI/AAMI EC11

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13.3 Safety standards

Safety standard	IEC/EN 60601-1 IEC/EN 60601-2-25
EMC	IEC/EN 60601-1-2
Protection class	Device as a system: Class I in accordance with IEC/EN 60601-1
Conformity/classification	CE/IIa in accordance with directive 93/42/EEC
Protection	This device is not designed for outdoor use (IP 20)

13.4 WLAN standards

Modules	WL1837MOD
FCC ID **IC ID**	Z64-WL180DBMOD 451I-WL18DBMOD
Transmission standards	IEEE 802.11 a, b, g, n
Safety/encryption	WPA2 enterprise / ieee802.1, WPA2-PSK, WPA-PSK, WEP64/128/256, TKIP, AES
Frequency range	Dual-band 2.4 GHz and 5 GHz
Max. power output 2.4 GHz (1DSSS)	+16.5 dBm
Max. power output 5 GHz (OFDM6)	+18 dBm

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15 Appendix - Symbols

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

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

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

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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

EC REP
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Germany

Device availability in your market is subject to regulatory approval.

SCHILLER
The Art of Diagnostics

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