

SCHILLER

CARDIOVIT FT-2

User Guide



001

Smith John | 21 years 4 months | Male



60

min

99 --/--



25 mm/s, 10 mm/mV

ECG quality good

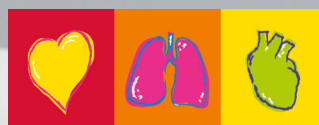
An ECG recording can now be taken

Patient

Manual



Art. no: 2:511436 Rev. a



SCHILLER
The Art of Diagnostics



Sales and Service Information

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Sales information can also be obtained from:

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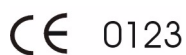
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The CARDIOVIT FT-2 bears the CE-0123 mark (Notified Body: TÜV-SÜD Produkte Service GmbH, Ridlerstr. 65, 80339 Munich, Germany), indicating its compliance with the essential requirements of Annex I of the Regulation (EU) 2017/745 (MDR) regarding safety, 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.

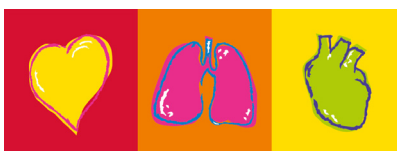


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1 Safety notes



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



For additional safety measures and safety notes which need to be followed for the CARDIOVIT FT-2 in combination with the SpiroScout SP plus:

- Read the spirometry supplement to the CARDIOVIT FT-2 user guide

1.1 Intended purpose

- ▲ The CARDIOVIT FT-2 is a electrocardiograph device intended to be used by or under the direct supervision of a licensed physician in healthcare facilities to acquire ECG signals from body surface electrodes, record, analyse, display and print ECGs to support diagnosis in adult and paediatric patients at rest.

Indications

- ▲ The CARDIOVIT FT-2 is intended to support detection and diagnosis of abnormalities in conduction, rhythm, and myocardial perfusion of the heart at rest.

Contraindication

No known contraindication for resting ECG.

Intended users

- ▲ The CARDIOVIT FT-2 is intended to be used by or under the direct supervision of a licensed physician.

Patient target group

- ▲ The CARDIOVIT FT-2 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)

Affected body regions

- ▲ The CARDIOVIT FT-2 system is only in contact with the user.

Context of use

- ▲ The CARDIOVIT FT-2 is intended for indoor use in healthcare facilities.
- ▲ The CARDIOVIT FT-2 needs to be operated according to the technical data (see section 13, p. 131).
 - The CARDIOVIT FT-2 system is transportable by means of a trolley. The CARDIOVIT FT-2 unit is not portable.

Re-Use

- ▲ The CARDIOVIT FT-2 is reusable.

1.2 Limitations



- ▲ The CARDIOVIT FT-2 is not intended:
 - 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
 - to be used as a vital signs physiological monitor
 - for use with high-frequency surgical units

1.3 Residual Risk / Undesirable Side effects

There are no known residual risk or side effect.

1.4 Responsibility of the operator



- ▲ Specify the responsibilities of the personnel for operation and maintenance of the device.
- ▲ Have software updates and upgrades exclusively performed by trained and approved service technicians.
- ▲ Ensure that the personnel have read and understood this user guide and in particular this section Safety notes.
- ▲ Have damaged or missing components immediately replaced.
- ▲ Observe the maintenance intervals given in section Maintenance and disposal ([see section 12, p. 115](#)) to ensure safety, reliability and performance of the device.
- ▲ Observe the operating and maintenance instructions.
- ▲ In addition to the user guide, observe statutory and other binding regulations for the prevention of accidents and environmental protection.

1.5 Organisational Measures



- ▲ Before putting the device into operation, have the features and necessary safety measures explained by a medical product representative.
- ▲ Keep this user guide in an accessible place for reference purposes. Make sure that the user guide is always complete and legible.

Packaging

- ▲ Do not use the device and disposables if the packaging is damaged or has been unintentionally opened before use.
- ▲ Do not use the device if the packaging has been exposed to environmental conditions outside of those specified ([see section 13.1, p. 131](#)) and contact SCHILLER.

1.6 Safety-conscious operation



- ▲ **CAUTION** - Only operate the device in accordance with the specified technical data ([see section 13, p. 131](#)).
- ▲ Immediately report any changes that impair safety (including operating behaviour) to the person responsible.
- ▲ Danger of electric shock during defibrillation:
 - Do not touch the device during a defibrillation.
 - Ensure that the electrodes (including the neutral electrode) do not come in contact with conductive objects, even when these are earthed.
 - Ensure that the patient does not come in contact with conductive objects, even when these are earthed.
 - Ensure that people with simultaneous patient contact do not come in contact with conductive objects, even when these are earthed.
- ▲ Pacemaker malfunction:
 - Observe a distance of at least 20 cm between the device and pacemaker.
- ▲ Injuries, incorrect information and/or damage to the device:
 - Only use accessories and disposables recommended or supplied by SCHILLER, including the patient cable. Using hardware that is not approved by SCHILLER is at the user's own risk and the warranty might become void, [see section 1.12, p. 16](#).
 - 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.
 - Do not modify this device without the manufacturer's permission.



- ▲ Danger of incorrect treatment due to mixed up patients and/or data:
 - Always cross-check patient data carefully.
 - For the visit ID, only use a unique number issued by your health institution; do not use general information such as name of the department or physician.
- ▲ Equipment damage due to defibrillation. The device (type CF) is only defibrillation protected when the original SCHILLER patient cable is used:
 - If possible, remove the electrodes before defibrillation.
- ▲ Equipment damage due to spilled liquid:
 - Do not place any liquids on the unit.
 - If liquid is spilled on the device, immediately disconnect the device from the power supply and wipe it. Before using the device again, have it tested and repaired, if necessary.

1.7 Safety facilities



- ▲ Danger of injury for the patient or user when using the device with defective cables:
 - Do not use the device if the protective earth is suspect or if the mains lead, power supply unit or device is damaged or suspected of being damaged.
 - Only connect to a power supply with protective earth connection.
 - Immediately replace damaged cable connections and connectors.
 - Do not modify electrical safety devices, such as fuses.
- ▲ Danger of injury to the patient or user due to an electrical shock:
 - Do not touch the power source during a thunderstorm
 - Do not touch the plug when your hands are moist/wet
- ▲ Damage to the cable due to mechanical stress:
 - When disconnecting a cable, pull the plug and not the cable
 - Route the cable so as to help prevent people from tripping or the cable being run over by, for example, the trolley

1.8 Operation with other devices



- ▲ The CARDIOVIT FT-2 can be used together with other medical devices such as:
 - ECG
 - patient cable and electrodes
 - ECG suction pump
 - Spirometry sensor
 - Printer
 - Thermal paper
 - Installed on a trolley
 - Networks
- ▲ Accessories connected to the device need to be certified according to the respective IEC standards (e. g. IEC 60950 for data processing equipment, IEC 62368-1 for audio/video, information and communication technology equipment, and IEC 60601-1 for medical electrical equipment). In addition, any configurations need to fulfil standard IEC 60601-1. Everyone 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 potential equalisation as the CARDIOVIT FT-2.
- ▲ Any other connected device to patient may increase the patient leakage current, because of summation of the leakage current.
- ▲ There is no danger when using the ECG unit simultaneously with electrical stimulation equipment. However, the stimulation units should only be used at a sufficient distance from the electrodes. If in doubt, the patient should be disconnected from the device.
- ▲ Portable communication devices, HF radios and devices labelled with the  symbol (non-ionising electromagnetic radiation) can affect the operation of this device ([see section 12.8, p. 126](#)).
- ▲ This device can safely be used with pacemaker patients:
 - Observe a distance of at least 20 cm between the device and pacemaker.

1.9 Cybersecurity

1.9.1 Networks and access security FT-2



- ▲ Connecting CARDIOVIT FT-2 to an IT network could result in previously unidentified risks to patients, operators or third parties. The responsible organisation needs to identify, analyse, evaluate and control any additional risks resulting from the CARDIOVIT FT-2 connected to IT networks including other equipment. Subsequent changes to the IT network might introduce new risks and require additional analysis.
- ▲ Danger to the patient due to disruption of data transmission or due to incorrectly transmitted data:
 - If the device is part of a network (LAN, WLAN, HIS, etc.), the network operator must take appropriate security measures to protect the transmission of data.
 - Network safety is the sole responsibility of the network operator.
 - Additional safety notes: [see section 9, p. 81](#).
- ▲ In order to guarantee the access security of the **CARDIOVIT FT-2**, Schiller AG recommends the following:
 - defining access authorisation, so that no unauthorised alterations of the FT-2 are possible [see section 11.5.1, p. 104](#).
 - Do not divulge login credentials to third parties.
 - Use a password with minimum 8 digits and it should include a combination of letters (capital, small), numbers, and characters.
 - A safe password should include a combination of letters, numbers, and characters.
 - Always logout after use and using the Automatic Logout function [see section 11.5.1, p. 104](#).
 - Using the PDF export function, follow the safety measures in chapter [9.3](#).

1.10 Maintenance



- ▲ Danger of electric shock:
 - Do not open the device, it does not contain any serviceable parts.
 - Maintenance work may only be performed by qualified technicians authorised by SCHILLER.
 - This includes batteries that can only be changed by service personnel. Battery replacement by inadequately trained personnel could result in excessive temperatures, fire or explosion.
- ▲ Only perform maintenance when the device is not in use.

1.11 Cleaning/disinfection



- ▲ Risk of cross-contamination:
 - Do not reuse disposable accessories marked with the symbol 
 - Some electrodes are disposable accessories: [see section 12.9, p. 128](#)
- ▲ Equipment damage:
 - Clean and disinfect the device according to the instructions in this user guide ([see section 12.6, p. 121](#)).
 - Observe applicable statutory requirements regarding cleaning/disinfection.
 - Only use detergents and disinfectants recommended by SCHILLER ([see section 12.6, p. 121](#)). Do not use aggressive or abrasive detergents.
- ▲ Switch off the device and disconnect it from the power supply before cleaning/disinfection.
- ▲ Never immerse the device or cables in liquid.
- ▲ Do not sterilise the device.

1.12 Terms of warranty

According to the Terms and Conditions, your CARDIOVIT FT-2 is warranted against defects in material and manufacture (visit <https://www.schiller.ch>).

Excluded from this warranty is damage resulting from negligence or improper use. 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 of a defect, send the device to your SCHILLER- representative or directly to SCHILLER. SCHILLER can only guarantee the safety, reliability and performance of the device if:

- assembly operations, extensions, readjustments, modifications or repairs are carried out by persons authorised by SCHILLER,
- the SCHILLER device as well as any approved accessories are used according to the instructions provided in this user guide, and
- if the maintenance intervals as stated in section Maintenance are observed ([see section 12, p. 115](#)).

There are no express or implied warranties which extend beyond the warranties listed here. 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 loss of data saved on the computer or on the device. The operator is solely responsible for backup of data.

1.13 Serious incidents



- ▲ If any serious incident occurs in relation to the CARDIOVIT FT-2, 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.

1.14 Safety symbols and signs

1.14.1 Symbols used in this document

The safety and warning messages are designed and phrased according to the applicable standards.



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



- ▲ For a possibly dangerous situation which could lead to severe personal injury or to death.
- ▲ Embedded warning messages of this level are indicated with the signal word **WARNING!**.



- ▲ For a possibly dangerous situation which could lead to personal injury.
- ▲ Embedded warning messages of this level are indicated with the signal word **CAUTION!**.



- Warning concerning equipment damage or system failure.
- Embedded warning messages of this level are indicated with the signal word *NOTICE!*.



- ▲ For general or supplementary safety notes as listed in this section with or without the signal word **CAUTION** or **WARNING**.



- ▲ For electrical hazards or precautionary measures when dealing with electricity.



- ▲ For interferences caused by non-ionising electromagnetic radiation.



Especially important or helpful information



Reference to other documents



Required tools/equipment

1.14.2 Safety symbols on the device and printer (optional)



Refer to instruction manual/booklet: Reading the user guide before using the device is compulsory



Caution: Observe the warning and safety notes given in the user guide



Non-ionising electromagnetic radiation: The device may cause or be susceptible to electromagnetic disturbances.

The device contains an HF transmitter (WiFi).



Symbol for the recognition of electrical and electronic equipment. Equipment, components and accessories no longer used must be disposed of in a municipally approved collection point or recycling centre. Alternatively, you can return the device to your supplier or to the manufacturer for disposal. Improper disposal can harm the environment and human health.

IP20

Protection class: IP20. According to DIN EN 60529. Protected against ingress of solid foreign bodies ≥ 12.5 mm. Not protected against ingress of water, may only be used indoors.



MRI unsafe: Do not use the device in or near Magnetic Resonance Imaging equipment (MRI)



Equipotentiality: Potential equalisation stud ([see section 2.2, p. 22](#))



Defibrillation-proof type CF applied part, according to IEC 60601-1: Patient cable connector. Only defibrillation protected if used with the original SCHILLER patient cable.

For additional symbols: [see section 16, p. 125](#).

1.14.3 Symbols used on accessories/disposables



Do not reuse: Disposable item



Expiry date



Electrodes: Use within one day after opening

For additional symbols: [see section 16, p. 125](#).

1.14.4 Safety symbols and signs on the trolley (optional)

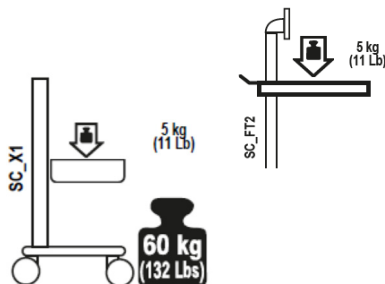
The following symbols are related to the Trolley manufactured by Multix Solutions s.r.l. For detailed description see latest User Guide from Multix Solutions s.r.l.



- ▲ **CAUTION** - Pushing over obstacles prohibited (e.g. power cables or door thresholds) see 10.1.5 Moving trolley over obstacles, Page 90.



- ▲ **CAUTION** - It's forbidden to sit on the cart



Trolley label with:

- Total mass including safe working load 60 kg
- Maximum load basket/console 5 kg

2 Introduction

The CARDIOVIT FT-2 is a 12-channel ECG device designed to record, display and measure resting ECGs. The multi-touch screen allows easy and intuitive operation to efficiently enter patient data, quickly record ECGs and define settings.

As an option, spirometry measurements can be recorded, displayed and printed. For further information: see spirometry supplement to the user guide.

2.1 Device



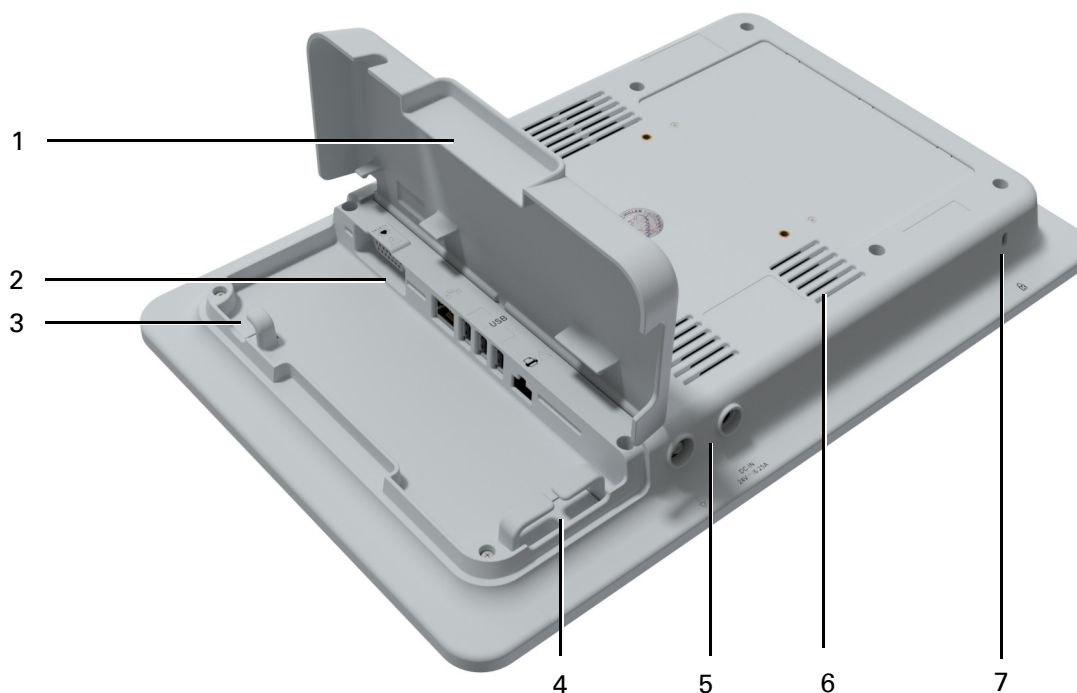
- (1) LCD multi-touch screen
- (2) Connector panel on right-hand side, [see section 2.2, p. 22](#)
- (3) Connector panel at bottom, [see section 2.2, p. 22](#)
- (4) Function indicator: is lit green when connected to the power supply
- (5) On/off button: is lit when the device is switched on

2.2 Connectors

NOTICE

- Equipment damage due to not approved external hardware:
 - Only connect external hardware approved by SCHILLER.
 - Connecting not approved hardware is done at the user's own risk and may render the warranty invalid.

Overview – back



- (1) Cover for connector panel on right-hand side: pull to open
- (2) Connectors on right-hand side (see following)
- (3) Cable routing for patient cable
- (4) Cable routing for various cables
- (5) Connectors at bottom (see following)
- (6) Air vents ([see section 3.1, p. 29](#))
- (7) Kensington lock

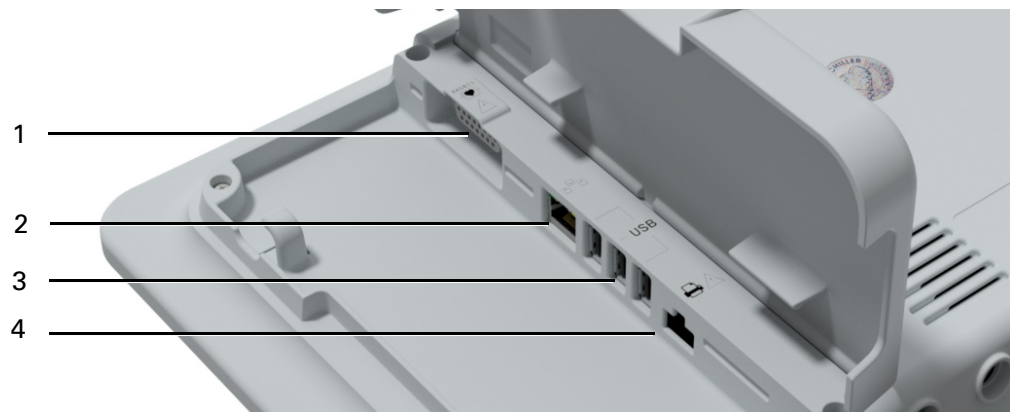
Connector panel right-hand side

! WARNING

- ▲ Danger to the patient due to modifications of the electrical system:
 - Do not connect the external printer via USB (see section 10.3.)
 - Only connect the thermal printer described in section 10.2 (see (4) below and [see section 10.2, p. 91](#))
- ▲ Danger to the patient due to the summation of leakage currents:
 - Only connect external hardware approved by SCHILLER
 - Any other equipment used with the patient must use the same potential equalisation as the CARDIOVIT FT-2.

NOTICE

- Equipment damage:
 - Only connect or disconnect the thermal printer when the device is switched off ([see section 2.2, p. 22](#))



(1) ECG patient cable connection (applied part)

- ▲ **WARNING** – Do not remove the patient cable as long it is applied to the patient or connect the patient cable to another device.
- ▲ **WARNING** – The device (type CF) is only defibrillation protected when the original SCHILLER patient cable is used.

(2) RJ45 Ethernet connection (LAN) for:

- Network connection

- ▲ **WARNING** – Accessories connected to the device need to be certified according to the respective IEC standards (e. g. IEC 60950 for data processing equipment, IEC 62368-1 for audio/video, information and communication technology equipment, and IEC 60601-1 for medical electrical equipment)

(3) 3 × USB ports type A for:

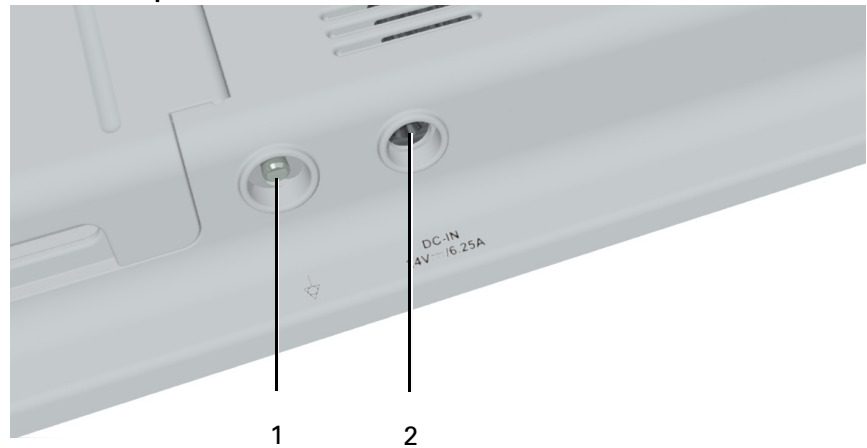
- PDF export
- Software updates
- Connection of barcode scanner (optional)
- Connection of Spiro sensor SpiroScout SP plus (optional)

- ▲ **CAUTION** – Do not connect the external printer via USB.

(4) Connection of thermal printer (optional): see section [10.2](#)

- ▲ **CAUTION** – Only connect the printer described in section [10.2](#) to this port.

Connector panel at bottom



(1) Potential equalisation connector

(2) Power supply connector (DC IN, 24 V/6.25 A)

2.3 Applied parts

- Patient cable
 - Connector: see section Connector panel right-hand side, above
 - Types: [see section 4.2, p. 36](#)
 - Ordering information: [see section 12.9, p. 128](#)
- Electrodes
 - Applying: [see section 4.6, p. 40](#)
 - Ordering information: [see section 12.9, p. 128](#)

2.4 Features

2.4.1 Standard features

- 12-lead resting ECG with display of all 12 channels
- Recording preview with display of reversed leads/lead-off
- Automatic resting ECG recording (duration: 10 seconds) with user-defined layouts
- Manual ECG printout in real time; leads, speed and amplitude can be changed



The manual ECG printout feature is only available with the thermal printer ([see section 10.2, p. 91](#)).

- Rhythm ECG recording up to 20 minutes
- Pacemaker detection
- Display of measurement results
- Recording review before accepting/transmitting
- Internal memory for at least 350 resting ECGs, 100 rhythm ECGs and 100 spirometry recordings
- Connectivity:
 - LAN (Ethernet)
 - WLAN
- EMR integration (Electronic Medical Record) via:
 - SCHILLER Link
 - SCHILLER Gateway
 - SCHILLER Server
- PDF export to USB stick
- Access control with user name and password

2.4.2 Optional features

Software

- Interpretation with ETM Sport
- Worklist



Licensing: [see section 11.3.6, p. 102](#)

Hardware

- Spirometry [see section 11.13, p. 113](#)
- Thermal printer

2.5 Optional Accessories

- [see section 12.9, p. 128](#)

2.6 Configurations

The following three configurations are available:

- CARDIOVIT FT-2
- CARDIOVIT FT-2 with trolley
- CARDIOVIT FT-2 with trolley and thermal printer

2.7 Installation

The device is being installed by SCHILLER. The features and procedures are explained by a medical product representative.

2.8 Transmission – Overview

Recordings can be transmitted as follows:

LAN

Transmission via a local network (Ethernet) via RJ45 cable ([see section 2.2, p. 22](#))

WLAN

Wireless transmission via WLAN

PDF export

Export of PDF reports to a USB stick

Moreover:

Automatic transmission

After accepting (and therefore storing) a recording, it can be transmitted automatically: Menu > **Settings** > **General** > **Workflow** ([see section 11.3.4, p. 101](#)).

Manual transmission

Recordings can be transmitted from the memory ([see section 7.5, p. 73](#)).

Integration options with an EMR system (EMR: Electronic Medical Record):

- SCHILLER Link
- SCHILLER Gateway
- SCHILLER Server

For additional information: [see section 9, p. 81](#).

2.9 Program

2.9.1 Main menu

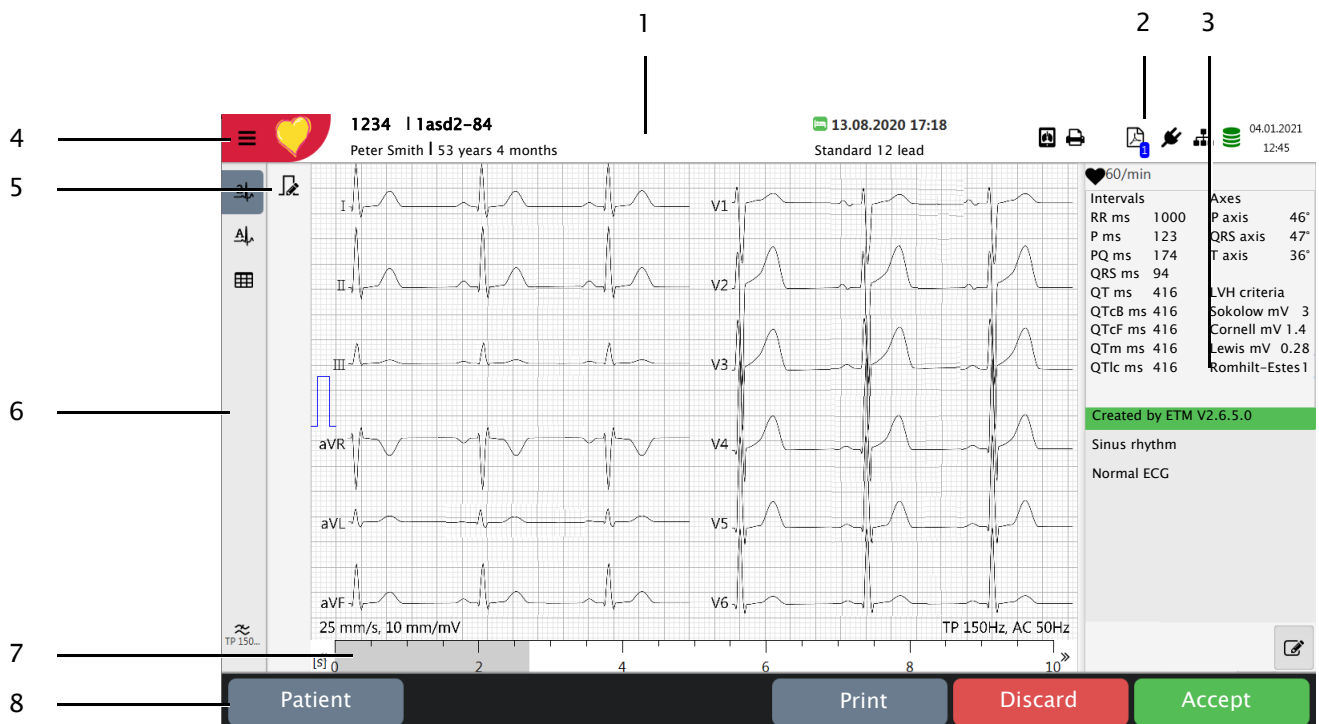


The main menu (icon on the left) offers access to the following features:

- Worklist (optional)
- Recorder
- Memory
- Logout (if access control is activated)
- **Settings** menu
- **Maintenance** menu

2.9.2 Display

The display varies according to the task being carried out. However, the upper, lower and right/left parts of the display always contain the same information categories:



- (1) Patient data including patient ID and visit ID, as well as type and recording date/time and lead configuration
- (2) Information on the printer, transmission, power supply, network, memory, as well as date and time: tap the icon to display further information (only for printer and network)
- (3) Information area
- (4) Access to the main menu
- (5) Settings for the current display: tap an icon to display the selection or to activate/deactivate the feature

- (6) Taskbar left: tap to expand and display further information (available functions depend on the current view)
- (7) Time axis: move the grey area to scroll through the recording, or swipe left/right with your finger
- (8) Taskbar bottom with function keys (available functions depend on the current activity)



The ECG procedure is described in detail in chapter 6.

The spirometry procedure is described in the separate spirometry supplement to the user guide.

3 Initial operation



- ▲ Serious injury caused by an electrical shock:
 - Do not use the device if the protective earth cable is suspected of being damaged or if the mains lead/power supply unit is damaged or suspected of being damaged.
 - This equipment must only be connected to a supply mains with protective earth.
- ▲ Danger of explosion! The device is not designed for use in areas where an explosion hazard may occur (e.g. presence of flammable gases such as anesthetic agents).



- ▲ The device is not for use in or near magnetic resonance imaging equipment.

3.1 Location



- Equipment damage:
 - Do not store or operate the device in a wet, humid or dusty environment.
 - Do not expose the device to direct sunlight or heat from other sources.
 - Do not allow the device to come into contact with acidic vapours or liquids.
 - [see section 13.1, p. 131](#)
- Equipment overheating:
 - Do not cover the air vents (position of air vents: [see section 2.2, p. 22](#))
- Device malfunction:

Do not position the device in close proximity to the following equipment:

 - X-ray equipment
 - Diathermy units
 - Large transformers
 - Electric motors
 - High-frequency devices

3.2 Connecting cables/accessories

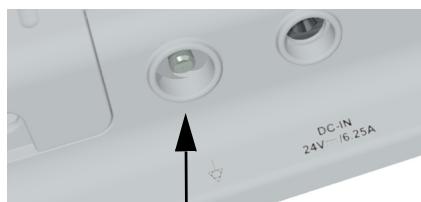
See section 2.2



External power supply unit incl. connection cable

Potential equalisation cable

Any accessories



1. Connect the external power supply unit's cable to the mains supply
2. Connect the external power supply unit's output to the device
→ The function indicator is lit ([see section 3.4, p. 31](#)).
3. Connect the device to the building's potential equalisation by means of the potential equalisation cable.
4. Connect any required accessories and any optional devices ([see section 2.2, p. 22](#)):
 - ECG patient cable
 - Network cable
 - Barcode scanner
 - SpiroScout SP plus
 - Suction electrode system

3.3 Potential equalisation



- ▲ Danger of ventricular fibrillation triggered by equalising currents between different device potentials. This may be the case if the device is used together with medical devices for direct cardiac application:
 - Connect both devices to the building's joint potential equalisation.



Potential equalisation cable (optional): article number 2.310005



Connect the device to the building's potential equalisation by means of the potential equalisation cable.

3.4 Power supply

The device is either powered by an external power supply unit via mains supply, or by the internal rechargeable battery.

The external power supply unit is part of the medical-electrical equipment (i. e. the CARDIOVIT FT-2).

The power supply mode is indicated at the top right of the display as follows:



Power supply via external power supply unit, the battery is being charged



If the device is connected to the mains, the green indicator next to the On/off button is lit (see [section 2.1, p. 21](#)).



Power supply via internal rechargeable battery



Full



High



Half full



Almost empty



Empty

Battery capacity

The internal battery provides power for up to four hours.

If the device is battery-operated, the battery symbol on the display indicates the remaining battery capacity. When the battery is fully charged, the symbol is solid.

If the device is battery-operated and battery capacity is low ($\leq 15\%$), the battery symbol is flashing red.

Printouts are only possible if the battery capacity is higher than 20 %.

Charging the battery

The battery is charged when the device is connected to the mains supply. The device can remain connected to the mains supply without damage to either the battery or the device. After 4 hours of charging, the capacity is at least 80 % if the device is switched off.

Isolating from the mains supply

NOTICE

- Cable damage:
 - Unplug the cable by pulling the plug, not the cord.

Disconnect the mains cable from the external power supply unit.

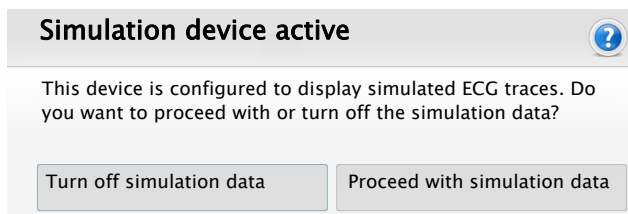


Position the device so that it can quickly and easily be isolated from the power supply.

3.5 Switching on and off

Press the On/off key to switch the device on or off (see section 2.1, p. 21).

- If the device cannot be switched on:
 - see section 12.5, p. 118
- If the device does not react and cannot be switched off, shutdown is forced as follows:
 - Press and hold the On/off key for approx. 10 seconds until the key is no longer lit.
- Settings for automatic switch off: see section 11.3.3, p. 101.
- Simulation data: If configured, the following dialogue is displayed when the device is switched on:



- To switch off simulated data and use the device with a patient, tap **Turn off simulation data**.

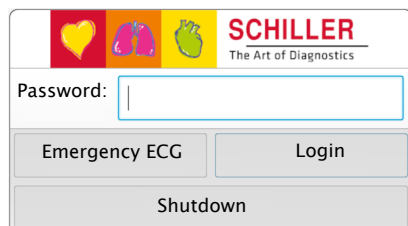
3.6 Logging on/off

CAUTION

- ▲ Risk of unauthorised access to patient data:
 - Activate access control ([see section 11.5.1, p. 104](#))
 - Have default passwords changed by the responsible person

If access control is not activated, no password is required.

If access control is activated, the following dialogue is displayed:



The login screen displays the SCHILLER logo and 'The Art of Diagnostics' tagline. It features a 'Password:' label followed by a text input field. Below the input field are three buttons: 'Emergency ECG', 'Login', and 'Shutdown'.



The Emergency ECG screen displays the SCHILLER logo and 'The Art of Diagnostics' tagline. It features a 'User name:' label followed by a text input field, and a 'Password:' label followed by a text input field. Below the input fields are three buttons: 'Emergency ECG', 'Login', and 'Shutdown'.

Login

Enter password and tap **Login**.

For access control mode **Local** or **SCHILLER Server**: also enter the user name.

- The start screen is displayed: The start screen depends on the workflow setting ([see section 11.3.4, p. 101](#)) as well as on the user privileges ([see section 11.5.1, p. 104](#)).

Emergency ECG

In order to perform an ECG quickly and without login, tap **Emergency ECG**.

- The recording screen is displayed.

No other functions or settings are available.

The user is automatically logged off once the recording has been accepted.

Logout

Tap **Main menu > Logout**.

- The login dialogue is displayed.

The following settings are available for access control ([see section 11.5.1, p. 104](#)):

- **None**: No user name or password is required, the device can be used directly after switch on.
- **Basic**: Separate passwords are used for device login and access to the settings and memory.
- **Local**: User and password are defined locally in the settings. Different access rights are available.
- **SCHILLER Server**: User, password and access rights are defined on the SCHILLER Server.

User roles and privileges are individually assigned to each user and determine the available features. If a feature is not available, it means that the logged in user does not have the required user privileges.

Users and their privileges are defined locally (for devices that are not networked), or on the SCHILLER Server (if networked).

Automatic logout after a set duration can be activated in the settings ([see section 11.5.1, p. 104](#)).

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3.7 Initial Settings

The system settings (time, date, device ID etc.) as well as ECG settings (formats for automatic recordings, user-defined leads, print options, interpretation, definition of rhythm leads etc.) are described from page 97.

At initial operation, define the following important settings:

- Date and time
- Language and keyboard
- Units
- Device ID
- Visible and mandatory fields for patient data
- Workflow settings
- Connectivity settings
- Access control settings
- Print settings (optional)
- ECG settings (patient cable type, lead sequence, preview information and report information)

4 Electrodes

WARNING

- ▲ Danger of electric shock when touching conductive parts:
 - Ensure that neither the patient nor the leading parts of the patient connection nor the electrodes (including the neutral electrode) come in contact with other persons or conductive objects.
 - This applies even when such conductive objects are earthed.
- ▲ Risk of cross-contamination:
 - Do not reuse disposable accessories marked with the symbol 
 - Clean and disinfect re-usable accessories and patient cable before applying on a new patient [see section 12.6.2, p. 122](#).



For further information: consult the electrodes' user guide.

4.1 Basics

In order to obtain optimal ECG signals and achieved highest recording quality:

- Ensure good electrode contact: Keep resistance between skin and electrodes to a minimum.

Therefore:

- Only use electrodes recommended by SCHILLER ([see section 12.9, p. 128](#))
- To increase the electrode's conductivity and adherence:
 - Check the disposable electrodes' expiration date before use: if the expiration date has passed, the electrodes' contact gel might be dried up.
 - If necessary, shave the skin where the electrodes are to be applied.
 - Thoroughly clean the areas with soapy water.
 - Let the skin dry.
 - ¹Apply gel
- Check electrode resistance as detailed in section Signal quality (see page 41)
- If electrode resistance is too high:
 - Remove the electrode.
 - Use abrasive cleaning pads or abrasive cleaning gel to remove the uppermost layer of the epidermis.
 - Re-apply the electrode. For disposable electrodes: use a new electrode.

1. Electrode gel is integral with disposable electrodes and no extra gel needs to be applied when disposable electrodes are used. For White Sensor electrodes, solid conductive gel is incorporated in the adhesive.

- Ensure that the patient is warm and relaxed before you start the recording
- For children: If adult electrodes would have to be placed so close together that they overlap:
 - Use paediatric electrodes ([see section 12.9, p. 128](#)).

4.2 Patient cable



Two types of patient cables are available:

- Type IEC (International Electrotechnical Commission)
- Type AHA (American Heart Association)

The cable type is indicated on the cable.

Select the cable type in the menu Lead & cable ([see section 11.10.1, p. 109](#)).

The cable colours and labels are as follows:

Electrodes	IEC		AHA	
	Label	Colour	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

4.3 Connecting the patient cable and electrodes

4.3.1 Patient cable with clip

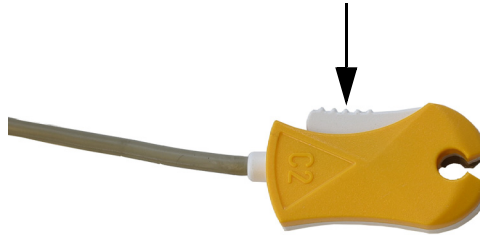


Patient cable, e. g. art. no. 2.400184

Blue Sensor electrodes, art. no. 2.155025, or

Limb/vacuum electrodes, art. no. 2.000041/2.000052

Press the clip together to attach it to the electrode:



With Blue Sensor electrodes (art. no. 2.155025)



With limb/vacuum electrodes (art. no. 2.000041/2.000052)



4.3.2 Patient cables with banana plugs

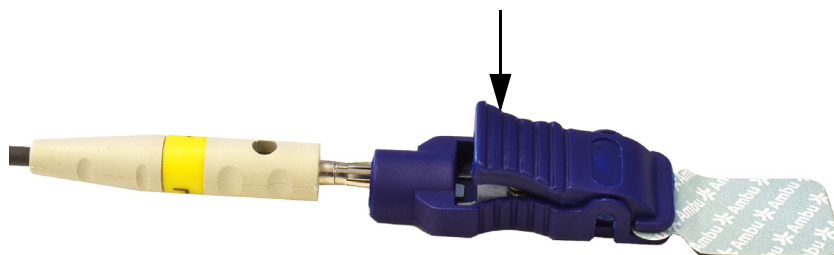


**With adapter and White Sensor electrodes
(art. no. 2.155032 and 2.155034)**

Patient cable, e. g. art. no. 2.400187

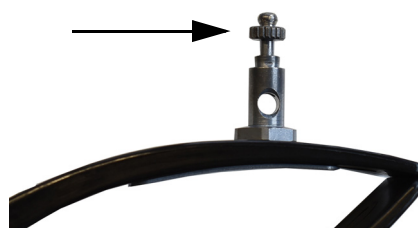
Adapter, art. no. 2.155032, with White Sensor electrodes, 2.155034, or Limb/vacuum electrodes, art. no. 2.000041/2.000052

1. Connect the banana plug to the adapter
2. Press to open the adapter (see arrow) and insert electrode



**With limb/vacuum electrodes
(art. no. 2.000041/2.000052)**

1. Fully open the screw on the electrode



2. Insert the banana plug
3. Tighten the screw



4.4 Selecting the lead sequence

Two lead sequences are available:

- Standard
- Cabrera

Selecting the lead sequence:

1. Open Menu **Settings > ECG > Lead & Cable**
2. Select the lead sequence

(see section 11.10.1, p. 109)

4.5 Selecting the lead configuration

The lead configuration is selected in the preview screen (see section 6.2, p. 51).

The lead configurations available in the preview are defined in the settings (see section 11.10.1, p. 109):

- **Standard 12-lead**
- **Paediatric**
- **Right precordials (C3r – C6r)**
- **Standard with C4r**
- **Left posterior C7 – C9**
- **Nehb (chest)**
- **Balanced**

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

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

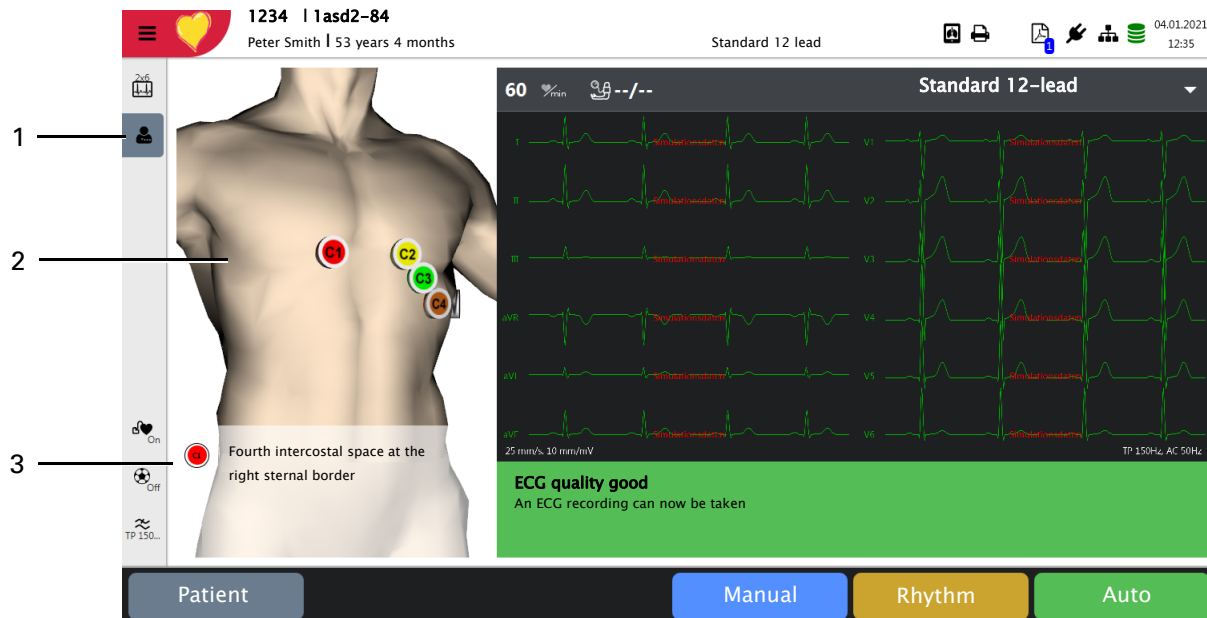
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To guarantee accurate signal measurements: for paediatric recordings, set the myogram filter to **Off** = 250 Hz.

If adult electrodes would have to be placed so close together that they overlap: use paediatric electrodes (see section 12.9, p. 128).

4.6 Displaying electrode positions

Electrode positions can be indicated in the preview screen (see section 6.2, p. 51). To do so, the view **Hookup** needs to be activated (setting: see section 11.10.5, p. 110):



- (1) **Hookup** screen
- (2) Electrode positions
- (3) Description of the position for the selected (i. e. tapped) electrode

Display the description of a specific electrode position:

1. Use a finger to turn/move the torso until the desired electrode is visible.
2. Tap the electrode.
 - The description is displayed (see illustration above)

4.7 Checking the electrodes and patient cable

In the preview (see also section 6.2), the ECG signal quality is checked and the electrode positions can be displayed (see section 4.6, p. 40).

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Available views are defined in the settings (see section 11.10.5, p. 110).

Signal quality

The program checks the following criteria:

- Excessive signal noise
 - Cause: poor electrode contact
- Mains interferences
 - Cause: mains filter not activated (see section 11.10.3, p. 109)
- Electrodes reversed
- Electrodes off

The electrode status is displayed at the bottom right:



(1) The lead colour corresponds to the signal quality; in this example, in red (see following).

(2) In this example, reversed electrodes are indicated.

Signal quality colours

- Status green: good signal quality
- Status yellow: excessive signal noise:
 - Re-apply the electrode(s)
- Status red: electrode(s) reversed or off:
 - Re-apply the electrode(s)



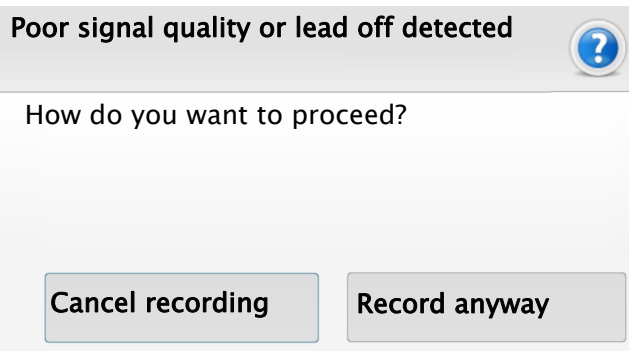
If F (LL) or N is not connected or has come off, the electrode resistance cannot be measured and all leads are marked red.

The colours for signal quality (here: green, yellow and red) can be changed in the settings ([see section 11.10.4, p. 110](#))

- If electrode resistance is too high:
 - Press on the electrode. If the resistance is still too high:
 - Remove the electrode.
 - Use abrasive cleaning pads or abrasive cleaning gel to remove the uppermost layer of the epidermis.
 - Re-apply the electrode. Use a new electrode.



If an automatic resting ECG recording is started despite a high-resistance electrode, lead off, incorrect electrode placement or high signal causing ECG amplifier saturation or overload, the following message is displayed:



→ Cancel recording: Return to the Preview screen

5 Patient Data and Recording Overview

WARNING

- ▲ Incorrect interpretation due to incorrect patient data:
 - Check the patient data before accepting the recording
 - If date of birth, gender or digitalis information has changed: a new interpretation is created.
- ▲ Risk of mixing up patients if the device is connected to an EMR system:
 - For the visit ID, only use a unique number issued by your health institution.
 - Do not use general information such as name of the department or physician as visit ID.

In the **patient data** screen, patient data as well as recording data is entered and edited.

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If no data is entered, the program enters the following data:

- Patient ID: unique designation, generated by the program
- Last name: **Emergency ECG**
- First name: date and time
- The interpretation is generated as if for a 50-year old male patient

Before accepting the recording, data can be entered:

1. Tap the **Patient** button
2. Enter the data
3. Tap the **Review** button
4. **Accept** the recording

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The displayed entry fields depend on the settings (see section 11.7.1, p. 106). If the fields do not fit onto one page, a second page is available: **Patient data 1** and **Patient data 2**.

All entry fields (apart from Medication) can be defined to be mandatory, see section 11.7.2, p. 107.

Available fields are amongst others:

Patient ID

Unique patient identification number

Visit ID

WARNING! See warning at the beginning of this section.

Patient reference number, e. g. hospital number; max. 50 characters

First and last name

max. 50 characters each

Date of birth and age

Configurable format for date of birth (see section 11.4.1, p. 103)

Gender, ethnicity

Select ("–" = undefined)

Height, weight

Units are configurable (see section 11.4.4, p. 103)

Pacemaker

Yes, No or Unknown



This setting only serves as information. The device detects pacemaker impulses regardless of this setting. If pacemaker pulses are detected, the interpretation indicates that it is a pacemaker ECG.

If **Yes** is set, the visual display of pacemaker impulses in the ECG preview is activated (see section 6.2, p. 51) and the pacemaker button on the review screen is set to "On".

Digitalis

Check box **Digitalis**, tick if applicable.

Indication

Reason for medication

5.1 Custom fields

In addition to the entry fields listed above, the user can define three entry fields. In the settings (see section 11.7.3, p. 107), the fields' **label** and available **values** are defined.

The values are available for selection as drop-down list in the patient data screen:

Label	
	✓ Value 1 Value 2 Value 3

Separate the values by inserting Enter after each value.

If no value has been defined, free text can be entered in the field.



Custom fields are only displayed if set to visible in the setting **Visible fields** (see section 11.7.1, p. 106)

5.2 Input options

WARNING! See warning at the beginning of chapter 5.

Data is entered and edited as follows:

- Via virtual keyboard directly in the entry fields
- Retrieval from the server by means of patient ID or Visit ID
 - by entering data via virtual keyboard
 - by reading data with a barcode scanner
- Via worklist (optional)
- Deleting data to enter a new patient
- Using the data from the previous patient



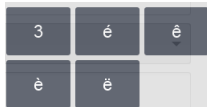
5.2.1 Virtual keyboard



Toggle between special characters/figures and characters.



Switch to capitals, or back to lower case characters.



Displaying accented characters etc.:
Press and hold the required button and select the character.



Jump to the next field.

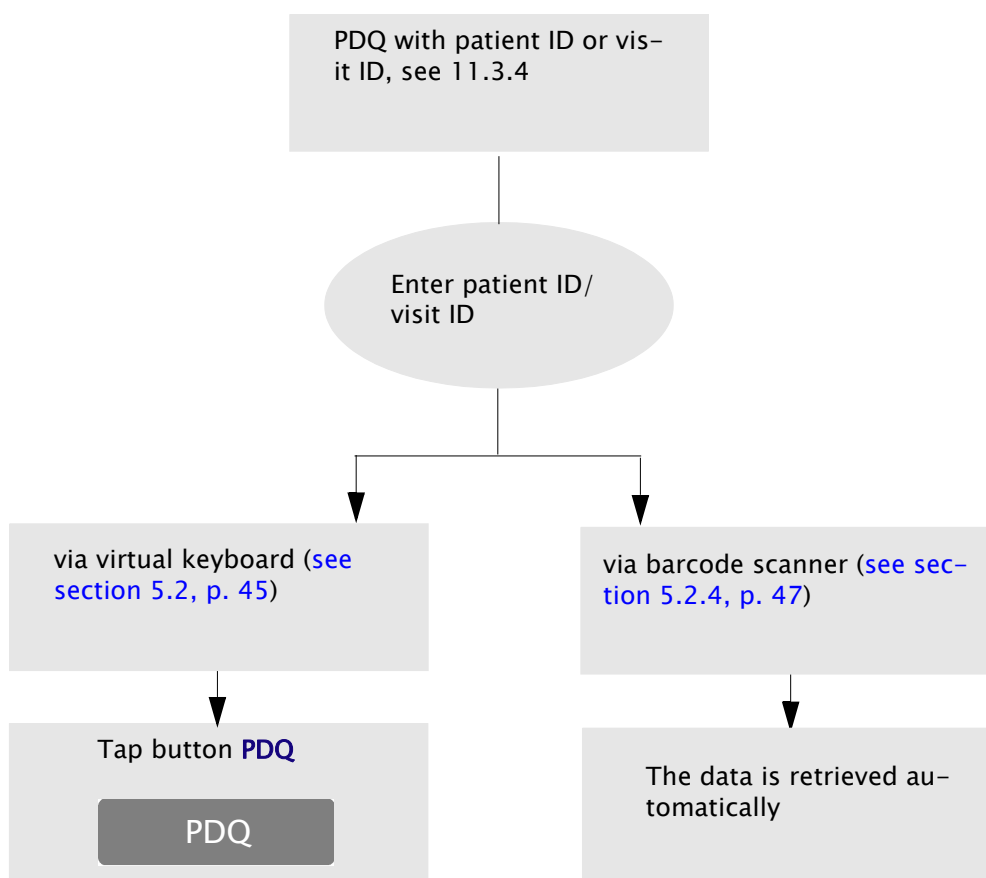


Delete characters.

5.2.2 Patient data query (PDQ)

If the device is connected to an EMR system via LAN or WLAN, patient data can be automatically retrieved from the database. To do so, the patient ID or visit ID needs to be entered (depending on the setting, [see section 11.3.4, p. 101](#)). This is called **PDQ** (Patient Data Query).

Procedure



5.2.3 PDQ in the worklist

If the workflow "Worklist" is active, the same search can be performed in the worklist (see section 8, p. 75):

1. Tap search field
2. Read the patient ID or visit ID using the barcode scanner
→ The corresponding work item is shown in the worklist.

5.2.4 Barcode scanner (optional)



Configuration of the barcode scanner: document with article number 2.510721.



Patient IDs or visit IDs can be read using a barcode scanner ([see section 5.2.2, p. 45](#)).

The following barcode scanner has been tested by SCHILLER and may be used with the device:

Symbol Model LS 2208, from Motorola

Connect the barcode scanner to the device's USB port ([see section 2.2, p. 22](#)).



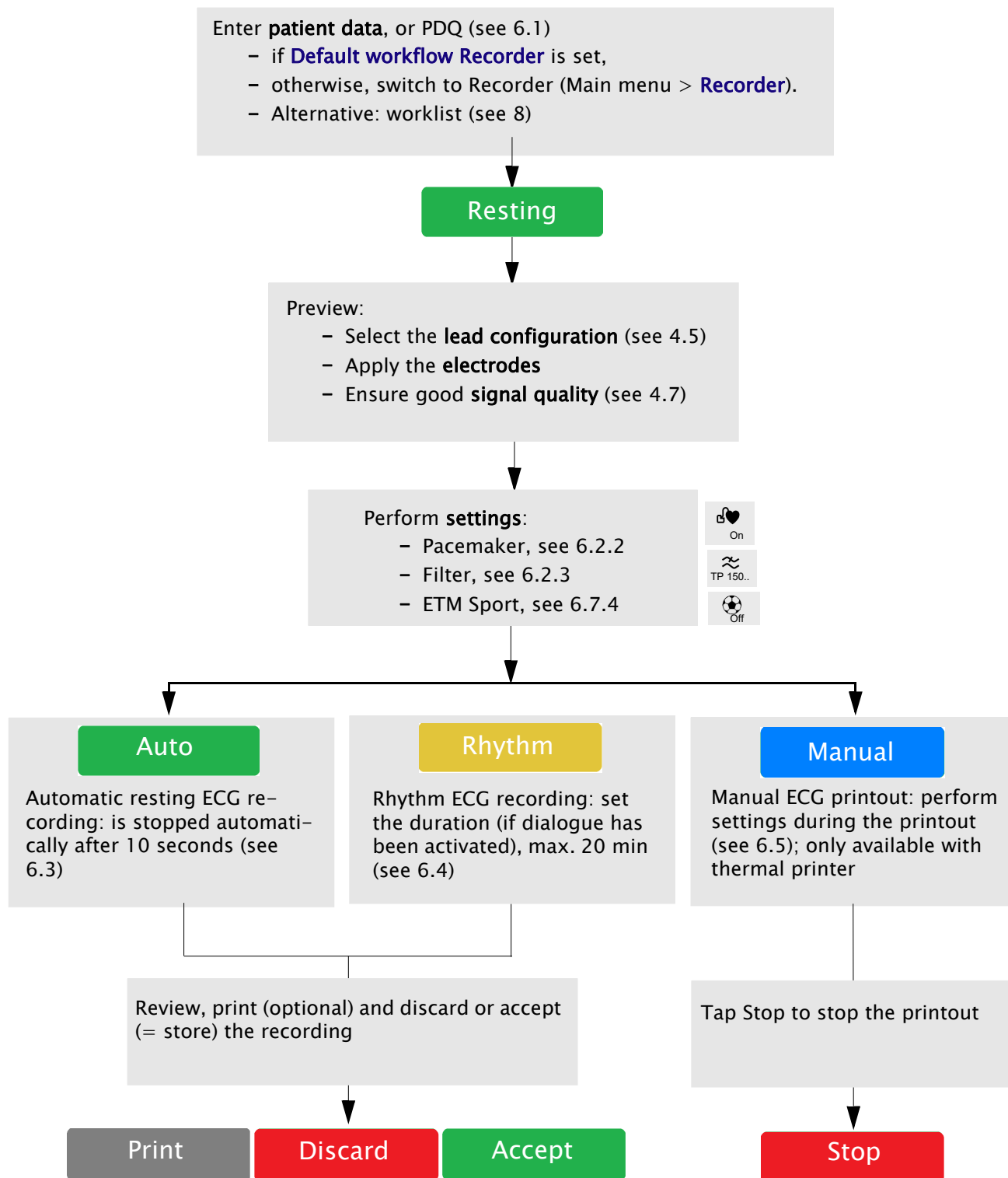
Country-specific character sets are selected in the settings: Menu **Settings > Regional > Keyboard > Barcode scanner layout**

6 ECG recording

WARNING

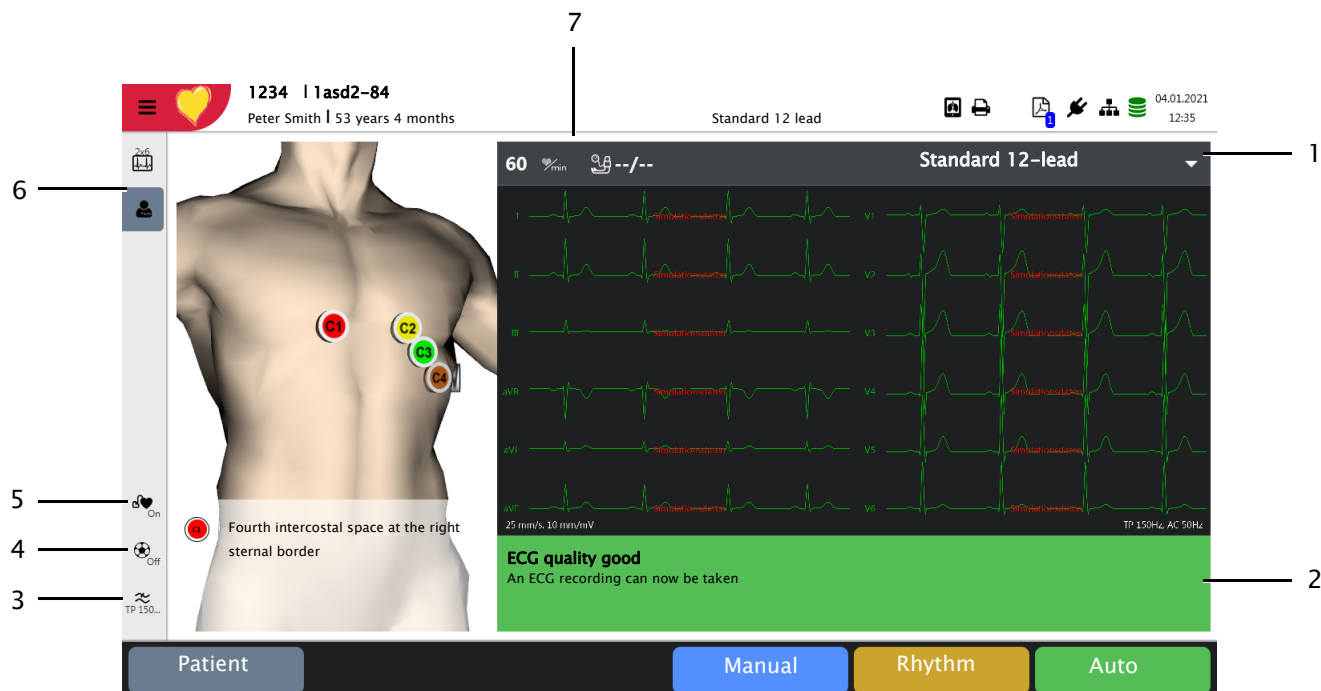
- ▲ Danger of electric shock when touching conductive parts:
 - Ensure that neither the patient nor the leading parts of the patient connection nor the electrodes (including the neutral electrode) come in contact with other persons or conductive objects.
 - This applies even when such conductive objects are earthed.
- ▲ Risk of injuries to the patient or user when operating the device with defective cables:
 - Do not use the device if the protective earth is suspect or if the mains lead, power supply unit or device is damaged or suspected of being damaged.
- ▲ Danger of ventricular fibrillation triggered by equalising currents between different device potentials. This may be the case if the device is used together with medical devices for direct cardiac application:
 - Connect both devices to the building's joint potential equalisation.
- ▲ Incorrect heart rate following heavy artefacts or loose electrodes due to poor ECG signal:
 - Check the signal quality ([see section , p. 41](#)).
- ▲ A diagnostic ECG according to IEC 60601-2-25 might not be possible if the myogram filter 25 Hz or 40 Hz has been selected:
 - Observe the guideline on filters issued by your health organisation.

6.1 Procedure



ETM Sport is only displayed if the interpretation option is installed.

6.2 Preview



In the preview, the following parameters can be defined (before the recording is started):

- (1) Lead configuration (see section 4.5, p. 39)
- (2) Signal quality (see section 4.7, p. 41)
- (3) Filter: low-pass filter 150 Hz, 40 Hz or 25 Hz, or Off (see following)
- (4) ETM Sport: On or Off (see section 6.7.4, p. 67)
- (5) Display of pacemaker pulses: On or Off (see section 6.2.2, p. 52)

Moreover:

- (6) Selecting the Preview view: is configured in the menu **Preview**, see following.



Depending on the view, the amplitude and speed as well as the displayed leads can be selected.

- (7) Heart rate display and entering measured blood pressure values (see section 6.2.4, p. 53).

Before the recording is started, patient data can be edited or complemented:

1. Tap the **Patient** button.
→ The patient data screen is displayed.
2. Enter the patient data.
3. Tap **Resting**.
→ The preview is displayed again.

6.2.1 Display settings

The views available in the taskbar on the left (see (6) above) are defined in the settings (see [section 11.10.5, p. 110](#)).

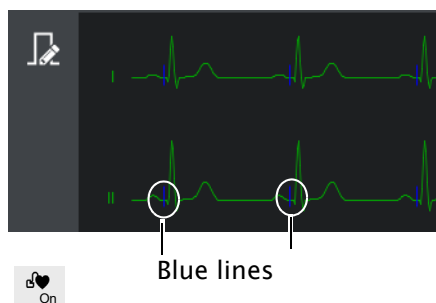
The lead sequence (Standard or Cabrera) as well as the default amplitude and speed are also defined in the settings (see [section 11.10.1, p. 109](#) and [section 11.10.5, p. 110](#)).

The colours and line widths are defined in the settings (see [section 11.10.4, p. 110](#)).

6.2.2 Pacemaker detection

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Regardless of the pacemaker setting in the patient data (see [section 6.1, p. 50](#)), the device detects pacemaker pulses. If pacemaker pulses are detected, the interpretation indicates that it is a pacemaker ECG.



Pacemaker pulses can be displayed in the preview. Pacemaker pulses are indicated as vertical, blue lines. These lines indicate the time of occurrence; however, they give no indication of the amplitude or pulse width of the pacemaker pulses.

If **Yes** is set in the patient data, the display of pacemaker pulses in the ECG preview is activated (see [section 6.2, p. 51](#)).

In order to manually activate the display of pacemaker pulses: tap the pacemaker icon (see illustration above).

6.2.3 Filter



Regardless of the filter settings in the preview, ECGs from the memory can be displayed and printed with any filter ([see section 7.4, p. 72](#))

Myogram filter



- ▲ A diagnostic ECG according to IEC 60601-2-25 might not be possible if the myogram filter 25 Hz or 40 Hz has been selected:
 - Observe the guideline on filters issued by your health organisation.
- ▲ To guarantee accurate signal measurements:
 - For paediatric recordings, set the myogram filter to **Off** = 250 Hz.



The default myogram filter is defined in the settings ([see section 11.10.3, p. 109](#)).

This low-pass filter suppresses disturbances caused by strong muscle tremor.

The following filter settings are available:

- **Off** (= 250 Hz)
- **25Hz**
- **40Hz**
- **150Hz**

Tap the filter icon (see (3) in the illustration above) until the desired filter is selected.

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 printed.



The default mains filter is defined in the settings ([see section 11.10.3, p. 109](#)).

6.2.4 Blood pressure



Blood pressure measurement device (separate device, independent of the CARDIOVIT FT-2)

Blood pressure values, which were measured with a separate device, can be entered manually:

1. Tap the blood pressure icon (see (7) in the illustration on page 51).
2. Enter blood pressure values via the virtual keyboard.
 - The blood pressure values is displayed until a new value is entered.

6.3 Automatic Resting ECG Recording

The automatic resting ECG recording is stopped automatically after 10 seconds.



Depending on the settings, once the recording is accepted, it is automatically transmitted, saved as PDF or printed (see section 11.3.4, p. 101). Deleting the recording after transmission/PDF export is also possible (see section 11.3.4, p. 101).

The printout format may differ from the displayed ECG. The information on the printout can be configured (see section 11.11.2, p. 111).

The recording is stored in the memory (see section 7, p. 69), unless the setting **Delete after export** is activated (see section 11.3.4, p. 101).

6.3.1 Starting and checking the recording

1. Tap **Auto**.

→ The 10-second recording is started, analysed and then displayed. The remaining duration is indicated at the

top: **0:03**

2. Check the recording (see following).

3. Enter or complement the patient data, if necessary (see section 6.1, p. 50).

4. Print the recording, if required (and if optional printer available).

5. Accept or discard the recording.

→ Accept: The recording is being stored. Icon in the status bar at

the top:

→ Discard: The recording is not stored.



Within the first 10 seconds, the recording can be cancelled:

Tap **Cancel**.

→ The preview is displayed again.



If an automatic resting ECG recording is started despite a high-resistance electrode, lead off, incorrect electrode placement or high signal causing ECG amplifier saturation or overload, the following message is displayed (see section 4.7, p. 41):

Poor signal quality or lead off detected



How do you want to proceed?

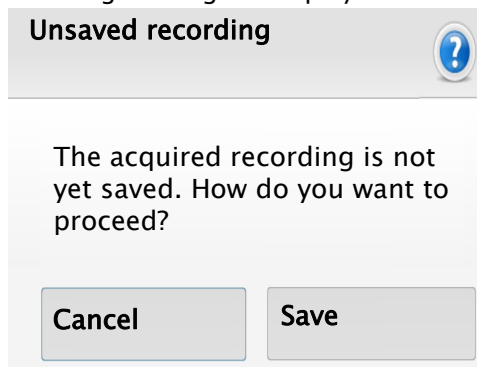
Cancel recording

Record anyway

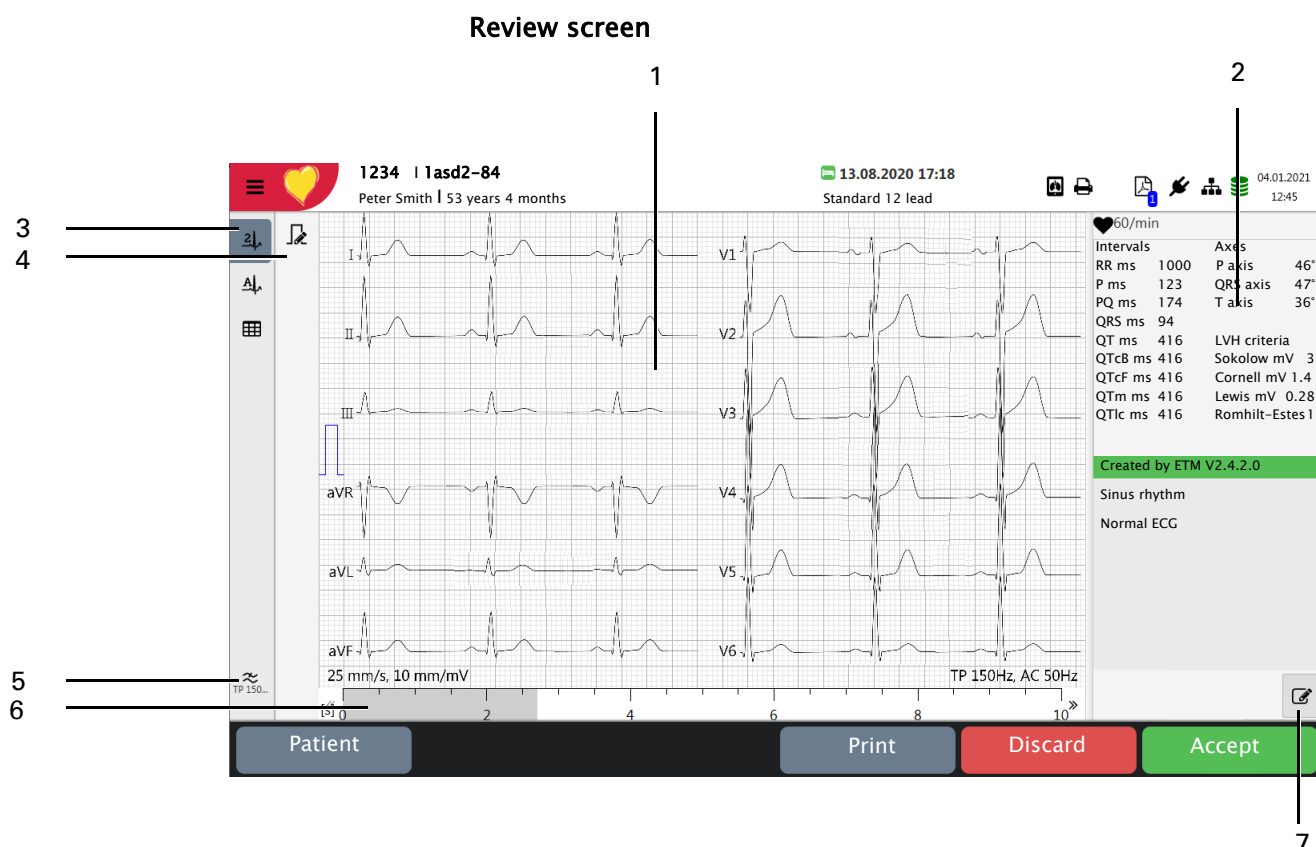
→ Cancel recording: Return to the Preview screen



If the recording screen is exited without accepting or discarding the recording, the following message is displayed:



→ Cancel: Return to the previous screen without saving.



- (1) ECG leads, depending on the selected view.
- (2) Additional data as well as interpretation.
- (3) Available views (configurable, [see section 11.11.1, p. 111](#)): tap the desired view to switch.
- (4) Change the amplitude and speed; change the rhythm lead (only in view **Averages**).
- (5) Change the filter ([see section 6.2.3, p. 53](#)).
- (6) Scroll through the recording: Move the grey bar to the right/left, or use one finger to swipe right/left.
- (7) Enter or edit the interpretation ([see section 6.7.2, p. 66](#)).



The colours and line widths are defined in the settings ([see section 11.10.4, p. 110](#)).

Abbreviation on the Review screen

Abbrev.	Description
60/min	Heart Rate is measured in the range of 15 to 300 beats per minute. The average heart rate (HR) is calculated based on the entire 10-second recording and shown as number of beats per minute.
RR	Intervals [ms] RR interval: The average time interval between two consecutive QRS complexes.

Abbrev.	Description
P	P wave duration: The time between the beginning of the first detected P wave from all 12 averaged leads and the end of the last detected P wave from all 12 averaged leads.
PR	PR interval: The time between the beginning of the first detected P wave taken from all 12 averaged leads and the beginning of the first QRS complex activity taken from all 12 averaged leads.
QRS	QRS complex duration: The time between the beginning of the QRS complex activity from all 12 averaged QRS complexes and the end of the last QRS complex activity from all 12 averaged QRS complexes.
QT	QT interval: The time between the beginning of the first QRS complex (beginning of ventricular depolarisation) taken from all 12 averaged leads and the end of the last T wave (end of repolarisation phase) taken from all 12 averaged leads.
QTcB	QT corrected (Bazett): As the QT interval is dependent on the heart rate, it is often converted to the normalised QTC interval, i.e. the QT interval that the patient would show at a heart rate of 60 bpm. Usually, the QTC value is 415 ± 40 ms.
QTcF	QT corrected (Fridericia): This is an alternative normalisation.
QTM	QT corrected (Hodges): This is an alternative normalisation.
QTlc	QT corrected (Framingham): This is an alternative normalisation.
Lead measurements	
P+	Amplitude of P wave (positive part)
P-	Amplitude of P wave (negative part)
Q	Amplitude of Q wave
Qd	Duration of Q wave
R	Amplitude of R wave
Rd	Duration of R wave
S	Amplitude of S wave
Sd	Duration of S wave
R'	Amplitude of R' wave
R'd	Duration of R' wave
S'	Amplitude of S' wave
S'd	Duration of S' wave
J	Amplitude of J point
ST	ST integral: averaged amplitude of the ST segment (from J point to half the distance between J point and max. T wave)
T+	Amplitude of T wave (positive part)
T-	Amplitude of T wave (negative part)
Electrical Axis	
P axis	Direction of the atrial depolarisation in the frontal plane based on P+ and P- waves of leads I and aVF.
QRS axis	Direction of the ventricular depolarisation in the frontal plane based on Q, R, S, R' and S' waves of leads I and aVF
T axis	Direction of the ventricular repolarisation in the frontal plane based on T+ and T- waves of leads I and aVF.

Abbrev.	Description
	Left Ventricular Hypertrophy Criteria definition, determined by the following systems:
LVH Criteria	• Sokolow–Lyon [mV] • Cornell [mV] • Lewis [mV] • Romhilt–Estes [Score points]

6.3.2 ETM Sport recording

ETM Sport compares ECG measurements with the normal and abnormal values indicated by the Seattle Criteria, thus supporting the physician in the diagnosis of abnormalities in athletes.

ETM Sport needs to be activated before an automatic resting ECG is started. If activated, the Seattle Criteria are displayed in the Review screen (see following) (International consensus standards for ECG interpretation in athletes, Drezner JA. et al., Br. J Sports Med 2017; 11:1-28. doi:10.1136/bjsports-2016-097333).



ETM Sport is only available for resting ECG recordings. If ETM Sport is activated, the **Standard 12-lead** configuration is automatically set and no other configuration can be selected.

Starting and checking the recording

Condition: Interpretation option is licensed (see section 11.3.6, p. 102)



1. Activate ETM Sport before the start of the recording in the Preview (see section 6.2, p. 51)
2. Tap **Auto**.
 - The 10-second recording is started, analysed and then displayed. The remaining duration is indicated at the top: **0:03**
3. Check the recording (see following).
4. Enter or complement the patient data, if necessary (see section 6.1, p. 50).
5. Print the recording, if required (and if optional printer available).
6. Accept or discard the recording.
 - Accept: The recording is being stored. Icon in the status bar at the top:
 - Discard: The recording is not stored.



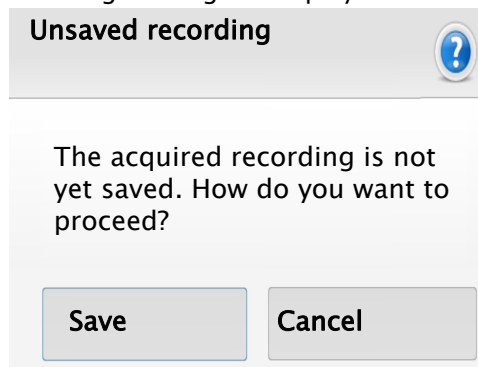
Within the first 10 seconds, the recording can be cancelled:

Tap **Cancel**.

- The preview is displayed again.



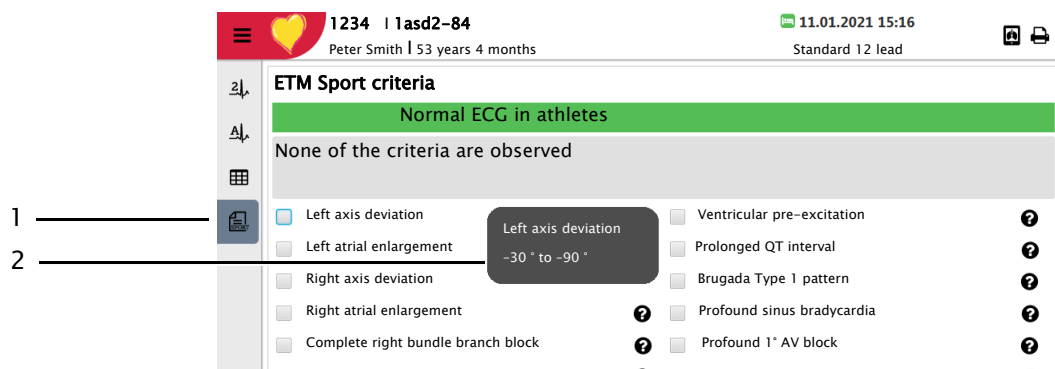
If the recording screen is exited without accepting or discarding the recording, the following message is displayed:



→ Cancel: Return to the previous screen without saving.

Review screen

In addition to the resting ECG information (see section , p. 56), the Seattle Criteria can be displayed:



(1) Display of the Seattle criteria

(2) Display of the description by tapping the question mark symbol.

6.4 Rhythm ECG recording

The duration of a rhythm ECG recording can be selected and is between 30 seconds and 20 minutes.



Depending on the settings, once the recording is accepted, it is automatically transmitted, saved as PDF or printed (see section 11.3.4, p. 101). Deleting the recording after transmission/PDF export is also possible (see section 11.3.4, p. 101).

The printout format may differ from the displayed ECG. The information on the printout can be configured (see section 11.10.7, p. 111).

The recording is stored in the memory (see section 7, p. 69), unless the setting **Delete after export** is activated (see section 11.9, p. 109).

6.4.1 Starting and checking the recording

1. Tap **Rhythm**.
 - Select the recording duration (if configured: see section 11.12.1, p. 112).
 - Otherwise, the default duration is used (see section 11.12.1, p. 112).
2. Tap **Start**.
 - The recording is started, analysed and then displayed. The remaining duration is indicated at the top: **1:45** .
3. Enter events, if required (see section 6.4.2, p. 63): .
4. Check the recording (see following).
5. Enter or complement the patient data, if necessary (see section 6.1, p. 50).
6. Print the recording, if required (and if optional printer available).
7. Accept or discard the recording.
 - Accept: The recording is being stored. Icon in the status bar at the top. .
 - Discard: The recording is not stored.



Within the first 10 seconds, the recording can be cancelled:

Tap **Cancel**.

→ The preview is displayed again.

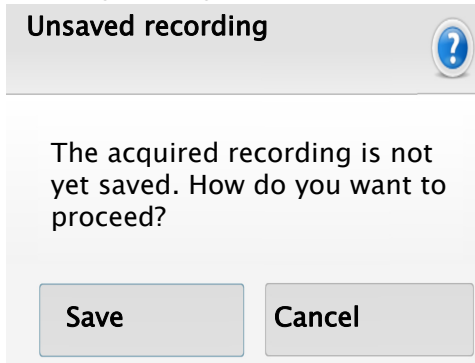
After 10 seconds, the button **Cancel** changes to **Stop**:

Tap **Stop** to stop the recording early.

→ The recording can be reviewed and accepted/discarded.

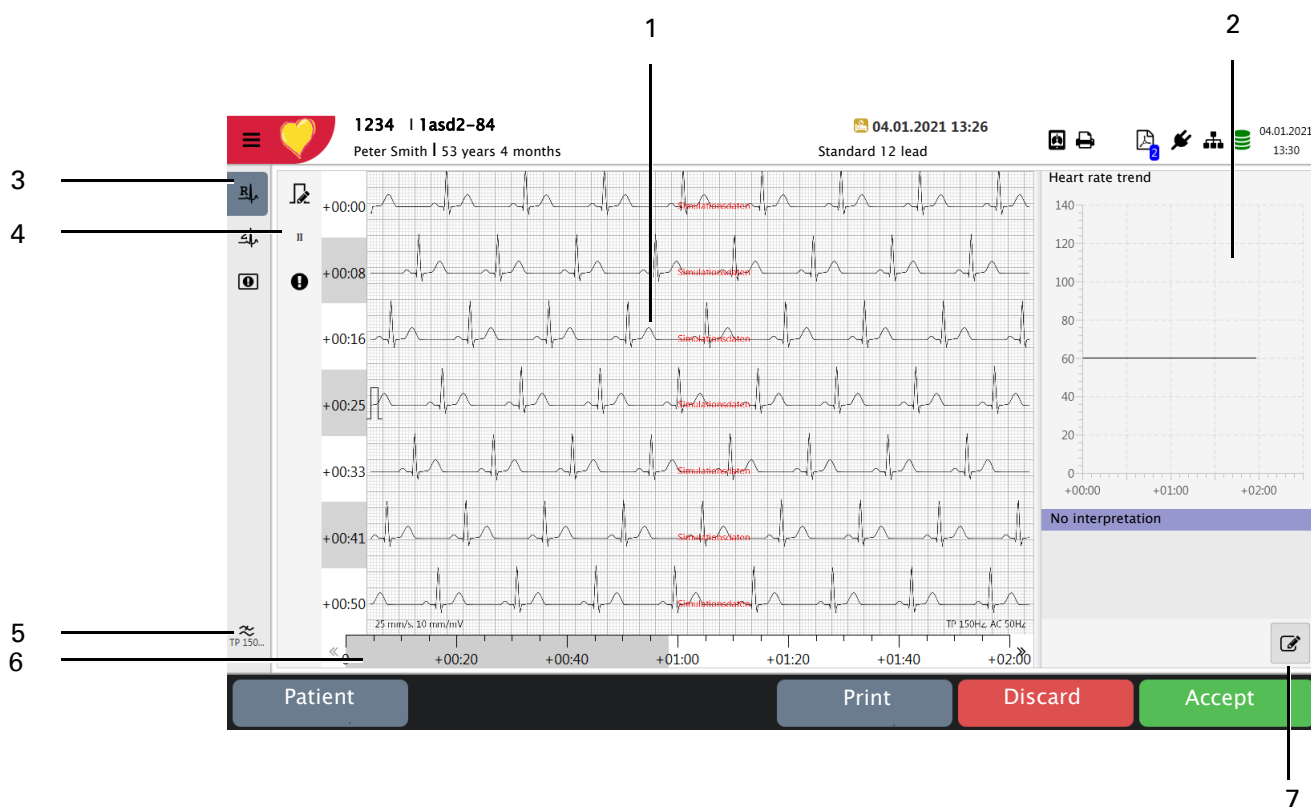


If the recording screen is exited without accepting or discarding the recording, the following message is displayed:



→ Cancel: Return to the previous screen without saving.

Review screen



- (1) ECG leads, depending on the selected view.
- (2) Heart rate trend and interpretation statements.
- (3) Available views (configurable, [see section 11.12.3, p. 112](#)): tap the desired view to switch.
- (4) Actions:
 - Changing lead amplitude and speed.
 - Changing rhythm lead (only in view **Continuous**).
 - Adding an event (see following).
- (5) Filter settings ([see section 6.2.3, p. 53](#))

- (6) Scroll through the recording: Move the grey bar to the right/left, or use one finger to swipe right/left.
- (7) Enter the interpretation ([see section 6.7.2, p. 66](#)).

6.4.2 Events

During the recording and review, events can be entered manually. Events can for example be symptom such as dizziness or palpitations.

Event descriptions can be pre-defined in the settings and then selected ([see section 11.12.2, p. 112](#)). Alternatively, the event description can be entered manually.



Events are indicated in the recording by an exclamation mark.

Adding events

During the recording



1. When an event occurs, tap the **Event** icon in the taskbar on the left:
→ The dialogue **Add event** is displayed.
2. Select the event description with the arrow on the right, or enter a description.
3. Tap **OK**.
→ The event is stored.

During review



1. Tap the Event icon (below the amplitude icon).
2. Select the time of occurrence: tap the desired position.
3. The dialogue **Add event** is displayed.
4. Enter or select an event description.
5. Tap **OK**.
→ The event is stored.

6.5 Manual ECG printout



Printer (optional)



This feature is only available with a thermal printer (optional, [see section 10.2, p. 91](#)). The device detects a connected thermal printer automatically and activates the manual printout.

With the manual printout, a real-time ECG is printed. The settings can be defined during the printout.



Manual ECG printouts are not stored on the device and cannot be transmitted, either.

The selected settings only apply to the printout, but not to the displayed leads.

Printouts are only possible if the battery capacity is higher than 20 %.

6.5.1 Starting the printout

1. Tap **Manual**.
 - The printout starts with the default settings ([see section 11.10.7, p. 111](#)).
2. Change the printout settings, if required:
 - Speed
 - Amplitude
 - Lead group (see following)
3. Enter or complement the patient data, if necessary ([see section 6.1, p. 50](#)).
4. Tap **Stop** to stop the printout.
 - The preview is displayed again.

6.5.2 Lead group

For both lead sequences (Standard and Cabrera, [see section 4.4, p. 39](#)), three lead groups each are available. Use the button **<Lead group>** (e. g. **V1 – V6**) to toggle between the lead groups. The leads for each lead group depend on the lead configuration ([see section 4.5, p. 39](#)). Example for lead configuration **Standard 12-lead**:

Lead group 1	Lead group 2	Lead group 3
All leads (I – V6)	All limb leads (I – aVF)	All precordial leads (V1 – V6)



The settings for speed, amplitude and lead configuration only apply to the printout. The display remains the same.

6.6 Possibilities after accepting a recording



This section only applies to resting ECGs and rhythm ECGs. Manual printouts are not stored and they cannot be transmitted nor deleted.

Use the settings to define the procedures once a recording is accepted/stored ([see section 11.3.4, p. 101](#)).

6.6.1 Transmitting

Recording can be transmitted automatically or manually, via Ethernet or WLAN, as follows:

- to an EMR system
 - SCHILLER Link
 - SCHILLER Gateway
 - SCHILLER Server

Alternatively:

- as PDF to a USB stick

For further information: [see section 9, p. 81](#)

6.6.2 Printing



Printer (optional)



This feature is only available with a printer (optional, [see section 10.2, p. 91](#)).

Printouts are only possible if the battery capacity is higher than 20 %.

Recordings can be printed automatically or manually. The settings are defined in the menu ([see section 11.10.7, p. 111](#)).

6.6.3 Deleting

Recordings can automatically be deleted from the memory once they have been transmitted ([see section 11.3.4, p. 101](#)). After deletion, the recording is no longer available in the memory; the recording can neither be displayed nor printed or transmitted.

6.7 Interpretation (optional)



- ▲ Incorrect interpretation due to incorrect patient data:
 - Check the patient data before accepting the recording.
 - If date of birth, gender or digitalis information has changed: a new interpretation is created.



Automatic interpretation by the program is only available for automatic ECG recordings and only if the lead configuration **Standard 12 lead** is selected (see section 4.5, p. 39).

For ETM Sport recordings, the lead configuration **Standard 12 lead** is automatically selected (see section 6.3.2, p. 59).



For detailed information on the interpretation algorithm, see the Interpretation manual (art. no.: 2.511035).

The interpretation can be displayed:

- during review and before accepting a recording
- when a recording is opened from the memory



Display and printout of the interpretation depend on the setting: Menu > **Settings > ECG > Interpretation** (see section 11.10.6, p. 110).

6.7.1 Interpretation Categories

Three categories of interpretation are indicated by colour:



Green: normal ECG



Yellow: borderline ECG finding



Red: abnormal ECG

6.7.2 Entering or editing the interpretation

The interpretation can be entered or edited before accepting a recording:



1. Tap icon **Edit interpretation**.
2. Edit the text (delete, move, add).



If the interpretation was automatically generated by the program and not edited by the user, the software version is indicated (e. g. **ETM V2.0**). If the interpretation was edited, the user is indicated. Example: **Created by Dr Smith**. This applies only when the **Security access Control** is set to **Local or Schiller server** (password and user name required).

6.7.3 Re-interpretation

If the date of birth, gender or digitalis information is modified before the recording is accepted, a re-interpretation is automatically generated.



The recording can only be accepted once the re-interpretation has been generated.

6.7.4 ETM Sport

For ETM Sport recordings, one of the following messages is added to the interpretation:

- **Normal ECG in athletes** (green marking): none of the criteria is met
- **Borderline ECG in athletes** (yellow marking): No further evaluation required in asymptomatic athletes with no family history of inherited cardiac disease or SCD.
- **Abnormal ECG in athletes** (red marking): These ECG findings are unrelated to regular training or expected physiological adaptation to exercise. These findings may suggest the presence of pathological cardiovascular disease, and require further diagnostic evaluation.

The Seattle Criteria are displayed and can be printed or transmitted, depending on the settings ([see section 6.3.2, p. 59](#) and [see section 11.10.6, p. 110](#)).

7 Memory

Automatic resting ECGs, rhythm ECGs and spirometry recordings are stored locally and can be transmitted to a patient database. Stored recordings can be viewed, printed, transmitted or deleted at any time.

Approx. 350 resting ECGs, 100 rhythm ECGs and 10 spirometry recordings can be stored on the CARDIOVIT FT-2. Recordings are stored by tapping **Accept** or **Stop**.



If the setting **Delete after export** is active, recordings are deleted from the memory after transmission and/or PDF export (see [section 11.9, p. 109](#)). Deleted recordings cannot be viewed, printed or transmitted.

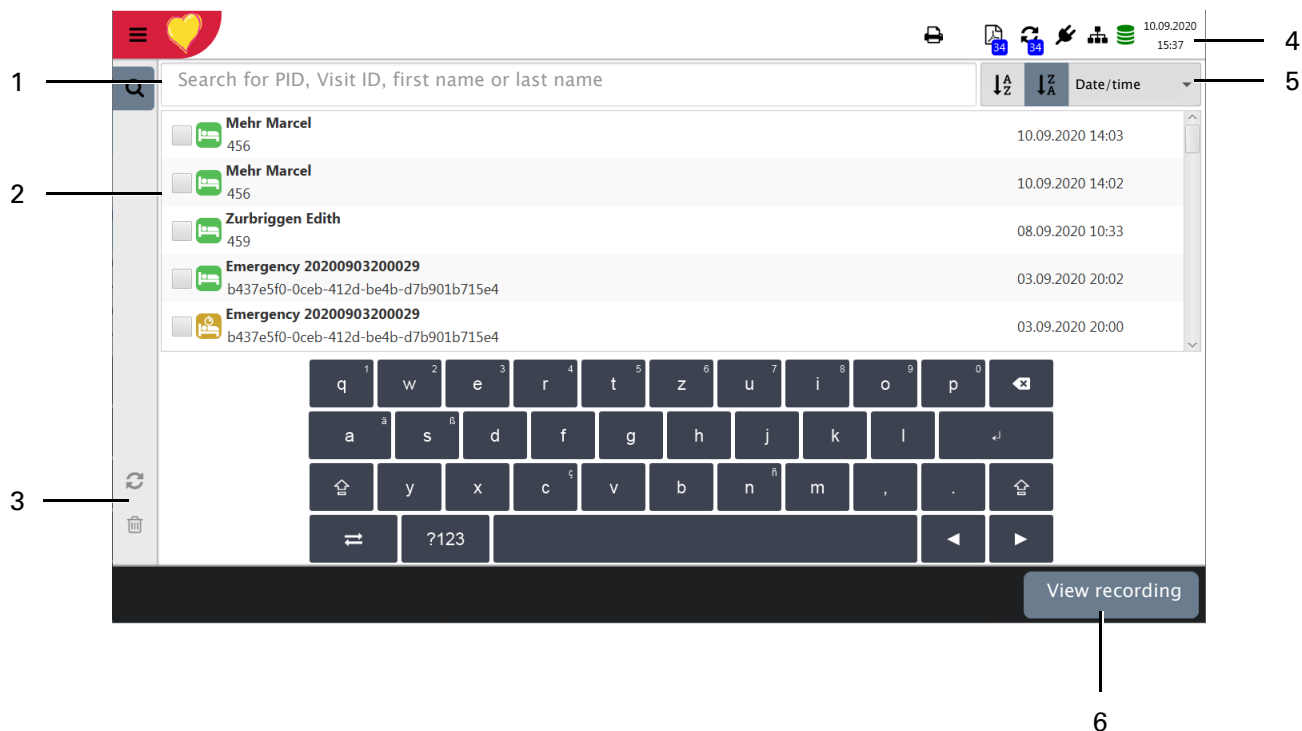
Memory capacity is indicated by the following symbols:



- Green symbol: memory capacity available
- Yellow symbol: memory almost full
- Red symbol: memory full, no more recordings possible. Recordings first need to be deleted from the memory (see following).

7.1 Overview

The memory is accessed from the main menu: Menu > **Memory**.
The following is displayed:



- (1) Search field:
Search for patients by means of patient ID, visit ID, first or last name. Enter the search term via keyboard or barcode scanner.
- (2) Search result, or all recordings (if no search term has been entered):



- Automatic resting ECG recordings
- Rhythm ECG recordings
- Spirometry recordings
- Selected recordings

- (3) Actions:



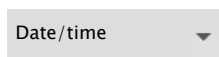
- Transmit selected recording(s) (see section 7.5, p. 73)
- Delete selected recording(s) (see section 7.6, p. 74)

(4) Status bar:



- Transmission status: number of recordings that have not yet been transmitted (see section 7.5, p. 73)
- Status PDF export: number of recordings in the queue (see section 7.5, p. 73).
- Printout status: Print jobs are queuing, are being printed or could not be printed (see section 7.4, p. 72)

(5) Sort recordings:



- Ascending/descending
- Sort by patient ID, visit ID, last name, date/time or synchronisation status (see section 9.6, p. 84)

(6) The selected recording is opened and can then be printed, if requested (if printer available (option)), and/or sent to a USB stick as PDF



Stored recordings can be displayed and printed in another format at any time (see section 7.4, p. 72)

7.2 Viewing recordings

Double-tap the recording

or

Select by tapping once, then tap **View recording** (see (6) in the previous illustration).

7.3 Displayed data

Recordings are displayed in the defined format (Menu > **Settings** > **Resting ECG/Rhythm ECG** > **Review**). The same settings are available as for the review screen before accepting a recording (see sections 6.3.1 and 6.4.1), with the following exceptions:

- Additional patient data view
- Interpretation cannot be edited anymore

7.4 Printing recordings



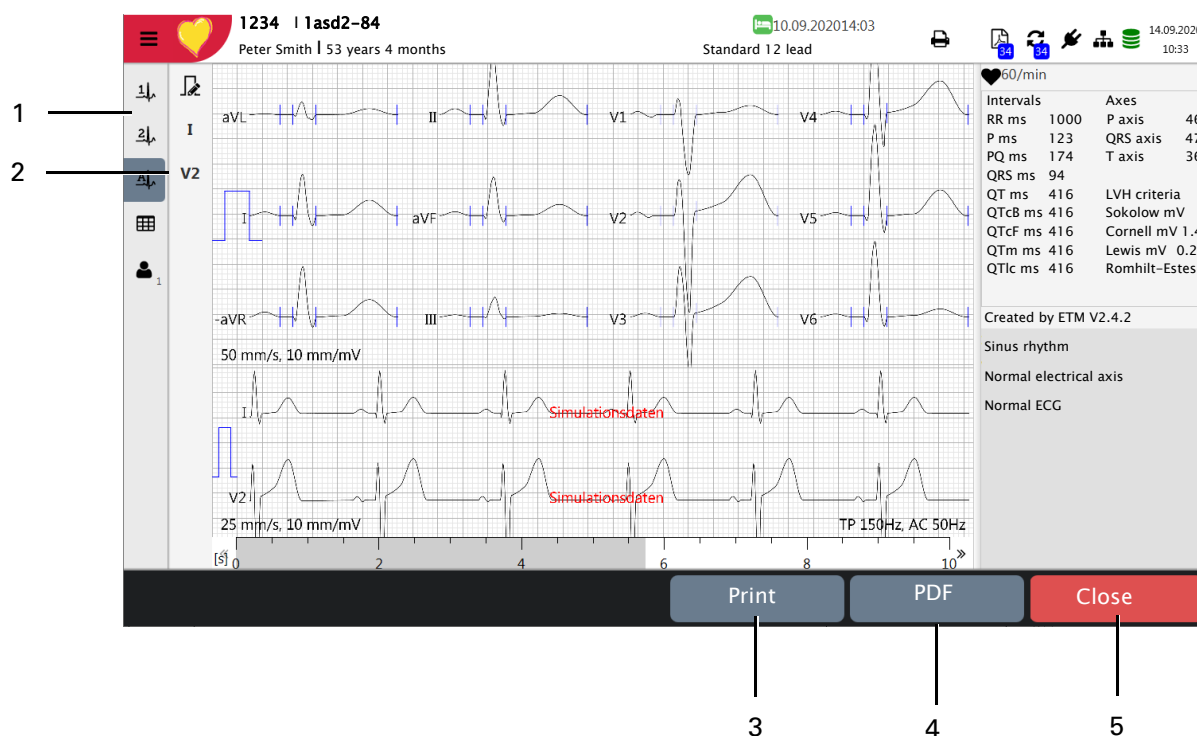
Printer (optional)



This feature is only available with a printer (optional thermal printer, [see section 10.2, p. 91](#), or external network printer, [see section 10.3, p. 95](#)).

Printouts are only possible if the battery capacity is higher than 20 %.

Opened recordings can be printed with the button **Print**. The print



format can be changed:

- (1) Selection of the view format (available views: [see section 11.11.1, p. 111](#))
- (2) Depending on the view: selection of additional settings for the display:
 - Amplitude
 - Speed
 - Rhythm lead 1
 - Rhythm lead 2
- (3) Printing the recording
- (4) Exiting the recording



The print job queue as well as ongoing and failed print jobs are indicated in the status bar with the **Printer** icon. To print a failed print job once again:

1. Tap the **Printer** symbol.
→ All failed print jobs are listed.
2. Tap **Retry**.
(see section 10.2.4, p. 94)
 - If no printout is possible:
 - Check that there is paper in the paper tray.
 - Ensure that the paper is inserted correctly, see section 10.2.3, p. 93.

7.5 Transmitting recordings

Stored recordings can be transmitted (again), unless they have been deleted with the setting **Delete after export** (see section 11.3.4, p. 101).

7.5.1 As PDF to a USB stick

1. Select recording(s)
2. Tap **View recording**
3. Tap **Export PDF** or transmit at once if the USB stick is already connected



Recordings in the queue are indicated in the status bar with the icon shown on the left.

7.5.2 To an EMR system

1. Select recording(s):
2. Tap **Upload recording(s)**



Recordings in the queue are indicated in the status bar with the icon shown on the left.

In the list, the transmission status is indicated as follows:



Transmission successful.



Error while transmitting.



The transmission settings are defined in the Menu > **Settings** > **Connectivity** (see section 11.6, p. 105).

If no transmission is possible: see section 12.5, p. 118.

7.6 Deleting recordings



Recordings can be automatically deleted after transmission ([see section 11.3.4, p. 101](#)). Deleted recordings cannot be viewed, printed or transmitted.

1. Select recording(s).
2. Tap **Delete recording(s)**.



Moreover, stored recordings can be automatically deleted from the memory after a defined number of days. This is activated in the settings: Menu > **Settings** > **General** > **Memory** > **Cleanup local recordings** ([see section 11.3.5, p. 102](#)).



If **Cleanup local recordings** is active, recordings are even deleted after the defined number of days if these recordings have not been transmitted to an EMR system or to a USB stick.

8 Worklist (optional)

In a worklist, physicians define recordings that need to be performed. The worklist contains information on the patient, the room/department and the recording type. The worklist is defined directly from the Hospital Information System (HIS). Once the recording has been made by the CARDIOVIT FT-2, it is sent back to the HIS for analysis, evaluation and storage.

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



- The worklist licence needs to be activated ([see section 11.3.6, p. 102](#)) and data transfer with the SCHILLER Server or with SCHILLER Gateway needs to be defined in the system settings ([see section 11.6.1, p. 105](#)).
- Definition of the worklist on the SCHILLER Server is described in the SCHILLER Server's user guide (art. no. 2.540070).
- Definition of the worklist using SCHILLER Gateway is described in the SCHILLER Gateway's user guide (art. no. 2.540115).



From the SCHILLER Server, a worklist can be sent to a specific device or to all devices on the system. The SCHILLER Server sends out work items based on the device ID. Therefore, the CARDIOVIT FT-2 only receives work items for the specific device, or work times intended for all devices.

The device ID is usually defined when the device is first set up. The device ID is indicated in **Menu > Settings > General > Station**.

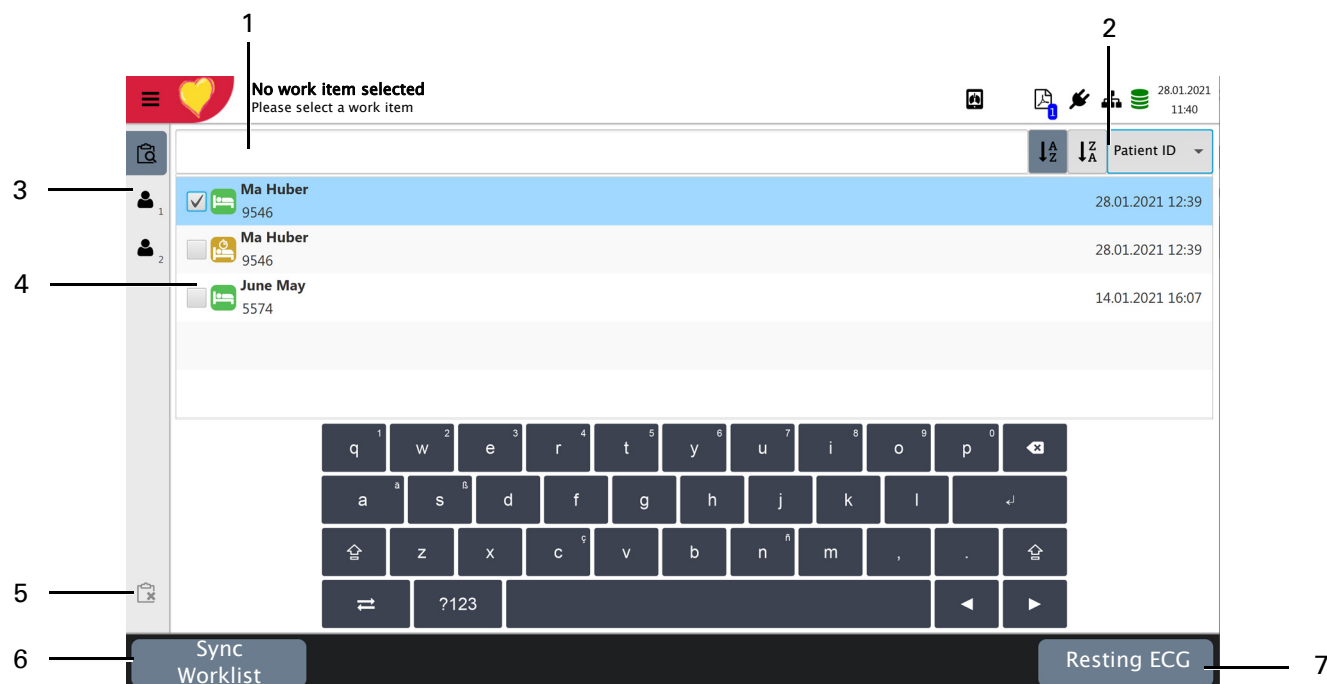
To display the worklist when the device is switched on (instead of the patient data):

1. Open **Menu > Settings > General > Workflow**
2. For **Default workflow**, select **Worklist**



Alternatively, the worklist can be opened from the main menu: **Main menu > Worklist**.

8.1 Display

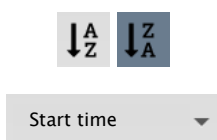


(1) Search field. Possible search terms:

- Patient ID
- Visit ID
- Order ID
- First/last name
- Location
- No search term entered: all work items are displayed

(2) Sort results:

- Ascending/descending
- By start time, patient ID, visit ID, order ID, last name or priority



(3) Available views:

- Search view (see example above)
- Patient data 1 + 2



The displayed patient data is defined in the settings (see [section 11.7.1, p. 106](#))

(4) Search result, or all work items (if no search term has been entered):

- Automatic resting ECG recordings





- Rhythm ECG recordings



- Spirometry Recordings



- Selected recordings

Work items are colour-coded in the worklist as follows:

- Not yet performed: white background
- Selected: grey background
- Completed: green background
- Cancelled: red background



During the next synchronisation, completed and cancelled work items are deleted from the worklist.

The displayed work item information depends on the settings (see [section 11.7.4, p. 107](#)).

(5) Deleting work items. This feature is only available if activated in the settings (**Menu > Settings > General > Workflow > Allow to cancel work order**)

(6) Retrieve worklist from the HIS (see also [see section 8.2, p. 77](#))

(7) Next step. This depends on the settings (see also section 8.3 below):

- If the worklist mode **Record from worklist** is selected, the recording environment is opened
- If the worklist mode **Record from work order details** is selected, the patient data screen is first displayed to review/edit the patient data ([see section 11.3.4, p. 101](#))

8.2 Receiving a worklist

There are two possibilities:

- Auto synchronisation with HIS: activate the setting **Auto sync. worklist** ([see section 11.3.4, p. 101](#))
- Manual synchronisation in the worklist screen: see (6) above

8.3 Performing a worklist item



Setting in [Menu > Settings > General > Workflow > Default workflow](#)

8.3.1 From the worklist



Patient data provided by the HIS cannot be edited. Exception: height and weight

1. Prepare the patient
2. Search and highlight the work item in the worklist (see above)
3. Review/edit the patient data, if necessary  1
4. Start the recording by tapping Resting or Spirometry. If no recording type has been defined in the HIS, both recording types are available
 - The recording screen is opened
 - ECG: [see section 6.2, p. 51](#)
 - Spirometry: see separate spirometry supplement

8.3.2 From the work item (details)



Patient data provided by the HIS cannot be edited. Exception: height and weight

1. Prepare the patient
2. Search and highlight the work item in the worklist (see above)
3. Review/edit the patient data by tapping [Details](#)
4. Start the recording by tapping Resting or Spirometry. If no recording type has been defined in the HIS, both recording types are available
 - The recording screen is opened
 - ECG: [see section 6.2, p. 51](#)
 - Spirometry: see separate spirometry supplement

8.4 Transmitting recordings to the HIS

Finished work items are automatically transmitted to the HIS after saving if defined in the settings (setting **Transmit after saving** and/or **Auto sync. worklist**, see section 11.3.4, p. 101). Automatic synchronisation takes place once per minute.

If a work item has been transmitted, it is no longer shown in the worklist once it has been synchronised. The synchronisation duration depends on the number of pending recordings.

8.5 Cancelling a work item

This feature is only available if activated in the settings: **Allow to cancel work order** (see section 11.3.4, p. 101 and see section 8.1, p. 76, (5) above).

9 Transmission

WARNING

- ▲ Connecting CARDIOVIT FT-2 to an IT network could result in previously unidentified risks to patients, operators or third parties.
- ▲ Danger to the patient due to disruption of data transmission or due to incorrectly transmitted data:
 - If the device 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.
 - Network safety is the sole responsibility of the operator.
- ▲ Danger to the patient due to equalising currents if non medical products are connected to the CARDIOVIT FT-2:
 - Connect both devices to the potential equalisation.
 - Additional safety notes: [see section 1.8, p. 13.](#)
- ▲ Data loss due to misuse:
 - Have default passwords changed by the responsible person.
- ▲ In order to guarantee the security of the network:
 - Isolate the CARDIOVIT FT-2 network from other networks
 - Define access authorisation for the configuration of the server, incl. the CARDIOVIT FT-2, so that no unauthorised alterations are possible
 - Reduce data transfer between the network and another system/network to a minimum
 - Operate the server with the latest anti virus/firewall programs to avoid impairment due to malware
 - Regularly install safety updates and software updates on the server



For settings: [see section 11.6, p. 105.](#)

See also section 7.5.

9.1 LAN

Data transmission via local LAN network (Ethernet) to the EMR system.

Connect the cable assembly to the RJ45 socket (see section 2.2, p. 22).

The network symbol in the status bar indicates the connectivity status:



Connection to the network established and EMR system accessible



Connection to the network established but EMR system not accessible



Connection to the network interrupted

- If no transmission is possible:
 - Check that the network cable is correctly connected
 - Check the settings and edit, if necessary (see section 11.6.2, p. 105)

9.2 WLAN



- ▲ Interference with pacemakers and other devices when data is transmitted via WLAN:
- ▲ During transmission, keep a distance of at least 20 cm between the patient and other devices.

The WLAN symbol in the status bar indicates the connectivity status:



Connected to the WLAN network and the EMR system



Connected to the network but no connection to the EMR system.
Signal strength is displayed with the number of bars.

- If no transmission is possible:
 - Check the settings and edit, if necessary (see section 11.6.3, p. 106)

9.3 PDF export

CAUTION

- ▲ Danger of data misuse. When exporting patient data to a USB stick, the operator needs to take appropriate security measures to protect the data:
 - Make sure that only authorised persons have access to the USB stick.
 - After transmission, delete the data from the USB stick.
 - Deactivate the PDF export function if it is not used.

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The USB stick needs to be formatted using the FAT32 file system. No other file systems are supported.

PDF reports can be transmitted to a USB stick once the recording is completed:

Connect USB stick to the device ([see section 2.2, p. 22](#)).

→ PDF report(s) are transmitted to the USB stick.

i

If the setting **Delete after export** is activated, recordings are deleted from the memory after PDF export ([see section 11.9, p. 109](#)). These recordings cannot be transmitted again.

The information contained in the PDF reports as well as PDF settings are defined in the settings:

- [see section 11.8, p. 107](#)
- Resting ECG: [see section 11.11.2, p. 111](#)
- Rhythm ECG: [see section 11.12.4, p. 112](#)
- Spirometry: see separate spirometry supplement
- If no export is possible:
 - Check that a USB stick is connected.
 - Make sure that the USB stick has free storage capacity; otherwise, delete some data.
 - Check that the USB stick is correctly formatted; otherwise, re-format.

9.4 Automatic transmission

Recordings can be transmitted automatically as follows:

1. Open Menu > **Settings > General > Workflow**.
2. Tap the desired options:
 - Transmit after saving
 - PDF to USB after save

9.5 Manual transmission

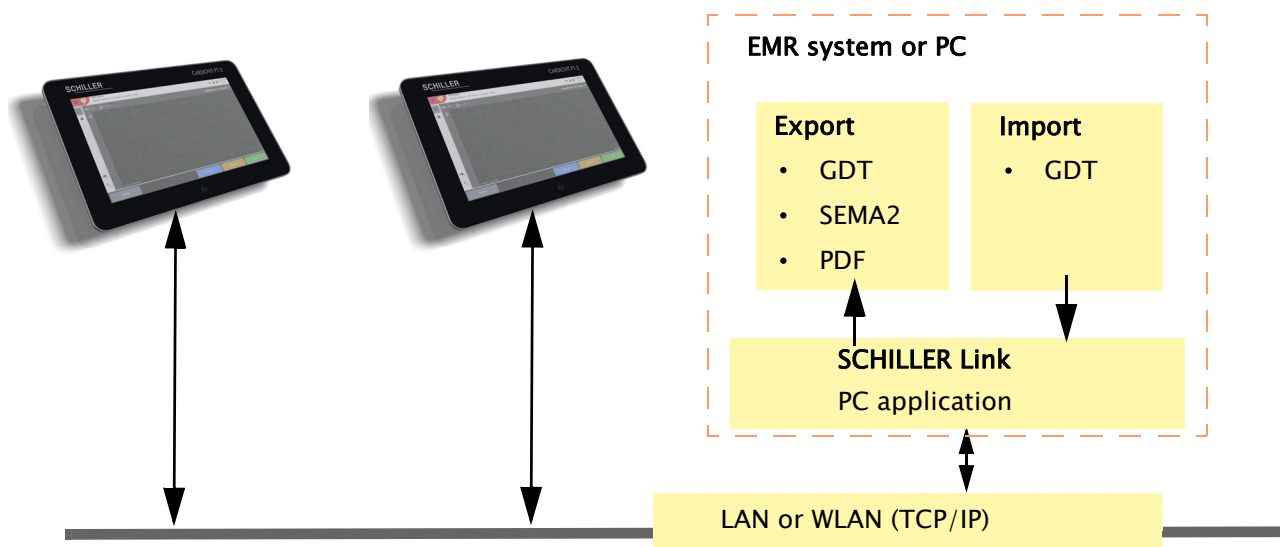
Stored recordings can be manually transmitted as described in [section 7.5](#).

9.6 Communication media

9.6.1 SCHILLER Link

SCHILLER Link is a PC application which enables communication between the EMR system and the CARDIOVIT FT-2. To do so, SCHILLER Link needs to be selected in Menu > **Connectivity** > **EMR integration** > **SCHILLER Link** (see section 11.6.1, p. 105).

Integration in the network is automatic, provided the CARDIOVIT FT-2 and SCHILLER Link are part of the same network:



Procedure with EMR system

1. Enter/select the patient in the EMR system.
2. Generate an order for this patient.
3. Load the GDT file into the SCHILLER Link's import folder.
4. Start the order in CARDIOVIT FT-2 and check the patient data.
5. Perform the recording with the CARDIOVIT FT-2.
6. Store the recording and transmit it automatically or manually to SCHILLER Link.
 - The EMR system imports the recording.
 - The recording can be analysed in the EMR system.



For additional information: consult the SCHILLER Link installation guide (Art. no. 2.540116) and the EMR system's user guide.

Procedure without EMR system

1. Enter the patient in the CARDIOVIT FT-2 (via keyboard or barcode scanner).
2. Perform the recording with the CARDIOVIT FT-2.
3. Store the recording and export as PDF (automatically or manually).
4. Check the PDF on the computer, print or forward as e-mail.



If needed, exported recordings can be exported again from the memory ([see section 7.5, p. 73](#)), provided that the setting **Delete after export** is not activated.

9.6.2 SCHILLER Gateway

SCHILLER Gateway is a PC application which enables communication between the EMR system and the CARDIOVIT FT-2. SCHILLER Gateway is intended for larger installations as well as for protocols used in a hospital environment (e. g. DICOM or HL7). SCHILLER Gateway does not have its own database and acts as an interface between the EMR system and the CARDIOVIT FT-2.



For details on the transmission: consult the user guide for SCHILLER Gateway (Art. no. 2.540115).

9.6.3 SCHILLER Server

Patient data can automatically be retrieved from a SCHILLER Server. This is called **PDQ** (Patient Data Query). To do this, the patient or visit ID is entered in the patient data screen manually or via barcode reader ([see section 5.2.2, p. 45](#)).

For patient data query to be possible:

- SCHILLER Server needs to be available via network.
- Server name, TCP/IP address etc. as well as all other transmission settings need to be defined in the system settings ([see section 11.6.1, p. 105](#)).



For details on the transmission: consult the SCHILLER Communication Handbook (Art. no. 2.540070).

10 Trolley and printer (optional)

10.1 Trolley

CAUTION

- ▲ Danger to the patient due to modifications of the electrical system:
 - Only use the recommended printers, i. e. thermal printer or external network printer (see following).
 - Do not place an external printer on the trolley.
- ▲ Deterioration of the ECG signal quality due to mechanical strain on the patient cable:
 - Lock the wheels when the trolley is stationary (see section 10.1.2, p. 89).
- ▲ Danger of injuries due to the trolley tipping over caused by abrupt stopping, uneven underground or excessive force:
 - Be cautious when moving the trolley, observe obstacles (e.g. power cables or door thresholds).
 - Unlock the wheels when moving the trolley.
 - Position the pump arm in transport position (see section 10.1.2, p. 89)
 - Use only the push handle to move the trolley.
 - Lock the wheels when the trolley is stationary (see section 10.1.2, p. 89).
 - Maximum load work basket/console: 5 kg
 - Maximum total load: 60 kg
 - Position the pump arm in transport position (see section 10.1.2, p. 89)



The trolley is installed by SCHILLER before delivery or on the spot. For more details, see the service manual (Art. no.: 2.540117).

10.1.1 Elements



Note: The picture may differ from the original product.

- (1) CARDIOVIT FT-2
- (2) Push handle
- (3) Work surface
- (4) Thermal printer (optional): [see section 10.2, p. 91](#)
- (5) Bracket for external power supply unit
- (6) Storage basket
- (7) Wheels

10.1.2 Locking the wheels

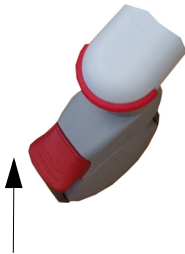
The wheels are equipped with spring-loaded braking mechanisms. This mechanism locks the wheels so that the trolley remains stationary:



Press the brake down with your foot.

→ The wheel is locked.

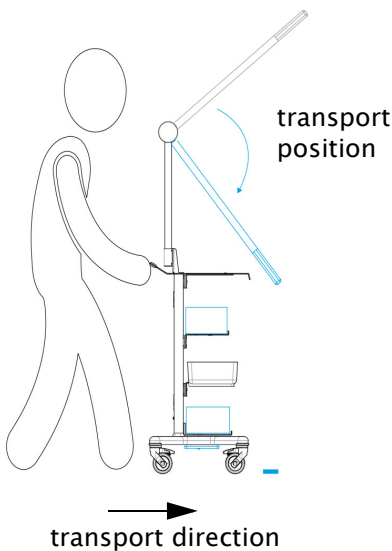
10.1.3 Unlocking the wheels



Press the brake upwards with your foot.

→ The wheel is unlocked.

10.1.4 Pump arm positioning for transport



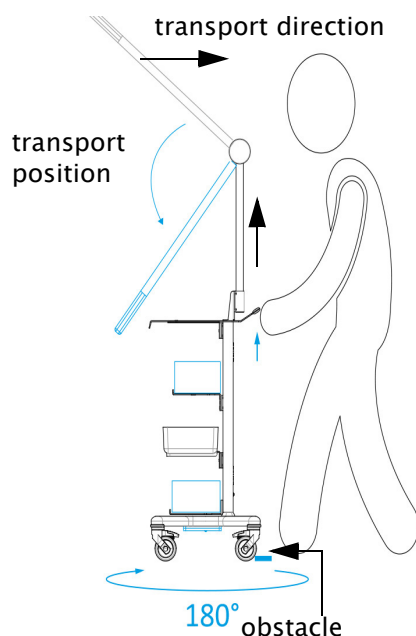
To preventing that the trolley with pump arm (optional) is tipping over:

- Move the pump arm down during transport to a another location
- Always use the push handle to move the trolley

10.1.5 Moving trolley over obstacles



▲ Danger of the trolley tipping over, if it is pushed over an obstacle.



To preventing that the trolley with pump arm (optional) is tipping over:

- Turn the trolley 180°, slightly lift the trolley upwards and pull the trolley over the obstacle.

10.2 Thermal printer

NOTICE

- Equipment damage:
 - Only connect or disconnect the thermal printer when the device is switched off ([see section 2.2, p. 22](#))

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The printer is only available together with the trolley.

The trolley and printer are installed by SCHILLER before delivery or on the spot.

i

The printer is delivered without thermal paper.

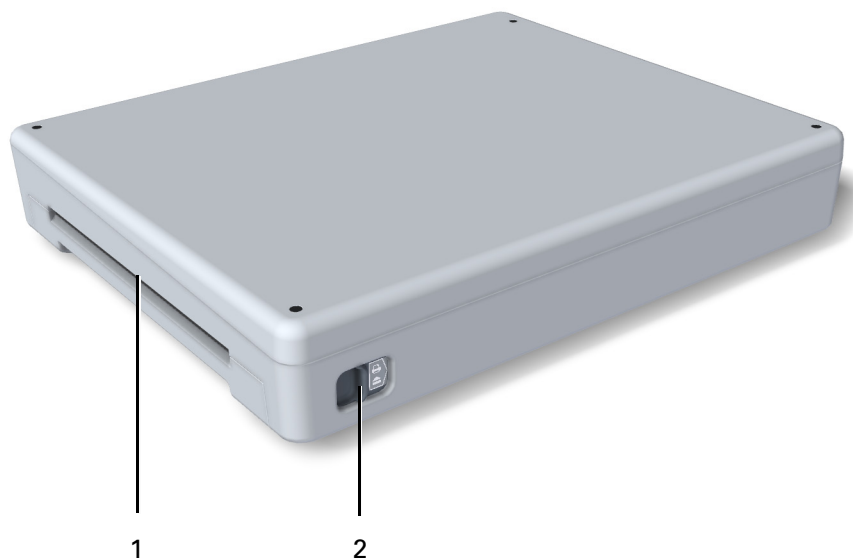
The thermal paper is sensitive to heat, humidity and chemical vapours. Flawless printing quality is only ensured if the thermal paper supplied by SCHILLER or paper of the same quality is used.

- 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.
- Before use, store the paper in its original cardboard cover.
- Store the paper in a cool, dark and dry location ([see section 10.2, p. 91](#)).
- 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 to a mounting sheet.



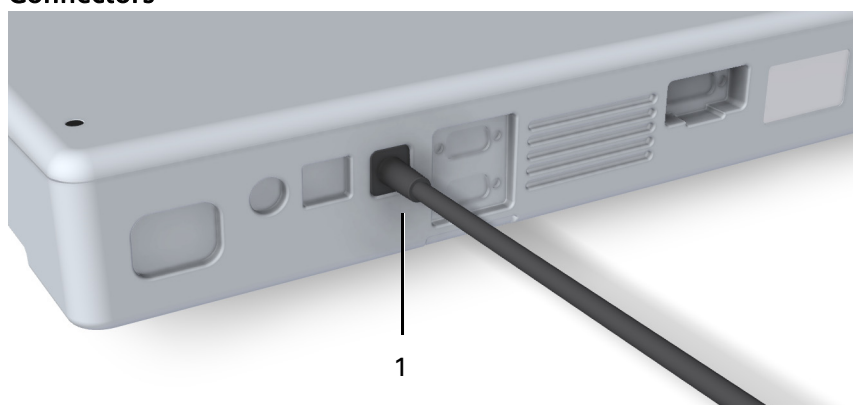
Printouts are only possible if the battery capacity is higher than 20 %.

10.2.1 Elements



- (1) Paper tray
- (2) Slide button to open paper tray

10.2.2 Connectors



- (1) Permanent connection to the CARDIOVIT FT-2 for power supply and data transfer.

Connection to the device: [see section 2.2, p. 22](#)

10.2.3 Inserting printing paper



Thermal paper: article number 2.157050

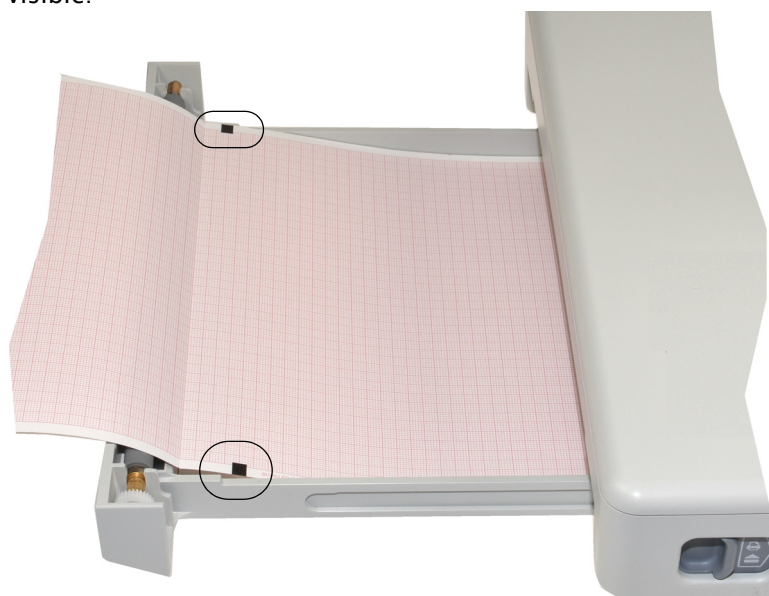
1. Press the slide button to the right



- The paper tray opens
2. If present, remove the remaining paper.



3. Insert the paper with the grid facing upwards and the black marks visible:



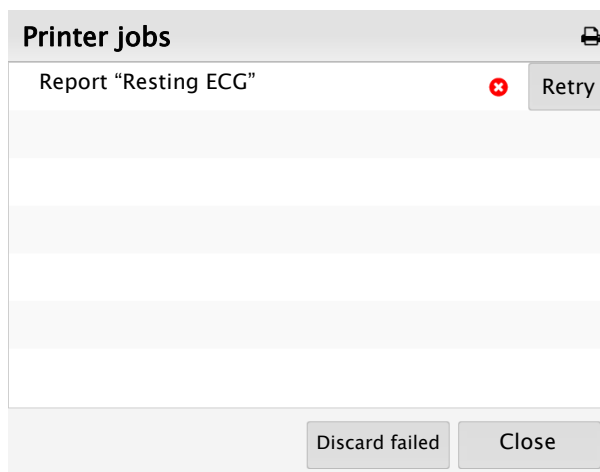
4. Pull out the top sheet.
 5. Push the paper tray shut until the locking catch clicks in place.
→ The printer is ready.
- If no printout is possible. [see section 12.5, p. 118](#)

10.2.4 Messages

In the status bar, messages on the printing status are displayed:

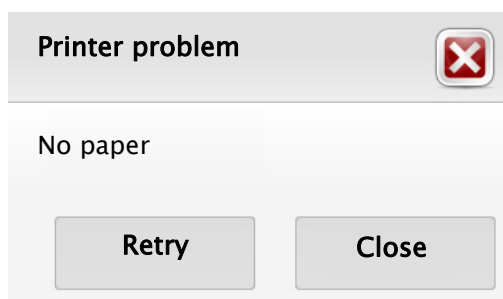


- Symbol is displayed: printout is ongoing, there are print jobs in the queue, or print jobs could not be printed
- Tap the symbol:



- Re-printing the print job: tap **Retry**
- Deleting failed print jobs: tap **Discard failed**

If no printout is possible, the message **Printer problem** is displayed and the reason is indicated:



10.2.5 Settings

Printer

Contrast and line width: [see section 11.9, p. 109](#)

Manual printouts

Lead group, speed, amplitude: [see section 11.10.7, p. 111](#). Manual printouts are automatically available when the device has detected a thermal printer.

Print after save

[see section 11.3.4, p. 101](#)

10.3 External printer

CAUTION

- ▲ Danger to the patient due to modifications of the electrical system:
 - Only use the recommended printers, i. e. thermal printer (see previous) or external (network) printer.
 - Do not place an external printer on the trolley.
 - Do not connect the external printer via USB.

As an alternative to the thermal printer ([see section 10.2, p. 91](#)), the CARDIOVIT FT-2 can be connected to a network printer. For network printers, the IP address is entered in the settings ([see section 11.9, p. 109](#)).

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The external printer needs to be enabled in the settings ([see section 11.9, p. 109](#)).

For more information on printer messages and settings: [see section 10.2, p. 91](#).

11 Settings



Default settings are shown **bold**.

11.1 Overview

Open the menu **Settings**:



1. Tap the symbol **Main menu**

2. Tap the symbol **Settings**

In the **Settings** menu, the following sub-menus are available:

Menu	Sub-menus
General	Info
	Station
	Power management
	Workflow
	Memory
	Licenses
	Update
Regional	Date & time
	Language
	Keyboard
	Units
	Patient ID system
Security	Access control
	Automatic logout
Connectivity	EMR integration
	Ethernet
	Wi-Fi
Data fields	Visible fields
	Mandatory fields
	Custom fields
	Worklist
Reports	General
	PDF
	Header
Printer	Thermal Printer
	External Printer

Menu	Sub-menus
ECG	Lead & cable
	Additional leads
	Filter
	Colours
	Preview
	Interpretation
	Manual printout
Resting ECG	Review
	Reports
Rhythm ECG	General
	Events
	Review
	Reports
Spirometry: see separate spirometry supplement	General
	Standards
	Scale
	Ethnic correction
	FVC measurements
	Reports

11.2 Managing settings

11.2.1 Storing settings

Changed settings are saved automatically. Exception: Ethernet and WLAN settings need to be saved by tapping **Apply**.

11.2.2 Import/export settings

Settings can be imported or exported. This feature is used if several devices within a practice/department need to have the same settings.



Passwords and users for access control mode **Local** are not exported or imported:

- Enter the passwords once the settings have been imported
- Re-define local users

Import settings



1. Tap symbol **Import/export settings**.

2. Select the USB stick containing the file that needs to be imported with the arrow icon.

3. Select the file to be imported: **Select settings file**.

4. Tap **Import settings**.

→ Existing settings are overwritten



- Inform all users that the previous settings may no longer be valid.
- Instruct all users to familiarise themselves with the new settings.

Export settings



1. Tap symbol **Import/export settings**.

2. Select the USB stick with the arrow icon.

3. Enter the file name.

4. Tap **Exporting settings**.

11.2.3 Exporting the audit log

The audit log file contains device-specific information without patient data for maintenance purposes.

Procedure:



1. Tap symbol **Export audit log**.

2. Select the USB stick from the drop-down menu.

3. Enter the file name.

4. Tap **Export audit log**.

11.2.4 Resetting to factory settings

With this feature, all user-specific settings are lost. The settings are reset to the factory defaults.

Procedure:

1. Tap symbol **Reset to factory defaults**:
→ The following message is displayed:



ATTENTION:

Resetting the device to factory defaults will remove all customisation done by the user! By default, the network configuration options will not be reset. Deselect the checkbox below if you also want to reset these settings.

2. If required, remove (tap) the tick **Do NOT reset network configuration**.
3. Tap **Reset to factory defaults**.
→ The factory defaults are applied.



- Inform all users that the previous settings are no longer valid.
- Instruct all users to familiarise themselves with the new settings.

11.3 General

11.3.1 Info

Sub-menu	Selection	Description
Various parameters		Indication of hardware and software versions
Write info to USB		Diagnostic file (.nfo) is written to the connected USB stick

11.3.2 Station

Sub-menu	Selection	Description
Device ID		Unique device identification
Institute		Enter the name of the institute
Department		Enter the name of the department
Technician		Enter the name of the technician
Network host name		The device's host name visible in the network

11.3.3 Power management

Sub-menu	Selection	Description
Display brightness		Select the display brightness with the slider
Dim backlight	On battery: 120 s Plugged in: 0 s	Enter the duration in seconds after which the backlight is dimmed.
Shut down device	On battery: 600 s Plugged in: 3600 s	Enter the duration in seconds after which the device is shut down.

11.3.4 Workflow

Sub-menu	Selection	Description
Transmit after saving	Active, Not active	Recordings are transmitted after saving (accepting), if configured (see section 11.6, p. 105)
Transmit spiro PRE recordings	Active, Not active	see separate Spirometry supplement to the user guide
PDF to USB after save	Active, Not active	Once stored (accepted), recordings are exported as PDF to a USB stick, if a USB stick is connected
Delete after export	Active , Not active	After transmission and/or PDF export, the recording is deleted from the memory. Deleted recordings cannot be viewed, printed nor transmitted (see section 7.6)
Print after save	Active , Not active	Only available with printer (optional) Recordings are printed after saving (accepting)
PDQ mode	PDQ by patient ID	See section 5.2.2
	PDQ by visit ID	See section 5.2.2
	None	PDQ is not used, even if EMR integration has been defined
Default workflow	Recorder Worklist	Defining the first screen shown after switch-on: Recorder: patient data are displayed. Worklist: worklist is displayed. Setting only available with worklist option

Sub-menu	Selection	Description
Worklist mode	Record from worklist Record from work order details	Record directly from the worklist, or the work order (details). Setting only available with worklist option
Auto sync worklist	Active Not active	Worklist is synchronised automatically. Setting only available with worklist option
Allow to cancel work order	Active Not active	The user can delete work items. Setting only available with worklist option

11.3.5 Memory

Sub-menu	Selection	Description
Cleanup local recordings	Not active Active	Once the defined duration in days has passed (see below), locally stored recordings are deleted. If active, recordings are even deleted after the defined number of days if these recordings have not been transmitted to an EMR system or to a USB stick.
Recording age in days	Default: 30	

11.3.6 Licenses

Sub-menu	Selection	Description
Available options		Licensed options are displayed
Activate license		Enter the license key, then tap Activate
Import license from USB		Import the file (.lic) from a connected USB stick

11.3.7 Update

Sub-menu	Selection	Description
Check SCHILLER Update Server (SUS)		Software update The check is performed via the SCHILLER Update Server. An Ethernet/WLAN connection including the corresponding network settings is required
Check USB device for update file		Alternatively, the update file can be stored on a USB stick

11.4 Regional

11.4.1 Date and time

Sub-menu	Selection	Description
Date format	DD.MM.YYYY YYYY-MM-DD mm/dd/yyyy	
Time format	hh:mm:ss h:mm:ss a	
Sync time with server		Only available if an EMR server is configured
Time zone	Various	Tap Change to select (only available if no EMR integration is defined)
Date, time		Set the date and time and apply it with Update time . Alternatively: use the button Sync time with server to retrieve the time from the server (if connected to the server).
Last time update		Last time update

11.4.2 Language

Sub-menu	Selection	Description
Language		Select the language from the drop-down menu. The device needs to be restarted.

11.4.3 Keyboard

Sub-menu	Selection	Description
Keyboard layout		Select the keyboard layout from the drop-down menu.
Barcode scanner layout		Select the barcode scanner layout from the drop-down menu.

11.4.4 Units

Sub-menu	Selection	Description
Weight	kg, lb, g	Select the unit from the drop-down menu
Height	cm, m, inch	
Temperature	°C, °F	
Altitude	m, ft	

11.4.5 Patient ID system

Sub-menu	Selection	Description
Patient ID system	None , Swedish, Danish, Finnish, Norwegian	Country-specific patient IDs. Select the patient ID system from the drop-down menu.

11.5 Security

11.5.1 Access control



- ▲ Risk of unauthorised access to patient data:
 - Activate access control

Sub-menu	Selection	Description
Mode	None	No access control
	Basic: Device login and password Settings login and password Memory login and password	Select whether a password is required for the device, settings and/or memory. Definition of the password.
	Local: User name Password/repeat password Privileges	Locally define users incl. passwords and privileges. Definition of the password. Select the privileges: Adjust system settings; Analyse recordings (from the memory); Create recordings; Edit interpretations.
	SCHILLER Server	EMR integration and admin rights for SCHILLER Server required. Access control is defined on the SCHILLER Server (see SCHILLER Communication Handbook, Art. no. 2.520036)
Automatic logout		Only available if access control has been activated
	Active, Not active	
	Logout timeout	Duration of inactivity in seconds after which the user is logged out

11.6 Connectivity

11.6.1 EMR integration

Sub-menu	Selection	Description
None		
SCHILLER Link	Enter device ID	Unique device identification
	Host/Port	
	Validate SSL certificate: Active, Not active	
SCHILLER Gateway	CA certificate	Upload CA certificate
	User	
	Password	
	Host/Port	
	Validate SSL certificate: Active, Not active	
SCHILLER Server	CA certificate	Upload CA certificate
	User	
	Password	

11.6.2 Ethernet

Sub-menu	Selection	Description
Use DHCP	Active , Not active	Automatically obtain IP address from the DHCP server. If this setting is not active, the following information has to be entered.
IP address		Identifier address of the device in the TCP/IP network
Subnet mask		Example: 255.255.255.0
Standard gateway		Gateway IP address
DNS server		IP address for DNS Server

11.6.3 Wi-Fi

Sub-menu	Selection	Description
General	Wi-Fi enabled: Active, Not active	If activated, the following settings are available
	SSID:	SSID = Enter network name
	Wi-Fi security: WPA/WPA2 personal WPA2 enterprise/ieee8021x*	Select the encryption protocol
Security	Password	for WPA/WPA2 personal
	<i>*for WPA2 enterprise/ieee8021x, the following additional settings are displayed:</i>	
	Authentication protocol: PEAP, EAP-TLS, EAP-TTLS	Select the authentication protocol
	User	Enter the user name
	Password	Enter the password
Advanced	Client certificate	Load the certificate via USB stick or network. Certificate structure: a single file in .pem format contains the 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.
	CA certificate	Load the certificate via USB stick or network
	Hidden	Use this for a connection with an anonymous network
Network	Anonymous identity	For WPA2 enterprise
	Use DHCP: Active , Not active	Automatically obtain IP address from the DHCP server. If this setting is not active, the following information has to be entered.
	IP address	Identifier address of the device in the TCP/IP network
	Subnet mask	Example: 255.255.255.0
	Standard gateway	Gateway IP address
	DNS server	IP address for DNS Server

11.7 Data fields

11.7.1 Visible fields

Sub-menu	Selection	Description
Recorder/memory	Various	Select the patient data fields shown before a recording, and put them in the desired order, see section 6.1, p. 50 Only activated fields are displayed
Worklist	Various	Select the patient data fields shown before a worklist recording, and put them in the desired order, see section 8.1, p. 76 Only activated fields are displayed

11.7.2 Mandatory fields

Sub-menu	Selection	Description
Resting and Rhythm EGG	Various	Select the patient data fields that need to be filled in
Spirometry		Select the patient data fields that need to be filled in. Date of birth, gender, ethnicity, height and weight are pre-selected and cannot be de-selected (see separate spirometry supplement)

11.7.3 Custom fields

Sub-menu	Selection	Description
		User-defined field that are shown in the patient data, if defined as Visible field (see above)
Generic data #1, 2, 3	Label	Name of the field
		Definition of values 1-3 that can be selected. Each line represents a value that can be selected from the drop-down list.
	Value	If no value is defined, free text can be entered in the patient data

11.7.4 Worklist

Sub-menu	Selection	Description
Worklist info 1 and 2	Various placeholders	Select the patient data displayed for worklist, as well as their order

11.8 Reports

11.8.1 General

Sub-menu	Selection	Description
Rhythm mode	Sequential Simultaneous	Sequential: For the individual lead groups, consecutive time segments are printed (only applies to printouts). Simultaneous: The same time segment is printed for all lead groups (only applies to printouts). If a print format with a rhythm lead is defined, Sequential is used, even if you have selected Simultaneous.
Default QTc calculation	• Bazett • Fridericia • Framingham • Hodges	Select the formula to calculate the corrected QT value (taking into account the heart rate).
Company info 1, 2, 3		Enter free text. This text is included in the report.

11.8.2 PDF

Sub-menu	Selection	Description
PDF conformance	None , PDF/A-1a, PDF/A-1b	Conformity level according to ISO 19005-1
PDF paper format	A4 , Letter	

Sub-menu	Selection	Description
PDF company logo		Upload company logo (284 × 53 pixel)
Use PDF company logo	Active, Not active	Logo is shown in the PDF

11.8.3 Header

Sub-menu	Selection	Description
	Various data such as patient ID, date of birth, gender etc.	Select the data shown in the report header. Select the data from the drop-down menu. If the field is meant to be empty, select (blank) .

11.9 Printer

Sub-menu	Selection	Description
Thermal Printer	Contrast: Value between 1 – 10. Default: 5 Line width: Normal , Thin, Thick	Only available with thermal printer (optional)
External Printer	Printer enabled: Active, Not active Printer host	Enable the external printer For network printers: enter the IP address
	Colour print	Select whether printouts on the external printer are in colour or black and white

11.10 ECG

11.10.1 Lead & cable

Sub-menu	Selection	Description
Patient cable	IEC AHA	Patient cable type: IEC (International Electrotechnical Commission) or AHA (American Heart Association)
Lead sequence	Standard Cabrera	see section 4.4, p. 39
Lead configurations	• Standard 12-lead • Paediatric • Right Precordials • Standard with C4r • Left posterior • Nehb (Chest) • Balanced	Select the available lead configurations (see section 4.5, p. 39): 1. Tap Append or Remove . 2. Change the order using the arrow buttons.

11.10.2 Additional leads

Sub-menu	Selection	Description
Rhythm lead 1, 2 and 3	All leads per lead configuration (see section 11.10.1, p. 109) Default: II, V2 and V5	Selecting the rhythm leads 1, 2 and 3 per lead configuration These rhythm leads are displayed by default in the Averages view of the review and for stored recordings. In this view, another rhythm lead can be selected (see sections 6.3.1 and 6.4.1)

11.10.3 Filter

Sub-menu	Selection	Description
Notch filter	Powerline off, AC 50 Hz, AC 60 Hz	see section 6.2.3, p. 53
Myogram filter	LP 250 Hz = Off, LP 25 Hz, LP 40 Hz, LP 150 Hz	see section 6.2.3, p. 53

11.10.4 Colours

Sub-menu	Selection	Description
Preview		Select the colours, grid and line width for the preview
	Background colour	
	Text colour	
	Grid colour	
	Grid colour lightness: Lightest, Light, Normal , Darker, Darkest	
	Invert grid	If active, the grid colour for the 1 mm grid is darkened based on the grid colour (if not active: the colour is brightened up)
	Line width: Normal , Thinner, Thicker	
	Line colour: good quality medium quality bad quality	
		Select the grid and line width for the review
	Background colour	
Review	Text colour	
	Grid colour	
	Grid colour lightness: Lightest, Light, Normal , Darker, Darkest	
	Invert grid	If active, the grid colour for the 1 mm grid is darkened based on the grid colour (if not active: the colour is brightened up)
	Line width: Normal , Thinner, Thicker	
	Line colour	

11.10.5 Preview

Sub-menu	Selection	Description
		Selection and order of the screens available for the preview.
	Preview	Tap Configuration (symbol  on the right) to select the lead speed and amplitude, if available.
	Rhythm 1×, 2×, 4×	Number of displayed columns
	Rhythm 1×3/1×4	1 column with 3 or 4 leads

11.10.6 Interpretation

Sub-menu	Selection	Description
Print interpretation	Active , Not active	The interpretation is printed, or shown in the PDF export.
Display interpretation	Active , Not active	The interpretation is displayed on the screen.

11.10.7 Manual printout

Sub-menu	Selection	Description
Default lead group	All Limb Precordials	Select the printed lead groups. The leads depend on the lead configuration.
Speed	5 mm/s, 12.5 mm/s, 25 mm/s , 50 mm/s	Speed of the printed leads.
Amplitude	5 mm/mV, 10 mm/mV , 20 mm/mV	Amplitude of the printed leads.

11.11 Resting ECG

11.11.1 Review

Sub-menu	Selection	Description
		Selection and order of the screens available for the review. Tap Configuration (symbol  on the right) to select the lead speed and amplitude, if available.
	Measurements	Table with all available measurements for all leads
	Averages	Averaged QRS complexes of all leads, plus 2 rhythms
	Rhythm 1x	All leads are displayed in 1 column
	Rhythm 2x	All leads are displayed in 2 columns
	Sequential	4 columns with 3 leads + 2 rhythms
	ETM Sport	Criteria and interpretation for ETM Sport (see section 6.7.4, p. 67)

11.11.2 Reports

Sub-menu	Selection	Description
		Selection and order of print formats for printed resting ECGs. Tap Configuration (symbol  on the right) to select the lead amplitude, if available.
12-lead	Various print formats	
9-lead	Various print formats	



- If several print formats have been selected, they are printed one after the other.
- Selections with 2p are printed on two pages (e.g.: Rhythms 10s, 25 mm/s, 2p)

11.12 Rhythm ECG

11.12.1 General

Sub-menu	Selection	Description
Rhythm length	Between 30 s and 20 min. Default: 2 min	Default duration of a rhythm ECG This duration can be manually changed before the start of the recording, if the dialogue is displayed (see following) (see section 6.4.1)
Show recording time dialogue	Active , Not active	If active, the recording duration can be selected manually before the start of the recording (see above)

11.12.2 Events

Sub-menu	Selection	Description
Manual events	Free text	Definition of manual events that can be added in rhythm ECGs (see section 6.4.2) Each line is handled as a single entry. When a manual event is added, all entries are displayed

11.12.3 Review

Sub-menu	Selection	Description
		Selection and order of the screens available for the review.
		Tap Configuration (symbol  on the right) to select the lead speed and amplitude, if available.
	Continuous	Table with all available measurements for all leads
	Rhythm 1×	1 column with 12 leads
	Rhythm 2×	2 columns with 6 leads
	Events	Event overview as well as event list

11.12.4 Reports

Sub-menu	Selection	Description
		Selection and order of print formats for printed rhythm ECGs. Tap Configuration (symbol  on the right) to select the lead amplitude, if available.
	Various print formats	



If several print formats have been selected, they are printed one after the other.

11.13 Spirometry (optional)

11.13.1 General

Sub-menu	Selection	Description
Spirometry enabled	Active, Not active	Tick to activate spirometry measurements, when SpiroScout SP plus sensor is connected.



For additional information for use which need to be followed for the CARDIOVIT FT-2 in combination with the SpiroScout SP plus:

- Read the spirometry supplement to the CARDIOVIT FT-2 user guide

12 Maintenance and disposal



Maintenance work not described in this section may only be performed by a qualified service technician authorised by SCHILLER AG. In the following sections, the interval and responsibility for maintenance work is detailed. Local regulations in your country may stipulate additional or different inspection intervals and tests:

- Check and observe the country's regulations in which the device is used.



The **Maintenance** menu (symbol  in the main menu) is only accessible by service technicians. A password is required to access the settings. For more details on this menu, see the CARDIOVIT FT-2 service manual (art. no. 2.540117).

12.1 Overview

Interval	Task
Before each use	Visual inspection (see section 12.2, p. 116)
Every 6 months	• Visual inspection (see section 12.2, p. 116) • Functional test (see section 12.3, p. 116)
At regular intervals ¹	Further periodic preventive inspection and maintenance action are to be performed by a qualified service personal. Please contact your local dealer for further information.
Approx. every 4 years, or if operation is substantially less than 1 hour	Have the battery replaced by a qualified service technician authorised by SCHILLER AG

1. The time interval for the electrical safety tests is a guideline and can vary according to local and country specific directives and according to unit use. The directive detailed here is the standard specification for reference. Local and country directives for safety testing of medical devices must be adhered to and take precedence. In addition the safety test must be carried out in the following circumstances:
 - If a unit is dropped, receives any large jolt or knock or is subject to severe vibration, etc.
 - If a unit has been subject to strong radiation or electrical shock (defibrillation), etc.
 - When a unit has been repaired or serviced that requires the case to be opened.
 - Additionally, a safety test can be carried out at any time if the unit isolation is suspected of being inadequate.

12.2 Visual inspection



- ▲ Danger of electric shock due to damaged device, cable or accessory:
 - Immediately replace a defective device, defective cables and/or accessories

During visual inspection, check the following parts for damages, wear and cracks:

- Casing
- Electrode cable sheathing and connectors
- Cable assemblies
- Power supply unit
- Plug and socket connectors
- Touch screen
- Trolley wheel brakes, no loosen screws, basket and working console securely fitted.

In addition:

1. Switch on the device.
2. Randomly perform some functions.

In this way, the correct functioning of the device and touch screen is tested.

12.3 Functional test

The functional test is performed every 6 months, or according to country-specific regulations.



If a test is not passed (see checklist below):

Contact the hospital's service department, SCHILLER (see page 2 of this user guide) or the local service centre:

Name, phone number:

Procedure

Condition: The device is connected to the mains supply via power supply unit

1. Switch on the device.
 - Home screen is displayed, no error message.
2. Tap Menu/function.
 - Touch screen reacts.
3. Disconnect device from the mains.
 - Battery capacity is displayed (see section 3.4, p. 31).
4. Print a recording from the memory (see section 7.4, p. 72) (if printer option is available).
 - Contrast and line width are OK.
 - No smudges.

Checklist

Serial number CARDIOVIT FT-2: _____

Task	Result	Date				
Visual inspection (see section 12.2)	Casing not damaged	☐	☐	☐	☐	☐
	Electrode cable and cable assembly intact	☐	☐	☐	☐	☐
	Plug and socket connectors intact	☐	☐	☐	☐	☐
	Power supply unit intact	☐	☐	☐	☐	☐
	Touch screen intact	☐	☐	☐	☐	☐
	Trolley brakes works no loosen screws, basket and working console securely fitted.	☐	☐	☐	☐	☐
Check ECG electrodes	Electrodes are compatible and expiration date has not yet passed	☐	☐	☐	☐	☐
Check the patient and mains cable	Available and intact	☐	☐	☐	☐	☐
Check the user guide	Available in the correct language and legible	☐	☐	☐	☐	☐
Functional test (see above)	Home screen without error message	☐	☐	☐	☐	☐
	Touch screen reacts when tapped	☐	☐	☐	☐	☐
	Battery capacity is displayed	☐	☐	☐	☐	☐
	Printout is legible and not smudged (optional)	☐	☐	☐	☐	☐

Carried out by: _____

12.4 Battery

NOTICE

- Reduced battery life:
 - If possible, store and operate the battery in the temperature range of 15 to 25 °C
 - Ideal charging capacity for storage: 50 to 80 %
- Deep discharge if the device is not used for more than 3 months:
 - Charge the battery
 - Ideal charging capacity for storage: 50 to 80 %
 - [see section 3.4, p. 31](#)

The battery does not require any maintenance.

The battery needs to be replaced if the operating time is significantly less than 1 hour (depending on the use, approx. every 4 years) ([see section 12.1, p. 115](#)).



The battery must only be replaced by a qualified service technician authorised by SCHILLER ([see section 12.1, p. 115](#)).

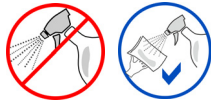
12.5 Trouble shooting

Error	Cause/note	Remedy
Unit does not switch on, blank screen	No power supply, indicator is not lit (see section 3.4)	1. Check the power supply unit for damages 2. Check the building's fuses • If the error persists: – see following
	Power supply OK, but indicator is not lit (see section 3.4)	Have the battery checked by the SCHILLER service department: if the battery is damaged, it might not be possible to switch on the device, even if it is connected to the power supply. Have the battery replaced.
Touch screen does not react when tapped	Software error	1. Shut down the device 2. Wait a couple of seconds, then switch the device on again • If not possible: – Force a shutdown as follows:
		1. Press and hold the On/off key for approx. 10 seconds until the key is no longer lit 2. Connect the device to the power supply 3. Switch on the device • If the error persists: – Call the SCHILLER service department
Touch screen does not react as expected	Excessive electro-magnetic interferences	Remove source of EMC interferences (see section 12.8, p. 126)
Cannot start recording	Memory full	Delete old recordings (see section 7.6, p. 74)

Error	Cause/note	Remedy
QRS complexes of different leads overlap	Incorrect setting for the patient	Change the amplitude setting (see section , p. 56)
	Poor electrode contact	Re-apply the electrodes (see section 4.7, p. 41) Note: Some patients have very high amplitudes and even on the lowest sensitivity settings, the QRS traces can overlap. - If the error persists: - Call the SCHILLER service department
Noisy recording	Poor electrode contact	Re-apply the electrodes (see section 4.7, p. 41)
	Patient not relaxed	Ensure that the patient is relaxed and warm
	Incorrect settings	1. Activate the myogram filter and change the cut-off frequency 2. Set the notch filter to the correct frequency • If the error persists: Call the SCHILLER service department
	Patient cable defective	Check the patient cable for damages and replace, if necessary
	Interferences by other devices	Increase the distance and switch off the source of interference (see section 12.8, p. 126)
Interferences, lines on display	Excessive EMC interferences	Check for sources of excessive EMC interferences (see section 12.8, p. 126)
Interpretation is not displayed	Wrong setting	1. Check that the interpretation option is licensed (see section 11.3.6, p. 102) 2. Check that the lead configuration Standard 12-lead is selected (see section 4.5, p. 39); otherwise, no interpretation is issued 3. Check that the setting Display interpretation is activated (see section 11.10.6, p. 110)
No printout after automatic ECG recording (when printer is available)	No paper	Insert paper (see section 10.2.3, p. 93)
	Incorrectly inserted paper	1. Remove the paper 2. Re-insert paper (see section 10.2.3, p. 93)
	Incorrect settings	1. Check that at least 1 print format is selected (see section 11.11, p. 111) 2. Check that the setting Print after saving is activated (see section 11.9, p. 109) • If the error persists: Call the SCHILLER service department
Interpretation, measurements or average complexes are not printed (when printer is available)	Incorrect settings	1. Check that the corresponding print format is selected (see section 11.11.2, p. 111) 2. Check that the lead configuration Standard 12-lead is selected (see section 4.5, p. 39); otherwise, no interpretation is issued 3. Check that the printout is activated for interpretation (see section 11.10.6, p. 110)

Error	Cause/note	Remedy
Printout blurred or irregular	Old paper inserted	Insert new paper (see section 10.2.3, p. 93) Note: observe the storage conditions for thermal paper (see section 10.2, p. 91)
	Dirty print head	Clean the print head (see section 12.6.5, p. 124)
	Incorrect line width/contrast setting	Change the printer settings (see section 11.9, p. 109) - If the error persists: - Call the SCHILLER service department
No printout is possible on the thermal printer (if printer available)	Old paper inserted	Insert new paper (see section 10.2.3, p. 93) Note: observe the storage conditions for thermal paper (see section 10.2, p. 91)
	Dirty print head	Clean the print head (see section 12.6.5, p. 124)
	Incorrectly inserted paper	Insert the paper correctly (see section 10.2.3, p. 93)
	Paper tray open	Close the paper tray (see section 10.2.3, p. 93)
	Printer cable disconnected	Switch off the device and connect the printer cable (see section 2.2, p. 22)
No printout is possible on the external (network) printer (if printer available)	External printer has not been activated	Activate in the settings (see section 11.9, p. 109)
	Incorrect settings for network printer	Enter the correct IP address (see section 11.9, p. 109)
	Printer switched off	Switch on the printer
	WiFi not enabled	Enable WiFi in the settings (see section 11.6.3, p. 106)
	Network cable incorrectly connected	Check that the network cable is correctly connected
Printout is interrupted	Excessive electro-magnetic interferences	Remove source of EMC interferences (see section 12.8, p. 126)
No transmission possible via LAN	Network cable incorrectly connected	Check that the network cable is correctly connected
	Incorrect settings	Check the settings and edit, if necessary (see section 11.6.2, p. 105)
No transmission possible via WLAN	WiFi not enabled	Enable WiFi in the settings (see section 11.6.3, p. 106)
	Incorrect settings	Check the settings and edit, if necessary (see section 11.6.3, p. 106)
No PDF export to USB stick possible	No USB stick connected	Connect a USB stick
	USB stick full	Delete data from the USB stick
No automatic transmission after re-cording	Incorrect settings	Check the settings and edit, if necessary (see section 11.9, p. 109)
PDQ not possible	Incorrect settings	Check the settings and edit, if necessary (see section 11.6, p. 105)

12.6 Cleaning and disinfection



- ▲ Danger of electric shock due to ingress of liquid:
 - Switch the device off before cleaning and disconnect the plug
 - Do not immerse the device or accessories in liquid
 - Do not spray detergent/disinfectant onto the device or accessories
 - Moisten the cloth with detergent/disinfectant (do not let it soak up too much liquid)
- ▲ Do not sterilise the device or accessories
- ▲ Do not autoclave the device or accessories
- ▲ Only use the detergents/disinfectants listed below
- ▲ Observe the manufacturer's instructions on using the detergent/disinfectant
- ▲ The device and accessories may become less resistant if an alkaline detergent or a detergent with a high alcohol concentration is left for a long time, or if a warm detergent/disinfectant is used:
 - Only use the detergents/disinfectants listed below at room temperature
 - Observe the manufacturer's instructions on using the detergent/disinfectant
- ▲ Damage to the cable due to mechanical stress:
 - When disconnecting a cable, pull the plug and not the cable
 - Route the cable so as to help prevent people from tripping or the cable being run over by, for example, the trolley

12.6.1 Overview



Detergents and/or disinfectants (see following)
Soft cloth



Inspect the device, accessories and cable before cleaning/disinfection:

- Device and accessories: no damages, keys and connectors are mechanically working fine
- Cable: no damages, wear, exposed wires or bent plugs
- All plugs engage securely



General procedure:

▲ Always clean the device before disinfection and let it dry

1. Wipe the device, accessories and cables on the surface with a slightly moistened (not wet) cloth.
2. Carefully wipe off excessive detergent/disinfectant.
3. Remove any grease marks and fingerprints with a mild detergent or a 50 % alcohol solution.
4. Make sure that no liquid runs into sockets, switches or gaps. If this still happens:
 - Leave the sockets etc. to air-dry and perform a functional test (see section 12.3, p. 116)

12.6.2 Cleaning

Interval

Before each use.

Approved detergents

- 50 % Isopropyl alcohol
- Neutral, mild detergent solution
- All products designed for cleaning plastic

Non-admissible detergents

Do not use detergents containing the following:

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

12.6.3 Disinfection

Interval

According to the health institution's regulations.

→ Clean the device before disinfection and let it dry.

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

Disinfectants that are not approved

- Organic solvents
- Ammonia-based disinfectants
- Abrasive disinfectants
- 100 % alcohol
- Conductive solution

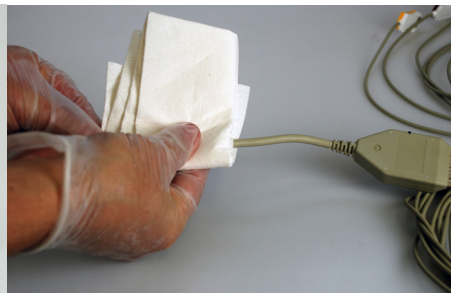
Do not use disinfectants containing the following:

- Ketone (Acetone)
- Quaternary ammonium compound
- Betadine
- Chlorine, wax or wax compound
- Sodium salt

12.6.4 Cleaning the cables

NOTICE

- Damage to the cable sheathing due to mechanical stress:
 - Only wipe 20 cm of cable at a time.
 - Never wipe the entire cable in one go.



1. Check the cable for damages:
Carefully bend all parts of the cable and check for cracks, damages, wear, exposed wires, bent plugs.
 - If damages are detected:
 - Replace the cable.
2. Slightly moisten a cloth with detergent/disinfectant (do not soak).
NOTICE! See notice above.
3. Gently hold the cable with the damp cloth in the centre of the cable and wipe 20 cm of cable at a time.
4. Then wipe the next 20 cm of cable.
5. Repeat step 4 until the entire cable is clean.

12.6.5 Cleaning the print head

If the thermal printer is available (optional).

Over a period of time, the ink from the grid on the paper can form a film on the print head. This can cause the print quality to deteriorate.

Interval

Once a month or when required.

Procedure

1. Open the paper tray and remove the paper (see section 10.2.3, p. 93).
2. Clean the print head with a slightly moist (not wet) cloth as shown.



12.6.6 Cleaning the trolley

Ensure that all cleaning materials used on the trolley are suitable for the material used in its construction. The list of cleaning solutions and disinfectants are provided as a general guide. If in doubt about the suitability of a cleaning solution or disinfectant, check that the solution is suitable for the materials as follows:

Trolley	Material
Console/Basket	ABS (polycarbonate-ABS)
Handle	Silicon
Housing	POLYESTER POWDERCOAT stain-less metal sheet

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

12.7 Disposal

WARNING

- ▲ Danger of explosion:
 - Do not burn the battery
 - Do not dispose of the battery in the household waste
- ▲ Danger of acid burns caused by materials contained in the battery:
 - Do not open the battery
- ▲ Danger to the environment due to improper disposal:
 - Dispose of packaging material, device, battery and accessories according to the country's regulations in which the device is used
- ▲ Risk of cross-contamination:
 - Do not reuse disposable accessories marked with the symbol 
 - After use, dispose of disposable accessories marked with the symbol  in the hospital waste
 - Some electrodes are disposable accessories: [see section 12.9, p. 128](#)
 - The customer is obliged to establish a quality management system for the handling of contaminated waste. The pertinent risk analysis must include the accessories and consumables, especially the disposables intended for single use.

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The battery must only be removed by a qualified service technician authorised by SCHILLER.

Device including battery and accessories no longer used must be disposed of in a municipally approved collection point or recycling centre for electronic devices.

Alternatively: return the device including battery and accessories to SCHILLER (see page 2).

Dispose of packaging materials in a municipally approved collection point or recycling centre.

12.8 Electromagnetic interferences



- ▲ Interference caused by radiated high-frequency electromagnetic energy:
 - Use the device in accordance with the user guide
 - Use portable high-frequency telecommunication devices (incl. RFID) in a distance of at least 0.3 meters to the CARDIOVIT FT-2 including cables.
 - Do not place the CARDIOVIT FT-2 on top of other electric/electronic devices
 - Observe the [12.8.1 Measures to prevent interferences, Page 127](#).

The distance depends on the output performance of the communication device:

High-frequency source/telecommunication device	Transmitted 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-talkie (FRS)				
Rescue, police, fire brigade, maintenance (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	1700–1990	1720/1845/1970	2	0.3
UMTS				
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

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

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

where:

d = minimum distance in meters

P = transmitted power in Watts



For further information: see service manual CARDIOVIT FT-2 article number: 2.540117.

12.8.1 Measures to prevent interferences

- Shut down the device
- Stop data transmission
- Increase distance to the source of interference (see above)
- Observe the minimum distance of 20 cm to a pacemaker
- Turn the device to change the angle of radiation
- Connect the device to a different mains connector
- Connect the potential equalisation cable
- Only use original accessories
- Immediately replace defective cables
- Connect the patient cable correctly
- Observe the maintenance intervals as stated in section [12.1](#)

12.9 Accessories and disposables



- ▲ Danger to the patient as well as risk of the warranty becoming invalid if accessories or disposables are used that are not approved:
 - Only use accessories and disposables approved by SCHILLER.

NOTICE

- Update of the Accessories you will find [15 Addendum Accessories Updates, Page 137](#)
- Accessories and disposables area available from the local SCHILLER representative or directly from SCHILLER (see page 2).

12.9.1 Patient cables

Part No.	Label	Description
2.400186	ECG D-SUB2 B 3.1/2.55 x10 IEC	10-wire patient cable IEC, banana plug, 3.1/2.55 m
2.400187	ECG D-SUB2 B 3.1/2.55 x10 AHA	10-wire patient cable AHA, banana plug, 3.1/2.55 m
2.400184	ECG D-SUB2 C 4.6/4.25 x10 IEC	10-wire patient cable IEC, clip type, 4.6/4.25 m
2.400185	ECG D-SUB2 C 4.6/4.25 x10 AHA	10-wire patient cable AHA, clip type, 4.6/4.25 m

12.9.2 Electrodes and ECG consumables

Part 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
2.155025	Ambu® BlueSensor R	Blue Sensor electrodes, Ø 48 mm (25 pieces)
2.155034	Ambu® WhiteSensor 0415M	White Sensor electrodes for resting ECG (500 pieces)
2.155032	Ambu® Snap Clip	Adapter for banana plugs (10 pieces)
2.155020	Set of 4 clamp electrodes	Electrode kit for adults (metal)
2.155000	Suction chest electrode	Suction electrodes chest, set of 6 pieces
2.158000	SPES MEDICA E.C.G. GEL	Electrode gel (50 ml)
2.158006	Signaspray® Electrode Solution and Skin Prep	ECG contact spray (bottle, 250 ml)
2.157050	ECG recording paper fanfold	Thermal paper, Z-folded, 210 mm wide (A4)

12.9.3 Mains lead/power supply

Part No.	Description
2.310005	Ground cable with 6mm MC plug Potential equalisation cable, 5 m
2.300000	POWER Cord, "Swiss", C13 straight, 3x1.00mm ² , 2.5m GREY Mains cable Switzerland, straight, 2.5 m
2.300002	Power cord SCHUKO EU C13, 180° straight Mains cable Schuko Europe, straight, 2.5 m
2.300011	POWER CORD, UK, C13 straight, 3x1.00mm ² , 2.5m RAL 7035 Mains cable UK, straight, 2.5 m
2.300012	Mains cable USA hospital grade, 2.5 m straight Mains cable USA, medical grade, straight, 2.5 m
2.300014	Mains cable, China, 90° angled Mains cable China, angled, 2.5 m
2.300016	Mains cable black, Japan, 90° angled Mains cable Japan, angled, 2.5 m
2.300025	Mains cable Brazil, 90° angled Mains cable Brazil, angled, 2.5 m
2.200134	Power supply Medical power supply 100 — 240 VAC, max. 2.0 A—0.7 A, 50 —60 Hz output 24V, 6.25A Note: Only qualified service technicians trained by SCHILLER may replace the power supply if built in the Trolley (as described in the service manual)

12.9.4 Accessories

Part No.	Label	Description
2.000147	Laser Barcode Scanner Set incl. short instructions	Barcode scanner set including barcode scanner (2.200208 // LS2208-SR20001R-UR) and SCHILLER User guide "Barcode scanner for use with SCHILLER units" (2.510721)

12.9.5 Trolley

Part No.	Label	Description
2.101210	Trolley X1 with console for FT-2	Trolley X1 Basis 2.101129 with console 2.101208 CARDIOVIT FT-2
2.101118	Drawer for trolleys X1, X2, X3, X4	Drawer
2.101119	Basket translucent for trolleys X1, X2, X3, X4, X5	Transparent basket
2.101209	Printer Holder for FT-2	Printer Holder for FT-2
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
2.101183	Holder Strässle for DT-80 for X4, X5	Holder for Strässle suction pump DT-80

Part No.	Label	Description
2.101186	Holder Strässle for DT-100 for X4, X5	Holder for Strässle suction pump DT-100
2.101217	Socket support	Multi-plug socket support
2.101216	Gel Support	Support for gel or sanitizer bottle

13 Technical data

13.1 Device

Feature	Value/description
Dimensions	424 × 274 × 44 mm
Weight	Approx. 3.82 kg
Display	TFT-LCD Multi-touch screen backlit, for graphical and alphanumeric presentation Resolution: 1366 × 768 dots, 15.6"
Power supply via external power supply unit	Medical-grade switching power supply unit, protection class I with functional earth Input: 100 to 240 VAC, maximum 2 to 0.7 A, 50 to 60 Hz Output to CARDIOVIT FT-2: 24 VDC, maximum 6.25 A, 150 W
Power supply via internal rechargeable battery	Mains-independent operation, internal rechargeable battery (lithium-ion polymer, 10.8 V, 9.22 Ah) Capacity: 4 hours normal operation without printout and without Wi-Fi Life expectancy battery at 25 °C and charge/discharge with 4.4 A: > 300 cycles with min. initial capacity of 80 % Charging duration to 80 %: approx. 4 hours with the device switched off
Power supply device	24 V, 150 VA
Interfaces	• Power supply connector (DC IN) • ECG patient cable connection • LAN (Ethernet 1 GB – RJ45) • Potential equalisation connector • 3 × USB type A (5 V/max. 0.5 A) • Connector for thermal printer
Internal memory	EMMC: Min. 2GB data storage for recordings (or 350 ECG, 100 rhythm ECG and 100 Spirometry recordings)
Operating conditions	• Temperature: +10 to +40 °C • Relative humidity: 15 to 95 % (non-condensing) • Atmospheric pressure: 700 to 1060 hPa (max. 3000 m above sea level)
Storage conditions	• Temperature: +5 to +50 °C • Relative humidity: 10 to 95 % (non-condensing) • Atmospheric pressure: 500 to 1060 hPa
Transport conditions	• Temperature: –10 to +50 °C • Relative humidity: 10 to 95 % (non-condensing) • Atmospheric pressure: 500 to 1060 hPa
Ideal ambient temperature for battery	+15 to +25 °C

13.2 ECG

Feature	Value/description
Patient input	Fully floating and isolated, defibrillation protected (only with original SCHILLER patient cable), type CF according to IEC 60601-1
Lead configurations	• Standard 12-lead • Paediatric • Right precordials • Standard C4r • Left posterior • Nehb (Chest) • Balanced
Display	• Display of selected leads (configurable): – Chart speed 12.5 / 25 / 50 mm/s (configurable) – Amplitude 5 / 10 / 20 mm/mV (configurable) • Filter status • Power supply • Leads • Electrode contact status • Heart rate • Date and time • Patient name and number • Transmission functions • Transmission status • Printer status • Memory status
ECG review	Displayed on an area of 118 × 192 mm with different layouts Chart speed: 12.5 / 25 / 50 mm/s; for rhythm ECG: 6.25 / 12.5 mm/s Amplitude (sensitivity): 5 / 10 / 20 mm/mV; for rhythm ECG: 2.5 / 5 mm/mV;
Filter	• Myogram filter: 25, 40, 150 or Off (Off = 250 Hz) • Notch filter: 50 or 60 Hz
Data record	• Patient data (name, age, height, weight, BP, device ID) • all ECG recording data (date, time, filter) • ECG measurements results (intervals, amplitudes, electrical axes) • Averaged complexes • Guidance on interpreting adult and paediatric ECGs
ECG amplifier	Complies with the requirements of IEC 60601-2-25 and ANSI/AAMI EC11 • Sampling frequency: 32 000 Hz (storage sampling frequency: 1000 Hz) • Skewing between channels: 0 s • Amplitude quantification: 50 nV/LSB
ECG interpretation algorithm ETM	Isoelectric segments after global QRS-onset (I waves) or before global QRS-offset (K waves) are excluded from the duration measurement of the respective adjacent Q, R or S wave. They are therefore also excluded from the lead-specific QRS duration measurements.

13.3 Trolley (optional)

Feature	Value/description
Dimensions	1710 × 631 × 590 mm (with pump arm and all assemblies)
Weight	24 kg
Maximum load basket/console	5 kg
Maximum total load	60 kg

13.4 Thermal printer (optional)

Feature	Value/description
Dimensions	384 × 318 × 74 mm
Weight	approx. 2.53 kg
Resolution	High-resolution thermal head printer; 8 dots/mm (amplitude axis); 40 dots/mm (time axis 25 mm/s). Dots per line 1728
Thermal paper format	Z-folded, 210 mm wide (A4)
Storage conditions for thermal paper	Max. 35 °C, max. 65 % rel. humidity
Speed	5 / 12.5 / 25 / 50 mm/s (5 / 12.5 mm/s only for manual printouts); for rhythm ECGs: 6.25 mm/s
Amplitude (sensitivity)	5 / 10 / 20 mm/mV; for rhythm ECG: 2.5 / 5 mm/mV

13.5 Fulfilled safety standards

Feature	Value/description
Safety standards	IEC 60601-1 IEC 60601-2-25
EMC	IEC 60601-1-2 The device can be exposed to the following interferences without any impairment: • Static discharges up to 15 kV • Field strength up to 10 V/m in the frequency range of 80 MHz to 2700 MHz • Magnetic fields 30 A/m, 50/60 Hz
Protection class	Device as a system: Class I in accordance with IEC 60601-1 CE according to EU MDR 2017/745: IIa
Conformity/classification	Hereby, SCHILLER AG declares that the radio equipment type CARDIOVIT FT-2 is in compliance with Directive 2014/53/EU. The full text of the EU declaration of conformity is available at the following internet address: https://www.schiller.ch/en/conformity
Ingress protection	IP 20, according to IEC 60529

13.6 Fulfilled WLAN standards

Feature	Value/description
Modules	WL1837MOD
FCC-ID	Z64-WL18DBMOD
IC-ID	4511-WL18DBMOD
Wi-Fi transmission standards	IEEE 802.11 a, b, g, n
Security protocol	WPA2 enterprise / ieee802.1, WPA2-PSK, WPA-PSK, TKIP, AES
Frequency range	Dual-band 2.4 GHz and 5 GHz

Feature	Value/description
Max. power output 2.4 GHz (1DSSS)	+16,5 dBm
Max. power output 5 GHz (OFDM6)	+18 dBm
PDF export	PDF /A-1 a or b to an attached USB memory stick

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15 Addendum Accessories Updates

NOTICE

- For the Addendum updated accessories see the following.
- If no addendum is attached, the accessory list in chapter [12.9 Accessories and disposables, Page 128](#) is up to date.

16 Appendix - Symbols

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

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

	Identification of the manufacturer
	Identification of the manufacturing date
	Identification of the distributor
	Identification of the importer
	Medical device
	Serial number
	Reference number
	Batch code
	Global Trade Item Number
	Catalogue number
	Quantity
	UDI: unique device identification as QR code machine readable and human readable as number (e.g.  (01) 0 7613365 00210 2 (21)xxxx.xxxxxx)
	Number of pieces in the packaging
	Authorised European representative

	Notified body (e.g.  0123 marking notified body TÜV SÜD)
	UKCA marking (UK Conformity Assessed)
	CE marking, affirms its conformity with European standards
	NRTL symbol (Nationally Recognised Testing Laboratory) TÜV SÜD as accredited NRTL certification provider
	Regulatory Compliance Mark for the Australian standards
	The device is recyclable
	Symbol for the recognition of electrical and electronic equipment. Device must not be disposed of in the household waste.
	Symbol for the recognition of a battery. Battery must not be disposed of in the household waste.
	The packaging is made in low density polyethylene and can be recycled.
	Federal law (USA) restricts this device to sale by or on the order of a physician
	Non ionising electromagnetic radiation. To indicate that the device contains a Radio Frequency (RF) transmitter to transmit data (e.g Bluetooth or WiFi)
	Contains a Bluetooth module
	Do not reuse
	Latex-free
	Use-by date (expiry date of battery, electrodes or other consumables)
	Temperature range for storage or transport, respectively
	Pressure range for storage or transport, respectively

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

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CARDIOVIT FT-2

Spirometry supplement to the user guide

Art. no.: 2.511443 Rev. a



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

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

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85622 Feldkirchen

Germany



The CARDIOVIT FT-2 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 Annex I of the Regulation (EU) 2017/745 (MDR) 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.



For additional safety measures and safety notes which need to be observed for the CARDIOVIT FT-2 in combination with the SpiroScout SP plus:

- Read the CARDIOVIT FT-2 user guide

1.1 Intended purpose

- ▲ The spirometry option is intended to be used by or under the direct supervision of a licensed physician in healthcare facilities to record, analyze, display and print measurements and waveforms of pulmonary function tests to support diagnosis in adult and pediatric patients.

Intended users

The CARDIOVIT FT-2 is intended to be used by or under the direct supervision of a licensed physician.

Indication

The CARDIOVIT FT-2 when used as a pulmonary function testing system is intended to support detection, diagnosis, and monitoring of abnormalities of the lung.



Contraindication

- ▲ The CARDIOVIT FT-2 when used as pulmonary function testing system is not intended for patients with the following diseases (relative contraindications):
- ▲ Due to increases in myocardial demand or changes in blood pressure
 - Acute myocardial infarction within 1 week
 - Systemic hypotension or severe hypertension
 - Significant atrial/ventricular arrhythmia
 - Non compensated heart failure
 - Uncontrolled pulmonary hypertension
 - Acute cor pulmonale
 - Clinically unstable pulmonary embolism
 - History of syncope related to forced expiration/cough
- ▲ Due to increases in intracranial/intraocular pressure
 - Cerebral aneurysm
 - Brain surgery within 4 weeks
 - Recent concussion with continuing symptoms
 - Eye surgery within 1 week
- ▲ Due to increases in sinus and middle ear pressures
 - Sinus surgery or middle ear surgery or infection within 1 week
- ▲ Due to increases in intrathoracic and intraabdominal pressure
 - Presence of pneumothorax
 - Thoracic surgery within 4 weeks
 - Abdominal surgery within 4 weeks
 - Late-term pregnancy
- ▲ Infection control issues
 - Active or suspected transmissible respiratory or systemic infection, including tuberculosis
 - Physical conditions predisposing to transmission of infections, such as haemoptysis, significant secretions, or oral lesions or oral bleeding

Patient target group

- ▲ The CARDIOVIT FT-2 is intended to be used for adult and paediatric 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)
- ▲ There are no restrictions regarding height, weight, gender or ethnicity of the patients.
- ▲ For spirometry, the patient must be able to understand and carry out the instructions on how to perform the examination.

Affected body regions

- ▲ The CARDIOVIT FT-2 system is only in contact with the user.

Ambient conditions

- ▲ The CARDIOVIT FT-2 is intended for indoor use in healthcare facilities.

- ▲ The CARDIOVIT FT-2 needs to be operated according to the technical data (see section 9, p. 85).

Re-Use

- ▲ The CARDIOVIT FT-2 and the spirometry sensor (SpiroScout SP plus) are reusable.

The spirometry mouthpieces (ScoutTube) are disposable items (single-use).

1.2 Limitations



- ▲ The CARDIOVIT FT-2 is not intended:
 - 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
 - to be used as a vital signs physiological monitor
 - for use with high-frequency surgical units

1.3 Spirometry – procedural practice



- ▲ In order to obtain correct predicted values and diagnoses, it is important that all patient data is entered correctly. In particular gender, date of birth, ethnicity, height and weight must be entered.
- ▲ The device must be verified before the first pulmonary function test of the day and when the environmental conditions have changed (see section 3.3, p. 23).
- ▲ The patient needs to be supervised and instructed by the operator (see section 3.5, p. 32).
- ▲ False measurements can result when the sensor is not held horizontally: ensure that the sensor is held horizontally at all times.
- ▲ The disposable ScoutTube mouthpiece of the SpiroScout SP plus sensor is designed for one-time use to eliminate the danger of cross contamination – do not use it for more than one patient
- ⊗. Do not attempt to clean the ScoutTube.

1.4 Maintenance



- ▲ Do not open the SpiroScout SP plus, it does not contain any serviceable parts.
- ▲ Maintenance work may only be performed by qualified technicians authorised by SCHILLER.
- ▲ Only perform maintenance when the device is not in use.

1.5 Cleaning/disinfection



- ▲ **WARNING** – Risk of cross-contamination:
 - Do not reuse disposable accessories marked with the symbol .
 - ScoutTube and nose clips are single-use disposables.
- ▲ **Equipment damage:**
 - Clean and disinfect the device according to the instructions in this user guide (see section 7, p. 73).
 - Observe applicable statutory requirements regarding cleaning/disinfection.
 - Only use detergents and disinfectants recommended by SCHILLER. Do not use aggressive or abrasive cleaners.
- ▲ Switch off the device and disconnect it from the power supply before cleaning/disinfection.
- ▲ Never immerse the device or cables in liquid.
- ▲ Do not sterilise the device.

1.6 Serious incidents



- ▲ If any serious incident occurs in relation to the CARDIOVIT FT-2, such incident needs to be reported to SCHILLER as well as the competent national authority in the country in which the user and/or patient is established.

1.7 Safety symbols and signs

1.7.1 Symbols used in this document

The safety levels are classified according to ISO 3864-2. The safety and warning messages are designed according to ANSI Z535.6. The safety signs are used according to ISO 7010.



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



- ▲ For a possibly dangerous situation which could lead to severe personal injury or to death.
- ▲ Embedded warning messages of this level are indicated with the signal word **WARNING!**.



- ▲ For a possibly dangerous situation which could lead to personal injury.
- ▲ Embedded warning messages of this level are indicated with the signal word **CAUTION!**.



- Warning concerning equipment damage or system failure.
- Embedded warning messages of this level are indicated with the signal word *NOTICE!*.



- ▲ For general or supplementary safety notes as listed in this section.



- ▲ For electrical hazards or precautionary measures when dealing with electricity.



- ▲ For interferences caused by non-ionising electromagnetic radiation.



Especially important or helpful information



Reference to other documents



Required tools/equipment

1.7.2 Symbols on the spirometry sensor (SpiroScout SP plus)



Refer to instruction manual/booklet: Reading the user guide before using the device is compulsory



Symbol for the recognition of electrical and electronic equipment. Equipment, components and accessories no longer used must be disposed of in a municipally approved collection point or recycling centre. Alternatively, you can return the device to your supplier or the manufacturer for disposal. Improper disposal can harm the environment and human health.



IP20

Type BF applied part: Safe for external applications; not defibrillation-proof

Protection class: IP20. According to DIN EN 60529. Protected against ingress of solid foreign bodies ≥ 12.5 mm. Not protected against ingress of water, may only be used indoors.

For further symbols: see CARDIOVIT FT-2 user guide

1.7.3 Symbols used on accessories/disposables

ScoutTube



Do not reuse: Disposable item



Non sterile



2021-06

Use by (YYYY-MM-DD or YYYY-MM) expiring date

2 Introduction

With the CARDIOVIT FT-2, spirometry measurements can be recorded, displayed and printed. The CARDIOVIT FT-2 measures the patient's respiratory flow with the SpiroScout SP plus spirometry sensor and calculates volumes and flow speed and can be configured with a single-use ScoutTube. A new ScoutTube must be used for every patient to help prevent patient cross contamination.

The following measurements are available:

- Forced Vital Capacity (FVC)
- Slow Vital Capacity (SVC)
- MVV (maximum voluntary ventilation)

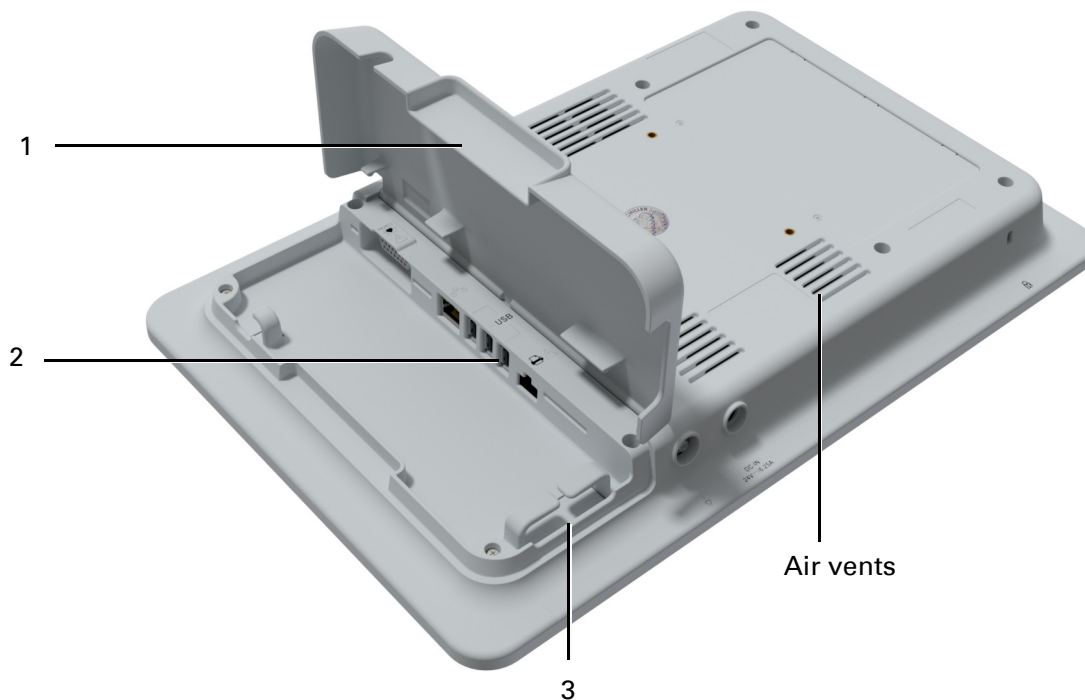
A number of American and International normal standards can be selected for predicted value calculation and diagnosis.

2.1 Connection of the SpiroScout SP plus Sensor

NOTICE

- Equipment damage due to not approved external hardware:
 - Only connect external hardware approved by SCHILLER.
 - Connecting not approved hardware is done at the user's own risk and may render the warranty invalid.
- Equipment overheating:
 - Do not cover the air vents (see below)

Overview

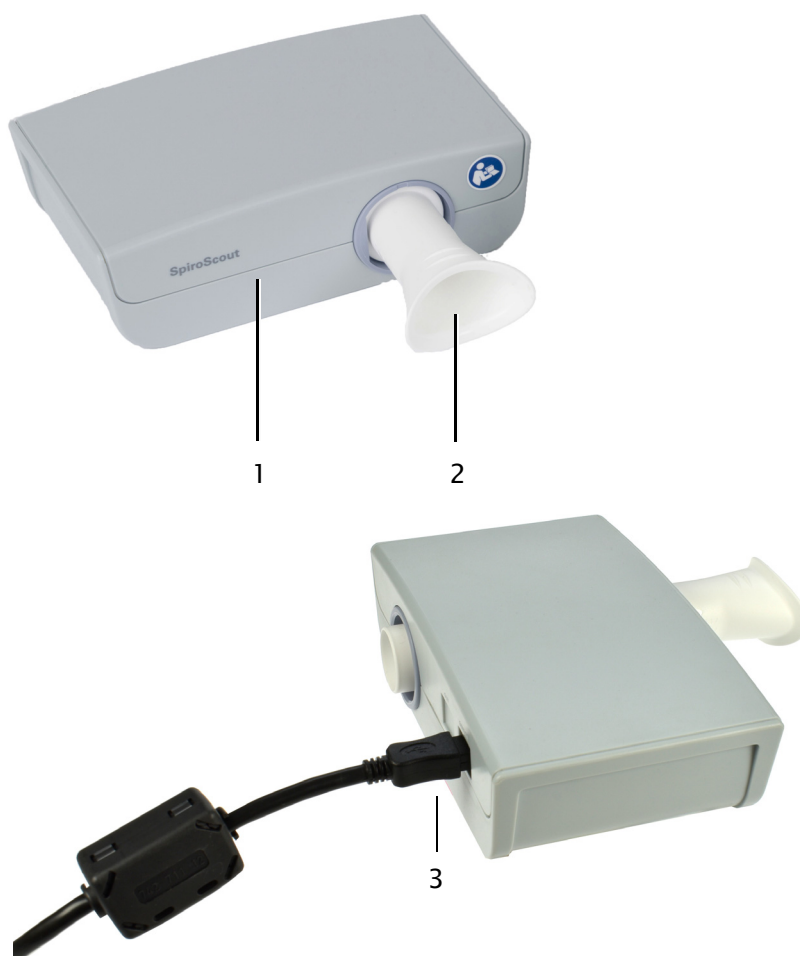


- (1) Cover for connector panel on right-hand side: pull to open
(2) USB connectors for SpiroScout SP plus Sensor connection
(3) Cable routing for SpiroScout SP plus Sensor USB cable

2.2 Applied parts

- Spirometry sensor SpiroScout SP plus
 - Connector: USB connectors, see section 2.1 above
- ScoutTube: disposable mouthpiece for SpiroScout SP plus
 - Inserting: see section 3.2.1, p. 22
 - Ordering information: see section 8.7, p. 83

2.3 Spirometry sensor (SpiroScout SP plus)



- (1) SpiroScout SP plus (applied part)
- (2) Disposable Single- use ScoutTube (applied part)
- (3) USB connection cable

2.3.1 Applied parts definition

The applied parts are all parts of the CARDIOVIT FT-2 that comes in-to contact with the patient. As Shown on the previous picture the following parts may come into contact with the patient:

- Sensor (hold from the patient during the test procedure)
- ScoutTube (taken into the mouth of the patient during the test procedure)

Notes:

- Test procedures may take about 20 second and some test are repeated 3 times.
- The applied parts (Sensor) is protected against electrical shock type BF.
- all applied parts fulfil the biocompatibility requirements of the applicable standards.

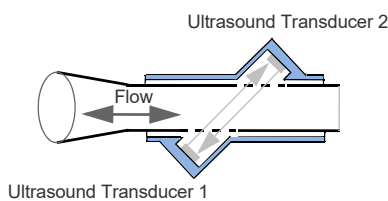
2.3.2 Measurement Principle

Ultrasound Technology

The SpiroScout SP plus measures flow based on ultrasound technology. Two diagonally opposed ultrasound transducers (piezo-elements) send and receive ultrasonic waves alternately and the difference in the sound transmission transit times between these two sensors is used to calculate flow direction and speed, and volume.

Without any air flow, the transit time of the ultrasound waves is the same in both directions and no flow is registered. Any air flow inside the insert will accelerate the waves in one direction and slow them down in the other and the higher the difference between the transit times of the ultrasonic waves, the higher the air flow.

All other factors (gas properties, humidity and temperature) are the same for both directions and cancel each other out.



2.4 Connectors

USB connector on the back to connect to the CARDIOVIT FT-2 (see section 2.3).

2.5 Installation

The device is being installed by SCHILLER. The features and procedures are explained by a medical product representative.

2.6 Switching on and off

Press the On/off key at the front to switch the device on or off:



2.7 Program

2.7.1 Main menu

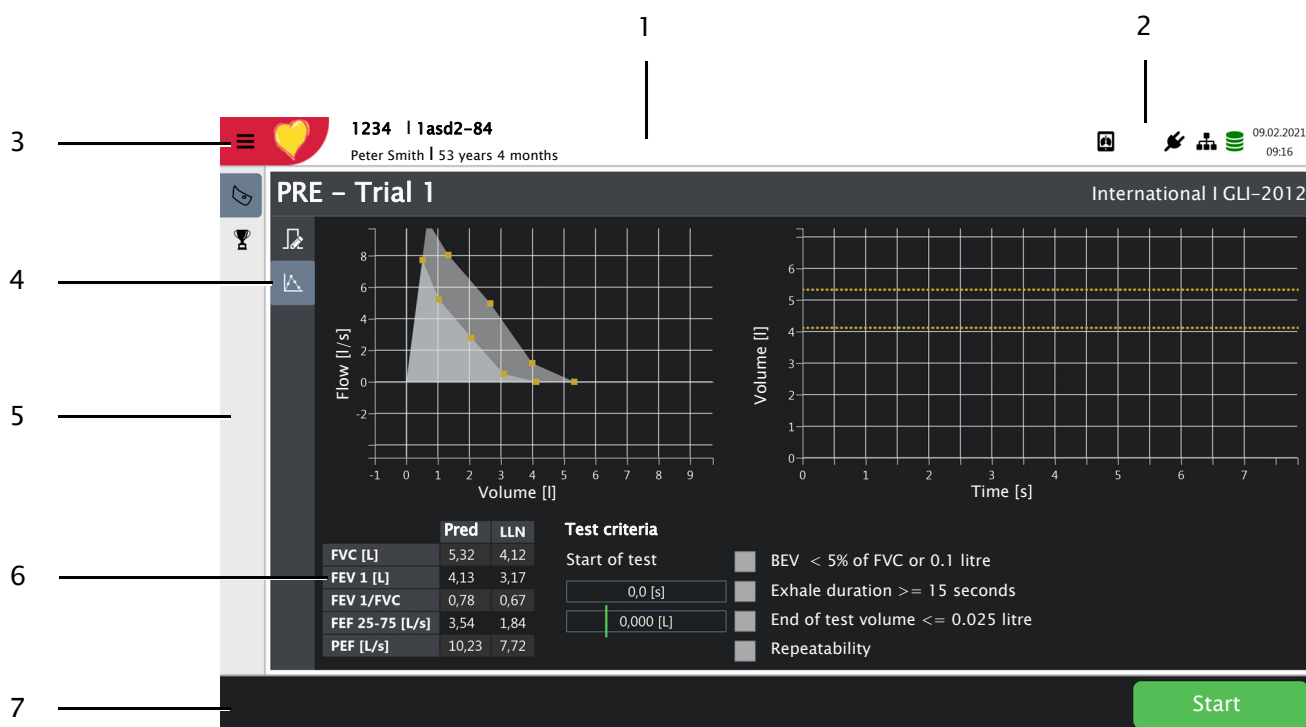


The main menu offers access to the following functions:

- Recorder
- Memory
- Worklist (optional)
- Logout (if access control is activated)
- **Settings** Menu
- **Maintenance** menu

2.7.2 Display

The display will vary according to the task being carried out. However, the upper, lower and right/left parts of the display always contain the same information categories:



- (1) Patient data including patient ID and visit ID
- (2) Information on the printer, transmission, power supply, network, memory, as well as date and time: tap the icon to display further information
- (3) Access to the main menu
- (4) Settings for the current view (e. g. display Pre/Post, predicted values, curve settings): tap the icon to show the selection or toggle
- (5) Taskbar left: tap to expand and display further information (available functions depend on the current view)

- (6) Display of predicted values etc. as well as the test criteria (depending on the current view)
- (7) Taskbar bottom with function keys (available functions depend on the current activity)

3 Spirometry recording



Spirometry recordings are only possible if spirometry is activated in the settings: **Menu > Spirometry > General > Spirometry enabled**.

3.1 Overview

The CARDIOVIT FT-2 measures the patient's respiratory flow with the SpiroScout SP plus spirometry sensor and calculates volumes and flow speed. The SpiroScout SP plus measures the airflow inside the mouthpiece by means of GANSHORN's ultrasound measuring technology.

The following measurements are available:

- Forced Vital Capacity (FVC)
- Slow Vital Capacity (SVC)
- Maximum voluntary ventilation (MVV)

A number of American and International normal standards can be selected for predicted value calculation and diagnosis.

3.1.1 FVC (forced vital capacity)

For this test, the patient exhales as quickly as possible, after maximal inhalation.

The patient is required to exhale as quickly as possible so it is important to have patient cooperation and that the patient understands what is required. The expiration can be immediately followed by a maximum inhalation.



For the FVC measurement, the back extrapolation method is used. If the back extrapolated volume is too large (> 0.1 litres or 5 % of FVC), the device issues a warning.

3.1.2 SVC (slow vital capacity)

For this test, the patient breathes normally 3 times, then inhales to maximum lung capacity, and then exhales as fully as possible.

3.1.3 MVV (maximum voluntary ventilation)



- ▲ Danger of hyperventilation:
 - Perform the test with the patient sitting down.

For this test, the patient breathes as deeply and as rapidly as possible over a period of at least 3 seconds (for normal patients).

3.2 SpiroScout SP plus

⚠ CAUTION



- ▲ Risk of injury to the patient due to inhalation of loose parts:
 - Before inserting a new ScoutTube in the SpiroScout SP plus, make sure that the ScoutTube is undamaged and that there are no loose parts inside.
- ▲ Risk of cross-contamination ScoutTubes is single-use:
 - Do not use the ScoutTube and disposable nose clip for more than one patient
 - Do not re-use or the ScoutTube and disposable nose clip
 - After use, dispose of the ScoutTube and disposable nose clip in the clinical waste
- ▲ To maintain hygiene:
 - Wash hands (or use hand sanitiser) before fitting and after removing.
 - When fitting, use the plastic packaging of the ScoutTube, paper tissues or wear protective gloves to prevent direct contact.
 - When removing the ScoutTube after use, use disposable protective gloves. Dispose of the protective gloves after use.

NOTICE

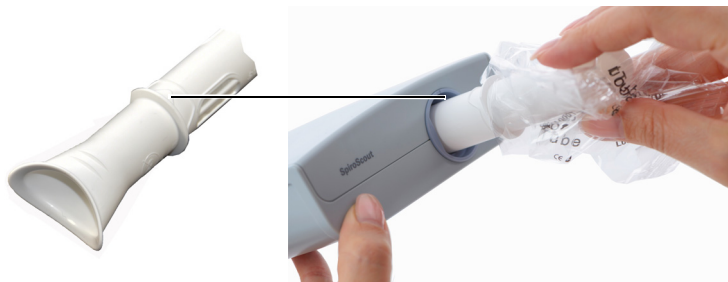
- Damage to the cable due to mechanical stress:
 - When disconnecting the sensor cable, pull the plug and not the cable
- Damage to the sensitive measuring device in the sensor:
 - Do not drop the sensor
 - Prevent any strong vibrations and shocks

3.2.1 Inserting the ScoutTube



- ScoutTube (see section 8.7, p. 83)
- Paper tissues or protective gloves

1. Position the protruding arrow on the ScoutTube (see illustration below) so that it matches the slot in the SpiroScout SP plus.
2. Fully push the ScoutTube into the sensor without using excessive force.



3.2.2 After completion of the test



- ▲ Observe all cross-contamination procedures when disposing of the ScoutTube. Wear protective gloves, do not let waste come into contact with any person.
- ▲ Wipe / clean the sensor and adapter with approved cleaning solution or disinfectant [7 Cleaning and Disinfection Sensor, page 73](#).

1. Pull the ScoutTube away from the sensor.
2. Dispose of the ScoutTube in the clinical waste.
3. Clean the sensor (see section 7, p. 73).

3.3 Volume verification

The SpiroScout SP plus is a pre-calibrated ultrasound sensor which does not require calibration. However, changes to the ambient conditions (e. g. temperature) may lead to inaccurate results. Correct functioning of the SpiroScout SP plus can be determined with a verification check. Therefore, regular verification checks are recommended to ensure the reliability of the tests.

ATS and ERS recommend regular verifications, i. e. before the first measurement of the day. The unit should also be verified for any significant change in temperature, pressure or humidity, or if the unit is moved to a different location (especially different altitude).

Verification checks the unit. The values need to be within 3% of the actual measured value.

3.3.1 Ambient parameters

Temperature [°C], ambient pressure [hPa], relative humidity [%], altitude above sea level [m] and syringe size [ml] need to be set for the program to determine the volume correction factors STPD and BTPS. The units can be changed if required (°C/°F, m/ft) ([Settings > Regional > Units](#)).

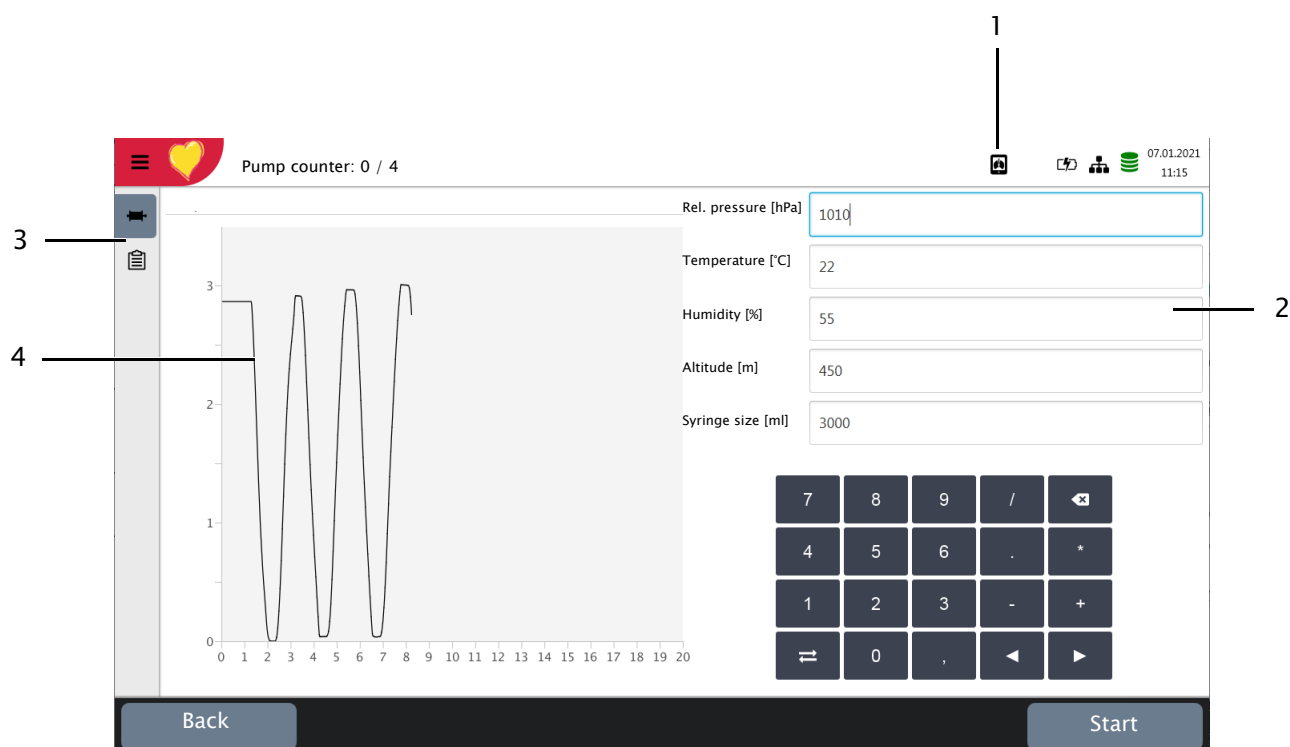
3.3.2 Volume verification view



Open the volume verification view by tapping the icon shown on the left.



If no sensor is connected, the following icon is shown: :
Connect the spirometry sensor (see sections 2.1 and 2.3).



- (1) Open view
- (2) Ambient parameters
- (3) Select the view: verification or history (i. e. earlier verification results)
- (4) Graphical representation of pump strokes

3.3.3 Procedure



- Hans Rudolph Calibration Kit 2.000202 including following parts:
 - Calibration pump, 3 litres (art. no. 2.100976)
 - SpiroScout SP plus holder (4.310728)
 - Adapter for calibration pump (art. no. 4.430384)
 - SpiroScout SP plus sensor (not included in the Kit)
 - ScoutTube (not included in the Kit)



- Thermometer, measuring range: +15 to 35 °C
- Barometer, measuring range: 700 to 1050 hPa
- Hygrometer, measuring range: 30 to 80 % relative humidity



It is important that the measuring equipment and calibration pump's accuracy is regularly verified.

The calibration pump's accuracy must be ± 0.5 %.

Keep the calibration pump at room temperature to prevent measurement errors.



The calibration pump needs to undergo a regular leak test (e. g. monthly):

1. Cork up the outlet
 2. Try to fill the pump
- If the pump leaks air, contact SCHILLER



The ScoutTube can be used several times, when it is stored protected against dust in a plastic bag.

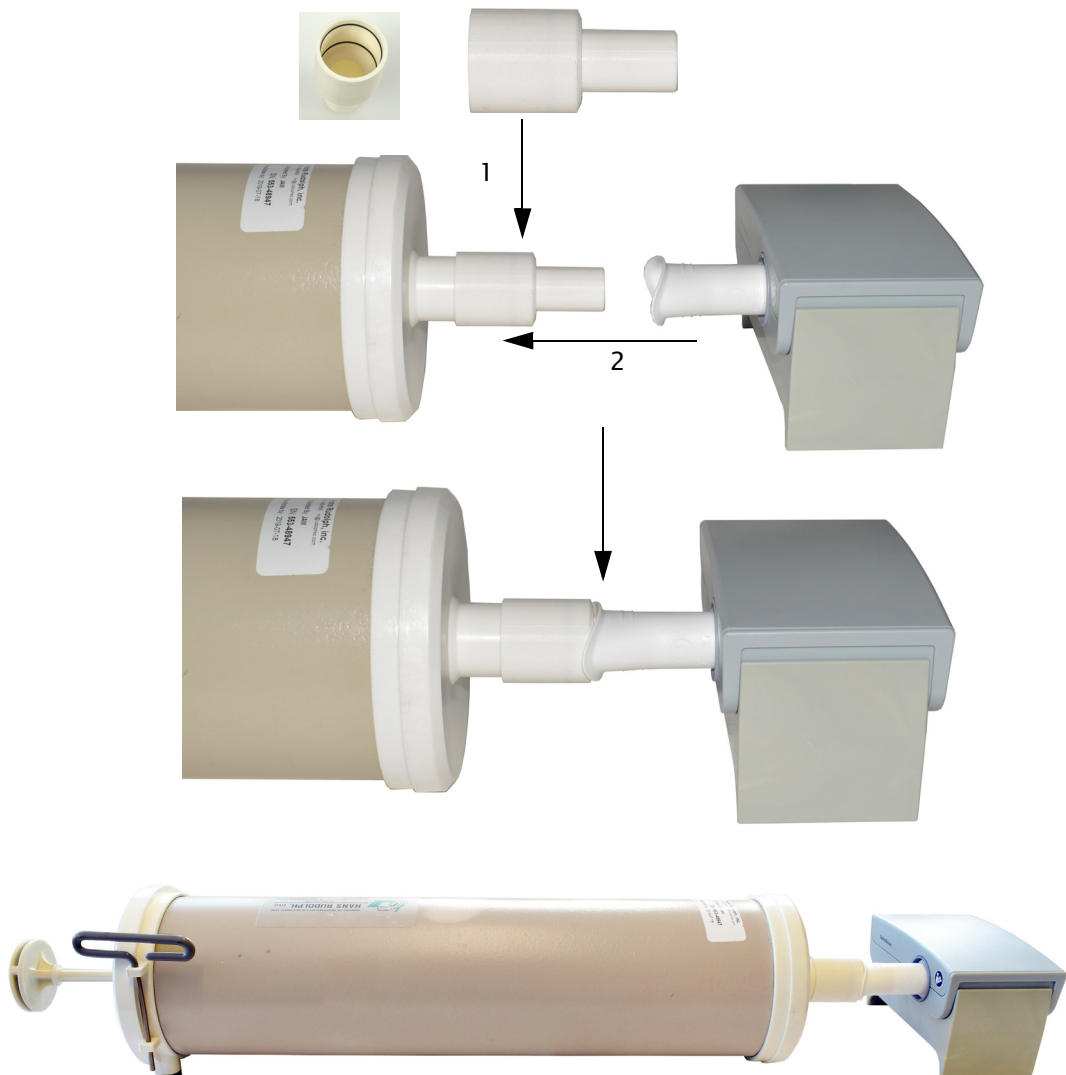
- Use a new one when calibration fails.
- Use a new one when opening a new box of ScoutTubes and dispose the old used ScoutTube.

- Used ScoutTube for verification shall not be used for patient.

NOTICE

3.3.4 Preparation

1. Place the calibration pump and the SpiroScout SP plus on a flat, stable surface.
2. Assembly the adapter (1) on the calibration pump. Make sure that the two O-ring are in place.
3. Move the SpiroScout SP plus with the inserted ScoutTube over the assembled adapter on the calibration pump (2).
4. Make sure that the ScoutTube is optimally inserted in the SpiroScout SP plus.
5. Check that there are no air leaks.

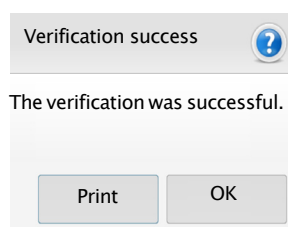


3.3.5 Verification procedure

1. Enter the ambient parameters (see section 3.3.2, p. 24 above)
2. Press Start
3. Perform four full pump strokes: every movement takes approx. 1.5 seconds
 - The volume is displayed
 - The verification is stopped automatically
 - A message is given indicating success/failure of the verification process

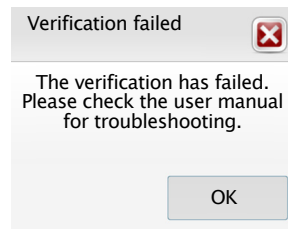
3.3.6 Verification success

A corresponding message is displayed and the verification result can be printed. If a USB stick is connected, the verification result can be stored as PDF on the USB stick.



3.3.7 Verification failed

A corresponding message is displayed.



The difference between the measured volume and the reference volume is too large ($>3\%$).

Check following:

- Setting of ambient parameters and the syringe volume.

If all values were correct check:

- Test setup (wrong placement ScoutTube in the adapter can cause turbulences and test will fail)
- Leakage of the assembly
- Replace ScoutTube and repeat the verification. See also section 8.4.

If the verification still fails: the device may be defective, contact SCHILLER.

3.3.8 Results

Verification results are displayed in the **History** view (see section 3.3.2, p. 24 above) and can be printed or stored as PDF on a USB stick (if a USB stick is connected).

Amongst others, the following values are displayed:

Date

Date of last verification

Averaged flow (ml/s)

Flow, averaged over the verification duration

BTPS IN / EX

Calculated BTPS factor (Body Temperature, Ambient Pressure, Saturated with water vapour). This factor compensates differences regarding humidity saturation in inspired and expired air. The unit is set to measure the exhaled volume (100 % humidity, temperature 36.8 °C), so when the inhaled volume is measured, this factor is applied.

3.4 Additional patient data

CAUTION

- ▲ Predicted values and diagnosis incorrect due to incorrect patient data:
 - Verify gender, date of birth, ethnicity, height and weight once more after all values have been entered.
 - If no ethnicity is selected, the predicted values are calculated based on the default ethnicity of the selected standard.
 - Enter sex at birth: It is birth sex and not gender that is the determinant of predicted lung size.
- ▲ Distorted measurements due to incorrect positioning of the sensor:
 - Make sure that the sensor is held horizontally during the measurement.
- ▲ Risk of mixing up patients when the device is connected to an EMR system:
 - For the visit ID, only use a unique number issued by your health institution.
 - Do not use general information such as name of the department or physician as visit ID.



For information on general patient data: see CARDIOVIT FT-2 user guide

For spirometry recordings, additional data fields are available. A page with these additional fields is displayed when **Spirometry** is tapped in the patient data view before a recording is started:

Adult/Paediatric Norm

Adult/Paediatric Norm is shown automatically and varies depending on entered for the age of the patient.

If all patient data are set correctly the preferred reference values can be selected. For the default setup see **Settings > Spirometry > Standards** and for the selectable references see section 5.5, p. 65.

Smoker

Unknown, Never smoker, Former smoker, Smoker

Intensity

Number of cigarettes per day

Years smoking

Enter the number of years smoking

Pack years

Pack years are calculated from the cigarettes smoked per day and number of years smoking as follows:

$$\text{Pack years} = \frac{\text{Cigarettes/day}}{20 \text{ (cigarettes per pack)}} \times \text{years smoked}$$

Years non smoking

Number of years not smoking

Remarks

Free text

Asthma

Yes or no

COPD

Chronic obstructive pulmonary disease: Yes or no

SpO₂

Enter the measured SpO₂ value (max. 3 digits).



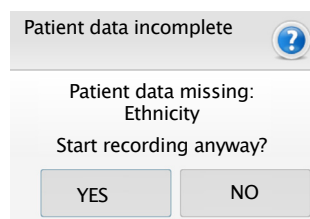
This value needs to be measured with an external device, not with the CARDIOVIT FT-2.

3.4.1 Spirometry mandatory fields

Just like for ECGs, mandatory fields can be defined for spirometry recordings.

For spirometry, the mandatory fields date of birth, gender, ethnicity, height and weight are pre-selected and cannot be deselected (see section 6.2.7, p. 72).

If a recording is started despite empty mandatory fields, a corresponding message is displayed. The user is prompted to confirm that the recording can still be performed:



If mandatory patient data is missing, no predicted values are calculated or displayed.

3.4.2 Information on spirometry-specific patient data

Patient data that affect the predicted values (DOB, ethnicity, gender, height and weight) can no longer be edited once the first trial has been acquired.

For patients unable to stand erect, height may be estimated using ulna length (preferred for children) or arm span. These estimates depend on the gender, age and ethnicity. Ulna length should be measured with calipers to avoid error introduced using a tape measure.

Additional information by the ATS (American Thoracic Society) and ERS (European Respiratory Society) for height estimation:

Height estimation using ulna length: *Gauld LM, Kappers J, Carlin JB, Robertson CF. Height prediction from ulna length. Dev Med Child Neurol 2004;46:475-480. 57.*

Height estimation using arm span: *Quanjer PH, Capderou A, Mazicio-glu MM, Aggarwal AN, Banik SD, Popovic S, et al. All-age relationship between arm span and height in different ethnic groups. Eur Respir J 2014;44:905-912*

3.5 Preliminaries

The following preliminaries must be performed before a recording is started (in accordance with ATS/ERS 2019):

- When making the appointment, give the patient the following requirements, and when he/she arrives, check with the patient and enter any deviations:
 - No smoking and/or vaping and/or water pipe use within 1 h before testing (to avoid acute bronchoconstriction due to smoke inhalation)
 - No consumption of intoxicants within 8 h before testing (to avoid problems with coordination, comprehension and physical ability)
 - No vigorous exercise within 1 h before testing (to avoid potential exercise-induced bronchoconstriction)
 - Not wearing clothing that substantially restricts full chest and abdominal expansion (to avoid external restrictions on lung function)
- When making the appointment, instruct the patient to withhold specific medications, if required. The decision to withhold medications before testing is a clinical one made by the referring healthcare professional.
- Record the type and dosage of any inspired, oral or injected medication that may alter lung function, and when the medication was last administered.
- Record any observed signs or symptoms such as cough, wheeze, dyspnoea or cyanosis.
- Perform the test in a quiet environment.
- Provide drinking water and tissues for the patient.
- Ensure that the patient is relaxed and wears comfortable clothing or loosens tight-fitting clothing.
- Measure the patient's weight and height (without shoes).
- Have the patient sit on a chair with arm rests, no wheels and with height adjustment. Adjust the height of the chair so that his/her feet are flat on the floor. If required, provide a footstool.
- If the test is performed with the patient in another position than sitting, this needs to be documented.
- In some circumstances, such as patients with tracheostomy or nasal resection, non invasive adjustments such as sealing face mask, tubing connectors or occlusion valves can be applied and must be documented.
- Explain the purpose of the test and that the patient's cooperation is fundamental for successful lung function testing.
- Instruct and if necessary demonstrate the breathing manoeuvre with the patient and explain the important points.
- Instruct the patient not to talk during the measurement.
- Instruct the patient to sit erect, keep his/her shoulders down and slightly lift his/her head.
- Position the nose clip on the patient's nose.

- Instruct the patient to hold the sensor with both hands and take the ScoutTube into their mouth. The teeth slightly touch the ScoutTube and the lips form a seal around the mouthpiece. The patient may only breathe through the ScoutTube; if air escapes through the corners of the mouth, the results may be distorted.

3.6 Test procedure overview



- ▲ Risk of injury to the patient due to inhalation of loose parts:
 - Before inserting a new ScoutTube in the SpiroScout SP plus, make sure that the ScoutTube is undamaged and that there are no loose parts inside.
- ▲ Risk of cross-contamination:
 - Do not use the ScoutTube and disposable nose clip for more than one patient
 - Do not re-use the ScoutTube and disposable nose clip
 - After use, dispose of the ScoutTube and disposable nose clip in the clinical waste
 - Use paper tissues or wear protective gloves when inserting and removing the ScoutTube. After use, dispose of the gloves/paper tissues in the clinical waste

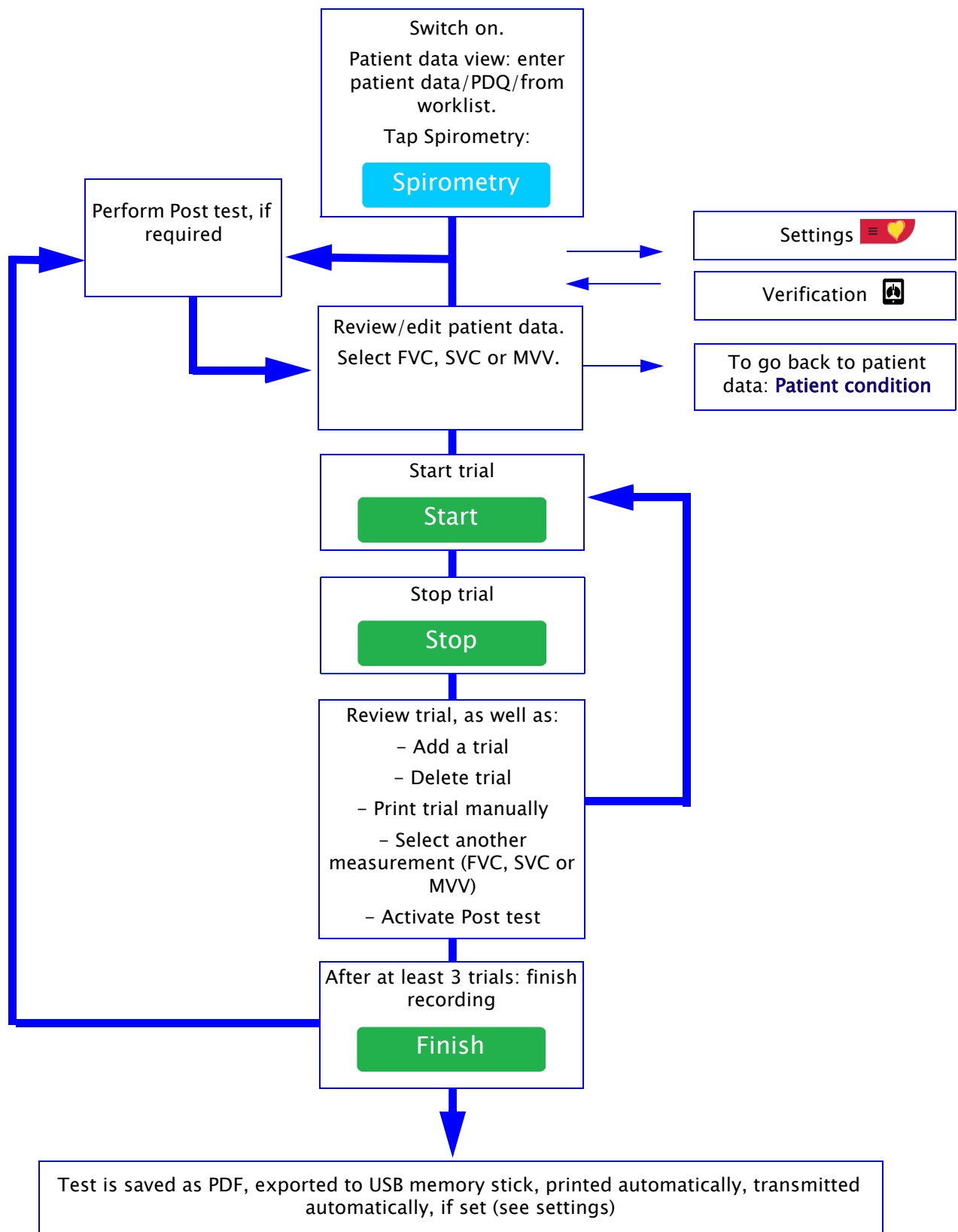


If the guideline GRS 2015 is set (see section 6.2.2, p. 71), the FVC test and SVC test are effectively combined and the FVC test is followed by SVC in one manoeuvre.



- ScoutTube (art. no. 2.101123)
- Nose clip (art. no. 2.101218)

Overview



For all measurements, the procedure is similar:

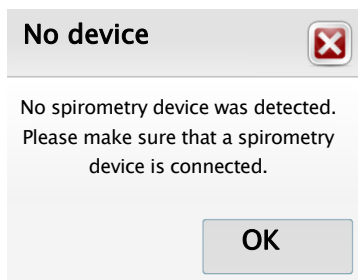
1. Enter the patient data (see CARDIOVIT FT-2 user guide and see section 3.4, p. 29) or open work item (see CARDIOVIT FT-2 user guide)
2. Check that patient data is correct.
3. Clean the sensor (see section 7, p. 73)
4. Select a measurement: FVC, SVC or MVV.
5. Insert a new ScoutTube in the sensor (see section 3.2.1, p. 22)
6. Hand the SpiroScout SP plus to the patient. During the measurement, the patient needs to hold the sensor like a pair of binoculars. Shoulders down, head slightly lifted up.
7. Just before starting the measurement, close the patient's nasal airways with a nose clip. The nose clip closes the nostrils to ensure that all the air expelled during the test is exited through the mouth and is therefore measured.
8. Instruct the patient to hold the sensor still and not breathe any air into the sensor for at least one second before and after **Start** is pressed.



9. Start trial Start
10. Instruct the patient to seal the ScoutTube with their lips. A tight seal is necessary to prevent air leakage.
11. Instruct the patient to breathe regularly and steadily until the breathing level (functional residual capacity, FRC) is stable. This usually requires at least three tidal breathing manoeuvres. The trial starts:
 - As soon as the patient starts to breathe into the ScoutTube, the device begins to record the expiratory flow. The flow curve is displayed.
12. Stop the trial Stop
13. Review the trial (see section 4.1, p. 49) and delete or add a trial, if required.
14. Perform at least 3 trials (repeat steps 8. – 13. above)
15. Finish the recording, see section Finishing the recording.



If no spirometry sensor (SpiroScout SP plus) is connected when a trial is started, the following information is displayed:



3.7 FVC measurement

1. Instruct the patient to breathe normally through the mouth for three or more tidal breaths.
 - As soon as a stable breathing level is reached, the forced vital capacity can be measured. If necessary (e. g. for children), an animation (incentive screen) can be displayed, see section 3.7.2, p. 41 below
2. Start the trial **Start**.
3. Instruct the patient to inhale as deeply as possible until the lungs are filled to their maximum and TLC level is reached.
4. Then instruct the patient to exhale as forcefully, quickly and completely as possible until RV level is reached (FVC and FEV1 are measured).
 - It is important that the air is exhaled quickly for an accurate measurement of the volume within the first second.
 - The patient continues to exhale until no more air can be exhaled.
 - It is important that all lung air is exhaled to give an accurate measurement of lung capacity (in one entire breath).
 - After exhalation, the patient can breathe normally.
5. Monitor the test criteria, see Quality control during the measurement below.
6. Stop the trial **Stop** if the test criteria are met (if the test criteria are not met: see section 3.7.1, p. 37 below).
 - The trial is displayed
7. Review the trial (see section 4.1, p. 49)
8. According to ATS/ERS criteria (2019), at least three acceptable trials need to be performed. If any trial is not satisfactory for whatever reason, delete it and perform another trial (see section 3.7.3, p. 43). The maximum amount of trials that are stored depends on the selected guideline.
 - **Add trial**
 - Deleting a trial (see section 3.7.3, p. 43)

3.7.1 Quality control during the measurement

During the trial, the start/end of test criteria are checked.

End of test criteria are reached when:

- the back-extrapolated volume (BEV) is $< 5\%$ of FVC, or < 0.1 l (the larger value is assumed)
- the exhalation duration is ≥ 15 seconds, or
- the end of test volume is ≤ 0.025 l for ≥ 1 second.

According to the ATS/ERS 2019 guidelines, the end of test criteria are met when the first and second, or the first and the third criterion are met. Therefore, it is not required that all criteria are reached in order to meet the guidelines.

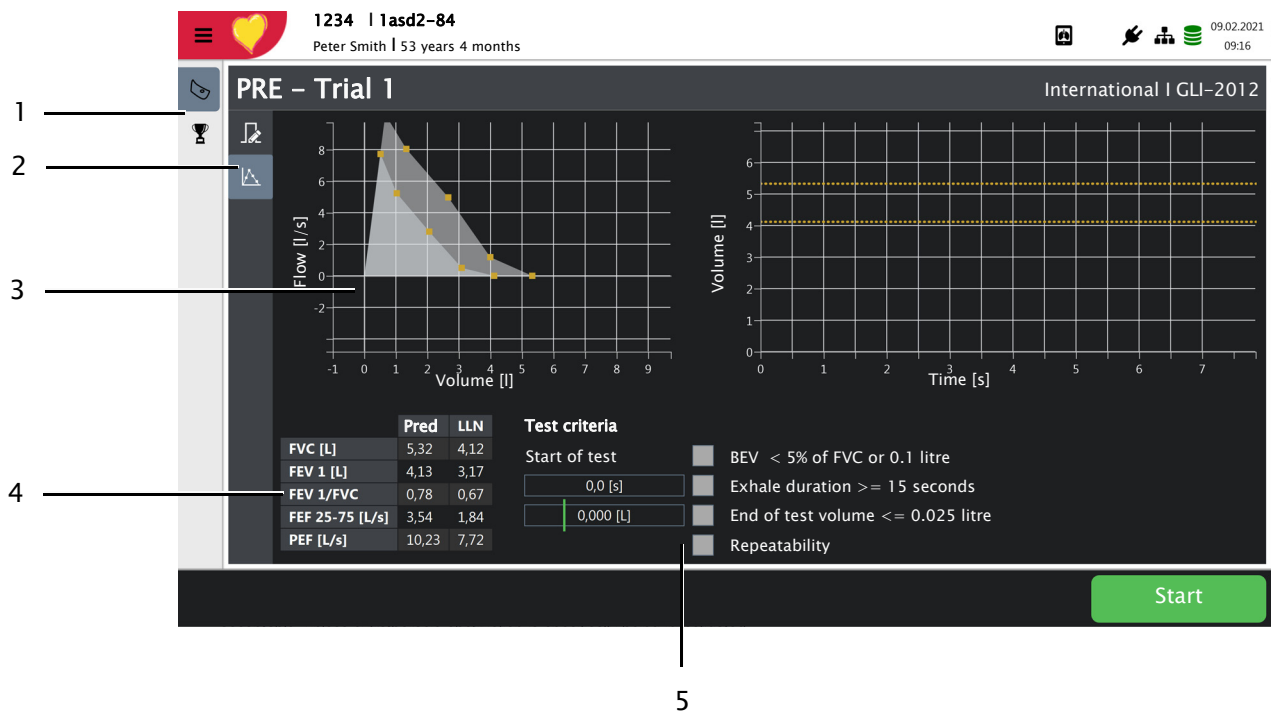
The criteria are graphically displayed, see following.



In addition, from trial 2, the program states whether the repeatability criterion according to the ATS/ERS 2019 guideline is met:

- Age > 6 years: difference between the two largest FVC values is ≤ 0.15 l, and difference between the two largest FEV1 values is ≤ 0.15 l.
- Age ≤ 6 years: difference between the two largest FVC values is ≤ 0.1 l or 10 % of the largest value (the larger value is assumed), and difference between the two largest FEV1 values is ≤ 0.1 l or 10 % of the largest value (the larger value is assumed)

The quality control guidance indicators show these parameters during the test:



- (1) Select the view: FVC graph or incentive screen (animation) (see following)
- (2) Graph settings: change the scaling and show/hide predicted values and LLN

i

The default scaling is defined in the settings (see section 6.2.3, p. 71).

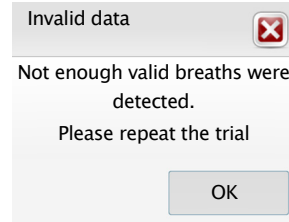
The displayed predicted and LLN values are defined in the settings (see sections 6.2.5 and 6.2.1).

- (3) Flow-volume and volume-time graphs
- (4) Predicted values and LLN
- (5) Display of test criteria (see above)

No valid breath

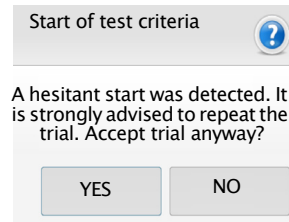
If a trial is stopped but test criteria have not been met, the following warnings are displayed:

If **Stop** is tapped before a valid breath has been detected, the trial needs to be repeated:



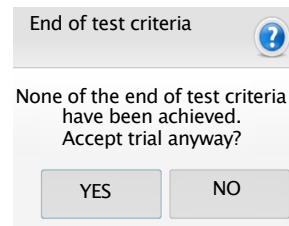
Start of test criterion not met

If **Stop** is tapped before the start of test criterion has been met, finishing the trial needs to be confirmed:



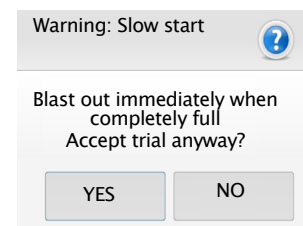
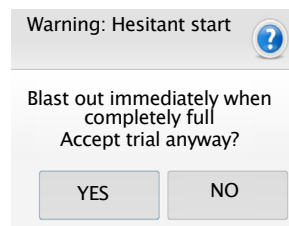
End of test criterion not met

If **Stop** is tapped before an end of test criterion has been met, finishing the trial needs to be confirmed:



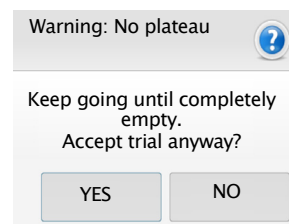
Hesitant start/Slow start

If a hesitant or slow start is detected:



No plateau

If no plateau is reached:



Hesitation at maximum volume

If hesitation has been detected when at maximum volume:

Warning: Hesitation at maximum volume 

Blast out when completely full.
Accept trial anyway?

YES

NO

Low forced expiration volume

If the forced expiration volume is low:

Warning: Low forced expiration volume 

Take the deepest breath possible and keep going until completely empty.
Accept trial anyway?

YES

NO

Slow filling

If inspiration has been too slow:

Warning: Slow filling 

Breathe in faster before blasting out.
Accept trial anyway?

YES

NO

Abrupt stop

If an abrupt stop has been detected:

Warning: Abrupt stop 

If you feel your throat closing, relax, but keep pushing.
Accept trial anyway?

YES

NO

Suspected cough during first second

If a cough has been detected during the first second of expiration:

Warning: Suspected cough in first second of expiration 

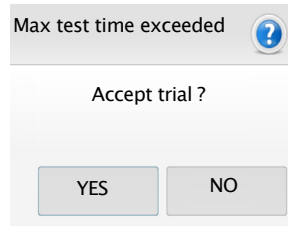
Try having a sip of water before the next blow.
Accept trial anyway?

YES

NO

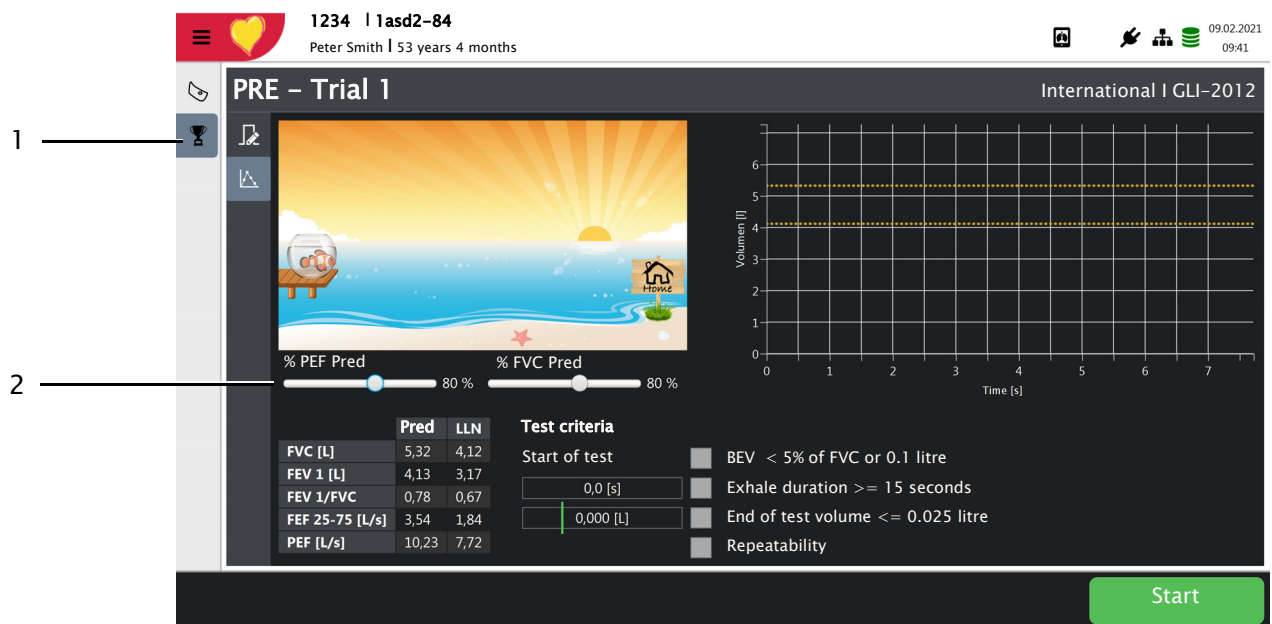
Max test time exceeded

If the maximum test duration has been exceeded:



3.7.2 Incentive view (FVC only)

For children or frail patients, an animation view can be displayed during the trial. This view is more easily understandable and encourages the patient to reach the end test criteria.



(1) Display the incentive screen

(2) Set the predicted values for PEF and FVC

When the trial is started, the fish starts to move in the fishbowl. When the PEF threshold is reached (peak expiratory flow), the fish jumps out of the bowl and into the sea.



The goal is to make the fish swim to the far right (Home):

→ The FVC threshold is reached.

If the patient fails, the predicted values for PEF and FVC can be adjusted using the sliders (see (2) above).



The type of graph shown on the right is set in the Settings: V(t) graph or f(V) graph (see section 6.2.1, p. 70)

3.7.3 Deleting trials

After a trial and before the recording is finished, trials can be deleted:

1. Tap the icon Delete  (see section 4.1, p. 49)
2. Confirm deleting the trial:



3.7.4 Finishing the recording



- ▲ Observe all cross-contamination procedures, e. g. wearing rubber gloves, not letting clinical waste come into contact with anyone, remove and dispose of the ScoutTube in the clinical waste. Dispose of disposable nose clips in the clinical waste.
- ▲ Disinfect reusable nose clips as instructed by the manufacturer.
- ▲ Clean/disinfect the sensor with approved cleaning solution or disinfectant (see section 7, p. 73).

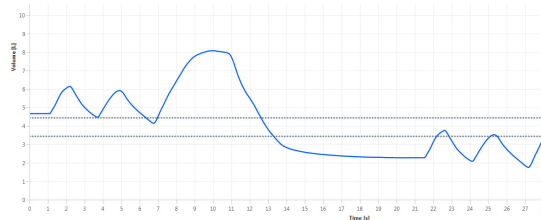
After three successful trials:

- Start another measurement (**SVC**, **MVV** or **FVC**, respectively, depending on the already performed measurement)
- **Print** the recording
- **Post measurement needed**: tick this box so that a Post measurement can be performed. Post trials are carried out in the same way as Pre trials (see section 3.10, p. 47)
- **Finish** the recording. If activated in the system settings, the recording is automatically printed and exported if a USB stick is connected (**Settings > General > Workflow: Transmit after saving; PDF to USB after save; Print after saving**)

3.8 SVC measurement

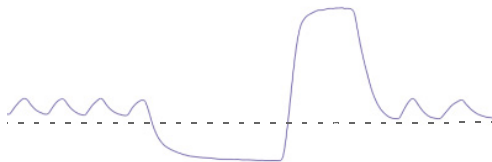
The slow vital capacity measurement is done by either performing an IVC or EVC manoeuvre:

1. Start the trial **Start**.
2. Wait until a stable breathing level has been reached.
→ Slow vital capacity can now be measured.
3. Instruct the patient to breathe normally through the mouth for three or more tidal breaths.
EITHER:
4. **EVC**: Instruct the patient to inhale completely until TLC level is reached (IC is measured).
5. Then the patient should exhale fully until RV level is reached (EVC is measured).
6. Instruct the patient to perform some tidal breaths.
→ The manoeuvre is finished.



OR:

7. **IVC**: Instruct the patient to fully exhale until RV level is reached (ERV is measured).
8. Then the patient should inhale fully until TLC is reached (IVC is measured).
9. Instruct the patient to perform some tidal breaths.
→ The manoeuvre is finished.



10. Stop the trial **Stop** if the test criteria are met (see following).
 - If **Stop** is tapped before an end of test criterion has been met, finishing the trial needs to be confirmed:

End of test criteria



None of the end of test criteria have been achieved. Accept trial anyway?

YES

NO

→ The result is displayed.

11. Review the trial (see section 4.1, p. 49)

12. Perform at least three acceptable trials. If any trial is not satisfactory for whatever reason, delete it and perform another trial (see below). The maximum amount of trials that are stored depends on the selected guideline.

- **Add trial**
- Deleting a trial (see section 3.7.3, p. 43)

13. After three successful trials, finish the recording (see section 3.7.4, p. 43)

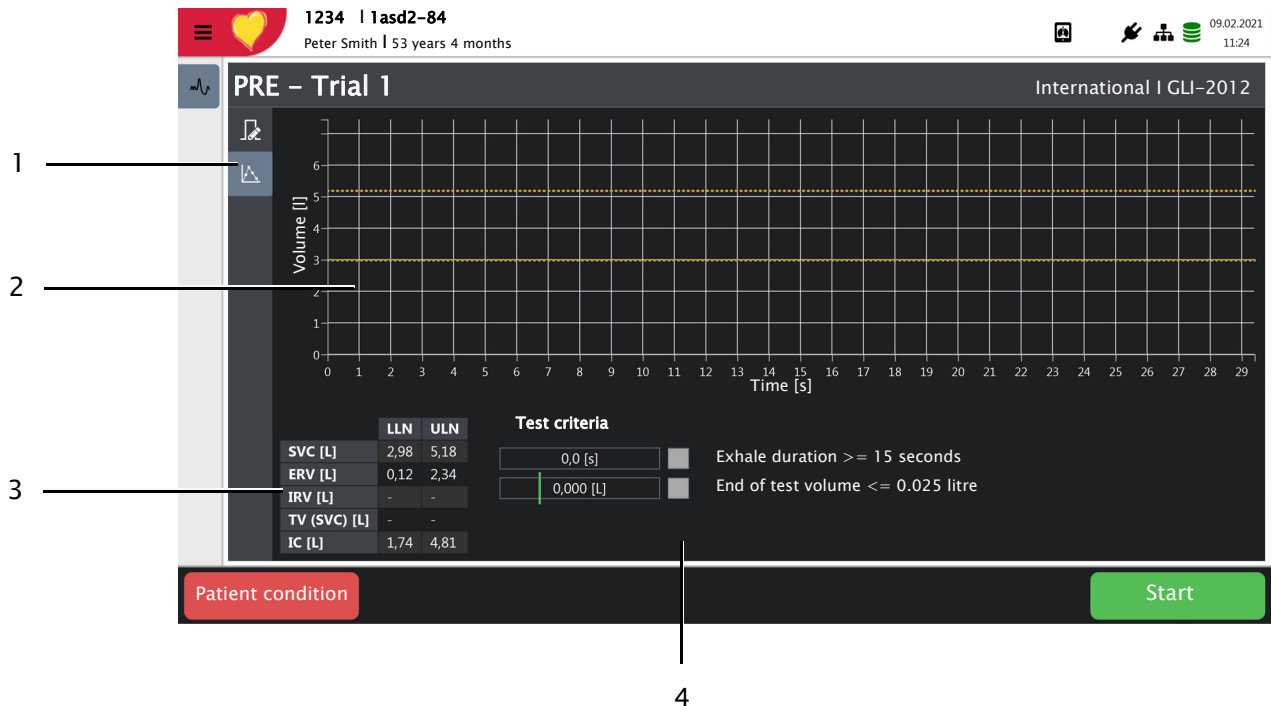
3.8.1 Quality control during the measurement

During the trial, the end of test criteria are checked.

End of test criteria are reached when:

- the exhalation duration is ≥ 15 seconds, or
- the end of test volume is ≤ 0.025 l for ≥ 1 second.

The quality control guidance indicators show these parameters during the test:



(1) Graph settings: change the scaling and show/hide LLN/ULN

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The default scaling is defined in the settings (see section 6.2.3, p. 71).

(2) Volume-time graph

(3) LLN and ULN

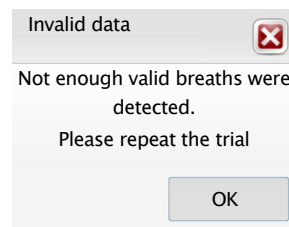
(4) Display of test criteria (see above)

3.9 MVV measurement



- ▲ Danger of hyperventilation:
 - Perform the test with the patient sitting down
-

1. Start the trial  .
2. Instruct the patient to inhale and exhale as quickly as possible for a duration of 3 seconds.
 - The result is extrapolated to show what could be achieved over one minute.
3. Stop the trial. 
 - If **Stop** is tapped before three valid breaths have been detected, the trial needs to be repeated:



- The trial is displayed
4. Review the trial (see section 4.1, p. 49)
 5. According to ATS/ERS criteria (2019), at least three acceptable trials need to be performed. If any trial is not satisfactory for whatever reason, delete it and perform another trial (see below). The maximum amount of trials that are stored depends on the selected guideline.
 - **Add trial**
 - Deleting a trial (see section 3.7.3, p. 43)
 6. After three successful trials, finish the recording (see section 3.7.4, p. 43)

3.10 Post medication tests

Post medication tests can be performed for example to check the effect of asthma medications or other medications, for allergy tests, or to monitor a change in treatment. For Post tests, within 24 hours of a recording (Pre test), a medication is administered and then another recording is performed. The results of the Pre and Post test are compared.

Post trials are carried out in the same way as Pre trials (the maximum number of stored trials depends on the selected guideline and is between 3 and 8 trials). On the report, Pre and Post medication curves are given. The results shown are best results (Pre/Post), results as a percentage of predicted values (both Pre and Post), the percentage change between Pre and Post results, and the Z-score (see section 4.7, p. 53).

If activated, the interpretation based on the Pre medication test as well as on the Post medication test is also given on the printout.

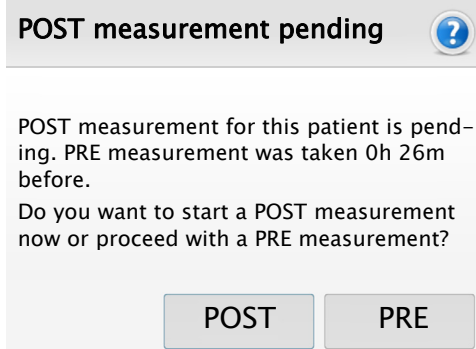
Procedure

Post trials can only be performed if Pre trials have been recorded previously and if **Post measurement needed** has been activated in the Review screen (see section 3.7.4, p. 43 and see section 4.1, p. 49).

WARNING

- ▲ Risk of mixing up patients when the device is connected to an EMR system: For the visit ID, only use a unique number issued by your health institution. Do not use general information such as name of the department or physician as visit ID.

1. Open the **Main menu > Recorder**
→ The patient data view is displayed
2. Search the patient (by entering the patient ID, using PDQ or **Previous patient**: see CARDIOVIT FT-2 user guide)
→ Patient data is populated
3. Check the patient data and edit if necessary: The patient data listed in section 3.4.1 is mandatory.
4. Tap **Spirometry**
→ The following dialogue is displayed:



5. Tap **POST**

- Additional patient data is displayed (see section 3.4, p. 29):
Check the patient data and complement/edit if required



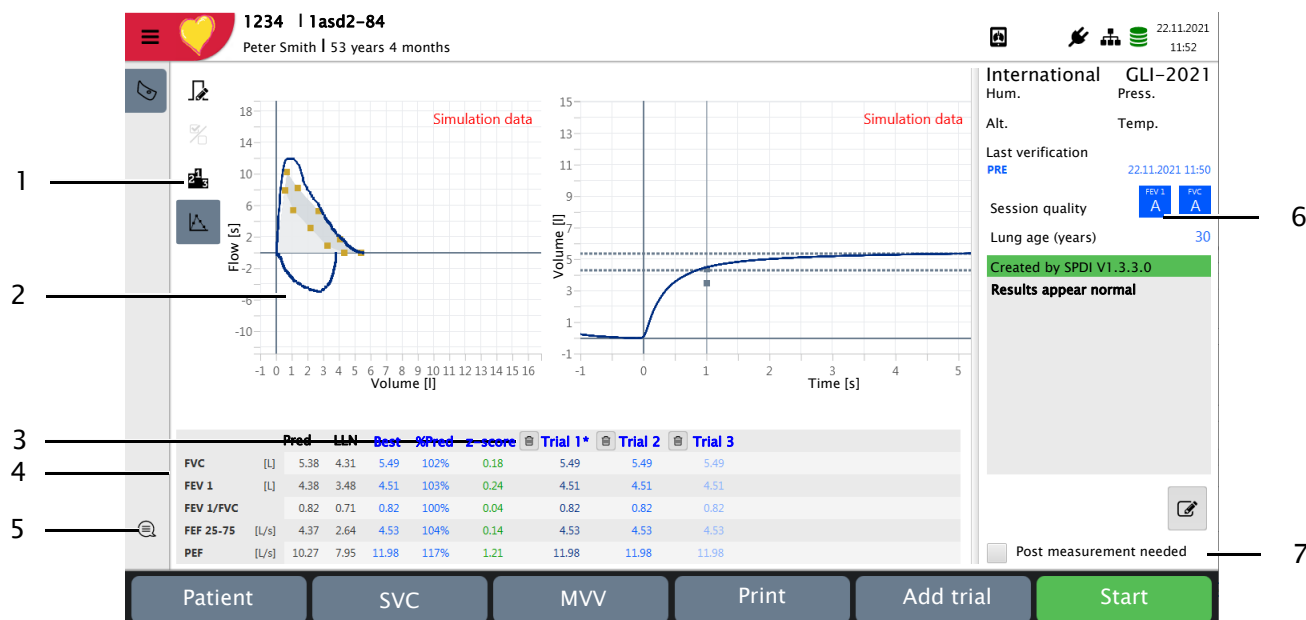
If **PRE** is selected, a new Pre measurement is recorded.

6. Tap **FVC** (or **SVC** or **MVV**) (only the same measurement type is available as for the Pre test)
7. The recording screen is opened. For the recording procedure: see section 3.6, p. 33 and following pages.

4 Review

4.1 Overview

After a trial, the results are displayed. The view depends on the measurement but some of the same elements are always present:



(1) Select the view:



Scaling (default settings: see section 6.2.3)



Switch between Pre and Post trials as well as Pre/Post comparisons, if Post trials are available



Select the displayed Pre trial if several Pre tests are available and only Pre trial is selected above: * = best trial, or trial 1 / 2 / 3



Show/hide predicted values (default setting: see section 6.2.1)

(2) Displayed curve(s) (see above)

(3) Delete a trial (see section 3.7.3)

(4) Measurement table (default setting FVC: see section 6.2.5; see also section 6.2.1)

(5) Add remarks

(6) Various information:

- Selected predicted values (see section 6.2.2)
- Last verification
- Date and time of the trial(s)
- Trial quality (Pre and Post, if available; see section 4.8)
- Lung age, if activated (see section 6.2.1)
- Interpretation including editing

(7) Activate Post measurement

4.2 Pre and Post measurements

In all views:

- Pre graphs (and the measurements in the table, and all associated information (for example session quality)), are shown in blue.
- Post graphs (and the measurements in the table, etc.), are shown in red.

Different combinations are possible when Pre and Post trials have been performed.

4.3 Best trial

In accordance with ATS/ETS 2019 Spirometry Standard, the best measurement is defined as follows:

largest sum of FVC + FEV1

The following values are replaced with the highest respective value from the three best manoeuvres:

FVC, FIVC, FEV (all parameters), FIV (all parameters), PEF, PIF. In addition, FET is taken from the largest FVC of the three best trials.



The best trial is indicated by an asterisk(*) in the measurement table and is the trial shown with a thicker line in the graphs.

4.4 Predicted values

The predicted values are calculated based on the patient's gender, age, height and weight, ethnicity, and the selected standards (see section 5, p. 57).

The %Pred value is given for both Pre and Post trials and is the percentage difference compared to the predicted value.

The %Diff value is the percentage difference between the Pre and Post measurements.

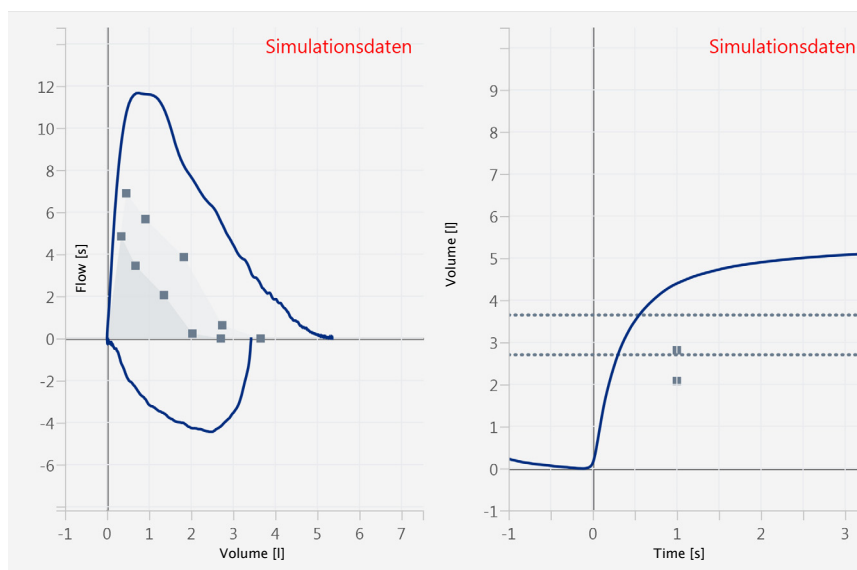


The predicted values (%) given on the report may differ slightly from the values that would be obtained if calculated manually. The reason is that the measured and predicted values on the printout are rounded to two decimal places, the processor however, uses the actual values – measured to three decimal places – to calculate the % of predicted value. This accounts for a possible variation.

In the FVC and SVC views (recording and results) LLN and predicted values can be superimposed if patient data has been entered and if activated in the settings (see section 6.2.1, p. 70: [Displaying predicted values in the graph](#)).

Tap the icon  to shown/hide the predicted values.

4.4.1 FVC



FVC flow curve (F(v)) (see above, on the left)

The shaded area shows the LLN values and specific predicted values are shown as dots:

- PEF – Peak Expiratory Flow

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The unit for PEF values is defined in the settings: l/s or l/min (see section 6.2.1, p. 70)

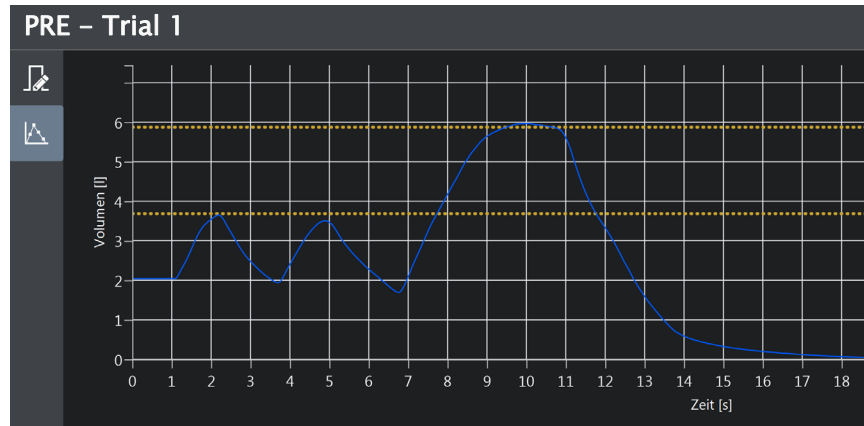
- FEF25/MEF75 – Flow speed of the expired air at 25% of forced vital capacity (FVC)
- FEF50/MEF50 – Flow speed of the expired air at 50% of FVC
- FEF75/MEF25 – Flow speed of the expired air at 75% of FVC
- FVC

FVC volume curve (V(t)) (see above right)

- FEV 1.0 – Flow speed of the expired air at one second

4.4.2 SVC

The upper line shows the ULN values (upper limit of normals), the lower line the LLN values for SVC



4.4.3 MVV

For MVV recordings, the predicted values and LLN are given in the measurement table at the bottom.

4.5 LLN

LLN = Lower limit of normal

A fixed cut-off point across the entire age range is not the best way to assess spirometry values; therefore, LLN is an alternative method to assess spirometry values. LLN is the lower fifth percentile of the Gaussian bell curve and 95 % of healthy people achieve higher results than the LLN value. (Note: there is still a risk of 5 % for false-positive results.)

LLN is calculated for every parameter and takes into account age, ethnicity, gender and height. If a spirometry value is lower than the LLN it is considered to be abnormal.

4.6 ULN

ULN = Upper Limit of Normals

The upper limit of normal (ULN) is the counterpart (opposite) to LLN (see above).

ULN is not used with FVC measurements, but might be relevant for SVC (lung volume). If a spirometry value is higher than ULN, it is considered to be abnormal.

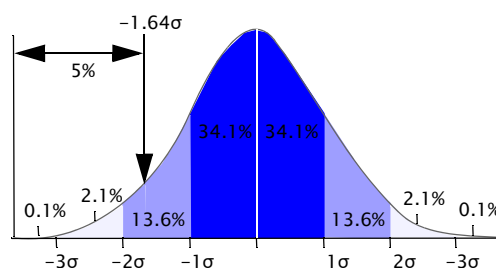
4.7 Z-score

The Z-score gives an objective indication of a statistical quality of the results.

In healthy subjects, spirometry data varies with age, height, gender and ethnicity. After taking these into account, we are left with the residual (measured – predicted value). If the residual is normally distributed, the average of residuals is 0.

The Z-score is another way of describing the LLN and is the number of standard deviations a certain value is above the mean value of the data set (the Z-score will be negative if the value is lower than the mean). A spirometry value is considered too low if it is more than -1.64 standard deviations from the predicted value (which is the same as the lower 5th percentile).

The advantage of Z-score is that it permits comparison of values between different populations.



4.8 Test quality (FVC/FEV1 and SVC)

The quality is assessed in accordance with ATS/ERS 2019 recommendations.

For FVC and SVC recordings, a quality level (F to A) is displayed after the trial. This quality level states whether the trial was acceptable. Quality levels A to C indicate reliable results. Quality levels D to F indicate poor test quality. Quality level A can only be achieved after at least 3 trials. See also section 4.1 above, point (5).



If the quality level indicates poor test quality (i. e. levels D to F), repeat the trial.



When Pre and Post trials are made, the session quality is given for both. As for graphs and measurements, the Pre session quality is shown in blue and the Post session quality is shown in red.

4.8.1 FVC and FEV1

Step	Criteria
A	- At least 3 acceptable tests AND - the difference between the two largest FEV1 and FVC values is less than or equal to 0.15 l; when age ≤ 6: 0.1 l or 10 % of the highest value of FVC or FEV1, whichever is greater
B	2 acceptable tests AND - the difference between the two largest FEV1 and FVC values is less than or equal to 0.15 l; when age ≤ 6: 0.1 l or 10 % of the highest value, whichever is greater
C	- At least 2 acceptable tests AND - the difference between the two largest FEV1 and FVC values is less than or equal to 0.2 l; when age ≤ 6: 0.15 l or 10 % of the highest value, whichever is greater.
D	- At least 2 acceptable tests AND - the difference between the two largest FEV1 and FVC values is less than or equal to 0.25 l; when age ≤ 6: 0.2 l or 10 % of the highest value, whichever is greater.
E	- At least 2 acceptable tests AND - the difference between the two largest FEV1 and FVC values is less than or equal to 0.25 l; when age ≤ 6: 0.2 l or 10 % of the highest value, whichever is greater 1 acceptable test
U	No acceptable test AND at least 1 usable test
F	No acceptable test AND no usable test

4.8.2 SVC

Step	Criteria
A	- At least 3 acceptable tests AND - the difference between the two largest SVC values is less than or equal to 0.15 l or 10 % of the highest SVC value; when age ≤ 6: 0.1 l or 10 % of the highest SVC value, whichever is smaller
B	2 acceptable tests AND - the difference between the two largest SVC values is less than or equal to 0.15 l or 10 % of the highest SVC value; when age ≤ 6: 0.1 l or 10 % of the highest SVC value, whichever is smaller
C	- At least 2 acceptable tests AND - the difference between the two largest SVC values is less than or equal to 0.2 l or 10 % of the highest SVC value; when age ≤ 6: 0.15 l or 10 % of the highest SVC value, whichever is smaller
D	- At least 2 acceptable tests AND - the difference between the two largest SVC values is less than or equal to 0.25 l or 10 % of the highest SVC value; when age ≤ 6: 0.2 l or 10 % of the highest SVC value, whichever is smaller
E	- At least 2 acceptable tests AND - the difference between the two largest SVC values is greater than 0.25 l or 10 % of the highest SVC value; when age ≤ 6: 0.2 l or 10 % of the highest SVC value, whichever is smaller, or 1 acceptable test
F	No acceptable test

4.9 Interpretation

Interpretation depends on the results as well as the patient data, reference values and compensation factors. It is therefore important that the patient data is entered correctly and settings, compensation factors and reference values are defined by the user. In particular the following will affect interpretation:

Patient data: age, height, weight, gender and ethnicity.

Interpretation and reference standards as well as ethnicity compensation factors are set in system settings (see section 6.2, p. 70).

An interpretation is displayed if:

- Patient data has been entered and if the patient data together with the selected standard deliver valid predicted values
- At least three trials have been performed

The interpretation can be edited by the user. In this case, the name of the user having edited the interpretation is given, i. e. **Created by Dr Smith**. See also section 4.1, point (6). This applies only when the **Security access Control** is set to **Local or Schiller server** (password and user name required).

Individual interpretation is given for Pre and Post tests, if available.

4.10 Lung age

Lung age is calculated based on the entered patient age and the ratio of predicted and measured values.

The lung age is displayed if activated in the spirometry settings (see section 6.2.1, p. 70: [Printing lung age](#)).

5 Diagnostics

5.1 Physician's responsibility

The interpretation and measurement program on SCHILLER devices is provided for the exclusive use of qualified physicians or personnel under their direct supervision. The numerical and graphical results and the interpretation of a recording must be examined with respect to the patient's overall clinical condition. The recording preparation quality and the general recorded data quality, which could affect the report data accuracy, must also be taken into account. It is the physician's responsibility to make the diagnosis or obtain expert opinion on the results and to institute correct treatment, if indicated.

5.2 Guideline

The guideline is selected in the settings (see section 6.2.2, p. 71):

- ATS/ERS 2019
- GRS 2015

5.3 Interpretation standard

The interpretation standard is selected in the settings (see section 6.2.2, p. 71):

- American/ITS
- International
- GOLD
- NICE
- NLHEP

5.3.1 American/ITS

For the USA and Canada, diagnosis of possible respiratory problems is based on the ITS interpretation standard which uses the LLN (Lower Limits of Normal) calculations. These calculations apply to patients between the age of 5 and 85. The LLN FEV1% value is calculated as follows:

Categorisation of airway obstruction

Predicted value minus measured value (%):

Category	Women			Men		
	FEV1 /FVC		FEV3 /FVC	FEV1 /FVC		FEV3 /FVC
Normal	<9.1	and	<5.4	<8.3	and	<4.6
Airway obstruction suggested	<9.1	and	≥5.4	<8.3	and	≥4.6
Mild	9.1	and	18.1	18.3	and	16.5
Moderate	18.2	and	36.3	16.6	and	33.1
Severe	≥36.4			≥33.2		

- If $FEV_{0.5}/FEV_1 < 0.60$, then state:
 - **Upper airway obstruction suggested**
- With the result $SVC/FVC > 1.10$ or $FIVC/FVC > 1.10$, the diagnosis is:
 - **Air trapping may be present**
- If there is an obstruction and expiration time < 5 s, the diagnosis is:
 - **Airway obstruction may be underestimated**
- If $FEV_{0.5}/FVC < 0.56$ s, the diagnosis is:
 - **Poor initial effort suggested**

Chest restriction categories

Predicted VC minus measured VC (litres)

Category	Women	Men
Normal	< 0.68	< 1.12
Mild restriction	0.68 to 1.18	1.12 to 1.95
Moderate restriction	1.19 to 1.69	1.96 to 2.79
Severe restriction	≥ 1.7	≥ 2.8

- If $FVC > SVC$, then $SVC = FVC$
- If $FIVC > SVC$, then $SVC = FIVC$

Ratio of Post/Pre

Category	FVC Post / Pre	or FEV 0.5 Post/ Pre ¹ or FEV 1.0 Post/Pre	or FEF25–75% Post/Pre ²
Markedly improved	≥ 1.25	≥ 1.25	≥ 2
Improved	1.15 to 1.24	1.12 to 1.24	1.45 to 1.99
Not clearly improved	1.05 to 1.14	1.05 to 1.11	1.10 to 1.44
Not improved	< 1.05	< 1.05	< 1.10

1. If expiratory time post/pre is > 1.10 , then FVC is not used because increased FVC may be due to the increased expiratory time, and not increased flow.
2. If the ratio of expiratory Post/Pre is < 0.90 and FVC Post/Pre is not between 0.96 and 1.04, then FEF25–75% is not used because reduced expiratory time and reduced FVC can increase the FEF25–75% without change in the flow itself.

5.3.2 International

Possible respiratory problems are diagnosed on evaluation of the following factors:

Diagnosis	FVC or SVC	FEV1%
Normal	>LLN	>LLN
Restrictive	<LLN	–
Obstructive	–	<LLN
Combined	<LLN	<LLN

The diagnostic settings are performed in the spirometry settings (see section 6.2.2, p. 71).

Diagnostic norms are predicted using the VC value (if taken). If VC values are not recorded, FVC is used. That is:

$$SVC = 100 \times \frac{SVC}{SVC_{\text{Predicted}}}$$

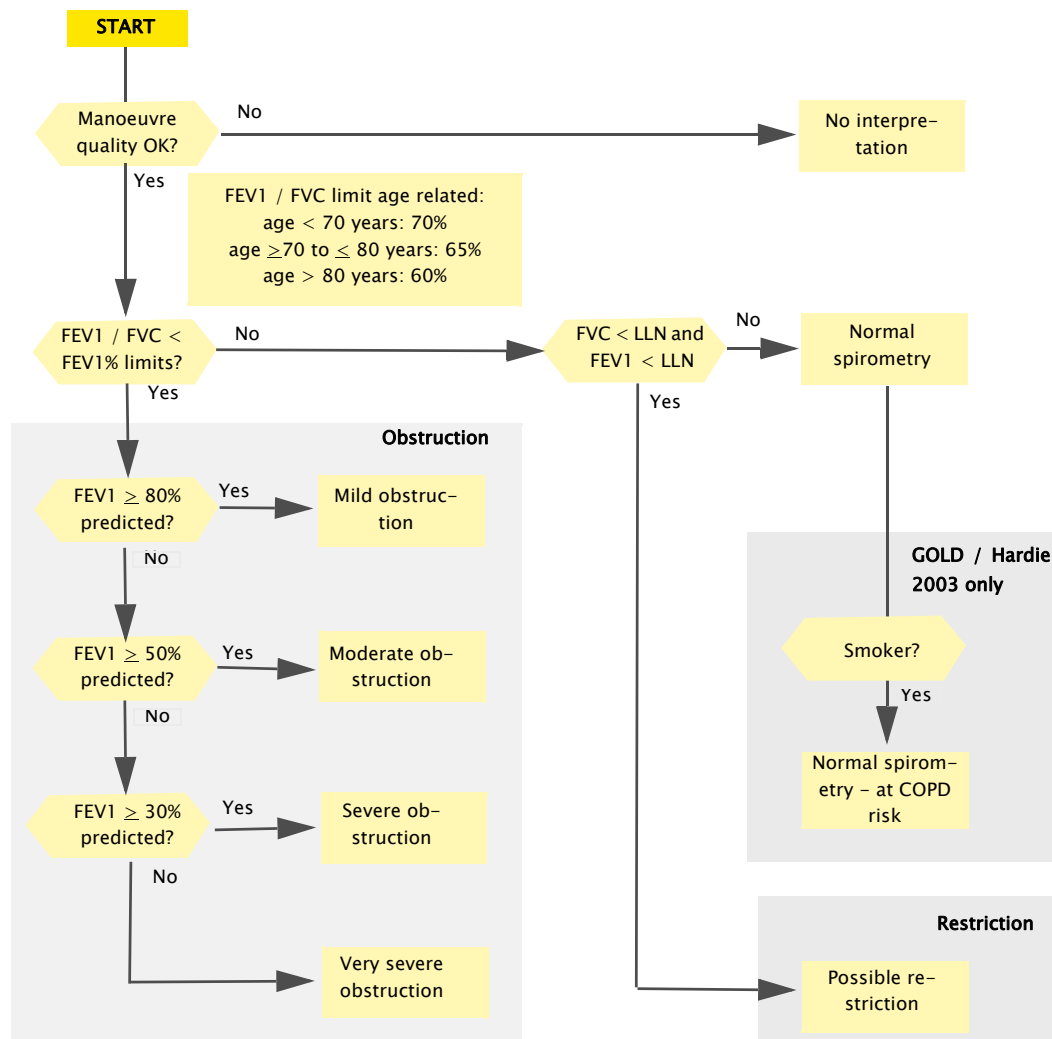
otherwise:

$$FVC = 100 \times \frac{FVC}{FVC_{\text{Predicted}}}$$

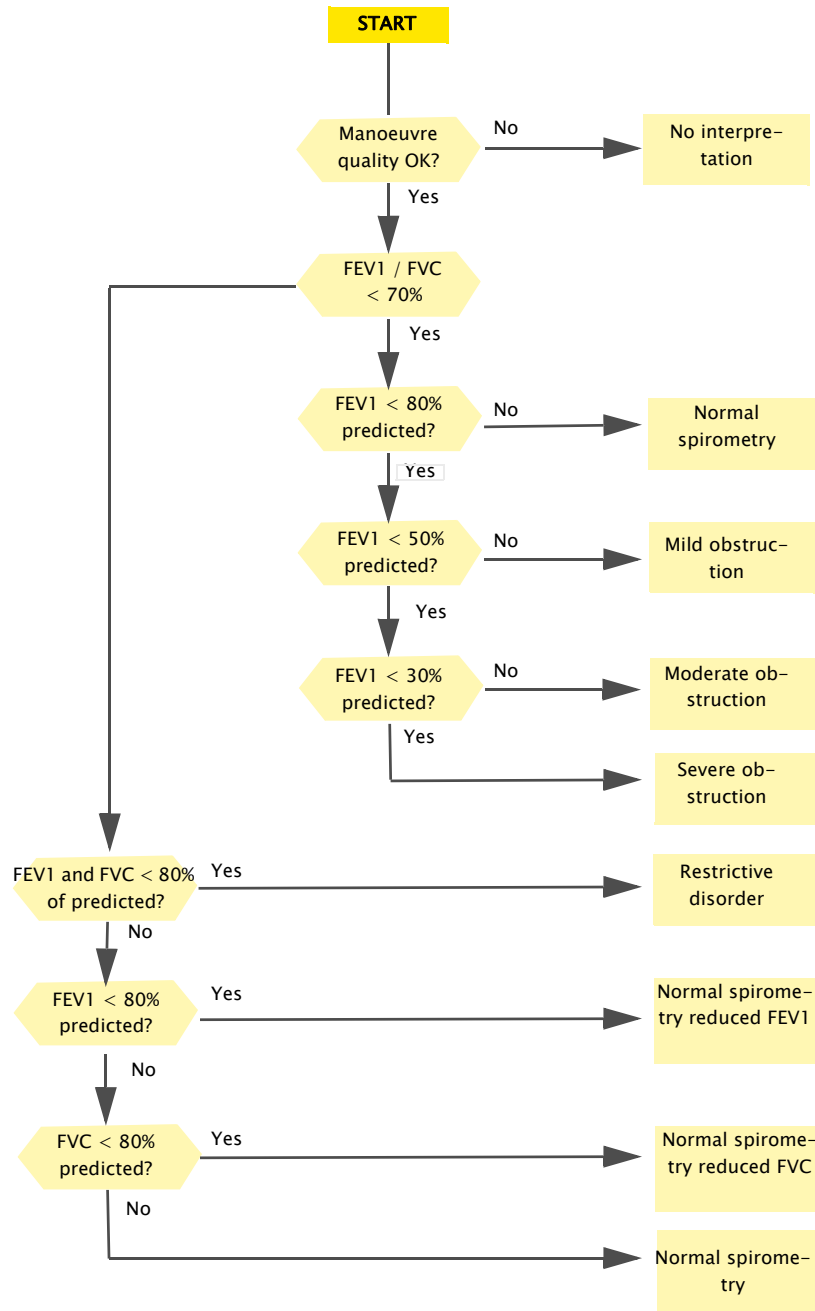
otherwise:

$$FEV1\% = 100 \times \frac{FEV1}{SVC} \quad \text{or} \quad 100 \times \frac{FEV1}{FVC}$$

5.3.3 GOLD/Hardie

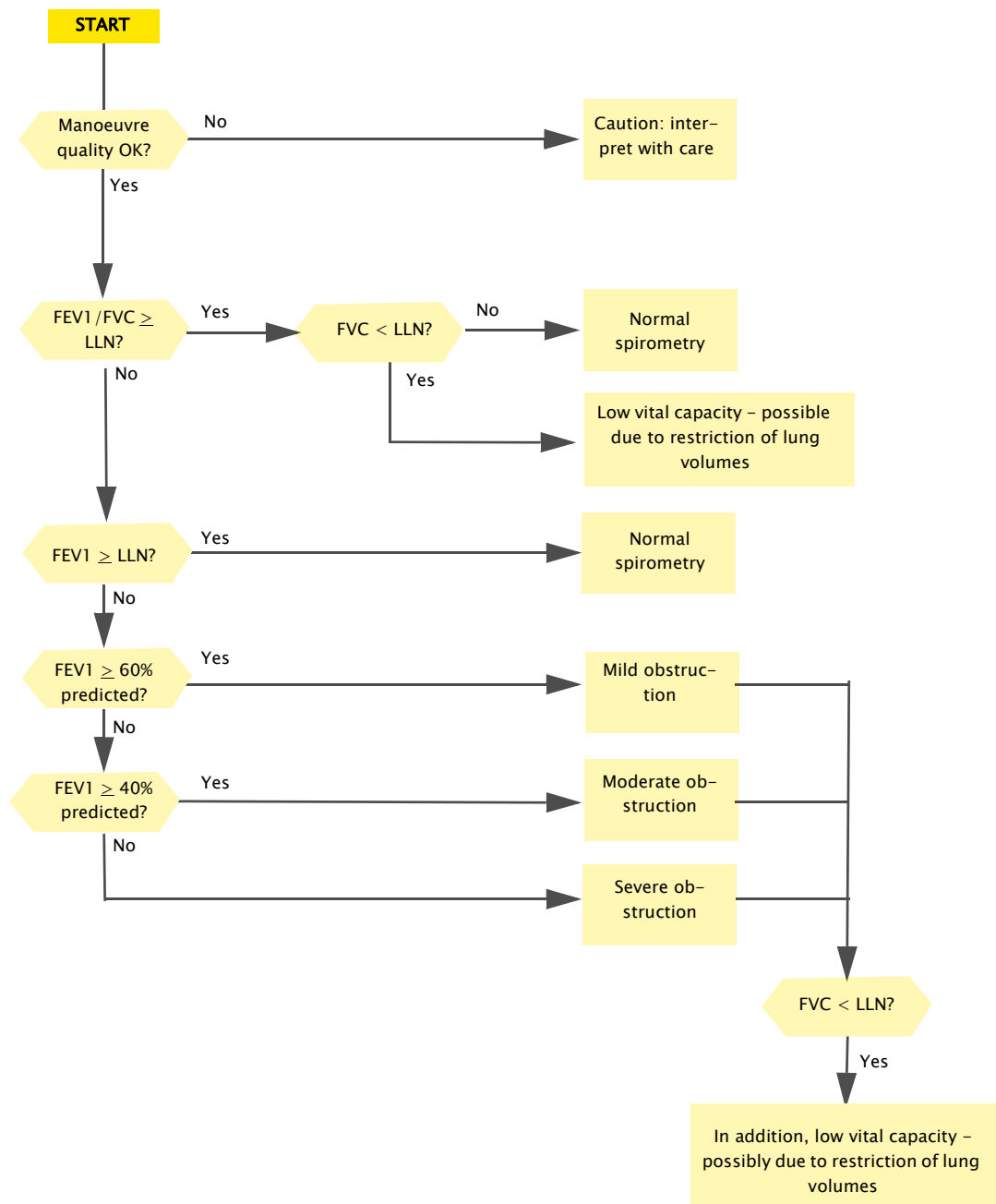


5.3.4 NICE



According to this algorithm, the NICE 2010 interpretation does not detect restrictive disorders. However, the CARDIOVIT FT-2 always identifies restrictive disorders if FVC and FEV1 < LLN and at the same time FEV1% > LLN.

5.3.5 NLHEP



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- If the selected predicted value does not define a lower limit of normal (LLN), LLN must be calculated as predicted value – $1.645 \times \text{RSD}$ (residual standard deviation). If RSD is not defined, the LLN for FEV1 / FVC must be set at 90% of the predicted value, the LLN for FEV1 at 80% of the predicted value and the LLN for FVC at 80% of the predicted value.
- If the quality grade is D and the results are within the limits, the interpretation will state: "normal spirometry, insufficient test quality, data not suitable for comparison".

5.4 Measurements

Parameter	Unit	Explanation
FVC	[l]	Forced (expiratory) Vital Capacity. Volume achieved by the quickest possible exhalation after a maximal inhalation.
FEV0.5, FEV0.75, FEV1, FEV3, FEV6	[l]	Forced Expiratory Volume. Lung volume in litres, measured after 0.5, 0.75, 1, 3 or 6 seconds forced expiration.
FEV0.5 / FVC, FEV0.75 / FVC		Forced expiratory air volume measured in the first 0.5/0.75 second as a percentage or ratio of forced vital capacity.
FEV1 / FVC, FEV3 / FVC		Forced expiratory air volume measured in the first/the first three second(s) as a percentage or ratio of forced vital capacity.
FEF	[l/s]	Forced Expiratory Flow. Flow in terms of differing lung volumes measured in litres per second.
FEF25 – 75	[l/s]	Flow speed of the expired air at 25 to 75% of the forced vital capacity (FVC).
FEF75–85	[l/s]	Flow speed of the expired air at 75 to 85% of the forced vital capacity (FVC).
FEF0.2 – 1.2	[l/s]	Averaged flow between 0.2 and 1.2 litres of the forced vital capacity (FVC)
PEF	[l/s]	Peak expiratory flow.
FEF25/MEF75	[l/s]	Flow speed of the expired air at 25% of the forced vital capacity (FVC).
FEF50/MEF50	[l/s]	Flow speed of the expired air at 50% of the forced vital capacity (FVC).
FEF75/MEF25	[l/s]	Flow speed of the expired air at 75% of the forced vital capacity (FVC). MEF75 = FEF25, MEF50 = FEF50, MEF25 = FEF75
ERV	[l]	Expiratory Reserve Volume. Possible further expiration starting from the normal expiration level.
IRV	[l]	Inspiratory Reserve Volume. Possible further inspiration starting from the normal inspiration level.
TV	[l]	Tidal Volume. Expiration and inspiration volumes during normal respiration.
SVC	[l]	Slow Vital Capacity. Lung volume measured from a complete expiration following a deep inspiration.
MV	[l/min]	Expired or Minute Ventilation. Volume of expired air in litres per minute measured over a minimum of one minute.
MVV	[l/min]	Maximum Voluntary Ventilation. Maximum volume of air which can be moved on expiration while breathing as deeply and as rapidly as possible.
RR	[/min]	Respiration Rate. Number of breaths per minute.
FIVC	[l]	Forced Inspiratory Vital Capacity. Inspiration volume achieved between a maximal expiration and a maximal inspiration.
FIV1	[l]	Forced inspiratory air volume in litres measured in the first second.
FIV 1 / FIVC		Forced inspiratory air volume measured in the first second as a percentage or ratio of forced inspiratory vital capacity.
FIV1 / FVC		Forced inspiratory air volume measured in the first second as a percentage or ratio of forced expiratory vital capacity.
PIF	[l/s]	Peak inspiratory flow. Maximum inspiratory flow speed in litres / second.

Parameter	Unit	Explanation
FIF50 (=MIF50)	[l/s]	Flow speed by 50% of the forced inspiratory vital capacity.
FET	[s]	Forced Expiratory Time: length of expiration in seconds.



This list of measurement values is provided to give an outline of the main measurements. The report may not give all of these values.

5.5 Reference values

The norm is set in system settings (see section 6.2.2, p. 71).



The ATS/ERS 2019 guidelines recommend using the GLI reference values.

5.5.1 Valid age range for norms

The valid age range is shown as minimum and maximum age (in years) as follows:

Description	Min. age	Max. age
Austria	7	70
Berglund	18	75
Composite	6	90
Crapo 1981/ITS	7	90
DR. Chhabra 2014	18	70
DR. Udwadia 1987	7	80
ECCS 1993/Quanjer	6	70
Forche 97	5	90
GLI-2012	3	95
Gore	18	78
Gulsvik	18	75
Hedenstroem	20	70
Indonesian	13	60
Kainu 2015	18	84
Knudson/ ITS	6	90
Knudson 76/ ITS	8	80
Koillinen 1998	6	90
Morris/ITS	20	90
Nhanes III	8	80
Pereira	6	80
Perez-Padilla 2006	40	90
Polgar/ITS	7	18
SEPAR	6	85
Thailand	10	75
Viljanen	6	65

5.5.2 Influences on predicted values

The predicted values can vary depending on the following factors:

- Age
- Height and weight
- Gender
- Selected standards
- Ethnicity

5.5.3 Ethnic correction factors for predicted values

The ethnic correction factor depends on the patient ethnicity, the ethnic correction factor defined in the settings see section 6.2.4, p. 71, and/or the selected predicted values, according to the table below.

If available, the correction factor (fixed or regression equation) defined in the selected norm will be used. Otherwise, the correction factor defined in the spirometry settings is applied:

Predicted values	Ethnicity			
	African	Hispanic	Asian	Other
Austria	Ethnic Corr	Ethnic corr.	Ethnic corr.	Ethnic corr.
Berglund	Ethnic corr.	Ethnic corr.	Ethnic corr.	Ethnic corr.
Composite	Specific factor or regression equation (age dependent)	Specific regression equation or Ethnic corr. (age dependent)	Specific factor or regression equation (age dependent)	Ethnic corr.
DR. Chhabra 2014	Ethnic Corr	Ethnic Corr	Ethnic Corr	Ethnic Corr
DR. Udwadia 1987	Ethnic corr.	Ethnic corr.	Ethnic corr.	Ethnic corr.
Crapo/ITS	Specific factor or regression equation (age dependent)	Specific regression equation or Ethnic corr. (age dependent)	Specific factor or regression equation (age dependent)	Ethnic corr.
ECCS/Quanjer	Specific regression equation or Ethnic corr. (age dependent)	Ethnic corr.	Specific regression equation or Ethnic corr. (age dependent)	Ethnic corr.
Forche 97	Ethnic corr.	Ethnic corr.	Ethnic corr.	Ethnic corr.
GLI-2012	Specific regression equation	Ethnic corr.	Ethnic corr. Other	Specific regression equation
Gore	Ethnic corr.	Ethnic corr.	Ethnic corr.	Ethnic corr.
Gulsvik	Ethnic corr.	Ethnic corr.	Ethnic corr.	Ethnic corr.
Hedenstroem	Ethnic corr.	Ethnic corr.	Ethnic corr.	Ethnic corr.
Indonesian	Ethnic corr.	Ethnic corr.	Ethnic corr.	Ethnic corr.
Kainu 2015	Ethnic corr.	Ethnic corr.	Ethnic corr.	Ethnic corr.
Knudson/ITS	Specific factor 85%	Ethnic corr.	Specific factor 85%	Ethnic corr.
Knudson 76/ ITS	Specific factor 85%	Ethnic corr.	Specific factor 85%	Ethnic corr.
Koillinen 1998	Ethnic corr.	Ethnic corr.	Ethnic corr.	Ethnic corr.
Morris/ITS	Specific factor 85%	Ethnic corr.	Specific factor 85%	Ethnic corr.
Nhanes III	Specific regression equation	Specific regression equation	Ethnic corr.	Ethnic corr.
Pereira	Ethnic corr.	Ethnic corr.	Ethnic corr.	Ethnic corr.
Peraz-Padilla 2006	Ethnic corr.	Ethnic corr.	Ethnic corr.	Ethnic corr.
Polgar/ITS	Specific factor 85%	Ethnic corr.	Specific factor 85%	Ethnic corr.

Predicted values	Ethnicity			
SEPAR	Ethnic corr.	Ethnic corr.	Ethnic corr.	Ethnic corr.
Thailand	Ethnic corr.	Ethnic corr.	Ethnic corr.	Ethnic corr.
Viljanen	Ethnic corr.	Ethnic corr.	Ethnic corr.	Ethnic corr.



If no ethnicity is selected, the predicted values are calculated based on the default ethnicity of the selected standard.

6 Settings



Default settings are shown **bold**.



In this spirometry supplement to the user guide, only spirometry settings are described in detail. For general and ECG settings: see CARDIOVIT FT-2 user guide

6.1 Overview

Open the menu **Settings**:



1. Tap the symbol **Main menu**



2. Tap the symbol **Settings**

The following sub-menus are available:

Menu	Sub-menus
General	Info
	Station
	Power management
	Workflow
	Memory
	Licenses
	Update
Regional	Date & Time
	Language
	Keyboard
	Units
Security	Patient ID system
	Access control
Connectivity	Automatic logout
	EMR integration
	Ethernet
Data fields	Wi-Fi
	Visible fields
	Mandatory fields (see 6.2.7 below)
	Custom fields
Reports	Worklist
	General
	PDF
	Header

Menu	Sub-menus
Printer	Internal printer
	External printer
ECG	Lead & cable
	Additional leads
	Filter
	Colours
	Preview
	Interpretation
	Manual printout
Resting ECG	Review
	Reports
Rhythm ECG	General
	Events
	Review
	Reports
Spirometry (see following)	General
	Standards
	Scale
	Ethnic correction
	FVC measurements
	Reports

6.2 Spirometry

6.2.1 General

Sub-menu	Selection	Description
Spirometry enabled	Active, Not active	Tick to activate spirometry measurements
SpiroDef	Active, Not active	Tick to activate measurement with the SpiroDef filter (Filter currently not available)
PEF unit	Litre/second , Litre/minute	
Show z-score	Active , Not active	Is shown in the measurement table
Show % prediction	Active , Not active	Is shown in the measurement table
Show lung age	Active , Not active	Is displayed and printed/in PDF
Show last verification	Active , Not active	Is displayed and printed/in PDF
Show prediction graph	Active , Not active	Predicted values are shown in the graph by default. However, the values can be manually hidden (see 3.7.1)
Incentive graph	V(t) chart , f(V) chart	Type of graph shown in the incentive screen (see 3.7.2)

6.2.2 Standards

Sub-menu	Selection	Description
Guideline	ATS/ERS 2019, GRS 2015	Select the spirometry guideline
Interpretation	American/ITS, GOLD, International, NICE, NLHEP	Select the interpretation standard (see 5.3)
Adult reference values	Various	Select the reference values for adults (see 5.5)
Paediatric reference values	Various	Select the reference values for children (see 5.5)
MVV formula	Predicted MVV, 25*FEV1, 35*FEV1	Select the MVV formula (see 5.5)

6.2.3 Scale

Sub-menu	Selection	Description
FVC Volume	5/10/20 mm/l	Default scaling for FVC volume
FVC Time	5/10/20/30/40 mm/s	Default scaling for FVC speed
SVC/MVV volume	5/10/20 mm/l	Default scaling for SVC/MVV volume
SVC/MVV time	5/10/20/30/40 mm/s	Default scaling for SVC/MVV speed

6.2.4 Ethnic corrections

Sub-menu	Selection	Description
	African Asian Hispanic Other	Define the correction factor for different ethnicities (see 5.5.3)

6.2.5 FVC measurements

Sub-menu	Selection	Description
	Various measurement values	Select the measurement values displayed for FVC. The first 5 selected values are displayed during the trial; all selected values are shown in the review screen; the first 8 selected values are given in the report.

6.2.6 Reports

Sub-menu	Selection	Description
		Selection and order of print formats for printed spirometry recordings. Tap the Scaling (symbol  on the right) to select the scale amplitude, if available.
Various print formats		



If several print formats have been selected, they are printed one after the other.

6.2.7 Mandatory fields

In the menu [Settings](#) > [Data fields](#) > [Mandatory fields](#) > [Spirometry](#), mandatory patient data is defined.

The following mandatory fields for spirometry cannot be deactivated: Date of birth, gender, ethnicity, height, weight.

6.2.8 Transmitting spiro PRE recordings

In the menu [General](#) > [Workflow](#) > [Transmit spiro PRE recordings](#), the user can choose to transmit spiro recordings with only a PRE medication test.

Such PRE recording is flagged on the server to require a POST recording. So if the user starts a spiro recording for the same patient, he/she is asked if a POST recording or a new PRE recording shall be performed.



This setting is only available if [Transmit after saving](#) is active.

7 Cleaning and Disinfection Sensor

7.1 Safety information SpiroScout SP plus

WARNING

- ▲ Switch the device off before cleaning and disconnect it from the mains by removing the plug.
- ▲ Observe the following safety notes when cleaning/disinfecting the device:
 - Never immerse the device or cabling in liquid.
 - Never pour or spray liquid directly onto the device.
 - Make sure that no liquid penetrates the connections or openings.
 - The device must not be autoclaved or sterilised with steam.
- ▲ Never use any of the following solutions or similar products to clean the equipment: ethyl alcohol, acetone, hexane, abrasive or scouring powder or material, any cleaning material that damages plastic.
- ▲ Unit connectors must not come in contact with soap or water. Do not immerse in liquid when cleaning. Do not spray the unit directly. Only clean the device and cables with a damp cloth slightly moistened (not wet) on the surface only.
- ▲ Always follow the instructions provided by the manufacturer of the detergent/disinfectant regarding use and dilution of the detergent/disinfectant.
- ▲ When cleaning, ensure that all labels and safety statements, whether etched, printed or stuck to the unit, remain in place and remain readable.
- ▲ Some patients have intolerances (e.g. allergies) to disinfectants or their components. If you have such a patient or you are not sure, remove possible residues with careful cleaning.
- ▲ The wearing of protective gloves (e. g. of butyl rubber) is recommended.
- ▲ Damage to the cable due to mechanical stress:
 - When disconnecting a cable, pull the plug and not the cable
 - Route the cable so as to help prevent people from tripping or the cable being run over by, for example, the trolley

CAUTION

- ▲ Risk of cross-contamination:
 - Do not use the ScoutTube and disposable nose clip for more than one patient
 - Do not re-use the ScoutTube and disposable nose clip
 - After use, dispose of the ScoutTube and disposable nose clip in the clinical waste
 - see section 3.2, p. 22

7.2 Manufacturing Materials SpiroScout SP plus

PC polycarbonate is used in the construction of the SpiroScout SP plus. Only use cleaning materials that are compatible. All materials according to EN ISO 10993-1 / -5 / 10 are tested on the finished product.

With time, the device casing may become less resistant for the following reasons:

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

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

7.3 Cleaning Interval

The SpiroScout SP plus comes into contact with the patient, and it is recommended that it is cleaned after each use. If there is any visible soiling the device must be cleaned immediately.

7.4 Cleaning / Disinfecting



- ▲ Observe the following safety notes when cleaning/disinfecting the device.
- Switch the device off before cleaning
- Never immerse the device or cabling cable in liquid
- Never pour or spray liquid directly onto the device
- Make sure that no liquid penetrates the connections or openings
- The device must not be autoclaved or sterilised with steam

Before cleaning/disinfecting the unit thoroughly inspect for any signs of damage.



- ▲ Do not spray the device directly.
- ▲ Make sure that no liquid penetrates the device.



- ▲ With the ScoutTube removed wipe the SpiroScout SP plus with a damp cloth **slightly moistened (not wet)** with one of the approved cleaning solutions. Clean cable assemblies by gently wiping from the centre of the cable.

Use a clean lint-free cloth moistened with detergent and wipe the unit to clean.

Wipe off any excess cleaning solution. Do not let the cleaning solution run into or accumulate in connector openings or crevices. If liquid penetrates the device or connectors this can interfere with correct functioning: dry the area with warm air, and then check the equipment to confirm that it operates properly. Leave the device and sensors in a warm, dry room for 48 hours and then check the equipment to confirm that it operates properly. If the functioning is still affected, contact SCHILLER.

7.5 Approved Cleaning Solutions

The list of cleaning solutions and disinfectants are provided as a general guide. If in doubt about the suitability of a cleaning solution or disinfectant, check that the solution is suitable for the materials used in the construction of the sensor assembly PC/ ABS (polycarbonate-ABS) / Polyethylene. The following can be used:

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

Also see PDD_03_06_GME_Hygieneanweisung_rev10_EN and publications of the Robert-Koch Institute (RKI):

- https://www.rki.de/DE/Content/Infekt/Krankenhaushygiene/Desinfektionsmittel/desinfektionsmittel_node.html.

Recommended

SCHILLER recommends the following

Cleaning Solution Manufacturer

Descogen I	Antiseptica chem.-pharm. Produkte GmbH
Bodedes forte	Bode Chemie

7.6 Cleaning Materials that must not be used

Never use products containing the following:

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

7.7 Disinfection

Use commercially available disinfectants intended for clinics, hospitals and practices to disinfect the device. Disinfect in the same way as described for cleaning ([previous page](#)).

7.7.1 Admissible Disinfectants

- Isopropyl alcohol 50%
- Propanol (35%)
- Ethyl hexanal
- Aldehyde (2–4%)
- Ethanol (50%)
- all products that are suitable for PC/ABS plastic

Recommended

GANSHORN recommends the following

Disinfectant	Manufacturer
Descogen I	Antiseptica chem.-pharm. Produkte GmbH
Gigasept FF	Schülke und Mayr GmbH
Lysetol V1	Schülke und Mayr GmbH
Sekusept Forte S1	Ecolab
Korsolex Basic	Bode Chemie
Korsolex Extra	Bode Chemie
Celanispet Wipes	Dr. Schuhmacher
Mikrozid AF wipes	Schülke und Mayr GmbH
Mikrozid universal wipes premium	Schülke und Mayr GmbH

7.7.2 Non-admissible Disinfectants

Never use products containing the following:

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



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

8 Maintenance and disposal



Maintenance work not described in this section may only be performed by a qualified service technician authorised by SCHILLER AG. In the following sections, the interval and responsibility for maintenance work is detailed. Local regulations in your country may stipulate additional or different inspection intervals and tests:

- Check and observe the country's regulations in which the device is used.



The **Maintenance** menu (symbol  in the main menu) is only accessible by service technicians. A password is required to access the settings. For more details on this menu, see the CARDIOVIT FT-2 service manual (Art. no. 2.540117).

8.1 Overview

Intensity	Task
Before each use	Visual inspection (see section 8.2, p. 78) by the user
Every 6 months	• Visual inspection (see section 8.2, p. 78) by the user • Functional test (see section 8.3, p. 78) by the user
At regular intervals	• The system must be verified on a regular basis see section 3.3, p. 23. No other periodic maintenance is required for the SpiroScout SP plus and the connected device. • Further periodic preventive inspection and maintenance action are to be performed by a qualified service personal. Please contact your local dealer for further information.
Approx. every 4 years, or if operation is substantially less than 1 hour	Have the battery replaced by a qualified service technician authorised by SCHILLER AG

8.1.1 Service life of the SpiroScout SP plus

Definition: “End of Life” – EoL / Life time of the product

The service life of the product has been specified as 10 years when used as intended and in compliance with maintenance and inspection specifications.

8.2 Visual inspection



- ▲ Danger of electric shock due to damaged device, cable or accessory:
 - Immediately replace a defective device, defective cables and/or accessories

During visual inspection, check the following parts for damages, wear and cracks:

- Casing
- Cable assemblies
- Power supply unit
- Plug and socket connectors
- Touch screen
- Casing, connectors and cable of the SpiroScout SP plus

In addition:

1. Switch on the device.
2. Randomly perform some functions.

In this way, the correct functioning of the device and touch screen is tested.

8.3 Functional test

The functional test is performed every 6 months, or according to country-specific regulations.



If a test is not passed (see checklist below):

Do no longer use the device and contact the person responsible:

Name, phone number:

SpiroScout SP plus

A functional check of the SpiroScout SP plus is carried out by performing a verification procedure (see section 3.3, p. 23)

Checklist

Serial number CARDIOVIT FT-2: _____

Task	Result	Date
Visual inspection (see section 8.2)	Casing not damaged ☐	☐
	Cable assembly intact ☐	☐
	Plug and socket connectors intact ☐	☐
	Power supply unit intact ☐	☐
	Touch screen intact ☐	☐
Check the mains lead	Available and intact ☐	☐
Check the user guide	Available in the correct language and legible ☐	☐
Functional test (see above)	Successful SpiroScout SP plus verification ☐	☐

Carried out by: _____

8.4 Trouble shooting

Error	Cause/note	Remedy
Button Spirometry not available for start of recording	Spirometry not activated	Activate Spirometry: Settings > Spirometry > General > Spirometry enabled
No sensor connected: 	Spirometry sensor not (correctly) connected	Connect the spirometry sensor (see sections 2.1 and 2.3)
Volume verification not possible or fails	Temperature, humidity or pressure incorrect	Enter correct ambient values
	Calibration pump malfunction (e. g. piston leak, damaged)	Repeat the verification with another calibration pump
	Spirometry blockage (e. g. debris in the sensor or blocked by user's hand)	1. Make sure that the sensor/ScoutTube is not blocked 2. Repeat the verification
	Differences between room temperature and calibration pump temperature	Always keep the calibration pump at room temperature

Error	Cause/note	Remedy
Too much deviation during volume verification	Incorrect volume defined for the calibration pump	1. Enter the correct volume 2. Repeat the verification
	Pump not fully filled or emptied	Repeat the verification while fully filling and emptying the pump
	Pump speed too fast or too slow	Repeat the verification while following the instructions shown on the display
	Leak in the connection between the calibration pump and the spirometer	Check that the pump, adapter and ScoutTube are fully connected with no air leaks
	Improper assembly of the calibration pump and the spirometer	Check that the pump, adapter and ScoutTube are fully and properly connected with no air leaks (see section 3.3.3, p. 25)
		see section 3.3, p. 23
		If still no successful verification is possible: contact SCHILLER

8.5 Disposal



- ▲ Danger of explosion:
 - Do not burn the battery
 - Do not dispose of the battery in the household waste
- ▲ Danger of acid burns caused by materials contained in the battery:
 - Do not open the battery
- ▲ Danger to the environment due to improper disposal:
 - Dispose of packaging material, device, battery and accessories according to the country's regulations in which the device is used
- ▲ Risk of cross-contamination:
 - Do not reuse disposable accessories marked with the symbol 
 - After use, dispose of disposable accessories marked with the symbol  in the hospital waste
 - ScoutTube and nose clips are single-use disposables
 - The customer is obliged to establish a quality management system for the handling of contaminated waste. The pertinent risk analysis must include the accessories and consumables, especially the disposables intended for single use.



The battery must only be removed by SCHILLER.

Device including battery and accessories no longer used must be disposed of in a municipally approved collection point or recycling centre for electronic devices.

Alternatively: return the device including battery and accessories to SCHILLER (see page 2).

Dispose of packaging materials in a municipally approved collection point or recycling centre.

8.6 Electromagnetic interferences



- ▲ Interference caused by radiated high-frequency electromagnetic energy:
- Use the device in accordance with the user guide
 - Use portable high-frequency telecommunication devices in a distance of at least 0.3 meters to the CARDIOVIT FT-2 including sensor and cables
 - Do not place the CARDIOVIT FT-2 on top of other electric/electronic devices

The distance depends on the output performance of the communication device:

High-frequency source/telecommunication device	Transmitted 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-talkie (FRS)				
Rescue, police, fire brigade, maintenance (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	1700–1990	1720/1845/1970	2	0.3
UMTS				
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

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

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

where:

d = minimum distance in meters

P = transmitted power in Watts



For further information: see service manual CARDIOVIT FT-2 article number: 2.540117.

Measures to prevent interferences

- Shut down the device
- Stop data transmission
- Increase distance to the source of interference (see above)
- Observe the minimum distance of 20 cm to a pacemaker
- Turn the device to change the angle of radiation
- Connect the device to a different mains connector
- Connect the potential equalisation cable
- Only use original accessories
- Immediately replace defective cables
- Correctly connect cables
- Observe the maintenance intervals as stated in section 8.1

8.7 Accessories and disposables



- ▲ Danger to the patient as well as risk of the warranty becoming invalid if accessories or disposables are used that are not approved:
- Only use accessories and disposables approved by SCHILLER.

Accessories and disposables are available from the local SCHILLER representative or directly from SCHILLER (see page 2).



For general and ECG accessories: see CARDIOVIT FT-2 user guide

Spirometry

Part No.	Label	Description
1.500041	SpiroScout SP plus	SpiroScout SP plus complete, incl. ScoutTube (50 pieces) and nose clip (50 pieces)
2.101123	ScoutTube	ScoutTube (50 pieces)
2.101218	Nose clip	Nose clip (28 pieces)
2.000202	Hans Rudolph Calibration Kit	With the following parts included:
2.100976	Hans Rudolph calibration syringe	Calibration pump, 3 litres
4.430384	Adapter for Hans Rudolph pump	Adapter for calibration pump
4.310728	SpiroScout SP Plus holder	Holder for SpiroScout SP plus

9 Technical data



For general and ECG data: see CARDIOVIT FT-2 user guide

The ambient conditions for disposables (nose clip, ScoutTube, thermal paper) may vary from the values stated below. Refer to the disposables' packaging for more detailed information.

9.1 SpiroScout SP plus



The operating conditions for the SpiroScout SP plus might differ from the CARDIOVIT FT-2 operating conditions (see the CARDIOVIT FT-2 user guide). The operating conditions of the system are defined by the most restrictive values.

Feature	Value/description
Dimensions	15 cm x 5 cm x 9 cm (W x H x D)
Operating conditions	• Temperature: +15 to +35 °C • Relative humidity: 10 to 95 % (non-condensing) • Pressure: 700 to 1060 hPa
Transport and storage conditions	• Temperature: -20 to +50 °C • Relative humidity: 10 to 95 % (non-condensing) • Pressure: 600 to 1060 hPa
Measuring method	Ultrasonic
Airway resistance	0.002 kPa/l/s = approx. 0.02 cmH ₂ O/l/s
Dead space complete	18 cm ³
Mouthpiece	• ScoutTube: Single-patient use, disposable breathing insert with ergonomically shaped mouthpiece and standard cone 22 mm.
Power supply	Powered via USB
Measurement ranges	Flow: 0 to ± 18 l/s Volume: no limit
Measurement accuracy	Flow: ± 2 % or 50 ml/s (for a flow from 0 to 16 l/s) Volume: ± 2 % or 50 ml
Temperature drift	Max.: ± 2 %
Classification	Device: Active medical product, class IIa Applied part: Type BF

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