CARDIOVIT CS-104

User Guide

Art. no.: 2.511335 Rev. a

Sales and Service Information

The SCHILLER sales and service centre network is worldwide.

For the address of your local distributor, contact your nearest SCHILLER subsidiary. In case of difficulty a complete list of all distributors and subsidiaries is provided on our Internet site:

http://www.schiller.ch

Sales information can also be obtained from:

sales@schiller.ch

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SCHILLER
The Art of Diagnostics

Contents

Art. no.: 2.511335 Rev. a

Art. no.: 2.511335 Rev. a

Art. no.: 2.511335 Rev. a

Art. no.: 2.511335 Rev. a

Art. no.: 2.511335 Rev. a

Art. no.: 2.511335 Rev. a

Art. no.: 2.511335 Rev. a

Art. no.: 2.511335 Rev. a

Art. no.: 2.511335 Rev. a

Art. no.: 2.511335 Rev. a

1 Safety Notes

1.1 Intended Use

- The CARDIOVIT CS-104 is a 12-lead ECG and Spirometry (option) system intended to be used by trained medical professionals in healthcare facilities for cardiological diagnosis in adult and paediatric patients.
- Analysis of the ECG and Spirometry is accomplished with algorithms that provide measurements, data presentations, graphical presentations, and interpretations for review by the user.

1.2 Indication for Use

- The CARDIOVIT CS-104 is a 12-lead ECG device intended to acquire ECG signals from body surface electrodes, and record, analyse and display ECGs for cardiological diagnosis in adult and paediatric patients.
- Using the optional spirometry module and the associated accessories, the CARDIOVIT CS-104 is intended to record, analyse, display and print measures and waveforms of pulmonary function tests for the diagnosis of lung diseases in adult and pediatric patients able to understand the test instructions.

1.3 Optional Use

- The following options can be sold with the CARDIOVIT CS-104:
  - Exercise ECG (standard in some configurations)
  - Arrhythmia detection: detection of arrhythmias during exercise tests and resting rhythm acquisition.
  - Vector ECG: provides a 3-dimensional view on the electrical activity, and adds value to the diagnostic of the hearts backside
  - Spirometry Test: Indicated to assess patient's pulmonary health status and evaluate symptoms, signs, or abnormal laboratory test results. The spirometry module analyses flow/volume and volume/time waveforms recorded during pulmonary function tests. (standard in some configurations)

1.4 Characterisation of Users

- The CARDIOVIT CS-104 is intended to be used by trained medical professionals or under direct supervision of a licensed health care practitioner, in hospitals, clinics, physician offices and outreach centres.

1.5 Characterisation of Patients

- The CARDIOVIT CS-104 is intended to be used for adult and paediatric patients.
- The CARDIOVIT CS-104 is intended to be used as a spirometry system for adult and paediatric patients able to understand test instructions

Art. no.: 2.511335 Rev. a

1.6 Contraindications

▲ The CARDIOVIT CS-104 is not designed:
- 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.

1.7 Responsibility of the User

▲ The CARDIOVIT CS-104 with the MS-12 ECG Recorder or SpiroScout must only be used by qualified physicians or trained medical personnel.

▲ The numerical and graphical results and any interpretation given must be examined with respect to the overall clinical condition of the patient and the general recorded data quality.

▲ Ensure that personnel have read and understood these operating instructions. In particular this section safety notes must be read and understood.

▲ The operator is responsible for compliance with all applicable accident prevention regulations and safety regulations.

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

1.8 Organisational Measures

▲ Observe the operating and maintenance instructions. Keep all instructions in an accessible place for reference when required. Make sure that they are always complete and legible.

▲ In addition to this user guide, legal and other binding regulations for the prevention of accidents and for environment protection must be observed

1.9 Safety Facilities

▲ Operating the device without the correctly rated fuse or with defective cables constitutes a danger to life! Therefore:
- Do not operate the unit if the earth connection is suspect or if the mains lead, the power supply unit or the device is damaged or suspected of being damaged.
- Damaged cable connections and connectors must be replaced immediately.
- Electrical safety devices, such as fuses, must not be modified.
- Fuses must only be replaced with the same type and rating as the original.

Art. no.: 2.511335 Rev. a

1.10 Safety-Conscious Operation

- The CARDIOVIT CS-104 is CF classified. It is defibrillation protected only when the SCHILLER original patient cable is used. As a precaution however, when possible remove the electrodes before defibrillation.
- Ensure that the patient is informed about the procedure for stress testing and is aware of the risks (for example, of falling on a running treadmill). Ensure the patient is aware of the location and use of the emergency stop knob when using a treadmill.
- Do not touch the unit casing during defibrillation.
- To ensure patient safety, none of the electrodes, including the neutral electrode, nor the patient or any person with simultaneous patient contact, must come in contact with conductive parts, even when these are earthed.
- There is no danger when using the device for a patient with a pacemaker fitted. However, data transmission modules could affect the pacemaker functionality. To prevent a pacemaker malfunction, a distance of at least 25 cm must be kept between the device and the pacemaker as soon as the Bluetooth module is activated.
- Do not place any liquids on the unit.
- Only use the original SCHILLER patient cable and only use accessories and disposables recommended or supplied by SCHILLER. Use of other than recommended or supplied parts may result in injury, inaccurate information and/or damage to the unit.
- If the patient cable should become defective after defibrillation, an electrode becomes displaced, or an electrode resistance is too high, a lead-off indication is displayed.
- Precautions for Bluetooth pairing:
  - ensure that no two sensor pairing processes are started simultaneously to prevent incorrect pairing, and
  - ensure that only one recorder is in range of the receiver during advertising/pairing.

1.11 Trolley Installations - Transporting & Placement

- Be cautious when moving the Trolley. Quick stops, excessive forces and uneven surfaces may cause the trolley to overturn thus risking the unit to fall to the ground.
- If the unit falls to the ground, turn the power off immediately and disconnect from the mains. Contact a SCHILLER approved service centre. Continual use of the unit can result in fire or electric shock.

Art. no.: 2.511335 Rev. a

1.12 Maintenance

- ▲ No serviceable parts inside the CARDIOVIT CS-104 nor the ECG Recorders or SpiroScout. Refer servicing to a qualified technician authorised by SCHILLER only.
- ▲ Do not use high temperature sterilisation processes (such as autoclaving). Do not use E-beam or gamma radiation sterilization.
- ▲ Do not use solvent or abrasive cleaners on either the unit or cable assemblies.
- ▲ Do not under any circumstances, immerse an ECG recorder, SpiroScout, or any cable assembly in liquid.

1.13 Operation with other Devices

- ▲ Accessory equipment connected must be certified according to the respective IEC standards (e.g. IEC/EN 60950 for data processing equipment and IEC/EN 60601-1 for medical equipment). Furthermore, all configurations shall comply with the valid version of IEC/EN 60601-1. Everybody who connects additional equipment to the signal input part or signal output part configures a medical system and is therefore responsible that the system complies with the requirements of the valid version of IEC/EN 60601-1. If in doubt, contact the technical service department or your local representative.
- ▲ Any other equipment used with the patient must use the same common earth as the CARDIOVIT CS-104.
- ▲ Special care must be exercised when the unit is used with high-frequency equipment. Use the special high-frequency SCHILLER patient cable to avoid possible signal interference during ECG acquisition. However, the stimulation units should only be used at a sufficient distance from the electrodes and both devices must be connected to the same potential equalisation. If in doubt, the patient should be disconnected from the device.
- ▲ This device can safely be used with pacemaker patients.
- ▲ There is no danger when using this device simultaneously with electrical stimulation equipment.
- ▲ If the device is part of a medical system, only the original SCHILLER patient cable must be used with, and connected to, the CARDIOVIT CS-104.
- ▲ If the patient cable should become defective after defibrillation, a lead-off indication is displayed on the screen.
- ▲ Portable communication devices, HF radios and devices labelled with the  symbol (non-ionic electromagnetic radiation) can affect the operation of this device (see para. 18.10, Measures to Prevent Electromagnetic Interferences, page 163).

Art. no.: 2.511335 Rev. a

1.14 Extra Precautions for Spirometry

- In order to obtain correct predicted values and diagnosis, it is important that all patient data is entered correctly. In particular gender, date of birth, ethnic, height and weight must be entered.
- The unit must be calibrated before the first pulmonary function test of the day and after every significant temperature change.
- False measurements can result when the sensor is not held vertically - ensure that the sensor is held upright at all times.
- The disposable mouthpiece of the **SpiroScout sensor** is designed for one-time use to eliminate the danger of cross contamination - do not use the mouthpiece for more than one patient  . Do not attempt to clean the mouthpiece.
- See the CARDIOVIT CS-104 Spiro User Guide for full safety precautions.

1.15 Electrical and Power Source Related

- To avoid the risk of electric shock, this equipment must only be connected to a mains supply with protective earth.
- Operating the device without the correctly rated fuse, or with defective cables, constitutes a danger to life. Therefore:
  - Do not operate the unit if the earth connection is suspect or if the mains lead is damaged or suspected of being damaged.
  - Damaged cable connections and connectors must be replaced immediately.
  - The electrical safety devices, such as fuses, must not be altered.
- Ruptured fuses must only be replaced with the same type and rating as the original.
- Only use power cords provided by the dealer to ensure safety and EMC compliance.
- The CARDIOVIT CS-104 unit must be connected to an approved power source as shown on the specification label.
- The power cords must not be damaged. Applied pressure, heat, and stress can damage the power cord.
- The power cords must be routed properly so as to help prevent people from stepping on the cords or the cords being run over by, for example, the trolley
- Do not overload the mains outlet or extension cords. Electrical shocks or fires may occur from overloading.
- Do not touch the power source during a thunderstorm.
- If your hands are wet, do not touch the plug.
- Do not pull the power cord to remove it from the mains socket because this can damage the cable. Use your thumb and index finger to grip the plug itself.

Art. no.: 2.511335 Rev. a

1.16 Network Security

- ▲ It must be ensured that appropriate security measures are installed to protect the transmission of data.
- ▲ Security of the network is the sole responsibility of the network operator.
- ▲ SCHILLER takes no responsibility for the configuration of Windows.
- ▲ In order to guarantee the security of the network, Schiller AG recommends the following:
  - –defining access authorisation for the configuration of the host system so that no unauthorised alterations of the system are possible.
  - –installing the latest antivirus/firewall programs in order to prevent malware from affecting the system
  - –regularly installing security and software updates
  - –apply “Risk management of IT-networks” according IEC 80001-1.

1.17 Terms of Warranty

Your SCHILLER CARDIOVIT CS-104 is warranted against defects in material and manufacture, as stated in the general Terms and Conditions. Excluded from this warranty is damage caused by an accident or as a result of improper handling. The warranty entitles to free replacement of the defective part. Any liability for subsequent damage is excluded. The warranty is void if unauthorized or unqualified persons attempt to make repairs.

In case the device is defective, send it to your local SCHILLER representative or directly to the manufacturer. The manufacturer can only be held responsible for the safety, reliability and performance of the device if:

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

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

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

Art. no.: 2.511335 Rev. a

1.18 Additional Statements

FCC statement

This equipment has been tested and found to comply with the limits for a class A digital device, pursuant to both Part 15 of the FCC (Federal Communications Commission) Rules and the radio interference regulations of the Canadian Department of Communications. These limits are designed to provide reasonable protection against harmful interference when the equipment is operated in a commercial environment. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with this instruction manual, may cause harmful interference to radio communications. Operation of this equipment in a residential area is likely to cause harmful interference in which case the user will be required to correct the interference at his own expense.

This device contains FCC ID: **Z64-WL180DBMOD**

When using the WiFi networking option, operation of this equipment requires the prior coordination with a frequency coordinator designated by the FCC for the Wireless Medical Telemetry Service.

This device complies with Part 15 of the FCC rules. Operation is subject to the following conditions:

- This device may not cause harmful interference.
- This device must accept any interference received, including interference that may cause undesired operation.

⚠ CAUTION

▲ Any changes or modifications to this equipment not expressly approved by SCHILLER may cause harmful radio frequency interference and void your authority to operate this equipment.

▲ Within the 5150 to 5250 MHz band (5 GHz radio channels 34 to 48) the module type cB-0941 is restricted to indoor operations to reduce any potential for harmful interference to co-channel MSS operation.

Art. no.: 2.511335 Rev. a

1.19 Safety Symbols and Pictograms

1.19.1 Symbols Used in this Document

The safety level is classified according to ANSI Z535.4. The following overview shows the safety symbols and pictograms that may be used in the software or this handbook.

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

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

⚠ CAUTION — For possibly dangerous situations that could lead to personal injury. This symbol is also used to indicate possible damage to property.

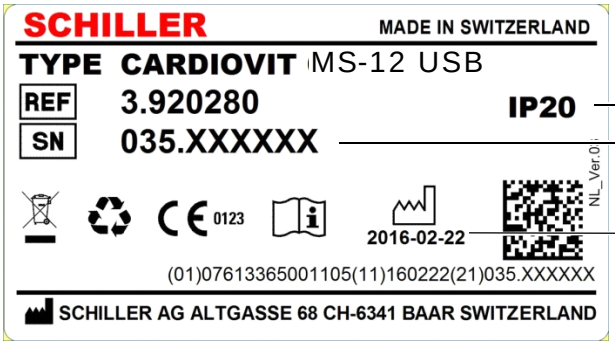
 For general safety notes as listed in this chapter.

 Important or helpful user information or safety information.

1.19.2 Symbols Found on the Device and Recorder

Type Label

The following is a typical label found on the ECG recorder.



IP protection class

Type reference and serial number

Manufacturing date

CARDIOVIT CS-104 Trolley Label

Art. no.: 2.511335 Rev. a

CE 0123 — Notified body of the CE certification (TÜV P.S.).

IP-20 — According IEC 60529. Protection against deposits of dust and protection against water ingress. (The first digit indicates the protection of the equipment against ingress of solid foreign bodies and dust and the second digit indicates the degree of protection of the equipment inside the enclosure from ingress of water).

May cause or be susceptible to electromagnetic disturbances.

CF symbol. The device's signal input is defibrillation-proof. CF symbol. This unit is classified safe for internal and external use. However, it is only defibrillation protected when used with the original SCHILLER patient cable.

Symbol for the recognition of electrical and electronic equipment.

Equipment/components and accessories no longer required must be disposed of in a municipally approved collection point or recycling center. Alternatively, you can return the equipment to your supplier or SCHILLER for disposal. Improper disposal can harm the environment and human health.

Ni-MH

Ni-MH

MS-12 blue battery type AA 2 x Ni-MH. Use Ni-MH conform charger only. Do not disassemble, mutilate, incinerate, or heat. Do not short circuit a battery. May cause burns.

At the end of the batteries life do not dispose in household waste. Batteries must be disposed of in a municipally approved collection point or recycling centre.

Manufacturer details

The date of manufacture in the yyyy-mm format.

Rx Only — Prescription Only. Federal law restricts this device to sale by or on the order of a physician.

REF SN — Reference and serial number of the unit

Read and follow the instructions in the accompanying documentation.

Read the user guide.

General symbol Bluetooth (transmission / reception)

Safety control sticker detailing the date of the next planned maintenance that must be observed.

Art. no.: 2.511335 Rev. a

Non ionising electromagnetic radiation, may cause or be susceptible to electromagnetic disturbances. The device contains an HF transmitter (WiFi).

The CARDIOVIT CS-104 radiates high-frequency electromagnetic energy and can disturb other devices if not installed and operated in accordance with the specification However, there is no guarantee that no interference can occur in certain installations. If the CARDIOVIT CS-104 causes interferences, these can be determined by switching the device off/on or by transmitting/not transmitting ECG data. The user can take the following measures to solve this problem:

- Increase the distance between the disturbed device and the CARDIOVIT CS-104. A minimum distance of 25 cm must be kept between the device and a pacemaker.
- Turn the device to change the angle of radiation.
- Connect the device to a different mains connector.

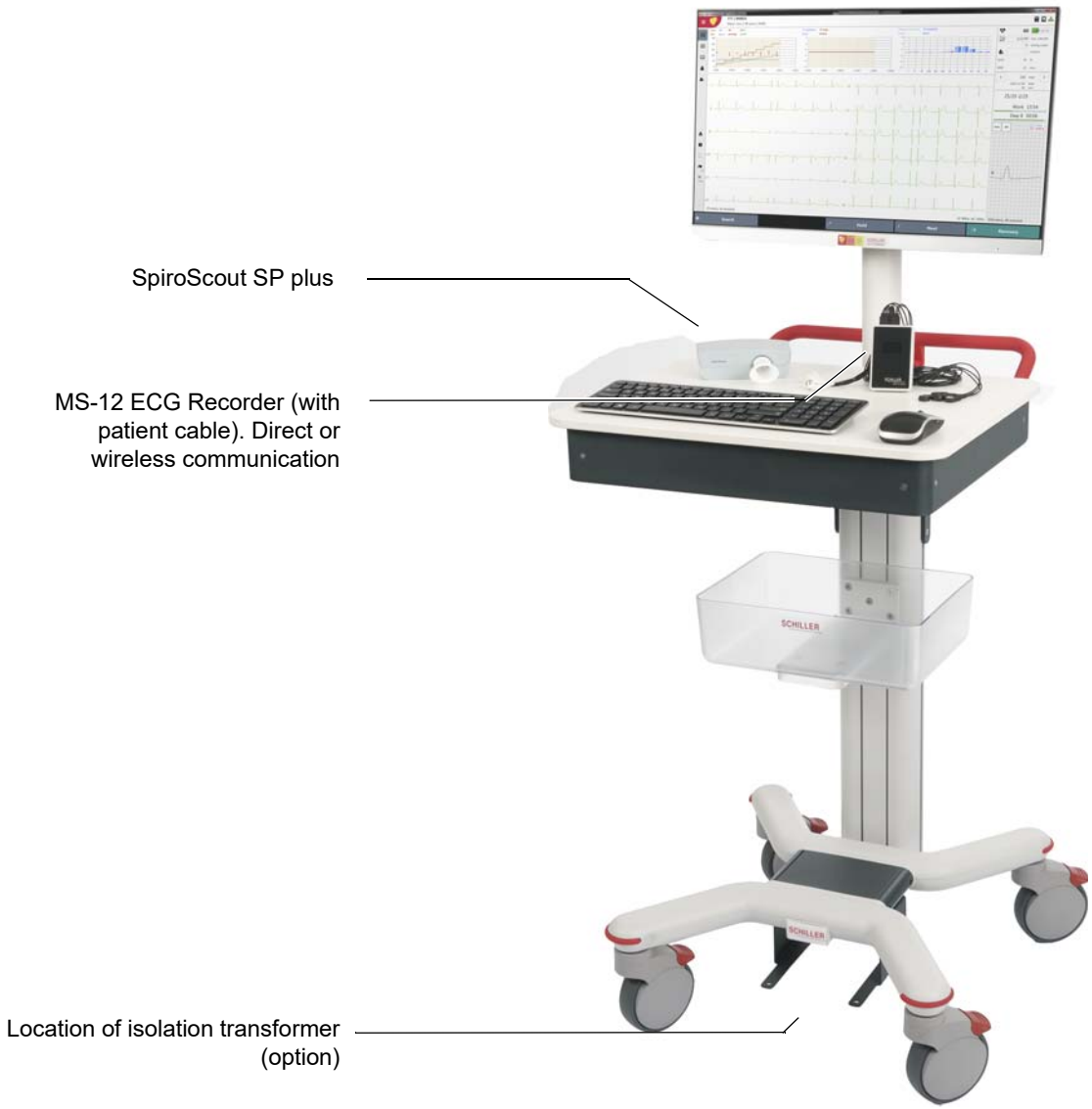
(see para. 18.10, Measures to Prevent Electromagnetic Interferences, page 163)

Art. no.: 2.511335 Rev. a

2 Introduction

2.1 Overview

The CARDIOVIT CS-104 a 12-lead ECG device intended to acquire ECG signals from body surface electrodes, and record, analyse and display ECGs for diagnosis in adult and paediatric patients. Dependent on configuration and options (see next page), spirometry can be included.



The software is installed on a standalone PC/laptop, or on a PC incorporated in a device trolley (as shown above).

For all configurations, an independent recording device is used that can be positioned for patient convenience. For ECG recordings the device is either the **MS-12 USB or MS-12 blue ECG,** or the **CARDIOVIT FT-1 Streame**r (see para. 2.6, ECG Recorders, page 26). For spiro recordings, the flow sensor is the **SpiroScout SP plus.**

Art. no.: 2.511335 Rev. a

2.2 Configurations

The CS-104 is available in the following configurations:

2.2.1 CARDIOVIT CS-104

- Installed on a PC.
  - Resting ECG (including Resting rhythm)
  - MS-12 blue or MS-12 USB or FT-1 streamer
  - Network connection with SCHILLER Server

2.2.2 CARDIOVIT CS-104 System

- Installed on a trolley with PC and 21’ monitor (see previous page)
  - Resting ECG (including Resting rhythm)
  - Exercise ECG (with stage printout on external printer (option)
  - MS-12 blue or MS-12 USB or FT-1 streamer
  - Network connection with SCHILLER Server

2.2.3 CARDIOVIT CS-104 Spiro

- Installed on a PC and not upgradable with any options
  - Spirometry software for FVC, SVC, and MVV measurment
  - SpiroScout SP plus sensor.
  - Network connection with SCHILLER Server

2.3 Options and Features

- The features and options available with the CS-104 are as follows:

Option	CS-104	CS-104 System	CS-104 Spiro
Network	Std	Std	Std
Resting ECG Recorder	Std	Std	-
Analyse All Recording Types (SEMA)	Std	Std	-
External Recorder	Std	Std	-
Visual Comparison (Serial)	Std	Std	-
Exercise ECG	Opt	Std	-
Spirometry	Opt	Opt	Std
ETM Interpretation	Opt	Opt	-
Vector ECG Calculation	Opt	Opt	-
HL7AEcg Export	Opt	Opt	-
Arrhythmia Detection	Opt	Opt	-
Advanced Interpretation Editor	Opt	Opt	-
FT-1 Streaming	Opt	Opt	-
Worklist	Opt	Opt	Opt

Art. no.: 2.511335 Rev. a

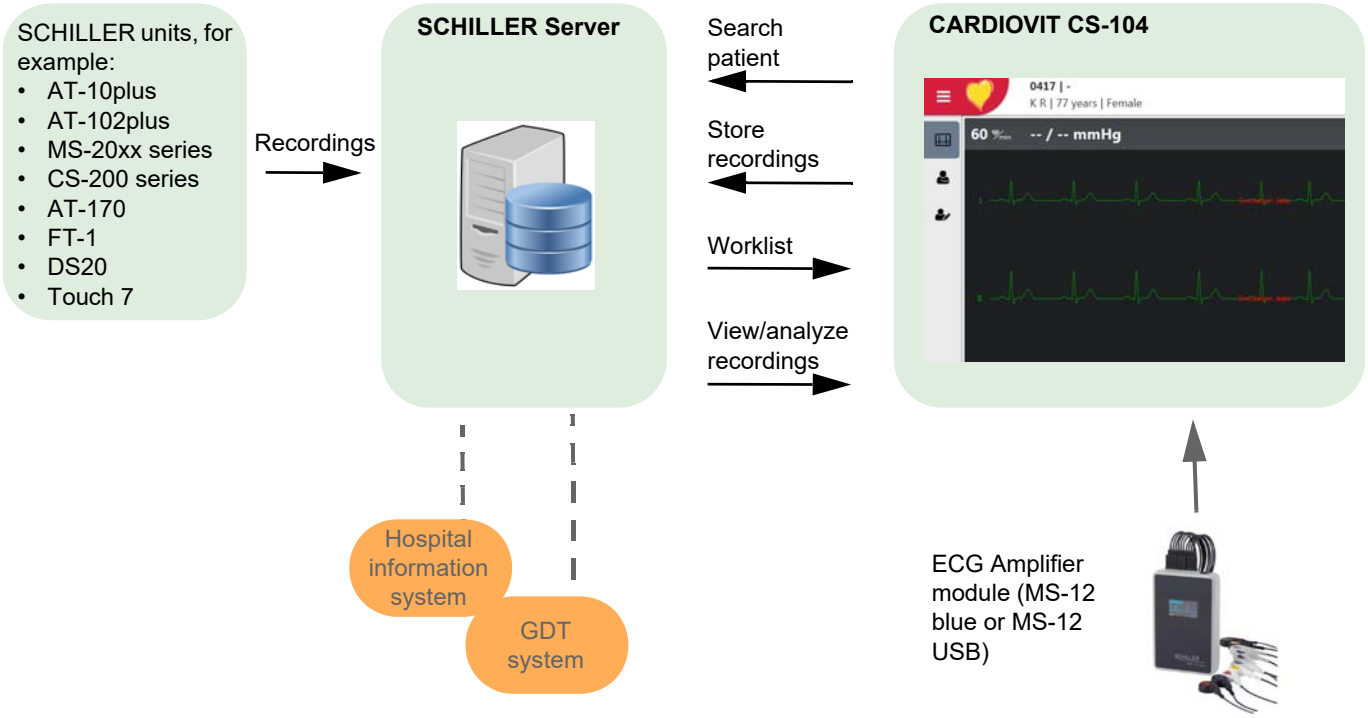
ETM and ETM Sport (interpretation)	ECG Interpretation with ETM Sport interpretation for athletes.
12 -Lead Exercise ECG	With stage printout on external printer (option)
Arrhythmia Detection	For Rhythm and Exercise Recordings
Vector ECG Calculation	Shows additional Vector ECG Measurements and allows x,y,z calculation by standard leads
Worklist	Downloadable list of recordings to be carried out by specific devices.
Spirometry	Spirometry software and SpiroScout SP plus sensor. The Spiro option can carry out the following tests: –FVC –SVC –MVV A number of American and International normal standards can be selected for predicted value calculation and interpretation. **Full details of the Spirometry option and operating instructions are detailed in the CARDIOVIT CS-104 Spiro User Guide.**

2.4 Installation

Installation of the CARDIOVIT CS-104 is normally carried out by SCHILLER staff on site. The installation procedure of the Software on a PC is detailed in the Annex (see para. 19, Annex - Installation, page 164).

Art. no.: 2.511335 Rev. a

2.5 Networking Overview



- Recordings that are opened by a user are locked. Another user can view the same recording, but no editing functions can be performed.
- If the server becomes disconnected or the network goes down it is not possible to access recordings. Any recordings already opened, or new recordings taken locally, are stored and then synchronised with the server when again connected.

2.6 ECG Recorders

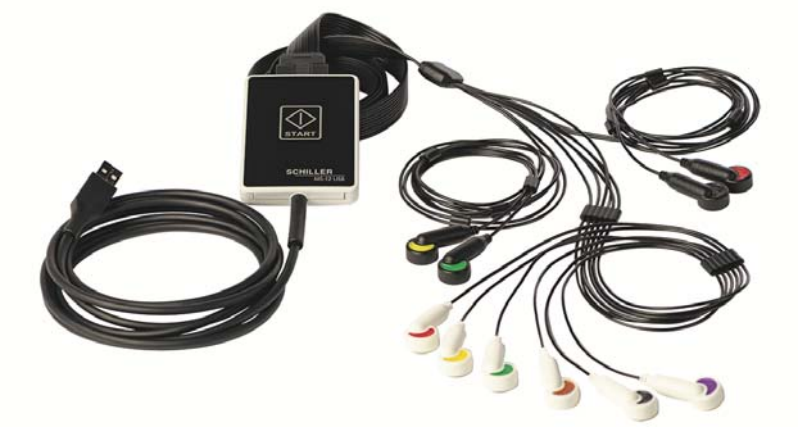
There are three ECG recorders available with the CARDIOVIT CS-104 as follows:

- MS-12 blue
- MS-12 USB
- FT-1 Streamer

The ECG recorder used will depend on your system configuration. An outline of the ECG recorders available is given here - details of the recorders are given at the end of this book (see para. 13, ECG Recorders, page 139).

Art. no.: 2.511335 Rev. a

2.6.1 MS-12 USB ECG Recorder



The **MS-12 USB ECG Recorder** communicates with the program via a USB cable connected directly to the PC. The MS-12 USB does not have a monitor screen but has a start button indicator to initiate an ECG in acquisition mode and also indicate connection and communication with the CS-104 program..

The following is included in the MS-12 USB package:

- 10-lead ECG patient cable snap or banana type, IEC or AHA
- Disposable ECG electrodes, set of 100
- USB cable assembly
- Ergo belt

2.6.2 MS-12 blue ECG Recorder

The **MS-12 blue ECG Recorder** is a wireless device that communicates with the CARDIOVIT CS-104 program using wireless bluetooth. This recorder is battery has a monitor screen for MS-12 blue settings and ECG display.

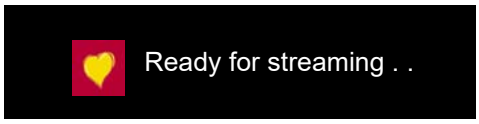
The following is included in the MS-12 blue package:

- 10-lead ECG patient cable snap, clip or banana type, IEC or AHA
- Disposable ECG electrodes, set of 100
- Bluetooth USB adapter
- Battery charger
- Four rechargeable batteries AA Ni-Mh
- Premium case

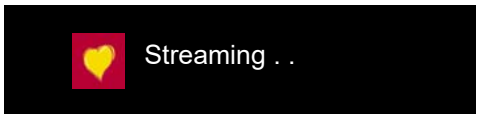
Art. no.: 2.511335 Rev. a

2.6.3 FT-1 Streamer

The **FT-1 Streamer** communicates with the program via a USB cable connected directly to the PC. When attached to the CS-104, the FT-1 acts as an ECG amplifier and all recording functions are carried out by the CS-104. The message 'Ready for streaming' is displayed on the screen when connected to the PC.

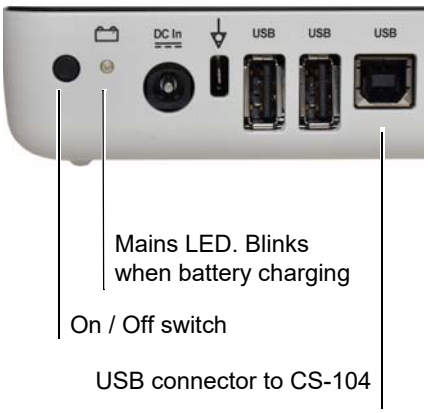


When a recording is commenced with the CS-104 application, the FT-1 indicates 'Streaming.' and transmits the ECG raw data to the PC where the data is displayed online in the CS-104 application.



Switching On / Off

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



Battery Charging

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

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

CARDIOVIT FT-1 Standalone

When the FT-1 Streamer is disconnected from the CS-104, it acts as a standalone recording ECG recording device.

Full details of the FT-1 Streamer are provided in the CARDIOVIT FT-1 user guide.

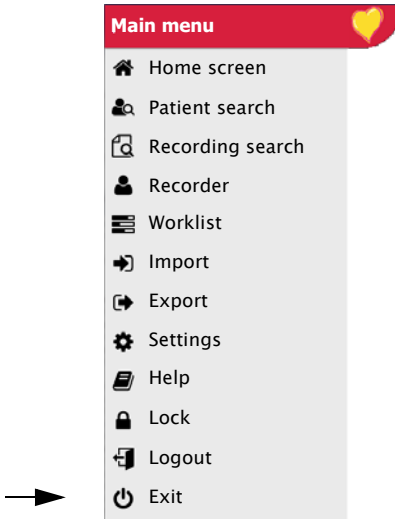
Art. no.: 2.511335 Rev. a

2.7 Switching On/Off and Opening the Program

2.7.1 CARDIOVIT CS-104 System (Trolley)

Switching the Unit On

The system is switched on with the push button switch on the back panel. The program is opened when the unit is switched on.

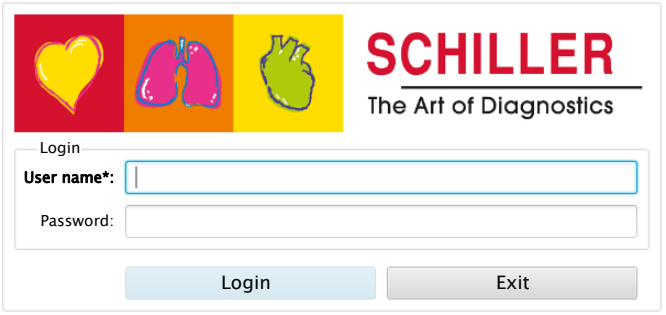


Switching the Unit Off

From the main menu select Exit, to exit the program and switch off the system. You are prompted to confirm switch off.

2.7.2 PC Based Installations

Click the desktop icon to open the program. The login screen is displayed:



(see para. 3.1, Login, page 32).

Art. no.: 2.511335 Rev. a

2.8 Power Supply

2.8.1 CARDIOVIT CS-104 (Trolley)

The CARDIOVIT CS-104 is supplied from the mains.

2.8.2 CARDIOVIT CS-104 Resting and CS-104 Spiro (PC Based)

The PC uses the standard power supply from the mains, battery or external power supply.

2.8.3 Power Supply for ECG Recorders

MS-12 blue

The MS-12 blue unit is battery operated - details of battery type, battery charging, changing and disposal, are detailed in the ECG Recorder section (see para. 13.1, MS-12 blue, page 139).

MS-12 USB

Low voltage power for the **MS-12 USB** is provided over the USB port of the PC. A power indicator lamp is lit all the time the unit is connected to the PC.

CARDIOVIT FT-1

The FT-1 can be operated form the mains supply (via a power supply) or battery power. Full details are provided in the FT-1 user guide.

2.8.4 Isolating the Mains Supply

- To isolate the power supply to the CARDIOVIT CS-104 or the PC, and the MS-12 USB remove the mains plug from the wall socket.
- To isolate the power supply to the MS-12 blue battery charger or to an external power supply for the Laptop PC, remove the mains plug to the charger from the wall socket.

2.9 Location

Do not keep or operate in a wet, moist, or dusty environment. Avoid exposure to direct sunlight or heat from other sources. Do not use in the vicinity of X-ray or diathermy units, large transformers or electric motors. The unit must be kept dry and is not designed for outdoor use.

Art. no.: 2.511335 Rev. a

2.10 Locking the Wheels of the Trolley

The wheels of the unit have spring-loaded braking mechanisms to lock the wheels and prevent the unit from moving during use.

▲ It is recommended that the wheels are always locked when the unit is stationary to prevent the unit from rolling and causing possible injury.

Lever in the **up position, wheel unlocked**

Lever in the **down position, wheel locked**

The unit wheels are locked by pressing the foot brake lever down until the wheel is locked. The lock is released by lifting the brake lever.

2.11 System and ECG Settings

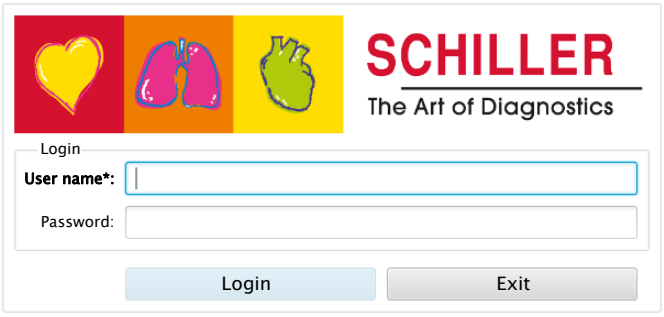
System settings (time, date, Device-ID etc.), general system settings, communication along with ECG, Spiro and other settings are defined in system settings (see para. 11, System Settings, page 116).

Art. no.: 2.511335 Rev. a

3 Software Overview

3.1 Login

Click the desktop icon to open the program. The login screen is displayed:



Enter your user name and password.

- It is possible to have system authentication of user ID and password with auto login. This means that when initially opened, the program is entered directly and the login screen is not displayed. To enable this function, the same user name must be defined in SCHILLER Server as set for PC login, and the single log-on option must be set in system settings (see para. 11.8.2, Single Sign On, page 128).

When system authentication is set, security can be compromised. It is recommended that this setting is only defined for PCs that are single or limited user.

- The function icons on the side and bottom function bars can be set for user preference. If a function icon is not available ensure it has been set for display (see para. 3.8, Display Configuration, page 40).
- User roles and privileges are assigned to individual users and that can affect access to a Workflow area and the functions that can be carried out. If a function is greyed and cannot be entered, it means that the user logged in does not have the privileges to perform the (greyed) task or the task is not available in the current screen. Individual users, and the user groups and privileges defined for individual users are defined by the SCHILLER Server or locally if not networked.

Art. no.: 2.511335 Rev. a

3.2 Workflow Screens and Main Menu

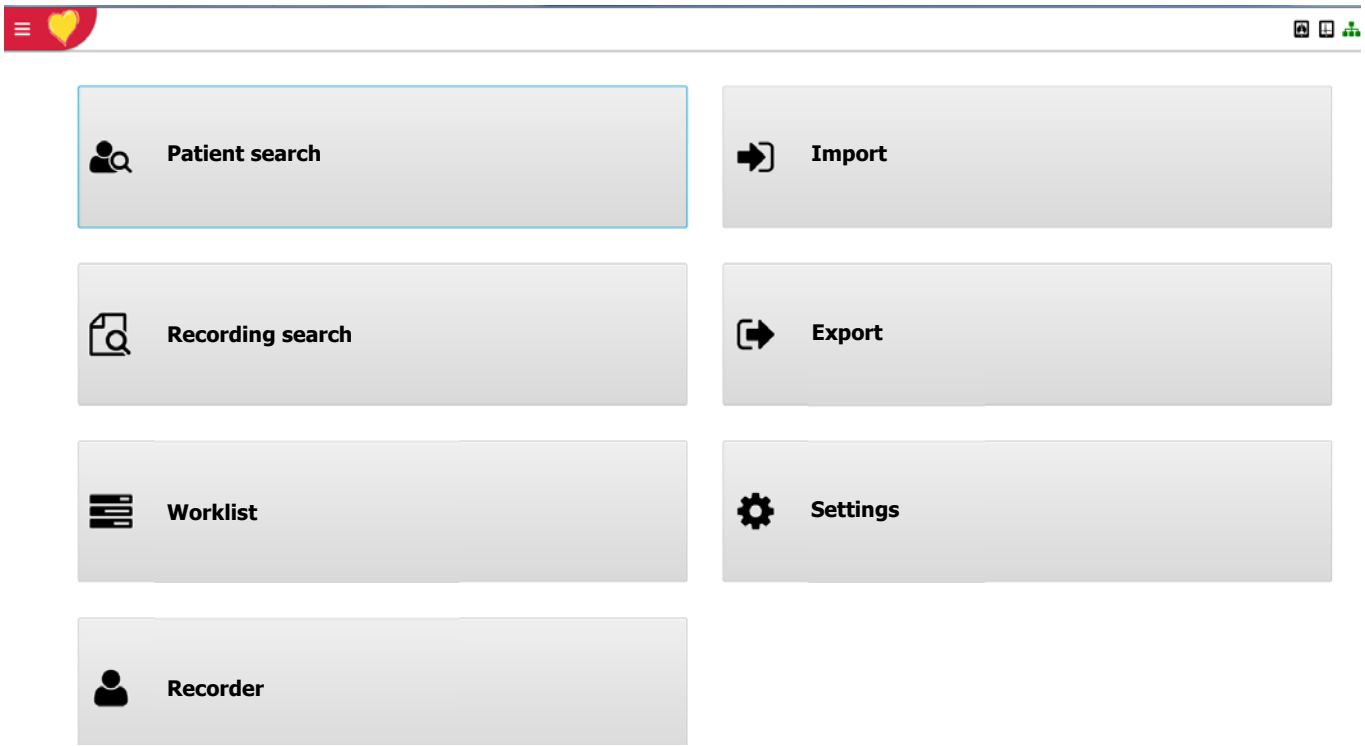
The program uses a Workflow model so that the user is given a defined logical sequence of steps and options for any given task.

The Workflow screens are entered by:

- Clicking the relevant icon on the Home screen, or
- Selecting the Workflow from the main menu by clicking on the SCHILLER icon top left of the screen.
- The initial screen when the program is opened, home screen tabs and main menu selections, can be defined in system settings (see para. 11.2.6, Workflow, page 120).

3.3 Home Screen

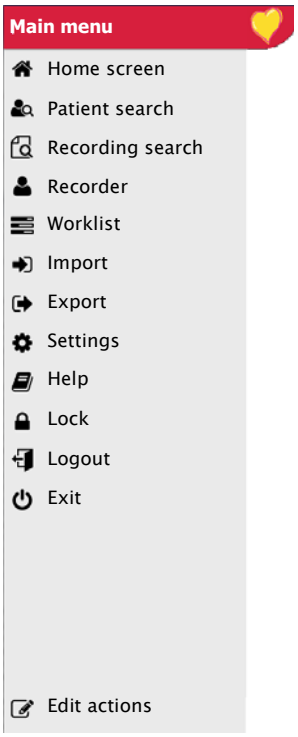
An example of the home screen is shown.



The content of the **Home screen and the options in the Main menu** (next page) can be user defined for preference (see para. 3.8, Display Configuration, page 40)

Art. no.: 2.511335 Rev. a

3.3.1 Main Menu



Home Screen

Displays the home screen (see above).

Patient Search

In this screen you can:

- Search for a patient (by Patient ID, patient name, date of birth, or visit ID)
- Edit, delete or enter a new patient
- Select patient and enter the Resting ECG screen, Exercise ECG screen, or the Spiro recording screen.

Recording Search

Enter this screen to search for recordings from selected patients (by Patient ID, patient name, date of birth, or visit ID), or all patients. The recordings can be ordered by date, type, patient, etc.

Recorder

In this screen you can:

- Search for a patient (by Patient ID, patient name, date of birth, or visit ID)
- Enter a new patient
- Enter the Resting ECG screen, Exercise ECG screen, or the Spiro recording screen.

Worklist

Enter this screen to search for work items for all or selected patients or groups of patients. The work item requirement can be ordered by patient, priority, order ID, etc. (see para. 9, Worklist, page 110).

Import / Export

Enter the Import / Export screen to import or export recordings from/to a defined location.

Settings

Here all the system settings are made (see para. 11, System Settings, page 116) including time / date, language, connectivity, ergo devices, etc.

Lock (Application)

Use this function to lock the current application. The login screen is displayed and the lock is maintained until the (same) user logs on again by entering the user password.

Logout

Use this function to logout from the program (and login as a new user if required).

Exit

Exit program.

Edit Actions

Defines icons in the grey sidebar and the home screen (see para. 3.8, Display Configuration, page 40).

Art. no.: 2.511335 Rev. a

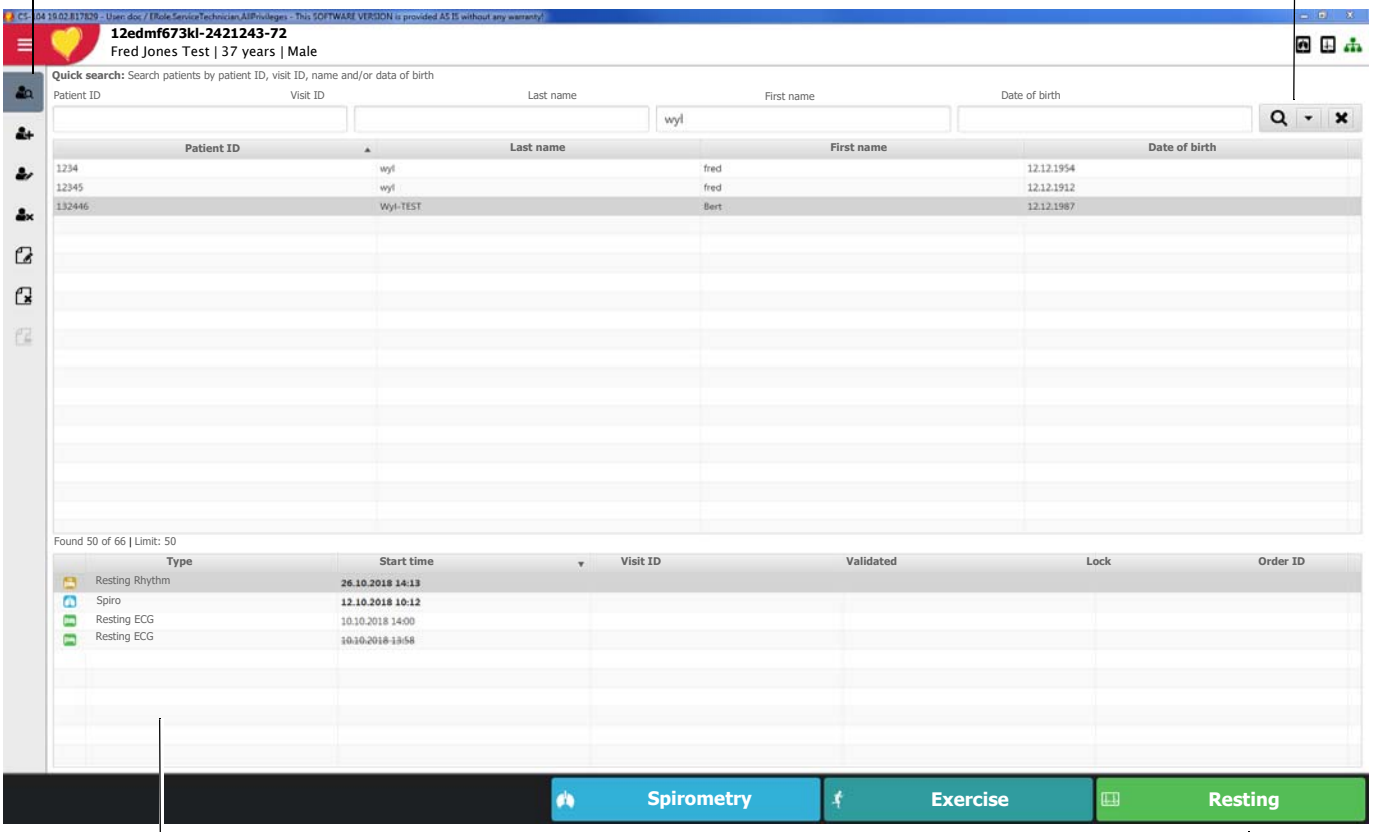
3.4 Screen Layout

The following display is from the patient search screen. Other screens will be different but the general layout remains constant for all screens.

Side bar icons to define actions when selected. The number of icons, order, and the actions that are taken, are user defined for each individual screen (see para. 3.8, Display Configuration, page 40).

Quick Search: Enter search criteria (or part of) and click to display all patients/recordings with defined parameters.

Click this icon with no data entered to **display all patients** (up to the defined maximum).

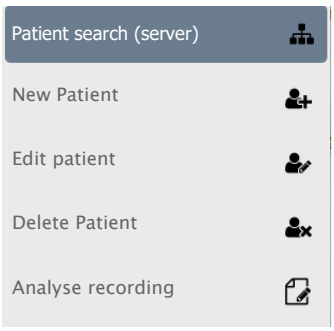


Patient recordings

Bottom icons to define actions according to the currently displayed screen. The number of icons and the actions can be defined by the user (see para. 3.8, Display Configuration, page 40).

Art. no.: 2.511335 Rev. a

3.4.1 Side Bar and Bottom (Main) Icons



Side bar icons are provided in every screen and will vary according to the screen displayed, user privileges, the number of icons set for display in system settings and the action defined (see para. 3.8, Display Configuration, page 40).

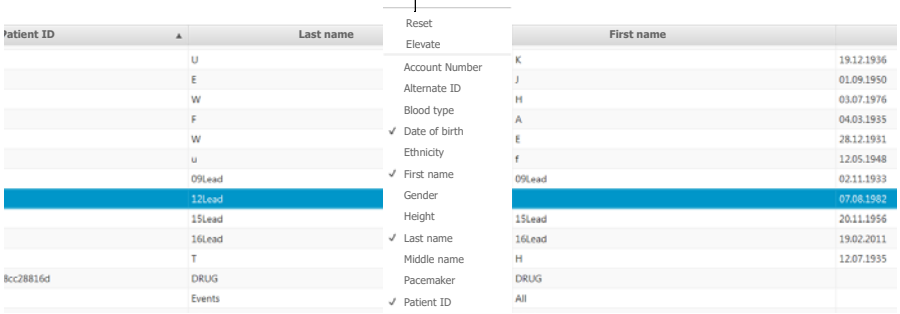
If you are unsure of the function of any icon, clicking in the area below the icons will expand to annotate the function of each icon as shown on the example of a typical icon bar in the patient search screen. Hovering over the icon will give a tooltip function of the icon. Click again to return to icon view.

Additionally, hovering over the icon will give a tooltip explanation of the icon.

3.4.2 Defining the Tables

Right click on any column title to enable/disable columns. Column data that can be set to include, Pat ID, Visit ID, name, blood type, ethnicity, weight, etc.

After defining the columns, click **Elevate** (the setting) to define the same table layout for all users (see para. 11.1, Overview, page 116). Click **Reset** to restore the system default setting for table layout.



3.4.3 Changing the Column Order

To change the column order click and hold the header and move to any desired position.

3.4.4 Sorting Columns

Click on any header field to sort the recordings in that order. Click on the same header again to sort in reverse order. The highlighted header indicates the sort field and the sort arrow indicates the sort order (as shown for Patient ID above).

Art. no.: 2.511335 Rev. a

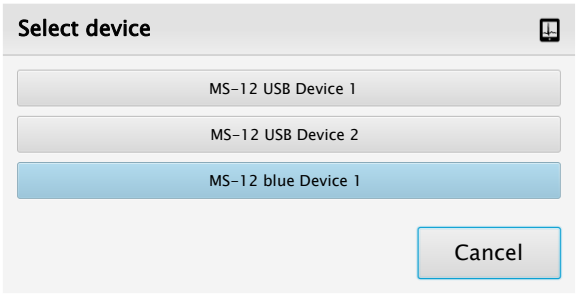
3.5 Selecting / Displaying the Recording Device

Spiro Recording Device(s)

ECG Recording Device(s)

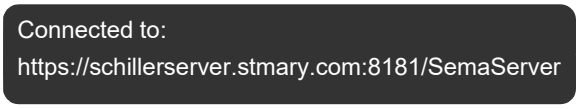
The recording device attached to the system is indicated in the top right of the screen. Hovering over the symbol will indicate the device connection, for example:

When more than one recording device is available, the user can select the required recording device:



3.6 Connection with the Server (if Networked)

Connection to the SCHILLER Server is indicated in the top right of the screen . Hovering over the symbol will indicate the server connection, for example:



The network symbol has three states as follows:

Connection to the server OK

- Symbol Green - Connected to network and SCHILLER Server

Network connected

- Symbol Black - Connected to network but no connection with SCHILLER Server

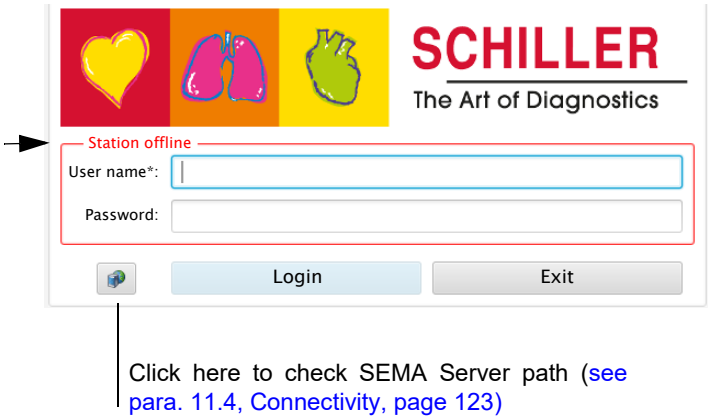
Not active

- Symbol black and a cross in the symbol (see following)

Art. no.: 2.511335 Rev. a

3.6.1 Offline

When connection to the server is lost for whatever reason, a cross appears . and on login offline mode is indicated:



In offline mode:

- Any opened recordings or patient data can continue to be edited and viewed but any edits cannot be saved until the server is reconnected (the save option is greyed).
- New patients can be defined and recordings can continue to be made and saved. These are stored locally, and will be synchronised with the server when reconnected.

Art. no.: 2.511335 Rev. a

3.7 Recordings

The CARDIOVIT CS-104 can record Resting ECG, Resting Rhythm ECG, Exercise ECG, and Spiro recordings. All patient recordings are displayed in the recordings column. If the device is licensed for 'analyse all', all recordings can be analysed. If this option is not licensed, only resting, resting rhythm, exercise and spiro recordings can be analysed. Analysis of ECG recordings are detailed later. Spiro recordings are detailed in the spiro option user guide. Details of analysing all other types of recording see the SEMA user guide.

3.7.1 Types of Recording

The type of recording is shown by icon and in the **Type** column:

- Unknown
- Resting ECG
- Resting Rhythm
- Exercise ECG
- Signal Averaged ECG
- Rescue (PDF only)
- Spirometry
- Holter blood pressure (PDF only)
- Body plethysmography (PDF only)
- Diffusion (PDF only)
- Provocation (PDF only)
- Resistance (PDF only)
- Ergo Spiro (PDF only)
- Holter ECG (PDF only)
- Monitoring (PDF only)

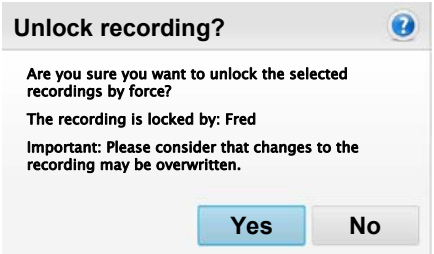
3.7.2 Opening a Recording

To analyse a recording highlight the recording and double click or click the analyse icon in the sidebar .

Locked Recordings

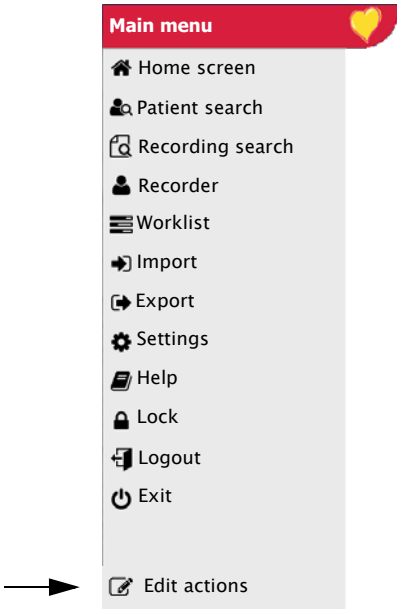
If the recording is shown locked, it indicates that the recording is locked (opened) by another user. The user that has locked the recording is displayed in the column.

It is possible to open a locked recording for viewing only; no editing functions will be possible. If you wish to edit a locked recording it must be unlocked first:



Art. no.: 2.511335 Rev. a

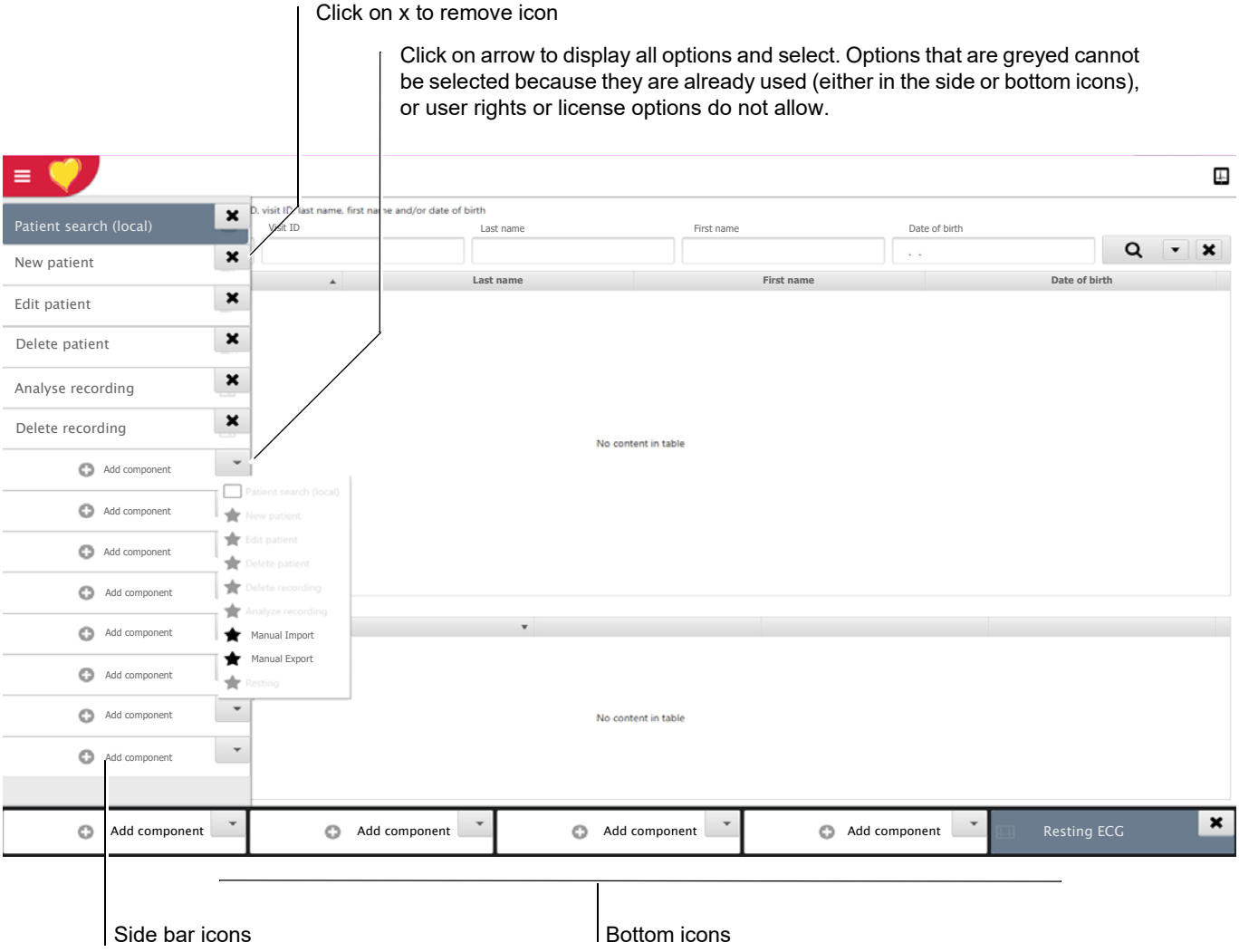
3.8 Display Configuration



In each screen side and bottom icons can be defined. The icons available will depend on the screen displayed and different functions are given for search and recording view screens. Once defined the icons are displayed every time that this type of screen is entered. To define the side and bottom icons proceed as follows:

- Enter the screen for which you wish to define the icons
- Click the **Main menu** icon
- Select **Edit actions**
- Add/delete icons as required
- Click on the Main menu icon again
- The edit action changes to **Save actions**

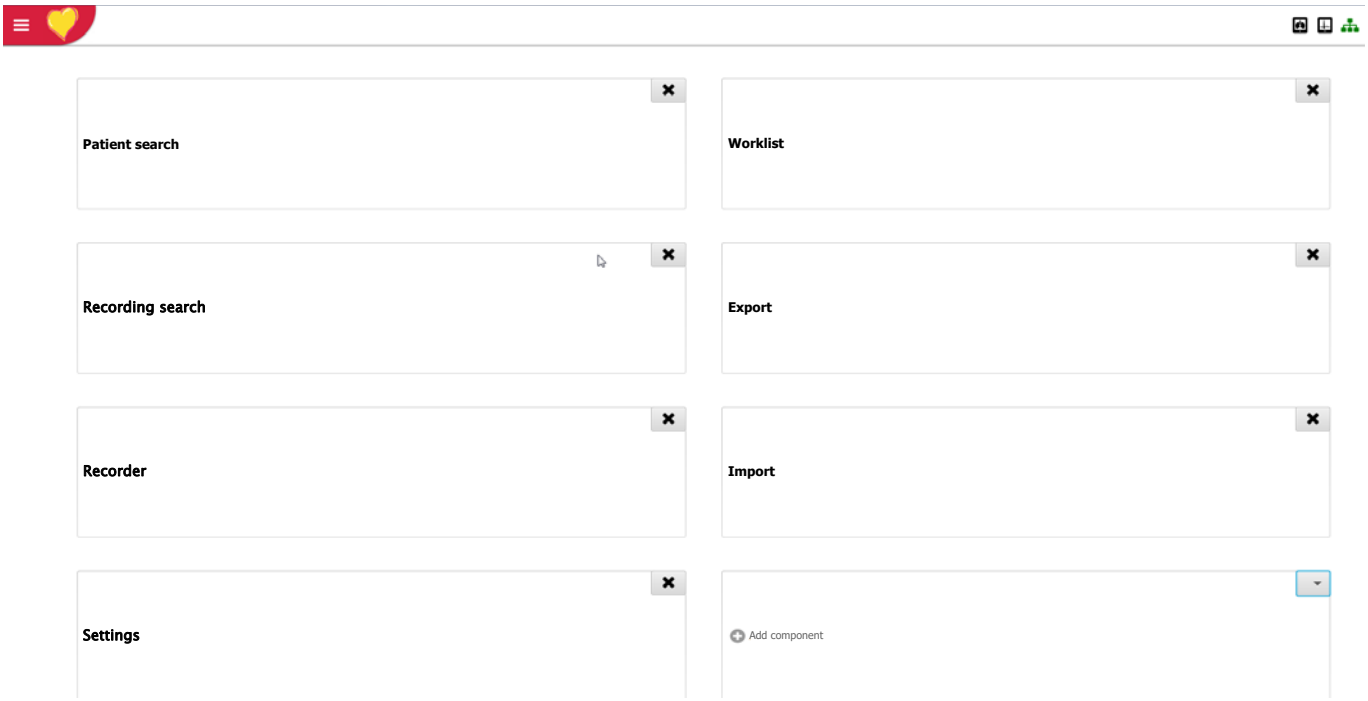
Note: The number of icons that are available for the side and bottom bars can also be user defined (see para. 11.2.4, Layout, page 120**).**



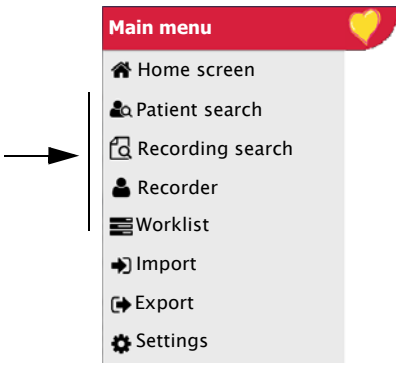
Art. no.: 2.511335 Rev. a

3.8.1 Home Screen and Main Menu Options

When the **Edit actions is selected in the Home screen** is clicked, the options in the Home screen and the main menu are defined:



3.9 Recording and Patient Search

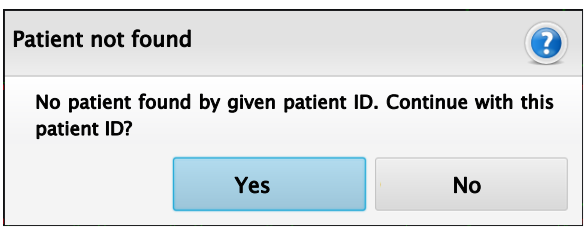


Search screens are available as follows:

- **Patient Search** - to search for a specific patient (by ID, name or date of birth), or display all patients
- **Recording Search** - to search for specific type or recording, or group of recordings by date, patient, interpretation, type, etc., or display all recordings.
- **Worklist** - to search for specific worklist recordings.

The search icon is displayed in the top right of the screen and the search parameter entry field at the top of the screen. All recordings / patients with the defined parameters are displayed.

The **Recorder** screen also has an effective search for a specific patient. Enter the Patient ID and press return - the patient data will be populated of the patient is already registered. If the patient ID is not found, a message is displayed and your are prompted to register a new patient.



Art. no.: 2.511335 Rev. a

3.9.1 Search Options

The search options are defined in system setting **(**see para. 11.7.1, Quick Search, page 128) and following options can be set, Patient ID, Visit ID, Last name, first name, Date of birth.

Patients are searched by patient ID,, name, date of birth, etc., in any combination for each category. For each category one or more of characters can be entered up to the exact text (to identify for example, a patient group). Leave fields blank to include all options in that category.

To display all patients / recordings click the search icon  **with no characters entered in the search field.**

3.9.2 Search Results

The search results are displayed and opened and sorted as described earlier. The recordings that are **bold indicate recordings that have not yet been opened.**

Note the number of patients / recordings that are displayed after a search has been initiated, can be limited if required (up to a maximum of 5000).This is set in system settings **(**see para. 11.7.2, Limit, page 128)**.**

3.9.3 Extra Search Options for Worklist (Filter Worklist)

The Filter Worklist search includes the following categories:

- **Recording type** - select the type of recording including:
  - Resting
  - Rhythm
  - Exercise
  - Spiro
  - Other recording type, for example, BP, Holter, are available for external devices / software.
- **Priority**- select as follows:
  - Any
  - High
  - Routine
  - Stat
  - Undefined
- **Patient ID**
- **Order ID**
- **Visit ID**

All parameters are defined by the workitem originator.

Art. no.: 2.511335 Rev. a

3.9.4 Barcode Reader

If a Barcode reader is attached, it can be used to enter the **Patient ID** / **Visit ID, or patient name.** SCHILLER has tested the following Barcode reader:

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

3.10 Patient Data

New patient

Edit patient Data

Delete patient

A new patient can be defined from the Patient search screen. Dependent on display configuration, the icons may be in the side bar or the bottom bar.

3.10.1 Entering / Editing Patient Data

- For correct predicted values and diagnosis, it is important that all patient data is entered correctly.
- If no date of birth and gender is entered, the interpretation is performed as if for a 50-year old male patient.
- The Patient ID can only be defined for a new patient. For an existing patient, the patient ID field is greyed and cannot be changed.
- The Patient ID must be entered to register a patient on the system. All other fields are optional (and can be entered at a later date as necessary).
- When auto ID is requested for the patient ID, the **SCHILLER standard** Patient ID generator is used. SCHILLER uses the **universally unique identifier** (**UUID**) standard. The intent of UUIDs is to enable distributed systems to uniquely identify information without significant central coordination (see para. 11.3.4, Patient ID System, page 122).
- When Swedish, Danish, Finnish, or Norwegian ID format is defined, a message is displayed if a PatID is entered that does not conform to the defined standard (see para. 11.3.4, Patient ID System, page 122).

Extra entries are given for spiro recordings (see para. 9, Worklist, page 110).

PID (Pat ID) The patient ID is a unique patient identifier. There is no restriction on the characters or format used.

Name, first name Enter patient's name and first name (max. 50 characters).

Date of Birth Enter the patient's date of birth dd-mm-yyyy (or in the format defined in system settings (see para. 11.3.1, Date and Time Format, page 122).

Art. no.: 2.511335 Rev. a

Gender Male, Female, undefined, or other

Ethnicity Select between:

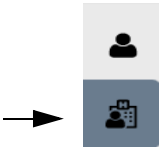
- American Indian / Alaska native
- Asian
- Black / African American
- Caucasian
- Hispanic
- Native Hawaiian / Pacific Islander
- Oriental
- Other
- Undefined

Height and Weight Enter the patient's height and weight. The units used are shown in parenthesis. The unit of measurement is defined in system settings.

BMI Calculated from the height and weight entered.

Pacemaker If the patient has a pacemaker fitted, it can be indicated here - yes / no / unknown.

3.10.2 Visit Data



In the new patient or edit patient screen below the patient icon the visit icon available to enter visit data.

The following Visit data can be entered/selected:

Visit

- **Select a previously defined Visit** - All visit data is populated. The visit ID and Admitted data cannot be edited, the location and referring physician can be edited.
- **Define new visit -** Click the **+** icon by the side of the entry field to define an new visit.

Visit ID There is no restriction on the characters used or the format to identify the Visit (max. 50 characters).

Admitted The date that the selected visit was registered, or today's date if a new visit is being defined. This field is read only.

Location Location of the visit - there is no restriction on the characters or format.

Ref. physician Referring physician.

Art. no.: 2.511335 Rev. a

3.11 Recording-Specific Data

When a recording is open and the recording details button is clicked , extra patient/visit and recording information is detailed.

The side bar icons are user set. If the recording detail icon or any other icons are not displayed, they can be set for display by clicking edit icons (see para. 3.4.1, Side Bar and Bottom (Main) Icons, page 36).

Some patient data is recording-specific and can be changed or added as follow:

Patient Demographics

- Height
- Weight
- Pacemaker

When edited, this also changes the general patient data (as well as the recording data).

Additional Information

Cardio Disease The patient's indication can be shown and edited here, e.g. Past cardiac infarction, pacemaker, cardiac insufficiency, past bypass, etc.

Other disease Any other disease that the patient may have, e.g. Diabetes, hepatitis, gall stones, etc.

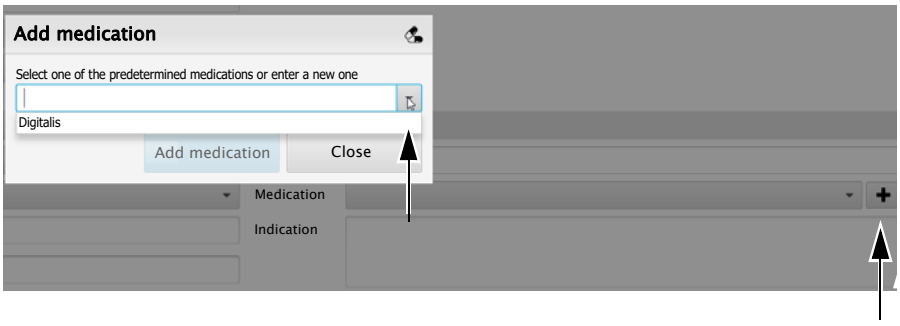
Consciousness Define here the patients condition, e.g. somnolent, anxious, etc.

Generic Recording Fields Up to three extra fields can be added to the Additional Information area. These can be any user defined extra information titles and text can be entered freely or predefined text can be defined. The generic recording fields are defined in system settings (see para. 11.2.7, Custom Fields, page 120).

Room, Medication, Indication, Remark Four entries are given for extra patient and recording details.

Digitalis

When the Medication field is selected an option for digitalis is given. When this is selected it can affect the interpretation of the recording and you are prompted to analyse the recording:



Art. no.: 2.511335 Rev. a

4 Recording an ECG

⚠ CAUTION

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

4.1 Placing the Electrodes

- Electrode placement assistance and electrode check is also given in the ECG acquisition screen (see para. 4.3, Hookup Screen, Electrode Placement and Check, page 60).
- The IEC or AHA lead cable is set in ECG settings (see para. 11.11, ECG, page 132).

4.1.1 Electrode Identification and Colour Code

The electrode placements shown in this section are labelled with the colours according to Code 1 (IEC) requirements. The equivalent Code 2 (AHA) colours are given below.

	Code 1 (IEC)		Code 2 (AHA)	
	IEC Label	**Colour**	**AHA Label**	**Colour**
Limb	R	Red	RA	White
	L	Yellow	LA	Black
	F	Green	LL	Red
Chest according to Wilson	C1	White / Red	V1	Brown / Red
	C2	White / Yellow	V2	Brown / Yellow
	C3	White / Green	V3	Brown / Green
	C4	White / Brown	V4	Brown / Blue
	C5	White / Black	V5	Brown / Orange
	C6	White / Violet	V6	Brown / Violet
Neutral	N	Black	RL	Green

Art. no.: 2.511335 Rev. a

4.1.2 Basics

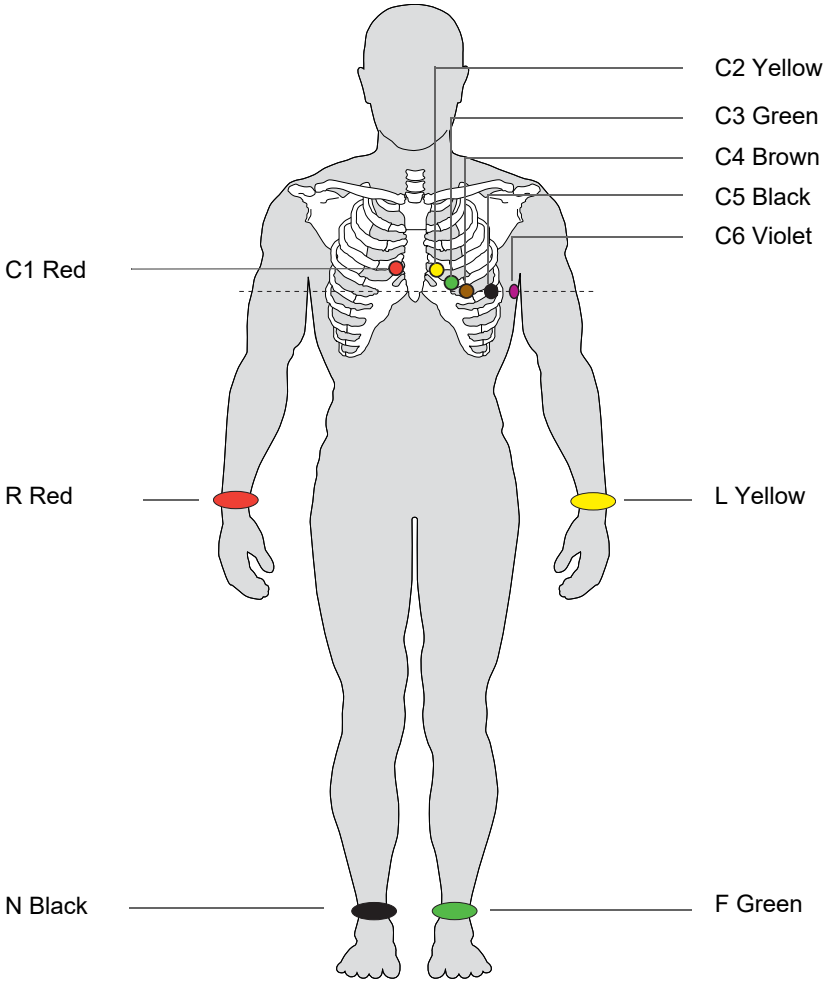
Careful application of the electrodes and good electrode contact is important for a good recording. A minimal resistance between skin and electrode is required to obtain the best ECG signal and ensure the highest quality ECG recording. Therefore, please note the following points:

1. Only use electrodes that are recommended by SCHILLER AG.
2. Ensure that the patient is warm and relaxed before you start the recording.
3. Before using disposable electrodes, check that the expiration date has not yet passed.
4. To increase the electrode's conductivity and adherence:
   – Shave the areas where the electrodes are to be placed, if necessary.
   – Thoroughly clean the areas with alcohol or soapy water.
   – Let the skin dry before applying the electrodes.
   – When applying the electrodes, ensure that a layer of gel is between the electrode and the skin[1].
5. Check the electrode resistance (see para. 4.4, Electrode Check, page 61). If the electrode resistance is higher than the acceptable level:
   – Remove the electrode and use an abrasive cleaning pad or abrasive cleaning gel[2] to remove the uppermost layer of epidermis. Reapply a new disposable electrode.

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

Art. no.: 2.511335 Rev. a

4.1.3 Standard 12-lead

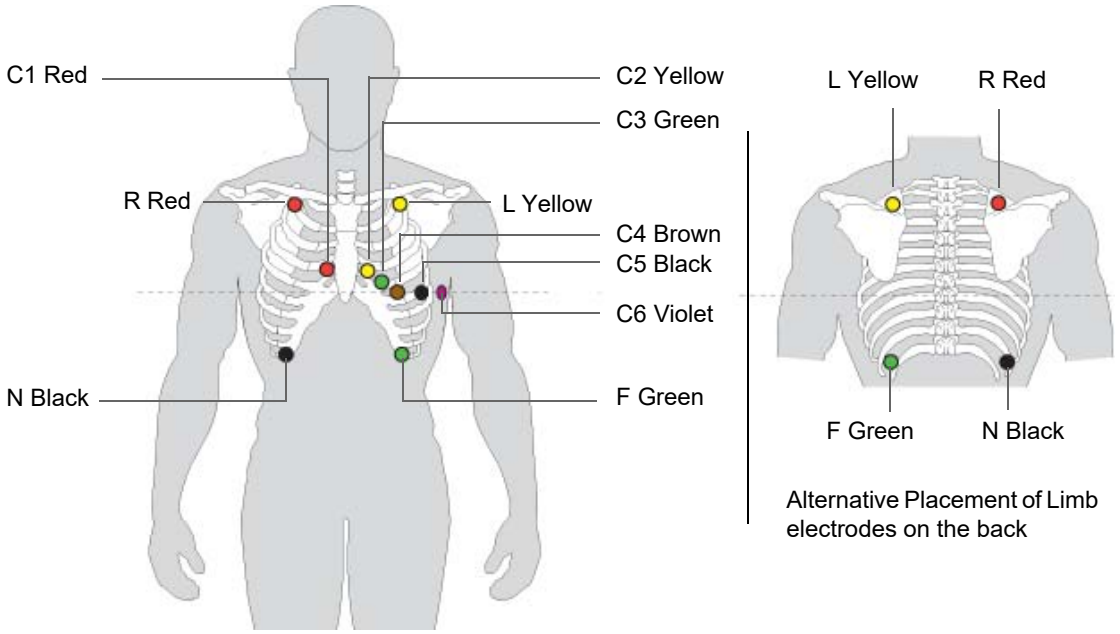


IEC Label	AHA Label		Electrode Placement
C1 white / red	V1 brown / red	→	Fourth intercostal space at the right sternal border
C2 white / yellow	V2 brown / yellow	→	Fourth intercostal space at the left sternal border
C3 white / green	V3 brown / green	→	Midway between C2 and C4
C4 white / brown	V4 brown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

- Auto Interpretation is only generated when standard 12-lead electrode lead configuration is set.
- The lead configuration is set in the lead configuration screen selected at the start of the recording.
- The electrode resistance is constantly monitored in the recording screen and a lead-off indication displayed if the resistance is too high.
- When making an ECG with a child it is sometimes physically difficult to position all electrodes. When this is the case electrode C4 can be placed on the right side of the chest.

Art. no.: 2.511335 Rev. a

4.1.4 Exercise ECG



Alternative Placement of Limb electrodes on the back

IEC Label	AHA Label		Electrode Placement
C1 white / red	V1 brown / red	→	Fourth intercostal space at the right sternal border
C2 white / yellow	V2 brown / yellow	→	Fourth intercostal space at the left sternal border
C3 white / green	V3 brown / green	→	Midway between C2 and C4
C4 white / brown	V4 brown / blue	→	Left mid-clavicular line in the fifth intercostal space
C5 white / black	V5 brown / orange	→	Left anterior axillary line on the same horizontal level as C4
C6 white / violet	V6 brown / violet	→	Left mid-axillary line on the same horizontal level as C4
L yellow	LA black	→	Slightly below left clavicle
R red	RA white	→	Slightly below the right clavicle
F green	LL red	→	Lower edge of the rib cage, or at the level of the umbilicus at the right mid-clavicular line
N black	RL green	→	Lower edge of the rib cage, or at the level of the umbilicus at the left mid-clavicular line

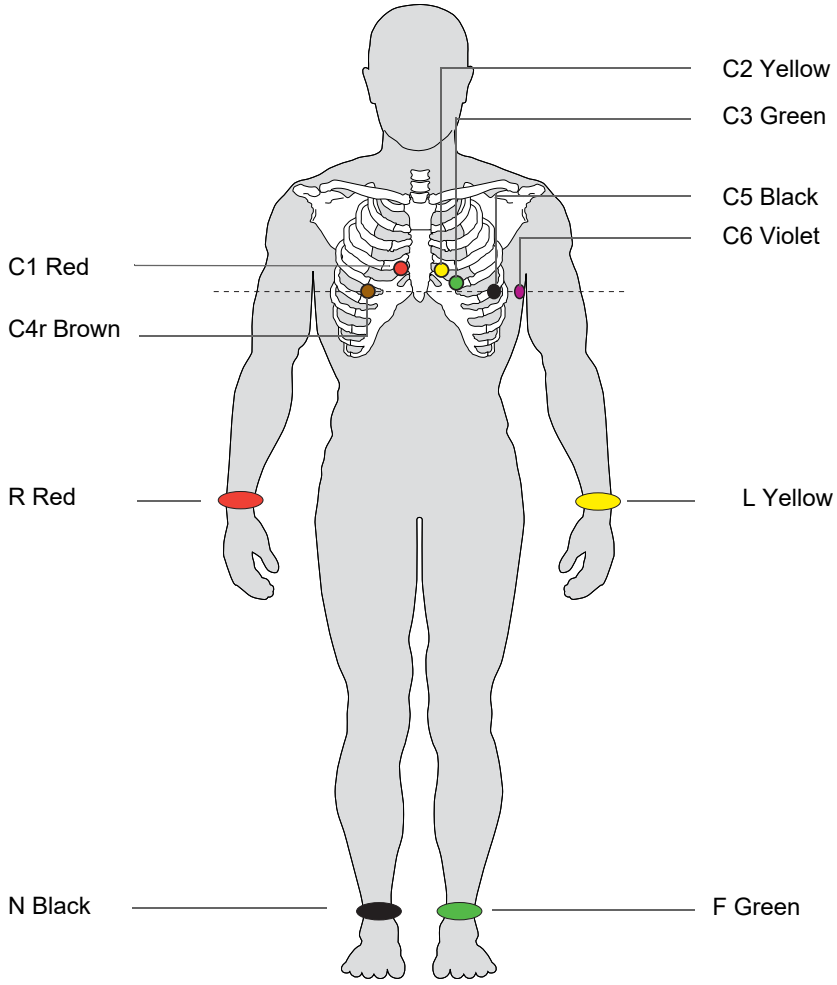
For exercise testing place electrodes C1 to C6 in the same positions as for the standard resting ECG detailed previously and place the R, L, F and N electrodes as follows:

– F, on the left torso at the bottom of the rib cage
– N, on right torso at the bottom of the rib cage
– L and R, place either on the back above the scapular or on the front just below the clavicle.

- The limb electrodes can also be placed on the back as shown above.
- The ECG recorded with the torso placement of the limb lead electrodes may differ from that recorded with the electrodes on the limbs. Affected characteristics are the Q-waves and the frontal axes, whereas ST levels are unlikely to change.

Art. no.: 2.511335 Rev. a

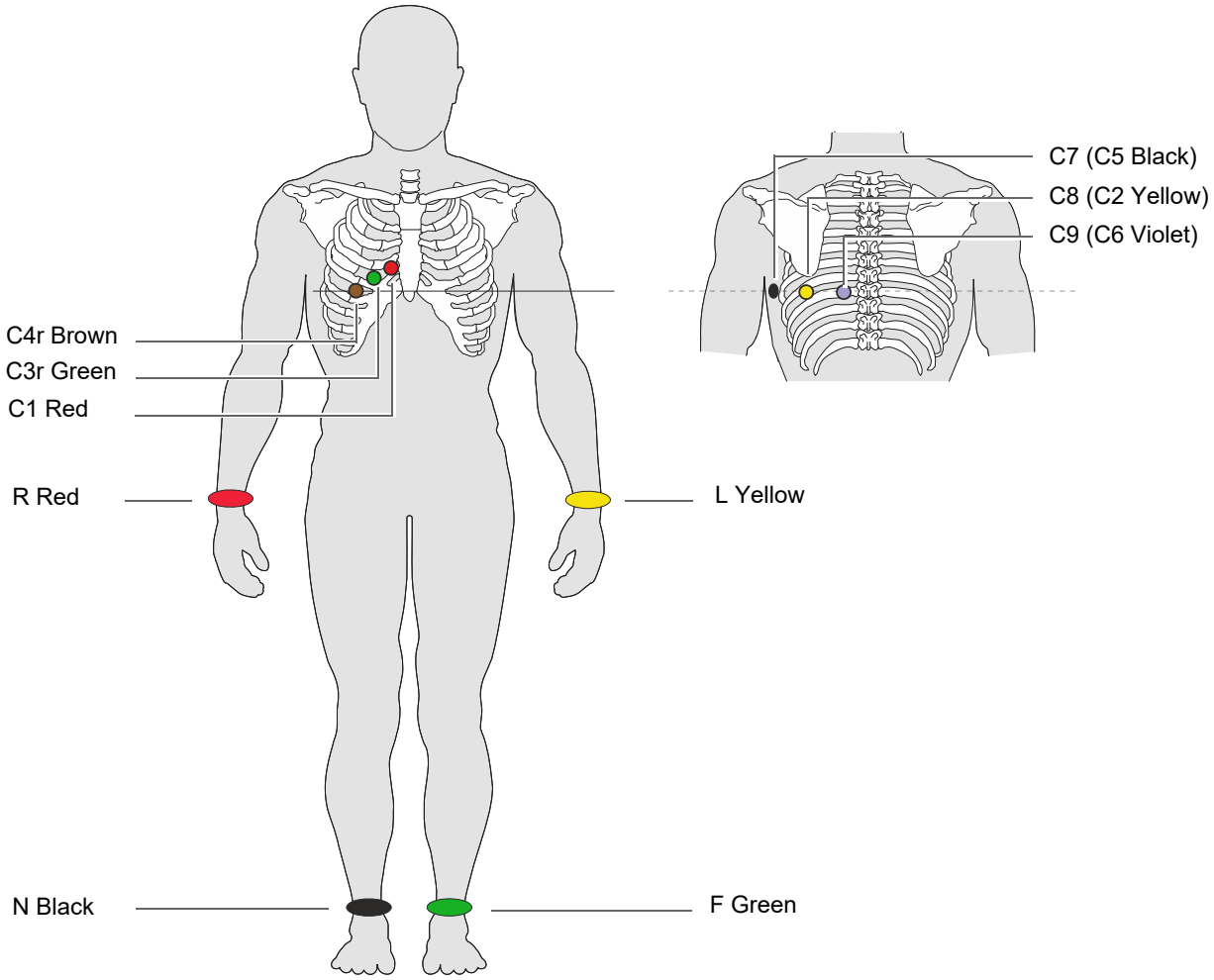
4.1.5 Right Precordial (C4r)



IEC Label	AHA Label	Electrode Placement
C1 white / red	V1 brown / red	➜ Fourth intercostal space at the right sternal border.
C2 white / yellow	V2 brown / yellow	➜ Fourth intercostal space at the left sternal border.
C3 white / green	V3 brown / green	➜ Midway between sites C2 and C4.
C4r white / brown	V4r brown / blue	➜ Fifth intercostal space right mid-clavicular line.
C5 white / black	V5 brown / orange	➜ Anterior axillary line on the same horizontal level as C4.
C6 white / violet	V6 brown / violet	➜ Mid-axillary line on the same horizontal level as C4.
L yellow	LA black	➜ Left arm
R red	RA white	➜ Right arm
F green	LL red	➜ Left foot
N black	RL green	➜ Right foot

Art. no.: 2.511335 Rev. a

4.1.6 Balanced

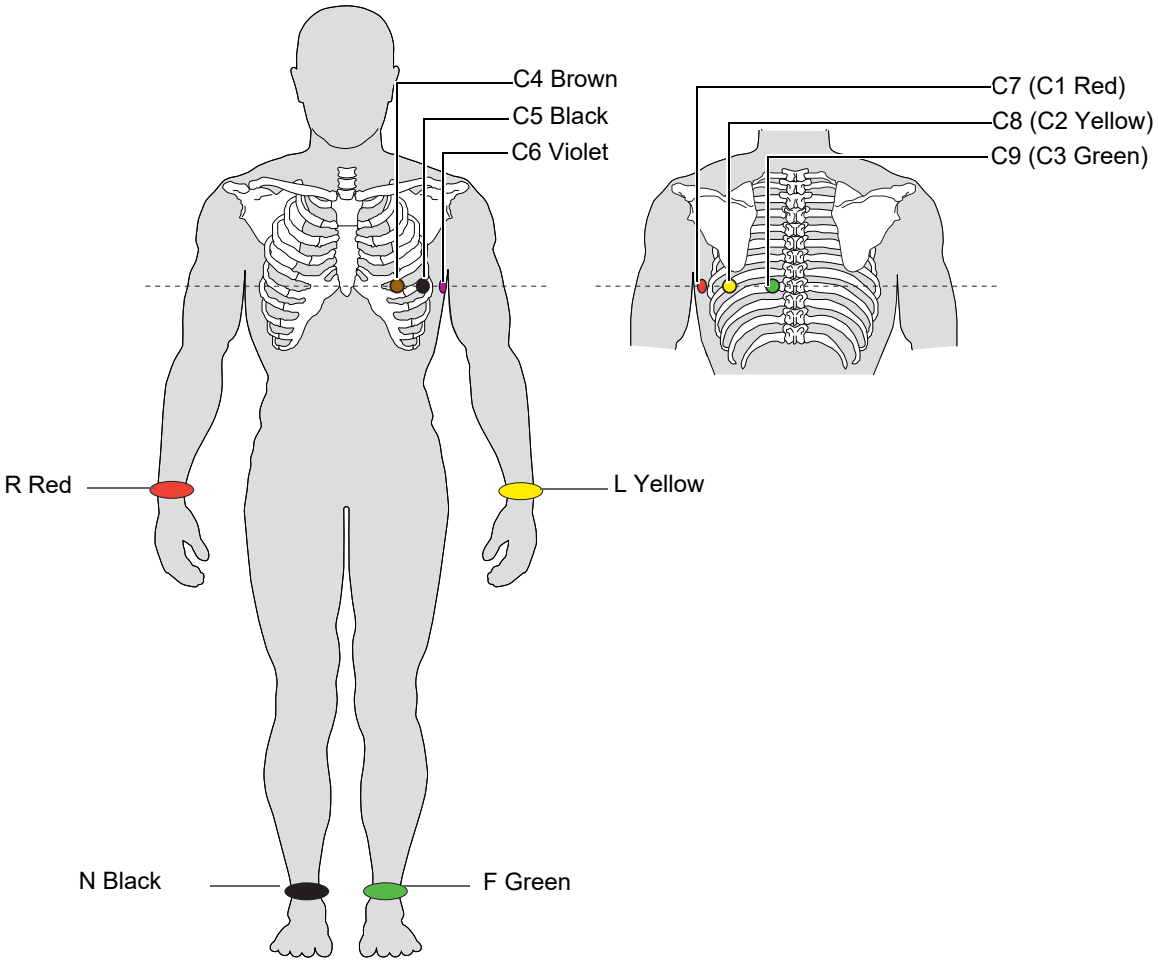


IEC label	AHA label		Positioning
C7 (C5 white / black)	V7 (V5 brown / orange)	→	Left posterior axillary line at the level of C4.
C8 (C2 white /yellow)	V8 (V2 brown / yellow)	→	Left of the mid-scapular line at the level of C4.
C9 (C6 white / violet)	V9 (V6 brown / violet)	→	Left paravertebral line at the level of C4.
C1 white / red	V1 brown / red	→	Fourth intercostal space at the right sternal border.
C3r white / green	V3r brown / green	→	Midway between C1 and C4R, right side of chest
C4r white / brown	V4r brown / blue	→	Fifth intercostal space right mid-clavicular line.
L Yellow	LA Black	→	Left arm
R Red	RA White	→	Right arm
F Green	LL Red	→	Left foot
N Black	RL Green	→	Right foot

Art. no.: 2.511335 Rev. a

4.1.7 Left Posterior C7-C9

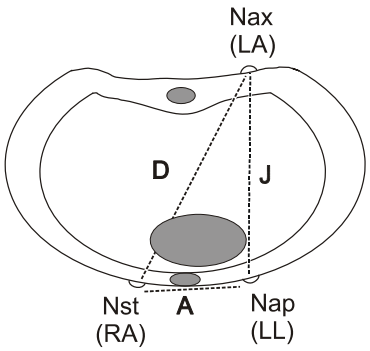
If an acute coronary occlusion is strongly suspected, it is recommended to also register posterior chest wall leads (C7–C9)



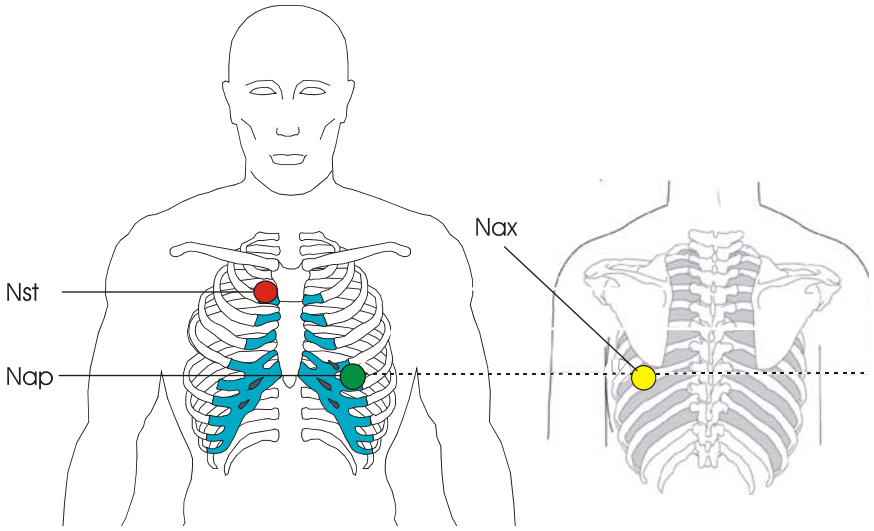
IEC label	AHA label		Positioning
C7 (C1 white /red)	V7 (V1 brown / red)	→	Left posterior axillary line at the level of C4.
C8 (C2 white /yellow)	V8 (V2 brown / yellow)	→	Left of the mid-scapular line at the level of C4.
C9 (C3 white /green)	V9 (V3 brown / green)	→	Left paravertebral line at the level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

Art. no.: 2.511335 Rev. a

4.1.8 Nehb Leads



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



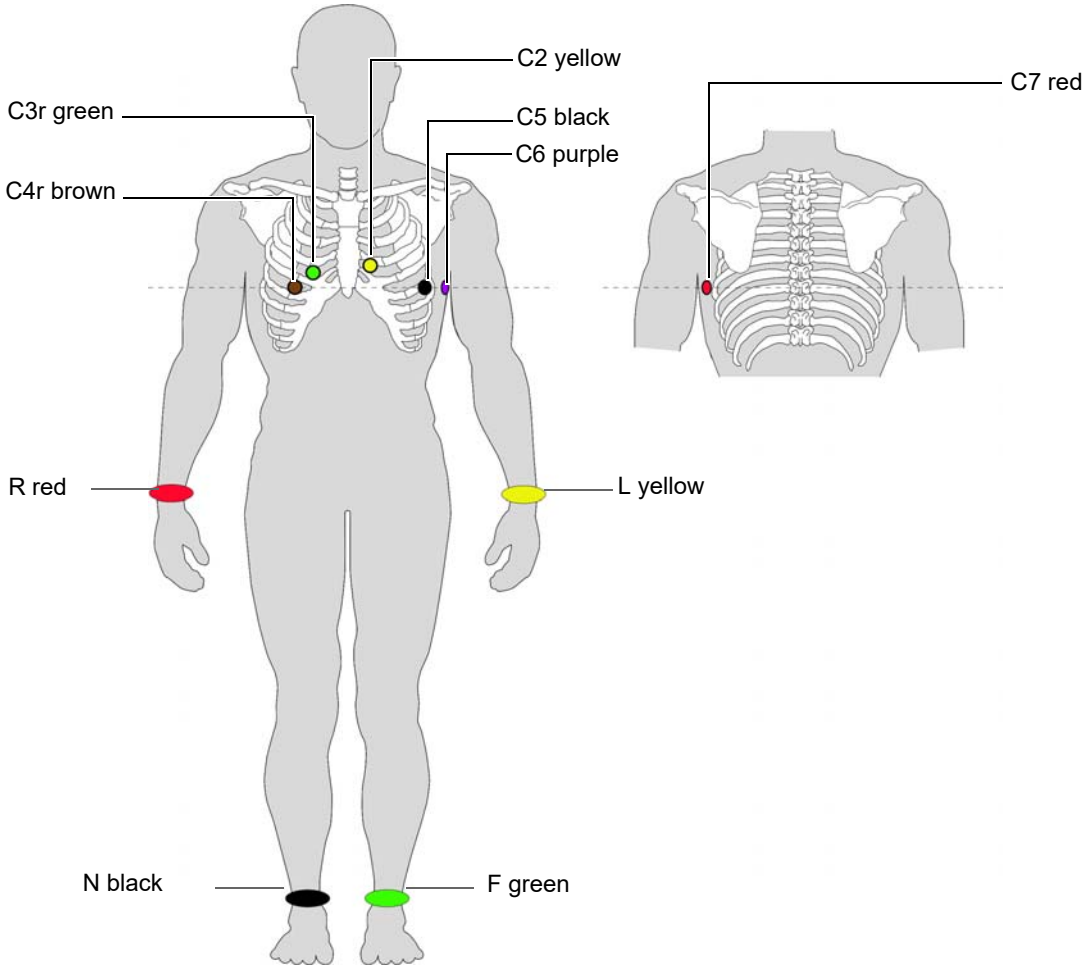
Place the electrodes as follows:

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

Place all other electrodes in the normal positions (see para. 4.1.3, Standard 12-lead, page 48)

Art. no.: 2.511335 Rev. a

4.1.9 Paediatric

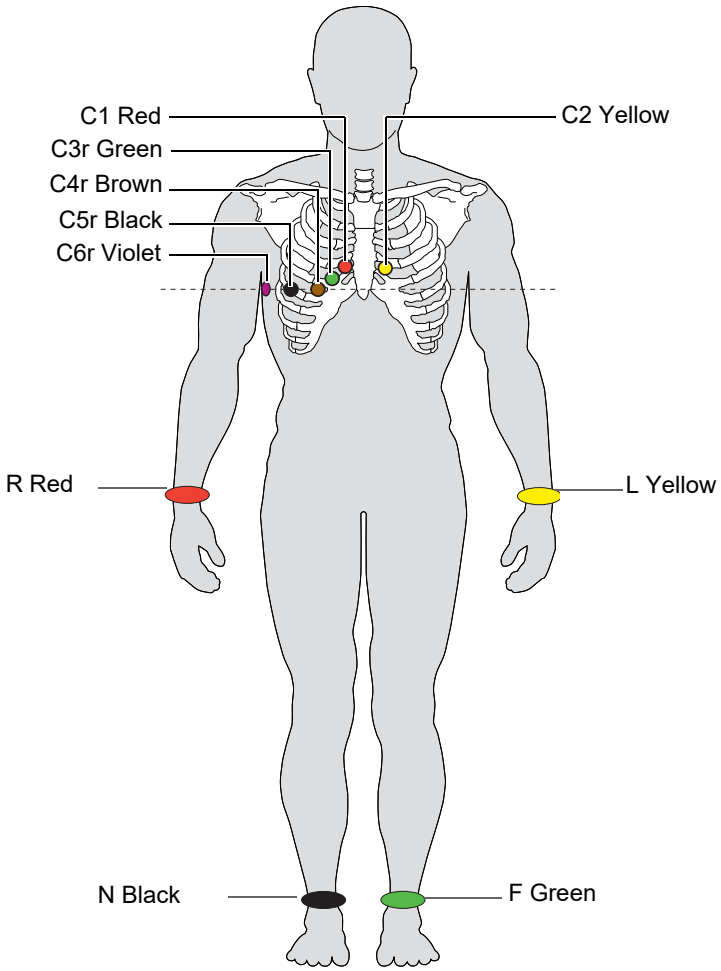


IEC label	AHA label		Electrode placement
C4r white / brown	V4 brown / blue	➜	Fifth intercostal space on the mid-clavicular line.
C3r white / green	V3 brown / green	➜	Above C4r, fourth intercostal space.
C2 white / yellow	V6 brown / violet	➜	Fourth intercostal space at the left sternal border
C5 white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

Art. no.: 2.511335 Rev. a

4.1.10 Right Precordials (C3r-C6r)

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

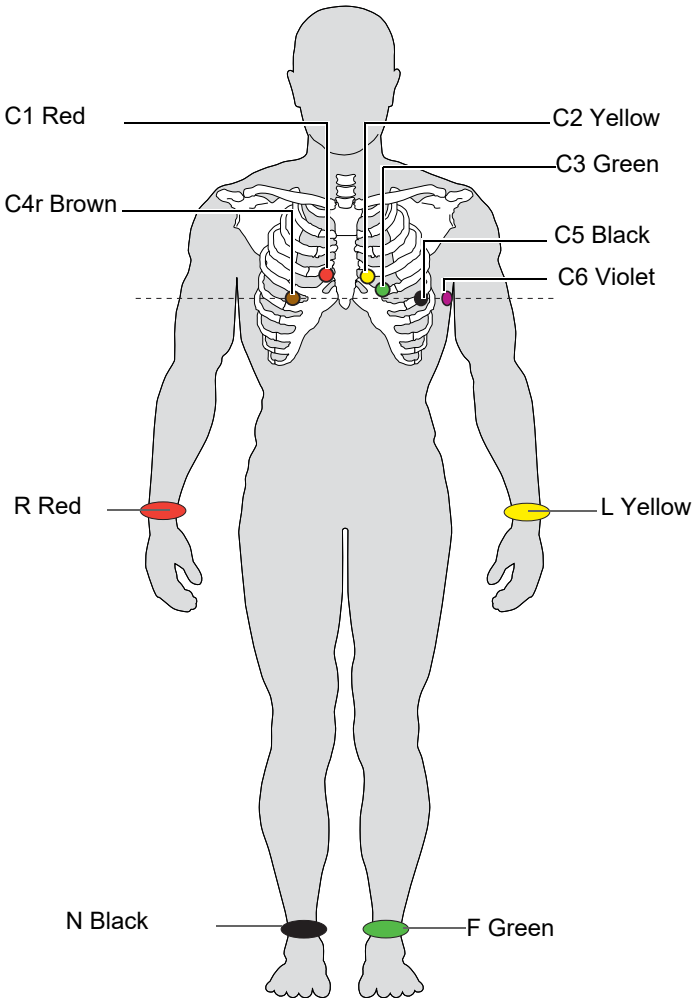


IEC label	AHA label		Positioning
C1 white / red	V1 brown / red	→	Fourth intercostal space at the right sternal border.
C2 white / yellow	V2 brown / yellow	→	Fourth intercostal space at the left sternal border.
C3r white / green	V3 brown / green	→	Designated point halfway between C1 and C4r.
C4r white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

Art. no.: 2.511335 Rev. a

4.1.11 Standard with C4r

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



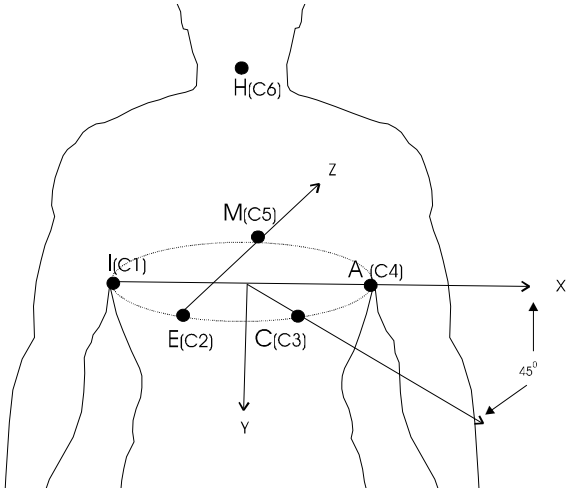
IEC Label	AHA Label		Electrode placement
C1 white / red	V1 brown / red	→	Fourth intercostal space at the right sternal border.
C2 white / yellow	V2 brown / yellow	→	Fourth intercostal space at the left sternal border.
C3 white / green	V3 brown / green	→	Midway between C2 and C4.
C4r white / brown	V4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

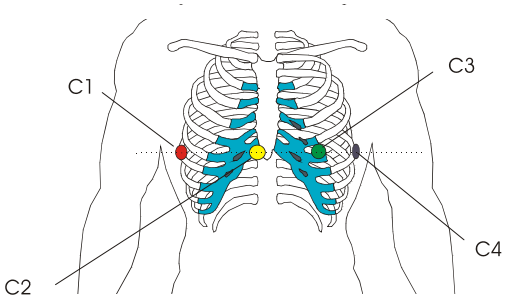
Art. no.: 2.511335 Rev. a

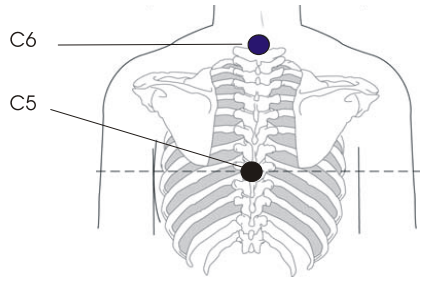
4.1.12 Frank Leads X, Y, Z

The orthogonal lead configuration is based on the theory of the heart as centre of a three-dimensional system of coordinates:

- ➜ lateral axis X
- ➜ longitudinal axis Y
- ➜ sagittal axis Z







With the patient lying down, attach the electrodes on a level with the fourth intercostal space. With a patient in a seated position, attach the electrodes in the fifth intercostal space.

Place all other electrodes in the normal positions.

IEC Label	AHA Label		Electrode Placement
C1 white / red	V1 brown / red	➜	**I (-X) -** right midaxillary line
C2 white / yellow	V2 brown / yellow	➜	**E (-Z) -** front midline
C3 white / green	V3 brown / green	➜	**C (+Y) -** between E (-Z) and A (+X)
C4 white / brown	V4 brown / blue	➜	**A (+X) -** left midaxillary line
C5 white / black	V5 brown / orange	➜	**M (+Z) -** back midline (on the back)
C6 white / violet	V6 brown / violet	➜	**H (-Y)** - neck (on the back)
L yellow	LA black	➜	Standard position - left arm
R red	RA white	➜	Standard position - right arm
F green	LL red	➜	Standard position - left foot
N black	RL green	➜	Standard position - right foot

Art. no.: 2.511335 Rev. a

4.2 Entering a Recording Screen

4.2.1 From the Patient Search Screen

Patient already Registered

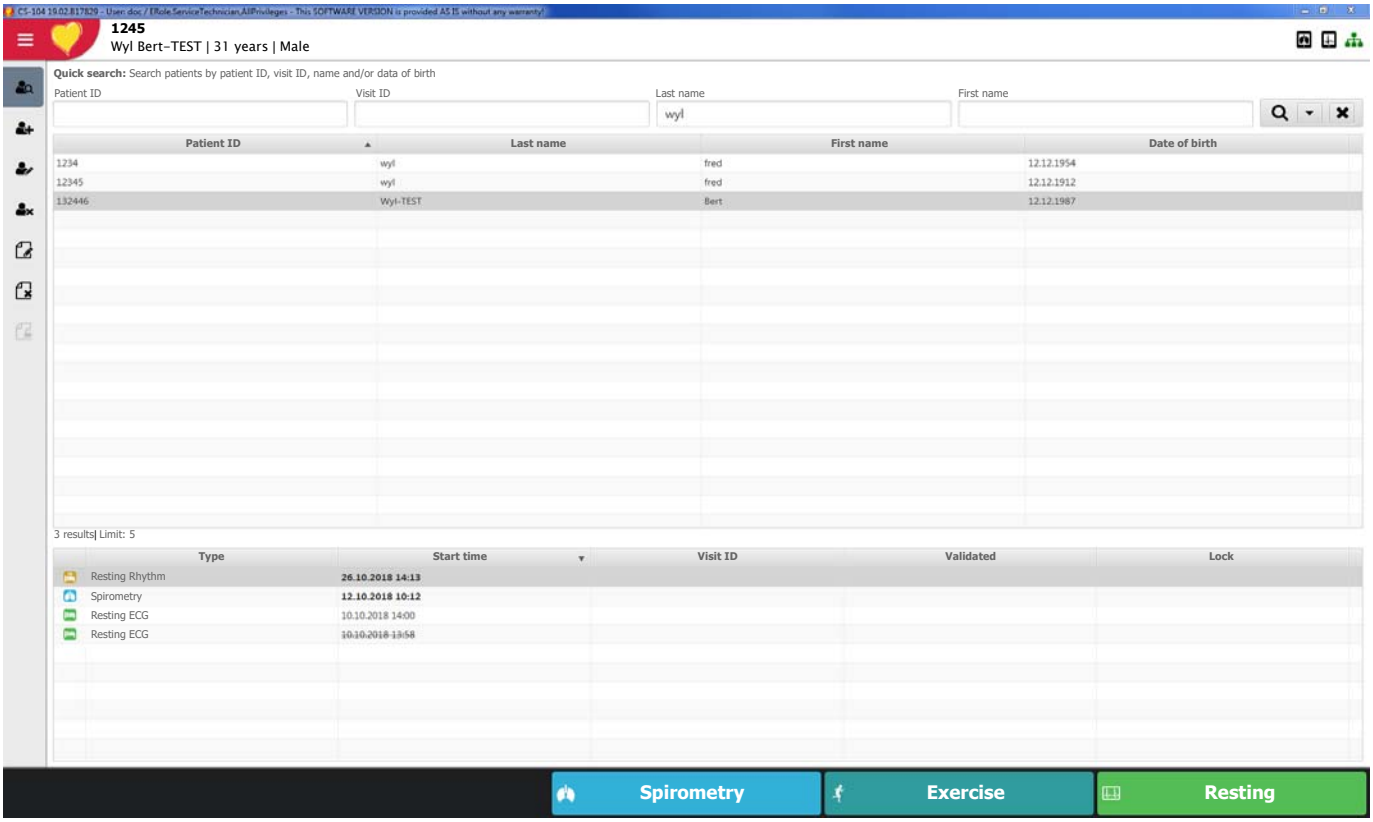
Search for the patient (see para. 3.8.1, Home Screen and Main Menu Options, page 41) and highlight to select.

New patient 

New Patient

Click the New Patient icon and enter patient details (see para. 3.10, Patient Data, page 43)

- Click **Resting** to enter the Resting and Rhythm recording screens.
- Click **Exercise ECG** to enter exercise ECG Recording screen.



Art. no.: 2.511335 Rev. a

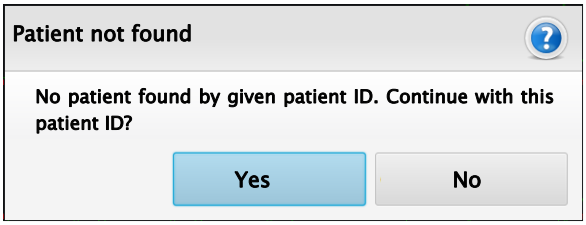
4.2.2 From the Recorder Screen

Patient already Registered

Enter the Patients ID and press return. The patient data is populated and a recording can be made as previously stated.

New Patient

Enter a patient ID that is not already registered and press return. The following message is given:



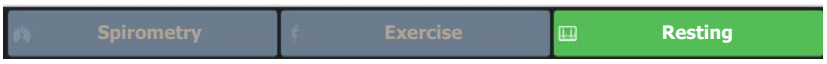
When Yes is selected, the patient screen is again displayed and patient data can be entered to define a new patient.

New Patient (Undefined Details)

Enter a patient ID and then select recording type from the bottom icons. The recording is taken and can be stored. Patient details can be added later.

Emergency Resting ECG

The recording is taken and can be stored by clicking the Resting icon (other options are not available) A random patient ID will be allocated - Patient details can be added later.



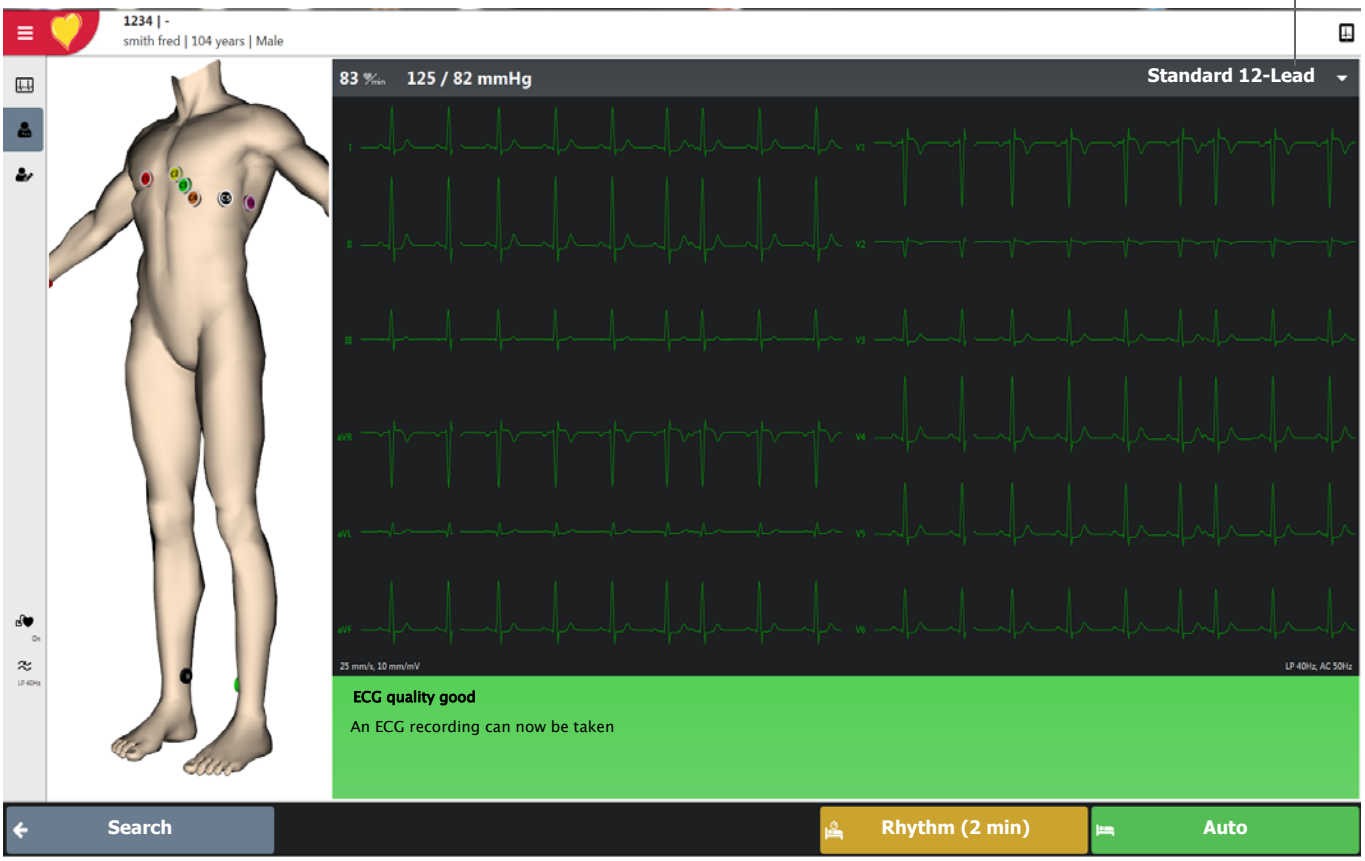
Art. no.: 2.511335 Rev. a

4.3 Hookup Screen, Electrode Placement and Check

Click the **Hookup icon** in the ECG screen to display the electrode screen in the left section of the screen.

Electrode placement graphic is displayed in the left area of the screen and the electrode status is shown in the bottom right information field of the screen. If an error is detected the suspected reason for the poor signal quality is displayed (see next page). Reapply the electrode.

Select the lead configuration (see next page) to display the electrode placement for the specified configuration.



Art. no.: 2.511335 Rev. a

4.4 Electrode Check

In the hookup screen, the following is checked and indicated on the bottom of the screen:

- Excessive noise (signal noise too high) due to poor electrode contact or mains interferences (mains filter not activated)
- Electrodes reversed
- Electrodes off or high resistance

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

Poor signal quality
Check that the electrodes are properly attached, the ECG cable is connected and the correct powerline filter is configured.

Electrode Off
One or more of the electrodes are not properly connected. Please check that all electrodes are placed at the correct position.

Lead reversal
Some of the electrodes seem to be interchanged. Please check that all electrodes are placed at the correct position.

4.4.1 Quality Indication on the ECG Trace

The signal quality is also indicated by the colour of the ECG trace as follows:

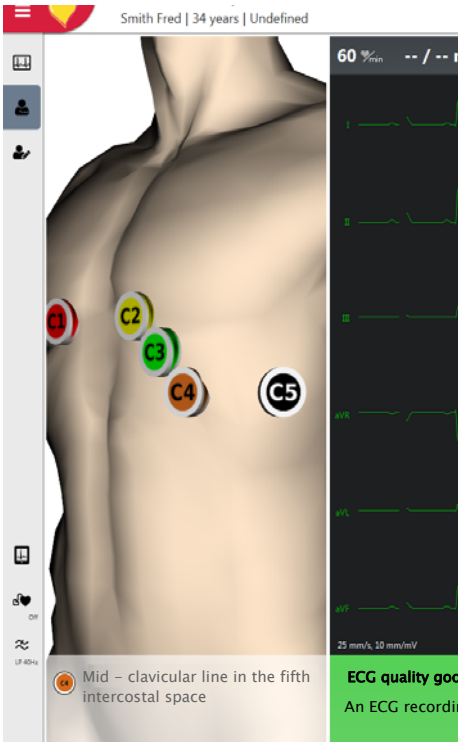
Green Trace: Good signal

Yellow Trace: Poor signal quality - you should be able to make a recording but the indicated lead(s) have an electrode that is higher resistance than is ideal.

Red trace: Bad signal quality and the lead should be checked.

The colours given here are the default trace colours but these colours can be redefined for user preference if required (see para. 11.2.10, Recorder View, page 121**).**

4.4.2 Electrode Placement



- Click anywhere in the screen to rotate and move the model for required view.
- Click on any electrode to zoom in on the electrode placement.
- When zoomed, electrode placement is given below the graphic.
- Click anywhere in the main ECG trace to zoom out again.

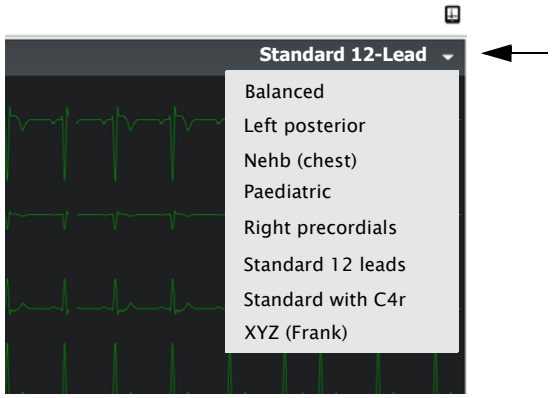
Art. no.: 2.511335 Rev. a

4.5 Standard or Cabrera Lead Sequence

Standard or Cabrera Lead Sequence is defined in system settings (see para. 11.11, ECG, page 132).

4.5.1 Selecting the Lead Configuration

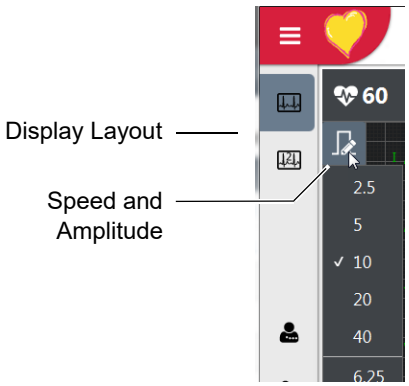
The lead display is displayed and selected in the top right corner.



Important

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

4.6 Display Layout and Speed and Amplitude



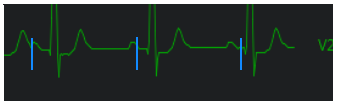
Display Layout

Select the Display layout with the top icons.

Speed and Amplitude

The speed and amplitude of the ECG trace are displayed and set in the top left of the screen when the settings icon is clicked.

4.7 Pacemaker Detection



Pacemaker pulses can be enabled/ disabled when the **pacemaker icon** 

is clicked. Detected pacemaker pulses are indicated on the ECG trace as blue vertical lines. Note that the pacemaker lines indicate time but are not representative of amplitude nor of pulse width.

Note that interpretation statements will indicate that it is a pacemaker ECG.

Art. no.: 2.511335 Rev. a

4.8 Filter

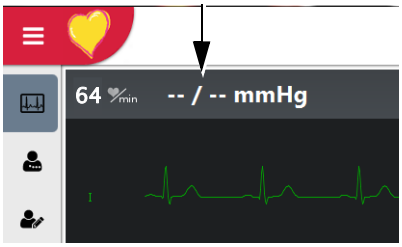
The filter is designed to help reduce muscle artefact. Toggle the filter with the **Filter icon** 

to set the low pass cut-off frequencies to **150 Hz, 40 Hz, 25 Hz,** or **Off.** The Low pass cut frequency is displayed in the icon. Exercise ECG also has an RNSF filter.

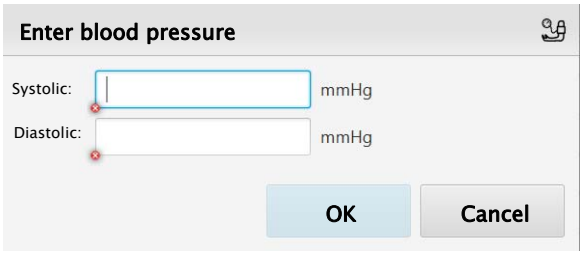
- The 150 Hz setting is effectively filter off.
- The default cut-off frequencies and filter settings are defined in system settings (see para. 11.11.3, Display Filter, page 132).

The side bar and bottom navigation buttons are user set. If the Filter, Pacemaker or any other icons are not displayed, they can be set for display by clicking edit icons (see para. 3.4.1, Side Bar and Bottom (Main) Icons, page 36).

4.9 Blood Pressure



Blood pressure can be entered by clicking the Blood pressure measurement in the top left of the screen. When clicked you are prompted to enter the BP:



BP measurement is different for exercise ECG, and BP intervals can be set automatically in the protocol; it is also possible to have a BP unit connected to the system. Details are given in the exercise recording section (see para. 11.14, Exercise ECG, page 133).

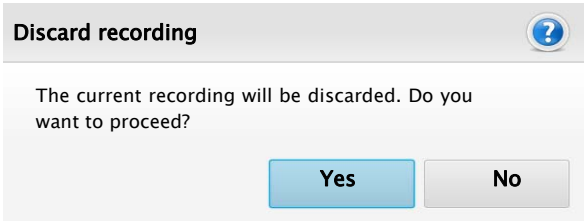
Art. no.: 2.511335 Rev. a

4.10 Saving a Recording

Click **Store recording** to save the recording.

4.11 Discarding a Recording

Click **Discard** to return to the ECG acquisition screen without saving the recording. Confirmation that the recording is not to be saved is requested.



- The Discard icon is only available when defined in the screen layout (see para. 3.8, Display Configuration, page 40)

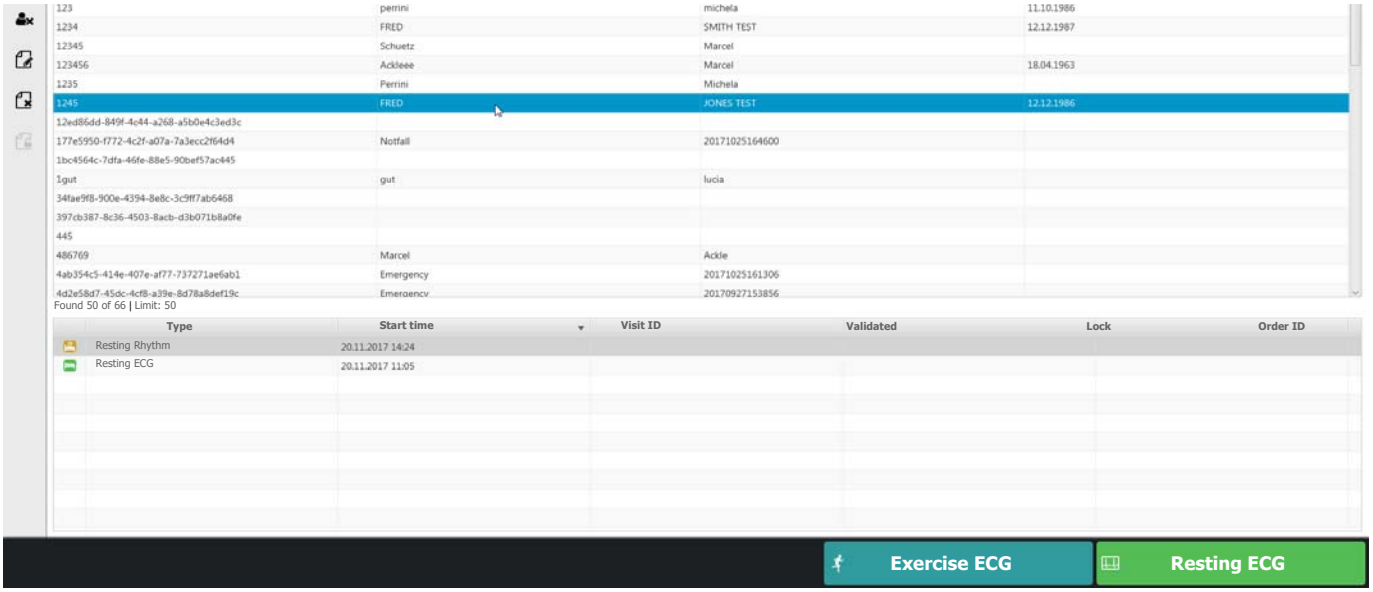
Art. no.: 2.511335 Rev. a

5 Resting ECG Recording

5.1 Procedure

To take an auto mode recording:

1. Prepare the patient and connect the electrodes (see para. 4.1, Placing the Electrodes, page 46).
2. Enter the Recording screen (see para. 4.2, Entering a Recording Screen, page 58).



3. Click **Resting ECG** icon.
4. Check the ECG and ensure a good trace.
5. Take an auto mode recording as follows:
   – Press the **Auto key** 

,

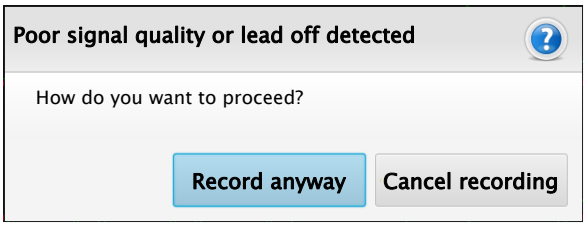
If using the MS-12 USB, pressing the **Start button** 

(the button will be blue and blinking), will perform the same function as activating the **Auto** key (see para. 13, ECG Recorders, page 139).

Art. no.: 2.511335 Rev. a

6. After approximately 10 seconds the result is displayed and the recording can be reviewed and analysed (see para. 8.1, General Analysis Settings and Options, page 82).

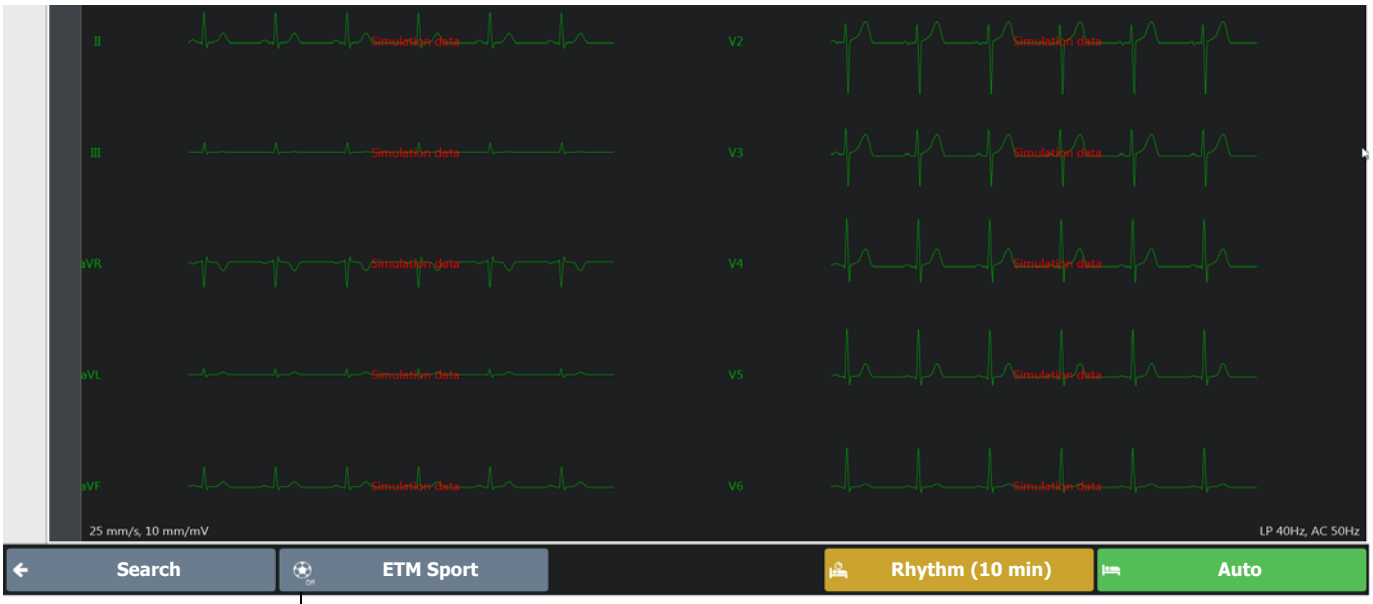
If a high resistance electrode, lead off or incorrect electrode placement is detected when an auto recording is requested, a message is given to indicate this.



It is recommended that the hookup screen (see para. •, Click Exercise ECG to enter exercise ECG Recording screen., page 58) is checked before taking a recording.

5.1.1 ETM Sport (Option)

The ETM Sport diagnoses abnormalities in athletes in a resting ECG that otherwise would not be diagnosed. The ETM Sport icon must be clicked before an Auto recording is made.



Indicates if ETM Sport is on or off. ETM Sport is for resting ECG only and when on, Rhythm recording is disabled.

When set, the Seattle criteria for athletes interpretation is displayed in the interpretation screen of the recording (see para. 8.2.12, ETM Sport Option, page 90).

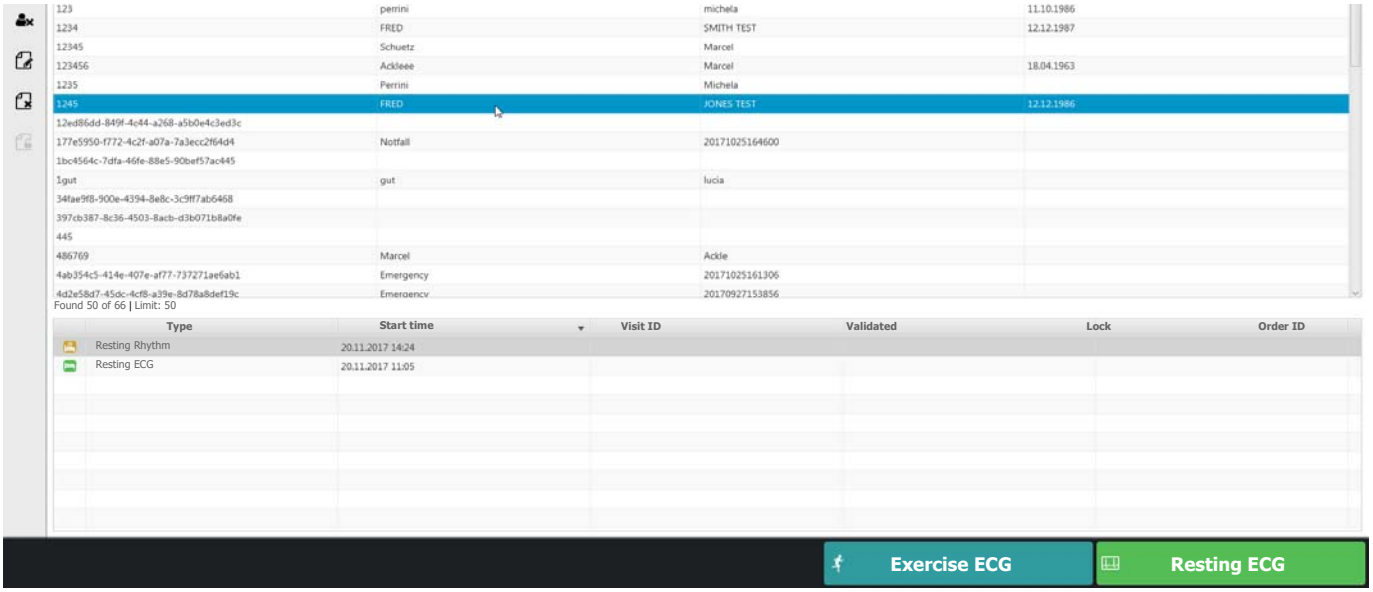
- The ETM Sport icon **must be set for display in the side or bottom icon bar** (see para. 3.8, Display Configuration, page 40).
- ETM Sport is only available for **Standard 12-Lead** configuration. If ETM Sport is activated, the Standard 12-lead configuration is automatically set and no other configuration can be set.

Art. no.: 2.511335 Rev. a

6 Rhythm ECG Recording

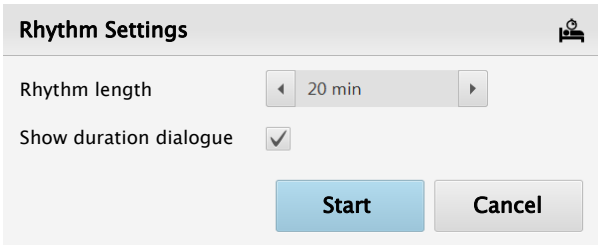
6.1 Procedure

1. Prepare the patient and connect the electrodes (see para. 4.1, Placing the Electrodes, page 46).
2. Enter the Recording screen (see para. 4.2, Entering a Recording Screen, page 58)



3. Click **Resting ECG** icon.
4. Check the ECG and ensure a good trace.
5. Press **Rhythm** 

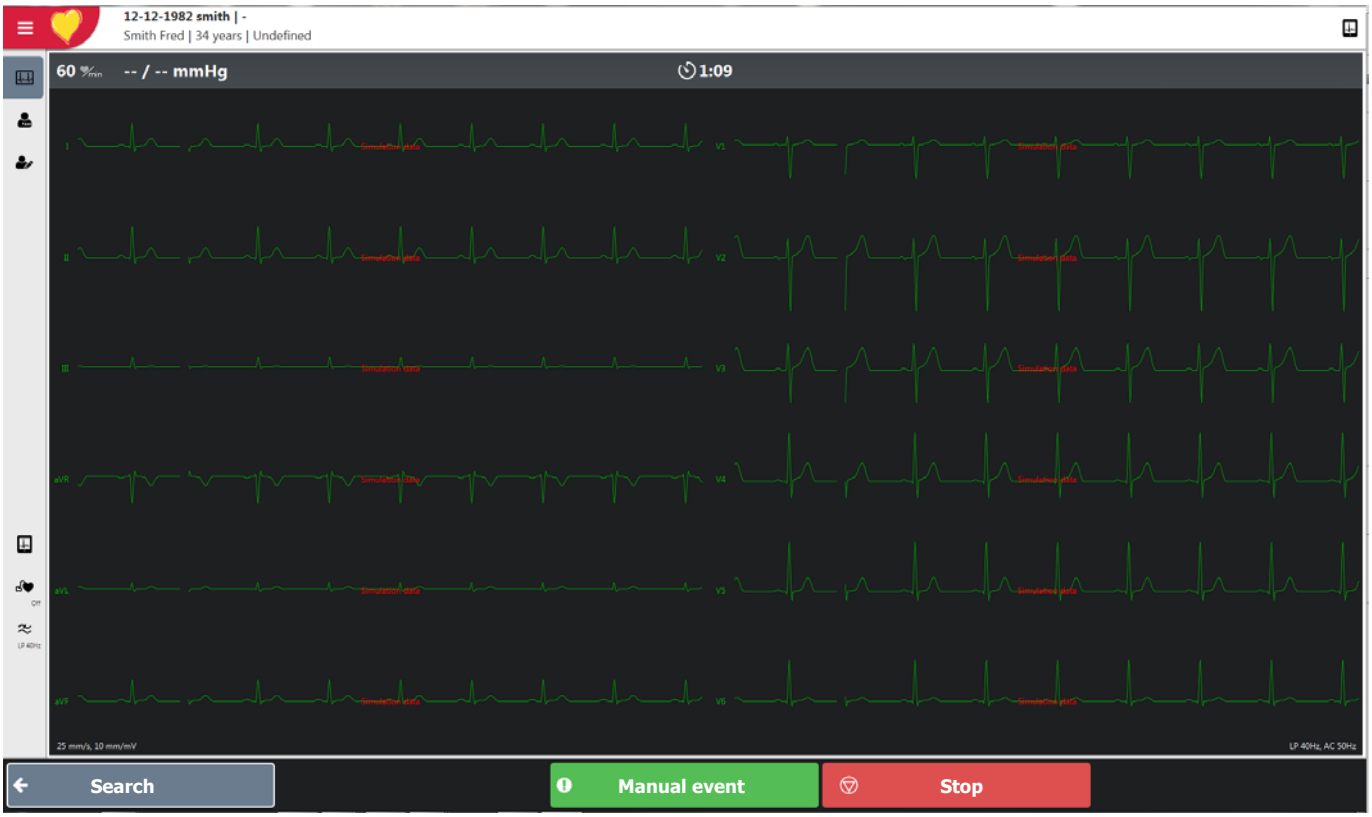
.
6. Select the recording duration in the dialogue.



The default rhythm length and whether or not the duration dialogue is displayed before a rhythm recording is taken, is defined in system settings (see para. 11.13, Rhythm ECG, page 133).

Art. no.: 2.511335 Rev. a

7. Click **Start** to commence rhythm recording.



- The recording will continue until the defined duration has elapsed.
- All settings, pacemaker display, blood pressure entry, filter, etc, are the same as for resting ECG (see previous pages).
- Manual events can be entered during the test (see following).
- Click **Stop** to stop the recording before the defined time.

In the first 10 seconds of the recording, the **Stop** button states **Cancel** to cancel the recording in the initial period.

6.1.1 Arrhythmia (option)

When the Arrhythmia option is enabled, an extra field is given to display the Ventricular Ectopic Beat Rate (VEBR). This gives the number of ventricular ectopic beats over the last minute.

Every time a VEBR is detected an event is registered (see para. 8.3.3, Events, page 97).

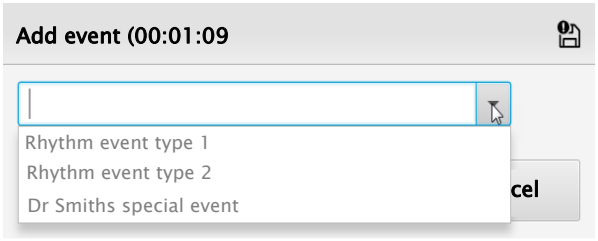
Art. no.: 2.511335 Rev. a

6.2 Events

6.2.1 Manual Events

To register an event click the **manual event** button.

- If defined for display in the bottom line shown as Manual event.
- If defined in the side line shown as .



Enter any text or click the arrow to the side to select predefined events (see note), and click OK. Events will be referenced in the recording (see para. 8.3.3, Events, page 97).

Manuel event text can be pre-entered if required, and available for selection when the arrow by the event entry is clicked. The manual event wording is defined in system settings (see para. 11.13, Rhythm ECG, page 133).

6.3 At the End of a Rhythm Recording

The recording is analysed and the result displayed.

– Click **Store recording** Store recording to save the recording or
– Click **Discard** Discard to return to the ECG acquisition screen without saving the recording.

Art. no.: 2.511335 Rev. a

7 Exercise ECG Recording

7.1 Safety Notes

⚠WARNING

- ▲ Do not use the ergo device if the earth connection is suspect or if the mains cable is in any way damaged.
- ▲ A stress test may only commence when the operating instructions of the ergometer have been read and understood. This applies particularly to the safety instructions. The instructions given in this book do not override those for the ergometer.
- ▲ A stress test may only be started if the patient has been informed of the test procedure and the risks involved (for example of falling on the treadmill). Ensure the patient is aware of the location of the emergency stop knob and its use.
- ▲ Ensure that the resting ECG confirms that the patient is able to carry out an exercise ECG.
- ▲ Ensure a charged defibrillator is to hand when carrying out an exercise test.

- ▲ To avoid possible interference from the Ergometer when carrying out an exercise test it is recommended that both the PC and the Ergometer are connected to the same common ground.
- ▲ The patient connection is fully isolated. However where possible during the recording, avoid contact between the patient and patient electrodes, and other persons or conductive objects (even if these are earthed).

7.2 Emergency Stop

- ▲ At any time after the test has started, stop the treadmill by pressing the **Emergency stop** on the treadmill.

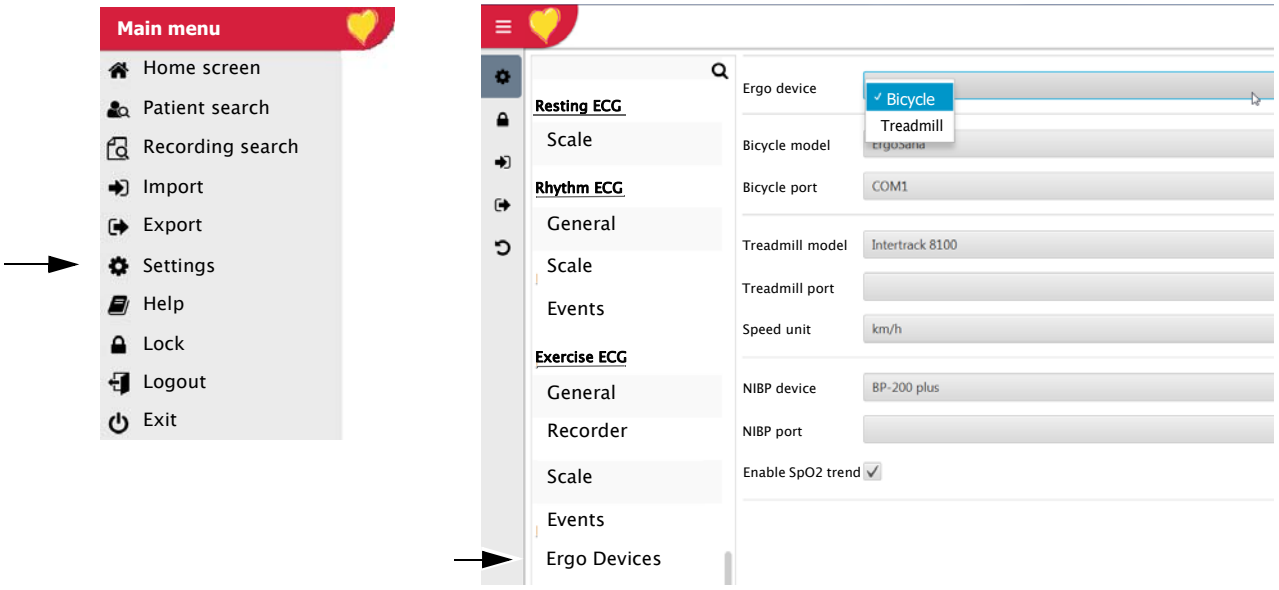
Art. no.: 2.511335 Rev. a

7.3 Settings to Check Before Taking an Exercise Test

7.3.1 Ergo Device and BP unit

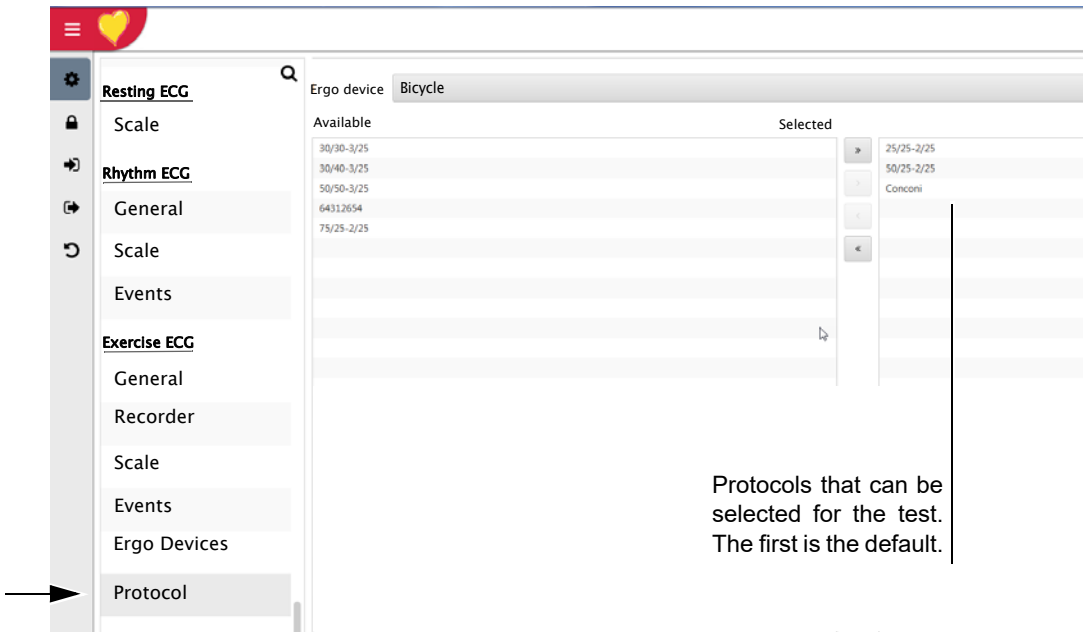
Click the SCHILLER icon the top left of the screen to display the main menu and select **Settings**. Scroll through the settings and select **Exercise ECG > Ergo devices**.

– Define/ confirm the ergo device
– Define/ confirm the BP unit, if used



7.3.2 Protocols

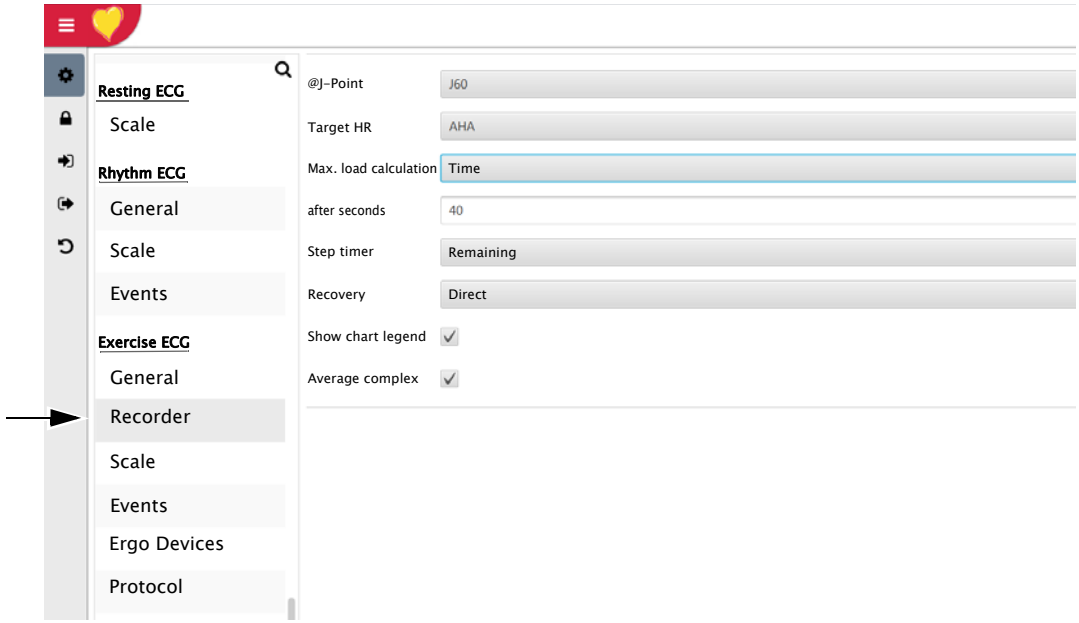
Define the protocols that can be selected for the test. Move available protocols to the **selected** column.



Art. no.: 2.511335 Rev. a

7.3.3 Default J-point, Target HR Calculation

Check / Define settings as required.



Details of protocols and all exercise settings are given in the settings section (see para. 8.4, Exercise ECG, page 99).

7.4 Exercise Test Procedure

1. Prepare the patient and connect the electrodes ((see para. 4.1, Placing the Electrodes, page 46)).
2. If using the MS-12 blue secure the MS-12 USB ECG Recorder to the patient using the ergo belt.
3. Enter the Recording screen (see para. 4.2, Entering a Recording Screen, page 58).
4. Click Exercise ECG icon Exercise.

- Check the ECG and ensure a good trace
- Take / enter BP measurement if required (see para. 4.9, Blood Pressure, page 63)
- Select the Protocol (or leave as default) using the arrow by the side of the protocol indication. The protocols that can be selected are defined in exercise settings (see previous page)

Art. no.: 2.511335 Rev. a

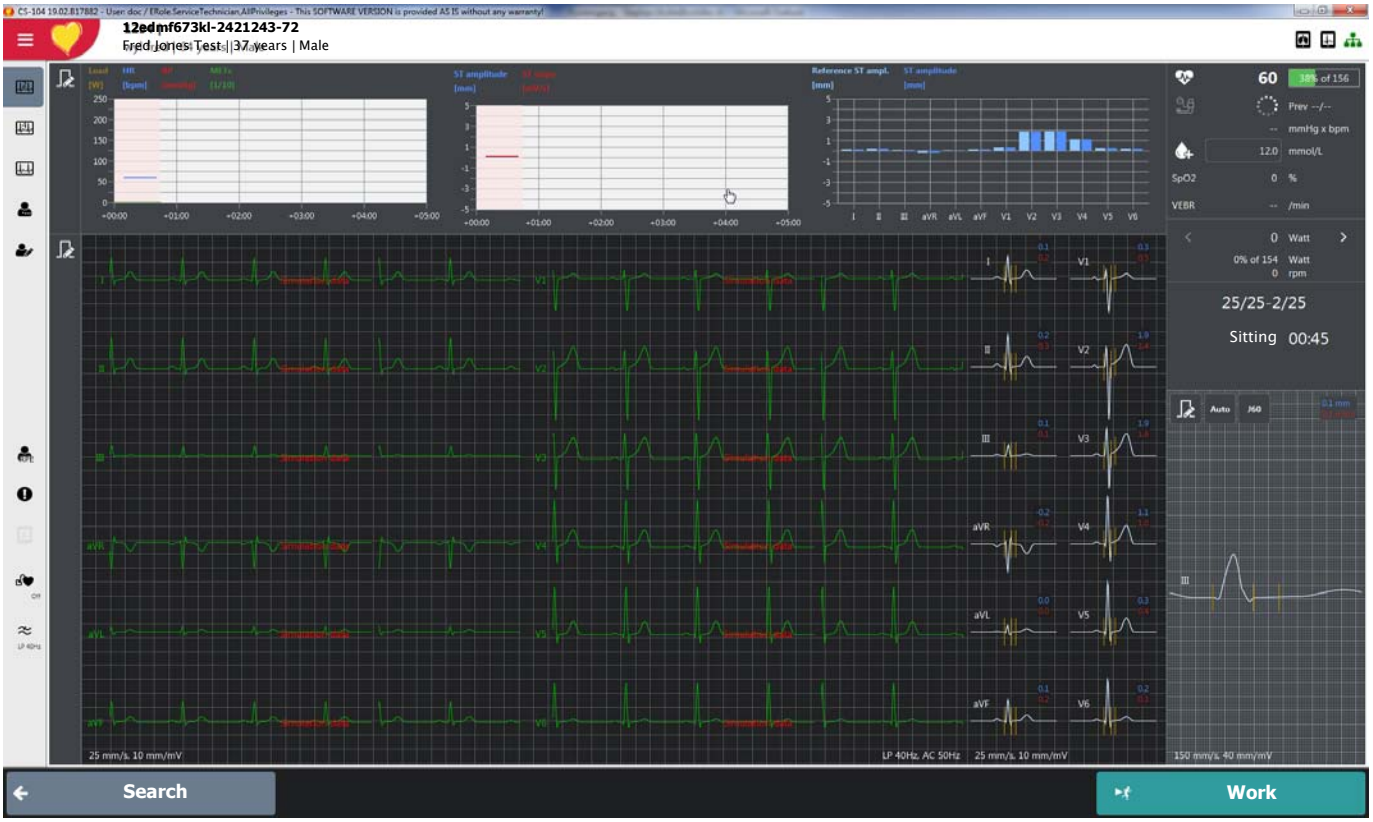
7.4.1 Starting an Exercise Test

⚠WARNING

▲ Danger of Injury. During the test the patient must be under constant observation. If a treadmill is used the emergency stop switch must be accessible at all times to both the patient and the person conducting the test.

Pre-Phase

1. Commence the test by selecting the **Start button.** The exercise **pre-phase** is started:
   - If a **treadmill protocol** has been selected, the timer display shows '**Standing'.**
   - If a **bicycle protocol** has been selected, the timer display shows **'Sitting**'.
   - The pre-phase time counter displays pre-phase elapsed time after the standing or sitting indication.
   - During this period the blood pressure cuff can be applied and for example, a BP measurement taken, SpO_2 measurement entered, J-point measuring point set, lactate measurement entered, etc.
   - After a period of 10 seconds a reference complex is displayed in the reference complex box in the bottom right of the screen and the average complexes of all channels with amplitude and slope, are displayed in the acquisition screen (if set in system settings (see para. 11.14, Exercise ECG, page 133).
   - The next step icon changes to **Work** or **Warmup.**



Art. no.: 2.511335 Rev. a

Start the Test

2. If a warm-up phase is defined in the protocol, click the **warm-up** icon
   – The test will start with the warm-up phase as defined in the protocol
   – The duration of the warm-up phase is not defined and the work phase can commence when it is felt the patient is ready.

Note:

- The warm-up phase optional and is defined in the protocol. If a warm-up phase is defined, the next step after the pre-phase is warm-up. If warm-up has not been defined for the protocol, the work stage is entered directly after the pre-phase.

3. Click the **Work button** to commence the test according to the protocol.

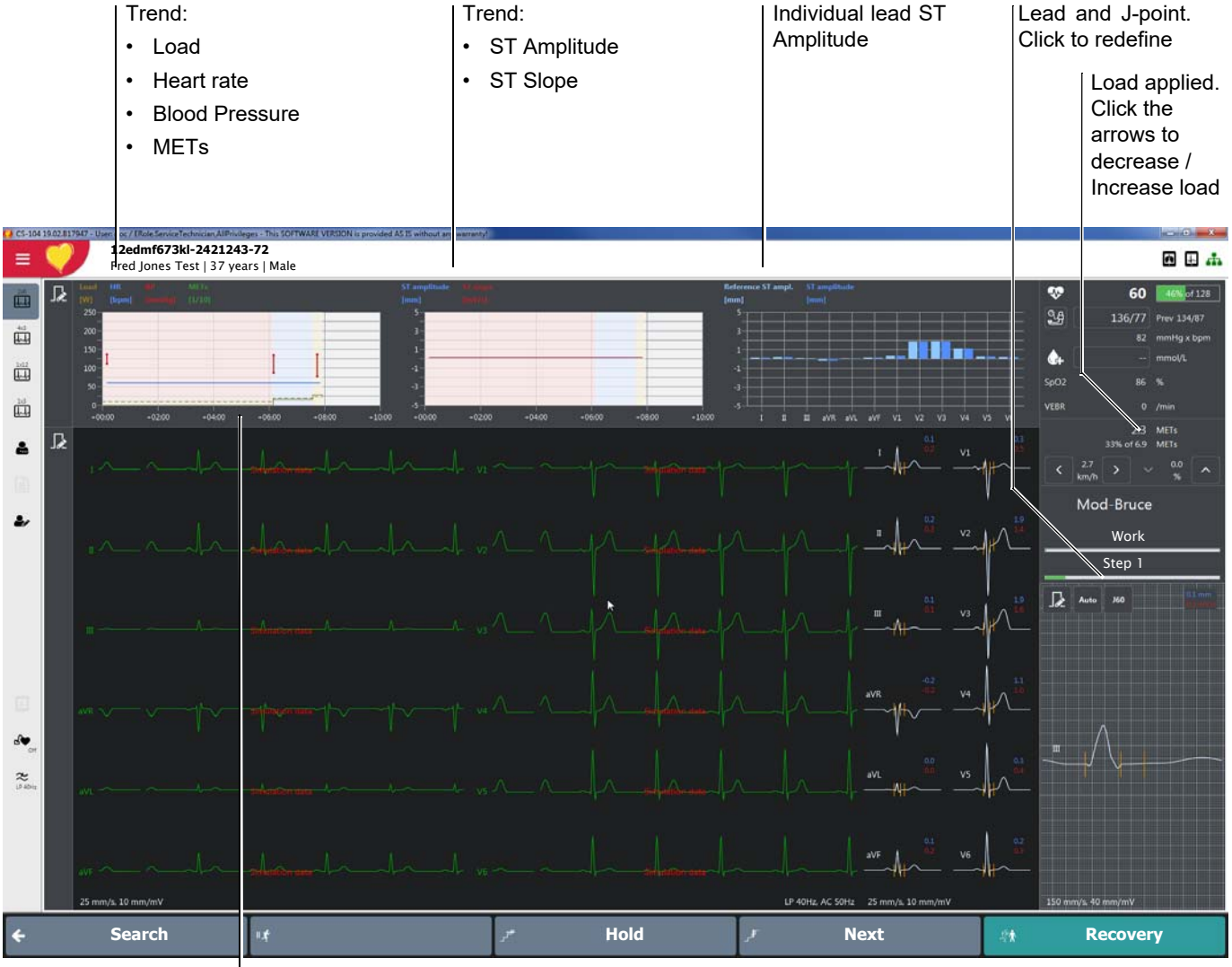
Note

- The maximum duration of a test is120 minutes. When approaching this time, the recovery stage is entered automatically to ensure at least one recovery step.

Art. no.: 2.511335 Rev. a

7.5 During the Test

The following is an example of the screen during an exercise ECG when using a bicycle ergometer.



Art. no.: 2.511335 Rev. a

7.5.1 Test Control Buttons

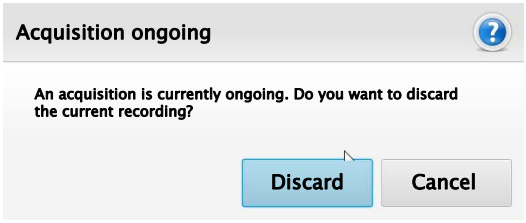
The test control button on the bottom of the screen are as follows:

Hold / Pause (treadmill) — Hold current stage. The button changes to **Resume** and the step counter is stopped (but total work counter continues) until the stage is resumed. During this time the load on the bike remains / the treadmill speed continues, until resume is again clicked.

Next — Go to next stage.

Init Recovery / Recovery (depends on setting) — Initiates the recovery phase and the button changes to End. The recovery stage is held for as long as defined in the protocol or until End button is pressed.

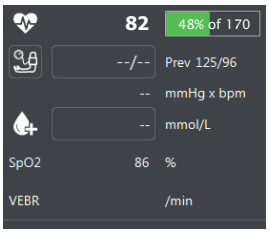
Search — Returns to the search and discontinues the current ECG acquisition. You are prompted to confirm:



7.5.2 Information and Settings Panel

Heart Rate — Averaged over 4 beats.

- The percentage of current heart to target heart rate is displayed after the heart rate (the formula used to define the target heart rate is defined in system settings (see para. 11.14, Exercise ECG, page 133).
- If the target is exceeded, the Heart rate indication changes from green to red and flashes to indicate that the target is exceeded.



Blood Pressure — Last entered/recorded blood pressure measurement (systolic/diastolic). The value is displayed until a new value is entered /measurement taken, or until a new exercise stage is entered. The previous BP is given beside the current value.

mmHg x bmp — The (last) BP measurement taken in the stage, multiplied by the heart rate.

Lactate — Select to enter the respective measurement and description.

SpO_2 — The SpO_2 measurement received from a connected device /entered manually. (see para. 7.5.5, SpO_2, page 78)

VEBR — (see para. 7.5.6, Arrhythmia (option), page 79).

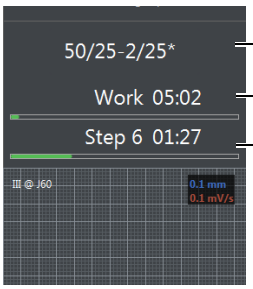
Art. no.: 2.511335 Rev. a

Current Load and percentage of target

- Current load in Watts (bicycle) or speed and elevation (treadmill).
- Percentage of the current load to the target load (must have patient height, weight and birth date entered)
- The load in Watts or Mets according to the user configuration and ergo device type.
- The current MET value and the METs interpolation time if set

The load can be increased / decreased with the arrows to the side of the value

Protocol information



Protocol identification. A star indicates that the protocol has been modified

Accumulative time that the patient has been under load (from the start of the test)

Current step and the time in that stage. Note: The time can be ascending or descending and this is set in exercise settings (see para. 11.14, Exercise ECG, page 133)

Reference Complexes

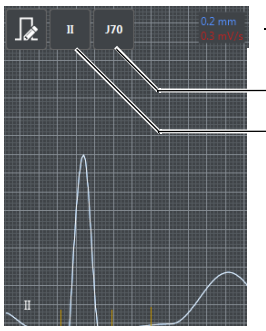
A zoom reference complex is at the bottom of right of the screen

The reference complex for all leads can also be displayed at the end of the ECG real time display. This is enabled / disables in system settings (see para. 11.14, Exercise ECG, page 133).

- The reference complexes are defined in the warm-up phase.
- The reference complex and the J-point can be changed at any time (see ST measurement previous page).
- The ST amplitude and slope measurements are shown at the top right of the zoom complex.
- The lead and J point are displayed top left of the zoom complex.
- The vertical lines on the reference complexes show measurement points are as follows:
  - The first line on the left gives the beginning of the QRS complex.
  - The second vertical line gives the end of the QRS complex.
  - The third vertical red line gives the J-point.

ST Measurement

The current ST measurement. The J-point is shown in the top right of the reference screen. The J-point can be changed at any time by clicking the J-point indicator.



Current ST measurement and slope

Define Measuring point

Define Lead

The Lead on which the ST measurement is made is selected next to the ST measurement display. When **Auto** is selected, the lead with the lowest amplitude is selected as follows:

- The lead with the minimal/lowest ST-Amplitude (depression) - positive or negative from any of the following leads from leads I, II, III, aVF, V2, V3, V4, V5, V6.

Art. no.: 2.511335 Rev. a

7.5.3 Trend Graphs

The trend graphs at the top of the screen give the following information:

- HR, BP, METS and Load Trend over the test.
- ST Amplitude and slope
- Reference ST amplitude / actual ST amplitude of every lead
  - The J-point is defined in the reference complex.

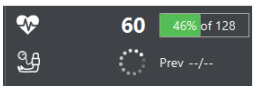
7.5.4 Blood Pressure

Automatic BP Measurement During the Test

Automatic BP measurements can be taken for any selected stage as set in the protocol (see para. 11.14.7, Protocol Editor, page 135). These can either be entered manually (measurement flashes when a measurement needs to be taken), or a measurement is taken automatically by a BP device attached to the unit. When BP measurements are defined in the protocol, BP measurement is started 10s after the pre phase, 50s before the end of work/recovery step or instantly if work/recovery stage is shorter than 50s.

A BP measurement can also be taken at any time during the test as follows:

Initiating a BP Measurement from an Attached Device

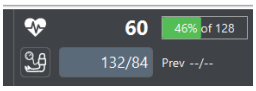


Initiate BP Measurement

Measurement in progress

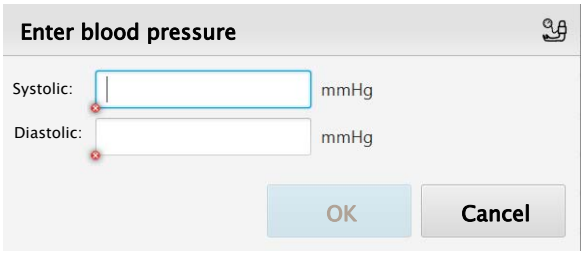
When an NIBP device has been defined (see para. 11.14, Exercise ECG, page 133), blood pressure measurements are initiated by clicking on the BP icon . During the measurement the measurment field displays a timing indicator. On completion, the BP measurement is displayed.

Manually Entering a BP Measurement



Click to manually enter BP Measurement

- Click on the measurement - the BP entry screen is displayed.



7.5.5 SpO_2

- SpO_2 measurements are taken either entered manually or taken by an SpO_2 device attached to the unit or incorporated in an BP unit (for example the SCHILLER BP-200 with SpO_2 option).

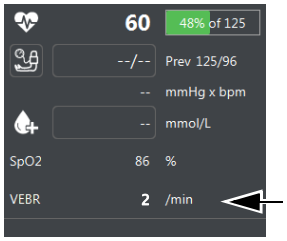
Manually entering an SpO_2 Measurement

SpO_2 measurements are entered manually by clicking on the SpO_2 icon.

Art. no.: 2.511335 Rev. a

7.5.6 Arrhythmia (option)

When the Arrhythmia option is enabled, an extra field is given to display the Ventricular Ectopic Beat Rate (VEBR). This gives the number of ventricular ectopic beats over the last minute.



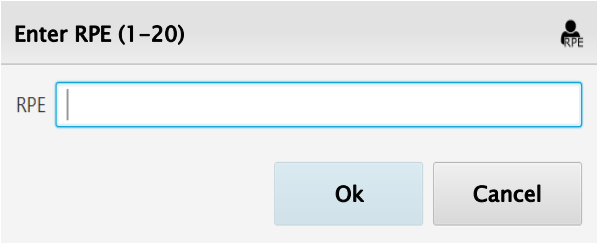
Every time a VEBR is detected an event is registered (see para. 8.3.4, Events View, page 98).

7.5.7 RPE

To enable RPE entry, the icon must be set for display in the side or bottom icon bar for display (see para. 3.8, Display Configuration, page 40).

Rating of perceived exertion (RPE is a subjective indication of patient exertion. The entered RPE is shown on the final report.

Select RPE from the side or bottom line icon bar



7.5.8 Events

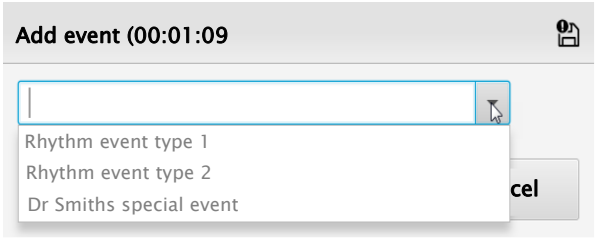
To enable manual events, the icon must be set for display in the side or bottom icon bar for display (see para. 3.8, Display Configuration, page 40).

- If defined for display in the bottom line shown as 

.
- If defined in the side line shown as  .

To register a manual event click the **manual event** button.

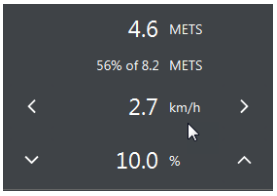
Art. no.: 2.511335 Rev. a



Enter any text or click the arrow to the side to select predefined events (see note), and click OK. Events will be referenced in the recording (see para. , Events, page 106).

Manuel event text can be pre-entered if required, and available for selection when the arrow by the event entry is clicked. The manual event wording is defined in system settings (see para. 11.13, Rhythm ECG, page 133).

7.5.9 Treadmill (Speed and Elevation) Control



Treadmill elevation and speed can be manually increased or decreased from the current values at any time in the test or stage in the protocol. Click the arrows up/ down to increase/decrease elevation, or left right to decrease/increase speed

7.5.10 Bicycle (Load) Control

Bicycle load can be manually increased or decreased from the current values at any time in the test in the same manner as for a treadmill. Click the left/right keys to decrease/increase the load

If a keyboard is attached, the arrow keys can also be used to change the load / speed / elevation as follows:

Key	Function
Left key	Reduce treadmill speed
Right key	Increase treadmill speed

If a protocol is manually modified, the name of the protocol has a asterisk **(*)** after the name to indicate that the current test protocol has been modified.

7.6 Ending the Test

Two options are possible to end the test, dependent on exercise settings, as follows:

- The recovery stage is entered directly.
- The current exercise stage completed before entering the recovery stage.

The settings for these two options are set in system settings Exercise > Recorder (see para. 11.14, Exercise ECG, page 133).

The options are as follows:

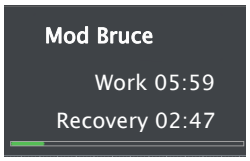
Art. no.: 2.511335 Rev. a

Directly enter the Recovery stage - control button displays **Recovery**

The recovery stage is entered directly and a load applied, or treadmill speed and elevation set, according to the recovery stage of the protocol. The protocol stage states Recovery and the total recovery time shown in the information box. The button designation changes to **End** and Recovery stage continues until **End button** is clicked.

Finish current stage before entering recovery stage - control button displays **Init Recovery**

Press **Init Recovery button** to enter the recovery stage. The current exercise stage is completed before the recovery stage is entered. The button changes to **Recovery** to directly enter the Recovery stage. At the end of the stage the recovery stage is entered the recovery stage time is displayed and test ended as described above.



The ergometer reverts to the defined recovery load or speed as defined in the protocol. ECG recording continues during the recovery phase. The recovery phase is held for as long as set in the protocol or until End is pressed.

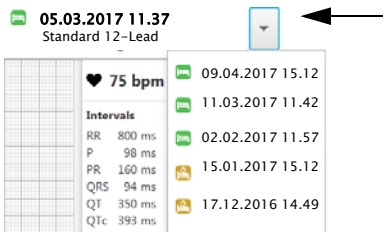
Art. no.: 2.511335 Rev. a

8 ECG Recording Analysis

8.1 General Analysis Settings and Options

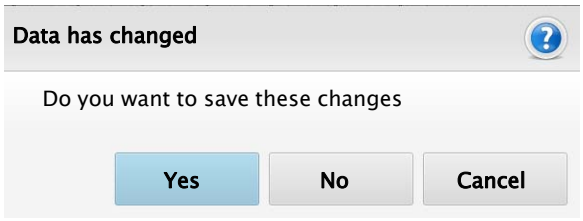
Recordings are opened from the patient search or recording search. The type of recording is identified in the column by text and/or recording type icon.

When a patient has more than one recording (of any type) a recording selector function can be enabled (see para. 11.2.5, Recording Selector, page 120). When enabled an icon appears in the top right of screen that enables selection of another recording from the same patient.



8.1.1 Saving after Editing

If you wish to save any changes to a recording click the **Save** button. If you attempt to leave a recording (after editing) without saving a prompt is given to save or not save.



If any editing functions are carried out that could affect the interpretation, you are prompted directly to check the interpretation before proceeding (see para. 8.2.11, Interpretation, page 90).

Art. no.: 2.511335 Rev. a

8.1.2 Reports - Printing a Recording or Generating a PDF File

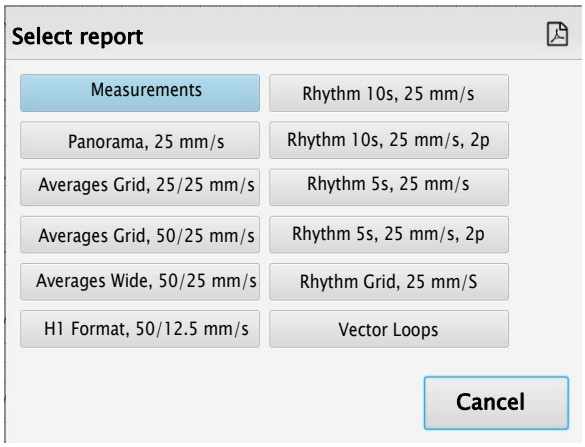
Print or generate a PDF file as follows:

Select PDF 

Select Print 

Select PDF / Select Print - When selected you are prompted to define one data option (from the data options displayed). The print option will print to the defined printer, the PDF option will prompt you to define the location where to save the PDF file.

The options will vary according to the type of recording and lead configuration.



The data for selection is defined in settings (see para. 11.10, Reports, page 129)

Combined reports can be user defined to group any combination of options in a single report (see para. 11.10.6, Combine Reports, page 131). These can then be selected as a print option and will appear in the list for print/PDF generation.

8.1.3 Direct Print or PDF Generation

PDF 

Print 

PDF / Print - When selected a PDF file or printout is generated directly. The data and format is set in system settings (see para. 11.10, Reports, page 129) and (see para. 11.11.5, Print Output and PDF Output, page 132).

Art. no.: 2.511335 Rev. a

8.1.4 Rejecting a Recording

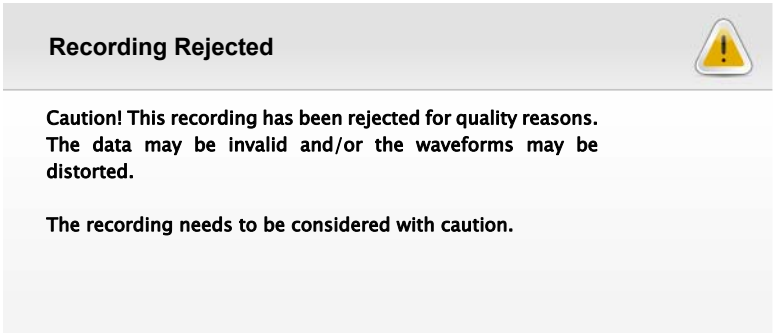
- The Reject button must be set in display configuration (for all types of recording) (see para. 3.8, Display Configuration, page 40).

If a recording needs to be rejected for poor quality, after the administration of drugs for example, or for any other reason, the user can reject a recording that is open by pressing the **Reject** icon. You are prompted to confirm:

When a recording has been rejected the following happens:

- A line is set through the recording entry

- The recording is set to **Read Only.**
- When the recording is opened the following dialogue is displayed:



- A new interpretation is also added to the recording with the above wording
- When a rejected recording is printed (or PDF produced), the text **Rejected** is printed across each page.

Art. no.: 2.511335 Rev. a

8.2 Resting ECG Recordings

8.2.1 Data Views and Functions

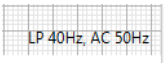
Click a view / function icon to display and select:

	Rhythm 1	This view shows all leads over the entire recording.
	Rhythm 2	This view displays all leads in two columns contiguously.
	Averages	The averaged leads with markers. The rhythm strips of two selected leads over the entire recording are also displayed.
	Sequential	This view displays the recording in four columns of 2.5 second segments contiguously. The rhythm strips of two selected leads over the entire recording are also displayed.
	Vector	Vector view and measurement of 12-lead standard ECG (option). License not required when leads (Frank, standard + X, Y, Z) have been captured on the original recording.
	Measurements	Table of amplitude and timing measurements for all channels.
	Remeasure	In this screen you can edit the measuring points. A zoomed view of a selected lead is given and measuring points can be edited and a new interpretation generated after editing.
	Visual Comparison	One recording from the same patient can be compared with the current recording.
	Recording detail	General and recording specific patient data (see para. 3.10, Patient Data, page 43).
	Rhythm 1, 2 p	This view shows all leads over the entire recording in two pages of 6 leads.
	Attachments	View any attachments that may be associated with the recording.
 	PDF / Print	Generates a report / prinout directly according to defined settings (see para. 11.10, Reports, page 129).
	Filter	Filter on/off and cut-off frequency.
	ETM Sport	Details of the ETM Sport program.
 	PDF / Print	Displays options and then generates a report / printout as user set (see previous page).
	Reject	Rejects a recording (not possible after a recording has been validated).

The view and function icons are user set (see para. 3.8, Display Configuration, page 40).

Art. no.: 2.511335 Rev. a

8.2.2 ECG Filter



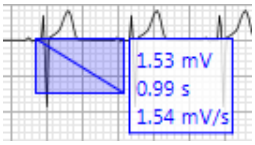
The filter is designed to help reduce muscle artefact. The cut-off frequencies and filter settings are defined in system settings (see para. 11.11.3, Display Filter, page 132).

Click the **LP Filter** icon 

to toggle the filter between the defined frequencies. When the filter is enabled the icon is highlighted and indicated in the bottom of the screen.

▲ When the filter is active, possible morphological signal distortion can occur.

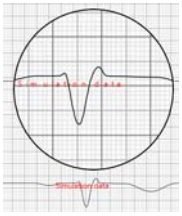
8.2.3 ECG Measurements



Click where you wish to commence measurement and drag the mouse to display measurements in relation to the start point. The measurement remains on the screen until the mouse is again clicked and a new measurement can be taken. The measurements calculated are as follows:

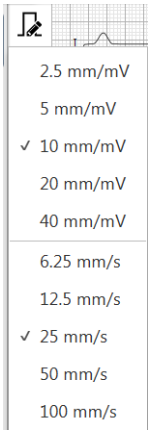
- Amplitude in mV
- Time in seconds
- Slope in mV/s

8.2.4 Zoom



Click the zoom icon  in the top left of the screen to display a zoom view above the selected section.

8.2.5 Amplitude and Speed



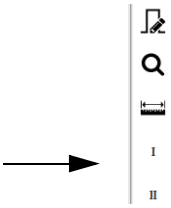
The amplitude and speed of the ECG trace is adjusted with the icon in the top left of the screen.

The amplitude and speed of a waveform can also be changed using the mouse wheel:

- Position the cursor in any ECG curve area and rotate the mouse wheel to increase / decrease the **trace amplitude**.
- Press the **Alt key** and rotate the mouse wheel to increase / decrease the **trace speed**.

Art. no.: 2.511335 Rev. a

8.2.6 Changing the Rhythm leads (Rhythm and Average Views)



Click the Lead designation to select the rhythm lead displayed.

8.2.7 Measurement Table

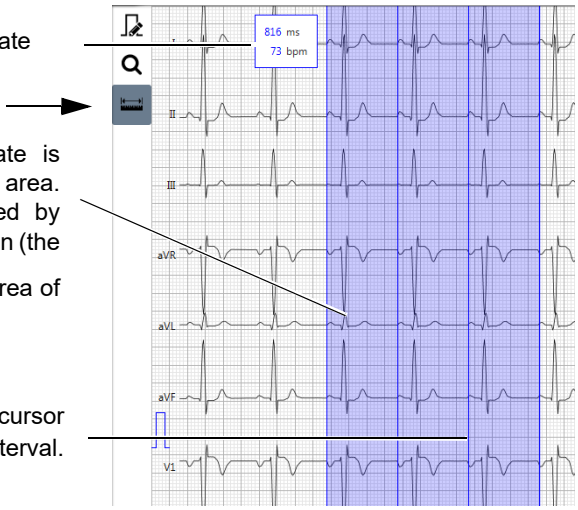
Select **Measurements** to display averaged ECG measurements in tabular form.

When a measurement point is edited (see following), the values automatically change in the measurement table.

8.2.8 RR Intervals

In the two Rhythm views, and on the rhythm strip in the averages view and sequential view, interval measurement and edit is possible. The Interval Measurement tool is enabled in the sidebar.

Measured interval and calculated heart rate



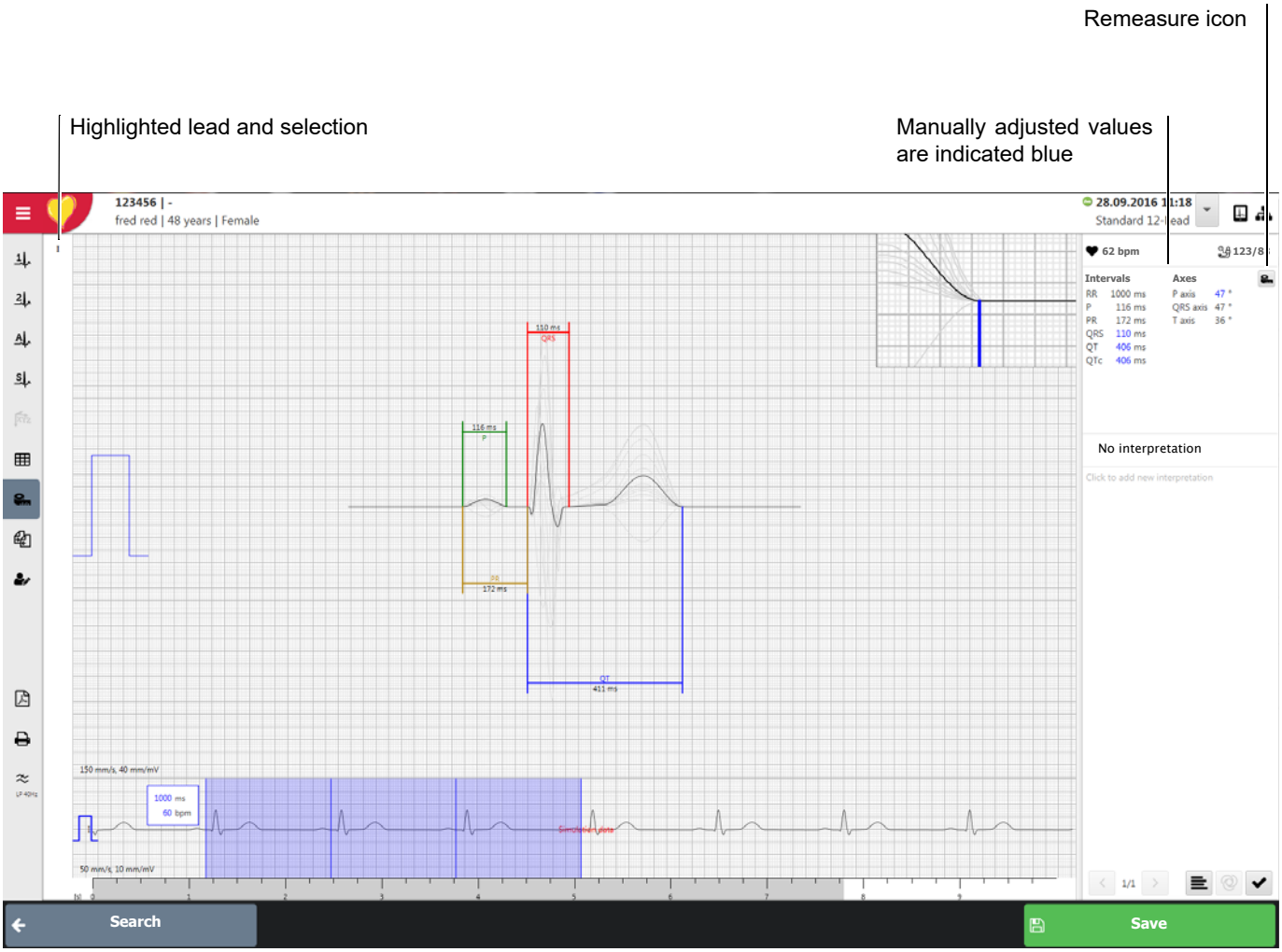
The current interval in ms and the heart rate is displayed by the side of the blue measurement area. The blue measurement section can be moved by positioning the cursor anywhere in the blue section (the cursor changes to a 'move' symbol), and area of can be moved to the desired position.

Clicking on any vertical interval marker (the cursor changes to an 'adjust' symbol ⟺) adjusts the interval.

Art. no.: 2.511335 Rev. a

8.2.9 Changing the Global Measurement Points

Select **Re-measure** (in the side bar or on the HR and measurements box) to display the remeasure and measurement interval screen. The highlighted lead is selected in the top left of the screen. All other leads are greyed for reference.



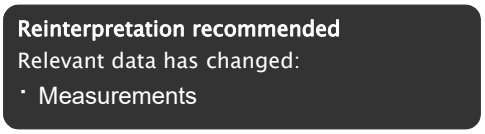
Click on any of the measurement markers. This displays an enlarged view of the selected area. Move the marker to redefine the measurement point. When a measurement point is edited, all calculated measurements (in the measurement box) are automatically recalculated.

Art. no.: 2.511335 Rev. a

8.2.10 Measurement Interval and Heart Rate

The RR interval and HR is displayed in the lower section of the screen with the measurement area highlighted blue. The interval can be adjusted (see para. 8.2.8, RR Intervals, page 87).

Because changing the global measurement points can affect the interpretation, when the measurement point is moved you are prompted to reinterpret the recording. The auto symbol appears in the top right of the screen indicating that reinterpretation should be considered. and the following message is given detailing the editing changes that have been made to the recording.



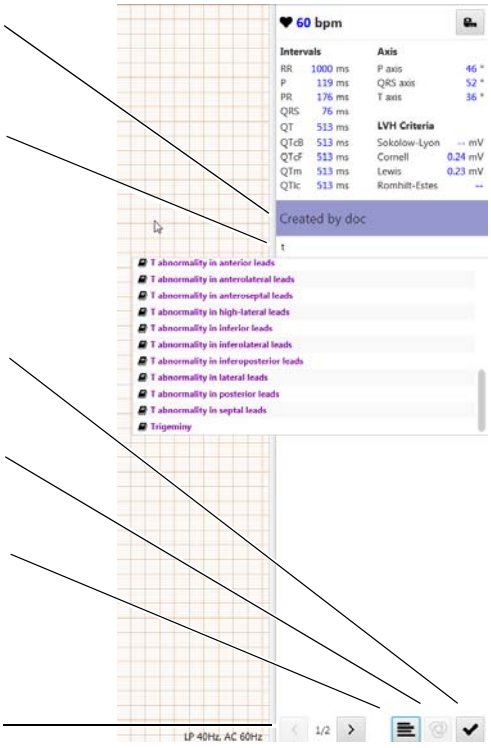
Art. no.: 2.511335 Rev. a

8.2.11 Interpretation

The interpretation is displayed below the heart rate and measurements. The user that entered the interpretation, the date, and if the interpretation has been validated or not is given in the header bar of the interpretation. If the interpretation has been generated by the interpretation program, the user is stated as the computer and ETM version.

Validation user - click for more details (interpretation date, institutes, etc.)

Manually entered interpretation black. Interpretation entered from templates shown coloured bold.



Validation: Click the tick box to validate the interpretation. When an interpretation has been validated, no further changes can be made to the interpretation unless the **revalidation privilege** has been set for the user.

Trigger an auto (ETM) interpretation

Editing: Enter text as required. Enter a character(s) and click the interpretation template icon (or press **CTRL > space bar),** to display interpretation templates and acronyms.

Once an interpretation is entered and the recording saved, the interpretation cannot be edited. However, further interpretations can be made and entered on a separate page. When this is the case, the number of interpretations is displayed and selected in the header bar of the interpretation.

Editing, validating, and re-validating an interpretation are user privileges and can only be performed when the privileges are enabled.

8.2.12 ETM Sport Option

(Seattle Criteria Interpretation for Athletes)

The **ETM Sport** icon must have been clicked in the recording data screen (see para. 5.1.1, ETM Sport (Option), page 66) to display the ETM Sport interpretation in the normal interpretation screen.

When the ETM sport was selected in the original recording, an extra line is given in the interpretation screen that states one of the following:

- Normal ECG in athletes
- Borderline ECG in athletes
- Abnormal ECG in athletes

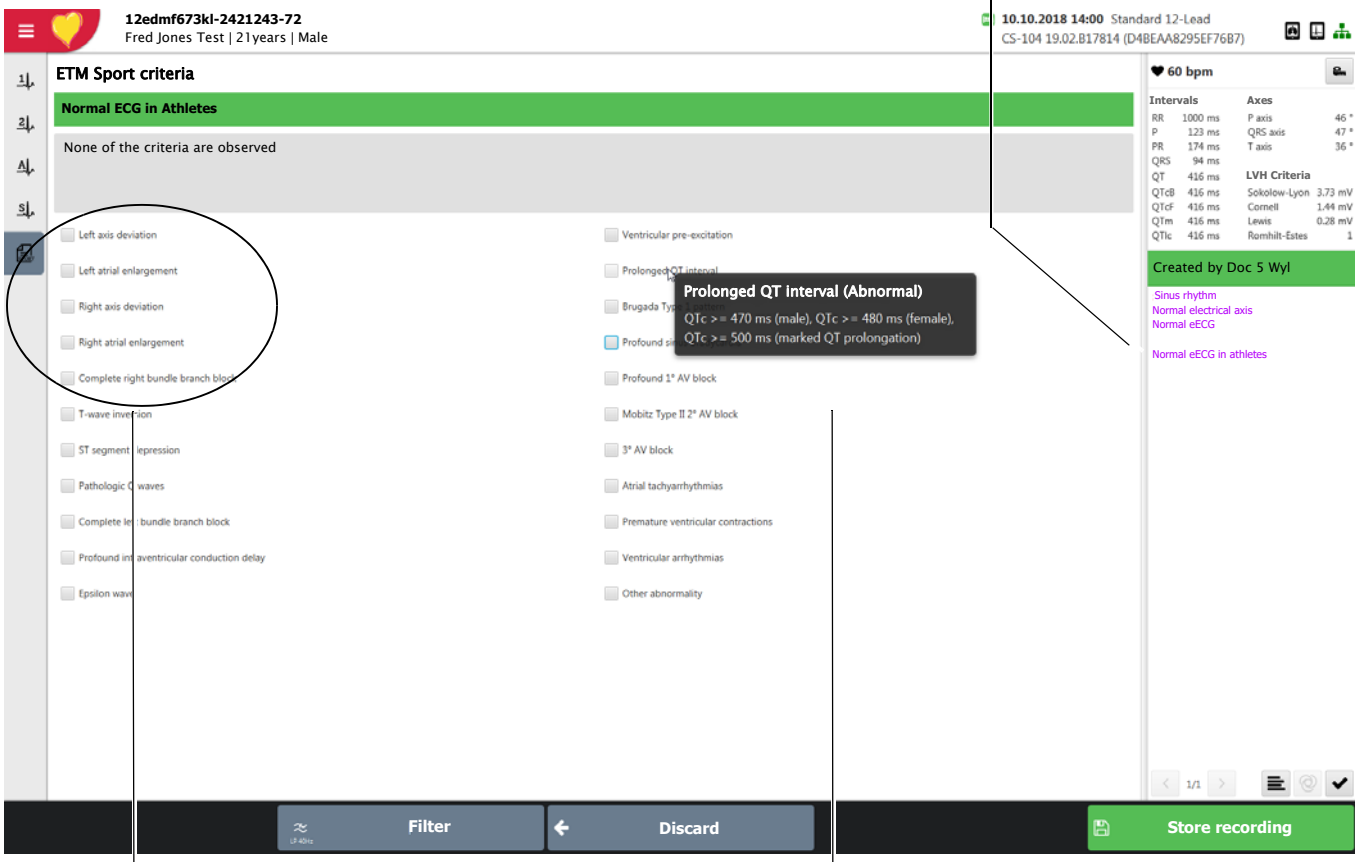
Art. no.: 2.511335 Rev. a

Editing ETM Sport Diagnosis and Displaying Diagnosis Criteria

The view and function icons are user set and must be defined for display in the Resting Analysis screen. To define the icons available (see para. 3.8, Display Configuration, page 40).

When the ETM Sport button is clicked in the side panel , further details of the interpretation according to the ETM Sport criteria is given:

ETM Sport diagnosis.



Borderline diagnosis - any one criterion in first 5 identified.

Abnormal diagnosis - two or more criteria in first 5 identified, or any one or more in the subsequent criteria identified.

Hovering over a criterion will give the measurement parameters used to assess the criterion.

Art. no.: 2.511335 Rev. a

The ETM interpretation is shown in the interpretation and is colour coded in the ETM screen. The interpretation changes when any criteria is edited:

Normal ECG in athletes (statement highlighted Green) — None of the criteria are observed.

Borderline ECG in athletes (statement and criterion highlighted yellow) — No further evaluation required in asymptomatic athletes with no family history of inherited cardiac disease or SCD.

Abnormal ECG in athletes (statement and criterion/criteria highlighted yellow) — These ECG findings are unrelated to regular training or expected physiological adaptation to exercise, may suggest the presence of pathological cardiovascular disease, and require further diagnostic evaluation.

The ETM sport interpretation will change as the ETM sport criteria are edited. The ETM sport interpretation will also change if the global measurement points are changed (and reinterpretation is triggered (see previous page)).

8.2.13 LVH

Left ventricular hypertrophy (LVH) refers to an increase in the size of myocardial fibres in the main cardiac pumping chamber. Such hypertrophy is usually the response to a chronic volume or pressure overload. The two most important pressure overload states are systemic hypertension and aortic stenosis. The major conditions associated with left ventricular volume overload are aortic or mitral valve regurgitation and dilated cardiomyopathy. Ventricular septal defects cause both right and left ventricular volume overload, while hypertrophic cardiomyopathy is an example of an inherited condition in which LVH (usually with asymmetric septal hypertrophy) occurs in the absence of any apparent hemodynamic pressure or volume overload. A physiologic type of hypertrophy with increase in wall thickness and left ventricular end-diastolic volume may occur in trained athletes. The athletic heart is often associated with electrocardiogram (ECG) voltage criteria for LVH.

LVH Criteria and Measurements

The LVH criteria displays the raw data in for Sokolow-Lyon, Cornell, Lewis, and Romhilt-Estes given as mV: **1mm ≡ 0.1mV**

The Sokolow-Lyon index

- S in V_1 or V_2 + R in V_5 or V_6 (whichever is larger) ≥ 35 mm
- R in aVL ≥ 11 mm

Cornell voltage criteria — The sum of the R wave in lead aVL and the S wave in lead V_3. The Cornell criteria for LVH are:

- S in V_3 + R in aVL > 28 mm (men)
- S in V_3 + R in aVL > 20 mm (women)

Lewis

- RI + SIII - RIII - SI
- If the value is greater than or equal to 1.7 mV, left ventricular hypertrophy can be assumed.

Art. no.: 2.511335 Rev. a

Romhilt-Estes point score system

Diagnostic >5 points; Probable 4 points:

ECG Criteria	Points
Voltage Criteria (any of): – R or S in limb leads ≥20 mm – S in V_1 or V_2 ≥30 mm – R in V_5 or V_6 ≥30 mm	3
ST-T Abnormalities: – ST-T vector opposite to QRS without digitalis – ST-T vector opposite to QRS with digitalis	3 1
Negative terminal P mode in V_1 1 mm in depth and 0.04 sec in duration (indicating left atrial enlargement)	3
Left axis deviation (QRS of -30° or more)	2
QRS duration ≥0.09 sec	1
Delayed intrinsicoid deflection in V_5 or V_6 (>0.05 sec)	1

Art. no.: 2.511335 Rev. a

8.2.14 Vector Cardiogram

Vector cardiograms and measurements can be displayed when leads Frank, or standard + X, Y, Z have been taken on the original recording.

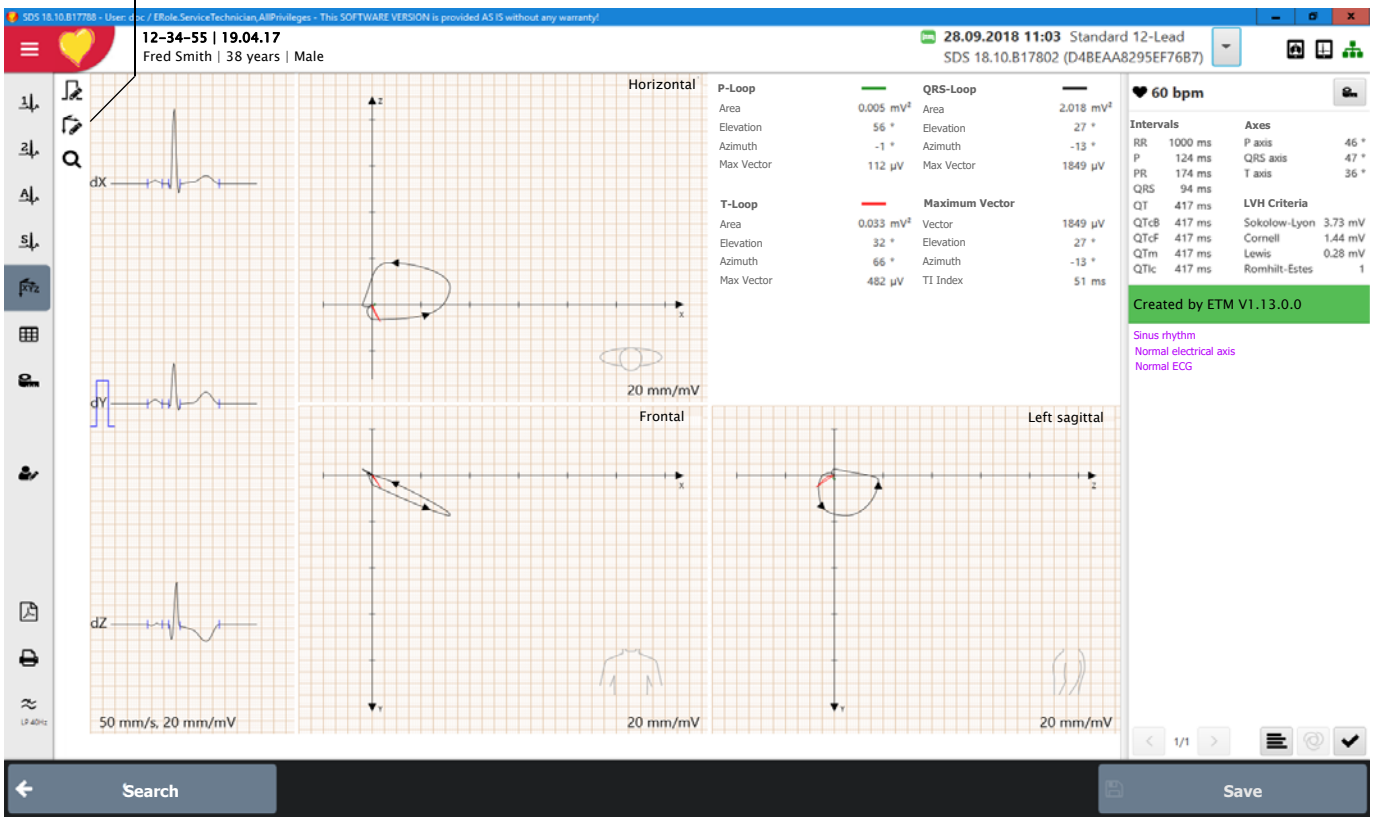
With the vector option, X, Y, Z leads can be calculated to enable vector cardiograms to be generated from a standard 12 lead recording.

Select **Vector ECG** .

A vector cardiogram traces the direction and magnitude of the heart's electrical activity during a cardiac cycle. It is produced from the three orthogonal leads X, Y, Z. The size (magnitude) and the direction of a vector are indicated by three spatial coordinates (X, Y and Z). The shape, the direction of the rotation, the orientation and the speed of rotation of the individual loops are the predominant factors for the analysis of the vector cardiogram. Vector loops are represented spatially and projected on the following three planes:

- Horizontal plane (X, Z)
- Frontal plane (X, Y)
- Sagittal plane (Z, Y)

The P wave, QRS and T loops can be displayed in any combination



Art. no.: 2.511335 Rev. a

8.2.15 Full Visual Comparison

Select **Visual comparison** to compare the current recording with an older Resting ECG recording taken with the same patient. The intervals, axes and interpretation are displayed at the side.

Note: It is only possible to select recordings that are **older than the original for comparison,** and the recording with which the original is compared is **read only**.

Select recording - when a patient has more than one other recording toggle though with the arrow keys

Art. no.: 2.511335 Rev. a

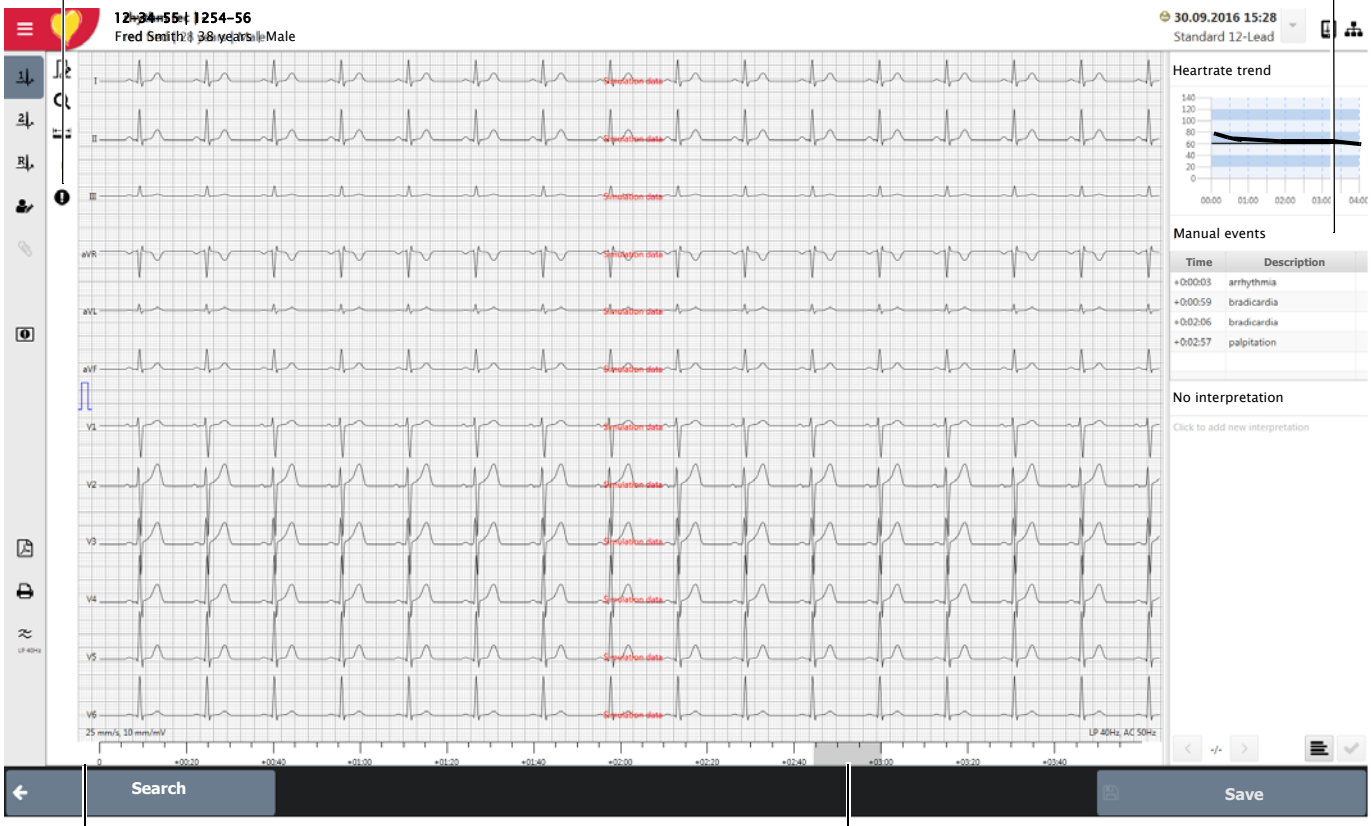
8.3 Resting Rhythm Recordings

8.3.1 Rhythm Screens View

Click the **Rhythm 1** icon or **Rhythm 2** icon to display all leads as single column or two columns resp. The scale adjusts automatically for the length of the recording and is displayed on the bottom. To jump to another time segment, move the time cursor with the mouse. The time can be nudged forward or backward by clicking to the left or right of the time cursor.

Move the cursor in the ECG trace to the required position and click the **add event icon** and enter the event annotation as required. The event is referenced in the event column.

The events column shows manually entered events. Click on any event to jump to the recording section in the rhythm screen.

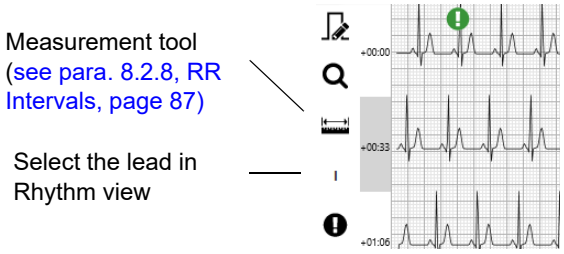


The width of the time position cursor indicates the time segment of the waveforms displayed. Move to scroll through the recording or use the arrow button on either end of time scale.

Art. no.: 2.511335 Rev. a

8.3.2 Full Disclosure View

Click Rhythm icon to display a single channel over the entire recording (full disclosure). The lead is selected in the side bar with the lead selection:



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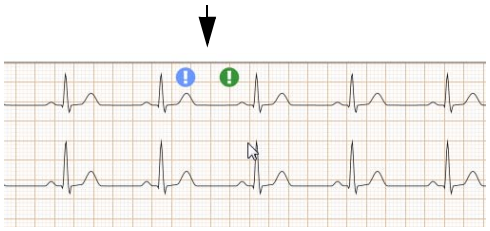
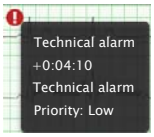
8.3.3 Events

Events are indicated in the recording by a round coloured coded explanation:



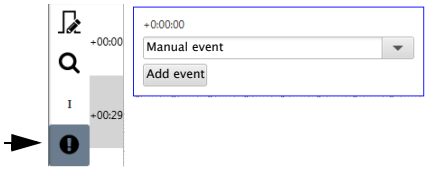
The events are coloured coded for the type of event as follows:

Green	Manual event, device NIPB measurement, manual NIBP measurement.
Blue	Reference marker
Gold	Symptom
Red	Arrhythmia, technical alarm, vital alarm trip high, vital alarm trip low



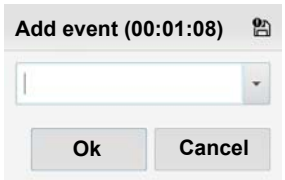
Event Details

- Hover over the event to display the event details.
- To keep the event details displayed, click on the event.



Adding a (Manual) Event

Click the manual icon in the side bar to activate, the cursor changes to a cross (**+**). Move the cursor in the ECG trace to the required position and click.

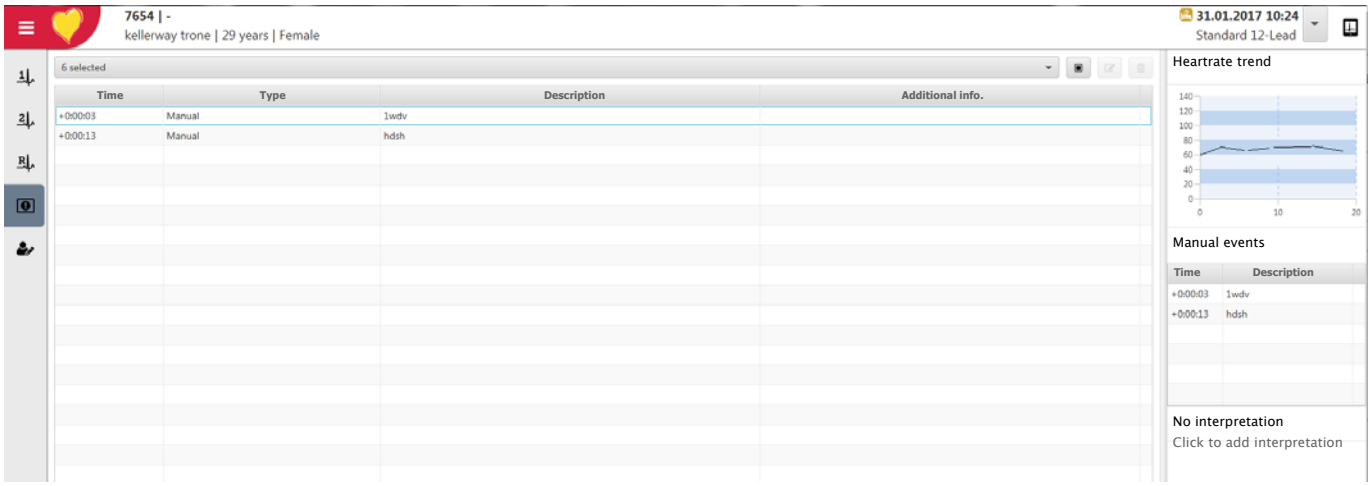


Enter the event annotation as required. The event is referenced recording. The event text can be added freely or manual event text can be defined for selection in system settings (see para. 11.13.3, Events, page 133)

Art. no.: 2.511335 Rev. a

8.3.4 Events View

Click the **events icon** in the side bar to view all events.



Click on an event to display the ECG trace where the event occurred.

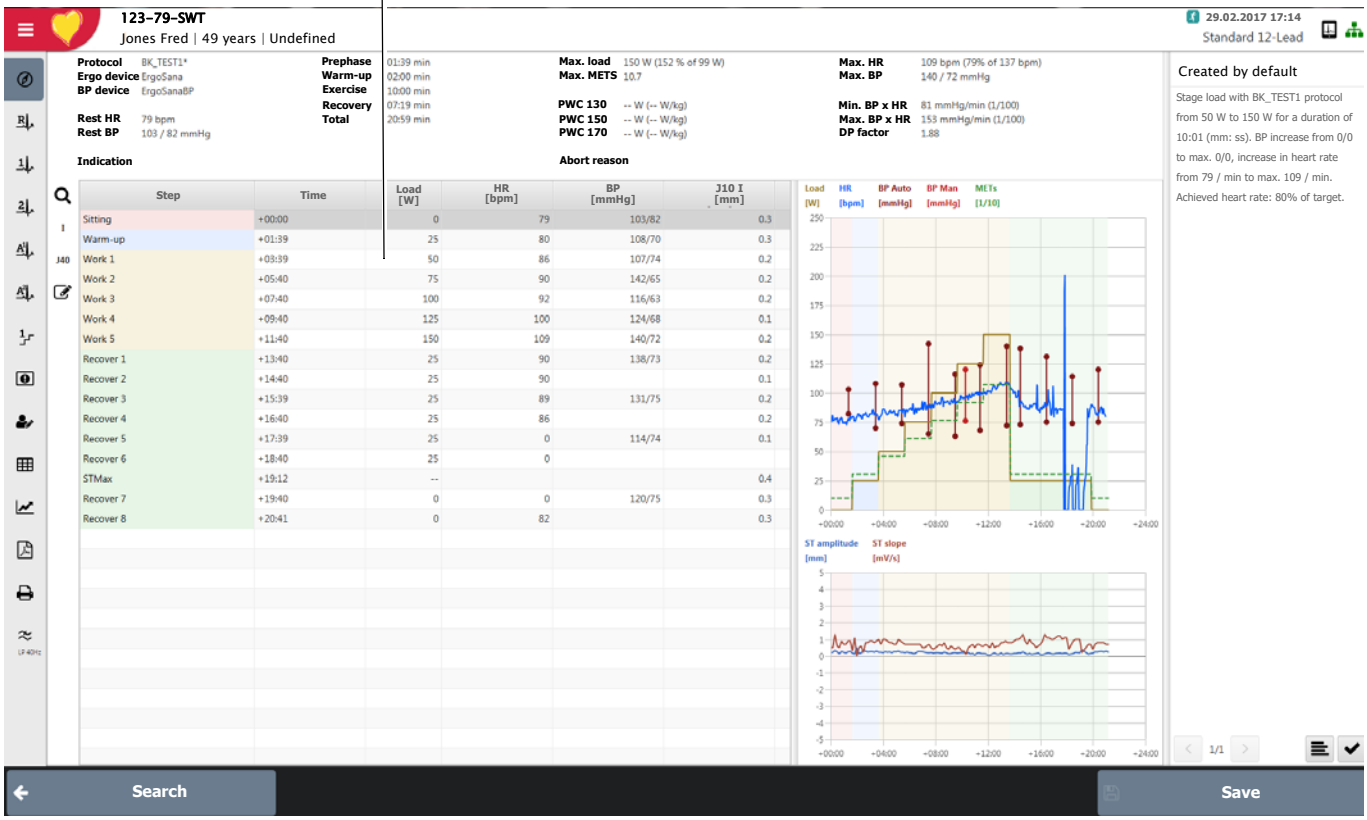
Art. no.: 2.511335 Rev. a

8.4 Exercise ECG

8.4.1 Summary

Select the **Summary** icon .

Double clicking in the step will enter the ECG step view (to display the last 10 seconds of the selected stage).



In all screens, where step data is displayed (in the example above the step table, and the heart rate /load/BP graphic, the steps are colour coded to help identification. The colour codes are as follows:

- Preliminary steps and information - light pink
- Warm-up step - light blue
- Work steps - light brown
- Recovery steps - light green

Art. no.: 2.511335 Rev. a

Test Summary

The test summary in upper section gives the following:

Protocol

The protocol name.

Ergo and BP device

Hardware used for the test.

Rest HR and BP

The resting heart rate and blood pressure taken before the test commences.

Prephase, Warm-up, Exercise, Recovery and Total

The duration (minutes) of each stage of the test.

Maximum Load

- Watts (bicycle) - maximum load achieved in Watts.
- METS (treadmill) - the maximum metabolic equivalent achieved.
- (% of expected load) - percentage of actual load reached against expected load (the expected load is calculated from the patient data including age, gender and height).

PWC 130/ 150/ 170

The physical working capacity (PWC) is based on the expected load of the patient that will result with the heart rate of 130, 150, 170/min. The measurement is derived from the linear relation between the heart rate during submaximal exercise and exercise load and correlates with VO2max. The formula used is as follows:

• Patient Age <18:	**Expected load = 0**
• Patient Age >= 18 and <=42:	**Expected load = W * 3**
• Patient Age >42:	**Expected Load = W * 2.1**

W = Weight in kg

Note that there is no difference for gender.

Maximum Heart Rate

Maximum heart rate achieved during the work/recover step and the percentage of the expected heart rate (in parentheses).

Max BP (Sys/dia)

The blood pressure taken in the Step with the maximum load.

Min / Max BP x HR

The min/max systolic blood pressure during the exercise stage multiplied by the heart rate at the end of that stage.

DP Factor

Double Product Factor is the value of (Max BP*HR) / (Rest BP*HR).

Abort reason

Reason the test was stopped.

Art. no.: 2.511335 Rev. a

Step Table

The step table gives an overview of the complete test with the following information for each stage:

BP The blood pressure measured during the stage or taken over from the previously entered BP. If more that one measurement has been entered during a stage the last entered measurement is given.

Dizz (%) * Subjective dizziness measurement entered during the test

Dysp. (%) * Subjective dyspepsia measurement entered during the test

HR The maximum heart rate measured in the step.

Jxx (mm), Jxx (mV/s) The averaged ST elevation at the end of the stage in mm or mV/s

- The point where the ST is measured can be user defined (see J-point set next page).

Lact. (mmol/l) Lactate measurement entered during the test

Load Load applied during the test

METS METS

Pain* Subjective pain measurement entered during the test

RPE Rating of perceived exertion (RPE is an subjective indication or patient exertion.

SpO_2 The SpO_2 measurement.

Speed (RPM)

VES Number of Ectopic beats detected during the stage.

* Not available with CS-104 but available on recordings from other devices (with full view rights).

Art. no.: 2.511335 Rev. a

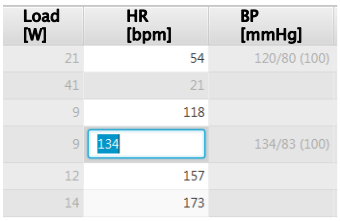
8.4.2 Editing the Results in the Step Table

Values that can be edited are highlighted and can be edited/added for every stage of the test. The following values can be edited:

- Heart rate
- Blood pressure
- VES
- SpO_2
- RPE

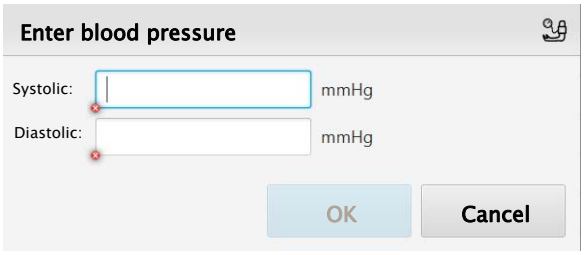
Editing the HR, VES, SpO2 or RPE

To edit click the edit icon . The values that can be edited are highlighted. Double click on the value and edit as required.

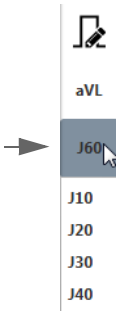


Editing a Blood Pressure Measurement or Entering a New Measurement

- To **edit a BP measurement** click the edit icon and then click on the measurement in the graph.
- To **enter a new BP measurement** click the edit icon and click in the graph where the BP measurement is to be positioned.



8.4.3 ST Measuring J point



To change the ST measuring point, click J-point edit icon and select a value between J10 and J100 (J-point plus 10 to 100 milliseconds). When this is changed, the slope and elevation are displayed with the redefined ST measuring point.

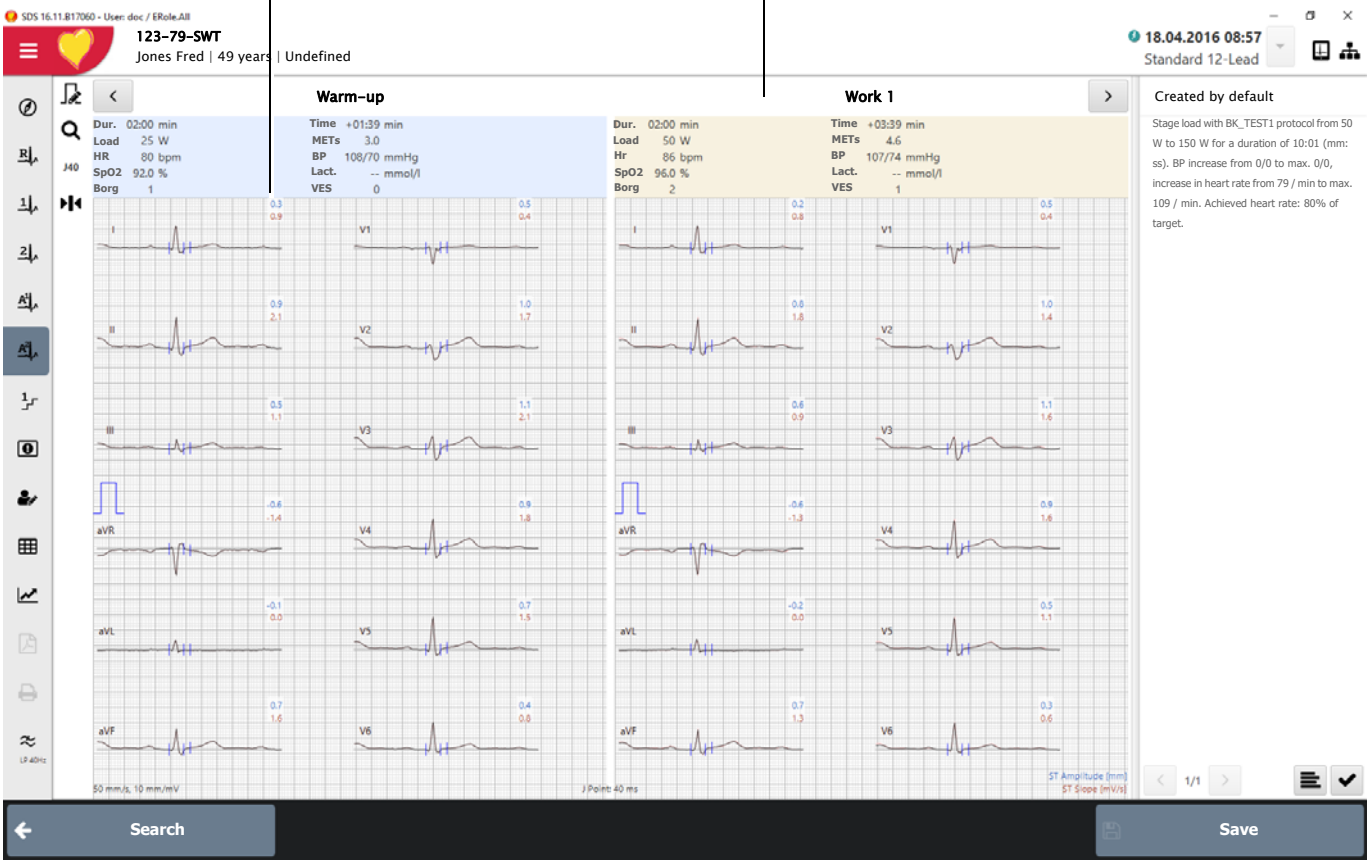
Art. no.: 2.511335 Rev. a

8.4.4 Average View

Click the **average icon** Average 1 or Average 2 . The averaged view displays the averaged complexes for all leads and all stages of the test. Average view 1 displays the leads in one column (more exercise stages displayed). Average view 2 displays two columns for complexes for each exercise stage (more ECG channels displayed).

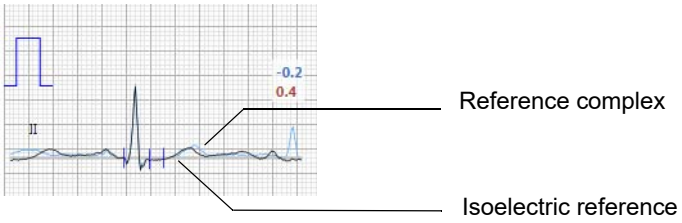
The two red and blue figures in the top right of every averaged complex give the ST elevation (mm) and slope (mV/s).

The stage header gives the stage (warm-up, work, recovery), load and heart rate at the end of stage. Time from the beginning of the test to the beginning of the stage. Also included are BP, SpO_2, Borg rating, VES count, and Lactate if entered, and METs



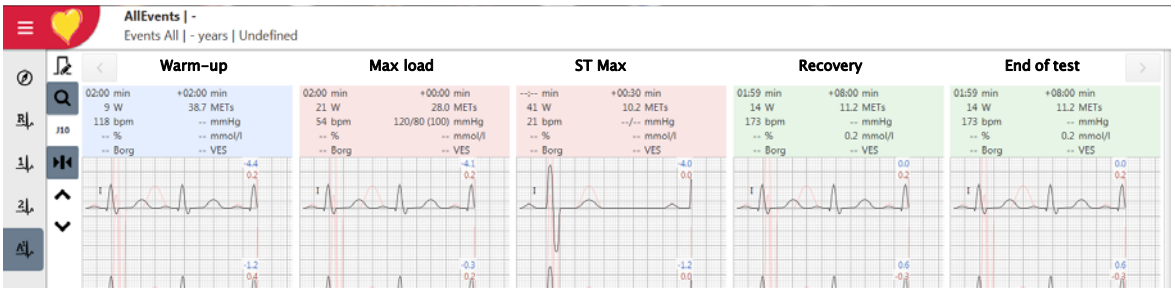
Isoelectric and Reference curve

Isoelectric lines and reference curves can also be displayed in the average view. These are set in system settings (see para. 11.14, Exercise ECG, page 133). When selected, the reference curves are superimposed in blue on the average complexes and the isoelectric line, in grey.



Displaying the Average Complexes for Pre-test Stages, Max load, ST Max and Recovery Stages

Click the max average icon in the side bar to display average ECG complexes for **Pre-test, Max load, ST max** (during the work stages), **Recovery** and **End of test.**



Art. no.: 2.511335 Rev. a

8.4.5 Rhythm View - Continuous (Single Lead Rhythm)

Click the **Continuous (Rhythm) icon** to display the rhythm ECG for each step.

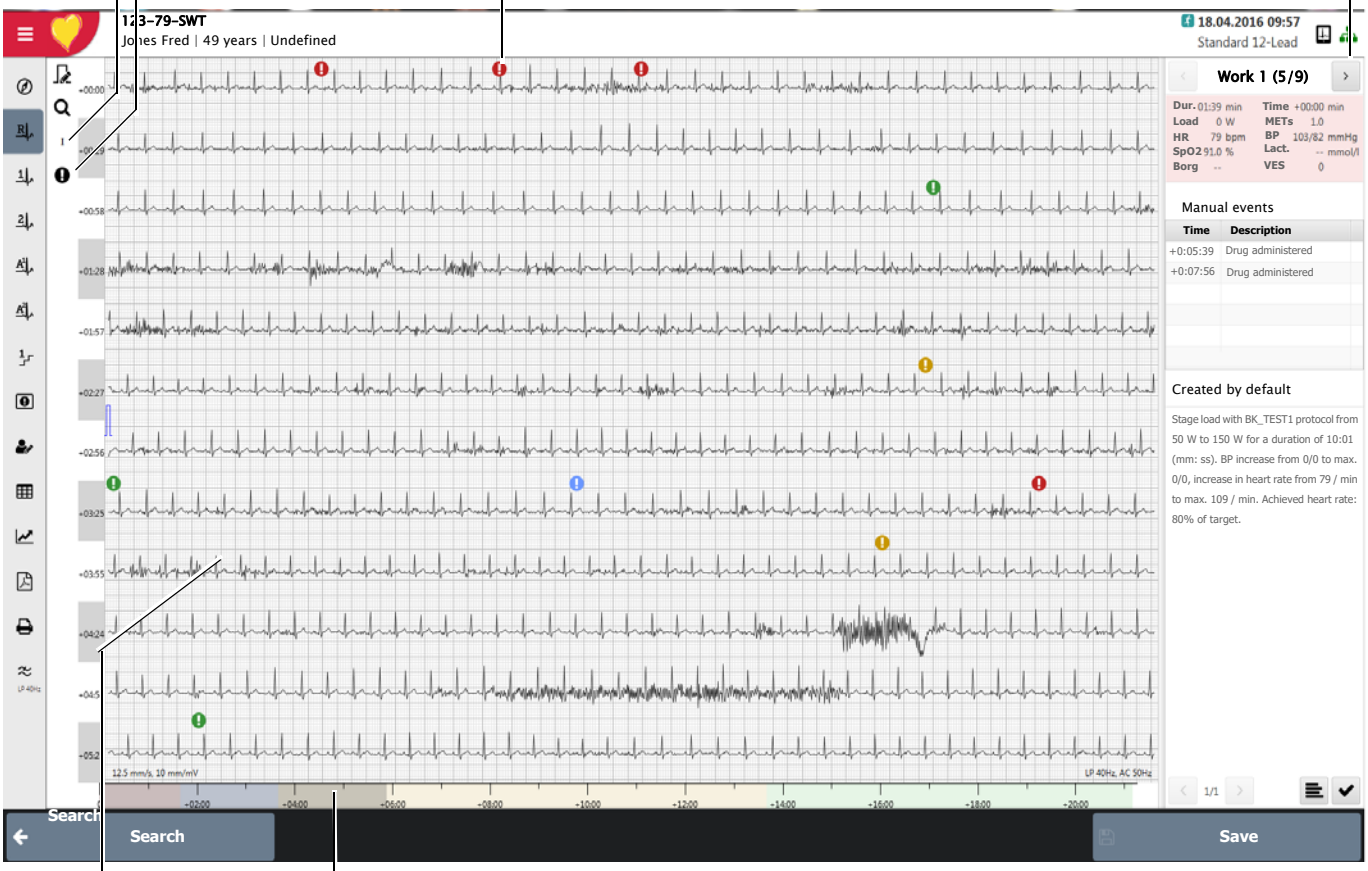
The scale adjusts automatically for the length of the recording and is displayed on the bottom. Lead selection, scaling, measurements of the ECG, and the side information bar and the interpretation are the same as for resting ECG.

Define Rhythm lead

Add Event

Events are indicated. Hover over the event to display the type of event (click the event to keep details displayed). The events are colour coded for the type of event (see para. 8.3.3, Events, page 97).

Select next/previous stage with arrow icons



The width of the time position cursor indicates the time segment of the waveforms displayed - when the speed is changed the width of the position cursor will change. Move through the recording by moving this bar or by selecting the exercise step (top right).

Double click anywhere in the trace to display the Full Disclosure Rhythm view (see next page) of the time where clicked.

Art. no.: 2.511335 Rev. a

Events

Manual events are displayed, edited, deleted and new events defined to all rhythm views as described in the Rhythm recording section (see para. 8.3.3, Events, page 97).

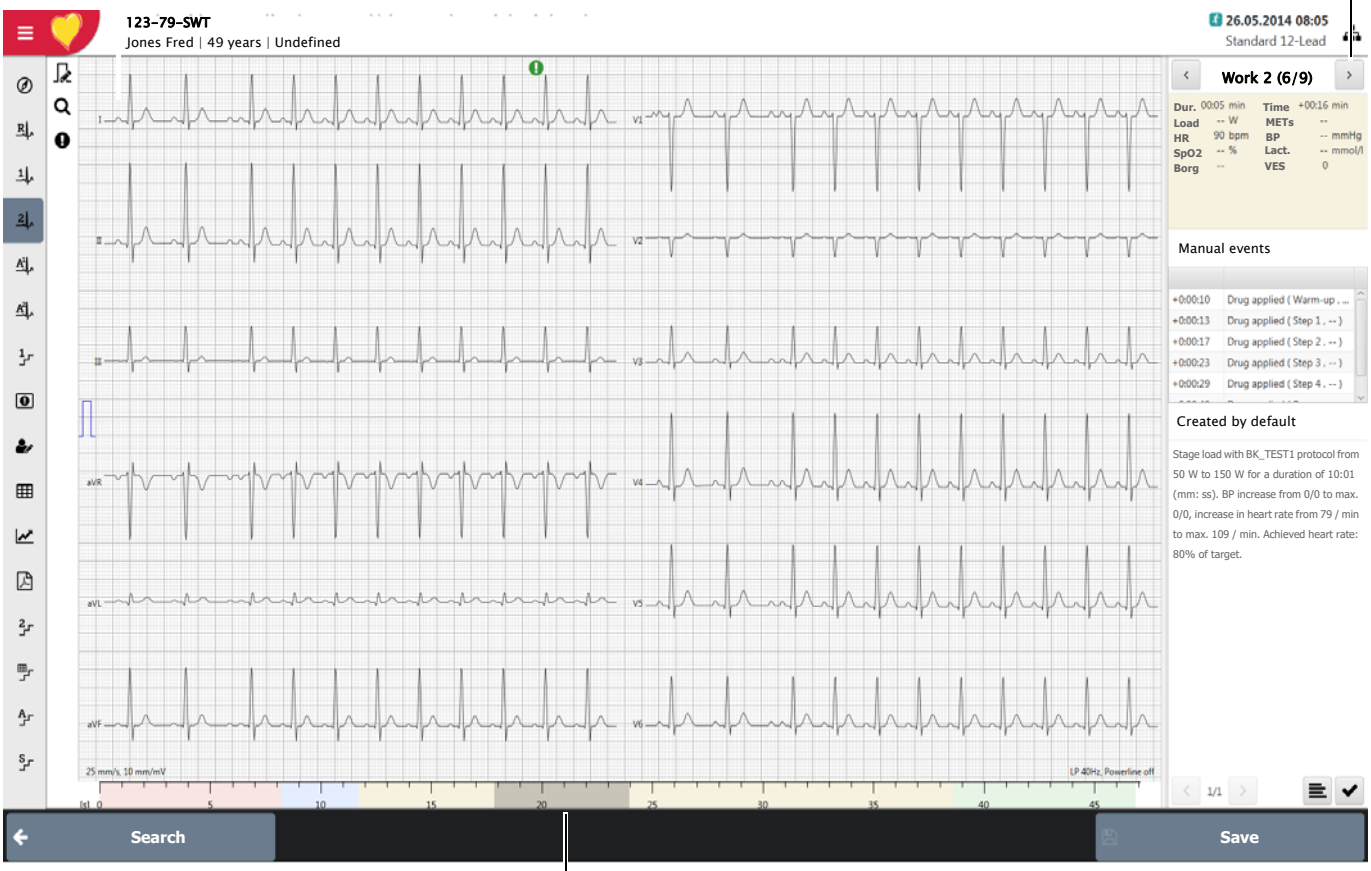
Notes:

- The events that are shown/not shown can be defined in system settings (see para. 11.13.3, Events, page 133).
- All editing functions, and interpretation are same as for resting ECG.

8.4.6 Rhythm View - Full Disclosure

Click the **Rhythm icon 1** or **Rhythm icon 2** . Rhythm 1 displays all leads in a single column and Rhythm 2 in two columns.

Select next/previous stage with arrow icons. The stage changes automatically as the recording is progressed.



The width of the time position cursor indicates the time segment of the waveforms displayed - when the speed is changed the width of the position cursor will change. Move the cursor to move through the recording.

Art. no.: 2.511335 Rev. a

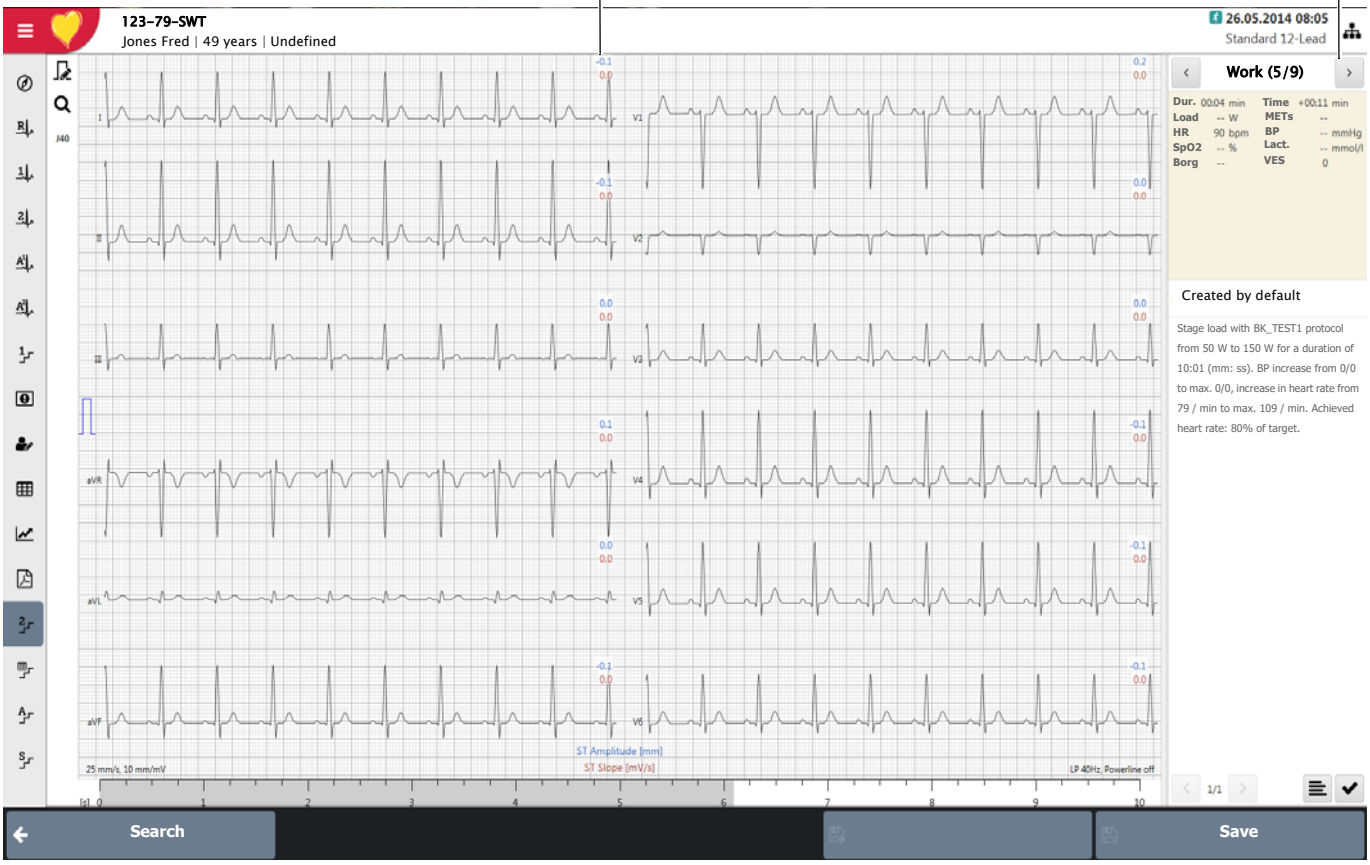
8.4.7 Rhythm View - Step

Click the **Step view icon 1** or **Step view icon 2**

The waveform displays the last 10 seconds of the selected stage and the averaged complex for every lead and the ST elevation and slope. View 1 displays the leads in one column (more exercise stages displayed). View 2 displays two columns for complexes for each exercise stage (more ECG channels displayed).

ST elevation and slope (see para. 8.4.4, Average View, page 103).

Select next/previous stage with arrow icons



At the side of the page the stages of the test are indicated:

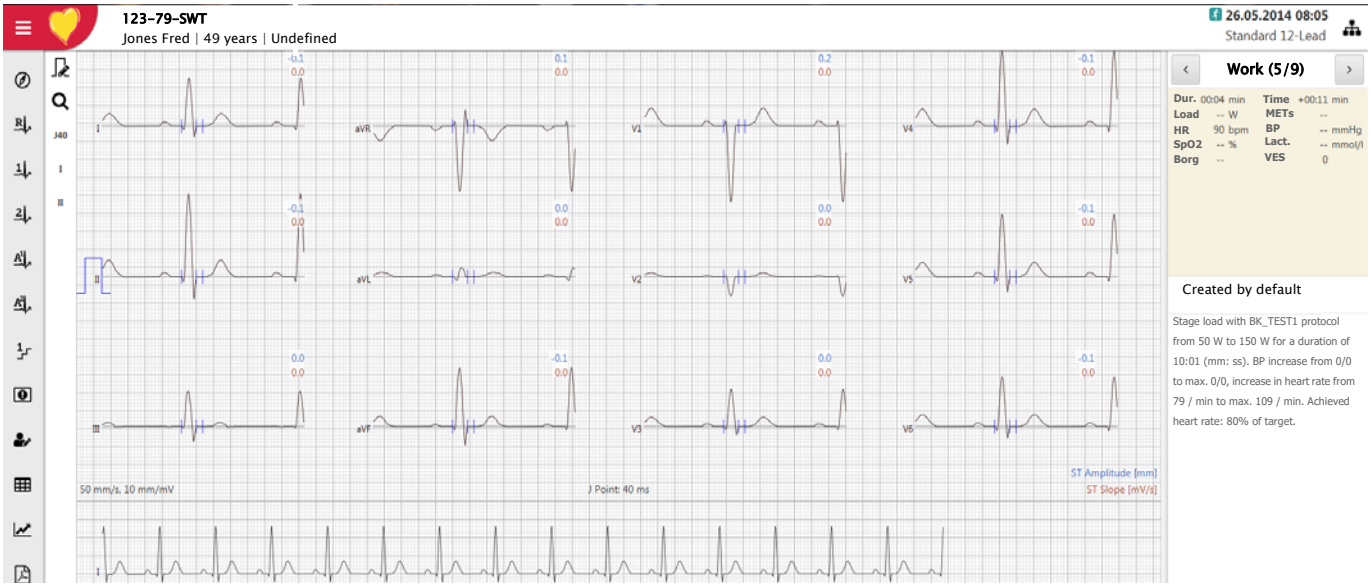
- The step type (warm-up, work, recovery) and duration
- Stage load applied
- Time from the beginning of the test to the beginning of the stage.
- BP
- SpO_2
- Borg rating
- VES count
- Lactate
- METS

Art. no.: 2.511335 Rev. a

8.4.8 Step Averages

Click the **Step average icon** or **step sequential icon** to display the averaged complexes of the last 10 seconds of the ECG of the selected stage. The averaged ST elevation and slope are also given.

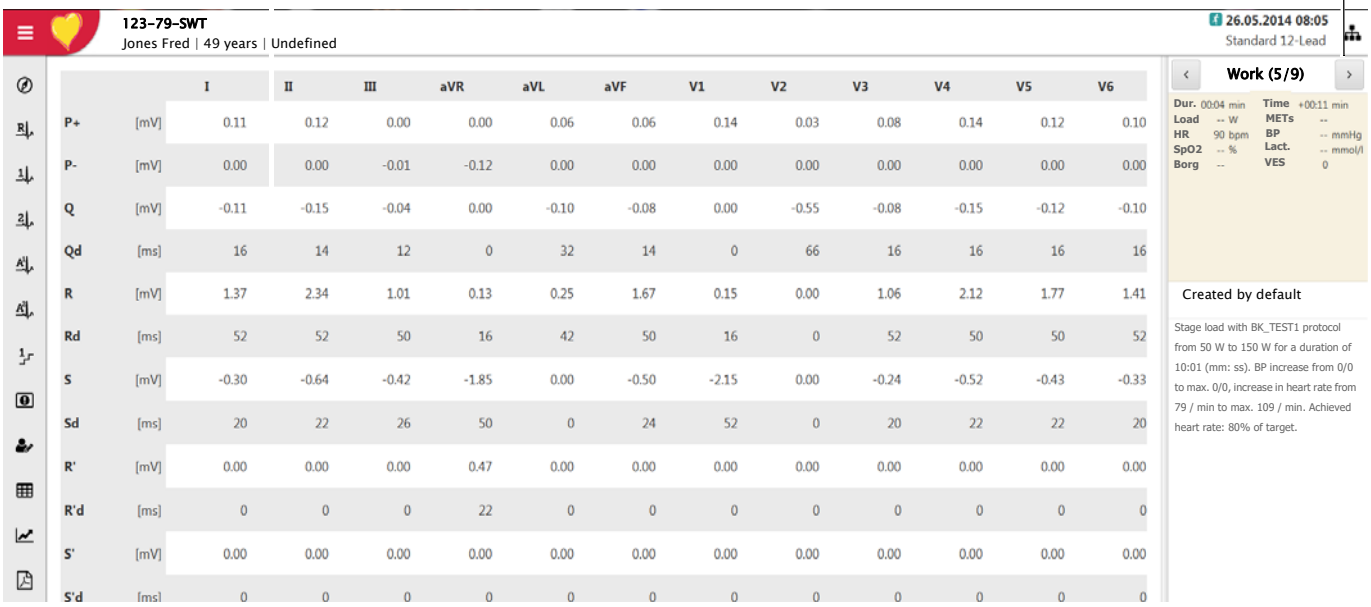
Two rhythm leads are given at the bottom of the screen showing a rhythm strip of the last 10 seconds of the stage. The rhythm leads are selected in the side bar.



8.4.9 Step Measurements

Click the **Step Measurements icon** to display the averaged measurements of all leads over the selected stage.

Select next/previous stage with arrow icons

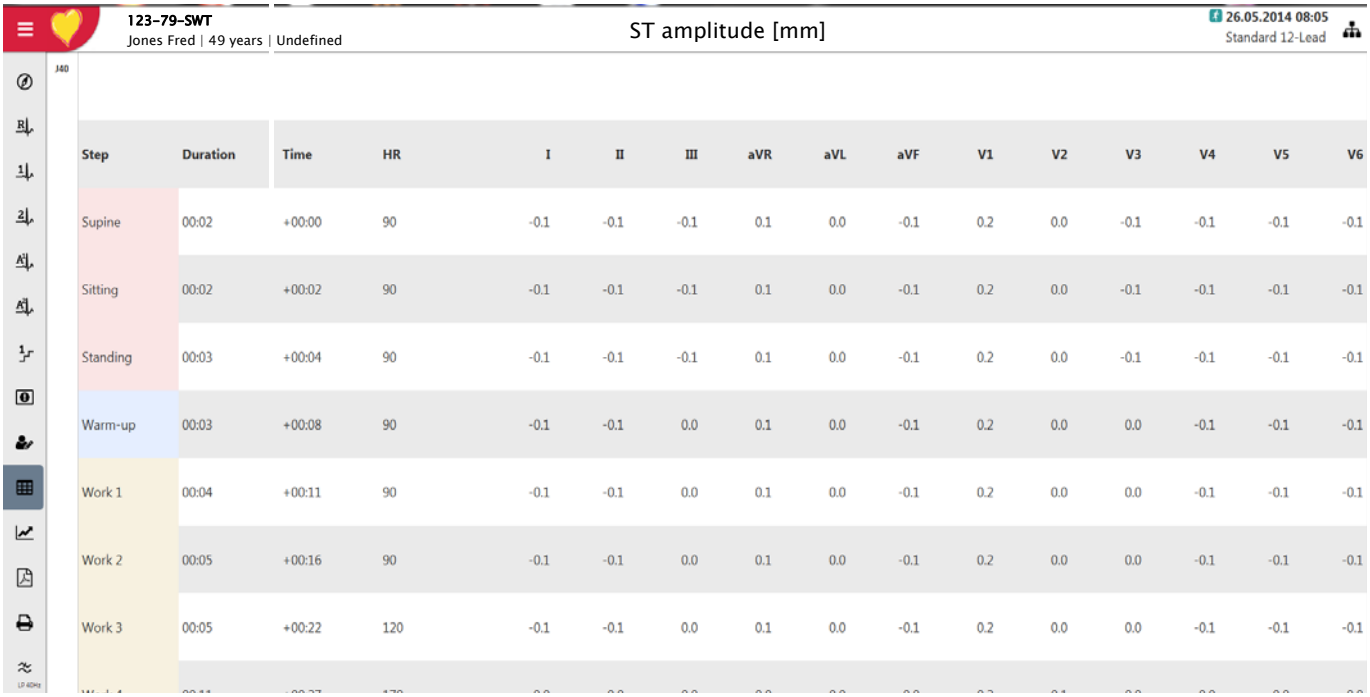


		I	II	III	aVR	aVL	aVF	V1	V2	V3	V4	V5	V6
P+	[mV]	0.11	0.12	0.00	0.00	0.06	0.06	0.14	0.03	0.08	0.14	0.12	0.10
P-	[mV]	0.00	0.00	-0.01	-0.12	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
Q	[mV]	-0.11	-0.15	-0.04	0.00	-0.10	-0.08	0.00	-0.55	-0.08	-0.15	-0.12	-0.10
Qd	[ms]	16	14	12	0	32	14	0	66	16	16	16	16
R	[mV]	1.37	2.34	1.01	0.13	0.25	1.67	0.15	0.00	1.06	2.12	1.77	1.41
Rd	[ms]	52	52	50	16	42	50	16	0	52	50	50	52
S	[mV]	-0.30	-0.64	-0.42	-1.85	0.00	-0.50	-2.15	0.00	-0.24	-0.52	-0.43	-0.33
Sd	[ms]	20	22	26	50	0	24	52	0	20	22	22	20
R'	[mV]	0.00	0.00	0.00	0.47	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
R'd	[ms]	0	0	0	22	0	0	0	0	0	0	0	0
S'	[mV]	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
S'd	[ms]	0	0	0	0	0	0	0	0	0	0	0	0

Art. no.: 2.511335 Rev. a

8.4.10 ST Table View

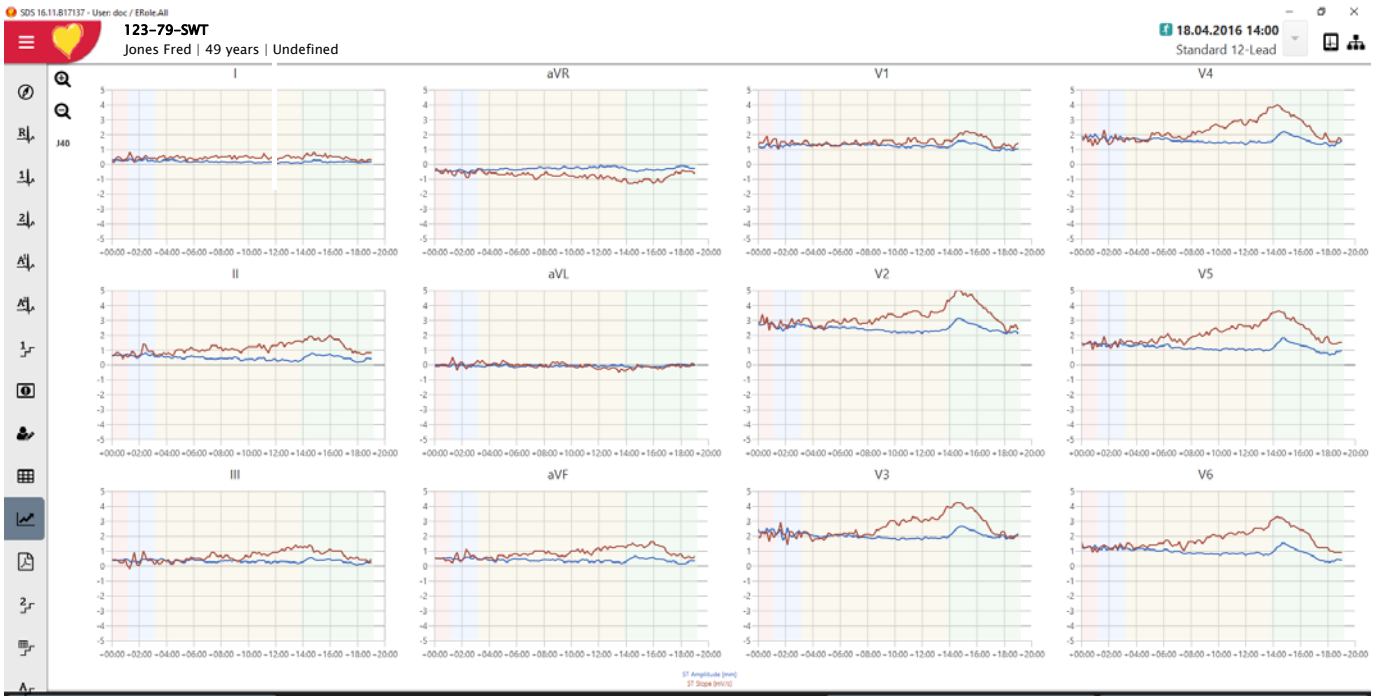
Click the ST Table view icon to display the ST measurements for every lead and every step.



Step	Duration	Time	HR	I	II	III	aVR	aVL	aVF	V1	V2	V3	V4	V5	V6
Supine	00:02	+00:00	90	-0.1	-0.1	-0.1	0.1	0.0	-0.1	0.2	0.0	-0.1	-0.1	-0.1	-0.1
Sitting	00:02	+00:02	90	-0.1	-0.1	-0.1	0.1	0.0	-0.1	0.2	0.0	-0.1	-0.1	-0.1	-0.1
Standing	00:03	+00:04	90	-0.1	-0.1	-0.1	0.1	0.0	-0.1	0.2	0.0	-0.1	-0.1	-0.1	-0.1
Warm-up	00:03	+00:08	90	-0.1	-0.1	0.0	0.1	0.0	-0.1	0.2	0.0	0.0	-0.1	-0.1	-0.1
Work 1	00:04	+00:11	90	-0.1	-0.1	0.0	0.1	0.0	-0.1	0.2	0.0	0.0	-0.1	-0.1	-0.1
Work 2	00:05	+00:16	90	-0.1	-0.1	0.0	0.1	0.0	-0.1	0.2	0.0	0.0	-0.1	-0.1	-0.1
Work 3	00:05	+00:22	120	-0.1	-0.1	0.0	0.1	0.0	-0.1	0.2	0.0	0.0	-0.1	-0.1	-0.1

8.4.11 ST Trend View

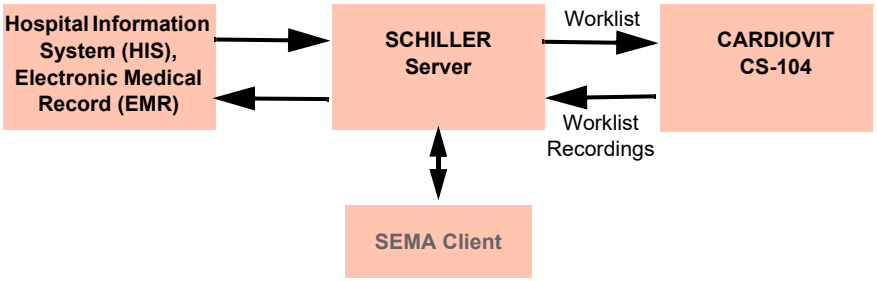
Click the ST Trend view icon to display the ST measurements in a graphical format for every lead. The blue line indicates the amplitude in mm. The red line gives the slope in mV/s.



Art. no.: 2.511335 Rev. a

9 Worklist

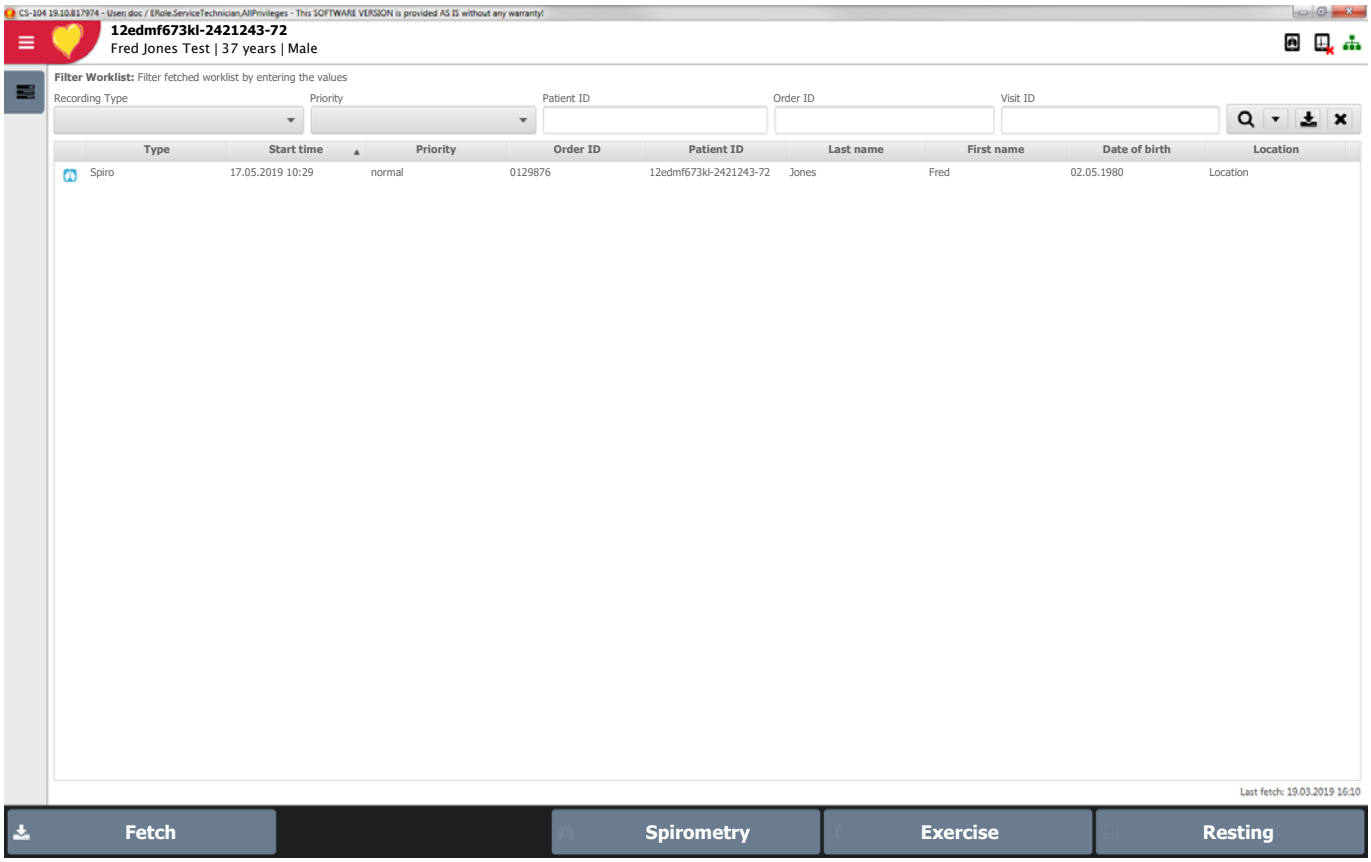
9.1 What is a Worklist



Worklist enables work requests to be sent from an external database system (EMR, GDT, HL7, etc.). The worklist comprises one or more worklist items that specify patient ID, and any combination of patient name and additional patient detail. The type of recording to be carried out, priority and start time, etc., can be specified and work items can be targeted for specific units or groups of units. Work items are fetched via the SCHILLER Server.

9.2 The Worklist Screen

From the home screen or main menu, select **Worklist**. The worklist screen is shown:



Art. no.: 2.511335 Rev. a

9.3 Downloading Work Items

The side bar and bottom icons are user set; the fetch icon and can be set for display in the side function bar or the bottom action bar (see para. 3.4.1, Side Bar and Bottom (Main) Icons, page 36).

Select search / worklist parameters and select the **Fetch (Download)** icon to update or refresh a worklist.

Two search criteria are available with the Worklist: a quick search and a worklist filter.

Worklist Filter

Worklist filter provides the following search criteria:

- **Recording type** - Any, Resting, Rhythm, Exercise, Spiro
- **Priority** - High, Routine, Stat (immediate), Undefined
- Patient ID
- Order ID
- Visit ID

Quick Search

Quick search provides the following search criteria:

- Patient ID
- Visit ID
- Last name
- First name
- Date of birth

9.3.1 Worklist Entries

The detail of each work item entry is given in the columns:

- **Recording Type** - Resting ECG, Resting Rhythm ECG, or Exercise ECG.
- **Start time** - expected start time for taking the recording
- **Priority** - High, Routine, or Stat (immediate)
- **Patient name**
- **Order ID** - The identification number of the work item defined by the requesting authority.
- **Visit ID** - The Visit ID of the work item defined by the requesting authority.
- **Location** - of the patient / acquiring department
- **Ordering provider**

Other work item details are possible and can be selected by right clicking in a header.

Art. no.: 2.511335 Rev. a

9.4 Performing a Worklist Item

1. Highlight the work item. The patient details are displayed in the top area of the screen.
2. Click the recording button at the bottom of the screen. The acquisition screen is entered for the recording type defined.

When a recording type is specified in the work item, only that type of recording will be able to be carried out, and only that recording icon will be able to be selected. Other buttons will be greyed.

3. Carry out the recording. The recording is sent to the ordering authority when completed.

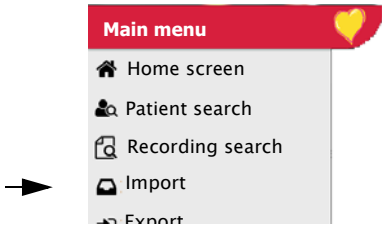
Art. no.: 2.511335 Rev. a

10 Importing and Exporting Recordings

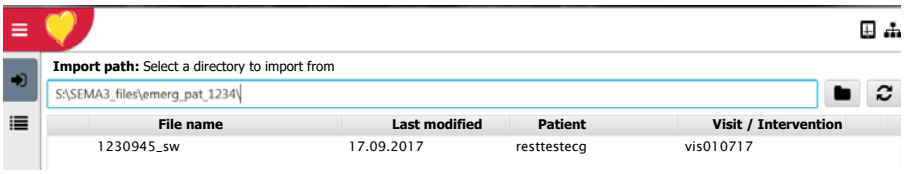
This function imports or exports SEMA format recordings from / to a specific location for test purposes, external analysis, etc.

- Imported recordings are automatically registered and stored on the database.
- The import / export function is only available when allowed in the user privileges.

10.1 Importing Recordings



1. Click the SCHILLER icon, top left of the screen, to display the main menu options and select **Import.**
2. Enter the directory from where the recording(s) are located and click **Start import.**

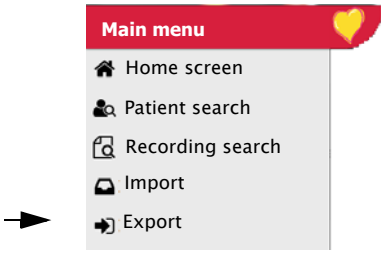


The recording(s) must be located in a folder - it is not possible to select an individual recording. When a selected folder has sub-folders, all recordings in the folder and all sub-folders are imported.

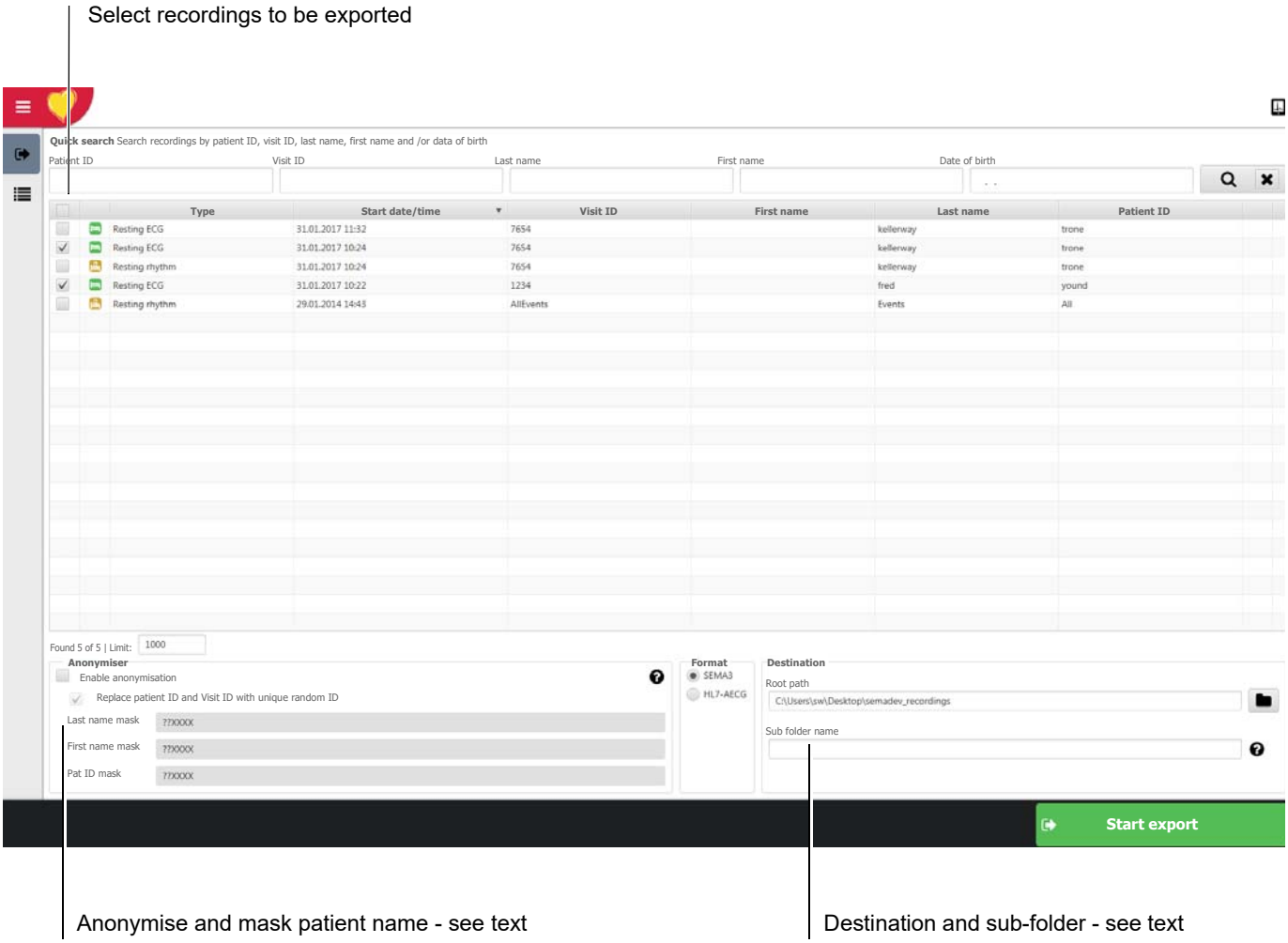
3. Click the Save and Close icon to return to the home screen. Imported recordings will be shown in the Patient search screen under the patient name, and in the Recording search screen.

Art. no.: 2.511335 Rev. a

10.2 Exporting Recordings



1. Click the SCHILLER icon to display the main menu options and select **Export.**
2. Search for patient(s) by ID, name, data of birth, etc.
3. Select recording(s) to be exported.
4. Define format - SEMA or HL7 - AECG
5. Set Anonymiser and mask name if required (see following)
6. Define destination and sub folder if required (see following)
7. Click **Start export.**



Anonymise

When **Enable anonymisation** is checked, the patient name is anonymised with the name entered in the mask details (patient ID and Visit ID remains the same)

When **Replace patient ID and visit ID with unique random ID** is checked, the pat ID and visit ID are also changed and a random patient ID and visit ID are applied when the recording(s) are exported[1].

1. When the system is prompted to provide the patient ID, it is generated using the **Universally unique identifier (UUID**) standard. The intent of UUIDs is to enable distributed systems to uniquely identify information without significant central coordination

Art. no.: 2.511335 Rev. a

Masking

Masking is giving an anonymous patient name. The name can be anonymised but part of a name can also be defined to help identify the patient (part masking - see following). To send a **recording anonymously** with masking:

- Check **Enable anonymisation** box
- The **Replace patient ID and Visit ID with unique random ID** can be checked / unchecked as desired (see previous).
- Define any combination of first, last and middle name

When the recording is exported the patient name is as defined.

Part Masking

When entering the mask name, the character '?' (question mark), can be used to enable part anonymisation of the name for easier identification.

Example

- A patients first name is **Frederick**
- If in the First name mask, **??..../??** is entered, this would result in a first name mask of: **Fr..../ck**

Destination and Sub Folder

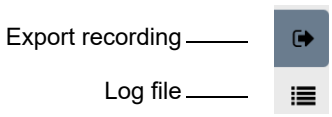
Placeholders can be used when defining the storage location and these are replaced with the actual value during the action. For example when defining the destination path for Export Recording:

- Destination root path could be set to: C:\Desktop\Export\
- The sub folder is set to %pid%
- The patient of the recording to be exported is for example 007, then
- The exported recording will be found in C:\Desktop\Export\007

If several recordings are selected for exporting and each patient ID is different for the selected recordings, each recording would be found within the sub-folder named as the patient ID of the recording. That is, the Placeholders will be replaced with the actual value during the action to be performed.

As many Placeholders can be added as required in the sub folder name field, in the format %placeholder%.

10.2.1 Log File



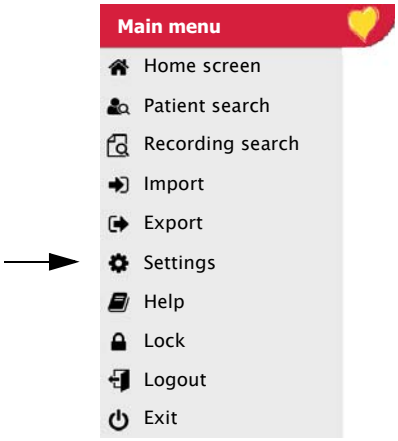
Select the log button to display any log files that have been generated.

Art. no.: 2.511335 Rev. a

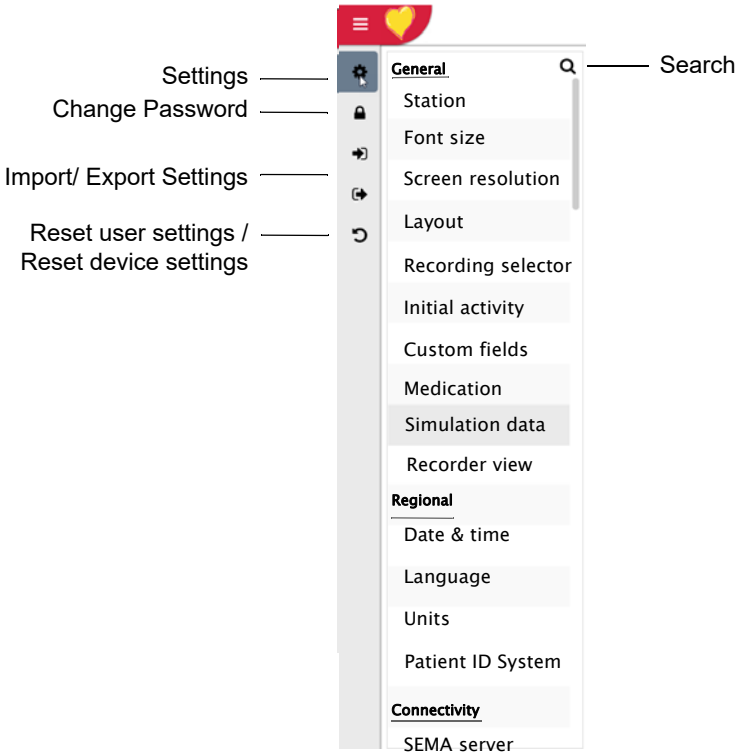
11 System Settings

11.1 Overview

The settings defined here will vary according to the privileges assigned to the user.



Click the SCHILLER icon, top left of the screen, to display the main menu and select **Settings.** Scroll through the settings to display all settings.



11.1.1 Settings Search

At the top of the settings screen is a **Search for setting** icon. Enter a character / sequence of characters to display all settings with the entered characters.

Art. no.: 2.511335 Rev. a

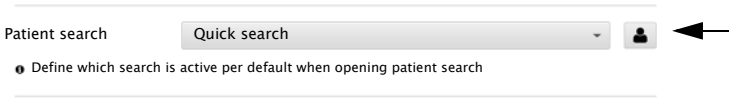
11.1.2 Setting Types

Settings are indicated in the setting field and defined as follows:

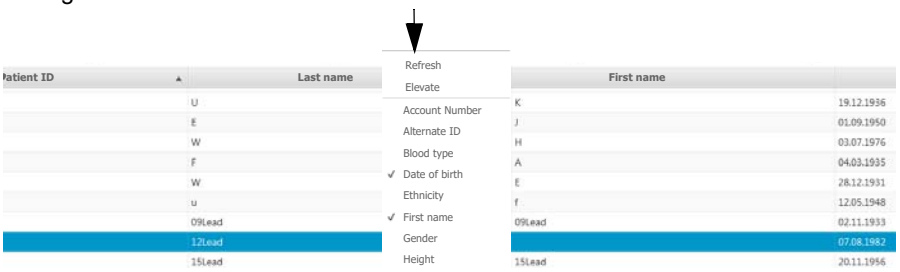
- System - system setting (requires restart)
- Global - setting applies to all users/devices
- Device settings
- User - setting applies individually to logged in user.

11.1.3 Elevating a User or Device Setting

User and device settings are applicable only to the currently logged in user/ device. However, these settings can be 'elevated' and applied to all users. To do this, after changing the setting, click the setting icon by the side of the entry to elevate. The icon greys and cannot be selected to indicate that it has been applied to all users.



In some user settings on the screen, for example when defining tables, the user settings can also be elevated.

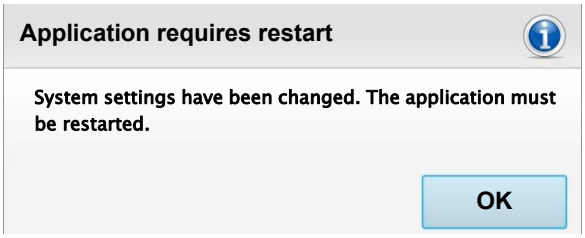


Right click on a column title, define the columns and click **Elevate**. Click **Reset** to define the system default setting (for table layout).

Any user/device settings that have been elevated by a user, can still be overwritten by other individual users if required.

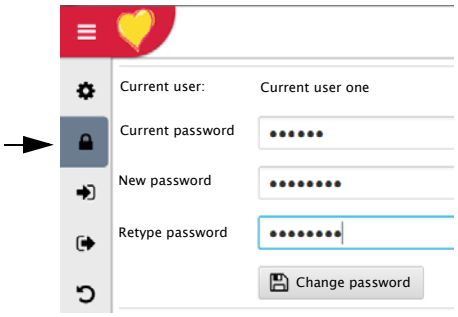
System Restart

Some settings require a system restart. When this is the case a warning message is given after the settings have been changed:



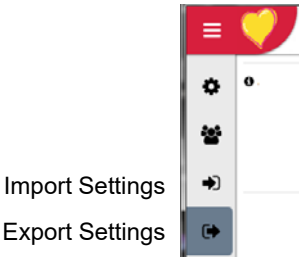
Art. no.: 2.511335 Rev. a

11.1.4 Changing the User Password



The password is initially set in the SCHILLER Server. The user, can reset his/her password after login as required or for security reasons. To change the user password click the password icon and enter your current user ID and password. When correctly entered, the new password field and confirmation field become active and the password can be changed.

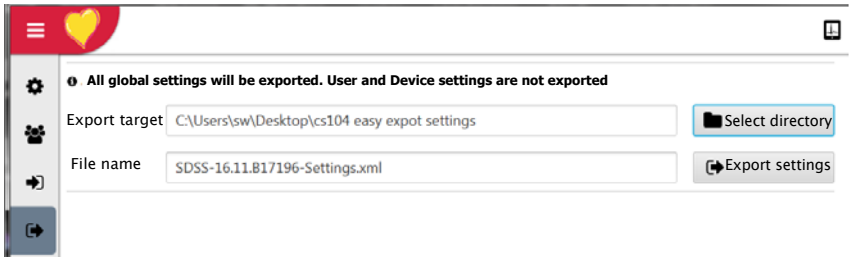
11.1.5 Importing /Exporting System Settings



If a number of installations are required to have the same settings for example, a settings import / export function is available to define the global settings. The settings are defined for one installation, exported to a USB stick, and can then can be imported to any other installation.

Exporting Settings

1. Define all settings.
2. Click the Export Settings icon.
3. Define the export directory (for example a USB stick), and file name.
4. Click export settings.
   – A message is displayed showing successful settings export.



Importing Settings

1. Click the Import Settings icon.
2. Define the import directory and file.
3. Click import settings
   – A message is displayed showing successful settings import

Art. no.: 2.511335 Rev. a

11.2 General

11.2.1 Station

Device ID

The Device ID defines the name and identity of the device / software.

Department and Institute

These option fields are entered to define the area to which the device / software belongs.

11.2.2 Font Size

The display font size can be set between small, normal, large and large.

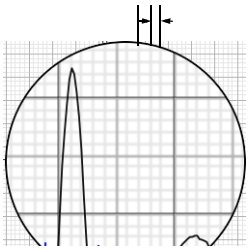
11.2.3 Screen Resolution

A blue and a red square are displayed and can be measured. The blue square edges should be 5 cm, the red square edges should be 2 inches.

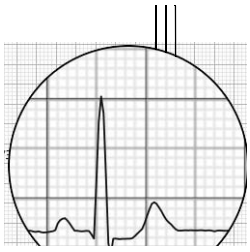
Three Resolution settings can be defined:

- **Overwrite system defaults** - When this is selected a new fields is displayed to enter the dots per inch (DPI). The blue and red squares change according to the setting.
- **User system defaults** - Use the resolution defined for the operating system.
- **Optimise for screen -** Because the pixel calculation can be different on screen sizes and resolutions, it is sometimes not possible to 'even' the grid and trace when displaying a recording. When optimise for screen is defined, the grid is 'evened' and trace is optimised.

Optimise for screen not set
- may display an irregular grid and unsmooth trace



Optimise for screen set
- optimises the display to give an even grid and smooth trace



If measurements are to be taken directly from the screen, it is important that the sides of the two squares are correctly calibrated.

Art. no.: 2.511335 Rev. a

11.2.4 Layout

Screen Size

This define the default layout of the program, select between:

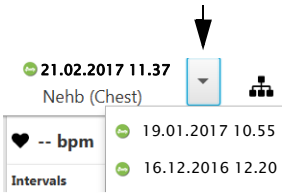
- Normal - optimal size centred
- Full screen - the program occupies the full monitor
- Maximised - the program occupies the complete screen: the top and bottom control and icon bars continue to be displayed.

Available Side and Main Action Bars

Define the number of function buttons given in the grey panel to the left side and the bottom (main) of every screen. Set between 5 and 25 for the side buttons and 1 to 10 for the bottom (main) buttons.

The content of the icons and the functions and actions available vary according to the screen displayed. The action bars are defined in the same way for all screens and described in the introduction (see para. 3.8, Display Configuration, page 40).

11.2.5 Recording Selector



Enable recording selector to allow other recordings from the same patient to be selected in the review screen. When enabled, an arrow appears in the top right of the screen for selection of other recordings without going back to the patient or recording screens (see para. 8.1, General Analysis Settings and Options, page 82).

11.2.6 Workflow

Initial Activity

Initial screen on Startup, select between:

- Home screen
- Patient search
- Recording search
- Recorder (new patient entry screen)
- Worklist (networked installations only)

11.2.7 Custom Fields

The custom field settings defined here are added to the recording details, in the additional information area (see para. 3.11, Recording-Specific Data, page 45)

Up to three fields can be defined that appear in the recording detail (patient data). Each of the three fields can be named individually. For each entry pre-defined text can be entered for user selection; When the value field is left blank (but a label defined) free text entry is available by the user.

- **Label field:**
  - In the Label field define the text title that will be the label of the entry field.
- **Value field:**
  - **Leave the Value field empty:** the user is free to enter any text as required.
  - **Define text options:** enter text in the value field as required. Separate text entries with a carriage return, that is, each entry on a separate line.

Art. no.: 2.511335 Rev. a

11.2.8 Medication

Define here the medication options that will be available for selection in the patient / recording data screen. Use a new line for each entry.

11.2.9 Simulation Data

Check the simulation box to activate simulation mode. This means that when an ECG or a spiro screen is entered, simulated fake data is displayed. This can be used for demonstration or teaching purposes. In the acquisition screen and on the report, **Simulation data** is printed on all traces.

To avoid the possibility of false data and diagnosis being attributed to an actual patient, do not activate this function in a working environment.

11.2.10 Recorder View

Here the settings for how the ECG is displayed on the screen are defined during acquisition. Settings include background and text colour, and trace colours and thickness.

The trace colour can be defined for the quality of the signal (see para. 4.4.1, Quality Indication on the ECG Trace, page 61), and the theme background (dark or light) set for user preference. The lower screen will display the colours as they are entered.

Art. no.: 2.511335 Rev. a

11.3 Regional

11.3.1 Date and Time Format

Select the required format for date and time on the printout and on the display as follows:

- **Date**: dd.mm.yyyy, yyyy.mm.dd, mm/dd/yyyy
- **Time:** hh:mm:ss (24 hour) or h:mm:ss aa (am/pm)

11.3.2 Language and System

System Language - select program language.

The **System country** setting defines the general country preferences, for example spelling, apostrophe use, etc.

11.3.3 Units

Select system units as follows:

- **Weight**: Grams, Kg or lbs
- **Length (or Height)**: Cm, metres or inches
- **Speed**: Km/h or mph
- **Altitude**: metres or feet
- **Temperature**: Degrees Centigrade (°C) or Fahrenheit (°F)

11.3.4 Patient ID System

When a new patient is defined, the Patient ID can entered manually, or can be generated automatically or to a specific format. The following ID formats are available:

- **None** - the patient ID is entered in any format required.
- **SCHILLER standard -** a patient ID generator is automatically used to define the Patient ID. SCHILLER uses the **universally unique identifier** (**UUID**) standard. The intent of UUIDs is to enable distributed systems to uniquely identify information without significant central coordination.
- **Swedish, Danish, Finnish, Norwegian** - The country ID format is defined and the patient ID should be entered in that format.

Art. no.: 2.511335 Rev. a

11.4 Connectivity

These settings are applicable for networked installations only.

11.4.1 SCHILLER Server

The SCHILLER Server screen gives the current server connection settings and details. This is usually defined on installation. The path is defined in the Host field and the port number (default 8080 or 8181). As the host is defined, the URL path is automatically entered in the URL field.

When the **Test server connection** button is clicked, the program pings the server to check the connection. When connection is established, a message is displayed to that effect. An overview of the SCHILLER Server is given in the SCHILLER Server communication guide.

11.4.2 SCHILLER Update Server (SUS)

The update server screen gives the current server connection settings and details. This is usually defined on installation. The path is defined in the host field and the port number (default 8080). As the host is defined, the URL path is automatically entered in the URL field.

When the **Test server connection** button is clicked, the program pings the server to check connection as described above.

When a Program Update is Detected

When Automatic Update is set, every time the user logs in, a check is made to see if an update is available. If there is a new update available, an indication is given on the opening screen.

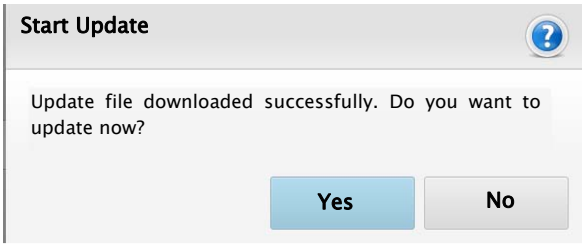
Four options are available:

- When the box is ignored, it disappears after a few seconds and the update is not performed.
- When **Info** is clicked, the release notes of the updated software are displayed.
- When **Update** is clicked the client program is installed (see following).
- If **Skip Update** is selected, the SEMA software is not updated. A small icon is present in header of SEMA to indicate that an update is available.

Art. no.: 2.511335 Rev. a

When Update is clicked, the program is downloaded from the SUS:

When the program has been downloaded you are prompted to install.



The program closes and the update starts. You are prompted to confirm and a progress bar is displayed.

When installed, click the CS-104 icon to open with the updated software.

Further details of the SUS are provided in the SUS configuration Guide (2.540096)

Art. no.: 2.511335 Rev. a

11.5 Import / Export

The settings here apply to GDT, SEMA2 and SEMA XML format import / export only. Standalone import/export of general recordings and rescue recordings is described earlier in this book (see para. 10, Importing and Exporting Recordings, page 113).

11.5.1 Import

Interface

Select the import interface to be used. Selected between:

- Disabled - no import/export interface used
- GDT
- SEMA2
- SEMA XML

Import Mode

Select **manual, automatic** or disabled. This is the setting for checking the import directory for GDT data.

Import Directory

The drive and the directory used to read the communication files for import. This information must be the same as in the EMR configuration.

11.5.2 Export

Interface

Select the output interface to be used. Selected between:

- Disabled - no import/export interface used
- GDT
- SEMA2
- PDF
- HL7

Export Directory

The directory used for working communication. The drive and the directory used to access exported files. This information must be the same as in the EMR configuration.

Attach PDF

Check this box to additionally generate a PDF file of the recording for export.

Export after recording

Automatically export a recording after it has been recorded.

Export after validation

Automatically export a recording after it has been validated.

Allow manual export

When this function is checked an extra option is given in the analyser Workflow screen to export recordings. The user must also have the privilege to export manually.

Print after recording

Automatically print a recording after it has recorded.

Print after validation

Automatically print a recording after it has been validated and saved

Art. no.: 2.511335 Rev. a

Filter (Resting, Rhythm, and Exercise ECG)

- Off - Recording is exported with no filtering.
- LP 25, 40, 150 - recording is exported with l**ow pass filter** set to the defined cut-off frequency.
- RNSF (exercise only) - recording is exported with RNSF (Robust noise suppression filter[1]).

11.5.3 GDT /SEMA2

Character set

IBM (standard) CP437, ISO8859-1(ANSI) CP 1252, ASCII, etc. This is set to the character set defined by the EMR system

EMR Device

The ID of the remote system with which the CARDIOVIT CS-104 will communicate. This is defined by the remote system.

Device ID

The device ID identifies CARDIOVIT CS-104 in the system to enable communication between CARDIOVIT CS-104 and the remote system. The ID must be unique in the system and can be any combination of up to four characters.

Because all information is assigned using these IDs, it is essential that all IDs be unique, especially in the case of multiple devices (for example 2 ECG devices from the same manufacturer).

File extension use

Select **auto increment** or **static**. When auto increment is selected, the file extension will increase by one every export, that is 0001, 0002, etc.

Export Measurements

This setting is how and where to export the measurement table and is set according to GDT system requirements. The options are as follows:

- After Interpretation - append the measurement table after the interpretation statement
- No Export - do not export the measurement table
- Pre-formatted result table
- Re-occurring test parameter fields

Details of these options are given in the SCHILLER Server communication guide.

1. The RNSF filter is a dual purpose filter specifically used for exercise testing. It is designed to help stabilise the baseline during exercise tests and to help reduce the physical and muscle artefacts that can be present during exercise testing. The RNSF addresses artefact frequencies both outside and within the ECG frequency range.

Art. no.: 2.511335 Rev. a

11.6 Interpretation

11.6.1 General

Attach Interpretation only if validated — Check the box to include only validated interpretations (in reports and printout).

Use Automatic Interpretation — Check the box to create an interpretation automatically for new resting ECGs

11.6.2 Default Acronyms

User defined interpretation acronyms can be added for the following recordings:

- Resting ECG
- Resting Rhythm ECG
- Exercise ECG
- Signal Averaged ECG
- Spirometry

For each entry pre-defined text can be entered for user selection; in the custom acronyms field enter acronym interpretation text as required separated by a carriage return, that is, each line represents interpretation text that is available and can be selected by the user in the interpretation screen of the recording.

11.6.3 Custom Acronyms

Only with the advanced interpretation option.

Enter user defined interpretation acronyms are required. each line represents and custom acronym that can be selected in the interpretation screen.

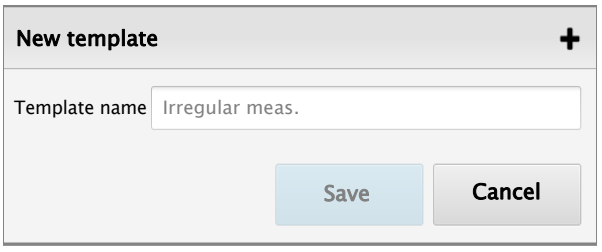
11.6.4 Templates

Only with the advanced interpretation option.

When more text, acronyms or options are required in one selection, acronym templates can be can be added for Exercise ECG, Resting ECG, Resting Rhythm ECG and Spirometry. The template name and the text for inclusion must be defined in the same way as for custom acronyms above.

When defined, the interpretation text and/or template name appears in the interpretation screen for selection (see para. 8.2.11, Interpretation, page 90). The entered acronyms or template text can be edited after selection if required.

Click the **+ button** to define a new template:



Art. no.: 2.511335 Rev. a

11.7 Search

11.7.1 Quick Search

Select the search fields:

- Patient ID
- Visit ID
- Last name
- First name
- Date of birth

11.7.2 Limit

This setting defines the maximum number of results displayed when a search is initiated in the **Patient Search** screen, **Recording Search** screen and the **Worklist** Select a number of patients / recordings or work items to display between 5 and 5000.

11.8 Security

11.8.1 Lock (Auto User Logout)

This is a security setting to disable the program if no user input is made within a defined time. After the time-out period, the program is locked and the user must login again to enable the program. Check the Lock enabled box to enable the lock screen setting. When this box is checked, the lock screen time can be defined up to 86400 seconds (24 hours).

11.8.2 Single Sign On

When system authentication is set, security can be compromised. It is recommended that this setting is only defined for PCs that are single or limited user.

Check this box to enable system authentication of user ID and password. This means that when the program is first opened no login is required because user authentication is carried out by the computer system. Also when application time-out is set, no password is required to reactivate the program.

To enable this function, the same user name must be defined for the user management screen as set for the PC.

Art. no.: 2.511335 Rev. a

11.9 Licenses

This screen details the host ID and license key number. It also details all options that are active. If more options are required after initial installation, contact SCHILLER with the Host ID on this page to receive a new license key to enable the options.

11.10 Reports

In this page the data that is to be included when a report is generated (a recording is printed or PDF file produced), is defined.

11.10.1 General (Company information)

Company Logo and Info

Click the company logo field to browse and insert a company logo on a report. The file must be a jpg, bmp, etc. The file can be any size and the program will scale the image to fit. Enter additional company information (address) as required.

Rhythm Mode

This is a general setting for all recording types printing 10s rhythm strips. Define the rhythm mode to be sequential or simultaneous.

QTC calculation

Select the default calculation between:

- Bazett
- Fridericia
- Framingham
- Hodges

Paper Format

A4 or letter.

11.10.2 Header

Select the information to be given in the header of a printout or PDF file. As many fields can be defined as required and the options include, name, ID, date of birth, height, gender weight etc. and also hospital/institute and physician details, etc.

11.10.3 Printer

Here the printer is defined. If **use default printer** is checked, the default printer defined for the PC is used.

Art. no.: 2.511335 Rev. a

11.10.4 PDF

Here the Default export path, PDF name and PDF conformance are defined.

Export Directory and File name

Enter the location where the PDF file that is generated will be stored. Click the Browse icon to define the location as required.

The file name of the PDF file is set in the default file name. The codes (Placeholders) of the information to be included in the file are detailed above the entry field. The codes can be separated by an underscore or space to make it clearer to read. As many placeholders can be added as required in the sub folder name field, in the format %placeholder%, for example:

%pid%_%lastname%_%recordingdate%.pdf

Placeholder	Information in PDF file name
	Unique ID of the recording
%pid%	Patient ID
%firstname%	Patient's first name
%lastname%	Patient's last name
%dateofbirth%	Patient's date of birth
%gender%	Patient's gender
%visitid%	Visit ID recording
%deviceid%	Device ID
%recordingdate%	Recording date (yyyyMMdd-HHmmss)
%recordingtype%	Recording type
%reportformat%	Report format name

Show file dialogue when generating PDF

Check this box to display a prompt every time a PDF file is generated to select the storage location of the PDF file. f this box is not checked the default path and name is automatically set (see above).

Conformance

PDF Conformance - select between none, PDF/A-1a or PDF/A-1b[1]

1. Part 1 of the PDF/A ISO standard [ISO 19005-1:2005] is a constrained form of Adobe PDF version 1.4 intended to be suitable for long-term preservation of page-oriented documents for which PDF is already being used in practice. Level B conformance (PDF/A-1b) indicates minimal compliance to ensure that the rendered visual appearance of a conforming file is preservable over the long term. Level A conformance (PDF/A-1a) indicates complete compliance with the ISO 19005-1 requirements, including those related to structural and semantic properties of documents (http://www.digitalpreservation.gov/formats/fdd/fdd000252.shtml, accessed March 2013).

Art. no.: 2.511335 Rev. a

11.10.5 Formats

In this page the formats available for the report / printout are selected.

Print / PDF settings can be set for the following type of recordings:

- Resting
- Resting Rhythm ECG.
- Exercise
- Spirometry

Each recording type will have different options. Different options are also given for different lead configurations. Select the recording type and lead configuration and then select all the formats required from the left (available formats) column.

If a combined report has been defined (see next paragraph), this will also be available for selection.

The top report will be the default format (when selected in the Print/PDF selection).

11.10.6 Combine Reports

Recording Type

– Select between Resting ECG, Resting Rhythm., EECG or Spiro (and ErgoSpiro, SAECG or Rescue).

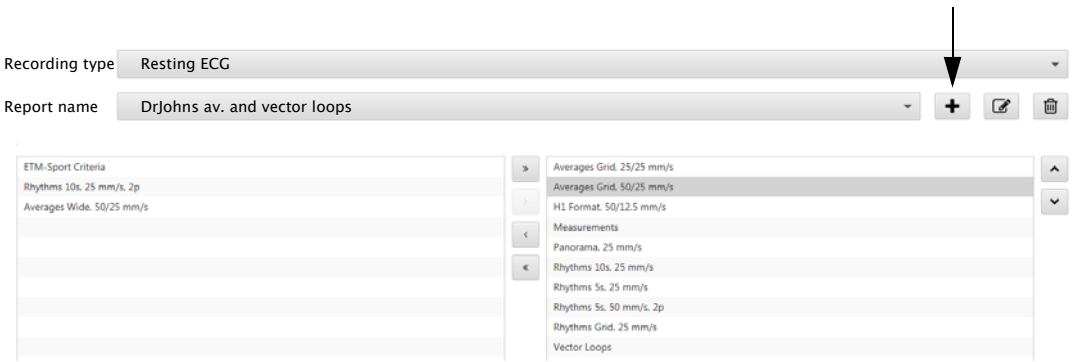
Report name

Any suitable name can be entered here for the report.

This is the name that will appear in the options when a recording is to be printed or a PDF generated.

Available and Selected Formats

In the left column are all the available formats and in the right column, the formats that have been included in the report. Add and subtract formats as required. The order of the reports are set with the arrows in the right hand side.



Define the report name and set data options and click the + button.

When a combined report has been set, it must be **defined in Formats** (above) so that it can be selected when a recording is to be printed or a PDF file generated.

Art. no.: 2.511335 Rev. a

11.11 ECG

Here the general ECG settings for acquisition and view are defined. Specific settings for different recording types are defined following.

11.11.1 General

Lead Sequence Standard or Cabrera

Rhythm lead 1, 2 and 3 Define the rhythm lead for display and print

Coding Select the lead set used for the patient cable, IEC or AHA (see para. 4.1.1, Electrode Identification and Colour Code, page 46).

Default Lead configuration Select between the following:

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

11.11.2 Power Line

Set to local mains supply frequency - 50 Hz, 60 Hz, or off.

11.11.3 Display Filter

The Low pass filter suppresses disturbances caused by strong muscle tremor and can be applied to stored ECGs and real-time ECGs. Depending on the recording device, an ECG recorded in auto mode is stored unfiltered. It is therefore possible to record, and print the stored ECG, either with or without a filter applied. In this screen the filters available can be defined for resting ECG and exercise ECG. The filter settings are Off, 25 HZ, 40 Hz and 150 Hz, and for exercise only, RNSF[1]. Any combination of filters can be enabled and applied with the **Toggle Filter** icon 

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11.11.4 Analyser View

Here the settings for how the ECG is displyed when reviewed and includes Grid colour, intensity, and trace thickness.

11.11.5 Print Output and PDF Output

Here the settings for how an ECG is printed or a PDF file is generated.and includes grid colour, intensity, and trace thickness.

1. The RNSF filter is a dual purpose filter specifically used for exercise testing. It is designed to help stabilise the baseline during exercise tests and to help reduce the physical and muscle artefacts that can be present during exercise testing. The RNSF addresses artefact frequencies both outside and within the ECG frequency range.

Art. no.: 2.511335 Rev. a

11.12 Resting ECG

11.12.1 Scale

Define the default scales (amplitude and speed) for rhythm and average complexes.

11.13 Rhythm ECG

11.13.1 General (Rhythm Length)

Define the default length for rhythm recordings. Check the **Show recording time dialog** box to display the duration dialog before a recording is made.

11.13.2 Scale

As for Resting ECG settings.

11.13.3 Events

Define the wording for manual events. As many entries as required can be added separated by a carriage return (that is new line). Each line is handled as a single event entry and is available when a manual event is added to a rhythm recording. The event entry is available during the recording when the Manual event button is clicked (see para. 6.2.1, Manual Events, page 69).

11.14 Exercise ECG

11.14.1 General

ST Trend

Define the settings for the ST trend graphs at the top of the screen:

- **Table / Trend split (%)**. This defines the relative sizes of the Table trend ratio. define for preference.
- **Show ST Trend** - check as required to display the ST trend graphic.
- **HR x BP units** - select between mmHg/min (1/100), or mmHg/min.

Averages

On the average screen display:

- **Show isoelectric line** - check as required
- **Show reference curve** - check as required

(see para. , Isoelectric and Reference curve, page 104)

11.14.2 Recorder

The following settings can be made:

J-point default

Select the default between 10 to 100

Target heart rate

Use the AHA formula or WHO formula

WHO formula:	220 – patient age	
AHA formula:	Patient age < 25:	→ 160
	Patient age > 75:	→ 115
	Otherwise:	→ 160 – (patient age – 25) * 0.9

Art. no.: 2.511335 Rev. a

Max. load calculation

Select between:

- **Max step load** - The current load within the work phase.
- **Time** - The current load of the step is taken as the max. load if the elapsed time within the step is greater / equal than the configured x second. If the load step is less than x, the load of the previous step is used as the max. reached load. When this option is selected the field below becomes active to enter the number of seconds.
- **Interpolated** - $\text{Max load} = SL1 + \frac{SL2 - SL1}{t1} * t2$
  - SL1: Load of previous step
  - SL2: Target/set load of current step
  - t1: Step duration in seconds
  - t2: Elapsed step time in seconds

Step timer

Display **remaining time** or elapsed time

Recovery

Select to recover either **Direct** or initialise recovery. This determines the action and recovery icon text to end the test. Direct means that the recovery phase is entered directly; initialise recovery means that the current exercise stage is completed before recovery stage is entered (set by user).

Average complex

Check this box to show the average reference complex (see para. 7.4, Exercise Test Procedure, page 72).

Show chart legend

Check this box to display the legend for the three graphs in the upper area (can be enabled / disabled (see para. 7.5, During the Test, page 75).

11.14.3 Scale

Set the default amplitude and speed scale for the following:

- Rhythm
- Continuous - (multi-line single lead view)
- Average

11.14.4 Events

Define the wording for manual events. As many entries as required can be added separated by a carriage return (that is new line). Each line is handled as a single event entry is available during the recording when the Manual event button is clicked (see para. 7.5.8, Events, page 79).

11.14.5 Ergo Devices

Ergo Device

Select the ergo device that wilt be used for the test - bike or treadmill.

Bicycle type / Treadmill type / NIBP device

Select the ergometer type / NIBP device from the list. If not listed select unsupported.

Bicycle port/ Treadmill port / NIBP device

Select the COM port to which the ergometer / NIBP device is connected.

When a NIBP device is defined that supports SpO_2 measurement, an extra box is displayed in the NIBP device settings to Enable SpO_2 trend.

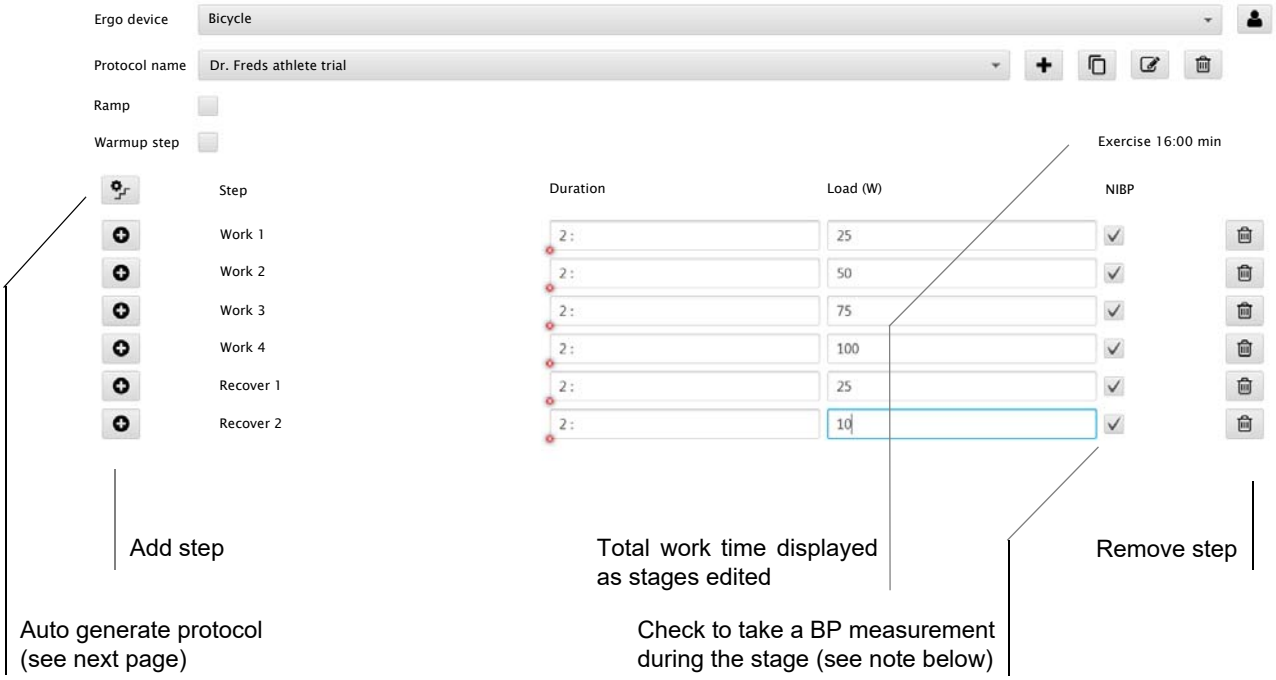
Art. no.: 2.511335 Rev. a

11.14.6 Protocols

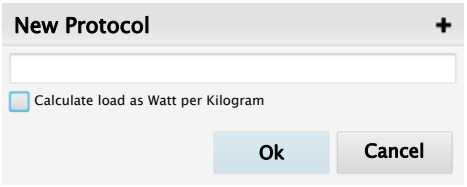
Select the protocols from the list that will be available when an exercise test is entered. The protocol on the top of the list will be the default (note that when an exercise test has started the protocol cannot be changed).

11.14.7 Protocol Editor

Bike and Treadmill protocols can be defined and viewed for selection in Protocols at the start of the test. The procedure to define a new protocol is a follows:



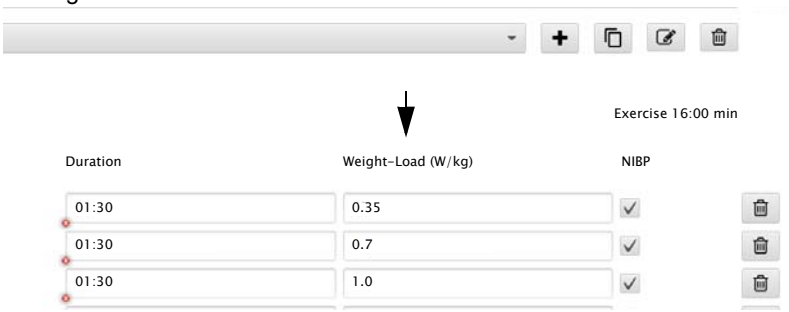
1. Select the ergo device (bike or treadmill).
2. Select the protocol on which the new protocol can be based.
3. Click the '+' icon.



Art. no.: 2.511335 Rev. a

4. Define the new protocol name and click Ok.

   – For bike protocols an extra check-box is given when a new protocol is set - **Calculate load as Watt per Kilogram**. When checked the work and load stages in the protocol change from Watt, to Weight - Load (W/kg) and the load applied during the exercise steps are calculated as a product of the patients weight:



5. Check the ramp box for a ramp protocol (step increase is carried out over the step and not a 'step increase').
6. Check the warmup step to define a warmup stage.
7. For each step check the BP box to initiate a BP measurement for that stage or display the BP input screen for manual entry.

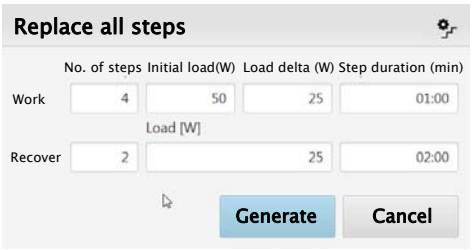
Note:

– A BP measurement is taken 10s after the pre phase and after the warmup phase (when a warmup phase has been set in the protocol).
– A BP measurement is initiated when checked for a stage, as follows:
– 50s before the end of work/recovery step OR
– instantly if work/recovery stage duration is less than 50s.

8. Define work and recovery stages load or elevation / speed.
9. Define the protocol for inclusion in the Protocol option when taking a test (see paragraph above).

Auto Protocol Editor

When the Auto protocol editor is selected , the protocol can be overwritten with a set number of work steps and recovery steps, and linear load increase and step duration.



11.15 Spirometry

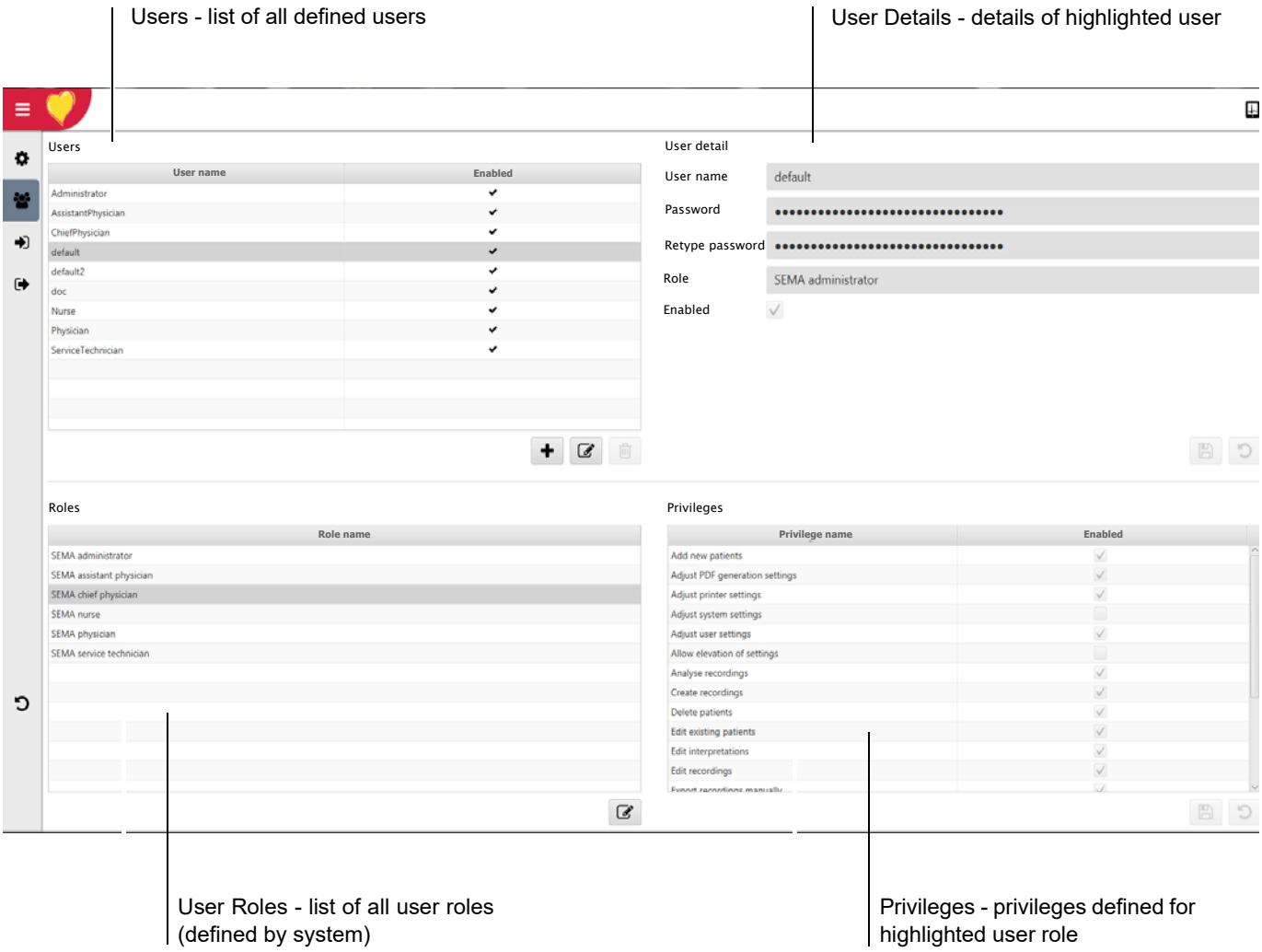
See CARDIOVIT CS-104 Spiro User Guide.

Art. no.: 2.511335 Rev. a

12 User Management

This section is for standalone installations only. When the CS-104 is networked with the SCHILLER server, user management is managed from the Server.

- User Roles are defined by the system with specific privileges and individual users are assigned a user role.
- The privileges for the user roles can be edited by the administrator.
- Every user is assigned to a specific Role.
- New users can be added at any time and existing users edited or removed.
- From **settings** select **User Management t**o show the user management screen.



Art. no.: 2.511335 Rev. a

12.1 Defining the Privileges for a User Role

1. In the **Roles column** highlight the user Role.
2. Click the edit button .
3. In the **privileges column**
   – Define the privileges for the group.
   – Click save to save changes or return to return with saving changes .

12.2 Defining a New User

1. In the **Users column**, click the new user icon .
2. In the **User detail** column:
   – Enter user name and define password - retype password to confirm (the user name and password are required for login).
   – Define the User Role (and associated privileges).
   – Click save to save changes or return to return with saving changes .

12.3 Deleting or Editing a User

1. In the **Users column**, highlight the user.

- To **delete** click the trash icon .
  – You are prompted to confirm deletion
- To **Edit** the user, make changes in the **User detail** column as described above.
- Click Save to save changes or return to return with saving changes

Art. no.: 2.511335 Rev. a

13 ECG Recorders

13.1 MS-12 blue

13.1.1 Control Button

The unit is controlled by the button on the top of the unit. The button has two functions depending on how long it is pressed:

Short press

A short press will:

- Switch the unit on.
- Highlight the next menu item.

Long press

A longer press (approximately 1.5 seconds) will:

- Open, or carry out the function of the highlighted menu item.

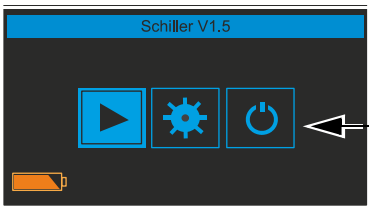
13.1.2 Switching the Unit On

To switch on the unit press the control button.

13.1.3 Switching the Unit Off

The unit can be switched off from the main menu and from the electrode screen.

13.1.4 Switching Off from the Main Menu



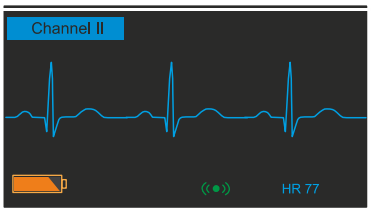
Highlight the off icon and press and hold the control button for approximately 1.5 seconds. The off icon is displayed flashing in the middle of the screen for a few moments and the unit is switched off.

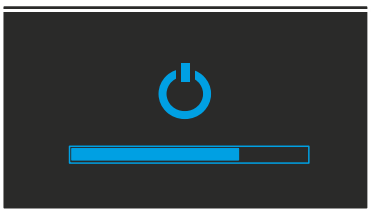
When the unit is not transmitting (main menu displayed), and no activity is detected (i.e. the control button is not pressed) the unit switches off automatically after 20 minutes.

Art. no.: 2.511335 Rev. a

13.1.5 Switching off from the Electrode (recording) ECG Screen

Press and hold the control button for 3 - 4 seconds. The off icon is displayed with time line progress displayed.





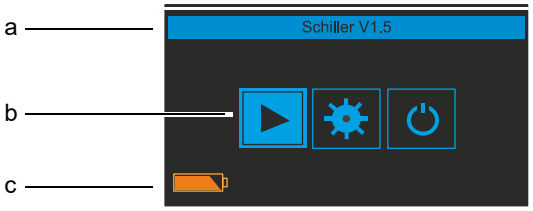
At the end of the time-out period, the off icon is displayed flashing in the middle of the screen for a few moments and the unit is switched off.

If the control button is released during the switch off period when the time line is displayed, switch-off is cancelled and the unit continues to transmit.

13.1.6 Display

The display provides limited information and options for unit functions.

The main menu, displayed when the unit is switched on, displays the following:



(a) Software version The software version of the unit is displayed in the top line.

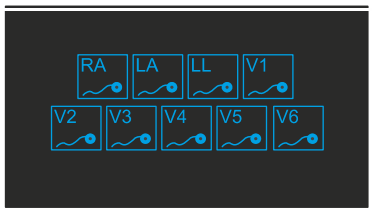
(b) Menu Options The menu option icons are given in the centre of the screen.

(c) Battery capacity The battery capacity is displayed in the bottom left of the screen ((see para. 13.1.12, Battery Capacity, page 143)).

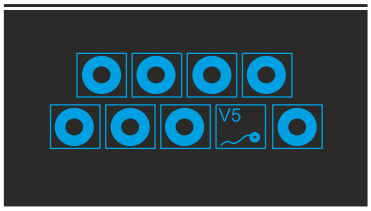
Art. no.: 2.511335 Rev. a

13.1.7 Electrode Screen

From the main menu (previous page), highlight the electrode icon and press the control button for 1.5 seconds. The electrode screen is displayed:



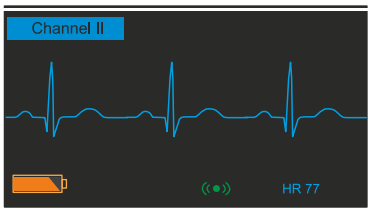
As the electrodes are placed on the patient, the electrode indication changes to a circle to indicate that connection has been made.



Electrode resistance that is within tolerance (to provide a good recording) is shown as a thick circle.

When a high resistance electrode is detected - either before the electrode is connected, or if the electrode becomes dislodged or becomes high resistance during a recording, the high resistance electrode symbol is displayed showing the lead designation.

When all electrodes are connected the screen displays the ECG screen.



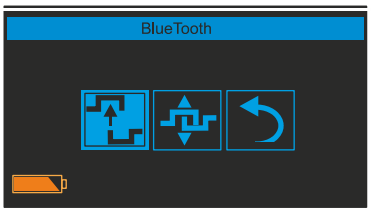
Press the control button to scroll through the ECG leads as required.

After approximately 30 seconds the ECG screen disappears and a smiley face appears on the screen to indicate ECG acquisition ☺

Art. no.: 2.511335 Rev. a

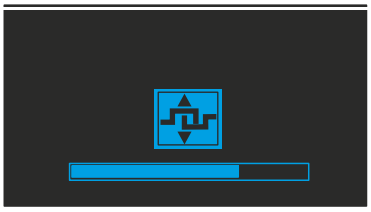
13.1.8 Bluetooth Screen

From the main menu (previous page), highlight the Bluetooth icon and press the control button for approximately 1.5 seconds. The Bluetooth screen is displayed:



13.1.9 Pairing

Highlight the Bluetooth connect icon and press the control button for approximately 1.5 seconds. The icon flashes alternately between the connection / disconnection icons and connection progress time line is displayed below the icon:



After connection has been made the main menu is displayed.

The pairing procedure is described later in this user guide (see para. 13.1.14, MS-12 blue Bluetooth Pairing Procedure, page 144).

13.1.10 Deleting Paired Connections

Highlight the Bluetooth disconnect icon and press the control button for 1.5 seconds. The hourglass icon is displayed briefly while disconnection is in progress. After disconnection the main menu is displayed and paired connections are lost.

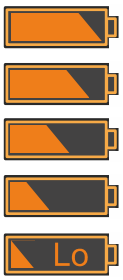
13.1.11 Power Supply

The MS-12 blue comes with a battery charger and a set of high capacity AA rechargeable batteries. Only use the supplied rechargeable batteries or equivalent rechargeable batteries of similar quality to ensure trouble free operation.

Two fully charged AA batteries provide unit power for several days. The actual operation time of any set of batteries is variable and depends on battery type, age, and charge/discharge history.

Art. no.: 2.511335 Rev. a

13.1.12 Battery Capacity

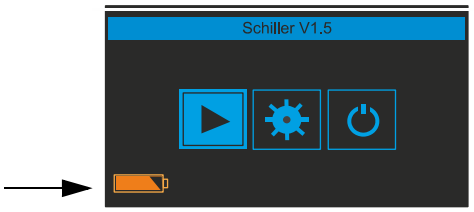


Full

Half full

Low capacity

The battery symbol in the lower left of the screen indicates the battery status. When the battery is full the symbol is filled.



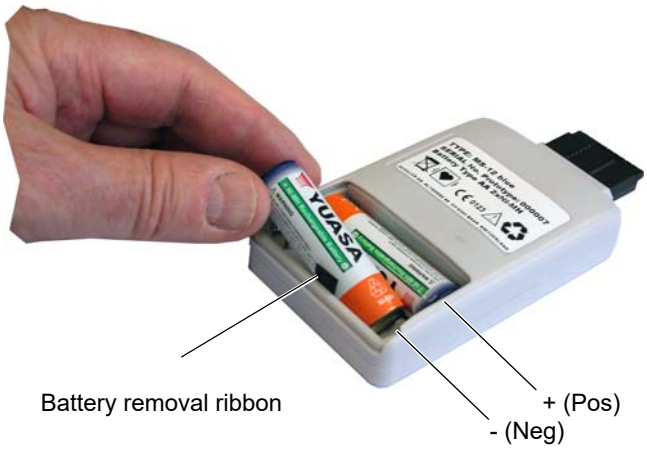
When the low capacity icon is displayed, battery capacity is limited and the batteries should be changed. Because of the high energy efficiency of the unit however, there may still be several hours of use after the low battery indicator is given.

When the batteries are exhausted, recording stops and pairing is lost. The SCHILLER logo scrolls across the screen for several minutes to indicate that data transmission has stopped and the batteries must be exchanged.

13.1.13 Changing the Batteries

Battery Removal

1. Slide the battery compartment cover away from the unit, apply pressure to the cover and push away from the unit.
2. Lift the battery removal ribbon and remove the batteries.



Replacing the Batteries

Only use rechargeable batteries. Ensure the batteries are fully charged when replacing.

1. Position the battery removal ribbon at the bottom of the battery compartment to facilitate later battery removal and insert two fully charged AA batteries; **ensure the correct polarity.**
2. Position the battery compartment cover in the two side grooves and press the cover home until it clicks in place.


Ni-MH


Ni-MH

Batteries that have reached the end of their life must be disposed of in municipally approved areas.

Art. no.: 2.511335 Rev. a

13.1.14 MS-12 blue Bluetooth Pairing Procedure

Note: The bluetooth pairing procedure is for the MS-12 blue unit only. The MS-12 USB unit is connected to the PC by a cable assembly that does not require pairing.

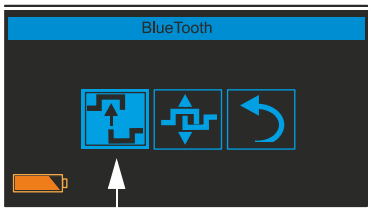
13.1.15 Pairing the unit with the PC

1. Click on the bluetooth icon in the task bar to display the menu and select **Add a Device.**

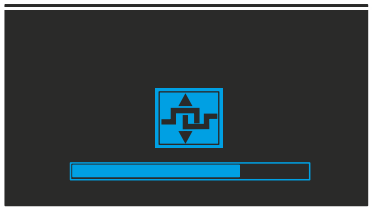
The **Show Bluetooth Devices** menu option will show all bluetooth devices already registered. It is also possible to add a device from this menu option.

2. The PC will search for any bluetooth devices in range and the PC displays the search screen.
3. During the period when the PC is searching, switch on the MS-12 blue unit and select the bluetooth option:

– From the main menu highlight the bluetooth settings icon and press the control button for approximately 1.5 seconds until the Bluetooth screen is displayed:

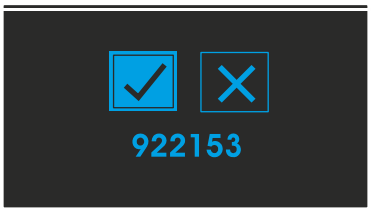


– Highlight the Bluetooth connect icon (first icon) and press the control button for approximately 1.5 seconds. The icon flashes alternately between the connection / disconnection icons and connection progress time line is displayed below the icon:



4. After a short period, the PC will recognise the MS-12 blue unit and will display it on the screen.
5. Highlight the unit and click **next**. A system generated pairing number is transmitted to the unit.
6. The screen on the MS-12 blue will display the system pairing number:

Art. no.: 2.511335 Rev. a



7. If the numbers are the same on the PC and the MS-12 blue unit, confirm connection as follows:
   – On the MS-12 blue (with the tick box highlighted as shown), press the control button for approximately 1.5 seconds.
   – At the PC click **next**.

Depending on the bluetooth driver and this screen displayed, Windows may ask for a password. If this is requested a password of 0000 can be entered.

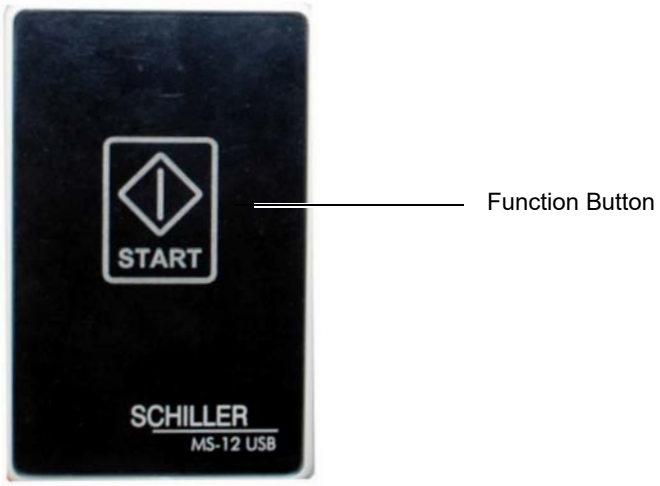
8. A confirmation message is displayed that the unit has been registered with Windows.

Art. no.: 2.511335 Rev. a

13.2 MS-12 USB Recorder

13.2.1 Function Button

The MS-12 USB ECG Recorder has a central function button.



The function button indicates its status of the MS-12 USB ECG Recorder as follows:

White Outline and Unlit — MS-12 USB is not connected to the PC, or the PC is switched off.

Illuminated Light Blue — MS-12 USB connected to the PC and powered (switched on).

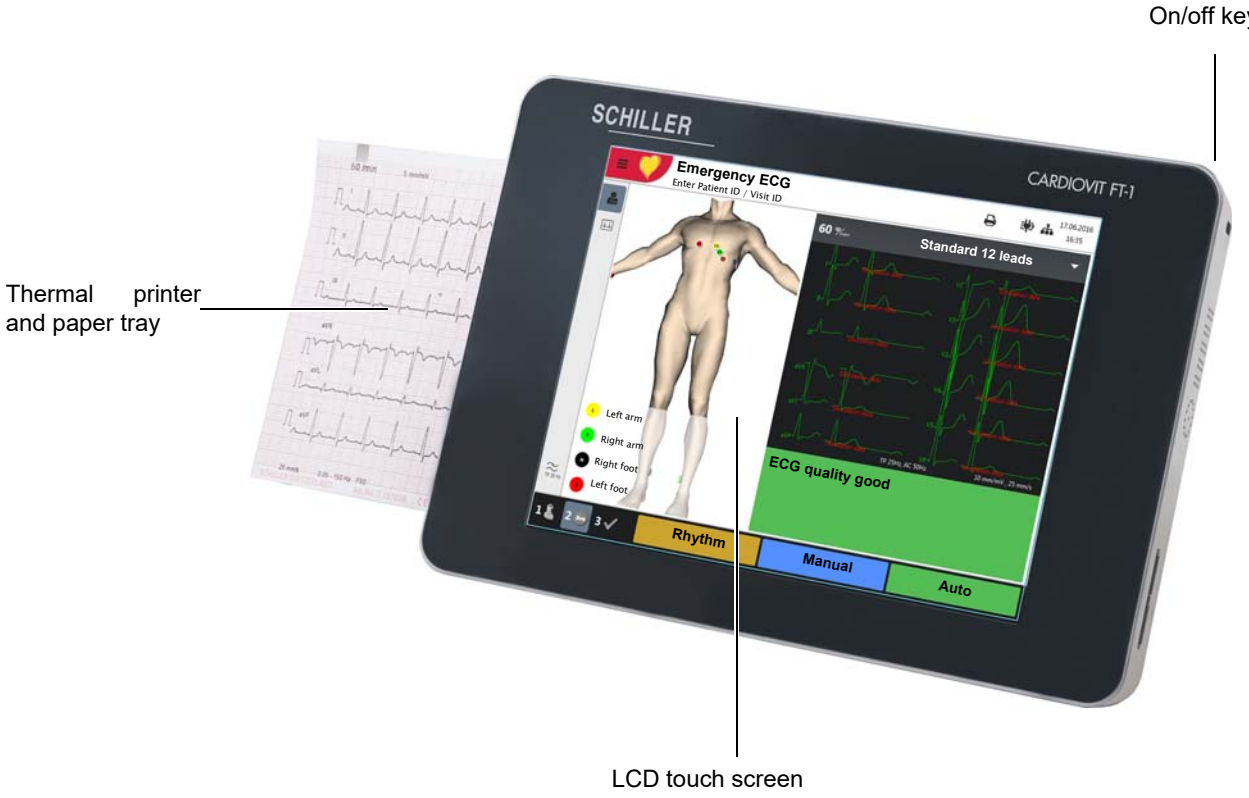
Light Blue Blinking — Button is active and in the **Resting ECG Screen,** pressing the function button will initiate an auto mode ECG. It is the same function as selecting the Auto icon 

in the program.

In the Rhythm, Exercise, or the Spiro Screen, the function key has no affect.

Art. no.: 2.511335 Rev. a

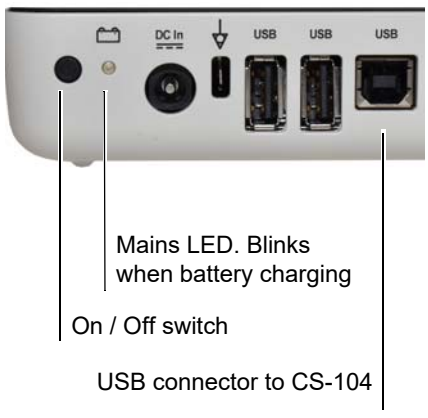
13.3 FT-1 Streamer



The **FT-1 Streamer** communicates with the program via a USB cable connected directly to the PC. When attached to the CS-104, the FT-1 acts as an ECG amplifier and all recording functions are carried out by the CS-104. The message '**Ready for streaming'** is displayed on the screen. This changes to 'Streaming' when transmitting data.

Switching On / Off

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



Battery Charging

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

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

CARDIOVIT FT-1 Standalone

When the FT-1 Streamer is disconnected from the CS-104, it acts as a standalone recording ECG recording device.

Full details of the FT-1 Streamer are provided in the CARDIOVIT FT-1 user guide.

Art. no.: 2.511335 Rev. a

14 Cleaning and Disinfection

⚠WARNING

- ▲ Switch the device off before cleaning and disconnect it from the mains by removing the plug.

⚠ CAUTION

- ▲ Do not, under any circumstances, immerse the apparatus into a cleaning liquid or sterilize with hot water, steam, or air.
- ▲ Do not autoclave the unit or any accessories.
- ▲ Use of cleaning solutions which have a high acid content or are otherwise inappropriate can cause damage to the equipment, including cracking and deterioration of the plastic case.
- ▲ Always follow the mixing/diluting instructions provided by the manufacturer of the cleaning solution.
- ▲ Never use any of the following solutions or similar products to clean the equipment: ethyl alcohol, ethanol, acetone, hexane, abrasive or scouring powder or material, any cleaning material that damages plastic.
- ▲ Unit connectors, and battery and electrode cable contacts, must not come in contact with soap or water. Do not immerse in liquid when cleaning. Do not spray the unit directly. Only clean the device and cable with a damp cloth **slightly moistened (not wet)** on the surface only. If liquid does penetrate the unit, switch it off immediately and send it to SCHILLER for testing
- ▲ The patient cable and other cable assemblies must not be exposed to excessive mechanical stress. Whenever disconnecting the leads, hold the plugs and not the cables. Store the leads in such a way as to prevent anyone stumbling over them or any damage being caused by the wheels of instrument trolleys.
- ▲ The wearing of protective gloves (e. g. of butyl rubber) is recommended.

14.1 Before Cleaning

Before cleaning any cable assemblies, the unit or any accessories, thoroughly inspect them for signs of damage as follows:

- Look for any signs of damage and any improper mechanical function of buttons or connectors.
- Gently bend and flex all parts of the patient cable. Inspect for splits in the sheathing, damage or extreme wear, exposed wires, or bent connectors.
- Confirm that all connectors engage securely.

Art. no.: 2.511335 Rev. a

14.2 Cleaning Interval

The recording device comes into contact with the patient, and it is recommended that it is cleaned after each use. Any visible soiling must be cleaned immediately.

14.3 Cleaning / Disinfecting

⚠ CAUTION

▲ Observe the following safety notes when cleaning/disinfecting the device.
- –Never immerse the device or patient cable in liquid
- –Never pour or spray liquid directly onto the unit patient cable
- –Make sure that no liquid penetrates the connections or openings
- –The device and / or patient cable must not be autoclaved or sterilised with steam

Before cleaning/disinfecting the unit thoroughly inspect for any signs of damage and any improper mechanical function of buttons or connectors. Switch off the recorder before cleaning.

▲ Do not spray the device directly.

▲ Make sure that no liquid penetrates the device.

▲ Clean the recorder with a damp cloth **slightly moistened (not wet)** on the surface only. Use cleaning agents that are mild and diluted with water that are suitable for PC polycarbonate - approved cleaning solutions are listed following,

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

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

Wipe off any excess cleaning solution. Do not let the cleaning solution run into or accumulate in connector openings, latches, or crevices. If liquid penetrates the device or into the connectors this may interfere with correct functioning. Remove the patient cable, the memory card and the battery. Leave the recorder in a warm, dry room with the battery chamber open for 48 hours and then check the equipment to confirm that it operates properly. If the functioning is still affected, contact the manufacturer.

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

Art. no.: 2.511335 Rev. a

14.4 Cleaning Cable Assemblies

1. Before cleaning, inspect the cable for damage as detailed above.
2. Wipe the equipment with a cloth slightly moistened (not wet) with one of the approved solutions listed below.
3. Gently grip the cable with the damp cloth in the center of the cable and slide the cable through the cloth 20 cm at a time until clean. Do not clean the whole length in one single action as this may cause bunching of the insulation sheathing.
4. Wipe off any excess cleaning solution. Do not let the cleaning solution run into or accumulate in connector openings, latches, or crevices. If liquid gets into connectors, dry the area with warm air.

14.5 Cleaning Solutions

14.5.1 Construction Material

Ensure that all cleaning materials used on the MS-12 USB ECG Recorder and cable assemblies 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:

MS-12 ECG Recorder Section	Material
Housing	PC/ ABS (polycarbonate-ABS)
Patient Cable	PE (Polyethylene)
USB Cable	PE (Polyethylene)

14.5.2 Approved Cleaning Solutions

- 50% solution isopropyl alcohol
- Neutral mild detergent solution
- All products designed for cleaning plastic.

Art. no.: 2.511335 Rev. a

14.5.3 Cleaning Materials that Must Not be Used

Never use products containing the following:

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

14.6 Disinfection

Disinfection removes certain bacteria and viruses. Please refer to the manufacturer's information. 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).

14.6.1 Approved Disinfectants

- Isopropyl alcohol 50%
- Propanol (35%)
- Ethyl hexanal
- Aldehyde (2-4%)
- Ethanol (50%)
- all products that are suitable for PC/ABS plastic

14.6.2 Recommended

SCHILLER recommends the following for disinfecting the unit:

- Bacillol® 30 Tissues
- Bacillol® 30 Foam
- Mikrozid® liquid
- Mikrozid® wipes

Art. no.: 2.511335 Rev. a

14.6.3 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:
  - Acetone
  - Ammonium chloride
  - Betadine
  - Chlorine, wax or wax compound
  - Ketone
  - Sodium salt

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

Art. no.: 2.511335 Rev. a

15 Maintenance

The following maintenance schedule and general maintenance procedures detailed apply to the CARDIOVIT CS-104 device and the ECG recorders that are available with the CARDIOVIT CS-104.

- Maintenance work not described in this section may only be accomplished by a qualified technician authorised by SCHILLER AG.
- The following table indicates the intervals and responsibilities of the maintenance work required. Local regulations in your country may stipulate additional or different inspection intervals and tests.

Interval	Maintenance step	Responsible
Before each use	• Visual inspection of the device and ECG electrodes	➜ User
Every 6 months		➜ User
Every 12months (or according to local regulations)	• Safety test according to IEC/EN 62353	➜ Qualified service personnel

15.1 Visual Inspection

Inspect the unit and cable assemblies for the following:

➜ Device casing not broken or cracked.
➜ Electrode cable sheathing and connectors undamaged. No kinks, abrasion or wear.
➜ USB cable sheathing and connectors undamaged. No kinks, abrasion or wear.

▲ Do not use if the unit, or any cable assembly or accessory, is damaged.
▲ Defective units, damaged cables, or damaged accessories must be replaced immediately.

15.2 Basic Functional Check

➜ Connect an ECG simulator to the ECG recorder, switch on the CARDIOVIT CS-104 and enter the acquisition screen (see para. 4.2, Entering a Recording Screen, page 58).
  – Ensure the ECG trace is displayed
➜ Remove an electrode lead from the simulator
  – Check the electrode hook up screen displays that the electrode is high resistance.

Art. no.: 2.511335 Rev. a

15.3 Safety and Functional Checks

- ▲ The MS-12 USB recorder is connected to a PC/Laptop via the USB cable. This configures a medical system and it is therefore the responsibility of the user that the system complies with the requirements of IEC/EN 60601-1.
- ▲ A recurrent test must be carried out at a minimum of every two years by a certified authority according to the CARDIOVIT CS-104 service handbook.

15.4 Tests After Defibrillation

Return the unit to an authorised SCHILLER facility for Recurrent test and test after repair according to IEC / EN62353.t

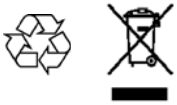
15.5 Decommissioning

Please observe the following points concerning the decommissioning and storage of the equipment:

- Backup all program data
- Disconnect all couplings and connections
- Clean all devices and components and disinfect them if necessary
- Correctly pack and, if applicable, correctly mark/label each individual component
- Observe the environmental conditions for storage and transportation

15.6 Disposal

15.6.1 Electronic Parts



At the end of the life cycle, the device and accessories must be disposed of in accordance with the applicable international and national waste control regulations for electronic components. Parts must be collected separately from ordinary unsorted municipal waste when marked with the label for separate collection of electronic and electric waste.

Please contact SCHILLER if you have any questions concerning the disposal of your equipment.

15.6.2 Consumables

Consumables must be disposed of in compliance with national and international rules and regulations.

Contamination Risk

– Depending on their classification consumables may be disposed as domestic waste or clinical waste.

⚠ CAUTION

- ▲ Consumables may be contaminated. The operator / 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.

Art. no.: 2.511335 Rev. a

15.7 Inspection Report

This page can be copied and used as a unit maintenance reference sheet.

15.7.1 Every Six Months

Inspection																							
Visual Inspection page 153	❐ ❐ ❐	❐ ❐ ❐	❐ ❐ ❐	❐ ❐ ❐	❐ ❐ ❐	❐ ❐ ❐	❐ ❐ ❐	❐ ❐ ❐	❐ ❐ ❐	❐ ❐ ❐	❐ ❐ ❐	❐ ❐ ❐	❐ ❐ ❐	❐ ❐ ❐	❐ ❐ ❐	❐ ❐ ❐	❐ ❐ ❐	❐ ❐ ❐	❐ ❐ ❐	❐ ❐ ❐	❐ ❐ ❐	❐ ❐ ❐	❐ ❐ ❐
Basic Functional Check page 153 ➜ Ensure the ECG trace is displayed ➜ Check the electrode hook up screen displays that the electrode is high resistance.	❐ ❐	❐ ❐	❐ ❐	❐ ❐	❐ ❐	❐ ❐	❐ ❐	❐ ❐	❐ ❐	❐ ❐	❐ ❐	❐ ❐	❐ ❐	❐ ❐	❐ ❐	❐ ❐	❐ ❐	❐ ❐	❐ ❐	❐ ❐	❐ ❐	❐ ❐	❐ ❐

15.7.2 Every 24 Months

Inspection	Results													
Safety and Functional Checks page 154 ➜ Confirm the date of the factory inspections and test.	• If the unit is due for the factory inspections and tests (every 24 months or according to local regulations), return the unit to your nearest authorised SCHILLER agent.	❐	❐	❐	❐	❐	❐	❐	❐	❐	❐	❐	❐	❐
	Date of Inspection and Inspector													

Art. no.: 2.511335 Rev. a

16 Trouble Shooting

The following table gives common faults, causes and possible remedies.

Fault	Possible Causes and indicators	Remedies
Interferences, lines on the display	• Excessive EMC interferences	➜ Check for sources of excessive EMC interferences.
'Noisy' traces.	• High resistance electrode contact. • Patient not relaxed. • Incorrect filter settings.	➜ Check electrode contact (see para. 4.4.1, Quality Indication on the ECG Trace, page 61) ➜ Re-apply electrodes. ➜ Ensure that the patient is relaxed and warm. ➜ Activate filter (see para. 4.8, Filter, page 63) ➜ Ensure mains filter is correct for mains supply (see para. 11.11.2, Power Line, page 132) ➜ If the trace is still noisy call your local SCHILLER representative.
Control icons, buttons or options not displayed	• Options not licensed, • Configuration does not support option • Control /action /view buttons not defined for view	➜ Check licensing options (see para. 11.9, Licenses, page 129) ➜ Define for view (see para. 3.8, Display Configuration, page 40)

16.1 Error Messages

System messages, error messages, and fault messages are provided in the program in the event of an error or if an action is attempted that is not licensed or authorised (by user privilege). Where possible suggested action(s) to be taken to resolve the problem are indicated in the message.

Art. no.: 2.511335 Rev. a

17 Accessories and Disposables

⚠WARNING

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

Your local representative stocks all the disposables and accessories available for the CARDIOVIT CS-104. A full list of all SCHILLER representatives can be found on the SCHILLER website (www.schiller.ch).

17.1 General

Article Number	Description
2.155031	SCHILLER Biotabs Ag/AgC, disposable electrodes, (x500)
2.155032	SNAP-CLIP Adapter for banana-plug cables pouch of 10
2.000041	Set of adult ECG electrodes incl. 6 suction electrodes, 4 clamp extremity electrodes and ECG electrode gel 50ml
2.155025	Blue Sensor Disposable ECG Electrode, ø 48mm, Set of 25
2.100060	Ergo belt

17.2 MS-12 blue

Article Number	Description
2.400225	10-wire patient cable banana connection IEC
2.400228	10-wire patient cable, clip type IEC
2.400222	10-wire patient cable, snap type, IEC
2.400224	10-wire patient cable banana connection AHA
2.400229	10-wire patient cable, clip type AHA
2.400223	10-wire patient cable, snap type, AHA

17.3 MS-12 USB

Article Number	Description
2.400330	10-wire patient cable banana connection IEC
2.400331	10-wire patient cable banana connection AHA
2.400226	10-wire patient cable snap connection IEC
2.400227	10-wire patient cable snap connection AHA

17.4 FT-1

Article Number	Description
2.310220	USB Cable

For other FT-1 accesoories see FT-1 user guide.

Art. no.: 2.511335 Rev. a

18 Technical Specification

18.1 CARDIOVIT CS-104 System

Dimensions	• Trolley: 1400 x 631 x 590 mm • With Monitor on support arm: 1600 x 631 x 590
Weight	• Trolley: 24 kg • With Monitor and support arm: 28 kg
Power supply	
Mains operation	100 - 240 VAC, 1.3 - 0.7 A, 50/60Hz
Computer	Installed in trolley (not accessible by the user)
Type	• TERRA MiniPC
Power Supply	• Meanwell GST 90 W, 19 Vdc output, Industry standard
Processor	• Intel Core i3 or i5 (option)
Memory	• 4 GB (max 32 GB)
Hard Disk	• 240 GB
Graphic card	• Intel HD Graphics 630 (1100 MHz)
Interfaces	• Front Panel – USB 3.0 (x2) – USB 2.0 (x2) – Mic-in – Line-out – SD card reader • Back Panel – USB 2.0 (x4) – RJ-45 (x2) – HDMI – Display Port (DP) – RS-232 (x2) – 4-pin dc power input (external power supply) – External switch connector (used for On/off button on back panel of trolley)
Monitor	• 23.8'' full HD, LCD / LED
Power Supply	• Rating: 12 Vdc, 2.5 A (adaptor source refer to user manual)
Network	
LAN Controller	• 2x Realtek RTL8111G, WOL/ PXE supports Teaming • Ethernet, Fast Ethernet, Gigabit Ethernet, IEEE 802.11b, IEEE 802.11g, IEEE 802.11n, IEEE
WiFi / WLAN	
Module	• Intel 7265 WLAN/BT Module integrated via M.2 (2230), two external antenna
Standards	• 802.11b/g/n/ac Frequency band: 2.4 GHz + 5 GHz (Dual-Band)
Safety/encryption	• WPA2-PSK, WPA-PSK, WEP64/128/256, TKIP, AES
	•
Max. power output 2.4 GHz (1DSSS)	• +16.5 dBm
Max. power output 5 GHz (OFDM6)	• +18 dBm
Bluetooth	Bluetooth 2.0 or higher

Art. no.: 2.511335 Rev. a

18.2 Requirements for PC Based Installations

18.2.1 CARDIOVIT CS-104

Processor	Dual-core, 1 GHz or faster, Intel Core 2 Duo
Working Memory (RAM)	2 GB (32-bit) or 4 GB (64-bit)
Hard Disk Space	Minimum 16 GB (32-bit) or 20 GB (64-bit). 100 GB free space recommended (an average ECG recording uses 60MB, ≈ 1600 recordings (1 year)
Graphics Card	Microsoft DirectX 9 graphics device with WDDM driver, minimum AMD Radeon HD 3200 or NVIDIA GeForce 9400
Screen Resolution	Min 1280 x 1024, recommended 1920 x 1200
Operating System	Windows
External Printer	Printout on normal paper with inkjet or laser printer
Network	Standard 100 Mbit/s Ethernet or standard WLAN configuration
Bluetooth	Bluetooth 2.0 or higher, or external bluetooth transceiver (MS-12 blue only)

18.3 ECG Recorders

18.3.1 MS-12 USB

Dimensions and Weight	
Height/Width//Depth	• 95 x 62 x 14 mm
Weight	• 140 gm including USB cable
USB Cable	USB cable for PC connection, unit power, and data transmission
Length	• 2.5 metres
Controls and Indicators	
Status and function Button	• Illuminated light blue indicating PC connection (and data transmission). • Blinking light blue indicating button is active.
Patient Input (applied part)	Fully floating and isolated, defibrillation protected (only with original SCHILLER patient cable), type CF.
Patient cable	• Replaceable
Electrodes	• 10
Automatic cable test	• Impedance
ECG Amplifier	Complies with IEC standard 60601-2-25 and ANS/I/AAMI EC11

Art. no.: 2.511335 Rev. a

18.3.2 MS-12 blue

Dimensions and weight	
Height/Width//Depth	• 90 x 58 x 20 mm
Weight	• 118 gm with batteries, 60 gm without batteries
Screen	• OLED
Patient input (applied part)	Fully floating and isolated, defibrillation protected (only with original SCHILLER patient cable), type CF.
Patient cable	• Replaceable
Electrodes	• 10
Automatic cable test	• Impedance
ECG Amplifier	Complies with IEC standard 60601-2-25 and ANS/I/AAMI EC11
Batteries	• 2 AA Ni-MH rechargeable
Operating time	• 36 hours, continuous operation (fully charged batteries)
Charging time	• 3 h for 100%
Bluetooth	
Data Transfer	• Bluetooth 2.0 and 2.1 + EDR
Module Type	• Class 2
Profile	• SPP
Safety	• Pairing to ensure data transfer to the correct address. Smart pairing supported.

18.3.3 FT-1 Streamer

Full details are provided in the FT-1 User guide.

18.4 ECG

General	
Leads	• Standard, Cabrera, NEHB, Frank, right precordial, left posterior, balanced (user configurable) • Simultaneous recording of all 10 active electrode signals (= 12 channels)
ECG analysis frequency (ETM)	• 1000 Hz
Resting ECG storage	• 1000 Hz, 1 µV
Time offset between ECG channels	• < 100 µs
ST measurements	• ST amplitudes, slope, integral, index
J and post-J point	• Manual or computer selected
Signal processing technique	• Incremental median updating
QRS detection and analysis	• Based on automatic lead selection
ECG output	• Real-time ECG/QRS beep/TTL synchronization output
Heart rate	• 15 to 300 bpm
Arrhythmia	• Automatic arrhythmia detection, documentation and annotation
Resting rhythm ECG	• Beat-to-beat ECG record and event review
Re-analysis	• Post-test medians re-measurement from J, post-J point selections
ECG interpretation	• (Optional) ETM Adult and paediatric ECG analysis program

Art. no.: 2.511335 Rev. a

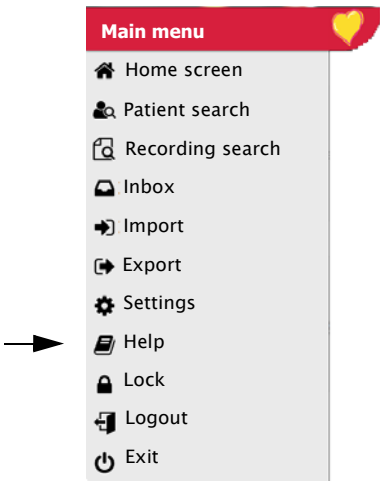
18.5 Standards

Safety standard	IEC/EN 60601-1
	IEC/EN 60601-1-25
EMC	IEC/EN 60601-1-2
Classification (IEC 60601-1)	
Applied Part	CF
Protection	IP20
Protection Class	II
Conformity/classification	CE/IIa in accordance with directive 93/42/EEC

18.6 Environmental Conditions

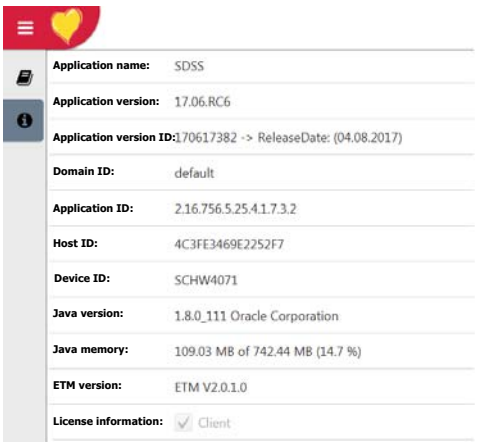
Environmental conditions (operating)	
Temperature	• + 10 °C to + 40° C (+ 50° F to + 104 °F)
Relative humidity	• 15 to 95 % (non-condensing)
Pressure	• 700 to 1060 hPa
Environmental conditions (storage and transport)	
Temperature transport	• - 10 °C to + 50° C (+ 14 °F to + 122° F)
Temperature storage	• + 5° C to + 50° C (+ 41° F to + 122° F)
Relative humidity (storage and transport)	• 10 to 95 % (non-condensing)
Pressure (storage and transport)	• 500 to 1060 hPa

18.7 Program Information



From the main menu click the Help icon and then select the info icon. Details of the program, release date, device ID, ETM version and license information is displayed for information:

Program log
Program info



Art. no.: 2.511335 Rev. a

18.8 Log Information

Click the Log icon to display program history data. This is for service personnel only.

18.9 End of Life Disposal

At the end of unit life, do not dispose in household waste. MS-12 USB units must be disposed of in a municipally approved collection point or recycling center for electrical waste.

Art. no.: 2.511335 Rev. a

18.10 Measures to Prevent Electromagnetic Interferences

"Non-ionising electromagnetic radiation"

The user can help avoid electromagnetic disturbances by keeping the minimum distance between portable and mobile HF telecommunication devices (transmitters) and the MS-12 blue/MS-12 USB Recorder. The distance depends on the output performance of the communication device, as indicated below.

HF source Wireless communication devices	Transmitter frequency [MHz]	Test Frequency [MHz]	Maximum Power P [W]	Distance d [m]
Various Transmitter devices (TETRA 400)	380-390	385	1.8	0.3
- Walkie-talkie (FRS) - Emergency services, Police, Fire, Maintenance (GMRS)	430-470	450	2	0.3
L TE (Long Term Evolution) Band 13/17	704-707	710/745/780	0.2	0.3
- GSM800/900 - LTE band 5 - Mobile telephone CT1+, CT2,CT3	800-960	810/870/930	2	0.3
- GSM1800/1900 - DECT (mobile telephone) - LTE Band 1/3/4/25 - UMTS (Universal Mobile Telecommunications System)	1700-1990	1720/1845/ 1970	2	0.3
- Bluetooth, WLAN 802.11b/g/n - LTE Band 7 - RFID 2450 (active & passive transponder and readers)	2400-2570	2450	2	0.3
WLAN 802.11a/n	5100-5800	5240/5500/ 5785	0.2	0.3

⚠ CAUTION

- ▲ Portable HF telecommunications equipment must not be used within 0.3 metres of the MS-12 blue/MS-12 USB recorders including the wiring.
- ▲ Do not operate the MS-12 blue/MS-12 USB near electrical / electronic devices and keep sufficient distance to all electrical devices.

For permanently installed HF telecommunications equipment (for example, radio and TV transmitters), the minimum distance to the transmitter can be calculated using the following formula: $d = 0.6 \times \sqrt{P}$.

d = recommended minimum distance in metres

P = radiated power in watts

(Formula based on the maximum immunity level of 10 V/m in the frequency range from 80 MHz to 3000 MHz).

For more information on operation in an electromagnetic environment according to IEC/EN 60601-1-2, please consult the MS-12 service manual.

Art. no.: 2.511335 Rev. a

19 Annex - Installation

The installation procedure given here is for PC based installations only. CARDIOVIT CS-104 units will have the software already installed and the assemble instruction are detailed in the Installaion and servce guide.

19.1 Installations using the MS-12 USB

⚠ CAUTION

- The MS-12 USB ECG Recorder and the FT-1 Streameris connected to a PC/ Laptop via the USB cable. This configures a medical system and it is therefore the responsibility of the user that the system complies with the requirements of IEC/EN 60601-1.
- After installation, a leakage current test is required of the system. This must include any accessories connected to the PC/laptop (e.g. printer). A recurrent test is required every year or as defined by local directives (see service handbook).
- If in doubt, contact the technical service department or your local representative.

19.2 Installation Notes and Requirements

Screen Resolution and Minimum Requirement

The Screen must have resolution of 1280 * 1024 or higher. The software may not function correctly at lower resolutions.

The minimum requirement for installation and the platforms that the program can be installed on are detailed in the technical description (see para. 18, Technical Specification, page 158).

Licensing

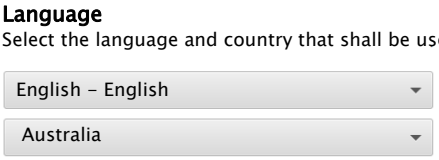
The software license key is generated on http://lic.schiller.ch/ and requires an **Activation key** supplied by SCHILLER and a **Host ID** (a unique code generated from the computer hardware). Ensure that you have your activation key before installation.

Art. no.: 2.511335 Rev. a

19.3 Installation

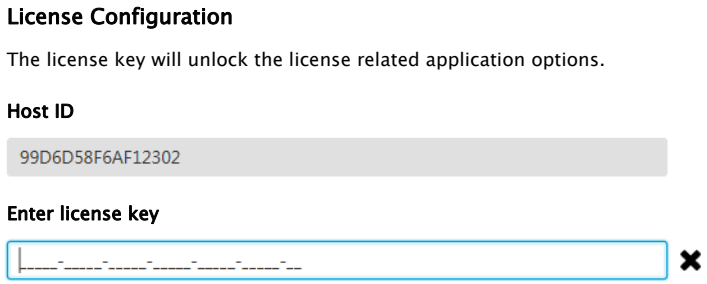
CARDIOVIT
CS-104

1. Open the installation program and install the program on the computer.
2. Select the program language and country system and click next.

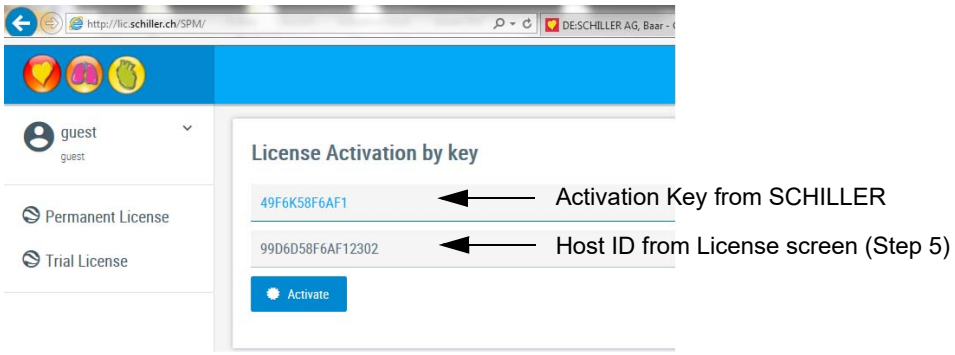


3. After initial installation, the CARDIOVIT CS-104 link icon appears on the desktop. Double click the icon to continue with the second part of the installation.

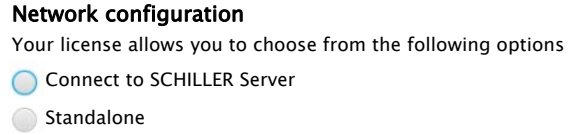
4. The License Configuration screen is displayed:



5. Make a note of the **Host ID** and the **Activation key** provided by SCHILLER.
6. Open the SCHILLER License generator **http://lic.schiller.ch/** and select **Open SCHILLER Licenser**.



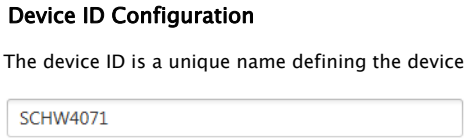
7. Enter the Host ID and the Activation key and click Activate to generate the license key.
8. Enter the License key in the License Configuration Screen (Step 5). Click next.
9. Define if the installation is to be networked or standalone.



10. If the networked option is selected you are prompted to enter the Server details.

Art. no.: 2.511335 Rev. a

11. Define the device ID.
    – This can be any ID (or the computers ID), that fits into your hospital system



12. Login with the user name and password **default, system (see user privileges below)**.

13. Connect Recording device(s)
    – **MS-12 USB ECG Recorder** - connect to a USB port on the PC. Driver software is automatically installed.
    – **MS-12 blue ECG Recorder** - Pair the bluetooth recorder to the computer (see following).
    – **SpiroScout SP plus** - If the Spiro option is to be installed, Connect the SpiroScout SP plus to a USB port on the PC. Driver software is automatically installed. Define the COM port used in system settings (see para. 11.15, Spirometry, page 136)

User Privileges

Note: The options displayed and the privileges given are dependent on the user logged in. For networked installations the users and privileges are defined in the SCHILLER Server. For standalone installations, Users are defined in system settings (see user guide).

19.4 Exercise ECG and BP Unit

If there are no available RS-232 COM ports on the computer and exercise testing is to be carried out or an external RS-232 BP unit connected to the system, the USB to RS-232 Serial Adapter is used to interface between the computer and the ergo device/BP unit.

19.4.1 Procedure to Connect the USB-232 Serial Adapter

If the computer has RS-232 ports, the ergo device and BP unit can be connected directly.

1. Using the cable assembly delivered with the unit, connect the USB-232 Serial Adapter to a free USB port on the PC. Check that the power LED on the adapter is lit.
2. Enter System Settings on the PC (Device Manager). Make a note of the new COM ports that have been assigned by the computer for the four ports of the adaptor (see below).
3. Connect the bike/treadmill and/or BP unit as required to the COM ports of the USB to RS-232 Serial Adapter. Make a note of the COM ports that are used.
4. Define the type of ergo device and the port used. Define the port used for the BP device (see para. 11.14.5, Ergo Devices, page 134).

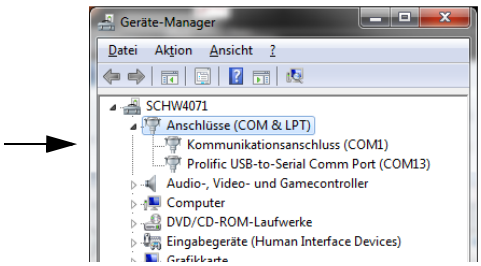
To prevent the computer ‘sleeping’ or ‘hibernating’ when there is no key activity during an exercise test, it is recommended that these functions are disabled in the System Settings of the PC/laptop.

Art. no.: 2.511335 Rev. a

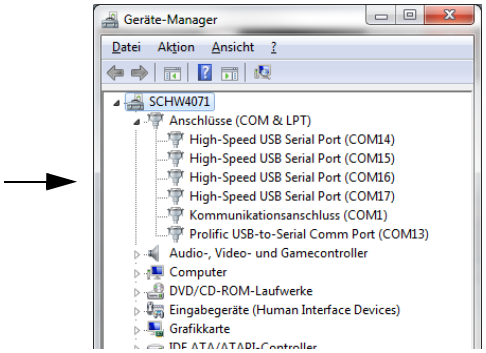
Checking the Ports Assigned for the USB to RS-232 Serial Adapter

The following procedure is an outline only and will vary according to operating system. To check the ports allocated for the USB-RS-232 Serial Adapter proceed as follows.

1. Enter the **Device manager** of the computer:
2. Click on the Ports (COM and LPT) option to display allocated ports:



Connect the RS-232 Serial Adapter. After a few seconds four extra ports are displayed. These are the four ports of the adapter.



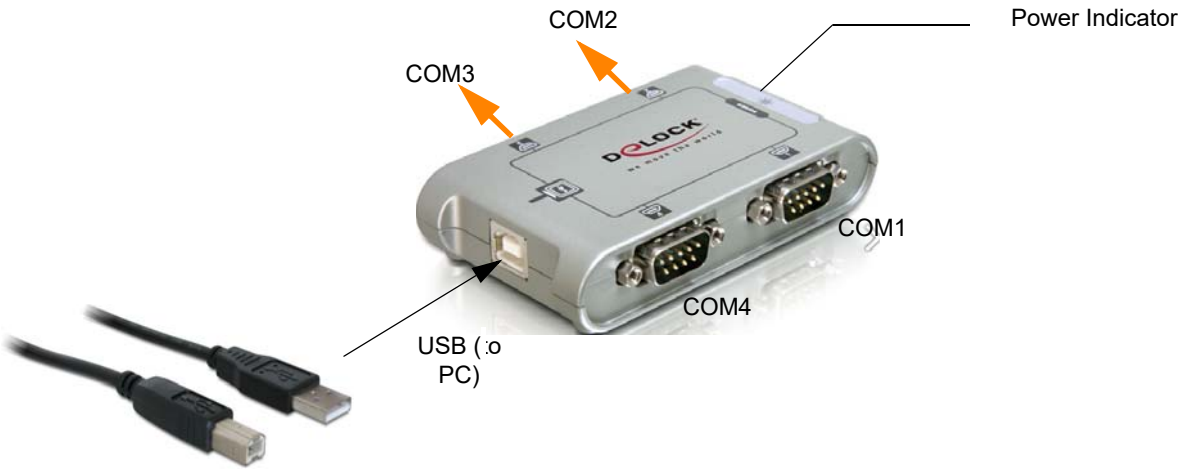
3. Make a note of the COM ports allocated.

- When the USB to RS-232 Serial Adapter is connected, the PC assigns four new ports automatically. Usually the ports are assigned in order, for example if COM1 to COM4 are already allocated in the PC, the new COM ports allocated on the PC could be COM5, COM6, COM7 and COM8. This would equate directly to the order of the COM ports on the adapter, that is to COM 1, 2, 3 and 4.
- If the adapter is reconnected at any time to another USB connector on the PC, the COM port numbers can change. This means that the COM ports do not correspond to the defined COM ports in the application. Therefore **ensure that the adapter is always connected to the same USB port on the computer**. If another USB connector is used and the COM ports change, the COM ports must be redefined.

Art. no.: 2.511335 Rev. a

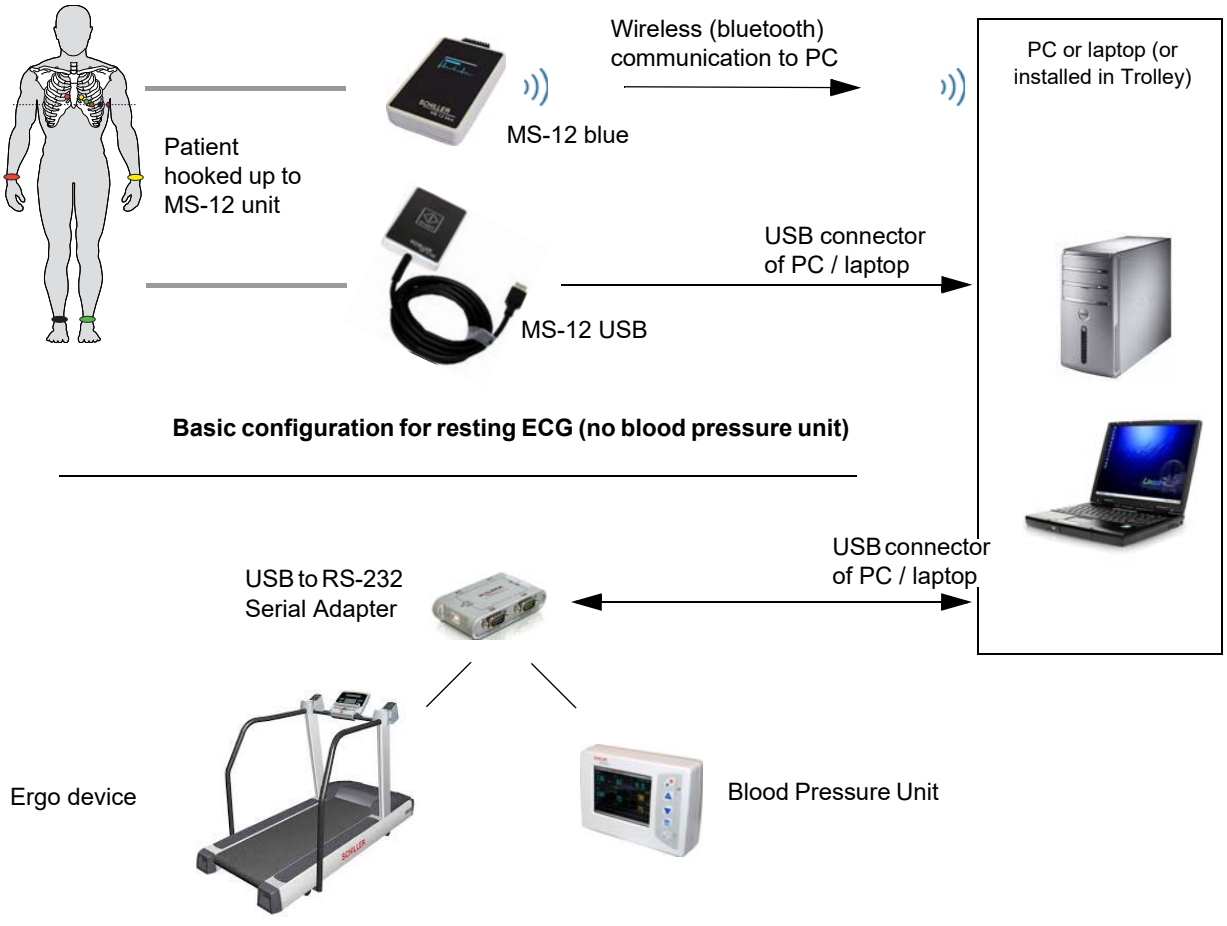
19.4.2 USB to RS-232 Serial Adapter

USB converter box for connection of an exercise ergo device and/or blood pressure unit, includes the USB lead.



Art. no.: 2.511335 Rev. a

19.5 Connection Overview



Basic configuration for resting ECG (no blood pressure unit)

Configuration for exercise testing and/or blood pressure unit

Art. no.: 2.511335 Rev. a

Art. no.: 2.511335 Rev. a

20 Index

Art. no.: 2.511335 Rev. a

Art. no.: 2.511335 Rev. a