CARDIOVIT MS-2010/2015

ECG and spirometry unit



User Guide

SCHILLER
The Art of Diagnostics

Art. no.: 2.510852 Rev.: h

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CE 0123

The CARDIOVIT MS-2010/2015 bears the CE-0123 mark (Notified Body TÜV-SÜD Produkte Service GmbH, Ridlerstr. 65, 80339 Munich, Germany), indicating its compliance with the essential requirements of the Annex I of the Medical Device Directive 93/42/EE regarding safety, functionality and labelling. The requirements apply to patients, users and third persons who come into contact with this device within the scope of its intended use.

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1 Safety Notes

1.1 Responsibility of the User



- This device must only be used by qualified physicians or trained medical personnel.
- The numerical and graphical results as well as any interpretation suggested by the device must be examined with respect to the patient's overall clinical condition and the quality of the recorded data.
- The indications given by this equipment are not a substitute for regular checking of vital functions.
- The responsibilities of the personnel for the operation and maintenance of the device must be specified.
- Ensure that personnel have read and understood these operating instructions, in particular this section **Safety Notes**.
- Damaged or missing components must be replaced immediately.
- It is the owner's responsibility that the valid regulations for safety and prevention of accidents are observed.
- The safety, reliability and performance of the device can only be guaranteed when the maintenance intervals as stated in section Maintenance are observed

1.2 Organisational Measures



- Before using the device, ensure that an introduction regarding the unit functions and the safety precautions has been provided by a medical product representative.
- Keep these operating instructions in an accessible place for reference when required. Make sure that they are always complete and legible.
- Observe the operating and maintenance instructions.
- In addition to this user guide, legal and other binding regulations for the prevention of accidents and for environment protection must be observed.

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1.3 Intended Use



- The CARDIOVIT MS-2010/2015 is an ECG unit used for the recording, analysis and evaluation of ECGs. Recordings made with the CARDIOVIT MS-2010/2015 can be used as a diagnostic aid for heart function and heart conditions. It can be used for all patients, regardless of sex, ethnicity or age.
- The CARDIOVIT MS-2010/2015 is used to diagnose cardiac abnormalities, detect acute myocardial ischemia and infarctions in chest pain patients, etc.
- The CARDIOVIT MS-2010/2015 is intended for use in hospitals, cardiological units, out-patient clinical units and general physicians offices.
- The CARDIOVIT MS-2010/2015 includes a low sensitivity setting. Low sensitivity will suppress certain non-specific ECG diagnoses; this can be used for example for screening of low-risk patients. The high sensitivity setting is used to detect cardiac abnormalities in all and high risk patients including those taking thrombosis medication.
- In addition, the device can transmit saved ECG recordings via GSM at 850/900/1800/1900 MHz.
- There is no danger when using the device for a patient with a pacemaker fitted.
- Only operate the device in accordance with the specified technical data.
- The device is not designed for sterile use nor is it designed for outdoor use.
- Do not use this unit in areas where there is any danger of explosion or in the presence of flammable gases such as anaesthetic agents.
- The device is CF classified. It is defibrillation protected only when the SCHILLER original patient cable is used. However, as a safety precaution, remove the electrodes before defibrillation, if possible.
- This product is not designed for internal use. This product is not designed for direct cardiac application.

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1.4 Safety-Conscious Operation



- ▲ Make sure that the staff have read and understood the operating instructions - particularly this section Safety Notes.
- ▲ Do not touch the unit casing during defibrillation.
- ▲ To ensure patient safety, none of the electrodes, including the neutral electrode, nor the patient or any person with simultaneous patient contact, must come in contact with conductive parts, even when these are earthed.
- ▲ Immediately report any changes that impair safety (including operating behaviour) to the person responsible.
- ▲ Do not place any liquids on the unit. If liquid is spilled on the device, immediately disconnect the device from the mains and wipe it. The device must be serviced before reusing.
- ▲ Only connect the original SCHILLER patient cable to the patient socket.
- ▲ If the patient cable should become defective after defibrillation, an electrode becomes displaced, or an electrode resistance is too high, a lead-off indication is displayed in the upper right part of the screen and an acoustic alarm issued.
- ▲ Only use accessories and other parts recommended or supplied by SCHILLER. Use of other than recommended or supplied parts may result in injury, inaccurate information and/or damage to the unit.
- ▲ To prevent pacemaker malfunction, a distance of at least 20 cm must be observed between the antenna of the CARDIOVIT MS-2010/2015 and the pacemaker as soon as the GSM module is switched on.
- ▲ The transmission of ECG recordings from the CARDIOVIT MS-2010/2015 is not permitted in areas in which mobile phones are not allowed.

1.5 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 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.

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1.6 Operation with other Devices



- Accessory equipment connected to the analogue and digital interfaces must be certified according to the respective IEC standards (e.g. IEC/EN 60950 for data processing equipment and IEC/EN 60601-1 for medical equipment). Furthermore, all configurations shall comply with the valid version of the system standard 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 the system standard IEC/EN 60601-1. If in doubt, consult the technical service department or your local representative.
- Any other equipment used with the patient must use the same common earth as the CARDIOVIT MS-2010/2015.
- 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.
- There is no danger when using this device simultaneously with electrical stimulation equipment. 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.
- If the device is part of a medical system, only the original SCHILLER patient cable must be used with, and connected to, the CARDIOVIT MS-2010/2015.
- If the patient cable should become defective after defibrillation, a lead-off indication is displayed on the screen and an audible alarm is issued (see page 42).
- Portable communication devices, HF radios and devices labelled with the  symbol (non-ionic electromagnetic radiation) can affect the operation of this device (see page 109).

1.7 Networks and Internet



- When the unit is part of a network, (LAN, WLAN, HIS, etc.), transmitting over a telephone network or any other transmission/reception medium, or if exposed to the Internet or other insecure networks, appropriate security measures must be taken to protect the stored patient data.
- Patient data security and security of the network is the sole responsibility of the user.

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1.8 Maintenance



- ▲ Danger of electric shock! Do not open the device. No serviceable parts inside. Refer servicing to qualified technicians authorised by SCHILLER only.
- ▲ Before cleaning and to isolate the mains power supply, switch the unit off and disconnect it from the mains by removing the plug.
- ▲ Do not use high-temperature sterilisation processes (such as autoclaving). Do not use E-beam or gamma radiation sterilisation.
- ▲ Do not use aggressive or abrasive cleaners.
- ▲ Do not, under any circumstances, immerse the device or cable assemblies in liquid.

1.9 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.
- ▲ If using the **SP-250 sensor**: the disposable mouthpiece of the SP-250 spiro 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.
- ▲ If using the **SP-260 sensor**: The mouthpiece of the SP-260 spiro sensor is reusable. Thoroughly disinfect the mouthpiece assembly before using for another patient. Replace the filter after every patient - do not use the filter for more than one patient.
- ▲ If using the **SpiroScout SP sensor**: The disposable ScoueTube mouthpiece of the SpiroScout SP 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..

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1.10 Terms of Warranty

Your SCHILLER CARDIOVIT MS-2010/2015 is warranted against defects in material and manufacture, as stated in the Terms and Conditions. Excluded from this warranty is damage caused by an accident or as a result of improper handling. The warranty entitles to free replacement of the defective part. Any liability for subsequent damage is excluded. The warranty is void if unauthorised or unqualified persons attempt to make repairs.

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

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

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

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

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1.11 Safety Symbols and Pictograms

1.11.1 Symbols used in this document

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



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



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



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



Disposable item; do not reuse.



For general safety notes as listed in this chapter.



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



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



Reference to other guidelines.



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

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1.11.2 Symbols used on the device



Potential equalisation



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



Symbol for the recognition of electrical and electronic equipment

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



The unit/component can be recycled.



Notified Body TÜV-SÜD Produkte Service GmbH, Ridlerstr. 65, 80339 Munich, Germany



Attention: Consult accompanying documents.



Consult the user guide.



The following applies to CARDIOVIT MS-2010/2015 units that are equipped with WLAN or GSM.

Attention: non-ionising electromagnetic radiation. The device contains an HF transmitter.

The CARDIOVIT MS-2010/2015 radiates high-frequency electromagnetic energy and can disturb other devices if not installed and operated in accordance with the user guide. However, there is no guarantee that no interference can occur in certain installations. If the CARDIOVIT MS-2010/2015 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 prevent electromagnetic interferences:

- Increase the distance between the disturbed device and the CARDIOVIT MS-2010/2015. A minimum distance of 20 cm must be kept between the device and a pacemaker.
- Turn the device to change the angle of radiation.
- Connect the device to a different mains connector.

For more details, see page 109.

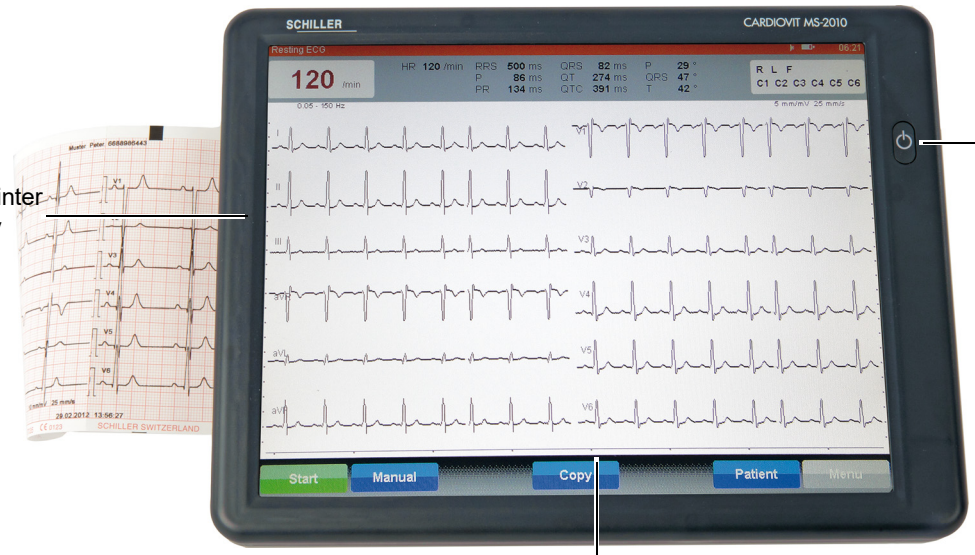
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2 Introduction

The SCHILLER CARDIOVIT MS-2010/2015 is a ECG unit designed to record, display, and measure resting ECGs. With the addition of a spirometry sensor, spirometry recordings can be performed. The touch screen allows easy and intuitive operation to efficiently enter patient data, record ECGs and adjust device settings.

The CARDIOVIT MS-2010/2015 has the following features:

2.1 Main Components of the CARDIOVIT MS-2010/2015



Thermal printer and paper tray

On/off key

LCD touch screen

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2.1.1 Standard

- Pacemaker detection
- Manual rhythm printout in real time (leads, speed and amplitude can be changed as required)
- Auto mode recording (10 seconds) with user-defined print formats
- Long-term rhythm recording
- Measurements
- Full disclosure of all 12 channels
- SCHILLER Communication module
- Print preview

2.1.2 Options

MS-2010/2015

- Interpretation
- Thrombolysis (with version C (interpretation) only)
- Barcode reader - to read a patient's ID and retrieve patient data from a database.
- Worklist: worklists for a specific unit can be defined remotely from a hospital information system. The worklist can define specific patients, locations and recording types to be taken by the unit. Completed recordings are sent back to the hospital information system either individually or collectively.
- [1]SCHILLER Communication Module featuring:
  - WLAN
  - mobile telemetric ECG data transfer, worldwide with quad-band GSM 850/900/1800/1900 MHz
- Culprit Coronary Artery Algorithm (CCAA)

MS-2015 16-channel ECG with the 14-lead patient cable

Spirometry

- The spirometry software is available when a spirometry sensor is attached to the spirometry interface on the right hand side panel and 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.
- Three flow sensors are available with the software as follows:
  - The **SP-250** with a combined mouthpiece and filter assembly - the mouthpiece assembly is disposable and must be changed for every patient.
  - The **SP-260** with disposable filter - after every patient the filter must be changed and the mouthpiece sterilised.
  - The **SpiroScout SP** with a disposable mouthpiece (ScoutTube) that must be changed for every patient.

1. For the MS-2010/2015, the communication module is either available with WLAN, or with both WLAN and GSM.

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2.2 Connections

MS-2010/2015

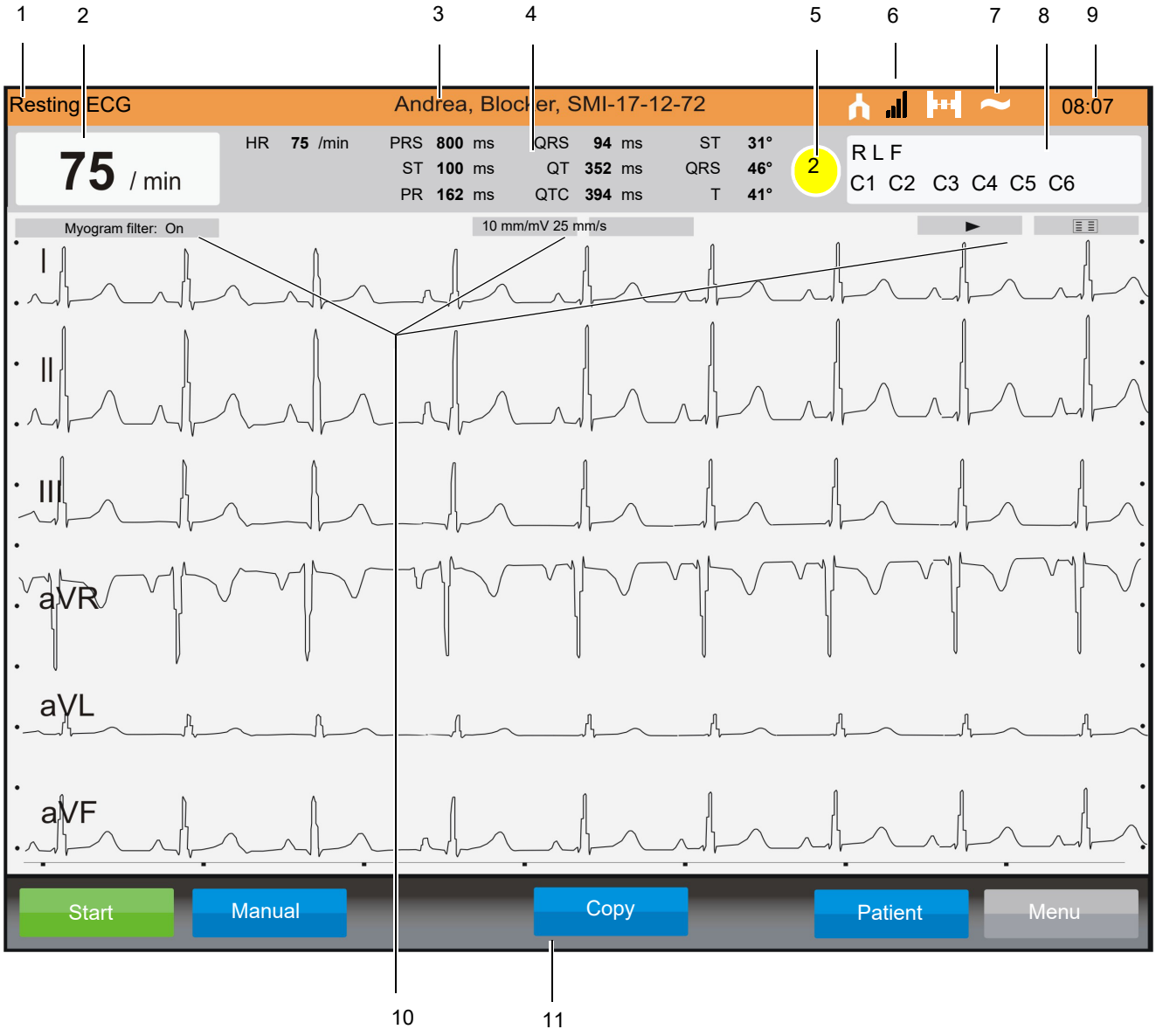
- DB9 connector for spirometry sensor
- RJ-45 Ethernet connector (network)
- USB interface to save recordings on a removable storage medium, for software updates and to connect a barcode reader.

MS-2015 The additional connectors Signal I/OUT are not used at the time of print.

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2.3 Display

The display will vary according to the task being carried out. In all screens, however, the top, middle and bottom areas always display the same category of information. The following is an example of a typical resting ECG screen.



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(1) Mode of operation

The mode of operation as follows:

- Resting ECG
- Spirometry

(2) Heart rate (HR)

Heart rate averaged over the last 8 beats.

(3) Current patient 

Patient name and Patient ID

(4) Measurement values

Intervals for the last auto mode recording (if an auto mode recording has been taken).

(5) Display of transmission errors 

This symbol 2 shows the number of ECG recordings that have not been transmitted. Touch the symbol to retry transmission.

(6) System symbols

These symbols indicate that the wireless network is connected and the signal strength.


Poor signal


Medium signal


Full strength signal

This symbol indicates the SCHILLER Communication Module status (SCM) and if a (wired) network is connected:


SCM module detected


Network connected

In addition, the symbol indicates if the unit is transmitting or receiving as follows:

– White symbol: idle
– Yellow symbol: transmitting data
– Green symbol: receiving data


Spirometry sensor connected

(7) Power source

The power source as follows:

- Mains connected (~)
- Internal rechargeable battery ()



- When running on battery power and the battery capacity is limited, the battery symbol is flashing.
- When mains is connected and the battery is charging, the battery symbol is displayed ‘filling’.

For a more detailed description, see section Power Supply (see page 27).

(8) Electrode status 

If an electrode indication is displayed in red and if an audible indication is given, it indicates that the electrode resistance is too high. In this case, the electrode must be re-applied (see page 42).

(9) Information field

In this field, the time is shown.

(10) Function keys display 

Function keys to activate/deactivate the filter and set waveform speed, amplitude and curve presentation for the display

(11) Function keys 

Function keys to start automatic or manual ECG recordings, to record events currently displayed, and to access the patient data and settings. The function keys change their function depending on the selected view.

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2.4 Touch Screen Operation

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



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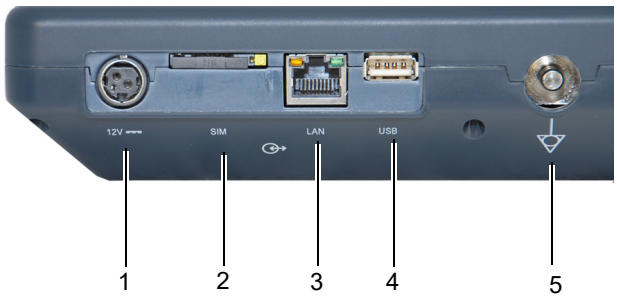
2.5 Connection panel

⚠ CAUTION

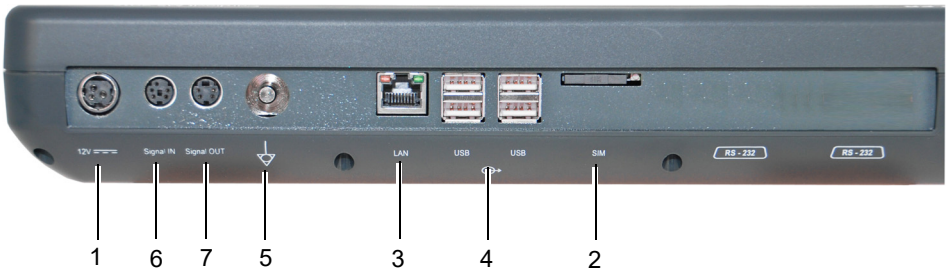
▲ All externally connected hardware must be approved by SCHILLER. Connection of any hardware not approved by SCHILLER is at the owner's risk. Moreover, the unit's warranty may become invalid.

2.5.1 Back panel

MS-2010



MS-2015



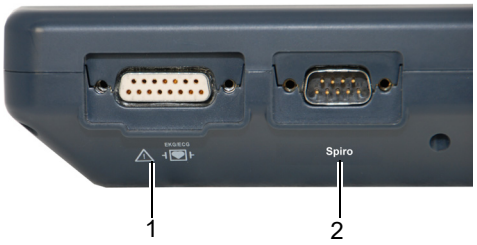
(1) Power input 12 VDC
(2) SIM card
(3) RJ-45 Ethernet LAN connection (Local Area Network).
(4) USB interface for connection of the SpiroScout SP Sensor (power supply of the sensor), barcode reader, storage device, etc.



(5) Potential equalisation stud. The potential equalisation stud is used to equalise the ground potential of the unit to that of any nearby mains-powered equipment. Use the hospital or building common ground for all mains-powered units.
(6) DC input 'DC IN' (not used)
(7) DC output 'DC OUT' (not used)

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2.5.2 Side panel



- The patient cable as well as the connector comply with the safety standard CF ⊣♥⊢, e.g. they are fully floating and isolated, defibrillation protected and suitable for the intracardiac application.
- The unit is only CF rated and defibrillation protected if used with the original SCHILLER patient cable.

(1) ECG patient cable connector

(2) DB9 connector used for connecting a spiro sensor (SP-250, SP-260, or SpiroScout SP) for pulmonary function testing.

– **Note**: the SpiroScout SP also requires connection to a USB connector on the back panel (see previous page)

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3 Operation

3.1 Start-up and Preparation

DANGER



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

3.1.1 Location

- Do not keep or operate the unit in a wet, moist or dusty environment. Avoid exposure to direct sunlight or heat from other sources.
- Do not allow the unit to come into contact with acidic vapours or liquids.
- The CARDIOVIT MS-2010/2015 must not be placed in the vicinity of X-ray or diathermy units, large transformers or electric motors.

3.1.2 Connection of external cable assemblies and ancillary equipment



1. Connect the external power supply unit to the mains.
2. Connect the external power supply unit's output to the back panel. The mains indicator lamp is lit.
3. Leave the CARDIOVIT MS-2010/2015 connected to the mains for 8 hours to fully charge the battery (see page 27).
4. Connect the potential equalisation cable.
5. Connect the patient cable (side panel).
6. Connect any ancillary and optional equipment (see page 23 and following page). These may include the following:
   – Spirometry sensor
   – Network cable

3.1.3 Potential equalisation



The potential equalisation stud at the back of the unit is used to equalise the ground potential of the CARDIOVIT MS-2010/2015 to that of all mains-powered equipment in the vicinity. Use the hospital or building common ground. A yellow/green ground cable is supplied as an option (article number 2.310005).

WARNING

▲ Danger of triggering ventricular fibrillation! If the MS-2010/2015 is used together with devices that are designed for direct cardiac application, both devices must be connected to the hospital/building common ground (potential equalisation) to prevent equalising currents between different device potentials.

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3.2 Switching on / off



The unit is switched on and off with the **On / Off** key. When switching off the unit, confirm the dialogue “Switch off device Yes/No” by selecting Yes.

The Start/Manual function keys are locked for 5 seconds when the device is switched on. The keys are dimmed during this period of time.

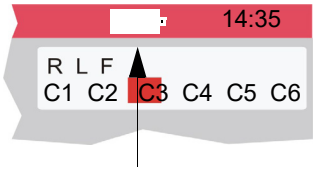
3.3 System and ECG settings

- The system settings (time, date, Device-ID etc.) and other general settings are described on page 89.
- Resting ECG settings (auto format, user defined leads, print options, lead test, QRS beep, interpretation, rhythm lead definition, etc.), are found on page 52. Calibration of the touch screen is detailed in the Maintenance section.

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3.4 Power supply

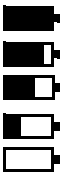
3.4.1 Mains and battery indicators



The unit can either be operated from the mains supply or from the built-in rechargeable battery. The power source is indicated on the top line of the screen.

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

- Mains via external power supply unit (~), after 15 seconds, the symbol switches to "Charging the battery"
- Internal rechargeable battery ( )



Battery capacity

The internal battery provides power for up to 3 hours for the MS-2010 and 2 hours for the MS-2015. When the unit is running on battery power (mains not connected), the battery symbol indicates the battery status. When the battery is full, the symbol is solid.

When running on battery power and the battery capacity is limited, the battery symbol flashes and an audible indication is given.

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 symbol 'fills', indicating that the battery is charging.



When fully charged, the mains symbol is shown.

3.4.2 Isolating the device from the mains supply

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

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3.5 Changing the Printing Paper

Important

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

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

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



1. Push the paper compartment release upwards to open the paper tray.



2. Remove the remaining paper and place a new paper pack into the paper tray with the printed (grid) side facing upwards and the black paper mark facing the top of the unit.

3. Pull out the first page as shown on the left.

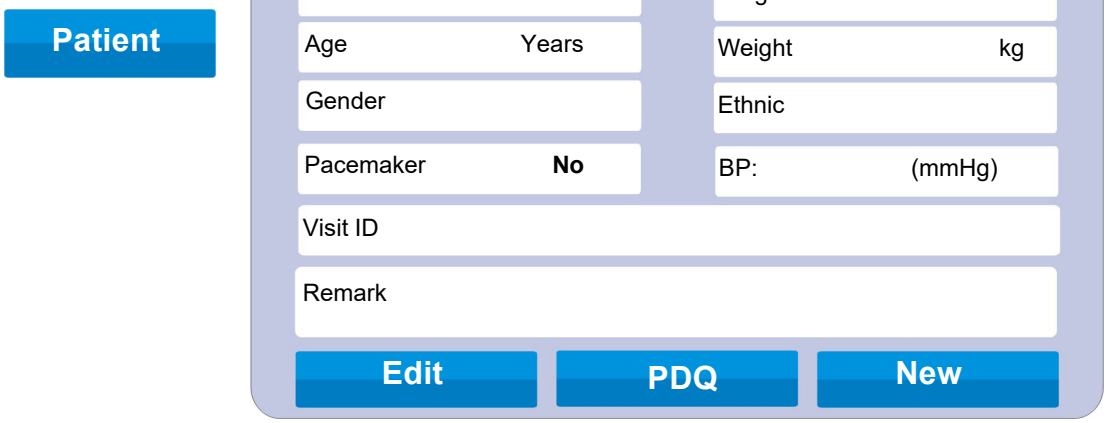


4. Push the paper tray home until it locks into place.

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3.6 Patient data

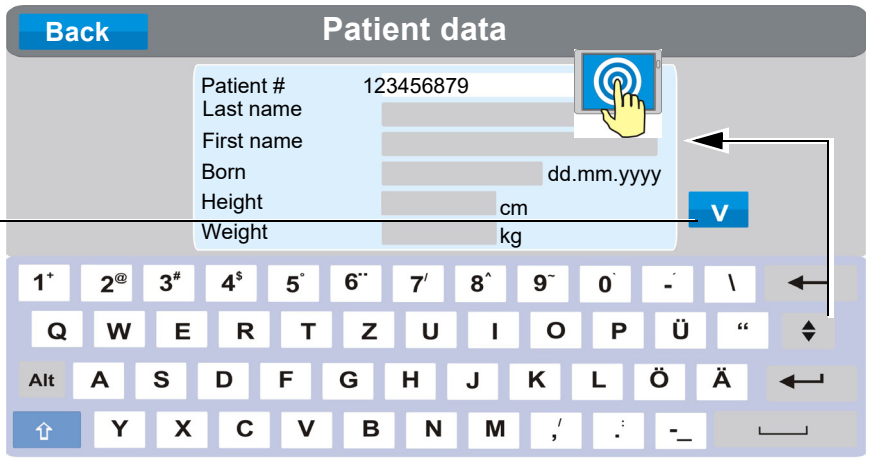
In the patient data screen, new patients can be entered and previously stored patient data can be edited. Press the **Patient** key to display the patient data screen.



Perform one of the following actions:

- change the current patient's data by pressing **Edit** or by entering the data directly on the screen
- download the patient data from the server by pressing **PDQ** and entering the patient #/visit ID
- enter a new patient by pressing **New**
- read the patient # with a barcode scanner

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Use the alphanumeric keyboard (shown) to enter patient data.

By pressing the **Alt** key, special characters are displayed.

By pressing the **Shift** key, capital letters are shown as well as the additional special characters "/" and ":".

Patient # Enter the patient's identification number.

Last name Enter patient's name (maximum 20 characters).

First name Enter patient's first name (maximum 20 characters).

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

Height Enter the patient‘s height between 20 and 250 cm (10 and 80 inches).

Weight Enter the patient‘s weight between 0.5 and 250 kg (5 to 500 lbs).

V

Gender Enter the patient‘s gender (M or F).

Ethnic The setting made here is used by the spirometry option when calculating norm values. The settings depend on the system language (defined in system settings - see page 89).

- Select one of the following:
  - white
  - black
- When American is set, the following options are available:
  - Caucasian
  - Hispanic
  - Black
  - Asian
  - Oriental

Details of these settings are provided in the Spirometry section.

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Visit ID

The "**Visit ID**" is a unique identification of the patient, which is provided by the health information system. (max. 50 characters). Further information on the "**Visit ID**"" and validation options related to the health information system can be found in the server manual.

⚠ CAUTION

The "**Visit ID**" must not be used to enter other types of information (e.g. technician, department, etc.). Misuse of the "**Visit ID**" field can lead to patients being mixed up if the device is connected to the SCHILLER server.

Pacemaker

Select if the patient has a pacemaker (YES/NO).

YES: If a pacemaker spike is detected during the ECG recording, this is indicated in the interpretation with “PACEMAKER ECG”.

NO: If a pacemaker spike is detected during the ECG recording, an interpretation is performed and displayed.

For both settings, pacemaker spikes are represented by vertical lines on the ECG trace. The vertical lines show the pacemaker pulse relative to time but these lines are not representative of amplitude, polarity or duration of the PM pulse.

Digitalis

Medication Digitalis Yes/No

Blood pressure

Enter the measured blood pressure values in mmHg.

V

Medication

Patient's medication

Room

Examination room

Doctor

Attending physician

Remark

Remarks about the patient.

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3.6.1 Patient data query (PDQ)

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

There are two modes of patient data query as follows:

PDQ

- **Manual** - The patient data is filled in when the **Get Data key** is pressed after the Pat ID/visit ID has been entered by the user or read with a barcode reader (see following).
- **Automatic** - The patient data is filled in automatically after the Pat ID/visit ID has been entered by the user or read with a barcode reader (see following).

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

- **Patient data query** - select between:
  - Patient ID
  - Visit ID
- **Database access** - select between:
  - Off - PDQ disabled
  - **Manual** - database accessed and patient data entered when the **Get Data** Key is pressed.
  - **Automatic** - database accessed and patient data entered as soon as the pat ID or visit ID has been entered

These settings along with other transmission settings are detailed in the system settings (see page 89).

PDQ with barcode reader

If a barcode reader is attached (see next page), scan the barcode to enter the patient ID / visit ID. The patient data fields are filled in a similar way as described above - if Manual is defined in system settings, press the Get Data key to enter all patient data. If Automatic is set, the patient data is entered automatically when the bar code reader is clicked.

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3.6.2 Barcode reader



A barcode reader can be attached to the USB2 port on the back panel to facilitate reading of the patient ID / visit ID. Only one barcode scanner has been tested by SCHILLER:

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

When a barcode reader is connected, the patient ID is read from the barcode (generated by the hospital system). If an external hospital patient database is available, all patient data is entered in the patient data fields of the MS-2010/2015 as described on the previous page.

A worklist can also be downloaded from a hospital patient database specifying patient data and the type of recording to be carried out. The worklist is described in more detail from page 65.

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4 Placing the electrodes

⚠WARNING

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

4.1 Basics

Careful application of the electrodes and good electrode contact is important for a good recording (see electrode positioning on pages 36 - 39).

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

1. Only use electrodes that are recommended by Schiller AG.
2. Before using disposable electrodes, check that the expiration date has not yet passed.
3. To increase the electrode's conductivity and adherence:
   - Shave the areas where the electrodes are to be placed, if necessary.
   - Thoroughly clean the areas with alcohol or soapy water.
   - Let the skin dry before applying the electrodes.
   - [1]When applying the electrodes, ensure that a layer of gel is between the electrode and the skin.
4. Check the electrode resistance as described in section 4.8.
5. If the electrode resistance is higher than the acceptable level:
   - Remove the electrode and use an abrasive cleaning pad or abrasive cleaning gel [2] to remove the uppermost layer of epidermis.
   - Apply the electrode. Always use a new disposable electrode.
6. Ensure that the patient is warm and relaxed before you start the recording.
7. After the recording, remove the electrodes. Clean the suction or vacuum electrodes according to the manufacturer's instructions.

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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.

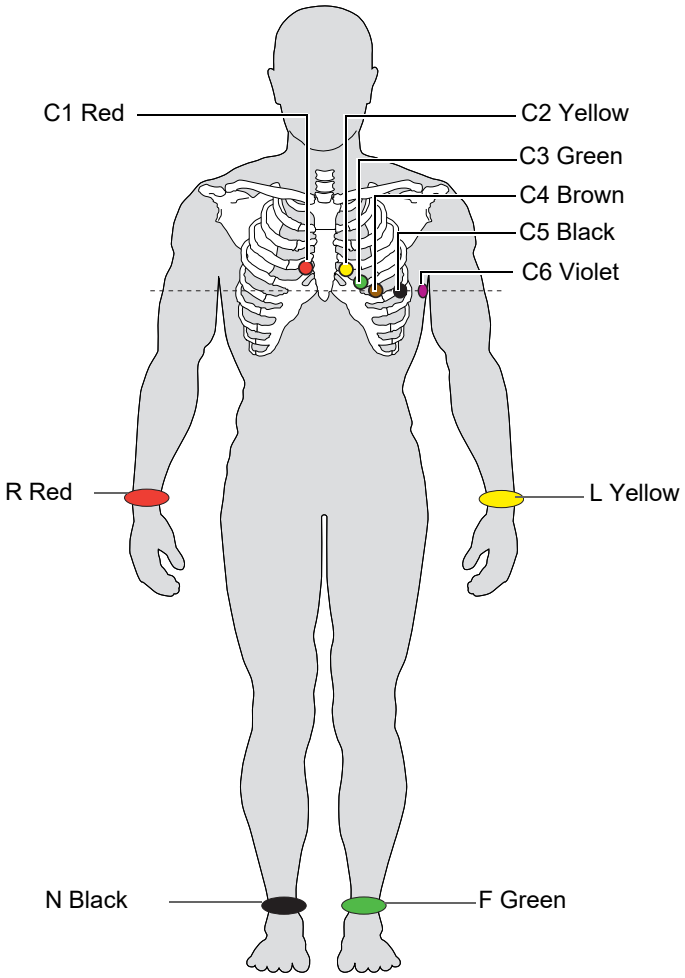
4.2 Electrode Identification and Colour Code

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.

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

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4.3 Standard 10-lead resting ECG



4.3.1 Electrode placement for standard leads

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

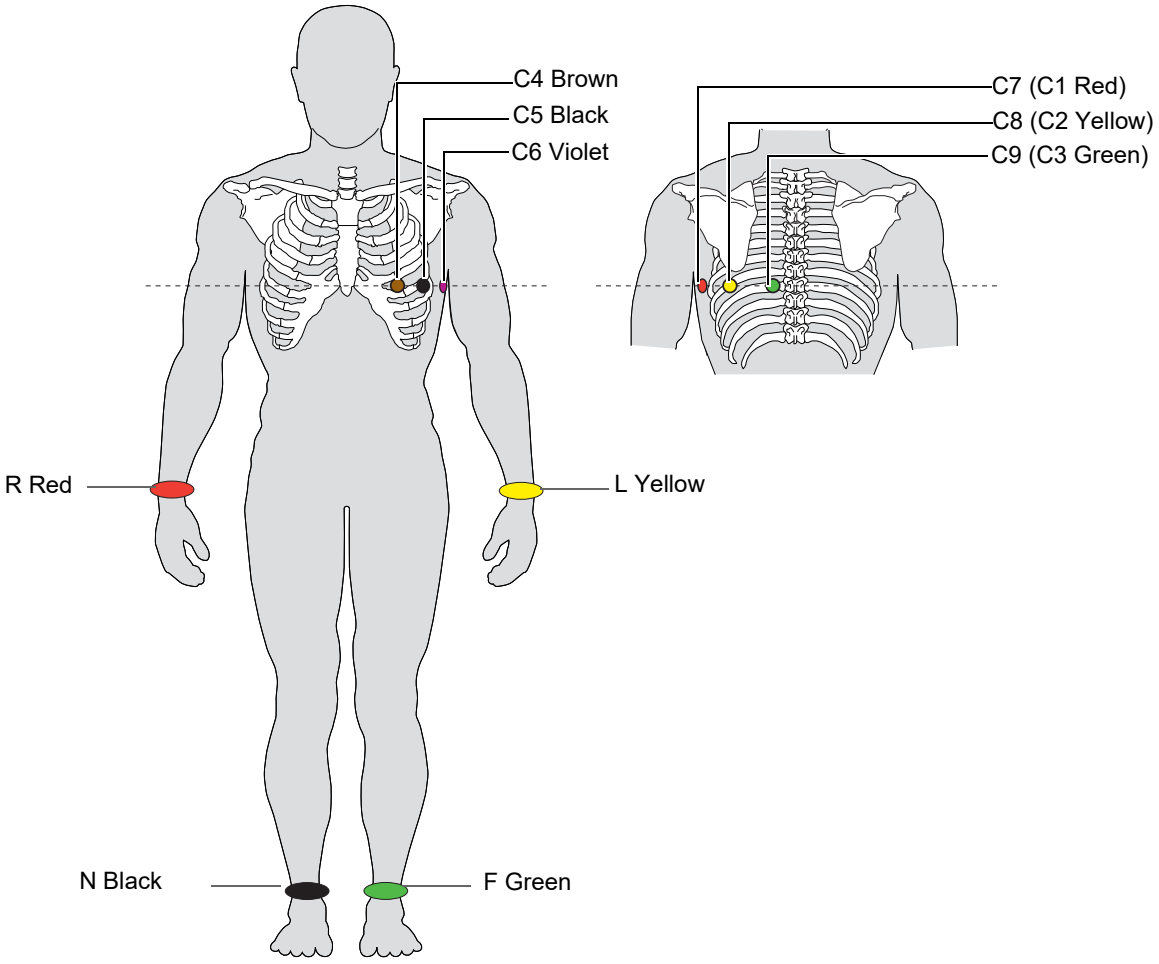
The electrode resistance can be checked in the electrode test screen (see page 42).

When performing an ECG recording with a child, it is sometimes physically difficult to place all electrodes. In this case, the electrode C4 can be positioned on the right hand side of the thorax and the lead view can be programmed to V4r (see section 4.9.2 page 43).

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4.4 Left posterior C7-C9

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

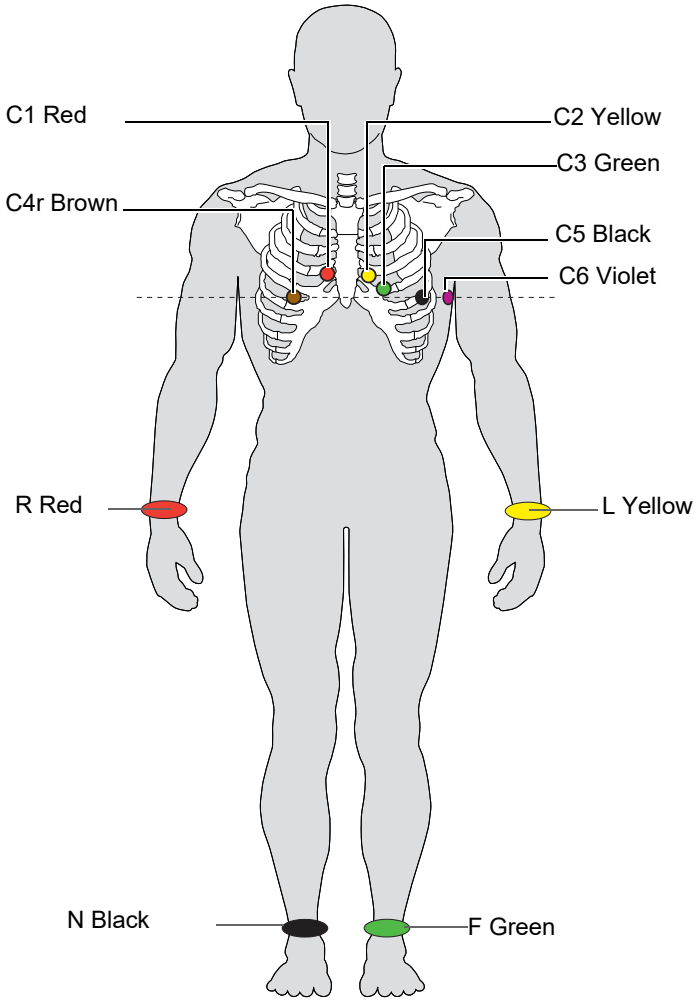


IEC label	AHA label		Positioning
C7 (C1 white /red)	V7 (V1 brown / red)	→	Left posterior axillary line at the level of C4.
C8 (C2 white /yellow)	V8 (V2 brown / yellow)	→	Left of the mid-scapular line at the level of C4.
C9 (C3 white /green)	V9 (V3 brown / green)	→	Left paravertebral line at the level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

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4.5 Right Precordial (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.

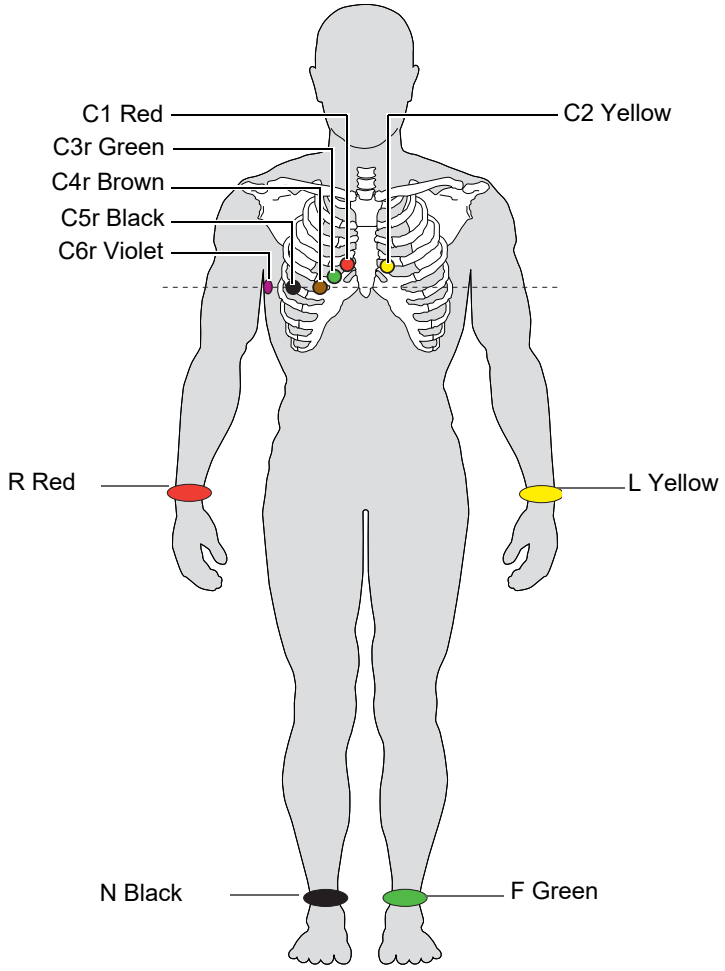


IEC label	AHA label		Positioning
C1 white / red	V1 brown / red	→	Fourth intercostal space at the right sternal border.
C2 white / yellow	V2 brown / yellow	→	Fourth intercostal space at the left sternal border.
C3 white / green	V3 brown / green	→	Midway between C2 and C4.
C4r white / brown	V4 brown /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

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4.6 Right Precordial (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 left ventricle's inferior wall (Circulation 2007).



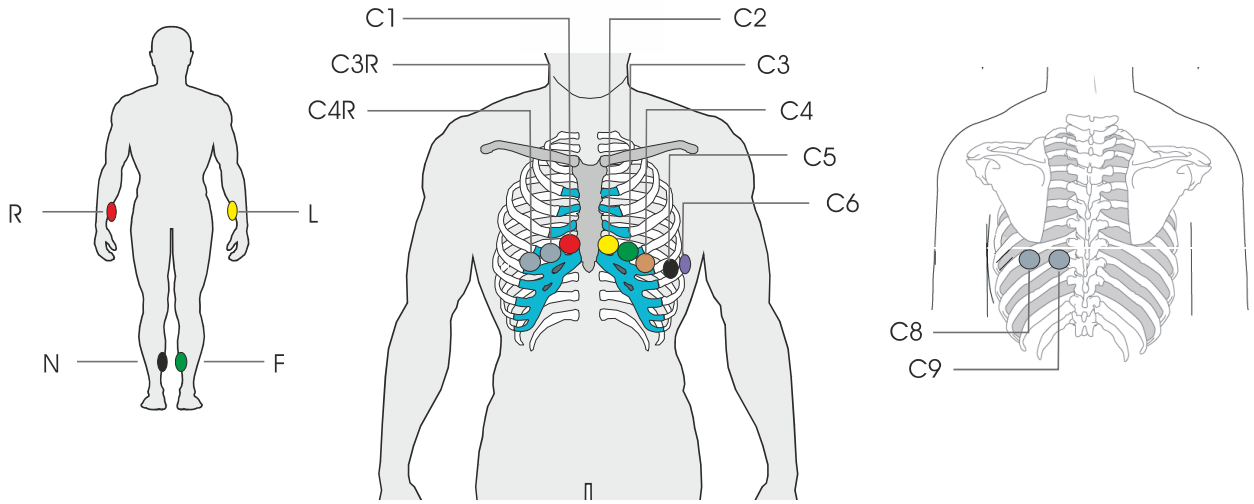
IEC label	AHA label		Positioning
C1 white / red	V1 brown / red	→	Fourth intercostal space at the right sternal border.
C2 white / yellow	V2 brown / yellow	→	Fourth intercostal space at the left sternal border.
C3r white / green	V3 brown / green	→	Designated point halfway between C1 and C4r.
C4r white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

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4.7 14-lead patient cable

This cable is only supported by the MS-2015. The 14-lead patient cable needs to be defined in the Settings > Leads > ECG cable (see page 54).

4.7.1 Adult Balanced 16 lead

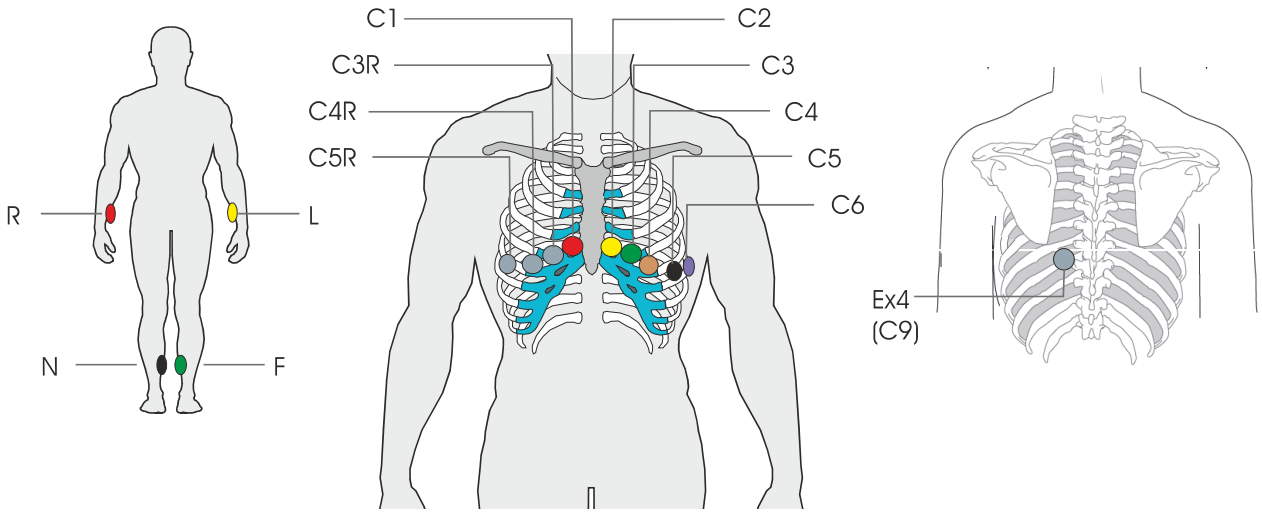


Designation	Colour	Location
C1	Red	Right side of sternum in the 4th intercostal space
C2	Yellow	Left side of sternum in the 4th intercostal space
C3	Green	Midway between C2 and C4
C4	Brown	Left midclavicular line in the 5th intercostal space
C3R/A4	Grey (or Pink*)	Midway between C1 and C4R, right side of chest
C4R/A3	Grey (or White*)	Midclavicular line in the 5th intercostal space, right side of chest
C5	Black	Anterior axillary line at same level as C4 and C6, midway between C4 and C6
C6	Violet	Left mid-axillary line (middle of the arm pit) at the same level as V4
C8/A1	Grey (or Blue*)	Under the left mid-scapular line at the same level as C6
C9/A2	Grey (or Green*)	Left para spinal border at the same level as C6
R	Red	Inside right arm between wrist and elbow
L	Yellow	Inside left arm between wrist and elbow
N	Black	Inside right calf between knee and ankle
F	Green	Inside left calf between knee and ankle

* When the A1 to A4 wire connectors have been subsitued with the detachable single wires balanced set 4 wires (C3r, C4r, C8, C9), article number 2.410099 (patient cable 2.400140), then the clip electrodes are colour coded as shown.

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4.7.2 Right-Precordial

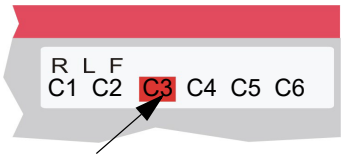


Designation	Colour	Location
C1	Red	Right side of sternum in the 4th intercostal space
C2	Yellow	Left side of sternum in the 4th intercostal space
C3	Green	Midway between C2 and C4
C4	Brown	Left midclavicular line in the 5th intercostal space
C3R/A4	Grey	Midway between C1 and C4R, right side of chest
C4R/A3	Grey	Midclavicular line in the 5th intercostal space, right side of chest
C5R/A2	Grey	Anterior axillary line at same level as C4R, right side of the chest
Ex4(C9)/A1	Grey	This can be placed as convenient - free choice (suggested C9 position)
C5	Black	Anterior axillary line at same level as C4 and C6, midway between C4 and C6
C6	Purple	Left mid-axillary line (middle of the arm pit) at the same level as C4
R	Red	Inside right arm between wrist and elbow
L	Yellow	Inside left arm between wrist and elbow
N	Black	Inside right calf between knee and ankle
F	Green	Inside left calf between knee and ankle

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4.8 Skin/Electrode Resistance

4.8.1 Electrode and patient cable check (lead test)

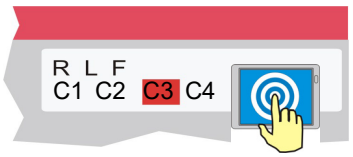


The electrode status is shown in the top right information field of the screen. If an electrode indication is displayed in red and if an audible indication is given, it indicates that the electrode resistance is too high. Reapply the electrode.

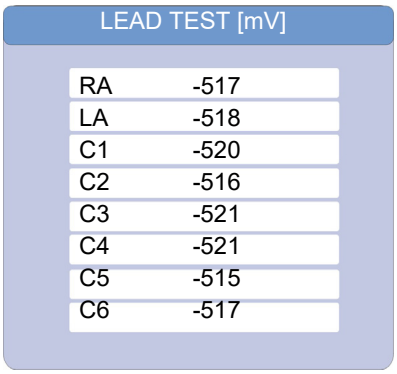
If F (LL) is not connected or has come off, the electrode resistance cannot be measured and all electrodes are marked red.

The lead test is provided as an integrity check for the electrode resistance and patient cable if suspected of being faulty.

Double-click on the electrode field to display the electrode resistance window and to check the electrode cable's integrity.



Double click



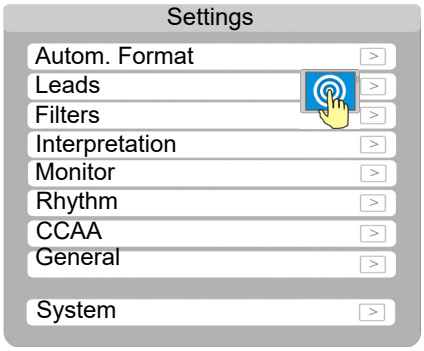
This table gives the electrode DC offset, e.g. the voltage drop in the patient cable and electrodes. The column on the right gives the detected voltage in millivolts measured between the electrode on the left leg and each of the other electrodes. It indicates any faults in the patient cable or electrode. The measured voltage value depends on where the electrodes are placed. The voltage readings that can be expected are as follows:

With patient connected	± 100mV: good connection, low resistance. An offset of up to ± 150 mV will give an acceptable recording.
With patient simulator connected	± 20 mV: this will depend on the patient simulator used and must be taken as a flexible measurement.
With all electrodes shorted together	±20 mV.
Without electrodes connected	between -350 and -500 mV

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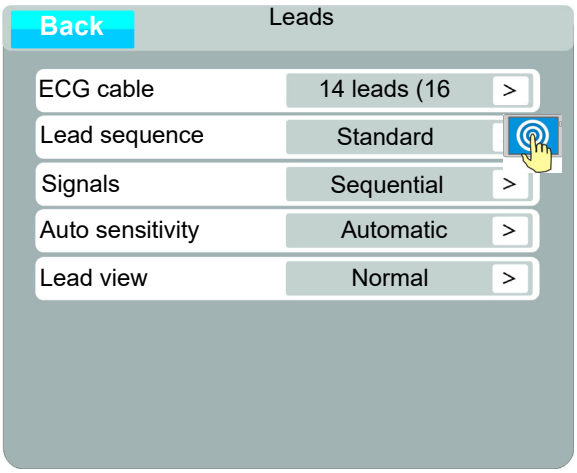
4.9 Lead sequence/lead view

4.9.1 Setting Standard or Cabrera lead sequence



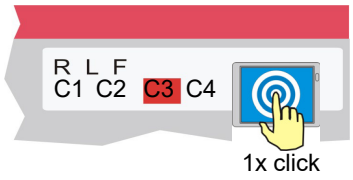
➜ The lead sequence is defined in the settings.
(**Menu > Settings > Leads > Lead sequence**).

➜ Set to Standard or Cabrera.



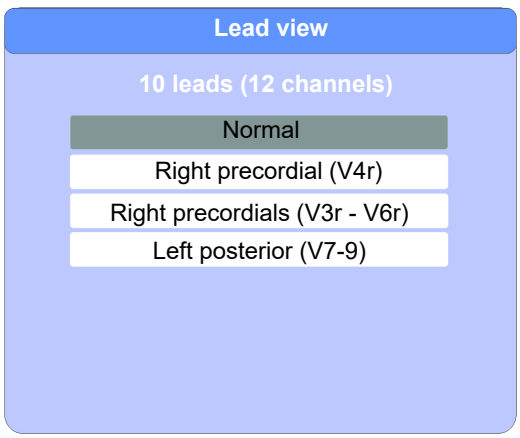
The menu option **ECG cable** is only available for the MS-2015.

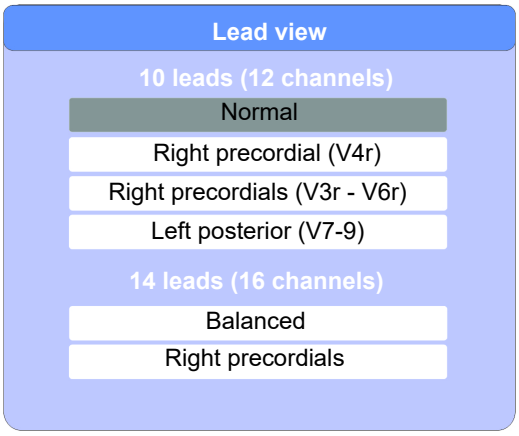
4.9.2 Select the lead view (Normal or other settings)



The lead view can be defined directly in the electrode screen or in the settings (**Menu > Settings > Leads > Lead view, see above**).

➜ Press the electrode screen once to open the lead view where you can select the Normal lead sequence (Standard or Cabrera) or one of the following lead views (depending on the ECG cable):





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

Important

Automatic interpretation is only possible when **Normal** is set.

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5 Resting ECG

⚠ CAUTION

- ▲ The safety notes at the beginning of this book must be read and fully understood before taking an ECG recording.
- ▲ The CARDIOVIT MS-2010/2015 device is CF classified ⊣♥⊢. The patient connection is fully isolated. During the ECG recording, ensure that neither the patient nor the leading parts of the patient connection nor the electrodes (including the neutral electrodes) come in contact with other persons or conductive objects, even when these are earthed.
- ▲ Do not operate the unit if the earth connection is suspect or if the mains lead is damaged or suspected of being damaged.
- ▲ If an external electronic device (e.g. a PC) is connected to the CARDIOVIT MS-2010/2015, use the potential equalisation stud for earth protection.

i

The format for the automatic printout can differ from the format displayed on the screen. For the two auto mode formats, the following can be freely programmed (before recording):

- Lead format
- Chart speed
- With the optional interpretation program installed, it is also possible to select the rhythm leads, measurement table, average cycles with optional markings and interpretation statements for the printout.

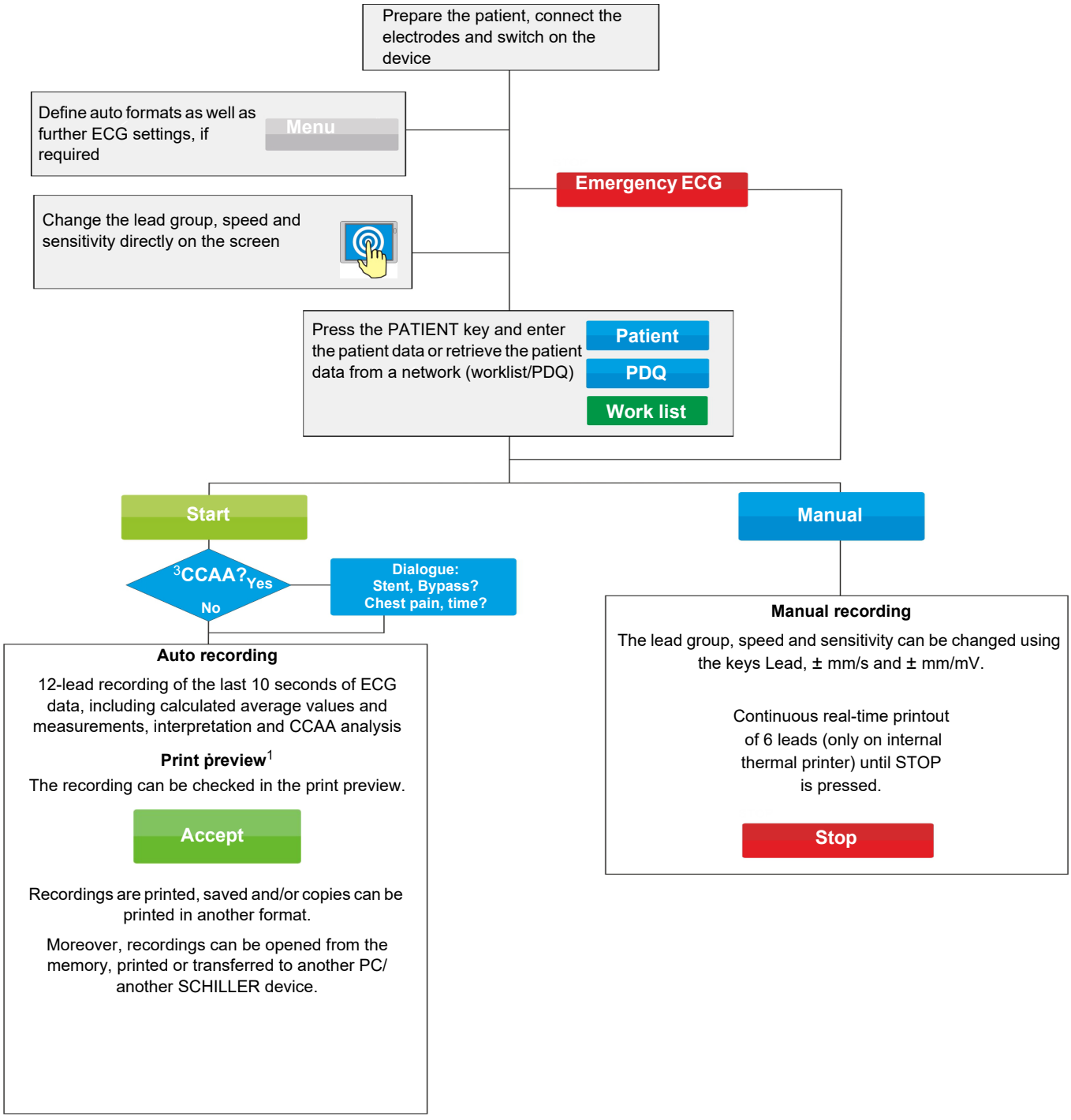
For further information and to define the auto formats, see page 52.

i

- Occasionally, the ECG signal acquisition resets to obtain new reference points. When this occurs, no ECG curves are displayed.
- If a reset occurs in the 10 seconds before an auto ECG is requested (AUTO key pressed), an auto mode ECG is issued; however, no average cycles are calculated and no interpretation is generated.

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5.1 Resting ECG - Procedural Flow Diagram



1. The print preview is only displayed if in **Settings > General > ECG print preview** is activated (see section 5.5.8). If the Print preview is deactivated, the ECG is automatically saved or printed.
2. The **Emergency ECG** button is only displayed if **Settings > System > Configuration > Operating mode "Connectivity"** is set. (see section 11.2).
3. The dialogue CCAA is only displayed if this option is activated Section 5.5.7 CCAA, page 56.

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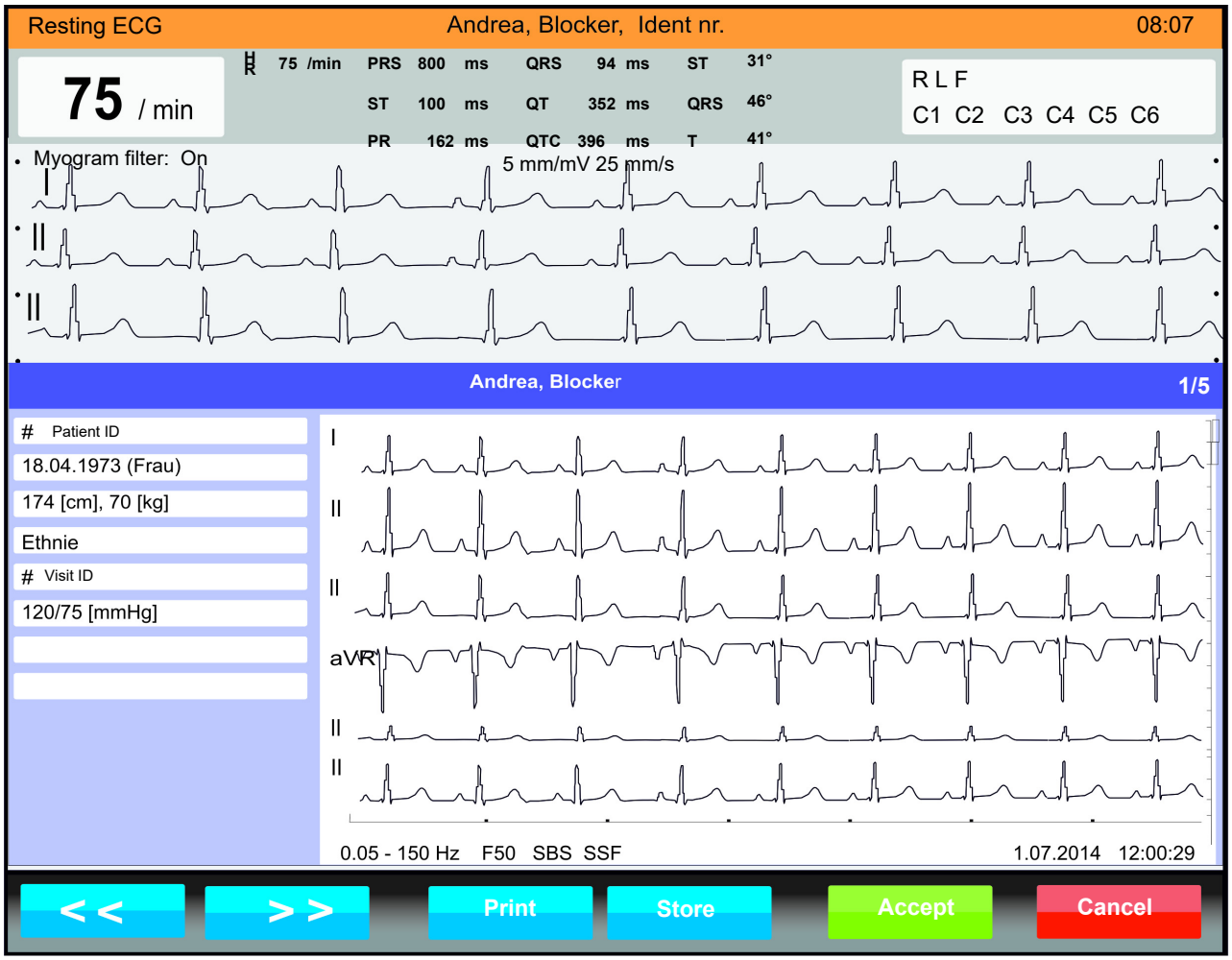
5.2 Automatic Mode Recording



To take an automatic ECG recording, press the **START** key.

After approx. 10 seconds, the recording is analysed and the result displayed in the Print preview[1]. The recording can be checked, accepted and further printouts obtained in different formats. The ECG data is saved until deleted by the user.

1. The print preview as well as the buttons **Print** and **Store** are only displayed if in 5.5.8**Settings > General,** the ECG print preview is activated, and automatic printout and storage are set to Off.



- ➜ Check the recording in the print preview by pressing the **Next** and **Back** buttons[1].
- ➜ Use the key **Accept** to save and print the recording[2].
- ➜ Use the key **Cancel** to exit the print preview.
- ➜ Select a recording for review and printout via the **Memory** menu.
- ➜ Open the menu **Memory** to send a recording to a different location (e.g. SEMA).
- ➜ Open the menu **Memory** to delete a recording from memory.

1. Depending on the last 4 settings in section 5.5.1, 3, 4 or 5 pages are displayed.
2. Automatic printout can be deactivated in the menu **Settings > General**.

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5.2.1 Printing, saving and transferring automatically

Menu > Settings > General

Select "ON" for "Auto printout", "Auto storage" and "Auto transmission" to automatically print, store and transmit a recording performed in auto mode.

- The transfer settings are detailed in section System settings (see page 90).
- Further ECG settings are described later in this section (see page 52).
- Printing and transfer from the memory is described in section Saving a recording (see page 63).
- All changed settings are remembered until the unit is switched off. If you wish to save the settings as default, go to **Menu > Settings > System > Software** and press the Save as default button before the unit is switched off (see page 89).

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5.2.2 Automatic printout

The printout gives the following:

- Patient data (as shown in the print preview, page 64)
- Time and date
- Heart rate
- Sensitivity
- Speed

And any combination of the following (for printout settings, see page 52):

- ECG recording of all 12 leads in either Standard or Cabrera format (according to selection)
- Interpretation
- Average cycles
- Markings (on the average cycles)
- Thrombolysis
- Intervals & axis
- Sokolow index (ECG index for hypertrophy)
- Detailed measurement table
- CCAA analysis

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5.3 Manual Rhythm Printout

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

Manual real-time printout is not available on an external printer because the data processing of inkjet and laser printers is too slow for real-time print. When a continuous real-time printout of the ECG is required, it is always printed on the internal thermal printer. The real-time ECG is not saved.

The chosen settings only apply to the printout.

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



The factory printout settings are **25 mm/s** and **10 mm/mV.**

Select lead sequence

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

The Standard and Cabrera lead sequences are as follows:

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

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

Select speed

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

Select sensitivity

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

This setting can be saved as default in **Menu > System > Software** > (see page 89).

Stopping the printout

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

5.3.1 Manual recording

The printout provides the following information:

- Six or twelve leads (see Menu **Settings > General**, section 5.5.8, page 56) including labels.
- At the bottom of the page: chart speed, Device ID, MTA ID, mains filter setting (50 or 60 Hz) and myogram filter cut-off frequency (if filter applied): 25 or 35 Hz.
- At the top of the page: heart rate averaged over 4 beats, sensitivity, patient name, patient #, date and time.

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5.4 Changing Lead Group, Amplitude and Speed for Display

⚠WARNING

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

The following settings can be freely chosen during data acquisition for the display and for a manual printout.

Different lead groups, speed and sensitivity are defined for the display and the manual printout. The display presentation can be changed directly via the touch screen.

5.4.1 Display

Leads 

Touch the screen at the top right ► to select one of the following presentations:

- 6 leads (use the arrow key to switch to the following 6 leads)
- 12 leads
- 6 leads in two columns
- 3 leads in four columns plus one rhythm lead

The Standard and Cabrera lead sequences are as follows:

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

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

Sensitivity (amplitude) 

Touch the screen slightly left of the centre to change the curve amplitude for the display (20,10 or 5 mm/mV; see page 22).

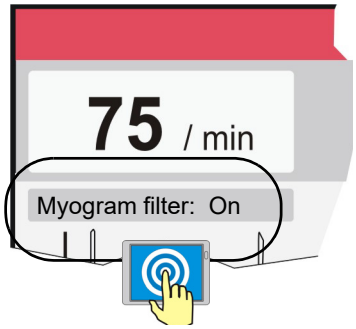
Speed 

Touch the screen slightly right of the centre to change the curve speed for the display (12.5, 25 or 50 mm/s; see page 22).

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5.4.2 Myogram filter

The myogram filter suppresses disturbances caused by strong muscle tremor. Activate/deactivate the **Myogram filter** in **Menu > Settings > Filters**. This setting can be saved as default in **Menu > System > Software** > (see page 89).



The filter can be activated/deactivated in the ECG screen. If the myogram filter is activated, **Myogram filter On** is displayed.

- The cut-off frequency is user-defined at 25 Hz or 35 Hz (see chapter 5.5.3, page 55).
- An ECG recorded in auto mode is stored unfiltered. It is therefore possible to print the stored ECG either with or without applying the myogram filter.

⚠ CAUTION

▲ When using the 25 or 35 Hz filter, the displayed or printed ECG does not always meet the requirements of a diagnostic ECG.

5.4.3 Other filters

Further filters can be applied to both resting and exercise ECG recordings as follows:

Baseline filter

The cut-off frequency for the baseline filter (0.05, 0.15, 0.30 or 0.60 Hz) is displayed in the information box. We recommend that 0.05 Hz is set, according to IEC recommendations.

Smoothing filter (SCHILLER SSF)

Suppresses high-frequency artefacts between the QRS complexes. SSF is printed on an auto mode printout when this filter is applied.

Baseline stabiliser (SCHILLER SBS)

Reduces baseline fluctuations without affecting the ECG. SBS is printed on an auto mode printout when this filter is applied.

Mains filter

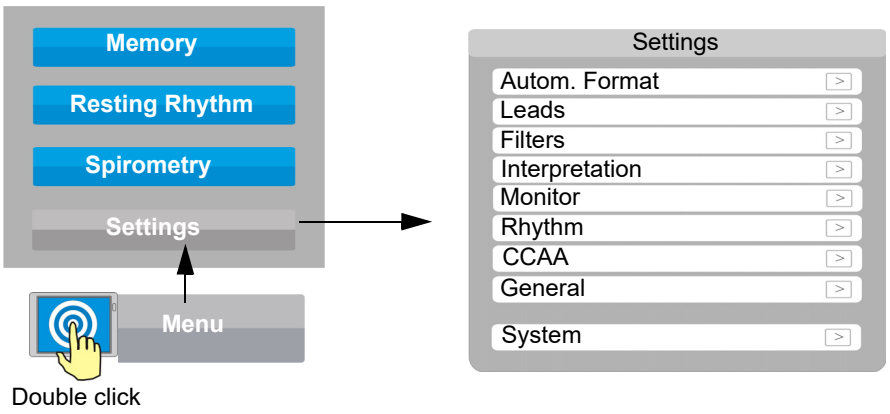
Prevents recording interference due to mains frequency oscillation. F50(50Hz) or F60(60Hz) is shown on the printout.

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

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5.5 ECG settings

When pressing the Menu key (double click), the option Settings is displayed. In the Settings menu, various changes can be performed. The following table gives an overview of all the settings available.



All changed settings are remembered until the unit is switched off. If you wish to save the settings as default, go to **Menu > Settings > System > Software** and press the Save as default button before the unit is switched off (see page 89).

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5.5.1 Auto format

Parameter	Options	Description
ECG printout	Off	No printout of the ECG given at the end of an auto mode recording (the recording can be stored in the memory and printed at a later stage, if required).
MS-2010/2015	4*3, +1 rhythm 1 page	Leads are printed in a 4*3 format at 25 mm/s, with the selected rhythm lead (R1) at the bottom of the page.
only MS-2010	4*3, +1 rhythm 2 page	Leads are printed in a 4*3 format at 25 mm/s, with the selected rhythm lead (R1) at the bottom of the page. (two pages).
only MS-2010	2*6 @ 25 mm/s, 1 page	Leads are printed in a 2*6 format at 25 mm/s (one page).
MS-2010/2015	2*6 @ 25 mm/s, 2 pages	Leads are printed in a 2*6 format at 25 mm/s (two pages).
only MS-2015	2*6 @ 50 mm/s, 1 pages	Leads are printed in a 2*6 format at 50 mm/s (one pages).
MS-2010/2015	2*6 @ 50 mm/s, 2 pages	Leads are printed in a 2*6 format at 50 mm/s (two pages).
Average cycles	Off	No printout of the ECG given at the end of an auto mode recording (the recording can be stored in the memory and printed at a later stage, if required).
MS-2015	4*3 @ 25 mm/s + 2 rhythms	Leads are averaged over the entire 10 seconds and printed in 4 groups of three at 25 mm/s. The selected rhythm lead (R1/2) is printed at the bottom of the page at 25 mm/s.
MS-2015	2*6 @ 50 mm/s + 2 rhythms	Leads are averaged over the entire 10 seconds and printed in 6 groups of 2 at 25 mm/s. The selected rhythm lead (R1/2) is printed at the bottom of the page at 25 mm/s.
only MS-2010	6*2 @ 25 mm/s + 1 rhythms	Leads are averaged over the entire 10 seconds and printed in 6 groups of 2 at 25 mm/s. The selected rhythm lead (R1) is printed at the bottom of the page at 25 mm/s.
Rhythm lead 1 or 2	I - V6	Define the first rhythm lead for printouts. The rhythm lead 2 is only available for the **MS-2015**.
Markings	On / Off	Select "On" or "Off" to print and display reference markings on the ECG average cycle printout. Vertical markers show the beginning and end of the P wave and QRS complex, and the end of the T wave.
Measurements	On / Off	Select On or Off to print and display a detailed table of measurement results.
Interpretation	On / Off	Select "On" or "Off" to print and display interpretation statements (only available for version C).
Intervals & axis	On / Off	Select On or Off to print and display a detailed table of intervals and axes.

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5.5.2 Leads

Parameter	Options	Description
ECG cable (only MS-2015)	10 leads (12 channels) 14 leads (16 channels)	Selection of the patient cable.
Lead sequence	Standard or Cabrera	This sets the lead sequence for manual and auto printouts as well as on the screen. Set to **Standard** or **Cabrera**.
Signals	Sequential or simultaneous	**Sequential** or **Simultaneous**. If Sequential is selected, consecutive time segments are used for the individual lead groups (this applies for printouts). If Simultaneous is selected, the same time segment is used for all lead groups (this applies for printouts). If a print format with a rhythm lead is defined, Sequential is used, even if you have selected Simultaneous.
Auto sensitivity (reduction)	Yes or No	**Yes** or **No**. The standard sensitivity for automatic recordings is 10 mm/mV. However, if the amplitudes are high, meaning that the QRS peaks would overlap, the sensitivity is automatically reduced to 5 mm/mV.
Lead view	**10 leads** • Normal • Right precordial (V4r) • Right precordials (V3r - V6r) • Left posterior (V7 - V9)	The lead view is set according to the selected lead type. The lead label on the display and on printouts changes accordingly. This setting can also be changed in the ECG screen, see section 5 page 44. **Please note**: automatic interpretation is only available if this is set to **Normal**.
	14 leads • Balanced • Right precordials	The selection for the 14-lead patient cable is only displayed if the 14-lead ECG cable has been programmed. **(only MS-2015)**

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5.5.3 Filters

Parameter	Options	Description
Baseline filter	0.05 Hz 0.15 Hz 0.30 Hz 0.60 Hz	The cut-off frequency can be set to **0.05 Hz, 0.15 Hz, 0.30 Hz** or **0.60 Hz** for resting ECGs. NOTE: The standard setting is 0.05 Hz. The higher setting should only be used when absolutely necessary because it can affect the original ECG signal, especially the ST segment.
Myogram filter	Off/25/35 Hz	The myogram filter suppresses disturbances caused by strong muscle tremor. The filter can be activated/deactivated in the ECG screen (see page 51). The cut-off frequency is user-defined at **25 Hz** or **35 Hz**. **Note**: An ECG recorded in auto mode is stored unfiltered. It is therefore possible to print the stored ECG either with or without applying the myogram filter.
Mains filter	50/60 Hz or Off	The mains filter is an adaptive digital interference filter designed to suppress AC interference without attenuating or distorting the ECG. Set the mains filter in accordance with the frequency of your local mains supply.
SBS Filter (baseline filter)	On / Off	The baseline stabiliser greatly reduces the baseline fluctuations without affecting the ECG signal. The purpose of this filter is to keep the ECG signals on the baseline of the printout. This filter is only effective in auto mode printout. The baseline stabiliser is applied to a recording (**On**), or not applied to a recording (**Off**). The cut-off frequency is set above (see Baseline filter).
SSF Filter (smoothing filter)	On / Off	**On** or **Off**. The smoothing filter (SSF: SCHILLER Smoothing Filter) is a low-pass filter to suppress high-frequency artefacts between the QRS complexes. When this filter is switched on, "SSF" is shown on the bottom line of the automatic printout.

5.5.4 Interpretation

Parameter	Options	Description
Unconfirmed report	On or Off	**On** or **Off**. **UNCONFIRMED REPORT** is/is not printed on automatic printouts as interpretation note (if the interpretation is installed).
Abnormal ECG	On or Off	**On** or **Off**. **ABNORMAL ECG** is/is not printed on automatic printouts as interpretation note (if the interpretation is installed).
Sensitivity	Normal or low	**Normal** or **low** sensitivity. Low sensitivity will suppress certain non-specific ECG diagnoses; this may be advisable when carrying out ECGs for screening.
Thrombolysis (option)	On or Off	**On** or **Off**. Thrombolysis is the breaking up of a blood clot. If the thrombolysis option is deactivated, the interpretation text **Possible infarct or other abnormality** is deactivated.

5.5.5 Monitor

Parameter	Options	Description
Rhythm lead	I - V6	Select the first rhythm lead displayed on the screen for resting ECGs.

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5.5.6 Rhythm

Parameter	Options	Description
Rhythm lead	I - V6	Selection of the rhythm lead for the display.
Recording time	30 sec./1/2/3/4 minutes	Enter the duration of the recording
Scale	6.25 mm/s 5 mm/mV 6.25 mm/s 2.5 mm/mV	Select the scaling for the display

5.5.7 CCAA

This menu option is only displayed when the CCAA option is activated.

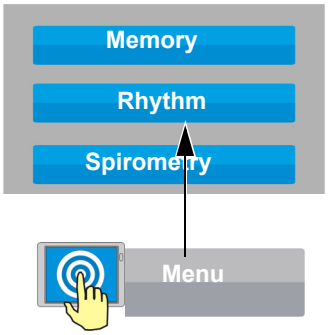
Parameter	Options	Description
CCAA	On or Off	**On** or **Off**.
PCI centre distance [h]	0-24 h	Max. duration for transport to the closest PCI centre without considering thrombolysis. (PCI = percutaneous coronary intervention). E.g. input: 2 hours: Recommendation: Consider thrombolytic therapy if PCI centre is further away than 2 hours.

5.5.8 General

Parameter	Options	Description
QRS beeper	On or Off	**On** or **Off**.
Autom. printout	On or Off	At the end of an Auto recording, print the results (**On**) or do not print (**Off**).
Autom. storage	On or Off	At the end of an Auto test, store the results (**On**) or do not store (**Off**).
Autom. transmission	On or Off	At the end of an automatic recording, transmit the results via network or WLAN (**On**) or do not transmit (**Off**).
ECG print preview	On or Off	The Options On/Off determine whether the print preview is displayed after an automatic ECG recording. The number of print preview pages depends on the settings for the last 4 parameters in section 5.5.1
Manual print channel	6 or 12	Printout of the leads I to aVF (6 channels) or I to V6 (12 channels).
QTc Formula		QTc is the QT interval value calculated for a heart rate of 60 bpm (i.e. RR = 1000 ms). Select one of the following formulas: • Bazett • Fridericia • Framingham • Hodges The selected formula and the QTc value are displayed in the preview and on the printout.

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6 Resting Rhythm



Double click

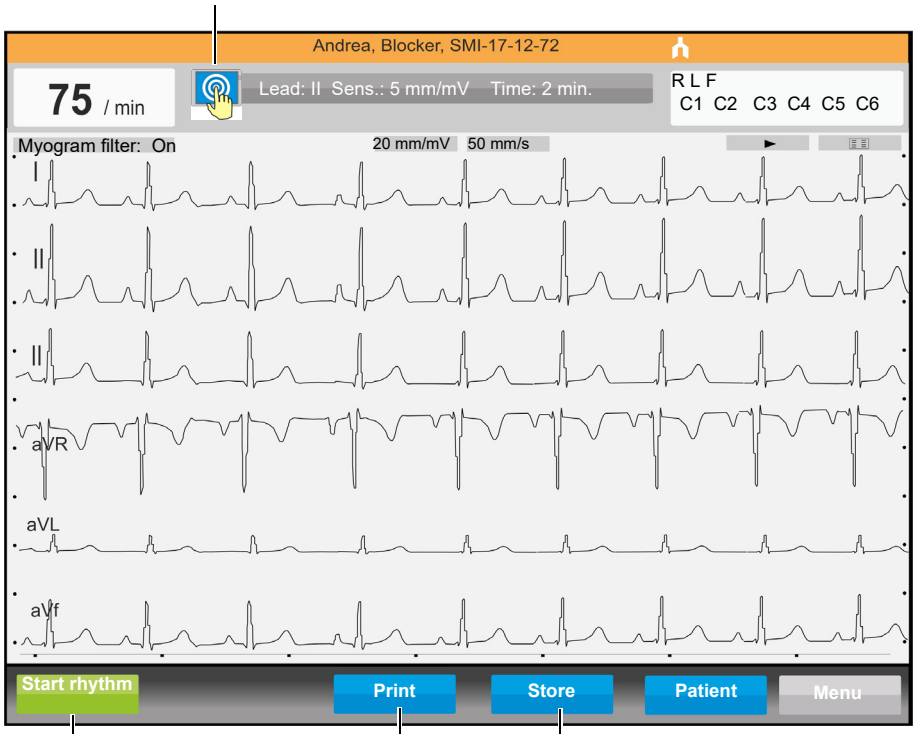
In resting rhythm mode, a recording of all leads is made for a duration set by the user. The recording can then be sent to SEMA (SCHILLER Evaluation and Management Administration software) for analysis. Note that only leads I, II, and leads V1 to V6 are transmitted. All other leads are calculated by SEMA.

➜ To enter the resting rhythm mode, double click on Menu and select Rhythm.

6.1 Display of the resting rhythm mode

Displaying the resting rhythm settings:

➜ Touch the dark grey bar to open the settings.



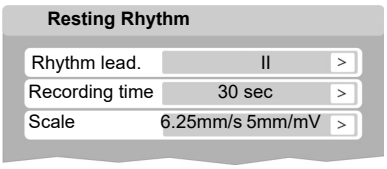
Start of the rhythm recording

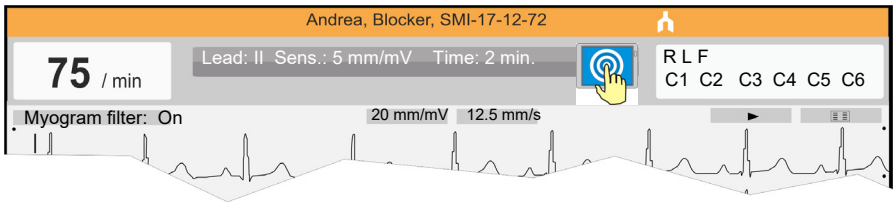
These buttons are only displayed if the Automatic printout and storage is set to Off (see section 5.5.8: **Settings > General**.

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6.1.1 Settings and preliminaries

1. Select the resting rhythm mode.





2. Touch the dark grey bar to open the **Resting rhythm** settings:

- Define the rhythm lead (I, II, III, aVR, aVL, aVF, V1 - V6).
  - During rhythm recording, all leads are recorded. This setting is for the printout only.
- Recording duration:
  - 30 seconds
  - 1 minute
  - 2 minutes
  - 3 minutes
  - 4 minutes
- Scaling (6.25 mm/s, 5 mm/mV or 6.25 mm/s, 2.5 mm/mV).
  - The amplitude and speed settings apply only for the printout. The amplitude and speed for the display can be changed by the user before the start of the recording; however, this does not influence the printout settings.

6.1.2 Starting the rhythm recording



1. Press the **Rhythm** key to start the recording.
2. The recording is started and the duration is given in minutes.

At the end of the recording, **Storing**... **xx%** is displayed in the information bar.

This is followed by **Initialising..** and then **Sending ..xx%**, (if auto send is defined - see 6.1.4).

6.1.3 Stopping the rhythm recording



Press the **Rhythm key** again at any time during the recording to stop a recording. The recording is stored and sent in the normal way.

6.1.4 Printing, Storing, Transmitting the Rhythm Recording

The recording can be sent to a database, stored or printed automatically after the recording has been made. The setting is the same as for the resting ECG (see page 47). If you open the memory from the Resting rhythm view, only resting rhythm recordings are shown. If you open the memory from the Resting ECG view, both resting rhythm and resting ECG recordings are shown. A preview of the recorded data (like for resting ECGs) is not available for resting rhythm recordings.

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7 Culprit Coronary Artery Algorithm (CCAA)

7.1 Introduction

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

The closer the occlusion site to the origin of the coronary artery, the larger the size of the area at risk. The algorithm indicates the location of the occlusion site and issues a recommendation based on the ECG data, patient history and distance to the closest PCI centre (**P**ercutaneous **C**oronary **I**ntervention). The recommendation is based on the following:

- **Prior Bypass/ Stent.** This data is entered before the ECG recording is taken (see Section 5.1 Resting ECG - Procedural Flow Diagram, page 45). If the patient has had prior bypass or stent, the ECG is not analysed further and the advice **Go to PCI centre** is given.
- **ST Score**. The sum of the absolute ST deviations in mm in 12 leads (excluding V4r). That is the total ST deviation (mm) of all leads (I, II, III, aVR, aVL, aVF, and all leads V1 to V6).
- **Occlusion Site.** The calculated occlusion site.

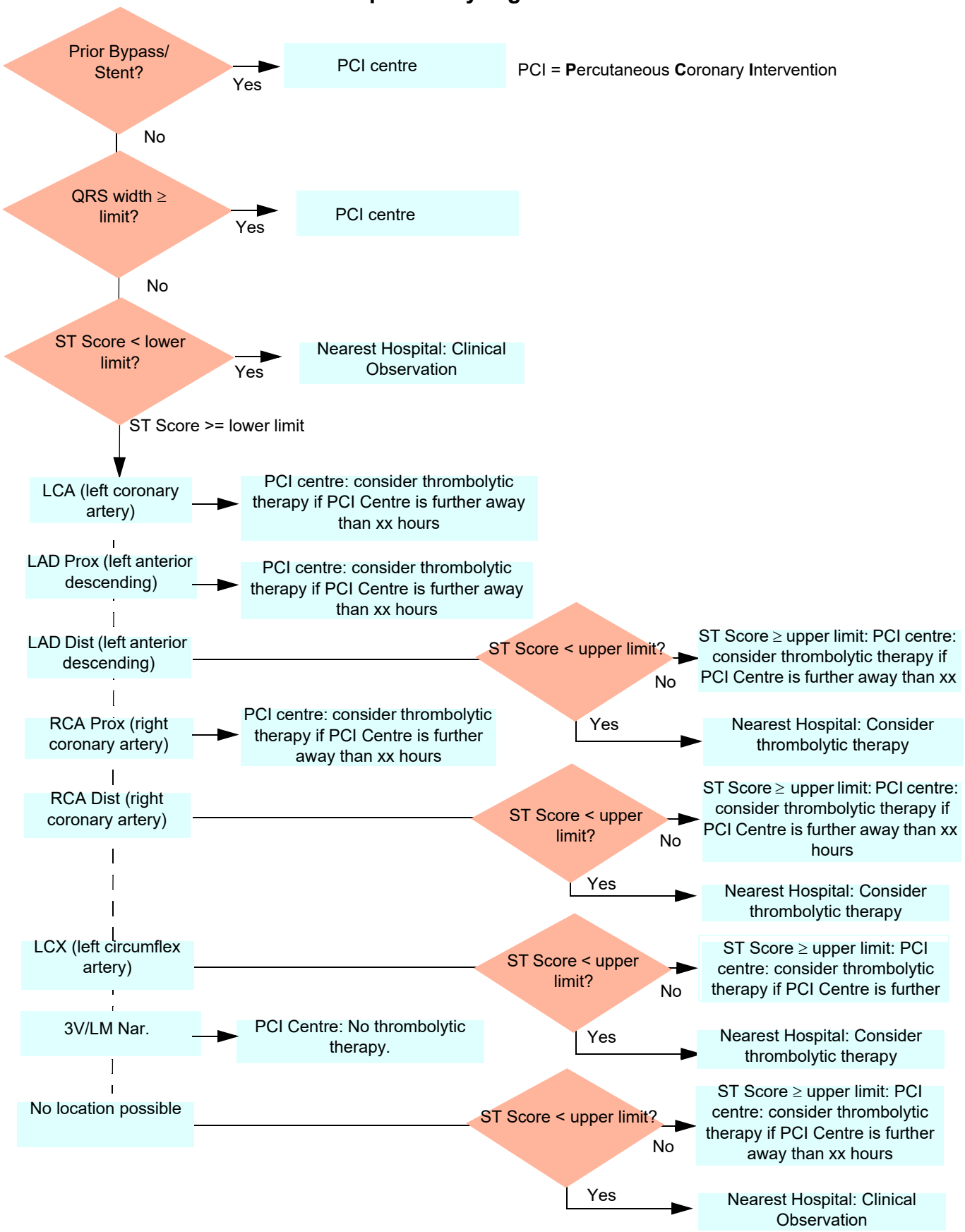
The site of occlusion is determined by the following:

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

- **PCI distance**. The time to travel to PCI centre.

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7.1.1 Culprit Artery Algorithm Decision Overview



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7.1.2 Starting the CCAA analysis

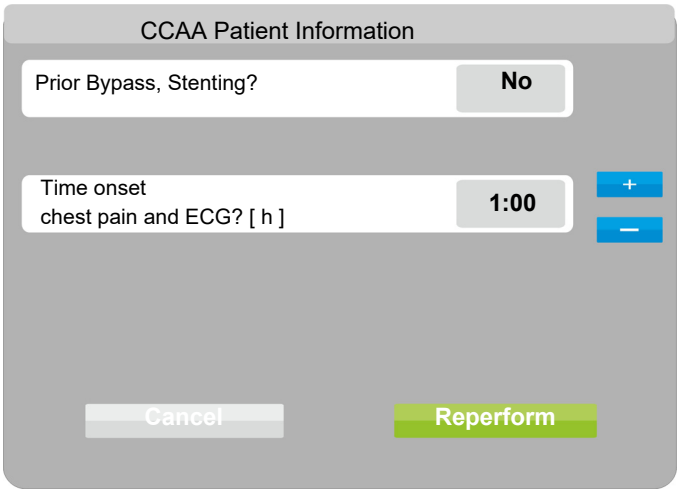
When Culprit Coronary Artery Algorithm analysis is set (see Section 5.5.7 CCAA, page 56), the following applies:

- The lead setting is automatically set to Right Precordial (V4r). Ensure that the C4 electrode is placed in the C4r (precordial) position (see page 38).
- Before an auto mode recording is taken, you are asked to confirm that the CCAA analysis is to be performed, and you have to enter extra patient information.

Procedure



1. To take an automatic ECG recording, press the **START** key.
2. Confirm the CCAA analysis by pressing "YES".
3. Enter the patient data in the following dialogue:



4. Press Perform to start the analysis

The data is shown in the print preview. The recording can be checked, accepted and further printouts obtained in different formats. The ECG data is saved until deleted by the user.

All other settings and features (saving, printing etc.) are the same as described in Section 5.2 Automatic Mode Recording, page 46.

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7.1.3 CCAA information on print preview/printout

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

- Manual entry before the start of the recording:
  - Previous bypass or stenting (Yes/No)
  - Time onset chest pain and ECG in hours
- QRS width (averaged) [ms]
- ST score (averaged) [mm]
- Occlusion site - assessed area of an occlusion
  - LCA (left coronary artery)
  - LAD Prox (left anterior descending)
  - LAD Dist (left anterior descending)
  - RCA Prox (right coronary artery)
  - RCA Dist (right coronary artery)
  - LCX (left circumflex artery)
  - 3V/LM Nar.

Advice

Statements given at the bottom of the page based on the score and entered data are as follows:

First line: Where to go will be one of the following:

- PCI centre
- Nearest Hospital

Second line: What to do will be one of the following:

- Clinical Observation
- Consider thrombolytic therapy if PCI Centre is further away than xx hours[1].
- Consider thrombolytic therapy

1. The user (physician) or rescue organisation needs to define the transport duration to the closest PCI centre for which the recommendation "Consider thrombolytic therapy" is issued. This value is defined in the Settings/CCAA Section 5.5.7 CCAA, page 56.

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8 Memory

Recordings can be stored locally and/or transmitted to a HIS or SEMA. This is done automatically after a recording has been completed. Recordings stored in the memory can also be transmitted at any time.

8.1 Saving a Recording

8.1.1 Automatic storage

The auto storage setting is defined in ECG settings:.

- **Menu key > Settings > General > Autom**. **Storage** (On/Off - see page 56).

8.2 Editing the Memory

In total (memory and worklist), approx. 350 recordings or 320 ECG and 30 rhythm recordings can be saved on the CARDIOVIT MS-2010/2015.

When
Menu > Memory is selected, stored recordings are displayed:

Select, print, send or delete one or several recordings.

Open (2):
- Resting ECG print preview (see 8.2.2)
- Spirometry patient data (transmitting or printing internally)
- Resting rhythm ECGs cannot be opened in the print preview!



Define the output (internal/external printer or USB stick) in the **Settings > System > Configuration** (see 11.2).



The recordings are listed by date. The type of recording is indicated below the date:

- RECG = resting ECG
- RRECG = resting rhythm recording
- Spiro = spirometry

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8.2.1 Transmitting, printing and deleting stored recordings

1. Select one or more recordings directly on the screen (1).
2. The recording is highlighted in green . (to deselect a recording, press the green marking again).
3. To select all recordings, press the key **Select all.**
4. Select one of the following options:
   – Send
   – Print (for ECGs “PDF➜ USB stick” or “PDF ➜ USB printer”)
   – Delete (Automatic erase after transmission can be set in the **Menu** > **Settings > System > Memory** see page 91.

If the selected operation cannot be carried out due to an error, an error message is issued (see page 97) and the following symbols/buttons are displayed:



Indicates the number of recordings that have not been transmitted. When this button is tapped, the system tries again to transmit the remaining (2) ECG recordings.

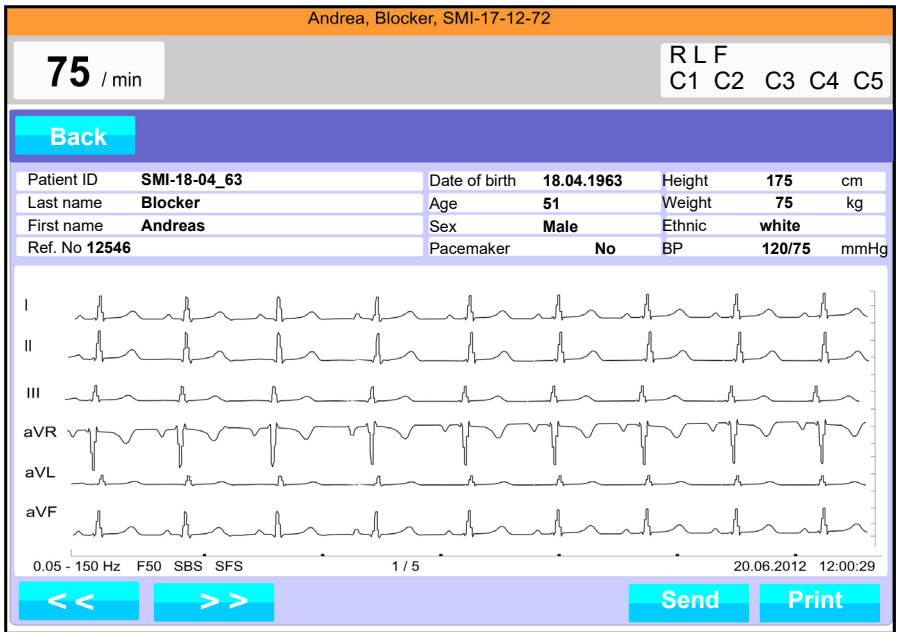


The recordings which have not been transmitted are marked in the memory view.

The transmitting options are detailed in section System settings (see page 95).

8.2.2 Open the print preview - print or send

1. Select the recording on the display **(2)**, page 63.
2. The recording is opened.
3. Select one of the following options:
   – Print preview << />>
   – Send
   – Print (for ECGs “PDF➜ USB stick” or “PDF➜USB printer”)



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9 Worklist (option)

The worklist function enables a physician / administrator to define a worklist of patients that require recordings to be made. The physician can define the patient, room / department, and specify the type of recording to be made. The worklist is defined directly from the Hospital Information System (HIS) (e.g. SEMA, GDT, etc.) and after the recording has been made by the CARDIOVIT MS-2010/2015, the recordings are sent back to the HIS for examination, validation and storage.

The HIS can also specify the recording type to be made or can state ‘undefined‘. When this is the case, only the patient demographics are sent to the unit.

- The unit must be set up to communicate with SEMA as defined in system settings (see page 90) to use the worklist function.
- The way that the worklist is defined by SEMA is described in the SEMA User Guide.

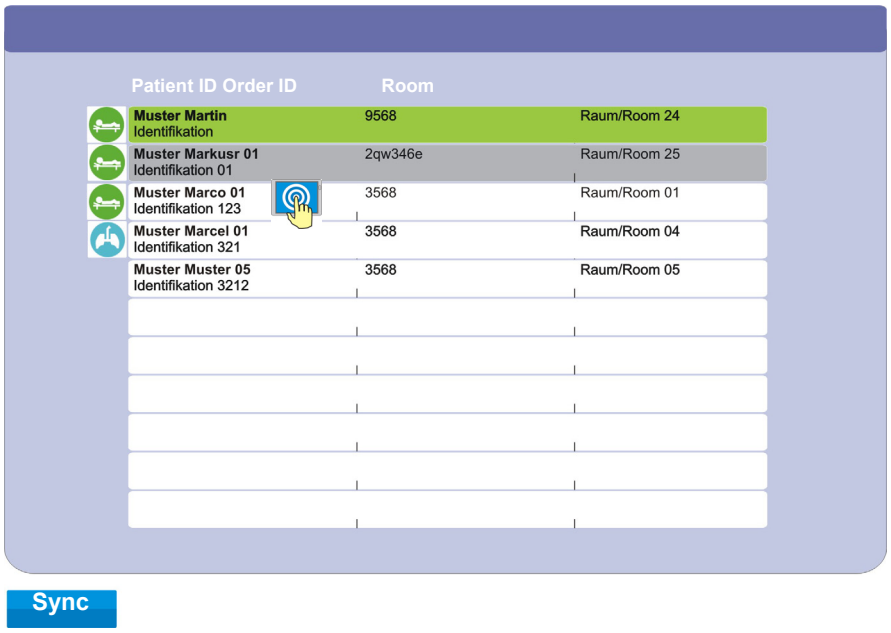
SEMA has options to send a worklist to a specific unit or to all units on the system. To receive a worklist from SEMA, the device identification of the CARDIOVIT MS-2010/2015 (Device ID in the system) must be the same as that defined for SEMA. This is usually set when the unit is first commissioned. The device identification can be viewed in the **Menu** > **Settings > System > Identification**.

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9.1 Receiving a worklist

To open the worklist proceed as follows:

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



.

Sync

2. To receive a worklist from a HIS, press the **Sync** key to download the worklist from the Server. Wait (up to a few minutes) for the worklist to be populated.

In the worklist, all patients are ordered by name, first name, identification no., order no. and room no. The following recording types are available:

- **RECG**: Resting ECG
- **SPIRO** - Spirometry recording
- No symbol: Recording type has not been defined. The recording type is assigned when the recording is performed.

Recording status:

White background Recording needs to be performed:

➜ Click on a recording to open the patient data; if you select Perform, the acquisition screen for the assigned recording type is opened.

Green background Recording has been performed:

➜ Click on the recording to open the print preview. In this preview, the recording can be reviewed or re-performed.

Grey background Recording has been cancelled:

The next time the worklist is synchronised, this recording is going to be deleted, both on the device and on the server.

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9.1.1 Taking a Worklist recording

1. Prepare the patient and click on a worklist item. The patient data screen is displayed.
2. Press the Perform key.

If you have selected the wrong worklist item, press **Back** to select a new worklist item - do not press Cancel. Cancelled worklist items (grey background) need to be reassigned by the server.

3. The acquisition screen is entered for the recording type defined (ECG or Spiro). If no recording type has been previously defined, you are asked to select the recording type.
4. Press the **Patient** key to enter the following additional patient data or to directly start the recording (step 6):
   - Height
   - Weight
   - Ethnic
   - Pacemaker
   - Digitalis
   - Blood pressure
5. Exit the patient data screen by pressing the **Home** key
6. Take the recording:
   - Resting ECG (see page 46)
   - Spiro (see page 80)
   - Resting rhythm (see page 58)
   - CCAA (see page 61)

7. The recording status is indicated by different colours.
   - green = the recording has been performed
   - grey = the recording has been cancelled by the user by pressing the key **Cancel.**
   - white = the recording has not yet been performed.

9.1.2 Sending worklist recordings to the HIS

- It is possible to send performed recordings on a worklist automatically or to have the unit prompt you to send worklist items. This is defined in the system settings (**Menu** > **Settings > System > Configuration** page 90).

Sync

1. Press the **Sync** key to transmit the recordings to SEMA. Wait (up to a few minutes) while the recordings are sent - the worklist will go blank after the files have been sent.

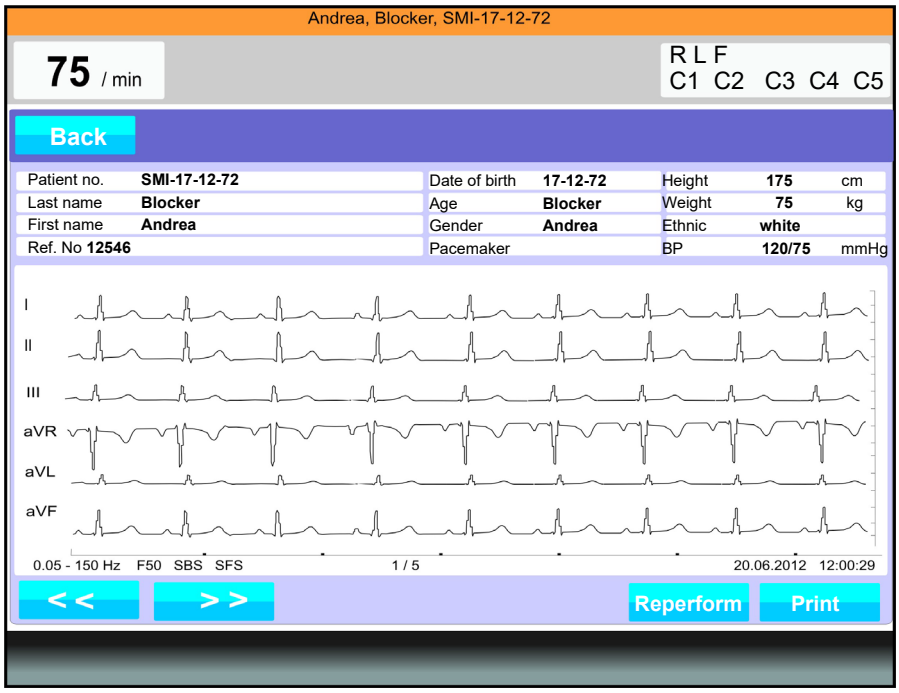
Any worklist items that have not been recorded (white), or have been cancelled (grey), remain in the worklist. This means that completed recordings can be sent at any time without losing other worklist items that have not been recorded.

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9.1.3 Reperforming or printing a worklist item



1. If you have performed a recording (item is displayed in green) and would like to repeat the recording, click on the desired recording. The print preview is displayed.
2. Select **Reperform**. You are prompted to confirm. The previous recording will be overwritten.
3. Click on **Print** to print the recording again.



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10 Spirometry

10.1 Intended Use

The spirometry program is designed to carry out pulmonary function tests on persons of all races and sex, from the age of 5 years. The objective of these tests is to diagnose a lung disease and assess the extent of the abnormality by following the course of a disease to determine the efficiency of treatment or the need for supplemental oxygen and mechanical ventilation. It is also useful when determining if pre-operative patients can withstand any intended surgery, to assess disability and to decide whether an individual can perform an occupational task requiring a certain workload.

Routine pulmonary function tests can be used to determine if a patient complaining of dyspnea (shortness of breath) or fatigue has a lung disease and, if so, whether it is an obstructive, restrictive or vascular disease or a disease of the ventilation control.

The spirometry option can be used to measure Forced Vital Capacity (FVC), Forced Expiratory Volume in one second (FEV1), $FEV_{1.0}$ / FVC, $FEF_{0.2\text{-}1.2}$, $FEF_{25\text{-}75\%}$, $FEF_{75\text{-}85\%}$, PEF, $FEF_{25\%}$, $FEF_{50\%}$, $FEF_{75\%}$, FIVC, $FIV_{1.0}$, $FIV_{1.0}$ / FIVC, PIF, $FIF_{50\%}$, SVC, ERV, IRV, TV, MVV, RR and TV, in patients 5 years of age or older.

10.2 Introduction

10.2.1 Spiro Sensors

The spirometry function is available when the spirometry sensor is plugged in to the RS-232 connector on the right hand side of the unit. Three sensors are available with the **MS-2010/2015** as follows:

- Pneumotach sensor **SP-250**
- Pneumotach sensor **SP-260**
- Ultrasound sensor **SpiroScout SP** (also requires connection to a USB connector on the back panel of the **MS-2010/2015** for power)

The **SP-250** and the **SpiroScout SP** both have disposable, single patient mouthpiece assemblies eliminating the need to clean the sensor after each use. The **SP-260** has a disposable filter that must be changed after every patient and the mouthpiece sterilised.

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10.3 Spirometry test – overview

Three pulmonary function testing modes are available for the measurement of inspiratory and expiratory values as follows:

- FVC Forced Vital Capacity
- SVC Slow Vital Capacity
- MVV Maximum Voluntary Ventilation

10.3.1 Forced Vital Capacity (FVC)

For this test, the patient needs to exhale as quickly as possible, after maximal inhalation.

The FVC test employs the `Back extrapolation` method. If the extrapolated volume is too large (>0.15 litres or 5% of FVC), then a warning appears on the display.

The patient needs to exhale as quickly as possible from the time of starting the test, so be sure that he/she understands what is required. If inspiratory measurements are required, the exhalation can be immediately followed by a maximum inhalation. The inspiration results will be given on the printout.

The coordinates represent the graph on which the curve will be drawn with the respiratory volume in litres being represented on the vertical axis and the time in seconds on the horizontal axis.

10.3.2 Slow Vital Capacity (SVC)

The patient should breathe normally 3 times and then inhale as much as possible to maximum lung capacity, and then exhale as fully as possible.

10.3.3 Maximum Voluntary Ventilation (MVV)

The patient should breathe as deeply and as rapidly as possible over a period of 6 to 12 seconds.

⚠ CAUTION

▲ Care should be exercised when performing this test as there is a danger of hyperventilation. Ensure that the patient is sitting down.

10.3.4 Checking the test quality

In order to judge the patient's lung function, it is essential to achieve a test with acceptable quality. The test quality depends on the patient's cooperation, which in turn depends on the quality of the instructions given by the examiner. Therefore, the MS-2010/2015 features an automatic quality control with notes for the examiner to facilitate instructing the patient. After each manoeuvre, the quality (E to A) is displayed on the screen, indicating whether or not the manoeuvre was acceptable. Quality level A **("End criteria met")** can only be achieved after at least 3 test manoeuvres. For more information on the quality levels, see section 10.12 page 84.

10.3.5 Interpretation of results

For the interpretation, it is important to take into consideration the test quality. Quality levels A to C indicate reliable results. Quality levels D to F indicate poor test quality; these results need to be interpreted carefully.

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10.3.6 Post medication tests (post test)

Post tests are performed to check the effect of asthma medications on the patient. Immediately after having performed a FVC or VC test (Pre test), an asthma-relieving medication is administered. After 10-20 minutes (duration until the medication has developed its full effect), another FVC or VC test is performed. Afterwards, the results of the pre and post test are compared.

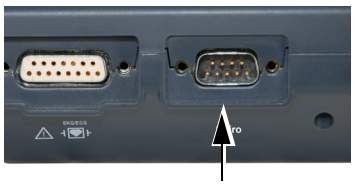
The post-medication tests are carried out in the same way as the pre-medication tests (three measurements are stored). On the printout that is generated at the end of the post-medication test, the pre- and post-medication curves are given. The measurement results are shown as the best results (pre/post), results as a percentage of those predicted, (both pre and post) and the percentage change (i.e. difference) between pre and post-medication results.

The diagnosis resulting from the pre-medication test is also given on this printout if set.

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10.4 Preparation

10.4.1 SP-250 and SP-260 Sensors

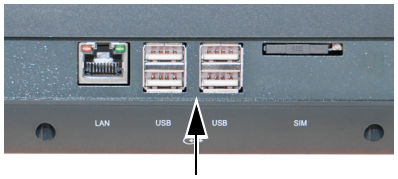


1. Connect the sensor to the spirometry interface on the right hand side of the device.

Note

If the sensor is connected when the device is already running, switch the unit off and on again so that the device detects the sensor and the spirometry function becomes available.

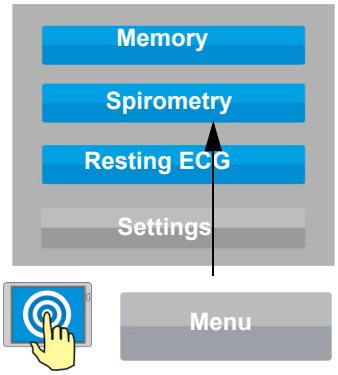
10.4.2 SpiroScout SP Sensor



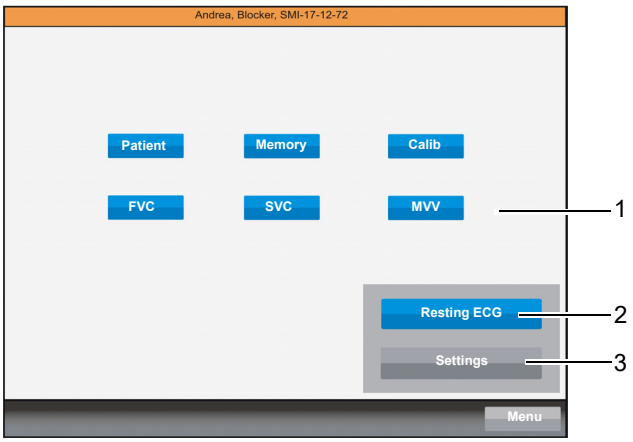
Using the 'Y' cable assembly supplied, connect the RJ45 connector (back of the SpiroScout SP) to:

- RS-232 connector on the right hand side of the device (above), and
- USB connector on the back of the device.





2. Switch on the device and select Spirometry from the menu.



3. The normal values and settings are specified in the menu **Settings (3)**.
4. To perform a spirometry test, press one of the buttons in row **(1).**
5. Select **Resting ECG (2)** from the menu to return to the resting ECG screen.

⚠ CAUTION

▲ The sensor cable must not be exposed to excessive mechanical stress. When disconnecting the sensor, pull the plug and not the cable.

▲ The sensor contains a sensitive measuring device. Do not drop the sensor and prevent any sudden blows.

i

The spirometry settings are detailed later on (see page 86). When the device is switched off, all settings are stored.

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10.5 SP-250 Sensor

⚠ CAUTION



▲ To exclude the risk of cross contamination, replace the disposable mouthpiece after every patient. Do not attempt to clean the mouthpiece.



1. Remove the disposable mouthpiece by gently but firmly pulling it away from the handle.
2. Dispose of the entire mouthpiece in the clinical waste.
3. Position a new disposable mouthpiece - align with guide slot in the sensor handle and gently but firmly click it in position.

i

The disposable mouthpiece can only be positioned in one direction and no force is necessary to insert it on the handle. Ensure that the orientation is correct by checking the guide protrusion in the mouthpiece against the guide slot in the handle.

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10.6 SP-260 Sensor

⚠ CAUTION



- ▲ The filter is **not reusable** - replace the filter after every patient - never use the filter for more than one patient.
- ▲ Thoroughly **disinfect** the mouthpiece assembly before using it for another patient.



1. Remove the mouthpiece by gently but firmly pulling it away from the handle.



2. Unscrew the mouthpiece anti-clockwise.



3. Remove the filter. **Thoroughly disinfect the two parts of the mouthpiece assembly.**



4. Position a new filter (Part No. 2.100123) in the threaded half of the mouthpiece as shown, and screw the two halves of the mouthpiece together. Ensure that the filter is firmly held with no air gaps.



5. Reinsert the mouthpiece in the handle. The mouthpiece can only be inserted in one direction. A moulded lip in the mouthpiece prevents incorrect insertion.



6. The sensor is now ready for the next patient.

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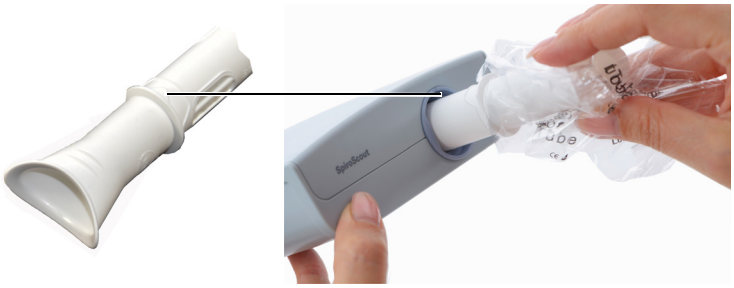
10.6.1 SpiroScout SP

CAUTION



- The disposable mouthpiece ScoutTube 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.
- After use, dispose the complete mouthpiece in the clinical waste.

The disposable mouthpiece can only be positioned in one direction and no force is necessary to insert it. Ensure that the orientation is correct by checking the guide protrusion in the mouthpiece against the guide slot. Align the arrow on the breathing insert with the notch in the SpiroScout SP and push the breathing insert until fully home.



Removing the ScoutTube

To remove the **ScoutTube**, pull it away from the Sensor, turning it a little counter clockwise, if needed.



At the end of the test

- Observe all cross-contamination procedures. Dispose of the **ScoutTube** in the clinical waste. Wear rubber gloves, do not let clinical waste come into contact with any person.

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10.7 Cleaning and Disinfection

Clean/disinfect the sensor cable and handle by wiping them with a damp cloth. Standard hospital disinfectant can be used to disinfect the SP-260 sensor mouthpiece as follows:.

Disinfectant	Maximum Immersion Time [hr.]	Concentration [%]
Sekusept Extra N	1	2
	1/2	3
Sekusept Forte	1	1,
Sekusept Plus	1	1,5
Sekusept Powder	1	2
Sekudrill	1/4	100
Velicin forte	1/4	25
Aseptisol	1/4	2,5
	1/2	1,5
	1	1,0
Gigasept	4	10
Lysetol V	4	10
Cidex	10	100

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10.8 Calibration and verification

The unit must be verified before the first pulmonary function test of the day and after every significant temperature change.

Note for SpiroScout SP sensors only

Because of the stable ultrasound technology, the SpiroScout SP does not require volume calibration, even if used frequently. The American Thoracic Society (ATS) recommends that calibration be checked every day.

10.8.1 Menu calibration



➜ Press the Calib key to display the menu for the sensor calibration.

In the **Sensor calibration** menu, you can choose to verify or calibrate the sensor.

Verification

± deviation	Message	Note
3 %	• Verification completed	➜ Measured values OK
> 3 % < 12 %	• Deviation too large, perform calibration	➜ A calibration needs to be performed
> 12 %	• Deviation too large, replace sieve, re-perform verification	➜ A calibration needs to be performed

Calibration

± deviation	Message	Note
< 12 %	• Calibration completed	➜ If the difference between expected (syringe) and measured values is less than 12 %, a new correction calculation is performed
> 12 %	• Deviation too large, replace sieve, re-perform verification	➜ It was not possible to calculate correction values. Replace the sieve or mouthpiece.

Last calib. Date of the last calibration

BTPS Factor Calculated BTPS factor (=> **B**ody **T**emperature, Ambient **P**ressure, **S**aturated with water vapour). This factor compensates differences regarding humidity saturation in inspired and expired air. The unit is set to measure the exhaled volume (100% humidity, temperature 36.8°), so when the inhaled volume is measured, this factor is applied. Ambient temperature is used to calculate the BTPS factor. This is sufficient for an accurate FIVC calculation. The calculation is as follows:

- Tu = ambient temperature in degrees centigrade
- 0.033 = 760 mm Hg at 22 °C
- 273.15 K = 0 °C

$$BTPS = 0.033 + \frac{273.15\ K + 36.8°C}{273.15\ K + Tu°C}$$

Calibration factor Calculated value between measured and effective calibration air volume.

Temperature Enter the ambient temperature in °C (or °F), according to the pre-defined device setting.

Syringe volume Entered air volume depending on the size of the calibration pump and times the air was pumped through the sensor; e.g. pumping 2 litres 3 times amounts to 6 litres (the recommended volume with a 2 litre pump is 4 litres; with a 3 litre pump, 6 litres).

Measured volume Air volume measured by the system

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10.8.2 Verification / calibration procedure

The procedure for the calibration is the same as for the verification; the only difference is that the correction values are set, based on the performed measurement.



➜ Proceed as follows for the verification/calibration:

1. Prepare the sensor:
   - SP-250: Position a new mouthpiece in the sensor.
   - SP-260: Exchange the filter and disinfect the mouthpiece.
   - SpiroScout SP: Use ScoutTube Adapter (Part. no.: 2.101137)
2. Connect the calibration pump to the mouthpiece. Ensure that there are no gaps.
3. Press the Calib/Verify key to display the menu.
4. Enter the ambient temperature and the syringe volume.
5. Press Done to confirm.
6. Press the Start key.
7. Pump 4 to 6 litres of air through the sensor.

Make sure that the flow sensor is kept still while pumping.

While pumping, the unit records the volume being pumped through the flow sensor and indicates it on the display.

Calibration	
Sensor	250/260
Last Calibration	18.04.2011
BTS factor	.1.136
Calibration factor	1.047
Temperature	20 °C
Syringe volume	6
Measured volume	5.87 l
Deviation	-.2.2 %
Calibration completed	

8. Press the STOP key when finished pumping.
9. **If you have performed a verification:**
   - a message informs you whether the verification is terminated or
   - if you have to perform a calibration or
   - if you have to change the sieve and re-perform the verification/calibration.

If you have performed a calibration:

- you can print the calibration report by pressing the PRINT key as soon as the message "Calibration terminated" is displayed
- you are prompted to change the sieve and perform a calibration if the difference between expected (syringe) and measured value is larger than 12 %.

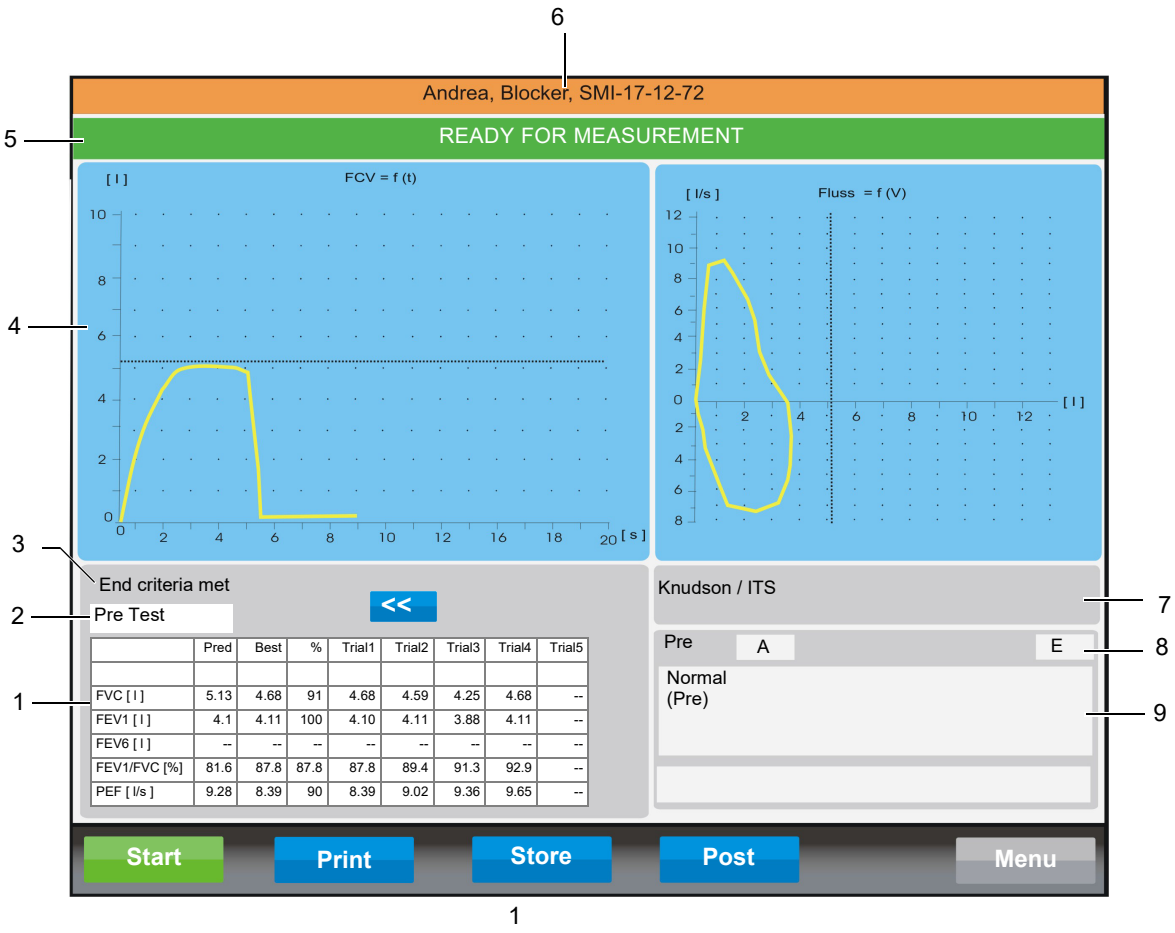
If the message **'EXCESSIVE DEVIATION'** is displayed, the difference between the measured volume and the entered reference volume is too large (> 12 %). Check the temperature, the syringe volume of the calibration pump as well as the entered reference volume. If all the settings were correct, exchange the filter/mouthpiece and repeat the verification/calibration.

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10.9 Spirometry measurement

⚠ CAUTION

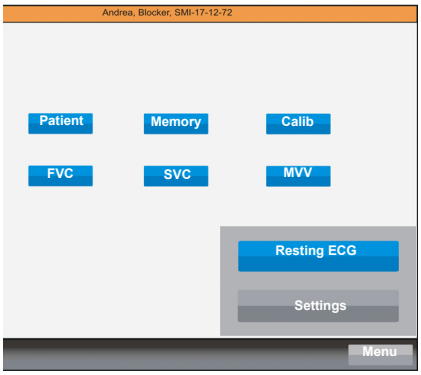
- ▲ It is important that all patient data is entered correctly. In particular sex, date of birth, ethnic, height and weight must be entered for correct predicted values and diagnosis.
- ▲ The unit must be calibrated with the first pulmonary function test of the day and after every significant temperature change.
- ▲ False measurements can result when the sensor is not held vertically - ensure that the sensor is held upright at all times during tests.



(1) Result table (last measurement)
(2) Pre or post measurement (see following)
(3) Message whether or not the performed measurement meets ATS/ERS criteria
(4) Selected test
(5) Messages / instructions
(6) Patient Data
  – Last name, first name
  – Patient ID
(7) Selected norm values (to calculate the predicted values)
(8) Quality level of pre/post measurement, A = end criteria met (3)
(9) Interpretation
(10) Function keys

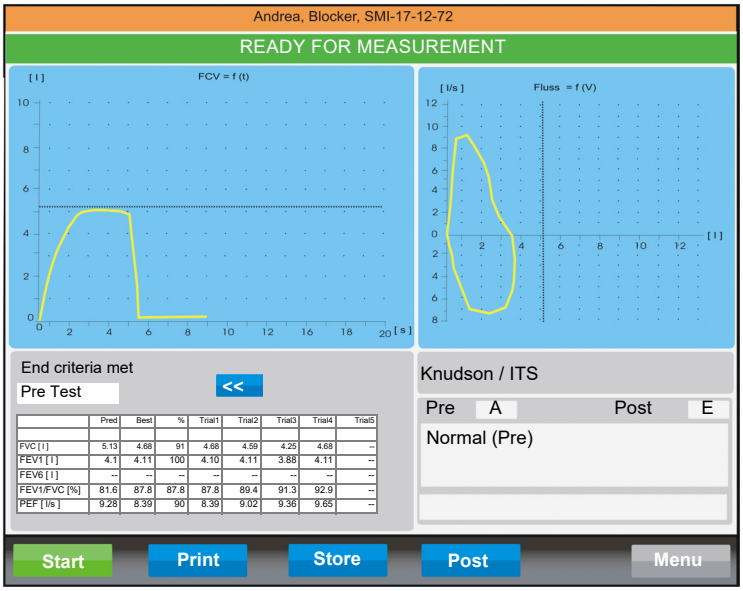
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10.9.1 Procedure



1. Open the spirometry screen. Press the **Menu** key and select **Spirometry**.
2. Calibrate the sensor (see page 77).
3. Define/change the spirometry settings and/or norm values, if required (see page 86). To do so, press the key **Menu > Settings** in the spirometry start screen.
4. Enter the patient data (see page 29) – the patient name and number are displayed at the top of the screen.
5. Select a test - FVC, SVC or MVV.

For all tests, the procedure is the same:



1. Press **Start**.
   - The flow sensor must be held still and no air should be breathed into the sensor for at least one second before and after the **Start** key is pressed.
   - Patient breathes into the mouthpiece.
   - As soon as the patient starts to breathe into the mouthpiece, the unit begins to record the expiratory flow. The corresponding curve is represented on the display. The break-off point for the expiration measurement is reached automatically (or the Stop key is pressed).
2. On completion of the test press the **Stop** key.
   - Once the Stop key is pressed, the curve of the last test taken is displayed in the centre of the screen along with the measurement results, which are displayed on the left of the screen.
3. Repeat as many times as required.

According to ATS/ERS criteria, the test needs to be performed at least three times.

4. **Store** the test for later review or to perform a post measurement.
5. Proceed as for a post-test, such as described in the following chapter (10.9.2).

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10.9.2 Post medication measurement (post test)

- A **post test** can only be started when a pre-medication test **(pre test)** has been performed and
  - the spirometry screen has not been left
  - no new patient has been registered.

Proceed as follows:

1. Open the spirometry screen.
2. Perform the pre-tests (see chapter 10.9.1)
3. Save the pre-test.
4. After having administered the medication, press the key **Post** in order to perform the same test procedure as for the pre-test.
5. **Save** the pre/post test recording for later printout.



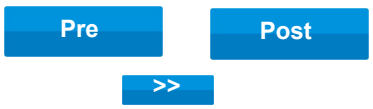
10.9.3 Printing a previously saved spirometry recording

1. Open the spirometry screen.
2. Press **Memory**, select the patient and recording and press **Print** to confirm.

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10.10 Displaying the Results

Following a series of measurements, the best results are stored along with the last test made. The measurements with the largest sum of FVC and FEV1 are saved. These results can be printed in graphical or tabular form.



Use the **Post/Pre** keys to display the corresponding measurement table. The measurement table is displayed, giving the highest measured values from all the tests taken (max. 5) and the predicted values (calculated from the entered patient data).

Use the icon >> to display the hidden values 2 - 5.

End criteria met

Pre Test

	Pred	Best	%	Trial1	Trial2	Trial3	Trial4	Trial5
FVC [l]	5.94	4.95	83	4.48	4.6	4.91	4.85	4.95
FEV1 [l]	4.78	4.58	96	4.16	4.28	4.54	4.5	4.58
FEV6 [l]	--	--	--	--	--	--	--	--
FEV1/FVC [%]	83	92.5	111	92.9	93	92.5	92.8	92.5
PEF [l/s]	10.57	10.99	104	10.43	10.21	10.61	10.70	10.99

End criteria met

Post test

	Pred	Pre	%	Post	%	%CH	Trial1	Trial2	Trial3	Trial4	Trial5
FVC [l]	5.94	4.95	83	4.88	82	-1	4.86	4.68	4.54	4.88	4.51
FEV1 [l]	4.78	4.58	96	3.65	92	-4	4.39	4.12	4.2	4.33	4.13
FEV6 [l]	--	--	--	--	--	--	--	--	--	--	--
FEV1/FVC [%]	83	92.5	111	87.8	108	-3	90.4	88.2	92.4	88.7	91.6
PEF [l/s]	10.57	10.99	104	8.39	94	-10	9.88	9.62	11.03	10.14	10.71

In the column "% (CH)", the difference between Pre and Post values is given in %



It is also possible to view the best results. This is defined in the spirometry settings (see page 86). "Best result" is detailed later in this section (see page 85).

In addition to the result table, the following information is displayed:

- message whether or not the performed measurement meets ATS/ERS criteria
- quality levels of pre and post measurements: A, B, C, D, E, F.
  (A means that the end criteria has been met).
- Interpretation

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10.11 Printing out recording data

Print

For the Print key, various printout formats can be defined in the spirometry settings (see page 86).

On the printout, either the **Best** or **All results (**defined in the spirometry settings – see page 86) are given, together with the following information:

- Patient Data
- Norm values as defined
- Date of the last calibration.
- Date and time of printout
- Software version
- PEF
- End criteria met / not met
- Quality level

and a combination of the following values, if activated in the settings:

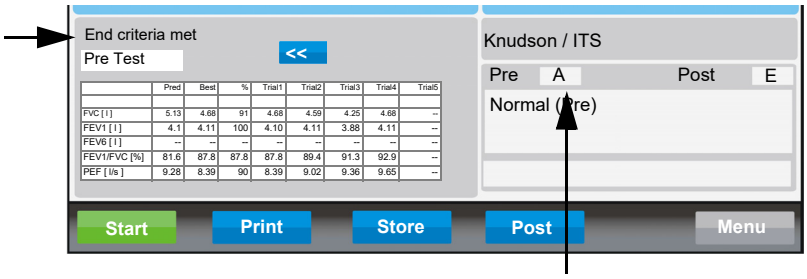
- FVC graph
- Flow graph
- Diagnosis

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10.12 Criteria according to ATS/ERS 2005

10.12.1 Display of the criteria

The criteria are continuously displayed during the recording.



10.12.2 Definition of criteria and quality levels

Level	Message	Criteria
A	End criteria met	• At least **3** acceptable tests (when age < 6: 2 acceptable tests) and • the difference between the two best FEV1 & FVC values is less than or equal to **100** ml (8**0** ml for FVC <1.0 l; when age < 6: **80** ml or **8** % of FVC)
B	End criteria not met	• At least **3** acceptable tests (when age < 6: 2 acceptable tests) and • the difference between the two best FEV1 & FVC values is less than or equal to **150** ml (**100** ml for FVC <1.0 l; when age < 6: **100** ml or **10** % of FVC)
C	End criteria not met	• At least **2** acceptable tests and • the difference between the two best FEV1 & FVC values is less than or equal to **200** ml (**150** ml for FVC <1.0 l; when age < 6: **150** ml or **15** % of FVC)
D	End criteria not met	• At least **2** acceptable tests but results are not reproducible, or • only one acceptable test **Message:** • Results not reproducible, or • only one acceptable test
E	End criteria not met	• Only **1** acceptable test and results are not reproducible **Message:** • Results not reproducible, or • only one acceptable test
F	End criteria not met	No acceptable test available

The message **End criteria met** is only displayed when quality level **A** has been achieved.

These results are in accordance with ATS/ERS 2005 recommendations. When subsequent tests are made, the result with the highest value is saved and given in the measurement columns.

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10.13 Best result and predicted values

10.13.1 Definition of Best

In accordance with the American Thoracic Society (ATS) Spirometry Standard (March 1987), the best measurement is defined as the highest value from the calculation:

largest sum of FVC + FEV1 (or FEV6)

Trial1 The MS-2010/2015 selects the best test, which is the test with the largest sum of FVC and FEV1 (as recommended by ATS and ERS).

Best When **Best** is selected in the menu Report type (see next page), the highest FVC (or FEV6) and FEV1 value of all valid tests is displayed (unless all tests are invalid). All other parameters are taken from the best test, defined by the largest sum of FVC and FEV1.

10.13.2 Predicted Values

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

The norm values are defined in the spirometry settings (see next page).

Ethnic influences on predicted values

The predicted values can vary depending on the following factors:

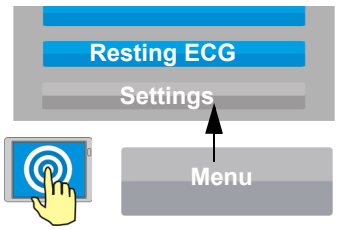
- Selected language on the unit
- Selected standard
- Patient's ethnicity

The influence of these factors is described later in this section (see page 120).

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10.14 Spirometry settings

All changed settings are remembered until the unit is switched off. If you want to save the settings as defaults, proceed as described in section 11.2 page 90.



➜ To define the spirometry settings, press the key **Menu Settings** (when in the spirometry screen). The following menus are displayed:

- Device
- Printout

10.14.1 Spirometry settings Device

Norm Values

Select between:

- Nhanes III (Hankinson)
- Knudson / ITS
- Knudson 76/ ITS
- Crapo / ITS
- Morris / ITS
- Polgar/ITS
- ECCS / Quanjer
- Forche 97 (Austria)
- Berglund
- Finland

An overview of the norm values is given later in this user guide.

MVV pred

Select between:

- Normals: the predicted MVV value is calculated based on the selected norm values.
- 25 * FEV1: the predicted MVV value is 25 times the predicted value for FEV1 (calculated based on the selected norm values).
- 35 * FEV1: the predicted MVV value is 35 times the predicted value for FEV1 (calculated based on the selected norm values).

Report Type

This defines the measurement on which the interpretation is to be based. When **Meas1** is set, the interpretation is based on the measured values when FVC + FEV1 is the maximum value. When **Best** is selected, the values are again defined from the FVC + FEV1 formula above with the exception that when the FVC or FEV1 value is higher in either Meas 2 or Meas 3, the highest FVC or FEV1 value is taken from Meas 2 or Meas 3. The highest value is taken (from the three measurements).

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Standard	Select between **International and American/ITS**. When American/ITS is selected, the result is displayed according to ATS recommendations and the message given on the printout ("ATS criteria met" or "> 200 ml" (ATS criteria not met)) depends on the difference between best and second best measurement (according to American Thoracic Society).
PEF unit	Peak expiratory flow in **litres/minute** or **litres/second**. This setting is also applies to the printout.

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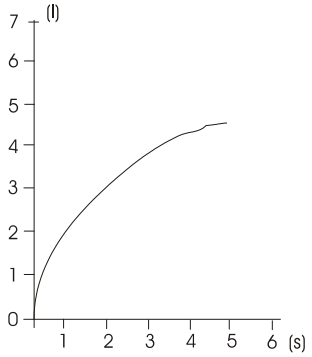
10.14.2 Spiro settings - Printout

These settings define the format and content for printouts obtained by pressing the **Print** key

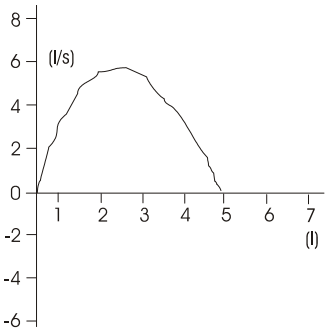
The following settings can be defined:

Format Printout of the **Best** or **All** measurements.

FVC graph Print (**Yes**) or do not print (**No**).



Flow graph Print (**Yes**) or do not print (**No**).



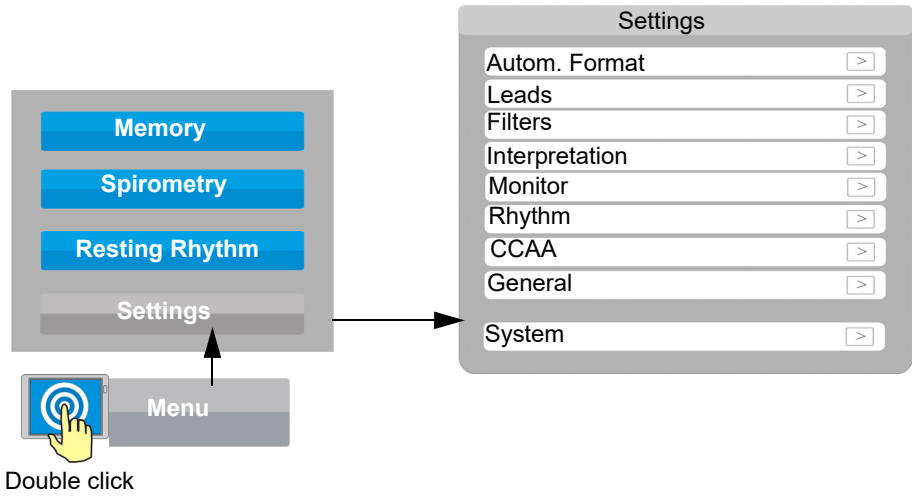
Diagnosis Print (**Yes**) or do not print (**No**) the diagnosis.

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11 General and system settings

11.1 System settings

By pressing **Menu > Settings** (double click on Menu), the settings options are displayed. Further settings and options can be selected in the menus. The following table gives an overview of all the menus and settings available.



11.1.1 Saving and restoring settings

Save as default All changed settings are remembered until the unit is switched off. If you wish to save the settings as default, **Menu > Settings > System > Software** must be entered and the Save as default key pressed before the unit is switched off.

Restore default If you wish to abolish settings that you have changed without switching off the device, select **Restore default**.

Factory default Select this setting to restore the factory defaults. To save the factory settings as default, select **Save as default.**

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11.2 System settings

Parameter	Options	Description
Identification	Device ID	This function is used to register the name and identity of the unit (e.g. department, section, etc.) and is printed on each automatic printout. It can be up to 20 characters long. This also identifies the device in a system when requesting a worklist from SEMA (see page 95).
	MTA	This function is used to register the name of the medical assistant or doctor carrying out the recording. The MTA is printed on each automatic printout. The maximum number of characters is 20.
Properties	Language	Select required language: German, English, French, Swedish, American, Italian, Spanish, Portuguese, Finnish, Swedish, Danish, Norwegian, Polski, Slovak, Slovenian, Russian, Czech, Croatian and Serbian. Note that for English and American, some of the designations used on the display and printout are different. For example, American uses the V1-V6 lead designation and the heart rate unit is BPM. Additionally, ethnic, predicted values and norm equations can be different with more options when American is selected. When the language is changed, this needs to be saved (see previous page) and the device needs to be switched off and then on again to save the setting.
	Volume	Select between **Low, Middle** or **Loud**. This sets the volume for system beeps, QRS beeps, etc. The volume must be confirmed as default as follows: Set the volume. Open **Menu > Settings > System > Software** and select **Save as default.** Exit the menu. Switch the unit off and then on again to confirm.
	Keypad	Select the keyboard type: QWERTZ/QWERTY/AZERTY/QWERTZ/QWERTY/AZERTY/Russian/QWERTYDN (å, æ, ø)/QWERTY-FS (å, ä, ö)/QWERTY (Central Easterner European languages). This is selected automatically when the language is set.
	Caps lock	Select between **On and Off**. If On is set, Caps lock is activated.
Configuration	Patient data query (PDQ)	Select **Patient ID** or **Visit ID.** This determines the patient field that must be entered to enable PDQ (patient data query). This can be entered via the keyboard or via a barcode reader (see page 33).
	Database access	Select between **Off, Manual** or **Automatic**. Off means that PDQ is disabled, Manual means that patient data is imported when the **Get Data key** is pressed, and Automatic means that the patient data is imported as soon as the Pat ID / Visit ID is entered.
	Startup	Select **Resting ECG or Worklist.** Determine which screen is shown when the device is switched on.
	Operating mode	**Normal or Connectivity.** Select Connectivity to display the button **Emergency ECG** in addition to the buttons **Worklist and PDQ** in the main view to skip MTA and/or Patient ID prompts.
	Prompt for MTA id	**Off / On (cached)** or **On (cleared)**. **On** activates the MTA dialogue when new patient data is entered. On (cached): previously entered MTA ID is saved and displayed again. On (cleared): previously entered MTA ID is deleted and new MTA ID needs to be entered (or re-entered).
	PDF export	Off/USB printer/USB stick. Printout to printer only works with special PDF printers! *(only resting ECG or resting rhythm)*
Communication	Interface	Select the interface used: Ethernet/WLAN or GSM

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Parameter	Options	Description
	Com type	Definition of the encryption or data compression (see page 92).
	Server	Definition of the server parameters (see page 92)
	TCP/IP settings	Definition of the IP address, net mask and Gateway parameters (see page 92).
	WLAN	Definition of the WLAN parameters (IP address/Net Mask/Gateway) (see page 93).
	GSM	Definition of the WLAN parameters (IP address/Net Mask/Gateway) (see page 94).
	Info	The current TCP/IP parameters are retrieved.
Memory	Autom. erase after transmission	On/Off. Data can be deleted automatically after transmission via Ethernet/ WLAN or GSM.
Date & Time	Set date	Set the date.
	Set time	Set the time. Daylight savings time is automatically updated via the SCM/SCS server. Select On for “Server time” to automatically update the time.
	Date format	Set the date format.
	Time format	Set the time format.
	Server time	Synchronisation with the server time
Units	Length	Units available are **cm** and **inch**.
	Weight	Units available are **kg** and **lb**
	Temperature unit	**Celsius** or **Fahrenheit**.
Info	Software version SW V1.00 Ctwa	Current software version of the CARDIOVIT MS-2010/2015 or MS-2015. Also displayed is the serial number of the unit and any options that are installed as follows: Base configuration (upper case) M = Measurements (Standard) C = interpretation T = thrombolysis W= worklist a= CCAA for example, "Cw" is a C unit with interpretation and worklist.
Software	Save as default	Save the current settings as default.
	Restore default	The current settings are reset to the saved default settings.
	Factory default	Restore the factory default settings

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Parameter	Options	Description
	Service	• Screen calibration (for more details see page 106) • SW upgrade • SW update (for service only) • Battery (information about the battery status) – Total energy = possible energy: 7500 -8800 – Remaining energy = charging status in % (100 % = Max. capacity) – Operation state = charge state • Usage – Erase entire memory (all ECGs and the entire worklist are deleted) – Erase worklist (the entire worklist and all corresponding ECGs are deleted) – Erase rhythm – Printer burn in (0...11). Setting for the thermal printer's darkness. Standard setting: 8. – SEMA 3 On/Off. Must be set to on to transmit all 5 Spiro measurement. – Hold GSM connection On/Off – Password On/Off (password prompt for the Settings menu) ms20xx – PM detection at start-up (On = Yes, Off = No) see Section 3.6 Patient data, page 29. • Test (service only)

11.2.1 Com type

Com type	Options	Description
Com type	---	No encryption and data compression selected.
	SSH+ZIP	Encryption and data compression
	ZIP	Only data compression
	SSH	Only encryption

11.2.2 Server - communication parameters

Server	Setting	Description
Server	192.016.040.001:8080	IP address and port of the server.
Page	/SCS/SCSServlet	Storage address at the server
User name	User name	User name (server)
Password	Password	Password (server)

11.2.3 TCP/IP settings (Ethernet)

TCP/IP	Setting	Description
IP address	0.0.0.0.	Identifier address of the device in the TCP/IP network. If 0.0.0.0 is set, the IP address will be set by the DHCP server.
Net mask	255.255.255.0	Subnet mask
Gateway	192.016.040.254	Gateway IP address. If you do not have a gateway, use the defined IP address.

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11.2.4 Defining WLAN

If you have the WLAN option, enter the name of the network and the password to access the network, as well as the encryption type as follows:

WLAN	Setting	Description
IP address	0.0.0.0.	Identifier address of the device in the TCP/IP network. If 0.0.0.0 is set, the IP address will be set by the DHCP server.
Net mask	255.255.255.0	Subnet mask
Gateway	192.016.040.254	Gateway IP address. If you do not have a gateway, use the defined IP address.
SSID	WLAN_XXX	Network name
Key	xxxxxxxxx.....up to 64 characters	Network key. (Only use safe keys with a combination of letters, numbers and special characters and the max. amount of 64 characters)
User name	wl user name	User name of the WLAN
Password	xxxxxxxxxxxx.....	
ID	[1]Off [2]WEP (shared key) WPA/WPA2 Pers WPA/WPA2 Enterp.	Selection of the encryption protocol **W**ired **E**quivalent **P**rivacy **W**i-Fi **P**rotected **A**ccess (TKIP) or **W**i-Fi **P**rotected **A**ccess 2 (AES)
Encryption	TKIP AES	Temporal Key Integrity Protocol =WPA Advanced Encryption Standard = WPA2
Authentication	[3]LEAP PEAP	LEAP = Lightweight Extensible Authentication Protocol. PEAP = Protected Extensible Authentication Protocol (EAP+TLS). PEAP can only be used with the corresponding authentication service (e.g. Radius server). According to IEEE 802.1X.

1. We strongly recommend to never use the MS-2010/2015 in an open network.
2. If possible, do not use this dated standard.
3. Not implemented at time of print.

Code (protocol used)	Information on the corresponding protocol
Off	SSID (open network!)
WEP (shared key)	SSID + key (open network!)
WPA Personal	SSID + key + encryption TKIP + authentication
WPA Enterprise	SSID + user name + password + encryption TKIP + authentication
WPA2 Personal	SSID + key + (encryption = AES+ authentication)
WPA2 Enterprise	SSID + user name + password + encryption AES + authentication

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11.2.5 GSM

Parameter	Dial-up (CSD)	GPRS
Phone number	E.g.: 0041 345 45 34	E.g.: gprs.swisscom.ch
User name	User name for dial-up	User name entry (Server)
Password	Password	Password (Server)

Contact your system administrator for details of the network setup. Typical setups are given in the SCHILLER Communication Handbook (Art. No. 2.520036).

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12 Transmission - Overview

12.1 Transmission Options

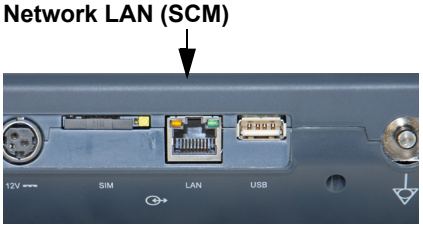
Transmission is possible over a network or telephone system when the optional **SCHILLER Communication Module (SCM)** is installed. Wireless transmission is possible when the optional WLAN module is installed. Direct transmission to another device is possible using the RS-232 interface. The transmission options are as follows:

- When the unit is part of a network, (LAN, WLAN, HIS, etc.), transmitting over a telephone network or any other transmission/reception medium, or if exposed to the Internet or other insecure networks, appropriate security measures must be taken to protect the stored patient data.
- Patient data security is the sole responsibility of the user.

WARNING

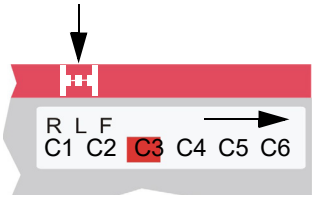
- When a non-medical device is connected to the interface, ensure that both units are securely connected to the same earth potential.
- When operating the unit on battery and simultaneously using non-medical devices, the interface must be fully isolated.
- An external device must only be connected using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

Network LAN (SCM)



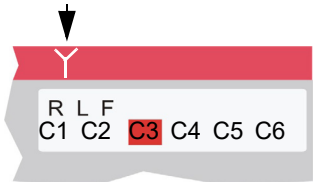
CARDIOVIT MS-2010/2015 to / from SEMA using an (Ethernet) wired LAN. For an Ethernet (network) connection, connect the cable assembly to the RJ-45 connector.

Wireless LAN (SCM with optional WLAN module)



CARDIOVIT MS-2010/2015 to / from SEMA (and HIS) via WLAN.

GSM



Transmission to SEMA via GSM.

To retrieve patient data queries and worklists from SEMA, the SCHILLER Communication Server (SCS) is required. A more detailed description of the transmission settings are given in the SCHILLER Communication Handbook.

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12.1.1 Automatic transmission

The automatic transmission setting is defined in Settings:

Menu > Settings > General > Autom. transmission (On/Off - see page 52).

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

12.1.2 Manual transmission

To transmit a recording, select the recording in the menu **Memory** and press **Send** (see page page 64)

12.1.3 Receiving data from SEMA

Patient data can be received from a Schiller Communication Server (SCS) and automatically entered on the CARDIOVIT MS-2010/2015. This is called patient data query (PDQ). To do this, the patient ID is entered in the patient data screen manually or via a barcode reader (see page 33).

- Transmission over the telephone system requires a modem - the internal modem option (in the SCHILLER Communications Module (SCM) option) must be installed.
- For PDQ, the SCS must be installed on the remote system.
- The Baud rate, telephone number, interface definition, TCP/IP addresses, etc., and all other communication settings are defined in System settings (see page 92).
- A communication overview is given in the SCHILLER Communication Handbook (Art. No. 2.520036).

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12.2 Error messages concerning the transmission

The following error messages might be displayed when working with the memory. The messages are displayed in the information box.

Message	Additional information
Error in SCM setup	• Check the system settings (see page 90).
Error at network interface	• Check the network settings (see page 90). • Check the network connection.
Transmission error	• General error message (check the signal strength, approx. 3 bars)
No network connection	• General error
Server rejected request	• General error
SSH server not available	• Check the encryption settings and the server
SSH server key not valid	• Check the system settings (see page 90).
SSH server time-out	• Check the system settings (see page 90).
No answer from server	• Check the network settings (see page 90). • Check the network connection.
Server response not valid	• Check the network settings (see page 90). • Check the network connection.
Server time-out	• Check the network settings (see page 90). • Check the network connection.
Server response: no data	General error
HTTP error xxx	General error code for service personnel. If this message is displayed for a longer period of time, contact the SCHILLER service department.
No file available	
No barcode scanner available	• Check if a barcode scanner is connected • Check the system settings (see page 90).
Undefined error	General error
Unknown server error	General error
Modem rejected config.	General error

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Message	Additional information
Network connection time-out	• Check the network settings (see page 92). • Check the network connection.
No physical network link	Check the network connection.
Error modem config.	General error
No GSM module available	
Invalid file	
Error while printing report	General error Check the system settings (see page 92).
WLAN connection failed	Check the system settings (see page 92).
No WLAN information available	Check the system settings (see page 92).
No WLAN module available	Check the system settings (see page 92).
SCS error	General error

In addition to these error messages, some error messages are issued directly by the SCHILLER Communication Server (SCS). These messages are detailed in the SCHILLER Communication Handbook.

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13 Maintenance

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

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

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

Interval	Maintenance step	Responsible
Before each use	• Visual inspection of the device and ECG electrodes	➜ User
Every 6 months	• Visual inspection of the device (see page 105, 13.6 Inspection Report) – Touch screen test – Cables and accessories – Power supply unit • Functional tests according to the instructions (see page 105, 13.6 Inspection Report)	➜ User
Every 12 months	• Battery capacity test according to section 13.5.2	➜ User
Every 12 months	• Safety test according to IEC/EN 62353 incl. visual inspection of the battery.	➜ SCHILLER AG authorised technician
Every 24 months	• Replacement of the battery, regardless of its capacity	➜ SCHILLER AG authorised technician

13.1 Visual Inspection

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

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

In addition to the visual inspection, switch on the CARDIOVIT MS-2010/2015, toggle through the menu and check some functions randomly. In this way, you can check that:

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

WARNING

▲ Defective units or damaged cables must be replaced immediately.

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13.2 Cleaning the casing and cables

⚠WARNING

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

⚠WARNING

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

⚠ CAUTION

▲ Do not autoclave the device and accessories.

▲ Do not immerse the unit in liquid.

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

▲ Always follow the 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.

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

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

Before cleaning the unit or any accessories, thoroughly inspect them.

- Look for any signs of damage and any improper mechanical function of buttons or connectors.
- Gently bend and flex cables, inspecting them for damage or extreme wear, exposed wires, or bent connectors.
- Confirm that all connectors engage securely.

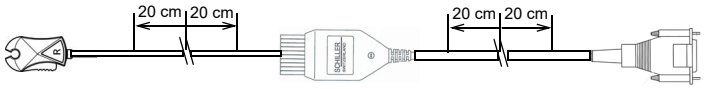
The casing of the CARDIOVIT MS-2010/2015 and the cable assemblies can be cleaned with a cloth slightly moistened (not wet) on the surface only. If necessary, a domestic non-caustic cleaner or a 70% alcohol solution can be used to remove grease and finger prints. Wipe the equipment with a cloth slightly moistened (not wet) with one of the approved cleaning solutions listed below.

Thoroughly 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 and then check the equipment to confirm that it operates properly.

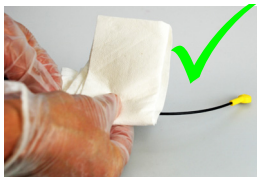
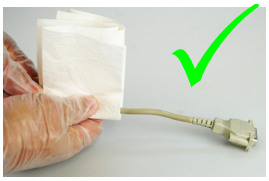
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13.2.1 Cleaning the cable assembly

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



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


13.2.2 Approved cleaning solutions

- 70 % isopropyl alcohol
- neutral, mild detergent
- all products designed for cleaning plastic.

13.2.3 Non-admissible detergents

Never use products containing the following:

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

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13.3 Disinfection

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

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

13.3.1 Admissible disinfectants

- Isopropyl alcohol 70%
- Propanol (70-80 %)
- Ethyl hexanal
- Aldehyde (2-4 %)
- Ethanol (70-80 %)
- All products that are suitable for ABS plastic

13.3.2 Non-admissible disinfectants

Never use products containing the following:

- Organic solvents
- Ammonia-based detergent
- Abrasive cleaning agents
- 100% alcohol, Virex, Sani-Master
- Sani-Cloth®, Ascepti® or Clorox® wipes
- HB Quat®
- Conventional cleaner (e.g. Fantastic®, Tilex® etc.)
- Conductive solution
- Solutions or products containing the following ingredients:
  - Acetone
  - Ammonium chloride
  - Betadine
  - Chlorine, wax or wax compound
  - Ketone
  - Sodium salt

13.4 Cleaning the Thermal Print Head

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

Open the paper tray and remove the paper. The thermal print head is located underneath the paper tray. With a tissue dampened in alcohol, gently rub the printhead to remove the ink residue. If the print head is badly soiled, the colour of the paper grid ink (i.e. red or green) will show on the tissue.

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13.5 Battery Maintenance

- Check the battery capacity every 12 months.

➜ The battery needs to be replaced if the running time for the:
  – MS-2010 is approx. 2 hours or less
  – MS-2015 is approx. 1 1/2 hours or less

- Regardless of its capacity, the battery needs to be replaced after 2 years.
- Storage and operation conditions outside the temperature range of 15-25 °C will reduce the service life of the battery!
- Make sure that the battery remains charged during storage. If the device is not used for more than 3 to 4 months, the battery needs to be protected from deep discharge by recharging it; the ideal capacity is 50-80%. If a fully charged battery is stored for a long period of time, this may reduce its service life.

13.5.1 Charging the battery

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

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

1. Connect the device to the mains supply.
2. The symbol (~) is displayed. After 15 seconds, the symbol switches to "Charging the battery" ( ).
3. Charge the battery for at least 3 hours.

13.5.2 Battery capacity test

⚠ CAUTION

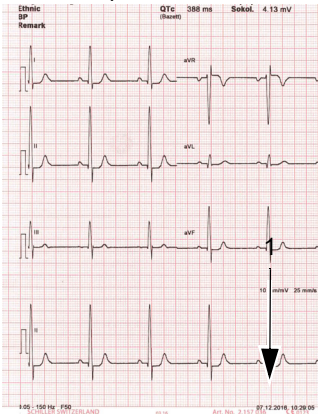
▲ The battery needs to be replaced by authorised service personnel if the running time of a charged battery is:
  – MS-2010 - 2 hours or less
  – MS-2015 - 1 1/2 hours or less.

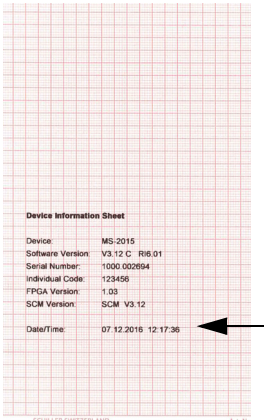
To check the battery capacity, proceed as follows:

1. Leave unit connected to the mains to fully charge the battery.
2. Open **Menu > Settings > System > Software > Service**, select **Battery** and check that the parameter **Remaining capacity** shows 100%.
3. Exit the battery menu and select menu **Test**.
4. Disconnect the mains supply to the unit.
5. Select parameter **Long-time print test** “OFF/ON” to start the capacity test.
6. A printout will be initiated and then a printout will be given every hour.
7. The time of each printout is given on the bottom of the printout **(1)**. The final printout gives the time where the battery capacity was at 30% **(2)**.

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8. Use the first and the last printout time to calculate the running time. If the running time falls below the limit stated above, have the battery replaced by authorized service personnel.





➜ The test can be stopped any time by exiting the menu or selecting **Long-time print test** “OFF/ON”.

13.5.3 Battery disposal



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

WARNING

▲ Danger of explosion! The battery must not be burned or disposed of in domestic rubbish.

▲ Danger of acid burns! Do not open the battery.

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13.6 Inspection Report

▲ The user guide, especially chapter 13, must be read before the inspection.
▲ **Recommended inspection interval:** Every 6/12 months

Serial no.: _____

Test	Results	Date				
Visual inspection 13.1	• Casing not damaged	r	r	r	r	r
➜ External condition						
	• Electrode connector port not damaged	r	r	r	r	r
➜ Availability and condition of accessories	• ECG Electrodes (expiration date and compatibility)	r	r	r	r	r
	• User Guide	r	r	r	r	r
	• Mains and patient cable	r	r	r	r	r
Functional test 2.3	• No error message shown in the standard display	r	r	r	r	r
➜ ECG test						
➜ Touch screen test	• Touch screen is working	r	r	r	r	r
➜ Battery capacity	Battery OK	r	r	r	r	r
Battery capacity test	Battery capacity OK	r	r	r	r	r
➜ Test according to section 13.5.2						
Remarks						
➜ Recurrent test conducted (every 12 months)			r		r	
Inspection carried out by:						

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

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

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13.6.1 Every Twelve Months

Inspection	Results	Inspection				
Battery Capacity Test ➜ Test according to section 13.5.2	➜ Replace the internal battery if the battery running time is less than: – MS-2010 - 2 hours – MS-2015 - 1.5 hours	❒	❒	❒	❒	❒
Safety Checks and Inspections ➜ Safety test according to IEC/EN 62353 incl. visual inspection of the battery.	• Return the unit to your nearest authorised SCHILLER agent.	❒	❒	❒	❒	❒
	Date of inspection:					
	Inspector:					

13.6.2 Lifed-item Replacement Every 2 Years

Inspection	Results	Replacement				
Internal Battery ➜ Replace the internal battery every two years (regardless of capacity).	• Unit sent to SCHILLER service centre for battery replacement.	❒	❒	❒	❒	❒
	Date of replacement:					
	Inspector:					

13.7 Screen Calibration

The screen is factory calibrated. Recalibration should not be necessary.

However, if the screen reacts inaccurately, it can be calibrated as follows:

1. Open the **Menu > Settings > System > Software > Service > Screen calibration.**
2. Follow the instructions and touch the crosses that are displayed on the screen.
3. If the calibration was within tolerance, the values are saved and you can exit the menu by pressing **Back**.

If you make an error, the calibration starts over again.

The screen calibration can also be accessed as follows:

➜ Press the On/Off key quickly 5 times, then press and hold the key a sixth time until the calibration screen is displayed.

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14 Trouble Shooting

14.1 Possible problems

Error	Possible causes and indicators	Error localisation and troubleshooting
Unit does not switch on; blank screen	• No mains supply; green mains indicator on the power supply unit is off.	→ Check the power supply unit and fuses. → If the mains indicator is lit, it indicates that power is reaching the unit and the internal power supply should be OK. Press and hold the On/Off key for 5 seconds. Wait a few seconds and switch the device on again.
	• Mains supply OK, but the indicator ~ is still not lit.	→ Check / change the battery. If the battery is faulty, it is possible that the unit cannot be switched on even if the mains supply is connected. → If the screen is still not lit, it indicates a software fault, monitor problem or internal power supply. Call your local SCHILLER representative.
QRS traces overlap	• Incorrect settings for patient.	→ Change sensitivity setting. → Ensure that the automatic sensitivity reduction is not switched off.
	• Bad electrode contact.	→ Check electrode contact and reposition the electrodes. → If the problem persists, call your local SCHILLER representative. → Note: Some patients have very high amplitudes and even on the lowest sensitivity settings, the QRS traces can overlap.
"Noisy" traces	• High resistance between skin and electrodes	→ Check the electrode contact (screen Lead test). Resistance readings should be ±200 mV. → Re-apply electrodes.
	• Patient not relaxed	→ Ensure that the patient is warm and relaxed.
	• Incorrect settings	→ Check all filter settings (**Menu > Settings > Filter**). → Activate the myogram filter and change the cut-off frequency. → Ensure mains filter is correct for mains supply. → If the problem persists, call your local SCHILLER representative.
No printout obtained after an auto mode recording	• No paper.	→ Ensure that paper is loaded.
	• Paper incorrectly loaded.	→ Reload Paper.
	• Paper jam.	→ Ensure that the paper has been installed correctly with the paper mark at the top.
	• Incorrect settings	→ Check Settings - ensure that at least one item is selected for print after an auto ECG is recorded.
	• Battery operation with less than 30% capacity: no printout possible	→ Connect the device to the mains and charge the battery → If the printer still doesn't work: Call your local SCHILLER representative.
Printout fades, is not clear or the printout is 'patchy'.	• Old paper inserted.	→ Ensure that new SCHILLER paper is inserted. → Note that the CARDIOVIT MS-2010/2015 thermal paper is heat- and light-sensitive. If it is not stored in its original seal, stored in high temperatures or is simply old, print quality can deteriorate. → Over a period of time, the printing ink from the grid on the paper can form a film on the thermal print head. Clean the thermal print head.
	• Dirty print head	→ Adjust the printhead according to the CARDIOVIT MS-2010/2015 service handbook.
	• Print-head out of adjustment.	→ If the problem persists, call your local SCHILLER representative.

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Error	Possible causes and indicators	Error localisation and troubleshooting
No printout of interpretation statement, average cycles or measurements	• Incorrect settings	➜ Check that the interpretation and measurement options are enabled for the printout and that the lead sequence is set to Normal. (see page 43 section 5, page 53 section 5.5.1 and page 55 section 5.5.4.
No final printout after an exercise test	• Incorrect settings	➜ Check that the final report is activated.
Battery load indicator seems inaccurate.	• Battery recharge circuit inaccurate	➜ Disconnect the mains and leave the unit on until it switches off. ➜ Reconnect the mains and leave for 8 hours (with the unit switched off) to fully charge the battery (and reset the charge circuit).
Battery almost empty	• Battery recharge cycle not optimal - when a battery is not fully charged, it may loose capacity • Old or defective battery	➜ Disconnect the mains and leave the unit on until it switches off. ➜ Reconnect the mains and leave for 8 hours (with the unit switched off) to fully charge the battery (and reset the charge circuit). ➜ Repeat the full discharge, full charge cycle twice. ➜ Replace battery.
Touch screen is blocked	• Software hangs up	➜ Switch off and on again after a few seconds. ➜ Press and hold the On/Off button for 10 seconds to force the device to switch off. Reconnect mains and switch on. ➜ If the problem persists, call your local SCHILLER representative.
Memory full	• The ECG recording cannot be stored because the memory is full.	➜ Delete old ECG recordings, see page 63.
Only 3 Spiro measurement are transmitted to SEMA	• Wrong Setting	➜ Set **Menu > Settings > System > Service> Usage >SEMA3 to ON**.

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14.2 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 CARDIOVIT MS-2010/2015. The distance of 0.3 m depends on the output performance/frequency of the communication device as indicated below.

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

⚠ CAUTION

- ▲ **Portable** HF telecommunication devices must not be used within a radius of 0.3 m from the CARDIOVIT MS-2010/2015 and its cables.
- ▲ Do not place the CARDIOVIT MS-2010/2015 on top of other electric/electronic devices - i.e. maintain a sufficient distance to other devices (this includes the patient cables).

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

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

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

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14.3 Accessories and disposables

WARNING

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

Your local representative stocks all the disposables and accessories available for the CARDIOVIT MS-2010/2015. A full list of all SCHILLER representatives can be found on the SCHILLER website (www.schiller.ch). In case of difficulty, contact our head office in Switzerland. Our staff will be pleased to help process your order or to provide details for all SCHILLER products.

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15 Technical Data

15.1 System

Dimensions	**MS-2010**: 258 x 193 x 50 mm, approx. 1.5 kg including thermal paper **MS-2015**: 359 x 282 x 58 mm, approx. 3.3 kg including thermal paper
Display	• Backlit LCD screen for graphic and alphanumeric representation • MS-2010 resolution: 800 x 600 dots, 10.4 “ • MS-2015 resolution: 1042 x 768 dots, 15 “
Power supply device	12 VDC 28 VA
Power supply: • **External power supply unit**	Medical grade switching power supply, protection class I *(Note: because the protective earth (PE) ends in the power supply, the protective earth test does not need to be performed.)*
Input Output	• 100 - 240 VAC, max. 1.0 A (100 V) - 0.6 A (240V), 50-60 Hz • 12 VDC, max. 2.5 A
• **Battery**	Operation with built-in rechargeable battery
Battery	Lithium-Ion 7.2V, 39.2 Wh, 5.4 Ah
Capacity	• **MS-2010** 3 hours of normal operation without printing • **MS-2015** 2 hours of normal operation without printing
Battery life	• Under normal operating conditions, 2 years
Charging time	• 100%: approx. 3 hours when the device is switched off
Printer	High-resolution thermal head printer; 8 dots/mm (amplitude axis); 16 dots/mm (time axis) @ 25 mm/s
Frequency range	• in accordance with ANSI/AAMI/IEC 60601-2-25
Chart paper	• MS-2010: thermo-reactive, Z-fold, 114 mm wide, optimal positioning on 105 mm • MS-2015: thermo-reactive, Z-fold, 21 x 29.7 cm (DIN A4; letter size), optimal positioning on 200 mm;
Chart speed	• 5/12.5/ 25/ 50 mm/s (5 mm/s only available for manual ECG printouts) • 6.5 mm/s (RRECG printouts)
Sensitivity	• 5 /10 / 20 mm/mV (manual printout), automatic baseline adjustment • 2.5 /5 mm/mV (RRECG printouts)
Interfaces	**MS-2010/2015** • RS-232 interface for spirometry sensor • ECG cable connection • Potential equalisation • Network connection • USB **MS-2015** • DC input (not used) • DC output (not used)
Memory	Memory for up to 350 ECG recordings or 320 ECG and 30 rhythm recordings

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

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15.2 ECG

Patient input	Fully floating and isolated, defibrillation protected (only with original SCHILLER patient cable)
Leads	• 12 simultaneous leads • Standard • Cabrera **MS-2015** • 16 simultaneous channels with 14-lead patient cable
Monitor	
Leads	• 3- to 12-channel display of the selected leads – selectable speed: 12.5, 25 or 50 mm/s – selectable amplitude: 5, 10 or 20 mm/mV
Status	• Filter status (on/off) • Power source • Leads • Electrode contact status • Heart rate (HR) • Date and time • Patient name and number
Filters	
Myogram filter (muscle tremor)	Adjustable at 25 or 35 Hz
Mains filter	Distortion-free suppression of superimposed 50 or 60 Hz sinusoidal interferences by means of adaptive digital filtering
SSF	SSF (SCHILLER Smoothing Filter)
SBS	SBS (SCHILLER Baseline Stabilizer)
Automatic lead programs	3-/12-channel presentation of 12 simultaneously recorded leads
Data record	• Patient data (name, age, height, weight, BP), Device ID, MTA ID • Listing of all ECG recording conditions (date, time, filter)
With optional interpretation (C) program	• ECG measurement results (intervals, amplitudes, electrical axes) • Average complexes with optional measurement reference markings • Guidance on interpreting adult and paediatric ECGs
ECG amplifier	Simultaneous recording of all 9/15 active electrode signals (= 12/16 channels)
technical data	• in accordance with ANSI/AAMI/IEC 60601-2-25

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15.3 Spirometry

SP-250 Sensor	
Measurement method	• Pneumotachometer
Flow impedance	• < 0.5 mbar / (l/s) at 6 l/s
Sensor mouthpiece	• Disposible, single patient use
SP-260 Sensor	
Measurement method	• Pneumotachometer
Flow impedance	• < 0.5 mbar / (l/s) at 6 l/s
Sensor mouthpiece	• Reusable mouthpiece, with single use filter (can be used for more than one patient when used with the SCHILLER PTF Filter)
SpiroScout SP	
Measurement method	• Ultrasound
Respiratory resistance	• 0.002 kPa/l/s = approx. 0.02 cmH_2O/l/s
Sensor mouthpiece	• ScoutTube: Single patient use, disposable breathing insert ergonomically shaped mouthpiece and standard cone 22 mm
Power supply	• Powered via USB • Other technical details and ambient conditions are detailed in the SpiroScout user guide (SCHILLER Art. No. 2. 511270)
Measurement ranges	Flow: 0 to ± 16 l/s Volume: 0 to ± 15 litres
Measurement accuracy	Flow: ± 5% or 200 mL/s Volume: ± 3% or 50 ml
Temperature drift	Max: ± 2%
Standards compliance	ATS, OSHA, NIOSH

15.4 Safety Standards

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

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15.5 WLAN standards (option)

Modules	**cB-OWS451i-04**
FCC ID **IC ID**	**PVH0941** **5325A-0941**
Transmission standards	**IEEE 802.11 a, b, g, n**
Encryption	Enterprise, WPA2-PSK, WPA-PSK, PEAP, (LEAP), EAP-TLS, WEP64/128
Max. transmitting power	20 dBm
Frequency range	Dual-band 2.4 GHz and 5 GHz

15.6 Telecommunication GSM (option)

Frequency range	Quad band GSM 850/900/1800/1900 MHz
Supported SIM cards	3 and 1.8 V
Data transmission	GPRS class B
Max. transmitting power	2 watts @ 850...900 MHz 1 watt @ 1800...1900 MHz
FCC identification **IC**	QIPMC75I 7830A-MC75I
Directives	• 99/05/EC (CE 0682) • 89/336/EC • 72/23/EC • 2002/95/EC
EU standards	• 3GPP TS 51.010-1 • ETSI EN 301 511 V9.0.2/301 489-1 V1.4.1/301 489-7 V1.2.1 (2000-09) • GCF-CC V3.28 • IEC/EN 90950-1 (2001)
North American standards	• CFR title 47 • UL 60950 • NAPRD 03 V3 V3.1.3 • RSS 133 (Issue2)

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16 Annex - spiro diagnostic tables

16.1 International

The diagnostic interpretation depends on the country. The factors used in the evaluation for diagnosis are automatically included in the respective language software.

The following diagnosis criteria are applicable for all unit language settings apart from "American".

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

Diagnosis	%FVC or %SVC	FEV1%
Normal	80%	>70%
Restrictive	<80%	-
Obstructive	-	<70%
Combined	<80%	<70%

The measurement FEV1/FVC, or FEV1/VC, respectively, is adapted on the screen and on the printout.

The diagnostic settings are selected in the spirometry settings (see previous page).

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

$$\%VC = 100 \times \frac{VC}{VC_{Predicted}}$$

otherwise

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

otherwise

$$FEV1\% = 100 \times \frac{FVC1}{VC} \text{ or } 100 \times \frac{FVC1}{FVC}$$

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16.1.1 American

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

Diagnosis of possible respiratory problems is based on the ITS interpretation standard. These calculations apply to patients between the age of 5 and 85.

When "American" is selected as system language, the following diagnosis criteria are applied:

16.1.2 Categorisation of Airway Obstruction

Predicted value minus measured value (%):

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

- If FEV 0.5/FEV 1 < 0.60, then state:
  Upper airway obstruction suggested
- Result: SVC/FVC >1.10 or FIVC/FVC >1.10, Diagnosis:
  Air trapping may be present
- If obstruction and expiration time < 5 sec, then state:
  Airway Obstruction may be underestimated
- If FEV0.5/FVC < 0.56 sec, then state:
  Poor initial effort suggested

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16.1.3 Chest Restriction Categories

Predicted VC Minus Measured VC (Litres)

Category	Women	Men
Normal	<0.68	< 1.12
Mild Restriction	0.68 to 1.18	1.12 to 1.95
moderate restriction	1.19 to 1.69	1.96 to 2.79
Severe Restriction	≥1.7	≥2.80

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

16.1.4 Ratio of Post/Pre

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

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

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16.2 Measured values

Parameter	Unit	Explanation
FVC	[l]	**Forced** (expiratory) **Vital Capacity.** Volume achieved by the quickest possible exhalation after a maximal inhalation.
FEV0.5, FEV1, FEV3, FEV6	[l]	**Forced Expiratory Volume.** Lung volume in litres, measured after 0.5, 1, 3 or 6 seconds forced expiration.
FEV0.5 / FVC	[%]	Forced expiratory air volume measured in the first half second as a percentage of forced vital capacity.
FEV1/FVC	[%]	Forced expiratory air volume measured in the first second as a percentage of forced vital capacity.
FEV3/FVC	[%]	Forced expiratory air volume measured in the first three seconds as a percentage of forced vital capacity.
FEF	[l/s]	**Forced Expiratory Flow.** Flow in terms of differing lung volumes measured in litres per second.
FEF25 - 75%	[l/s]	Flow speed of the expired air at 25 to 75% of the forced vital capacity (FVC).
FEF75 - 85%	[l/s]	Flow speed of the expired air at 75 to 85% of the forced vital capacity (FVC).
FEF0.2 -1.2	[l/s]	Averaged flow between 0.2 and 1.2 litres of the forced vital capacity (FVC)
PEF	[l/s]	Peak Expiratory Flow.
MEF75%	[l/s]	Flow speed of the expired air at 25% of the forced vital capacity (FVC).
MEF50%	[l/s]	Flow speed of the expired air at 50% of the forced vital capacity (FVC).
MEF25%	[l/s]	Flow speed of the expired air at 75% of the forced vital capacity (FVC).
		MEF75% = FEF25%
		MEF50% = FEF50%
		MEF25% = FEF75%
ERV	[l]	**Expiratory Reserve Volume**. Possible further expiration starting from the normal expiration level.
IRV	[l]	**Inspiratory Reserve Volume.** Possible further inspiration starting from the normal inspiration level.
TV	[l]	**Tidal Volume.** Expiration and inspiration volumes during normal respiration.
SVC	[l]	**Slow Vital Capacity.** Lung volume measured from a complete expiration following a deep inspiration.
MV	[l/min]	**Expired or Minute Ventilation.** Volume of expired air in litres per minute measured over a minimum of one minute.
MVV	[l/min]	**Maximum Voluntary Ventilation.** Maximum volume of air which can be moved on expiration while breathing as deeply and as rapidly as possible.
RR	[l/min]	**Respiration Rate.** Number of breaths per minute.
FIVC	[l]	**Forced Inspiratory Vital Capacity.** Inspiration volume achieved between a maximal expiration and a maximal inspiration.
FIV 1	[l]	Forced inspiratory air volume in litres measured in the first second.
FIV 1 / FIVC	[%]	Forced inspiratory air volume measured in the first second as a percentage of forced inspiratory vital capacity.
FIV1 / FVC	[%]	Forced inspiratory air volume measured in the first second as a percentage of forced expiratory vital capacity.
PIF	[l/s]	**Peak Inspiratory Flow.** Maximum inspiratory flow speed in litres / second.
FIF50% (=MIF50%)	[l/s]	Flow speed by 50% of the forced inspiratory vital capacity.

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16.3 Norm Values

The norm values used for the calculation of predicted values depend on the country:

- In Great Britain, Italy, Spain and Switzerland, the ECCS and Quanjer standards are used.
- In Sweden, the Swedish (Berglund) and Quanjer standards are used.
- In Finland, the Finnish and Quanjer standards are used.
- In Austria. the Austrian standards are used.
- In America and Canada, the norm values that are used are Knudson, Knudson 76, Crapo, Morris and Polgar. The American norm values are extended with values taken from the ITS (Intermountain Thoracic Society) recommendations.

The factors used in the evaluation for diagnosis and the specific norm values are included in the software and are described on the following pages.

Due to great differences in the size of the lungs of children, there are no standard values for children under 6 years of age.

16.3.1 Ethnic influences on predicted values

The predicted values can vary depending on the following factors:

- Selected language on the unit
- Selected standard
- Patient's ethnicity

These factors are described below.

All languages except "American"

For all languages except "American" (see page 89), **White** and **Black** (or None) can be selected. This setting influences the calculated predicted values in the following way:

Setting	Influence
white	The values are calculated according to the given formulas (= 100%)
black	85% of the given formulas

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When language setting "American":

When American language is set in the system settings (page 89), the ethnic setting in the patient data is **Caucasian, Hispanic, Black, Asian or Mexican**. These settings influence the predicted values in the following way (according to Intermountain Thoracic Society (ITS) recommendations):

Caucasian/white: The values are calculated according to the following tables (=100%), except for Nhanes III (Hankinson), for which different formulas are applicable (see page 125).

Black 85% of the calculated values, except for Nhanes III (Hankinson), for which different formulas are applicable (see page 125).

Hispanic The values are calculated according to the given formulas (= 100%)

Asian 85% of the given formulas

Mexican The values are calculated according to the following tables (=100%), except for Nhanes III (Hankinson), for which different formulas are applicable (see page 125).

The ethnics **C** (Caucasian), **H** (Hispanic), **B** (Black), **A** (Asian) and **M** (Mexican) are only available if "American" is selected as system language (see page 89). For all other languages, White (=100%) and Black (=85%) are available.

The ethnic compensation is calculated only when the following norm values are selected:

- Nhanes III
- Knudson
- Crapo
- Morris
- Polgar

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16.4 International norm standards

16.4.1 ECCS

The safety standards of the European Coal and Steel Community Standards (ECCS) are valid for adults of at least 25 years of age. Patients between the ages of 18 and 25 are calculated on the basis of a 25 year old. The calculation equations are as follows:

	Men	Women
SVC	6.103H - 0.028A - 4.654	4.664H - 0.024A - 3.284
FVC	5.757H - 0.026A - 4.345	4.426H - 0.026A - 2.887
FEV1	4.301H - 0.029A - 2.492	3.953H - 0.025A - 2.604
FEV1/SVC	-0.179A + 87.21	-0.192A + 89.10
MEF	1.944H - 0.043A + 2.699	1.252H - 0.034A + 2.924
PEF	6.146H - 0.043A + 0.154	5.50H - 0.030A - 1.106
MEF75	5.459H - 0.029A - 0.470	3.218H - 0.025A + 1.596
MEF 50	3.794H - 0.031A - 0.352	2.450H - 0.025A + 1.156
MEF25	2.605H - 0.026A - 1.336	1.050H - 0.025A + 1.107

H = Height in metres A = Age in years

16.4.2 Quanjer and Tammeling

The Quanjer and Tammeling comparison is valid for children between the ages of 6 and 17 as follows:

	Boys	Girls
SVC = FVC	1.00 $H^{2.7}$	0.95 $H^{2.7}$
FEV1	0.84 $H^{2.7}$	0.81 $H^{2.7}$
FEV1/SVC	0.84	0.84
MEF = PEF	8.2H - 6.8	6.6H - 5.3
MEF 50	5.6H - 4.4	4.6H - 3.3

H = Height in metres

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16.4.3 Forche 97 (Austria)

Boys 5 - 17.99 years (1.09 - 1.96 m)	Males 18 - 91 years (1.44 - 2.00 m)
$\ln(FVC) = -1.142 + 1.259H + 0.004070A \sqrt{W}$	$FVC = - 11.606 + 8.172H - 0.0339A \times 1.2869\ln(A)$
$\ln(FEV1) = -1.178 + 1.221H + 0.003841A \sqrt{W}$	$FEV1 = -8.125 + 6.212H - 0.0300AH + 0.9770\ln(A)$
$\ln(PEF) = -0.214 + 0.921H + 0.0467A + 0.0020W$	$\sqrt{PEF} = 1.798 + 2.311\ln(H) + 0.0159A - 0.000248A^2$
$\ln(PEF75) = -0.077 + 0.770H + 0.0373A + 0.0025W$	$\sqrt{PEF75} = 1.581 + 1.854\ln(H) + 0.0213A - 0.000283A^2$
$\ln(PEF50) = -0.322 + 0.843H + 0.0300A + 0.0035W$	$\sqrt{PEF50} = 1.490 + 1.290\ln(H) + 0.0125A - 0.000218A^2$
$\ln(PEF25) = -1.576 + 1.166H + 0.0219A + 0.0021W$	$\sqrt{PEF25} = 1.314 + 0.898\ln(H) - 0.0083A - 0.000026A^2$
$FEV1/FVC = 101.99 - 1.191H^2 - 3.962\ln(A)$	$FEV1/FVC = 101.99 - 1.191H^2 - 3.962\ln(A)$

Girls 5 - 15.99 years (1.10 - 1.82 m)	Females 16 - 91 years (1.40 - 1.90 m)
$\ln(FVC) = -3.842 + 4.1632 \sqrt{H} + 0.1341\sqrt{A} - 1.614Fi$	$FVC = -10.815 + 6.640H - 0.0408AH + 1.7293\ln(A)$
$\ln(FEV1) = -3.877 + 3.9809 \sqrt{H} + 0.1485 \sqrt{A} - 1.322Fi$	$FEV1 = -6.995 + 5.174H - 0.0314AH + 1.0251\ln(A)$
$\ln(PEF) = 0.411 + 1.793\ln(H) + 0.4251\ln(A) - 0.910Fi$	$\sqrt{PEF} = 1.832 + 1.838\ln(H) + 0.0078A - 0.0001722A^2$
$\ln(MEF75) = 0.455 + 1.616\ln(H) + 0.3738\ln(A) - 0.861Fi$	$\sqrt{PEF75} = 1.779 + 1.421\ln(H) + 0.0096A - 0.000179A^2$
$\ln(MEF50) = 0.256 + 1.643\ln(H) + 0.3481\ln(A) - 1.089Fi$	$\sqrt{PEF50} = 1.561 + 1.177\ln(H) + 0.0045A - 0.000140A^2$
$\ln(MEF25) = -0.772 + 2.002\ln(H) + 0.3063\ln(A) - 0.409Fi$	$\sqrt{PEF25} = 1.372 + 0.938\ln(H) - 0.0152A - 0.000036A^2$
$FEV1/FVC = 92.33$	$FEV1/FVC = 118.993 - 3.0320H^2 - 6.9053\ln(A)$

H = Height in metres A = Age in years

W = Weight in kg Fi = Body fat index = $\frac{H}{\sqrt[3]{W}}$

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16.4.4 Swedish standard (Berglund)

The Swedish (Berglund) standard is valid for adults between the ages of 18 and 75 years as follows:

	Men	Women
FEV%	91.79 - (0.373A)	92.11 - (0.261A)
SVC	1.09 [(4.81H) - (0.020A) - 2.81]	1.09 [(4.04H) - (0.022A) - 2.35]
FEV	1.09 [(3.44H) - (0.033A) -1.00]	1.09 [(2.67H) - (0.027A) - 0.54]

H = Height in metres A = Age in years

16.4.5 Finnish Standard

The Finnish standard is valid for adults from the age of 18 years as follows:

	Men	Women
SVC	$e^{(-0.00833A) + (0.6309 \times \log A) + (-1.4750/H) + 0.9047}$	$e^{(-0.01016A) + (0.6995 \times \log A) + (-1.4518/H) + 0.7763}$
FEV1	$e^{(-0.00587A) + (0.2756 \times \log A) + (-1.1655/H) + 1.0980}$	$e^{(-0.00920A) + (0.4772 \times \log A) + (-1.3284/H) + 0.9296}$
FVC	$e^{(-0.00827A) + (0.5860 \times \log A) + (-1.4468/H) + 0.9461}$	$e^{(-0.00982A) + (0.6358 \times \log A) + (-1.4137/H) + 0.8320}$
MEF 50	$e^{(0.00041A) + (-0.30870 \times \log A) + (-0.0148/H) + 1.34150}$	$e^{(0.00741A) + (-0.34710 \times \log A) + (-0.8581/H) + 0.9336}$
MEF25	$e^{(0.00771A) + (-0.28190 \times \log A) + (-0.0252/H) + 1.05970}$	$e^{(0.01548A) + (-0.34310 \times \log A) + (-0.8498/H) + 0.7966}$
FEV1/FVC	$e^{(0.00240A) + (-0.3104 \times \log A) + (0.2813/H) + 2.1519}$	$e^{(0.00062A) + (-0.1586 \times \log A) + (0.0853/H) + 2.0975}$
PEF	$e^{(-0.00211A) + (0.1049 \times \log A) + (-0.6774/H) + 1.3255}$	$e^{(-0.00677A) + (0.4017 \times \log A) + (-0.7422/H) + 0.9661}$

H = Height in metres A = Age in years
log = Logarithm to base 10

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16.5 Norm Values for the USA and Canada

16.5.1 Compensation factors according to Nhanes III

The following tables provide the compensation factors according to **Nhanes III** (Hankinson, Odencrantz and Fedan).

The coefficient Ht_{PRD} is used in the prediction equation; the coefficient Ht_{LLN} (replaces Ht_{PRD}) is used to determine to lower limits of normal. The formula used is as follows:

Lung function parameter = $b_0 + b_1$ x age (J) + b_2 x age^2 + b_3 x height^2 (cm)

The equation to calculate the FEV^1 predicted value for a 20-year-old white man is therefore as follows:

- $FEV_1 = b_0 + (b_1 \text{ x age (years)}) + (b_2 \text{ x age}^2) + (b_3 \text{ x height (cm)})$
- $FEV_1 = (-0.7453) + (-0.04106 \text{ x age}) + (0\text{-}004477 \text{ x age}^2) + (0.00014098 \text{ x height}^2)$

The predicted value for a 19-year-old person with a height of 182 cm is calculated as follows:

- $FEV_1 = (-0.7453) + (-0.04106 \text{ x } 19\ ) + (0.004477 \text{ x } 19^2) + (0.00014098 \text{ x } 182^2)$
- $FEV_1 = (-0.7453 + (-0.78014) + (0.004477 \text{ x } 361) + (0.00014098 \text{ x } 33124)$
- $FEV_1 = (-0.7453 + (-0.78014) + (1.616197) + (4.66982152)$
- = 4.76 litres

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Nhanes III equation for the calculation of predicted values and the lower limits of normal for spirometry parameters for males:

Male	Coefficient	Age	Age^2	Ht_{PRD} (cm)^2	Ht_{LLN} (cm)^2	R^2
Caucasian < 20 years	b_0	b_1	b_2	b_3		
FEV_1	-0.7453	-0.04106	0.004477	0.00014098	0.00011607	0.8510
FEV_6	-0.3119	-0.18612	0.009717	0.00018188	0.00015323	0.8692
FVC	-0.2584	-0.20415	0.010133	0.00018642	0.00015695	0.8668
PEF	-0.5962	-0.12357	0.013135	0.00024962	0.00017635	0.7808
FEF_{25-75}	-1.0863	-0.13939		0.00010345	0.00005294	0.5601
Caucasian ≥ 20 years						
FEV_1	-0.5536	-0.01303	0.000172	0.00014098	0.00011607	0.8510
FEV_6	-0.1102	-0.00842	0.000223	0.00018188	0.00015323	0.8692
FVC	-0.1933	-0.00064	0.000269	0.00018642	0.00015695	0.8668
PEF	1.0523	-0.08272	0.001301	0.00024962	0.00017635	0.7808
FEF_{25-75}	2.7006	-0.4995		0.00010345	0.00005294	0.5601
Black <20 years						
FEV_1	-0.7048	-0.05711	0.004316	0.00013194	0.00010561	0.8080
FEV_6	-0.5525	-0.14107	0.007241	0.00016429	0.00013499	0.8297
FVC	-0.4971	-0.15497	0.007701	0.00016643	0.00013670	0.8303
PEF	-0.2684	-0.28016	0.018202	0.00027333	0.00018938	0.7299
FEF_{25-75}	-1.1627	-0.12314		0.00010461	0.00004819	0.4724
Black ≥20 years						
FEV_1	0.3411	-0.02309		0.00013194	0.00010561	0.8080
FEV_6	-0.0547	-0.02114		0.00016429	0.00013499	0.8297
FVC	-0.1517	-0.01821		0.00016643	0.00013670	0.8303
PEF	2.2257	-0.04082		0.00027333	0.00018938	0.7299
FEF_{25-75}	2.1477	-0.04238		0.00010461	0.00004819	0.4724
Mexican <20 years						
FEV_1	-0.8218	-0.04248	-0.04291	0.00015104	0.00012670	0.8536
FEV_6	-0.6646	-0.11270	0.007306	0.00017840	0.00015029	0.8657
FVC	-0.7571	-0.09520	0.006619	0.00017823	0.00014947	0.8641
PEF	-0.9537	0.19602	0.14497	0.00030243	0.00021833	0.7530
FEF_{25-75}	-1.3592	0.10529		0.00014473	0.00009020	0.5482
Mexican ≥20 years						
FEV_1	0.6306	-0.02928		0.00015104	0.00012670	0.8536
FEV_6	0.5757	-0.02860		0.00017840	0.00015029	0.8657
FVC	0.2376	-0.00891	-0.000182	0.00017823	0.00014947	0.8641
PEF	0.0870	0.06580	-0.001195	0.00030243	0.00021833	0.7530
FEF_{25-75}	1.7503	-0.05018		0.00014473	0.00009020	0.5482

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Nhanes III equation for the calculation of predicted values and the lower limits of normal for spirometry parameters for females:

Female	Coefficient	Age	Age^2	Ht_{PRD} $(cm)^2$	Ht_{LLN} $(cm)^2$	R^2
Caucasian < 20 years						
FEV_1	-0.8710	0.06537		0.00011496	0.00009283	0.7494
FEV_6	-1.1925	0.06544		0.00014395	0.00011827	0.7457
FVC	-1.2082	0.05916		0.00014815	0.00012198	0.7344
PEF	-3.6181	0.60644	-0.016846	0.00018623	0.00012148	0.5559
FEF_{25-75}	-2.5284	0.52490	-0.015309	0.00006982	0.00002302	0.5005
Caucasian ≥ 20 years						
FEV_1	0.4333	-0.00361	-0.000194	0.00011496	0.00009283	0.7494
FEV_6	-0.1373	0.01317	-0.000352	0.00014395	0.00011827	0.7457
FVC	-0.3560	0.01870	-0.000382	0.00014815	0.00012198	0.7344
PEF	0.9267	0.06929	-0.001031	0.00018623	0.00012148	0.5559
FEF_{25-75}	2.3670	-0.01904	-0.000200	0.00006982	0.00002302	0.5005
Black <20 years						
FEV_1	-0.9630	0.05799		0.00010846	0.00008456	0.6687
FEV_6	-0.6370	-0.04243	0.003508	0.00013497	0.00010848	0.6615
FVC	-0.6166	-0.04687	0.003602	0.00013606	0.00010916	0.6536
PEF	-1.2398	0.16375		0.00019746	0.00012160	0.4736
FEF_{25-75}	-2.5379	0.43755	-0.012154	0.00008572	0.00003380	0.3787
Black ≥20 years						
FEV_1	-0.3433	-0.01283	-0.000097	0.00010846	0.00008456	0.6687
FEV_6	-0.1981	-0.00047	0.000230	0.00013497	0.00010848	0.6615
FVC	-0.3039	0.00536	-0.000265	0.00013606	0.00010916	0.6536
PEF	1.3597	0.03458	-0.000847	0.00019746	0.00012160	0.4736
FEF_{25-75}	2.0828	-0.03793		0.00008572	0.00003380	0.3787
Mexican <20 years						
FEV_1	-0.9641	0.06490		0.00012154	0.00009890	0.7268
FEV_6	-1.2410	0.07625		0.00014106	0.00011480	0.7208
FVC	-1.2507	0.07501		0.00014246	0.00011570	0.7103
PEF	-3.2549	0.47495	-0.013193	0.00022203	0.00014611	0.4669
FEF_{25-75}	-2.1825	0.42451	-0.012415	0.00009610	0.00004594	0.4305
Mexican ≥20 years						
FEV_1	0.4529	-0.01178	-0.000113	0.00012154	0.00009890	0.7268
FEV_6	0.2033	0.00020	-0.000232	0.00014106	0.00011480	0.7208
FVC	0.1210	0.00307	-0.000237	0.00014246	0.00011570	0.7103
PEF	0.2401	0.06174	-0.001023	0.00022203	0.00014611	0.4669
FEF_{25-75}	1.7456	-0.01195	-0.000291	0.00009610	0.00004594	0.4305

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16.5.2 Morris

The Morris equations are valid for women between 56 and 72 inches tall and within the age range 20 to 90 years, and for men between 58 and 80 inches tall and within the age range 20 to 90 years.

	Men	Women
FVC	0.1480H - 0.0250A - 4.241	0.1150H - 0.0240A - 2.852
FEV1	0.0920H - 0.0320A - 1.260	0.0890H - 0.0250A - 1.932
FEV1/FVC	-0.3118H + 0.2422A - 107.120	-0.0679H + 0.1815A + 88.700
FEF0.2 - 1.2	0.1090H - 0.0470A + 2.010	0.1450H - 0.0360A - 2.532
FEF25 - 75	0.0470H - 0.0450A + 2.513	0.0600H - 0.0300A + 0.551
FEF75 - 85	0.0130H - 0.0230A + 1.210	0.0250H - 0.0210A + 0.321

The Morris normals are extended with the following ITS equations:

	Men	Women
FEV0.	0.0831H - 0.0152A - 1.914	0.0605H - 0.0185A - 0.809
FEV3	-0.1359H - 0.0271A - 3.512	-0.1123H - 0.0257A - 2.745
FEV3/FVC	-0.1593H - 0.1450A + 112.090	-0.2380H - 0.1630A - 118.160
MVV	3.4040H - 1.2600A - 21.400	2.0500H - 0.5700A - 5.500

H = Height in inches A = Age in years

16.5.3 Crapo

The Crapo equations are valid for men between 61 and 77 inches tall and within the age range 18 to 89 years and for women between 57 and 71 inches tall and within the age range 18 to 89 years.

	Men	Women
FVC	0.1524H - 0.0214A - 4.650	0.1247H - 0.0216A - 3.590
FEV1	0.1052H - 0.0244A - 2.190	0.0869H - 0.0255A -1.578
FEV3	0.1359H - 0.0271A - 3.512	0.1123H - 0.0257A - 2,745
FEV1/FVC	-0.3302H - 0.1520A + 110,490	-0.5131H - 0.2520A + 126,580
FEF25 - 75	0.0518H - 0.0380A + 2.133	0.0391H - 0.0460A + 2.683
MVV Vol.	3.4040H - 1.2600A - 21.400	2.0500H - 0.5700A - 5.500

The Crapo normals are extended with the following ITS equations:

	Men	Women
FEV0.	0.0831H - 0.0152A - 1.914	0.0605H - 0.0185A - 0.809
FEV3.0/FVC	-0.1593H - 0.1450A + 112.090	-0.2380H - 0.1630A - 118.160

H = Height in inches A = Age in years

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16.5.4 Morris and Crapo Norm Values for Children

The following equations are valid for children within the age range 7 to 17.99 years:

Boys 7 - 17.99 years 43 -77 inch (1.09 - 1.96 m) Caucasian/Hispanic	Girls 7 - 17.99 years 43 -77 inch (1.09 – 1.96 m) Caucasian/Hispanic
FVC (ml) = $3.58 \times 10^{-4} \times H^{3.18}$SD = 13%	FVC (ml) = $2.57 \times 10^{-3} \times H^{2.78}$SD = 14%
FCV1 (ml) = $7.74 \times 10^{-4} \times H^{3.0}$SD = 13%	FCV1 (ml) = $3.79 \times 10^{-3} \times H^{2.68}$SD = 14%
PEF (l/min) = $3.35 \times 10^{-4} \times H^{2.79}$SD = 13%	PEF (l/min) = $2.58 \times 10^{-3} \times H^{2.37}$SD = 18%
FEF25-75% (l/min) = $7.98 \times 10^{-4} \times H^{2.46}$SD = 13%	FEF25-75% (l/min) = $3.79 \times 10^{-3} \times H^{2.16}$SD = 28%

Boys 7 - 17.99 years 43 -77 inch (1.09 - 1.96 m) Black/Asian	Girls 7 - 17.99 years 43 -77 inch (1.09 – 1.96 m) Black/Asian
FVC (ml) = $1.07 \times 10^{-3} \times H^{2.93}$SD = 17%	FVC (ml) = $8.34 \times 10^{-4} \times H^{2.98}$SD = 15%
FCV1 (ml) = $1.03 \times 10^{-3} \times H^{2.92}$SD = 17%	FCV1 (ml) = $1.14 \times 10^{-3} \times H^{2.89}$SD = 15%
PEF (l/min) = $1.74 \times 10^{-4} \times H^{2.92}$SD = 22%	PEF (l/min) = $5.51 \times 10^{-4} \times H^{2.68}$SD = 20%
FEF25-75% (l/min) = $3.61 \times 10^{-4} \times H^{2.60}$SD = 36%	FEF25-75% (l/min) = $1.45 \times 10^{-3} \times H^{2.34}$SD = 30%

H = Height in inches A = Age in years

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16.5.5 Knudson

The Knudson equations are valid for both children and adults in specific groups according to age and height as shown following:

	Men	Women
	H = 44 to 61 inches, A = 6 to 11 years	**H = 42 to 58 inches, A = 6 to 10 years**
FVC	0.1039H - 0,0A - 3.376	0.1092H - 0,0A - 3.749
FVC0.5	0.0760H + 0.0430A -3.050	0.0480H - 0,0610A - 1.740
FEV1	0.0884H - 0.0A - 2.814	0.0853H + 0.0A - 2.758
FEV1/FVC	-0.2065H + 0.0A + 100.439	-0.4849H + 0.6655A + 109.974
FEF25 - 75	0.0859H + 0.0A - 2,320	0.0559H + 0.0A - 0,812
PEF	0.1980H + 0.1660A - 8.061	0.1240H + 0.1570A - 3.920
FEF50	0.0960H + 0.0A - 2.545	0.0H + 0.1846A + 0.736
FEF75	0.0434H + 0.0A - 1.015	0.0277H + 0.0A - 0.166
MVV	4.6800H - 1.8A - 192.32	2.7600H + 3.4000A - 108.120
	H = 55 to 76 inches, A = 12 to 25 years	**H = 52 to 72 inches, A = 11 to 20 years**
FVC	0.1499H + 0.0739A - 6.887	0.1057H + 0.0699A - 4.447
FVC0.5	0.0760H + 0.0430A - 3.050	0.0480 x H + 0.0610 x A -1.740
FEV1	0.1318H + 0.0636A - 6.118	0.0892H + 0.0694A - 3.762
FEV1/FVC	-0.2065H + 0.0A + 100.439	-0.4849H + 0.6655A + 109.974
FEF25 - 75	0.1369H + 0.0749A - 6.199	0.0709H + 0.1275A - 2.801
PEF	0.1980H + 0.1660A - 8.061	0.1240H + 0.1570A - 3.920
FEF50	0.1379H + 0.1150A - 6.385	0.0732H + 0.1111A - 2.304
FEF75	0.1008H - 0.0057A - 4.242	
MVV	4.6800H + 1.8000A - 192.320	2.7600H + 3.4000A - 108.12

For patients over 18 years the following equations apply:

	Men	Women
FEV3	0.1359H - 0.0271A - 3.512	0.1123H - 0.0257A - 2,745
FEV3/FVC	-0.1593H - 0.1450A + 112.090	-0.2380H - 0.1630A - 118.160
	H = 62 to 77 inches, A = 26 to 91 years	**H = 58 to 71 inches, A = 21 to 91 years**
FVC	0.1524H - 0.0214A - 4.650	0.1247H - 0.0216A - 3.590
FVC0.5	0.0831H - 0.0152A - 1.914	0.0605H - 0.0185A - 0.809
FEV1	0.1052H - 0.0244A - 2.190	0.0869H - 0.0255A - 1.578
FEV3	0.1359H - 0.0271A - 3.512	0.1067H - 0.0257A - 2.745
FEV1/FVC	0.0H - 0.1050A + 86.686	-0.4704H - 0.1896A - 121.678
FEF0.2 - 1.2	0.1090H - 0.0470A + 2.010	0.1450H - 0.0360A - 2.532
FEF25 - 75	0.1471H - 0.0363A - 4.518	0.0531 x H - 0.0344 x A + 1.128
FEF75 - 85	0.0130H - 0.0230A + 1.210	0.0250H - 0.0210A + 0.321
PEF	0.2390H - 0.0350A - 5.990	0.1240H - 0.0250A - 0.740
FEF25	0.0900H - 0.0200A + 2.726	0.0690H - 0.0190A + 2.147
FEF50	0.1737H - 0.0366A - 5.409	0.0681H - 0.0289A + 0.609
FEF75	0.0787H - 0.0230A - 2.483	0.0244H - 0.0259A + 1.118
MVV	3.0300H - 0.8160A - 37.900	2.1400H - 0.6850A - 4.870

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In addition there are the following ITS equations:

	Men	Women
FEV3/FVC	-0.1593H - 0.1450A + 112.090	-0.2380H - 0.1630A - 118.160

16.5.6 Knudson 76

The Knudson 76 equations are valid for both males and females in specific age groups as follows:

	Men Age <25 years	Women Age under 20 years
FVC	0.1270H + 0.078A - 5.508	0.0838H + 0.092A - 3.469
FVC0.5	0.0762H + 0.043A - 3.054	0.0483H + 0.061A - 1.738
FEV1	0.1168H + 0.045A - 4.808	0.0686 x H + 0.085 x A - 2.703
FEV3	0.1321H + 0.066A - 5.531	0.0838H + 0.086A - 3.417
FEV1/FVC	-0.2210H - 0.140A + 103.64	-0.2819H - 0.109A + 107.38
FEF25 - 75	0.1499H + 0.0A - 5.334	0.0635H + 0.121A - 1.893
PEF	0.1981 x H + 0.166 x A - 8.060	0.1245H + 0.157A - 3.916
FEF25	0.1778H + 0.147A - 7.054	0.1118H + 0.144A + 3.365
FEF50	0.1295H + 0.081A - 4.975	0.0864H + 0.120A + 2.531
FEF75	0.0813 x H + 0.0 x A - 2.455	0.0 x H + 0.139 x A - 0.692

	Age >25 years	Age >20 years
FVC	0.1651H - 0.029A - 5.459	0.0940H - 0.022A - 1.774
FVC0.5	0.0940H - 0.017A - 2.746	0.0483H - 0.014A - 0.406
FEV1	0.1321 x H - 0.027 x A - 4.203	0.0686H - 0.021A - 0.794
FEV3	0.1600H - 0.031A - 5.245	0.0889H - 0.023A - 1.633
FEV1/FVC	-0.2210H - 0.140A + 103.64	-0.2819H - 0.109A + 107.38
FEF25 - 75	0.1143H - 0.031A - 1.864	0.0533 x H - 0.024 x A - 1.171
PEF	0.2388H - 0.035A - 5.993	0.1245H - 0.025A - 0.735
FEF25	0.2235H - 0.035A - 5.618	0.1092H - 0.025A + 0.132
FEF50	0.1753H - 0.015A - 5.400	0.0889H - 0.013A - 0.444
FEF75	0.1118H - 0.012A - 4.143	0.0H - 0.014A - 3.042

H = Height in inches A = Age in years

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16.5.7 Polgar

The Polgar equations are valid for both children and adults in specific groups according to age as follows:

	Men Age under 18 years	Women Age under 18 years
FVC	$0.0000071H^3 + 0.00057H^2 - 0.0123H + 0.14$	$0.0000076H^3 + 0.00048H^2 + 0.0112H + 0.13$
FVC0.5	0.076H + 0.043A - 3.05	-
FEV1.0	$0.00000087H^3$ + 0.00035H2 - 0.0086H + 0.1	$0.0000086H^3 + 0.00035H^2$ - 0.0086H + 0.1
FEF25 - 75%	0.1109H - 3.46	0.1109H - 3.46
PEF	0.2219H - 7.09	0.2219H - 7.09
MVV	4.68H - 1.8A - 192.32	2.76H - 3.4A - 108.12

	Age 18 to 25 years	Age 18 to 20 years
FVC	0.1499H + 0.0739A - 6.887	0.1057H + 0.0699A - 4.447
FVC0.5	0.0760H + 0.0430A - 3.050	0.0480H + 0.00610A - 1.740
FEV1.0	0.1318H + 0.0636A - 6.118	0.0892H + 0.0694A - 3.762
FEF25 - 75	0.1369H + 0.0749A - 6.199	0.0709H + 0.1275A - 2.801
PEF	0.1980H + 0.1660A - 8.061	0.1240H + 0.1570A - 3.920
FEF50	0.1379H + 0.1150A - 6.385	0.0732H + 0.1111A - 2.304
FEF75	0.1008H - 0.0057A - 4.242	0.0617H + 0.2923A - 4.401
MVV	4.68H + 1.8A - 192.32	2.76H + 3.4A - 108.12

	Age over 25 years	Age over 20 years
FEF3.0	-	0.1067H - 0.0257A - 2.745
FEF0.2 -1.2	0.1090H - 0.0470A + 2.010	0.1450H - 0.0360A - 2.532
FEF25 - 75%	0.1471H - 0.0363A - 4.518	0.0531 x H - 0.0344 x A + 1.128
FEF75 - 85%	0.0130H - 0.0230A + 1.210	0.0250H - 0.0210A + 0.321
PEF	0.2390H - 0.0350A - 5.990	0.1240H - 0.0250A - 0.740
FEF25	0.0900H - 0.0220A + 2.726	0.0690H - 0.0190A + 2.147
FEF50	0.1737H - 0.0366A - 5.409	0.0681H - 0.0289A + 0.609
FEF75	0.0787H - 0.0230A - 2.483	0.0244H - 0.0259A + 1.118
MVV	3.03H - 0.816A -3,7.9	2.14H - 0.685A - 4.87

H = Height in inches A = Age in years

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