CardioPulse Prime

Operating manual

REF: 2.511462 Rev A
CAT: 070-3063-00 Rev A

$R_x$only

SPACELABS
HEALTHCARE

Spacelabs Healthcare considers itself responsible for the effects on safety, reliability and performance of the equipment only if:

- assembly operations, re-adjustments, modifications or repairs are carried out by persons authorized by Spacelabs Healthcare, and
- the electrical installation of the relevant room complies with the requirements of the standard in force, and
- the equipment is used in accordance with the operations manual.

In the event of a serious incident, notify Spacelabs and the competent authority.

Spacelabs Healthcare will make available, on request, component part lists, descriptions, calibration instructions or other information which will assist appropriately qualified technical personnel to repair those parts of the equipment which are classified by Spacelabs Healthcare as field repairable.
Spacelabs Healthcare is committed to providing comprehensive customer support beginning with your initial inquiry through purchase, training, and service for the life of your Spacelabs Healthcare equipment.

Distributed by:
Spacelabs Healthcare
35301 SE Center Street
Snoqualmie, WA 98065
Telephone: (1) 800-287-7108
Telephone: (1) 425-396-3300

Manufactured by:
SCHILLER AG
Altgasse 68
CH-6341 Baar, Switzerland

CE 0123

The CardioPulse Prime (Type CARDIOVIT AT-102 G2) 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.

Rx_{only}

Caution: Federal law restricts this device to sale by or on the order of a physician.

REF: 2.511462 Rev A
CAT: 070-3063-00 Rev A
Issue date: 12.10.2021
Valid from SW 1.2.0

Table of contents

REF: 2.511462 Rev A / CAT: 070-3063-00 Rev A

REF: 2.511462 Rev A / CAT: 070-3063-00 Rev A

REF: 2.511462 Rev A / CAT: 070-3063-00 Rev A

REF: 2.511462 Rev A / CAT: 070-3063-00 Rev A

1 Safety notes

1.1 Intended Use

- ▲ The CardioPulse Prime is a 12-lead electrocardiograph intended to be used by or under the direct supervision of a licensed healthcare practitioner in healthcare facilities to acquire ECG signals from body surface electrodes, record, analyze, display and print ECGs for diagnosis in adult and pediatric patients.
- ▲ The spirometry option is intended to record, analyze, display and print measurements and waveforms of pulmonary function tests for the diagnosis in adult and pediatric patients.
  Note: The spirometry option is not available on the US market.
- ▲ The exercise option is intended to acquire ECG signals from body surface electrodes record, analyze, display and print ECGs of adult and pediatric patients undergoing stress exercise testing.
  Note: The Exercise option is not available on the US market.

1.2 Indications for use

- ▲ The CardioPulse Prime is intended to be used for screening and assessment of cardiovascular diseases including:
  - Resting myocardial ischemia
  - Myocardial infarction (acute and former)
  - Conduction system abnormalities including atrio-ventricular blocks, bundle branch block and pre-excitation syndromes
  - Long QT syndrome
  - Atrial abnormalities
  - Ventricular hypertrophy and strain
  - Pericarditis
  - Secondary repolarisation abnormalities such as electrolytes disturbances
  - Drug-induced abnormalities

REF: 2.511462 Rev A / CAT: 070-3063-00 Rev A

1.3 Contraindications

1.3.1 System

▲ The CardioPulse Prime is not intended for:

- sterile use
- use in areas where there is any danger of explosion or in the presence of flammable gases such as anesthetic agents
- direct cardiac application
- use in an MRI suite 

- outdoor use

▲ The CardioPulse Prime is not intended to be used as a vital signs physiological monitor.

1.4 Intended users

▲ The CardioPulse Prime is intended to be used by trained operators under supervision of a licensed health care practitioner.

REF: 2.511462 Rev A / CAT: 070-3063-00 Rev A

1.5 Patient target group

The CardioPulse Prime is intended to be used for adult and pediatric patients.

ECG

Pediatric patients are defined as follows:

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

1.6 Context of use

▲ The CardioPulse Prime is intended for indoor use in healthcare facilities.

1.7 Responsibility of the User

▲ The CardioPulse Prime must only be used by qualified physicians or trained medical personnel.

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

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

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

▲ Damaged or missing components must be replaced immediately.

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

▲ In case a serious incident has occurred in relation to the device, such incident needs to be reported to the manufacturer and the competent national authority in which the user is established.

1.8 Organizational Measures

▲ Before using the device, ensure that a medical product representative has explained its functions as well as the safety requirements.

▲ Keep this user guide in an accessible place for reference purposes. Make sure that it is always complete and legible.

▲ Observe the operating and maintenance instructions.

▲ These operating instructions do not override any statutory or local regulations, or procedures for the prevention of accidents and environmental protection.

REF: 2.511462 Rev A / CAT: 070-3063-00 Rev A

1.9 Safety-conscious Operation

- Make sure that the staff have read and understood the operating instructions, in particular this section Safety Notes.
- Only operate the device in accordance with the specified technical data (see section 12 Technical Data, page 99). Non-compliance with the specified technical data may result in injury, inaccurate information and/or damage to the unit.
- The device is CF classified. It is defibrillation protected only when the Spacelabs Healthcare original patient cable is used. However, as a safety precaution, remove the electrodes before defibrillation, if possible.
- Do not touch the unit 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 responsible person.
- Do not place any liquids on the unit. If liquid is spilled on the device, immediately disconnect the device from the AC power and wipe it. The device must be checked before reusing.
- Only connect the original Spacelabs Healthcare patient cable to the patient socket.
- If the patient cable should become defective after defibrillation, an electrode becomes displaced, or an electrode resistance is too high, a lead-off indication is displayed in the upper right part of the screen.
- Only use accessories and disposables recommended or supplied by Spacelabs Healthcare. 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 7.9 inches must be observed between the device and the pacemaker as soon as the Wi-Fi (wireless LAN) module is switched on.
- Should unexpected results be provided, the user must verify the connections according to section 10.1 Maintenance interval table, page 85.

1.10 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 AC power lead, the power supply unit or the device is damaged or suspected of being damaged.
  - Damaged cable connections and connectors must be replaced immediately.
  - Electrical safety devices, such as fuses, must not be modified.
  - Fuses must only be replaced with the same type and rating as the original.

REF: 2.511462 Rev A / CAT: 070-3063-00 Rev A

1.11 Operation with other Devices

- Accessories connected to the analogue and/or digital interfaces must be certified according to the corresponding IEC standards (e.g. IEC/EN 60950 for data processing equipment and IEC/EN 60601-1 for medical equipment). Furthermore, all configurations shall comply with the valid version of IEC/EN 60601-1. Everyone who connects additional equipment to the signal input part or signal output part configures a medical system and is therefore responsible that the system complies with the requirements of the valid version of IEC/EN 60601-1. If in doubt, contact the technical service department or your local representative.
- Any other equipment used with the patient must use the same common earth as the CardioPulse Prime.
- Special care must be exercised when the unit is used with high-frequency equipment. Use the original Spacelabs Healthcare patient cable to avoid possible signal interference during ECG acquisition or burns due to missing potential equalisation. However, the stimulation units should only be used at a sufficient distance from the electrodes and both devices must be connected to the same potential equalisation. If in doubt, the patient should be disconnected from the device.
- This device can safely be used with pacemaker patients.
- There is no danger when using this unit simultaneously with electrical stimulation equipment.
- If the device is part of a medical system, only the original Spacelabs Healthcare patient cable must be used with, and connected to, the CardioPulse Prime.
- If the patient cable should become defective after defibrillation, a lead-off indication is displayed on the screen (see Page 40).
- Portable communication devices, HF radios and devices labeled with the  symbol (non-ionic electromagnetic radiation) can affect the operation of this device (Page 97).

1.12 Network safety

- When the CardioPulse Prime is part of a *network (LAN, WLAN, HIS, etc.),* the operator of the network/data coupling must take appropriate security measures to protect the transmission of data. Networks that are not protected and maintained can lead to failure of the data transmission or to incorrect transmission of data, which in turn can result in danger to the patient. For further safety notes, see chapter 9.
- Standard passwords for access control must be changed by the responsible persons.

REF: 2.511462 Rev A / CAT: 070-3063-00 Rev A

1.13 Maintenance

- ▲ Danger of electric shock. Do not open the device. There are no serviceable parts inside. Servicing must only be performed by qualified technicians authorized by Spacelabs Healthcare.
- ▲ Before cleaning and to isolate the AC power supply, switch the monitor off and disconnect it from the AC power by removing the plug.
- ▲ Do not use high-temperature sterilization processes (such as autoclaving). Do not use e-beam or gamma radiation sterilization.
- ▲ Do not use aggressive or abrasive cleaners.
- ▲ Do not, under any circumstances, immerse the device or cable assemblies in liquid.

1.14 Terms of warranty

Your Spacelabs Healthcare CardioPulse Prime is warranted against defects in material and manufacture, as stated in the Terms and Conditions. Excluded from this warranty is damage resulting from negligence or improper use. The warranty entitles to free replacement of the defective part. Any liability for subsequent damage is excluded. The warranty is void if unauthorized or unqualified persons attempt to make repairs.

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

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

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

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

REF: 2.511462 Rev A / CAT: 070-3063-00 Rev A

1.14.1 Additional statements

FCC statement

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

This device contains FCC ID: **Z64-WL18DBMOD**

When using the WiFi networking option, operation of this equipment requires the prior coordination with a frequency coordinator designated by the FCC for the Wireless Medical Telemetry Service.This device complies with Part 15 of the FCC rules. Operation is subject to the following conditions:

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

⚠ CAUTION

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

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

REF: 2.511462 Rev A / CAT: 070-3063-00 Rev A

1.15 Symbols and Pictograms

1.15.1 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 user guide.

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

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

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

For general safety notes as listed in this chapter.

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

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

Reference to other instructions.

REF: 2.511462 Rev A / CAT: 070-3063-00 Rev A

1.15.2 Symbols used on the device

General used symbols see 14 Appendix - Symbols.

Note: All other symbol used for operating elements and connectors are described in chapter 2.5 and 2.6

Consulting of the user guide is mandatory before using the CardioPulse Prime.

Attention: Consult safety notes in the accompanying documents.

The device is not intended to operate in a MR environment. The device is unsafe in a MR environment. See warning section 1.3 Contraindications, page 6.

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 Spacelabs Healthcare patient cable.

IP20

The device is protected against foreign body diameter greater than >12.5 mm. No water protection. Only for indoor use!

Symbol for the recognition of electrical and electronic equipment

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

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

The CardioPulse Prime radiates high-frequency electromagnetic energy and can disturb other devices if the CardioPulse Prime is 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 CardioPulse Prime 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 CardioPulse Prime. A minimum distance of 7.87 inches must be kept between the device and a pacemaker.
- Turn the device to change the angle of radiation.
- Connect the device to a different AC power connector.

For more details, see Page 95.

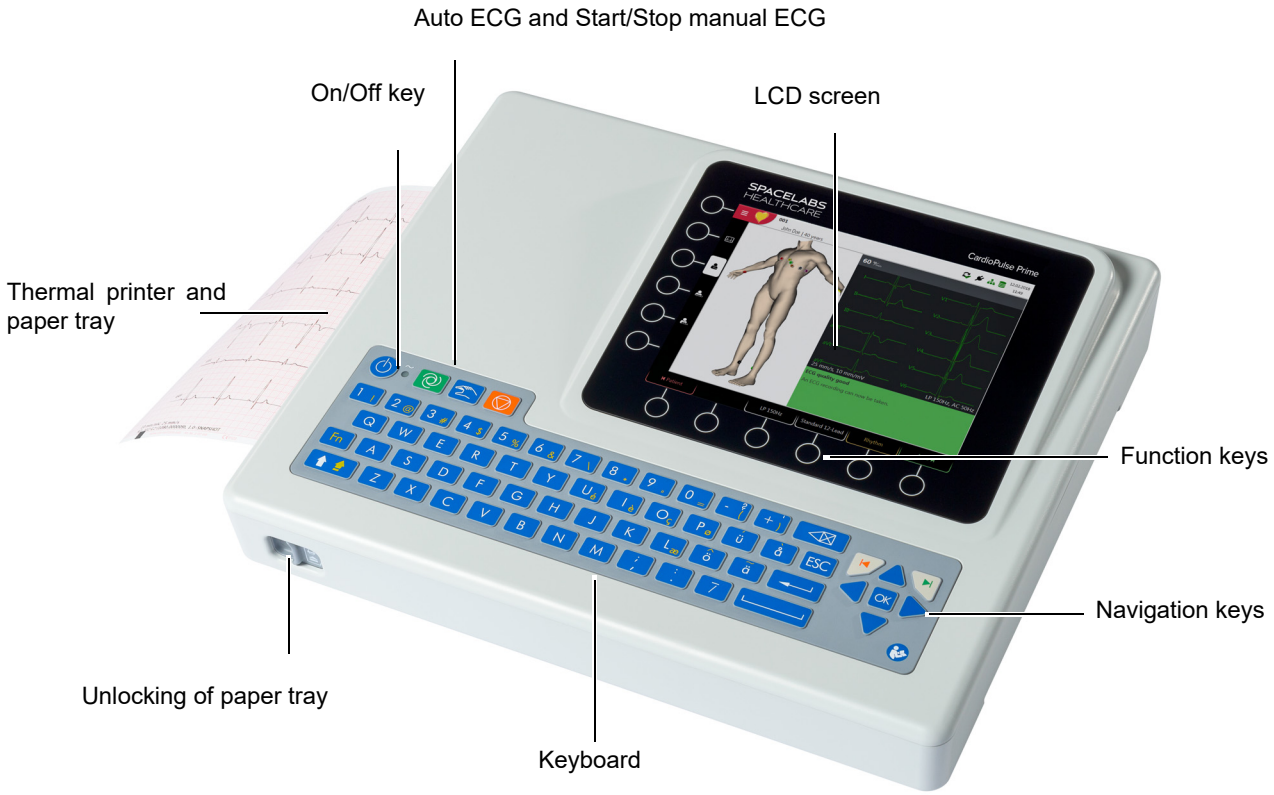
REF: 2.511462 Rev A / CAT: 070-3063-00 Rev A

2 Introduction

The Spacelabs Healthcare CardioPulse Prime is a 12-channel ECG unit designed to record, display and measure resting ECGs.

The CardioPulse Prime has the following features:

2.1 Main Components of the CardioPulse Prime



REF: 2.511462 Rev A / CAT: 070-3063-00 Rev A

2.1.1 Standard

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

2.1.2 Options

- Barcode reader - to read a patient‘s ID and retrieve patient data from a database
- Worklist

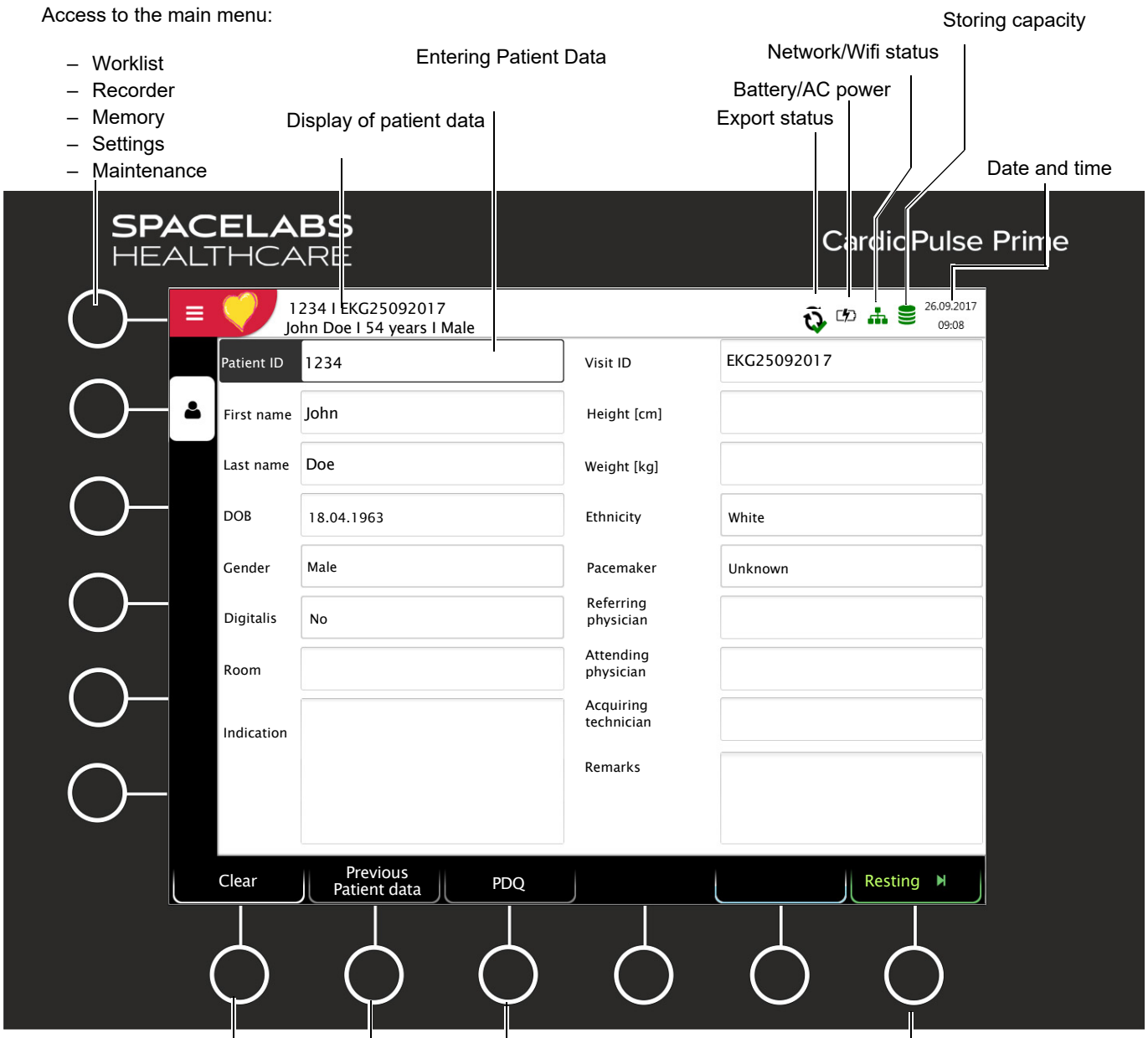
2.2 Connections

- Potential equalisation
- RJ-45 Ethernet connector (network)
- 2x USB interfaces for software updates with a USB stick, PDF export and connection of a Barcode reader.
- 2x RS-232 port DB9 is not intended for the US market
- ECG patient cable connector DB15
- Kensington lock

REF: 2.511462 Rev A / CAT: 070-3063-00 Rev A

2.3 Display

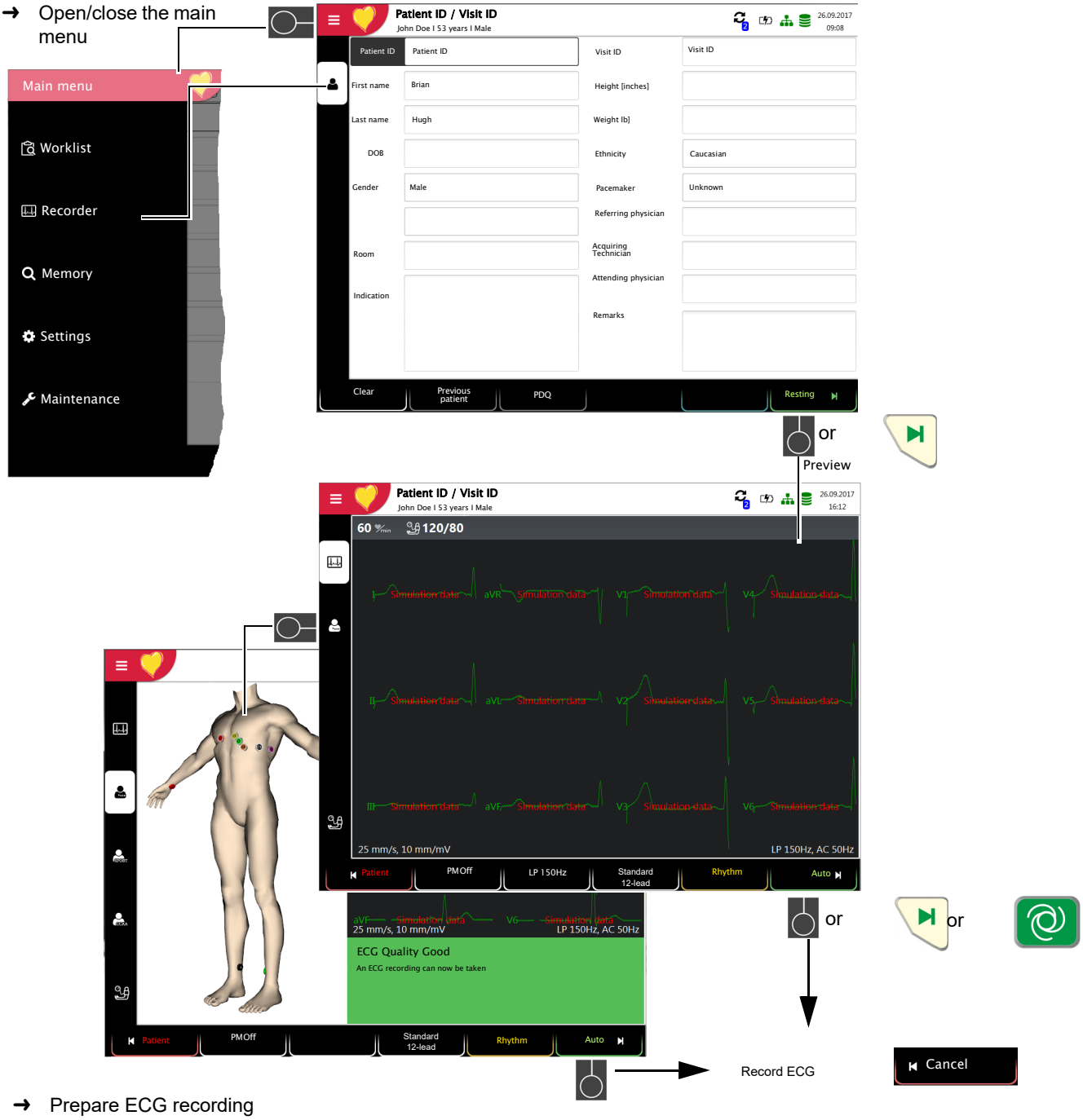
The display will vary according to the task being carried out. In all screens, however, the top and bottom areas always display the same category of information. Example for a typical patient data view:



REF: 2.511462 Rev A / CAT: 070-3063-00 Rev A

2.4 Display details

Displays and function keys during a resting ECG recording:



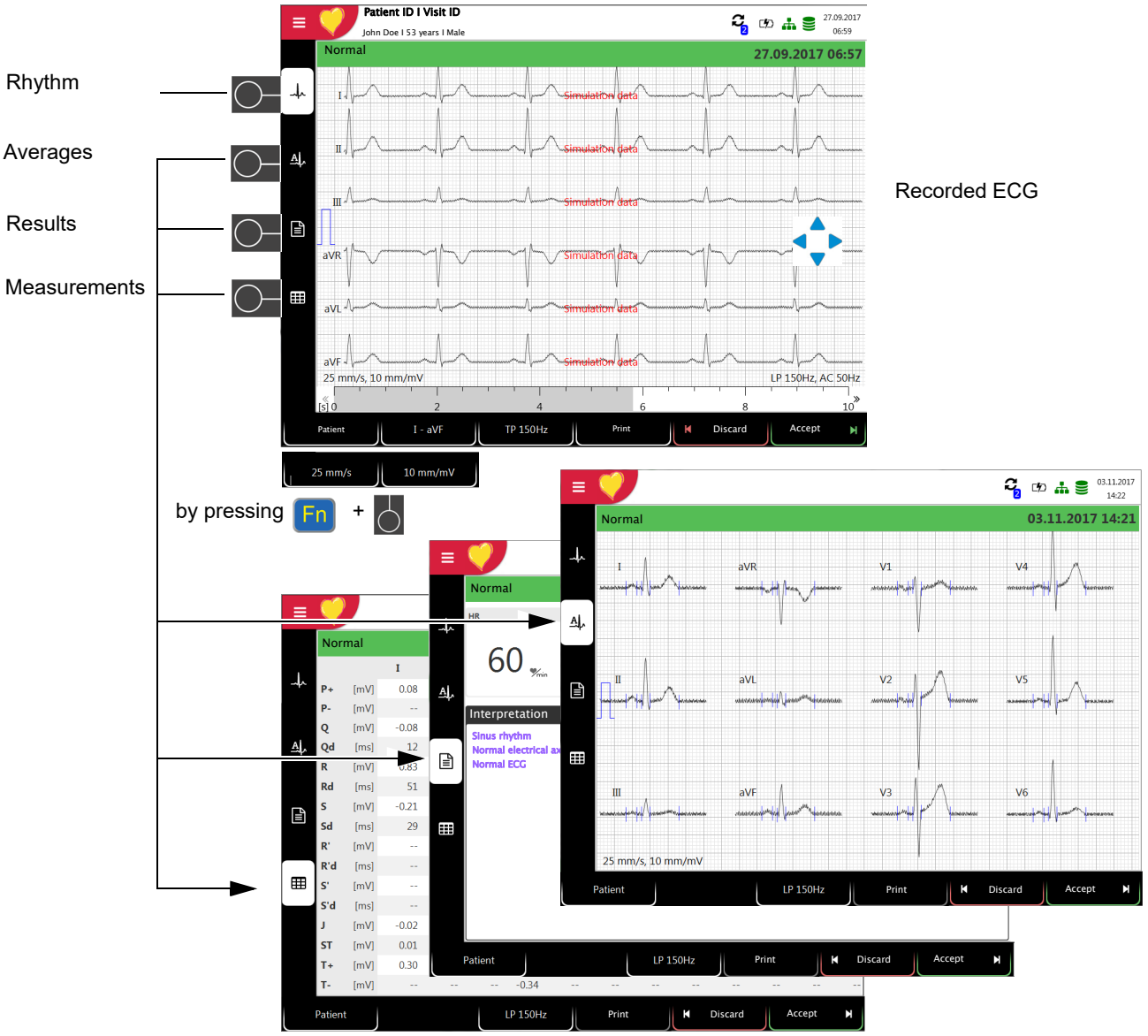
➜ Prepare ECG recording

- Determine electrode positions and apply electrodes
- Check the signal quality
- Pacemaker detection on/off
- Select Auto or Rhythm
- Enter blood pressure measurement manually

By pressing FN + , additional function keys can be used, such as:

Settings for speed/amplitude for ECG display and settings speed/amplitude and lead for ECG manual printout.

REF: 2.511462 Rev A / CAT: 070-3063-00 Rev A



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

➜ The recorded ECG is displayed and can be reviewed.

➜ Use navigation keys to rotate leads I...V6: scroll up or down and along the time axis (left-right).

➜ Display average values, results and measurements.

➜ Set the filter for display to 25/40/150 Hz or Off using the Filter function key.

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

➜ Use the FN key and the corresponding function key to set the amplitude and speed.

REF: 2.511462 Rev A / CAT: 070-3063-00 Rev A

2.5 Keyboard

(1) Power On/OFF	Press the On/Off button to switch the device on or off.
(2) Power Indicator	The power supply LEDs indicate the power source (see Page 23).
(3) Direct function key Auto Start	**Auto Start**: Auto recording procedure
(4) Direct function key Manual start	**Man. Start**: real time printout
(5) Direct function key Stop	**Stop**: stop printout / advance paper to beginning of new page
(6) Delete input	The entered data is deleted
(7) Menu selection and navigation	• **OK** key: the center key is to confirm current / displayed setting • **Left arrow key**: move cursor to the left / select previous menu option • **Right arrow key**: move cursor to the right / select next menu option • **Up arrow key**: move cursor upward • **Down arrow key**: move cursor downward • Red arrow key, left (back/cancel dialogue) • Green arrow key, right (select/confirm dialogue)

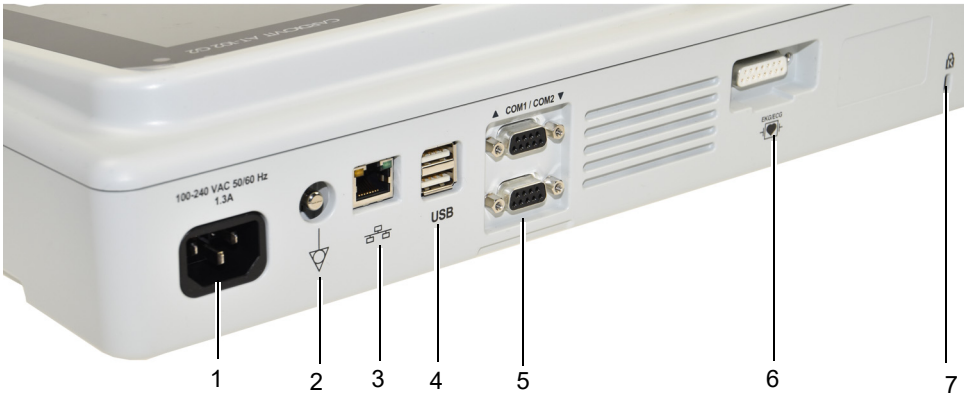
REF: 2.511462 Rev A / CAT: 070-3063-00 Rev A

2.6 Connections

⚠ CAUTION

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

2.6.1 Back panel



(1) Power supply unit connection 100 -240 VAC, 50/60 Hz, 1.3 A.

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

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

(4) 2 USB interfaces for the Barcode scanner and USB sticks.

(5) 2x RS-232-DB9 port is not intended for US market

(6) ECG patient cable connector

(7) Kensington lock

⚠ CAUTION

▲ The patient cable as well as the connector (6) comply with the safety standard CF, i.e. they are fully floating and isolated and defibrillation protected.

▲ The unit is only CF rated and defibrillation protected if used with the original patient cable see11.3.1 Patient cables.

REF: 2.511462 Rev A / CAT: 070-3063-00 Rev A

3 Operation

3.1 Initial operation

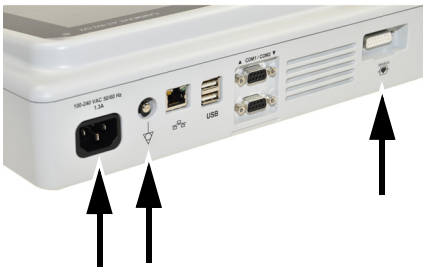
DANGER

▲ Electrical shock hazard. Do not operate the unit if the earth connection is suspect or if the power supply unit/AC power 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 vapors or liquids.
- The CardioPulse Prime should 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 AC power cable to the AC power.
2. The AC power indicator LED is lit.
3. Leave the CardioPulse Prime connected to the AC power for 4 hours to fully charge the battery (see Page 23).
4. Connect the potential equalisation cable.
5. Connect the patient cable.
6. Connect any ancillary and optional equipment (see Page 19). These may include the following:
   - Network cable
   - USB Barcode reader

3.1.3 Potential equalisation

The potential equalisation stud at the back of the unit is used to equalise the ground potential of the CardioPulse Prime to that of all AC-powered equipment in the vicinity. Use the hospital or building common ground. A yellow/green earth cable is supplied as an option (article number SLHC PN 161-0279-00).

WARNING

▲ Danger of triggering ventricular fibrillation! If the CardioPulse Prime 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 equalizing currents between different device potentials.

REF: 2.511462 Rev A / CAT: 070-3063-00 Rev A

3.2 Switching on / off

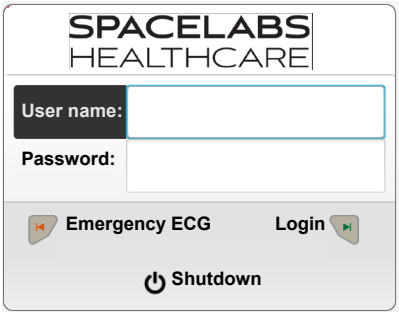
➜ The unit is switched on and off with the **On / Off** key.

- The switching off must be confirmed by pressing the key.
- If access control is activated, the **ON-OFF** key must be pressed twice.

3.2.1 Logging In / Out / Emergency ECG

⚠ CAUTION

▲ To prevent non-authorized users to access patient information, manipulate settings or the software, we strongly recommend changing the default password to a strong password according to the standard rules. (section 8.7.1 Setting user name and password for access control, page 79)



Login

➜ Enter the user name (administrator) and password (administrator) and press the key to log in.

Emergency ECG

➜ Press the key to bypass the login and perform an emergency ECG.

➜ Automatic Logout when accepting the ECG recording 

Logout

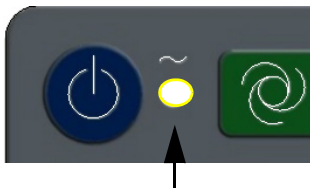
➜ Press the **ON-OFF** key  and in the following dialogue press the key to log off (Cancel or Switch Off)

- If **Emergency ECG** is selected, the login is bypassed for one acquisition. The Log-in screen appears again after accepting the emergency ECG recording. No other workflow is accessible.
- User roles and privileges are assigned to individual users and that can affect access to a workflow area and the functions that can be carried out. If a function is not available, it means that the user logged in does not have the privileges required. Individual users, and the user groups and privileges defined for individual users are defined by the administrator.

REF: 2.511462 Rev A / CAT: 070-3063-00 Rev A

3.3 Power supply

3.3.1 AC power and battery indicators



The unit can either be operated by the AC power supply or by the built-in rechargeable battery. The LED indicates that the device is connected to the AC power.

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

AC power via external power supply unit , battery is being charged

- Internal rechargeable battery operation ( )
- When running on battery power and the battery capacity is limited, the battery symbol is flashing red.

Full

Half full

Almost empty

Empty

Battery capacity

The internal battery provides power for up to 8.5 hours. When the unit is running on battery power (AC power not connected), the battery symbol indicates the battery status. When the battery is full, the symbol is solid.

When running on battery power and the battery capacity is low, the battery symbol turns red. If the capacity ≤ 10 %, the user will be informed to connect the device to the AC power.

Battery charging

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

3.3.2 Isolating from the AC power

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

REF: 2.511462 Rev A / CAT: 070-3063-00 Rev A

3.4 System and ECG settings

- The system settings (time, date, device ID etc.) and other general settings are described on Page 75.
- Resting ECG settings (auto format, user defined leads, print options, interpretation, rhythm lead definition, etc.) are described on Page 64.

3.4.1 Settings overview

Menu Settings	Sub-menu
ECG (Page 64)	• Lead & Cable • Filter & Formulas • Interpretation • Additional Leads • Resting rhythm • Color
Reports (Page 66)	• General • Manual printout • Resting ECG • Rhythm ECG •
Layouts (Page 64)	• Resting • Worklist
Connectivity (Page 72)	• EMR integration • Ethernet • WLAN
Regional (Page 75)	• Date / time • Language • Units • Patient ID system
General (Page 76)	• Info • Power management • Station • Update • Manage licenses • Visible fields • Mandatory fields • Custom fields • Access control • Workflow • Memory • Printer

REF: 2.511462 Rev A / CAT: 070-3063-00 Rev A

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 vapors. The following points apply to both storage, and when archiving the results:

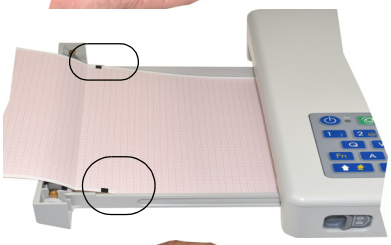
- Before use, keep the paper in its original cardboard cover. Do not remove the cardboard cover until the paper is to be used.
- Store the paper in a cool, dark and dry location.
- Do not store near chemicals, e.g. sterilization liquids.
- Do not store in PVC folders or envelopes made of recycled paper.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

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

1. Slide the latch to the right

2. Pull out the paper tray.

3. Remove the remaining paper.



4. Place a new paper pack into the paper tray with the printed (grid) side facing upwards.
5. Pull out the first page as shown on the left.

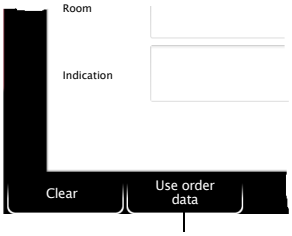
6. Push the paper tray home until it locks into place.

REF: 2.511462 Rev A / CAT: 070-3063-00 Rev A

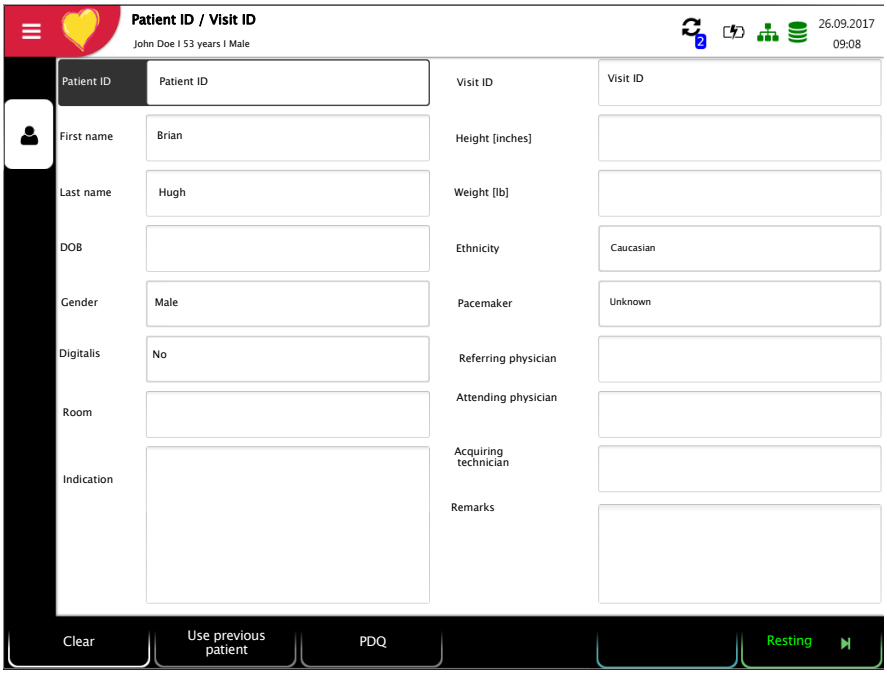
3.6 Patient / recording data

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

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



Only with Schiller Link



With the data of the current patient, you can:

- edit it directly in the entry fields
- obtain the data from the server by entering the Patient or Visit ID (configuration: see page 72)
- display the data by pressing the key "Use order data". This function key is only displayed when using the Schiller Link and when changing application and going to the screen "Patient data" (see section 9.1.4 Schiller Link, page 83)
- press Delete to reset the data and enter a new patient
- press "Previous patient" to use the previous patient's data
- read the Patient ID with a barcode scanner.
- Use the alphanumeric keyboard to enter the patient data.
  - Use the **Shift** key to switch the keyboard to capitals.

The order and visibility of the fields can be configured in the **Menu** > **Settings > General > Visible fields >** “Recorder” (see page 76).

REF: 2.511462 Rev A / CAT: 070-3063-00 Rev A

Patient data - left entry fields

Patient ID Enter the patient's identification number.

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

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

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

Gender[1] Enter the patient‘s gender - Male, Female, Other or Undefined

Digitalis Digitalis medication

Room Enter room

Indication Reason for medication

Patient data - right entry fields

⚠ CAUTION

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

Visit ID The **Visit ID** is a unique patient identification provided by the hospital information system (HIS) (max. 50 characters).
For more information on the **Visit ID** and on validation options with regard to the HIS, consult the user guide for the Schiller Server.

Height Enter the patient's height.

Weight Enter the patient's weight.

Ethnicity Select one of the following:

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

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

Regardless of this setting, for pacemaker patients the detection must be switched on before starting the ECG. A detected pacemaker pulse is therefore indicated in blue and the interpretation states that it is a pacemaker ECG.

Referring physician Referring physician

Attending physician Attending physician

Acquiring technician Acquiring technician

With the following settings, this "name" is read automatically, but can be overwritten at any time:

- **Menu** > **Settings > General > Station >** Parameter “Acquiring technician”

REF: 2.511462 Rev A / CAT: 070-3063-00 Rev A

- **Menu** > **Settings > General > Access control >** Access control mode > Local > “User name”
- **Menu** > **Settings > General > Access control >** Access control mode > Schiller Server > “User name”

Keys

Clear Deleting entered patient data.

Use previous patient The previous patient's data is entered again.

The fields described above are displayed by default. The order as well as additional fields can be configured in the **Menu** > **Settings > General > Visible fields > “**Recorder” (see page 76):

Age, Alternative PID, BMI and Generic data 1/2/3.

REF: 2.511462 Rev A / CAT: 070-3063-00 Rev A

3.6.1 Patient data query (PDQ)

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

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

- **Patient data query (PDQ)**: Select between:
  - Patient ID
  - Visit ID
- These settings along with other transmission settings are detailed in the system settings (see Page 61).

Patient data query with key PDQ

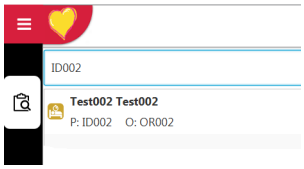
➜ Enter the patient ID or visit ID and press the **PDQ** key or OK to confirm the patient data query.

PDQ with Barcode reader

➜ Scan the Barcode to enter the **Patient ID** / **Visit ID**. Patient data is filled in automatically when the **Patient ID**/**Visit ID** is read with a Barcode reader.

- Connect the Barcode reader (see next page)
- Barcode scanner configuration: see document 2.510721.

3.6.2 PDQ in the worklist/memory



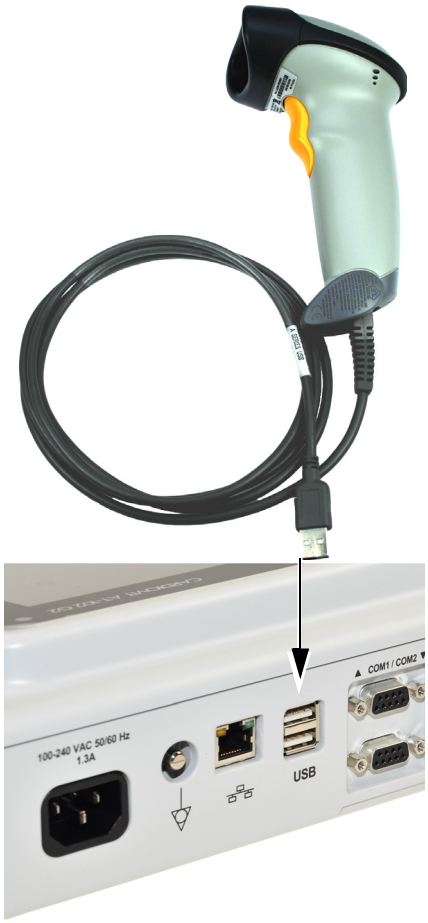
If you use the "Worklist" workflow, you can search/retrieve patient data in the same way in the worklist (see Page 55)

Select the Search field by pressing OK and read the **Patient ID** or **Visit ID** using the Barcode reader. The corresponding work item is shown in the worklist.

The same applies for searching recordings in the memory.

REF: 2.511462 Rev A / CAT: 070-3063-00 Rev A

3.6.3 Barcode reader



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

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

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

Country specific character sets can be set via the menu **Menu** > **Settings > Regional > Language > Barcode Scanner Layout.**

REF: 2.511462 Rev A / CAT: 070-3063-00 Rev A

4 Electrode placement

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 33 - 40).

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

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

REF: 2.511462 Rev A / CAT: 070-3063-00 Rev A

4.2 Electrode Identification and Color Code

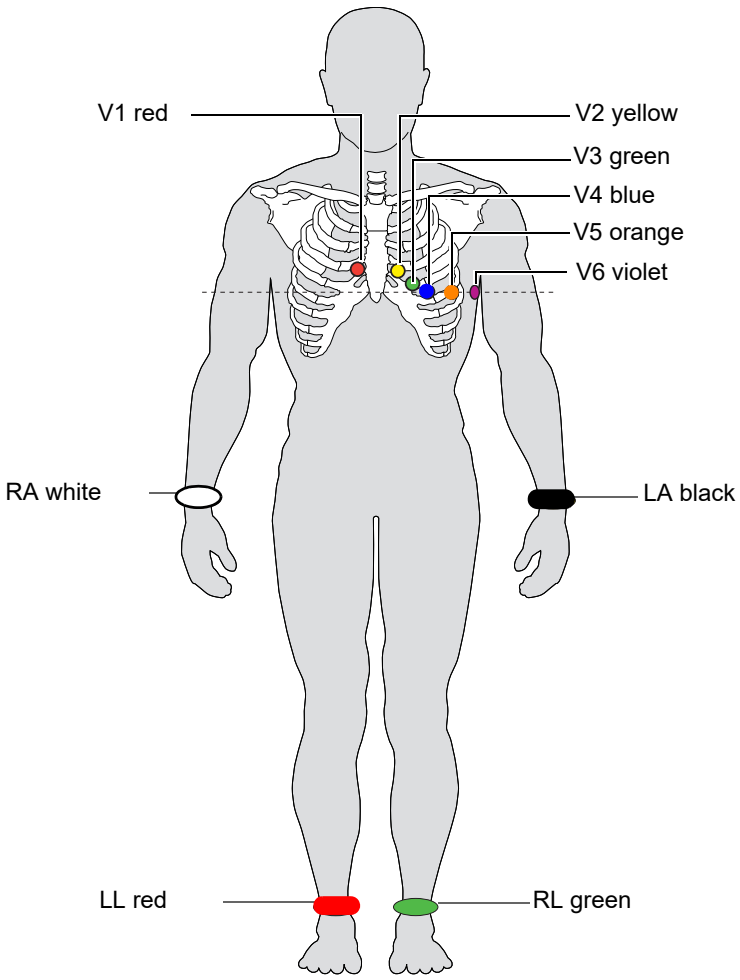
The electrode color codes in the following sections correspond to Code 1 (IEC) for the graphics and to Code 2 (AHA) in the tables

	IEC		AHA	
	IEC label	Color	AHA label	Color
Limb	R	Red	RA	White
	L	Yellow	LA	Black
	F	Green	LL	Red
Chest according 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/purple	V6	Brown/purple
Neutral	N	Black	RL	Green

The patient cable (type IEC or AHA) is set in the menu Lead & Cable, see chapter 8.2.1.

REF: 2.511462 Rev A / CAT: 070-3063-00 Rev A

4.3 Standard 10-lead resting ECG



4.3.1 Electrode placement for standard leads

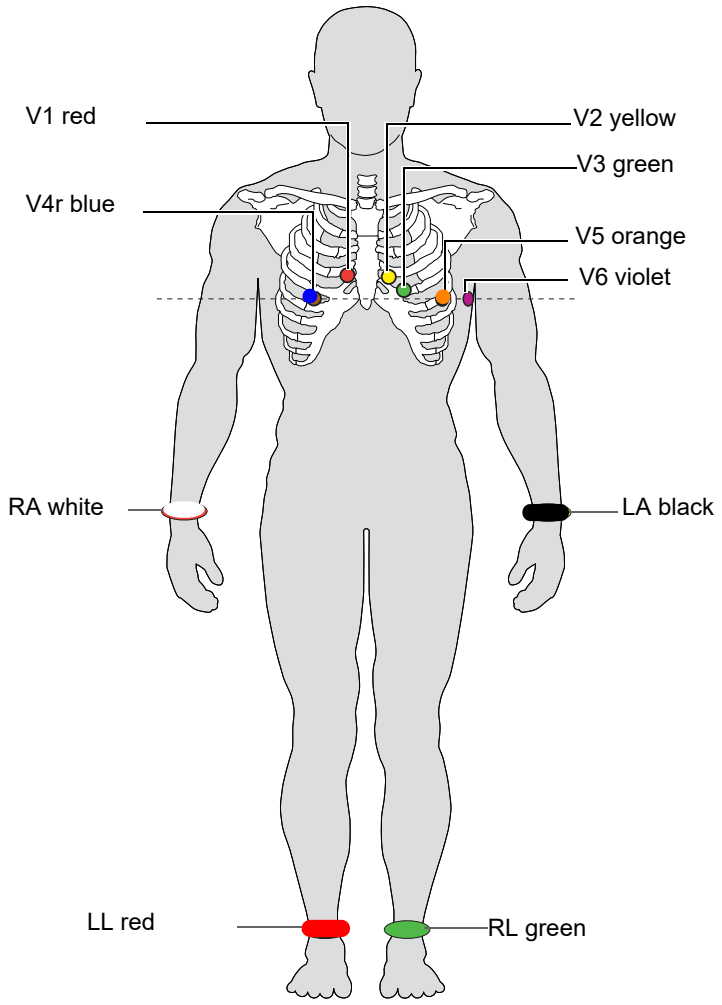
AHA label	Electrode placement
V1 red	→ Fourth intercostal space at the right sternal border
V2 yellow	→ Fourth intercostal space at the left sternal border
V3 green	→ Midway between C2 and C4
V4 blue	→ Fifth intercostal space on the mid-clavicular line
V5 orange	→ Anterior axillary line on the same horizontal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

The electrode resistance can be checked in the electrode test screen (see Page 40).

REF: 2.511462 Rev A / CAT: 070-3063-00 Rev A

4.4 Standard (V4r)

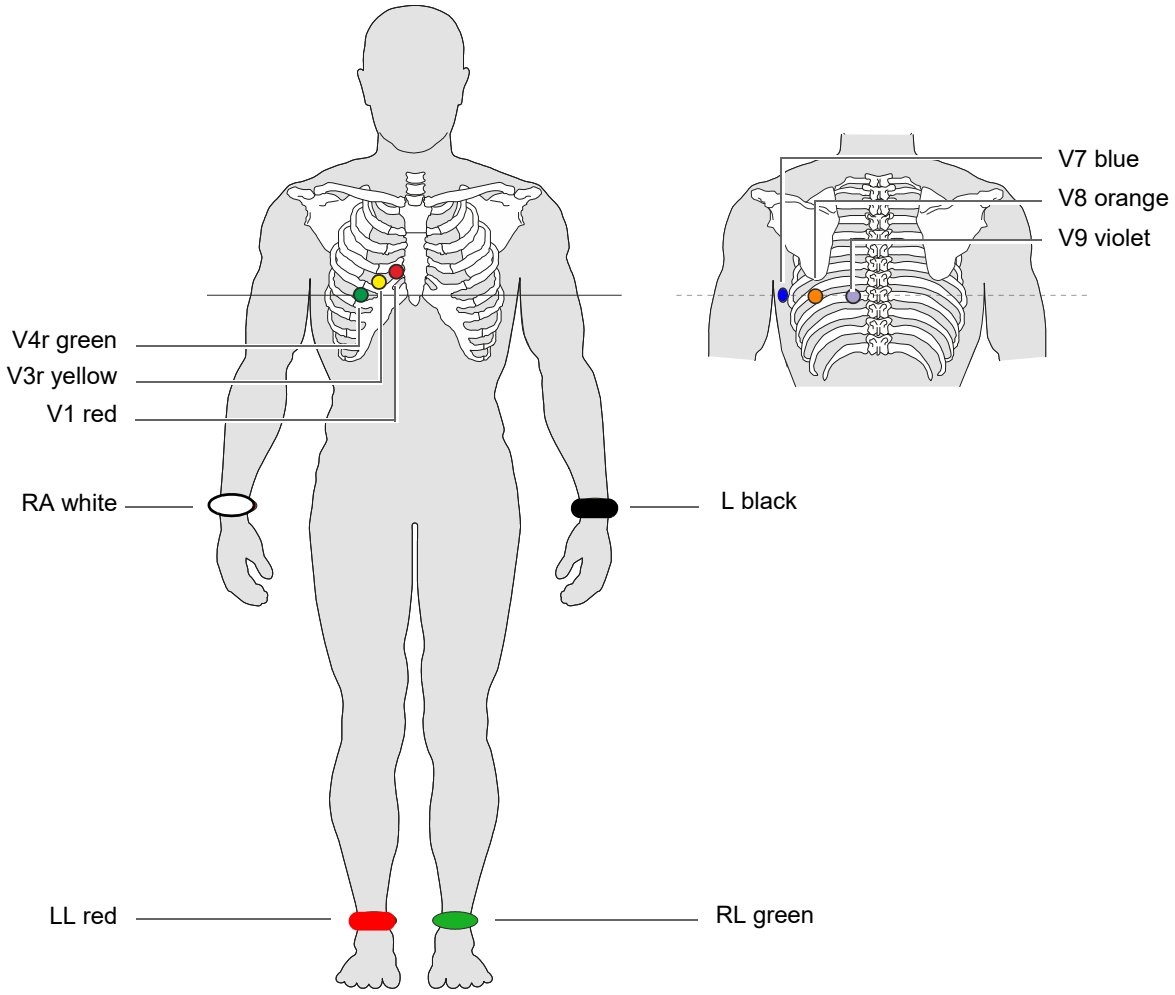
ACC/AHA guidelines recommend examining patients suffering from a myocardial infarction with inferior ST elevation for possible RV ischemia or RV infarction; this examination should be performed with a right precordial V4r lead.



AHA Label		Electrode placement
V1 brown / red	→	Fourth intercostal space at the right sternal border.
V2 brown / yellow	→	Fourth intercostal space at the left sternal border.
V3 brown / green	→	Midway between V2 and V4.
V4 brown / blue	→	Fifth intercostal space on the mid-clavicular line.
V5 brown / orange	→	Anterior axillary line on the same horizontal level as V4.
V6 brown / violet	→	Mid-axillary line on the same horizontal level as V4.
LA black	→	Left arm
RA white	→	Right arm
LL red	→	Left foot
RL green	→	Right foot

REF: 2.511462 Rev A / CAT: 070-3063-00 Rev A

4.5 Balanced



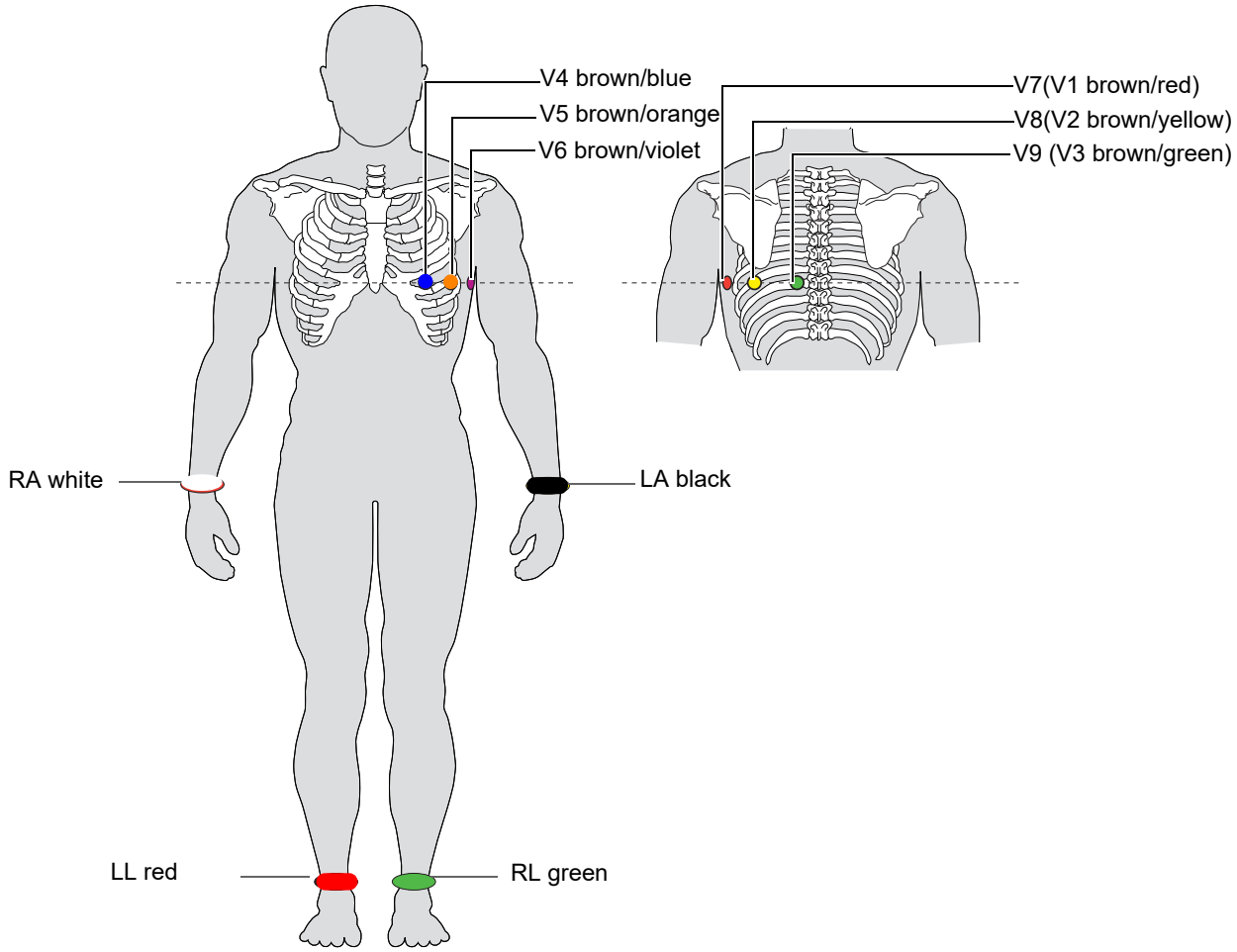
Balanced 10-wire Cable

AHA label		Electrode placement
V1 brown / red	→	Fourth intercostal space at the right sternal border.
V3r brown / yellow	→	Fourth intercostal space left of V1
V4r brown / green	→	Left of the mid-scapular line on the fifth intercostal space
V7 brown / blue	→	Left posterior axillary line at the level of V4r.
V8 brown / orange	→	Left posterior axillary line opposite of V4r
V9 brown / violet	→	Left posterior axillary line at the level of V4r, opposite C3
LA black	→	Left arm
RA white	→	Right arm
LL red	→	Left foot
RL green	→	Right foot

REF: 2.511462 Rev A / CAT: 070-3063-00 Rev A

4.6 Left posterior V7-V9

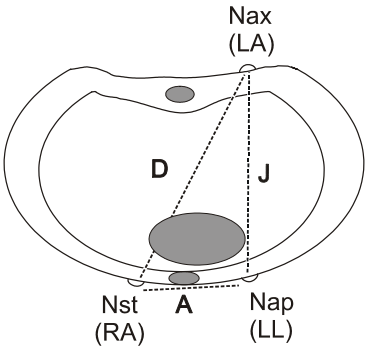
If an acute coronary occlusion is strongly suspected, it is recommended to also register posterior chest wall leads V7 to V9)



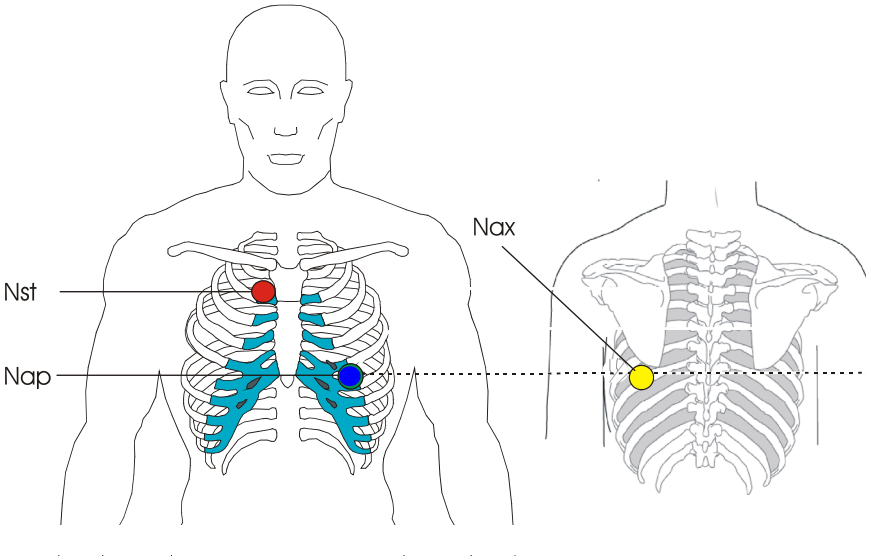
AHA label		Positioning
V7 (V1 brown / red)	→	Left posterior axillary line at the level of V4.
V8 (V2 brown / yellow)	→	Left of the mid-scapular line at the level of V4.
V9 (V3 brown / green)	→	Left paravertebral line at the level of V4.
V4 brown / blue	→	Fifth intercostal space on the mid-clavicular line.
V5 brown / orange	→	Anterior axillary line on the same horizontal level as V4.
V6 brown / violet	→	Mid-axillary line on the same horizontal level as V4.
LA black	→	Left arm
RA white	→	Right arm
LL red	→	Left foot
RL green	→	Right foot

REF: 2.511462 Rev A / CAT: 070-3063-00 Rev A

4.7 Nehb leads



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



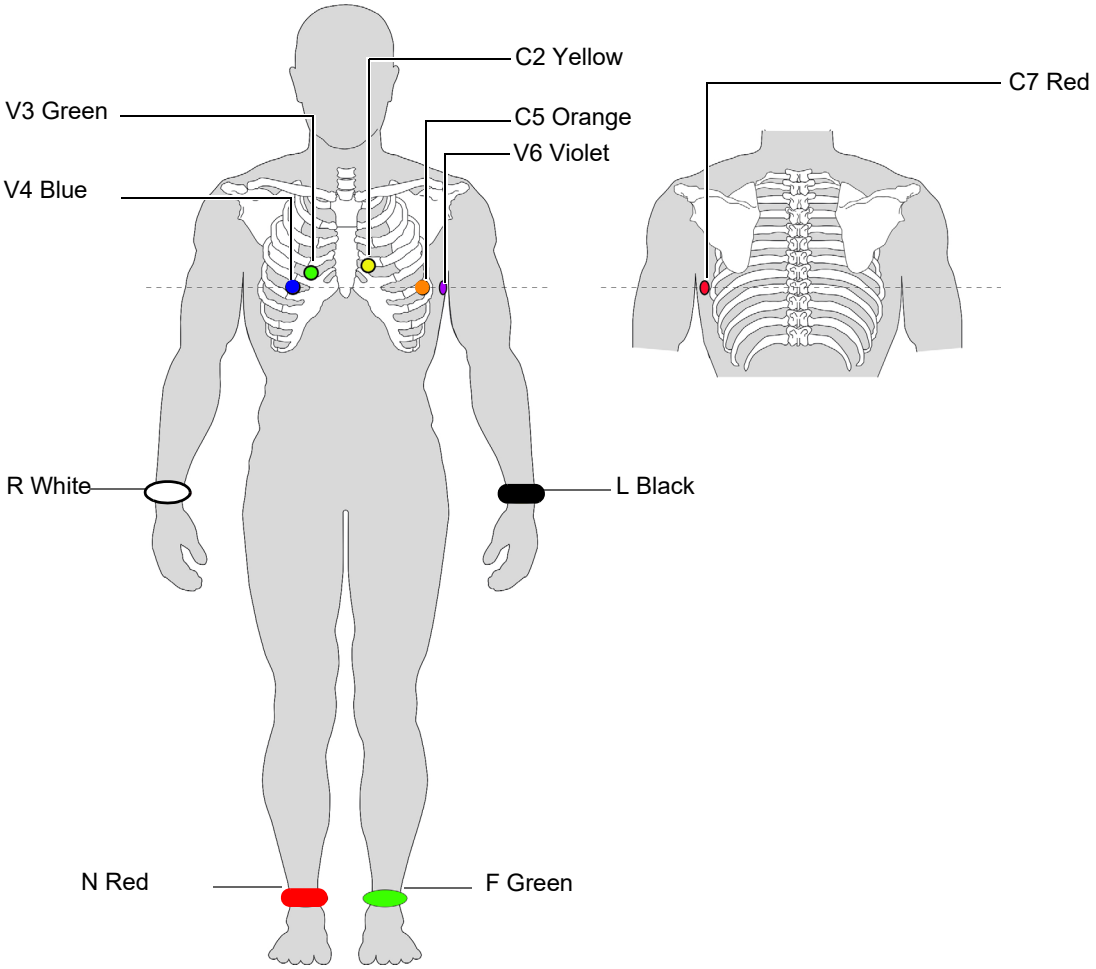
Place the electrodes as follows:

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

Place all other electrodes in the normal positions (Page 33).

REF: 2.511462 Rev A / CAT: 070-3063-00 Rev A

4.8 Pediatric

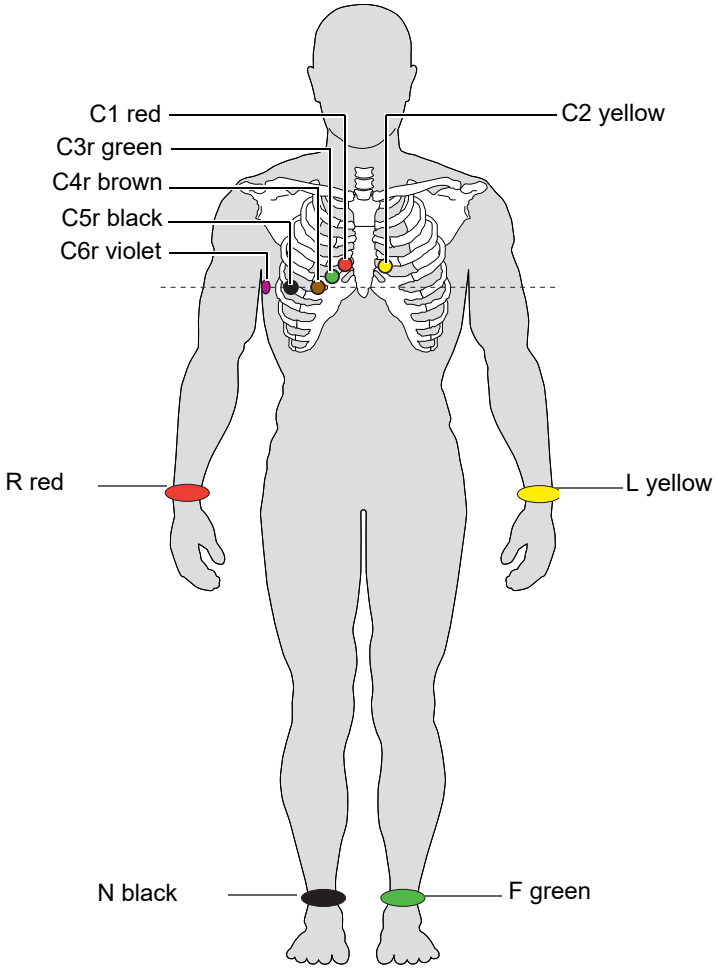


IEC label	AHA label	Electrode placement
C4r white / brown	V4 brown / blue	→ Fifth intercostal space on the mid-clavicular line.
C3r white / green	V3 brown / green	→ Fourth intercostal space, above C4r
C2 white / yellow	V2 brown / yellow	→ Fourth intercostal space at the left sternal border
C5 white /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

REF: 2.511462 Rev A / CAT: 070-3063-00 Rev A

4.9 Right precordials (C3r-C6r)

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



IEC label	AHA label		Action Alignment
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

REF: 2.511462 Rev A / CAT: 070-3063-00 Rev A

4.10 Skin/Electrode Resistance

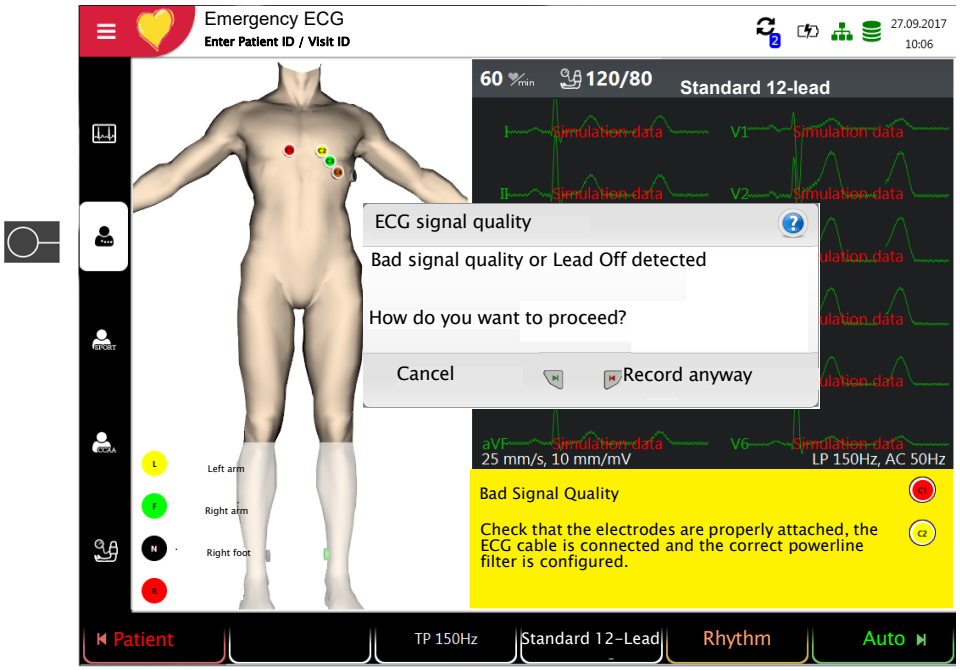
4.10.1 Electrode and patient cable check

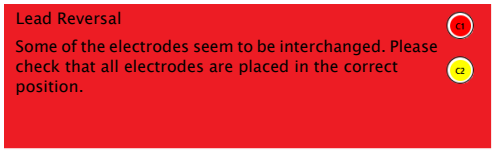
The electrode check is part of step 2 before the start of an ECG recording. The following is checked and displayed:

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

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

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

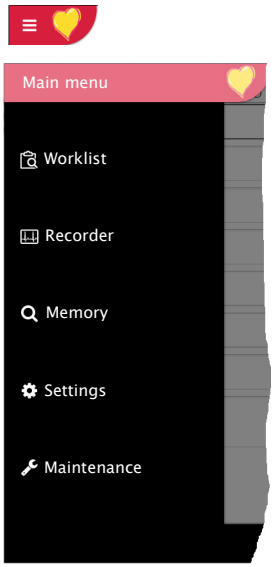




REF: 2.511462 Rev A / CAT: 070-3063-00 Rev A

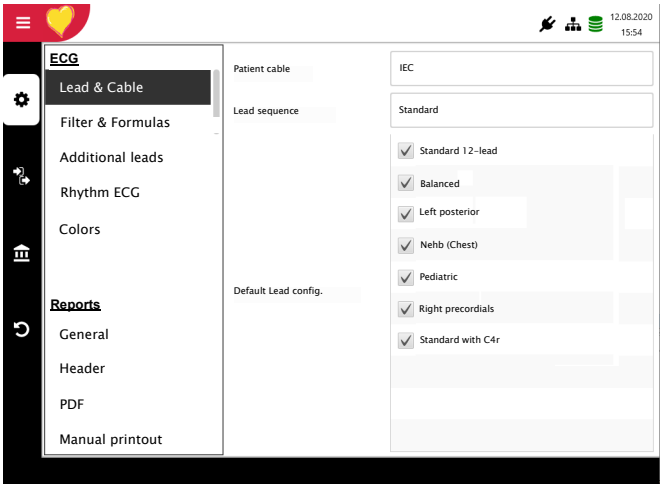
4.11 Lead sequence/lead view

4.11.1 Setting Standard or Cabrera lead sequence



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

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



4.11.2 Select the lead view (Standard or other settings)

The lead display can be set directly in the electrode screen using the lead selection key. Only lead configurations activated in the **Menu > Settings > ECG > Leads & cable > Default lead configuration** are available for selection.

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

Important

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

REF: 2.511462 Rev A / CAT: 070-3063-00 Rev A

5 Resting ECG

⚠WARNING

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

⚠ CAUTION

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

▲ The CardioPulse Prime 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 electrode) 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 AC power lead is damaged or suspected of being damaged.

▲ If an external electronic device is connected to the CardioPulse Prime, use the potential equalisation stud for earth protection.

i

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

The ECG display can be modified with regard to lead sequence (Standard or Cabrera), lead configuration, amplitude, speed and filter. For the preview, the following parameters can be freely programmed (before start of the recording):

- Amplitude
- Speed
- Filter
- Lead configuration
- Pacemaker detection On/OFF

Saved recordings can be displayed and printed in another format at any time.

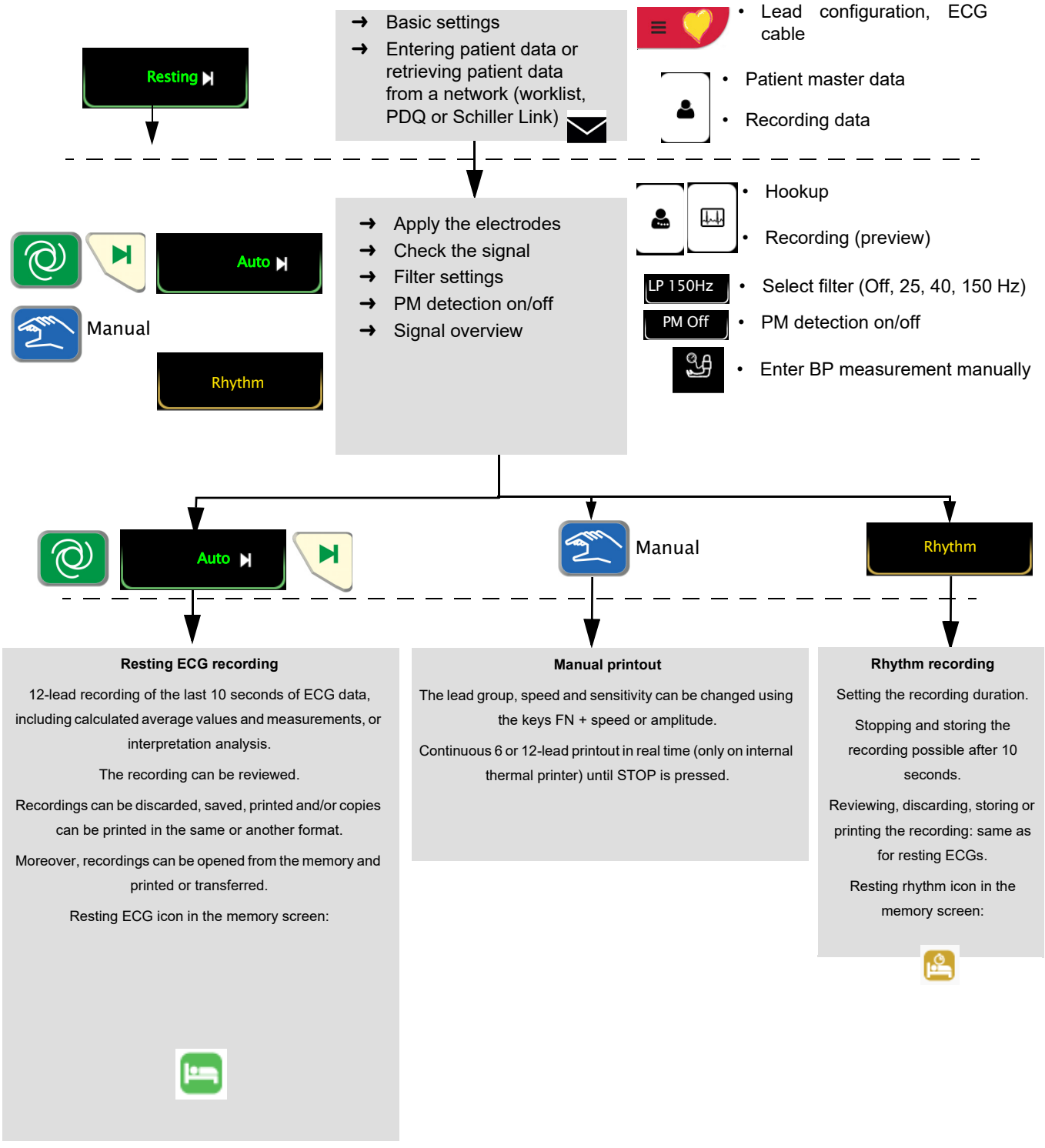
For further information on how to define the format, see Page 66.

⚠ CAUTION

▲ When using the 25 or 40 Hz filter, the displayed or printed ECG does not always meet the requirements of a diagnostic ECG.

REF: 2.511462 Rev A / CAT: 070-3063-00 Rev A

5.1 Resting ECG - Procedural Flow Diagram



REF: 2.511462 Rev A / CAT: 070-3063-00 Rev A

5.1.1 Printing, saving and transferring automatically

Menu > Settings > General > **Workflow**

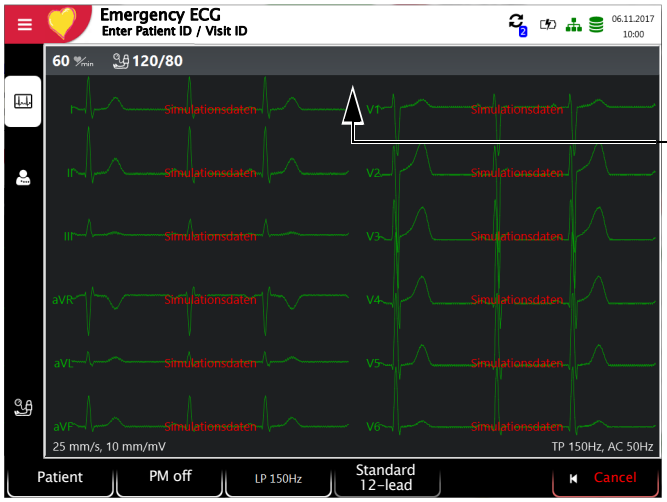
Activate **Print after acquisition**, **Transmit after acquisition** and **Delete after transmission** to automatically print and transmit a saved recording or to delete recordings after transmission.

- The transmission settings are detailed in the section Settings (see Page 72).
- Further ECG settings are described later in this section (see Page 64).
- Printing and transfer from the memory is described in the section Memory (see Page 51).
- The settings are saved automatically. The settings can be exported (see Page 63).

REF: 2.511462 Rev A / CAT: 070-3063-00 Rev A

5.2 Automatic resting ECG recording

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



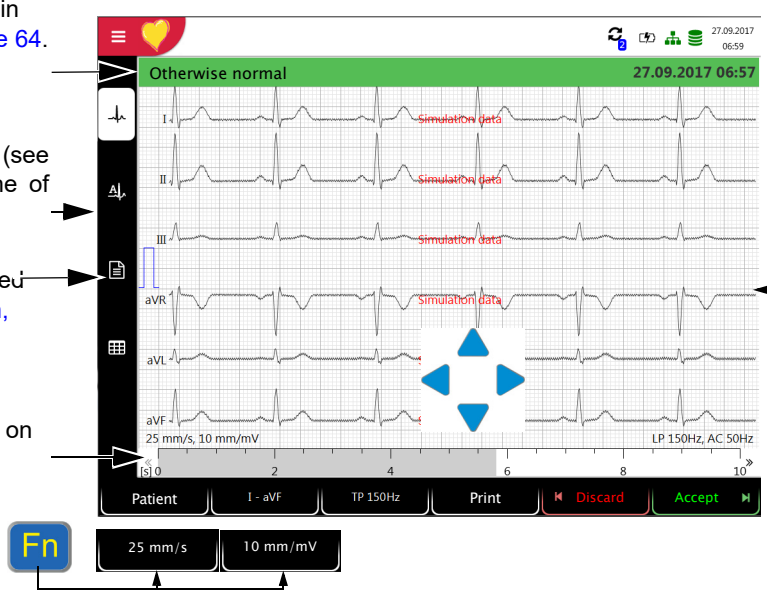
Remaining recording duration

Header text can be switched off in section 8.2.3 Interpretation, page 64.

Depending on the settings (see section 8.3), only some or none of these pages are displayed.

Interpretation text can be switched off in section 8.2.3 Interpretation, page 64.

The grey bar shows the position on the time axis.



Check the recording by moving the time axis (grey bar) and the keys (to scroll through channels).

- ➜ Select filter (Off, 25, 40, 150 Hz) LP 150Hz
- ➜ **Accept** the recording (recording is saved)
- ➜ Print the recording Print (see section 8.3.5 Resting ECG, page 68)
- ➜ Press **Discard** to exit the preview without storing the ECG.
- ➜ In the **Memory** menu, select a recording for review and printout.
- ➜ Open the menu **Memory** to delete a recording from memory.

REF: 2.511462 Rev A / CAT: 070-3063-00 Rev A

5.2.1 Automatic printout

The printout gives the following:

- Heart rate
- Patient name and ID
- Date and time
- Speed
- Sensitivity
- Filter
- Device ID
- Serial number
- Software version

And any combination of the following (for printout settings, see section 8.3 Menu Reports, page 66):

Patient data
- All patient data according section 3.6 Patient / recording data, page 26

Result
- Interpretation (can be switched off in **Menu > Settings > ECG > Interpretation** , see section 8.2.3 Interpretation, page 64).
- Intervals & axis

Measurements
- Detailed measurement table

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

Averages
- Averaged cycles with markings

REF: 2.511462 Rev A / CAT: 070-3063-00 Rev A

5.3 Manual Rhythm Printout

- Use this function to print a real-time ECG. The print parameters such as lead sequence, print speed and sensitivity can be changed by the user during the printout.
- The real-time ECG is not saved. The chosen settings only apply to the printout.

5.3.1 Starting manual printout

1. Manual printout can be started in the Recording view.
2. To set the speed, amplitude and lead for the printout, press the key **FN** to display the additional function keys. The print setting for speed, amplitude and leads can be done before or during the printout.
3. To start a manual real-time printout, press the **Manual** key.

The factory printout settings are **25 mm/s** and **10 mm/mV.** These settings are to be found in the menu section 8.3.4 Manual printout, page 67. The factory settings for the leads are to be found in the menu, section 8.2.4 Additional Leads, page 65**.**

Display speed and amplitude.

Printout speed, amplitude and lead.

Select lead sequence

→ To change the lead sequence for the printout (Standard I, II, III, aVR, aVL, aVF), press the right key **Leads I-V6** to select additional lad sequences.

The Standard and Cabrera lead sequences are as follows:

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

Select speed

→ To change the printout speed (12.5, **25** and 50 mm/s), press the key **Speed**.

Select sensitivity

→ To change the printout sensitivity (5, **10** and 20 mm/mV), press the key **Amplitude**.

Stopping the printout

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

The printout provides the following information:

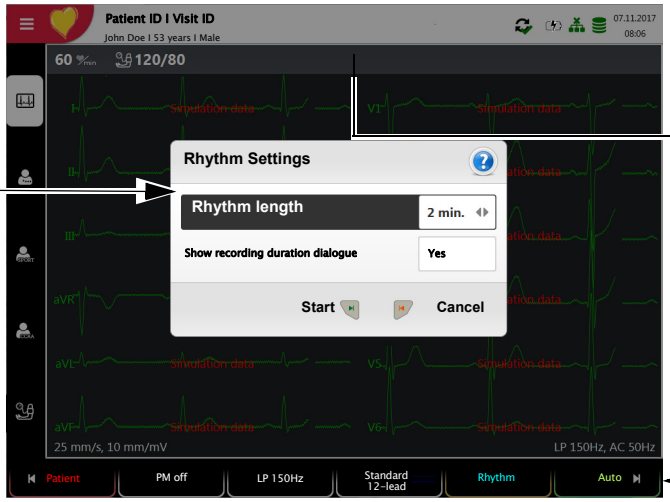
- Selected leads
- Patient name and ID
- Date and time
- Speed, sensitivity, filter, device ID, serial number device, software version

REF: 2.511462 Rev A / CAT: 070-3063-00 Rev A

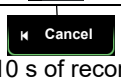
5.4 Rhythm recording

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

The dialogue "Rhythm settings" can be deactivated in the Settings menu or directly in the dialogue. To reactivate the dialogue, tick the option in the Rhythm ECG menu, see chapter 8.2.5.

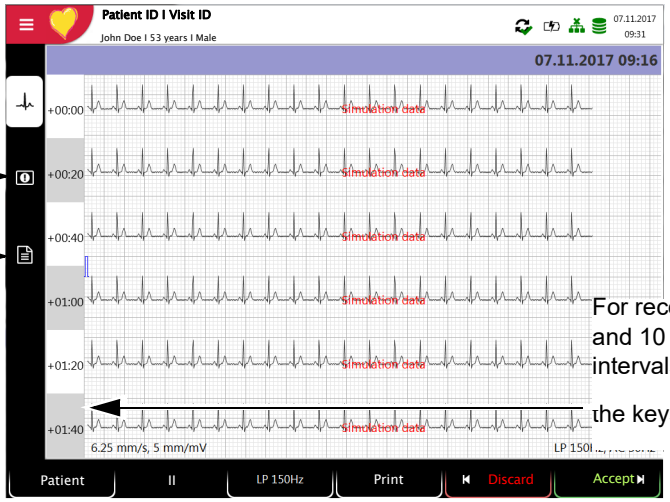


Once Start is pressed, the remaining recording duration is displayed 1:53



After 10 s of recording, the icon Cancel changes to Stop. Press Stop to end and store the recording.

During recording, events can be entered in the event dialogue.



Graphics showing the heart rate trend

Entering the interpretation

For recordings lasting between 3 and 10 minutes, additional time intervals can be displayed using the keys

Set the amplitude and speed

Check the recording using the keys **"FN & Lead"** (select leads) and the keys (select time interval).

- ➜ Key Select filter (Off, 25, 40, 150 Hz)
- ➜ Pacemaker detection on/off
- ➜ **Accept** the recording (recording is saved)
- ➜ **Print** the recording (see section 8.3.6 Rhythm ECG, page 69)
- ➜ Press **Discard** to exit the preview without storing the ECG.
- ➜ Select a recording for review and printout via the **Memory** menu .
- ➜ Open the menu **Memory** to delete a recording from memory.

REF: 2.511462 Rev A / CAT: 070-3063-00 Rev A

5.5 Changing the ECG display

The ECG preview is optimized for one or two columns with 6 leads each, or for 3 columns with 4 leads each. The amplitude and speed can be set to 5, **10** or 20 mm/mV, and to 12,5, **25** or 50 mm/s. The ECG preview for electrode hook-up cannot be changed.

5.5.1 Display

Leads

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

The Standard and Cabrera lead sequences are as follows:

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

The lead group is selected in the ECG settings (see Page 64).

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

- Standard 12-lead
- Standard C4r
- Balanced
- Left Posterior
- Nebh (chest)
- Pediatric
- Right Precordials

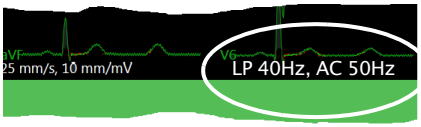
Additional settings for the preview and review

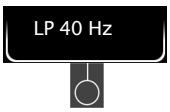
See section 8.4 Menu Layouts, page 70

REF: 2.511462 Rev A / CAT: 070-3063-00 Rev A

5.5.2 Myogram (low pass) filter

The Myogram (low pass) filter suppresses disturbances caused by strong muscle tremor. In **Menu > Settings > ECG > Filters & formulas,** the **Myogram filter is** defined.





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

- The cut-off frequency is user-defined at LP 25 Hz or LP 40 150 or 250 Hz (Filter Off) (see chapter 8.2, page 64).
- 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 40 Hz filter, the displayed or printed ECG does not always meet the requirements of a diagnostic ECG.

5.5.3 Other filters

The following additional filters are available:

Baseline filter

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

Notch filter

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

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

REF: 2.511462 Rev A / CAT: 070-3063-00 Rev A

6 Memory

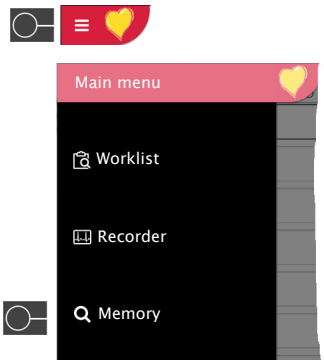
Recordings can be stored locally and/or transmitted automatically to Schiller Link or Server. Recordings stored in the memory can be viewed, printed, transmitted or deleted at any time.

6.1 Saving a Recording

Recordings are stored manually after completion of the acquisition.

6.2 Editing the memory

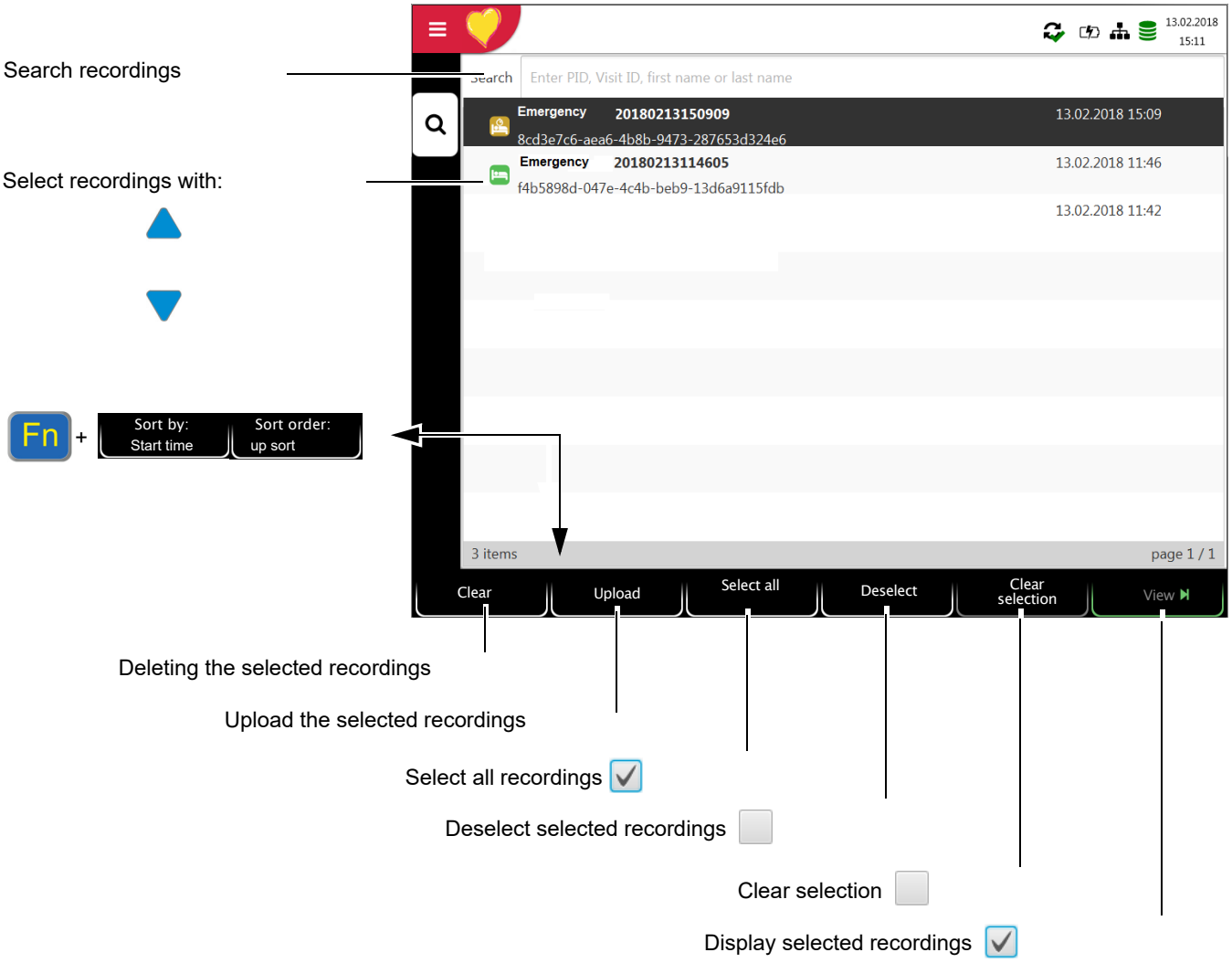
Approx. 350 resting ECGs, 100 resting rhythms can be stored on the CardioPulse Prime.



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

- The recordings are listed by date/time; however, different listing criteria can be selected and recordings can also be searched via the search function.
- Memory capacity is indicated by the icon in the status bar:
  - green = memory OK
  - yellow = almost full
  - red = memory full, no more recordings can be performed.

REF: 2.511462 Rev A / CAT: 070-3063-00 Rev A

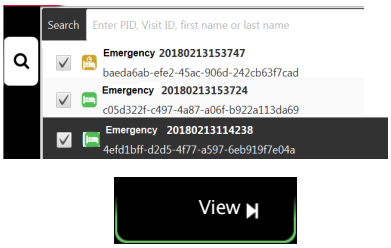


REF: 2.511462 Rev A / CAT: 070-3063-00 Rev A

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

Depending on the settings in **Menu > Settings > General > Workflow**, the recording is printed automatically as soon as it has been saved.

The following procedure shows how recordings can be selected from the memory and printed or exported to a USB stick.



1. Select the recording.
2. Press the function key "View".

➜ The recording is displayed according to the settings in **Menu > Settings > Resting ECG > Resting ECG review**, and the layout can be changed for the displayed recording at any time.

3. Press the function key **Print** to print the recording in the selected format, see section 8.3 Menu Reports, page 66.
4. Press the function key **PDF** to save the recording in the set format as PDF to a USB stick, see section 8.3.1 General, page 66

Example: resting ECG

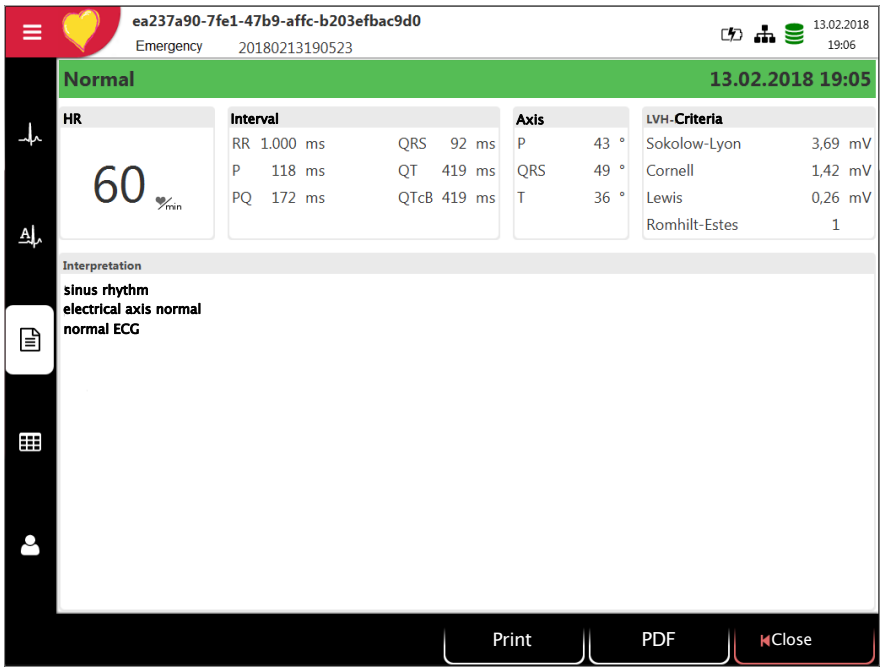
Rhythm

Averages

Results

Measurements

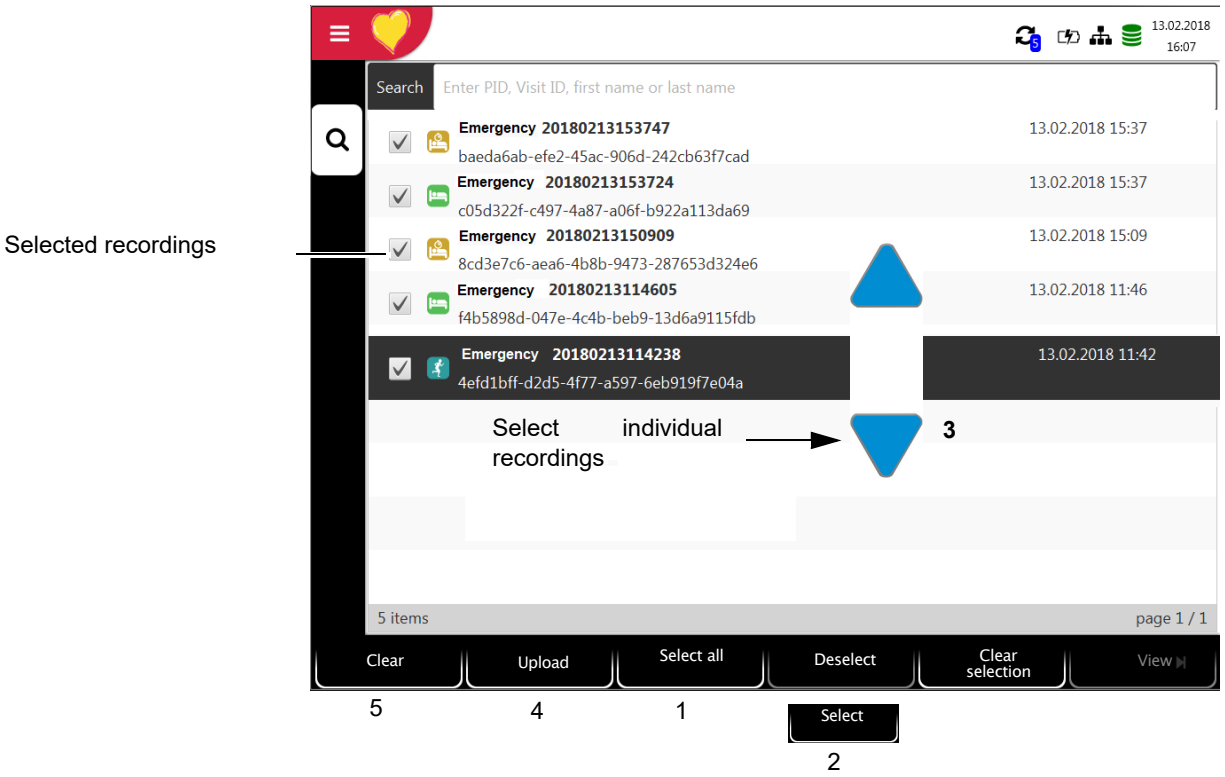
Patient data



REF: 2.511462 Rev A / CAT: 070-3063-00 Rev A

6.2.2 Transmitting and deleting stored recordings

Depending on the settings in **Menu > Settings > General > Workflow** (see Page 76), the recording is transmitted and deleted automatically as soon as the recording has been finished. If automatic transmission is not activated, recordings can be transmitted as follows.



➜ To select all recordings, press the function key **Select all (1).**

➜ To select a recording, use the navigation keys **(3)** to highlight the recording, and press the function key **Select (2).**

➜ To deselect a recording, highlight the selected recording with the navigation keys **(3)** and press the function key **Deselect (2).**

➜ To upload or delete recordings, select the desired function:

– Upload for an export to the Schiller server **(4)**.

– Delete **(5)** (automatic deletion after transmission can be set in **Main menu > Settings > General > Workflow**, see Page 76).

Should the network not be available, recordings that have not been transmitted are displayed with the symbol (see Page 84).

If the network is available and recordings have been transmitted, the symbol is displayed.

- The transmitting options are detailed in the section System settings (see Page 80).
- Use the setting **Menu > Settings > General > Memory >** Cleanup local recordings to automatically delete recordings after a defined period of time, see Page 77.

REF: 2.511462 Rev A / CAT: 070-3063-00 Rev A

7 Worklist (Option)

7.1 General information

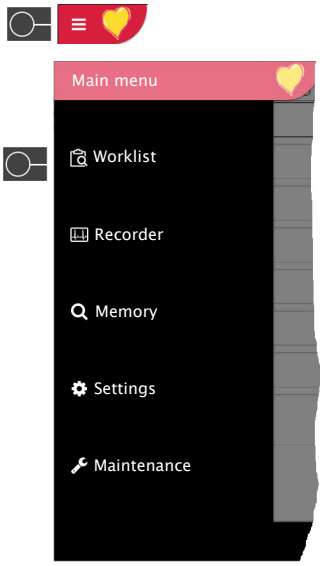
The Worklist function enables a doctor / administrator to define a worklist of patients that require recordings to be made. The doctor can define the patient, room / department, and specify the type of recording to be made. The worklist is defined directly from the Hospital information system (HIS); once the recording has been made by the CardioPulse Prime, it is sent back to the HIS for analysis, examination and storage.

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

- To be able to use the worklist function, the license must be activated.
- To be able to use the worklist function, the unit must be set up to communicate with the Schiller Server (see Page 72).
- The definition of the worklist on the Schiller Server is described in the Schiller Server user guide.

From the Schiller Server, a worklist can be sent to a specific unit or to all units on the system. To receive a worklist from the Schiller Server, the unit identification of the CardioPulse Prime (device ID in the system) must be the same as the one defined for the Schiller Server. This is usually set when the unit is first commissioned. The Device ID is shown in **Menu** > **Settings > General > Station**.

7.1.1 Worklist settings



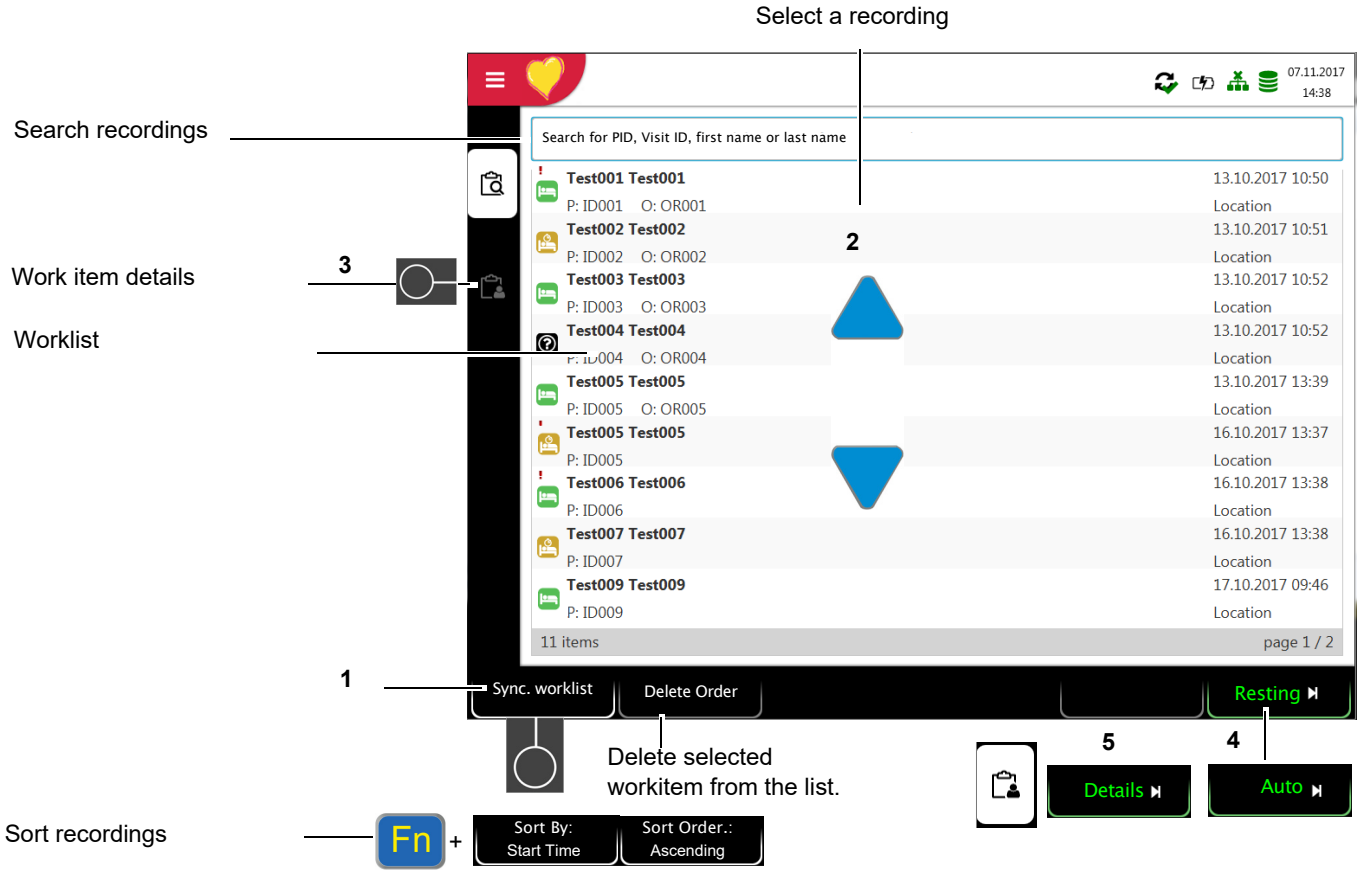
If worklists are to be used, the workflow can be adapted accordingly. To do so, set the Default workflow in **Menu** > **Settings > General > Workflow** to Record from worklist. In this way, the worklist is shown directly after power-up. However, worklist can also be selected manually from the menu.

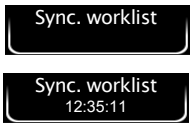
REF: 2.511462 Rev A / CAT: 070-3063-00 Rev A

7.2 Receiving a worklist

To open the worklist proceed as follows:

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





2. To receive a worklist from a HIS, press the **Sync. worklist (1)** key to download the worklist from the Schiller Server. Wait (up to a few minutes) for the worklist to be populated. If "Auto Sync Worklist" is programmed in the **Menu > Settings > General > Workflow**, the list is updated every minute and the update time is displayed on the key.

3. Depending on the setting in the Workflow menu, the following workflows are possible:

- Recording from worklist

➜ You can start the selected order **(2)** directly by pressing the key **(4),** or you can first check the workitem by pressing **(3)**, return to the worklist and then perform the recording **(4)**.

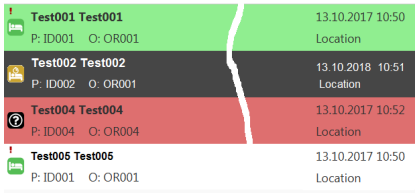
- Recording from workitem

➜ You can view the selected order's **(2)** details by pressing the key **(5)**. The recording can then be started directly in the Recording details view by pressing the key “Resting” **(4).**

REF: 2.511462 Rev A / CAT: 070-3063-00 Rev A

All patients given in the worklist are displayed with their last/first name, patient ID, order ID and room number. The following recording types are available:

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



Recording status:

- White background = recording to be performed.
- Dark grey background = selected recording.
- Green background = already performed recording. The next time the worklist is synchronized, these recordings are going to be deleted, both on the device and on the Schiller Server.
- Red background = recording was canceled and deleted.

- The order and visibility of the fields in the view "Workitem details" can be configured in the **Menu** > **Settings > General > Visible fields >** "Worklist" (see page 76).

REF: 2.511462 Rev A / CAT: 070-3063-00 Rev A

7.2.1 Taking a Worklist Recording

- This procedure corresponds with the worklist mode “Record from worklist”, see setting section 8.7 General, page 76, workflow.
- Patient data provided by the HIS cannot be edited (except for height and weight).
- If you have selected an incorrect work item, press the key , but **not** the key Clear. Select the new work item from the list, or use the Search field.

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

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

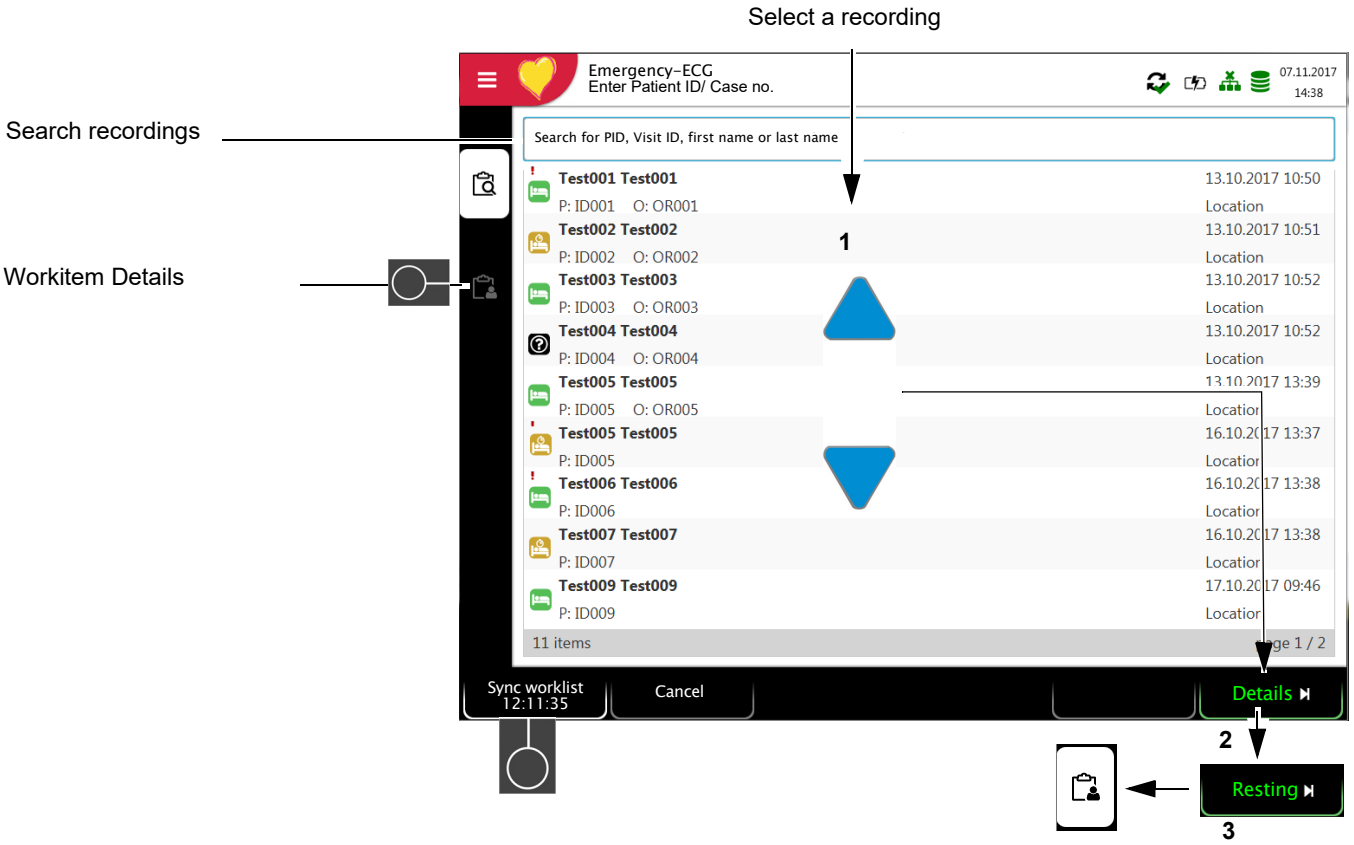
5. Take the recording:
   – Resting ECG (see Page 45)
   – Resting rhythm (see Page 48)

REF: 2.511462 Rev A / CAT: 070-3063-00 Rev A

7.2.2 Performing a recording from work order details

- This procedure corresponds with the worklist mode “Record from work order details”, see setting section 8.7 General, page 76, workflow.
- Patient data provided by the HIS cannot be edited (except for height and weight).
- If you have selected an incorrect work item, press the key , but **not** the key Cancel. Select the new work item from the list, or use the Search field.

1. Prepare the patient and select a work item.



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

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

5. Take the recording:
   - Resting ECG (see Page 45)
   - Resting rhythm (see Page 48)

REF: 2.511462 Rev A / CAT: 070-3063-00 Rev A

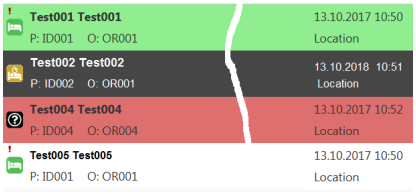
7.2.3 Sending worklist recordings to the HIS

- It is possible to automatically send performed worklist recordings. This is defined in system settings (**Menu** > **Settings > General > Workflow > Transmit after acquisition** Page 76).
- Recordings can also be transmitted manually in the memory.

Sync. worklist

→ In order to update the worklist, press **Sync. worklist.** Wait until the synchronization is completed, i.e. until the recordings are no longer displayed in the worklist (this can last a few minutes).

Pending work items are indicated by a white background and selected work items by a grey background.



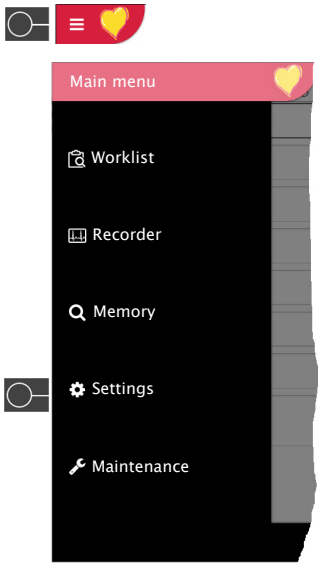
Completed work items (green) or those that have been canceled (red) are deleted from the worklist during the next synchronization.

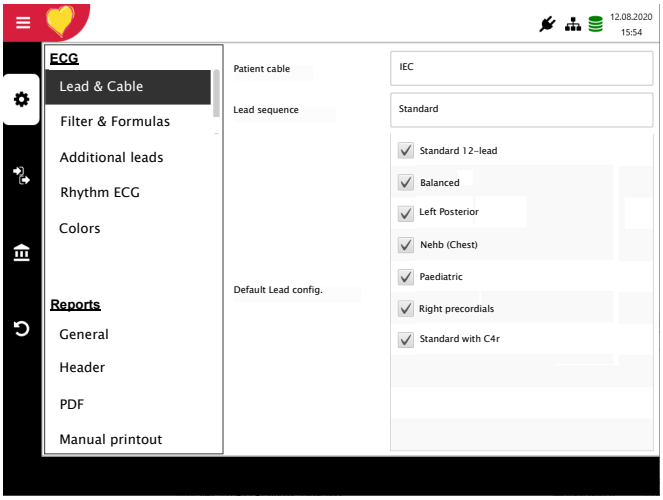
REF: 2.511462 Rev A / CAT: 070-3063-00 Rev A

8 General and System Settings

8.1 Navigation

When pressing the Menu key , the option **Settings** is displayed.





REF: 2.511462 Rev A / CAT: 070-3063-00 Rev A

8.1.1 Overview Menu > Settings

This menu can be protected with a password via the menu **Settings > General > Access control**.

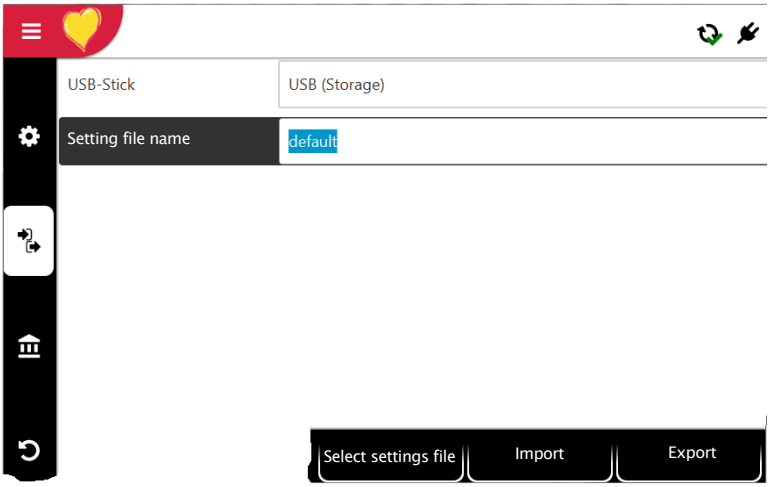
Settings overview

Menu Settings	Sub-menu
ECG (Page 64)	• Lead & Cable • Filter & Formulas • Interpretation • Additional Leads • Resting rhythm • Color
Reports (Page 66)	• General • Manual printout • Resting ECG • Rhythm ECG
Layouts (Page 64)	• Resting • Worklist
Connectivity (Page 72)	• EMR integration • Ethernet • WLAN
Regional (Page 75)	• Date / time • Language • Units • Patient ID system
General (Page 76)	• Info • Power management • Station • Update • Manage licenses • Visible fields • Mandatory fields • Custom fields • Access control • Workflow • Memory • Printer

REF: 2.511462 Rev A / CAT: 070-3063-00 Rev A

8.1.2 Saving and restoring settings

Changed settings are saved automatically. In **Menu > Settings**, settings from another device can be imported, or a backup of the settings can be restored (see Page 63).



Import/export settings

Select USB Storage and enter the file name to import or press the function key "Select setting files" in order to import or export the files.

Export audit log

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

Reset to factory settings

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

REF: 2.511462 Rev A / CAT: 070-3063-00 Rev A

8.2 ECG Menu

8.2.1 Lead & Cable

Menu	Parameter	Description / selection
Lead & Cable	Patient cable	**IEC** or AHA
	Lead sequence	**Standard** or Cabrera
	Default lead config.	☑ Lead configuration. Use the function key Leads to de-/activate leads, and change their order with Up/Down: • Standard 12-lead • Balanced • Right Precordials • Left Posterior • Nebh (chest) • Pediatric • Standard C4r

8.2.2 Filter & Formulas

Menu	Parameter	Description / selection
Filter & Formulas	Notch filter	Off / **AC 50** / AC 60 Hz
	Resting display filter	Off/LP25/LP40/**LP150 Hz**
	Default QTc calculation	**Bazett**, Fridericia, Framingham, Hodges

8.2.3 Interpretation

Menu	Parameter	Description / selection
Interpretation	Print Interpretation	**Yes**/No
	Display Interpretation	**Yes**/No
	Display abnormal/borderline header	**Yes**/No

REF: 2.511462 Rev A / CAT: 070-3063-00 Rev A

8.2.4 Additional Leads

Standard leads per lead configuration

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

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

8.2.5 Resting rhythm

Menu	Parameter	Description / selection
Resting rhythm	**Rhythm length**	30 s, 1, **2**, 3, 4, 5 and 10 minutes Setting the recording duration.
	Show recording duration dialogue	**Yes**/No The dialogue can be deactivated during the recording and can be activated here again.

8.2.6 Color

Menu	Parameter	Description / selection
Color	**Background color**	**Black,** white
	Line color (good quality)	**Green**, black, white, blue, red, yellow
	Line color (medium quality)	**Yellow**, green, black, white, blue, red
	Line color (low quality)	**Red**, yellow, green, black, white, blue
	Text color	**White**, blue, red, yellow, green, black

REF: 2.511462 Rev A / CAT: 070-3063-00 Rev A

8.3 Menu Reports

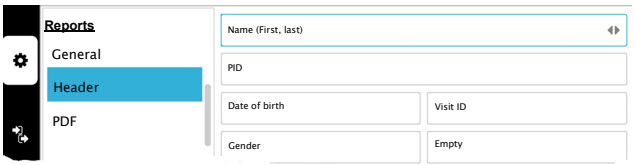
Therefore, saved ECGs can be displayed with different settings at any time.

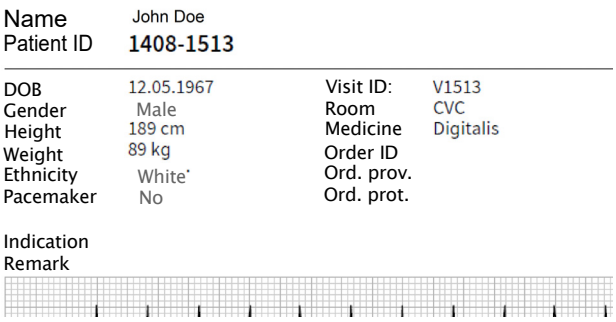
8.3.1 General

Parameter	Description
Rhythm mode	**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.
Company info 1, 2, 3	Enter company information on the PDF, lines 1, 2, and 3.

8.3.2 Header

Configuration and order of the information given in the header. Select "Empty" if a field should not be displayed.





8.3.3 PDF

Parameter	Description
PDF paper format	**A4** or Letter
PDF conformance	**None**, PDF/A-1a, PDF/A-1b
Company logo	Display of the imported company logo. **Import logo:** 1. Name of the logo “reportlogo.png”. Accepted file types are jpg, jpeg, png, bmp or gif. 2. Connect the USB stick containing the file “reportlogo” to the CardioPulse Prime. 3. Press function key “Import logo”. “reportlogo” is loaded and displayed.
Print company logo	**Yes**/No

REF: 2.511462 Rev A / CAT: 070-3063-00 Rev A

8.3.4 Manual printout

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

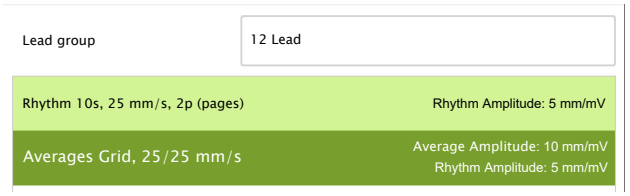
Parameter	Description
Default lead group	Selection of the lead group: **All**, extremities or precordials
Default amplitude [mm/mV]	5, **10**, 50 mm/mV
Default speed [mm/s]	12.5, **25** or 50 mm/s

REF: 2.511462 Rev A / CAT: 070-3063-00 Rev A

8.3.5 Resting ECG

Saved ECGs can be displayed with different settings at any time.

- Patient data is always printed.
- The order listed below can vary.
- Select (▲▼), activate/deactivate with OK or with function key , sort with keys Up/Down and Average/Rhythm amplitude 5/10/20 mm/mV.



Menu	Description / selection
Lead group	• Display of the leads listed below (12 or 9 leads). Select (with key OK or Activate) and define the order (function keys Up/Down) of the following print formats:
12 Lead	• **Rhythms 10s, 25 mm/s, 2p (pages)** • Measurements • Averages Grid, 25/25 mm/s • Averages Grid, 50/25 mm/s • Averages Wide, 50/25 mm/s • Panorama, 25 mm/s • Rhythms 10s, 25 mm/s • Rhythms 5s, 25 mm/s • Rhythms 5s, 50 mm/s, 2p • Rhythms Grid, 25 mm/s
9 Lead	• **Rhythms 10s, 25 mm/s, 2p** • Measurements • Averages Grid, 50/25 mm/s • Averages Wide, 50/25 mm/s • Rhythms 5s, 25 mm/s • Rhythms 5s, 50 mm/s, 2p

REF: 2.511462 Rev A / CAT: 070-3063-00 Rev A

8.3.6 Rhythm ECG

Saved ECGs can be displayed with different settings at any time.

- The order listed below can vary.
- Select (▲▼), activate/deactivate with OK or with function key , sort with keys Up/Down and Average/Rhythm amplitude 2.5/5/10 mm/mV

:

Parameter	Description / selection
Rhythm	**Continuous, 25 mm/s, 2:00 min**
	Continuous, 12,5 mm/s, 5.20 min
	Continuous, 6,25 mm/s, 10.40 min
	Rhythm 10s/ p (page)
	Rhythm 20s/ p (page)
	Rhythm summary

REF: 2.511462 Rev A / CAT: 070-3063-00 Rev A

8.4 Menu Layouts

In this menu, the views and layouts for **Preview** and the **ECG review** can be set.

8.4.1 Resting

Preview

Menu	Parameter	Description
Preview	View order	Select whether Hookup or Recorder is shown at the top.
	12-lead layout	**2x6 /** 4x3/ 1x6
	Amplitude	5/**10** /20 mm/mV
	Speed	12.5/**25**/50 mm/s

Resting ECG review

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

Menu	Parameter	Description
Resting ECG review	View selection and order	Select ☑ (with key OK or Activate) and define the order (function keys Up/Down) of the following views: • Rhythms • Averages • Results • Measurements
	Rhythm view 12 lead layout	**1x6 /** 1x12
	Rhythm view amplitude	5/**10** /20 mm/mV
	Rhythm view speed	12.5/**25**/50 mm/s
	Average view amplitude	**10**/20 mm/mV
	Average view speed	**25**/50 mm/s
	Display abnormal/borderline header	**Yes**/No

REF: 2.511462 Rev A / CAT: 070-3063-00 Rev A

Rhythm ECG review

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

Menu	Parameter	Description
Rhythm ECG review	View selection and order	Select ☑ (with key OK or Activate) and define the order (function keys Up/Down) of the following views: • Continuous/Rhythms • Rhythm summary • Results
	Continuous/Rhythm view amplitude	2.5/**5** mm/mV
	Continuous/Rhythm view speed	12.5/**6.25** mm/s

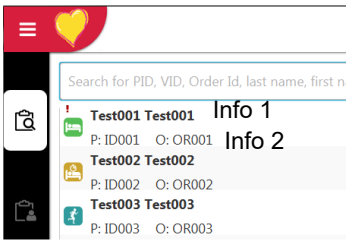
8.4.2 Worklist

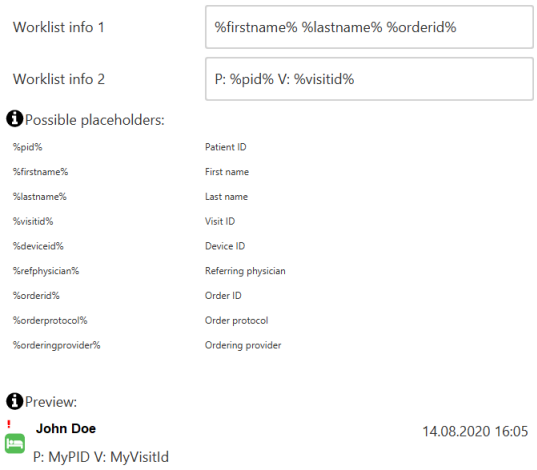
The worklist with Info 1 and 2 can be freely configured using the available placeholders.

The configuration is displayed in the Preview.

Default settings:

- Worklist info 1: %firstname% %lastname% (first/last name)
- Worklist info 2: P: %pid% V: %visitid% (patient ID, visit ID)





8.5 Connectivity

8.5.1 EMR integration

Menu	Parameter	Description / selection
EMR integration Server settings	EMR integration (EMR = electronic medical record system)	**None** – No input field displayed Schiller Link – Device ID is displayed Schiller Server – Host, port, user and password input fields are displayed. (See following)
	Host	Name of the server
	Port	Port address
	SSL Certificate Validation	Yes/**No**
	User	User name
	Password	Password

8.5.2 Ethernet

Menu	Parameter	Description / selection
Ethernet	Use DHCP	**Yes**/No. If this is not activated, the following parameters need to be entered:
	IP address	Identifier address of the device in the TCP/IP network.
	Subnet mask	Ex.: 255.255.255.0
	Standard Gateway	Gateway IP address.
	DNS server	Domain name of the server

REF: 2.511462 Rev A / CAT: 070-3063-00 Rev A

8.5.3 WLAN

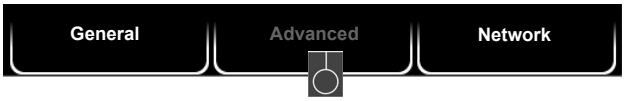
To select a WLAN network, press the function key “Browse networks”, select your network and confirm with the OK key. Once all parameters have been set, press the "Apply" function key .

General

Menu	Parameter	Description / selection
WLAN general	Wi-Fi enabled	Yes/**No**
	SSID	SSID = Enter network name.
	Wi-Fi security	Selection of the encryption protocol • WPA2 Pers SSID + key + (encryption = AES+ authentication • WPA2 enterprise / ieee802.1 (*further settings see* *) SSID + certificate + (encryption = AES+ authentication) SSID + user name & password + (encryption = AES+ authentication)
	Password	Enter password for Wi-Fi security “WPA2 Pers”
		**For WPA2 enterprise / ieee802.1 the following additional fields are displayed:*
	**Authentication protocol*	Select the authentication protocol: • PEAP • EAP-TLS • EAP-TTLS
	**User*	Enter user name
	**Password*	Enter password
	**Client certificate*	Load the certificate via USB stick or network . Download the certificate via USB port of the device when **EAP-TLS** is selected ➜ Connect USB stick to the device and press Import certificate from USB . Certificate from USB stick... Certificate structure: a single file in pem. format contains client certificate, of origin, private key. The private key may or may not be encrypted. If it is encrypted, the user name and password need to be entered.
	**CA Certificate*	Load CA Certificate (Certificate Authority) via USB stick or network. Certificate from USB stick...

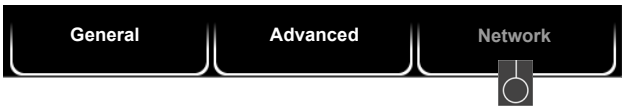
REF: 2.511462 Rev A / CAT: 070-3063-00 Rev A

Advanced



Menu	Parameter	Description / selection
WLAN Advanced	Hidden	“Yes” = if you want the SSID to be hidden in the Wifi network. “No” = if you want the SSID to be visible in the Wifi network.
	Anonymous identity	Enter an anonymous identity name

Network



Menu	Parameter	Description / selection
WLAN network	Use DHCP	**Yes**/No. If this is not activated, the following parameters need to be entered:
	IP address	Identifier address of the device in the TCP/IP network.
	Subnet mask	E.g.: 255.255.255.0
	Standard Gateway	Gateway IP address.
	DNS server	Domain name of the server

REF: 2.511462 Rev A / CAT: 070-3063-00 Rev A

8.6 Regional settings

Sub-menu	Parameter	Description / selection
Date/time	Various	• Date format (dd.mm.yyyy / yy-mm-dd / mm/dd/yyyy) • Time format (HH:mm:ss/h:mm:ss) • Time zone • Date and time settings (manual setting is only possible when **EPA integration** is programmed on None). ➜ Key Sync time with server. Time and date on the device are updated. The device needs to be restarted. This function is only possible when **EPA integration** has been set on “Schiller-Link” or “Schiller Server”.
Language	Language	Select a language
	Ext. Keyboard /Barcode Scanner Layout	Select the character set language for the external barcode scanner.
Units	Weight	Units available are g, **kg** and lb
	Length	**cm**, m, inch
	Speed	**km/h** or mph
	Temperature	**C**elsius or Fahrenheit
Patient ID system	Selection of the patient ID system used	**None**, Swedish, Danish, Finnish, Norwegian

REF: 2.511462 Rev A / CAT: 070-3063-00 Rev A

8.7 General

Menu	Parameter	Description / selection
Info	Various parameters	Software and hardware versions are displayed.
	Information **Send info to USB**	A diagnostic file (.nfo) is written to the connected USB USB memory stick.
Power management	**With battery**	
	Dim backlight [s]	120 seconds (2 min.). If set to 0, this function is deactivated.
	Shut down device [s]	600 seconds (5 min.). If set to 0, this function is deactivated.
	Connected (to the AC power)	
	Dim backlight [s]	0 seconds (2 min.). If set to 0, this function is deactivated.
	Shut down device [s]	3600 seconds (60 min.). If set to 0, this function is deactivated.
Station	Device ID	Device identification
	Institute	Name of the institute
	Department	Name of the department
	Technician	Name of the technician (this name appears automatically as acquiring technician in the patient data)
	Network host name	Set host name for network communication Standard = **at-102g2**
Update	Check Schiller Update Server	Update software The check is performed on the Schiller update Schiller Server. Therefore, an Ethernet/WLAN connection is required, including the necessary network settings for this connection
	Check USB device for update file	The Update is performed via the connected USB stick.
Manage licenses	Available options	Automatic interpretation, worklist,
	Activate license	Enter the license key and activate
	Import license from USB	Activation via USB stick (.lic file)
Visible fields	Workflow - Recorder Workflow - Worklist	The patient data fields displayed in the workflow Recorder and in the workflow Worklist can be configured (order and visible fields). The following additional fields can be displayed: Age, Alternative PID, BMI and Generic data 1/2/3 and Study description (Worklist only)
Mandatory Fields	Recording types	Rest and rest rhythm;
Custom fields	Generic data #1/2/3 • Label – Values 1, 2, 3	Definition of custom data fields. Designation and definition of values 1-3 that can be selected. If no value is defined, the value can be entered in field. In order for the fields to be displayed, they need to be activated in menu “Visible fields”. When they're active, these data fields can also be configured in the report header (see section 8.3.2 Header, page 66).

REF: 2.511462 Rev A / CAT: 070-3063-00 Rev A

Menu	Parameter	Description / selection
Access control (automatic logout when access control is activated, see menu “Automatic Log Off”) Important! To be performed by trained staff only.	Access Control Mode	• **Basic** Login when switching on the device and/or menu setting with password • **Local (Default factory setting)** Definition of users, passwords and privileges locally on the device • **Schiller Server** Access control is defined via the Schiller Server.
	Basic	
	Device login active	Yes, **No**. If Yes is selected, the login dialogue is displayed at switch-on.
	Device password	Define the password (default)
	Setting login active	Yes, **No**. If Yes is selected, the Settings menu is password-protected.
	Setting login active	Define the password (admin)
	Local	Default factory setting
	Setting login active	Administrator
	Setting login active	Enter password (administrator)
	Setting login active	Confirm password
	User rights	Selection of user rights: Edit system settings; analyze recordings (from memory); create recordings.
	Schiller Server	This requires a functioning EMR connection and Schiller Server Administrator rights. Access control is defined via the Schiller Server.
Workflow	Transmit after save	Yes, **No**. ECG data is transmitted after acquisition and storage of the recording
	PDF to USB after save	Yes, **No**. After saving, the PDF is transmitted automatically to the USB stick
	Delete after export	**Yes,** No. PDF and recording is deleted from the memory once it has been exported/transmitted to the USB stick/server.
	Print after save	**Yes,** No. ECG data is printed once it has been stored.
	PDQ mode	PDQ by **Patient ID** PDQ by Visit ID
	Default workflow	Select the first view: Worklist or Recorder
	Worklist mode	Recording from worklist or from work item (details)
	Auto sync worklist	Yes, **No**. Work list is synchronized every minute.
Memory	Cleanup local recordings	**No**/Yes Yes = recordings older than the value defined in “Recording age in days” will be deleted.
Printer	**Contrast**	1-10 **(5)**
	Line width	Thin, **normal**, thick

REF: 2.511462 Rev A / CAT: 070-3063-00 Rev A

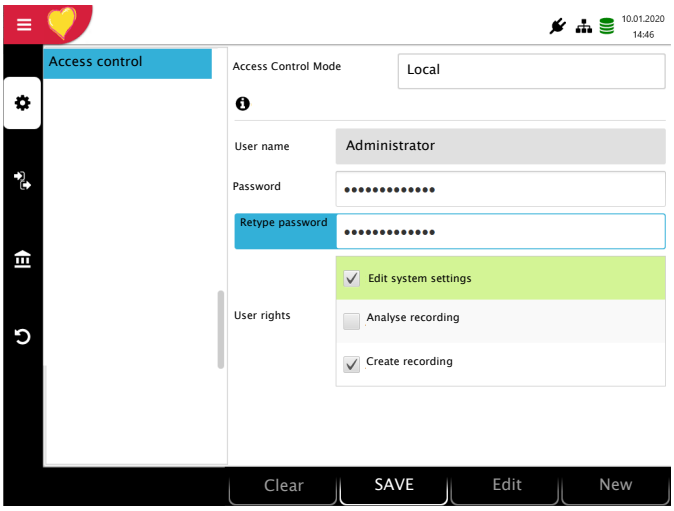
Menu	Parameter	Description / selection
Automatic log off (Only displayed when access control is activated)	**Automatic logout activated**	**Yes**/No
	Timeout logout [s]	**300**

REF: 2.511462 Rev A / CAT: 070-3063-00 Rev A

8.7.1 Setting user name and password for access control

CAUTION

- ▲ To prevent non-authorized users to access patient information, manipulate settings or the software, we strongly recommend changing the default password to a strong password according to the standard rules.
- ▲ Do not switch off access control if the device is connected to a network.



Function keys to:

- create a new user
- edit an existing user
- save settings
- delete a user

1. Choose the Access control menu.
2. Confirm with OK.
3. Activate Access Control Mode with OK key (blue).
4. Use "left" key to select mode Local.
5. Use “down” key to select user name.
6. Use “right/left” key to select user, if available
7. Select the function key:
   – “Edit” to enter a new password or define user rights.
   – “”New” to create a new user.

➜ User rights can be selected or deselected with the "OK" key. The "System settings" right cannot be disabled for the administrator.

8. Select the function key “Save”

REF: 2.511462 Rev A / CAT: 070-3063-00 Rev A

9 Transmission - Overview

⚠ CAUTION

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

9.1 Transmission Options

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

⚠ WARNING

- When a non-medical device is connected to the interface, ensure that both units are securely connected to the same earth potential.
- An external device must only be connected using the original interface cable assembly.
- The transmission of ECG data via WLAN can disturb other devices, including pacemakers. Therefore, keep a distance of at least 7.9 inches from the patient while an ECG is transmitted.

LAN

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

The network symbol has three states as follows:

The network symbol in the status bar at the top right, indicates the connection status of WLAN or LAN

- Symbol Green - Connected to network and Server
- Symbol Black - Connected to network but no connection with Server
- Symbol black and a cross in the symbol - no network connection

REF: 2.511462 Rev A / CAT: 070-3063-00 Rev A

Wifi

When Wifi is set, the symbols are as follows:

- Symbol Green - Connected to Wifi network and Server.
- Symbol Black - Connected to network but no connection with Server
- The strength of the signal is indicated with the number of bars.

Schiller Link/Schiller Gateway

Schiller Link/Schiller Gateway offers easy communication with an EMR system within the same network. This communication comprises the following: import (GDT) of examination requests including patient data and recording type from an EMR system, export of recordings to an EMR system in the formats GDT, Sema2 or PDF. To activate this communication, set **Schiller Link** in the menu Connectivity > EMR integration (see page 72).

Schiller Server/Schiller Gateway

For patient data queries from the EMR system, the Schiller Server/Schiller Gateway is required.

PDF export

Export of a recording in PDF format to a USB stick

9.1.1 Automatic transmission

The automatic transmission setting is defined in Settings:

Menu > Settings > General - **Workflow- Transmit after acquisition** (Yes/No - see Page 76).

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

9.1.2 Manual transmission

To transmit a recording, select the recording in the **Memory** and press **Export** (see Page 54)

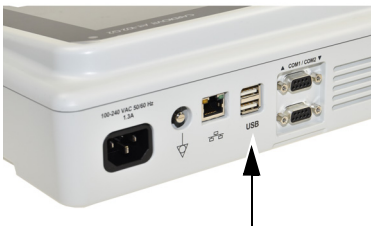
9.1.3 PDF export

Data integrity

⚠ CAUTION

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

REF: 2.511462 Rev A / CAT: 070-3063-00 Rev A

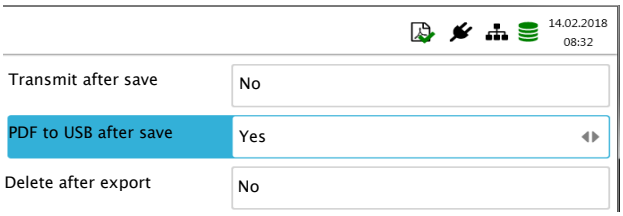


USB stick

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

Caution

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



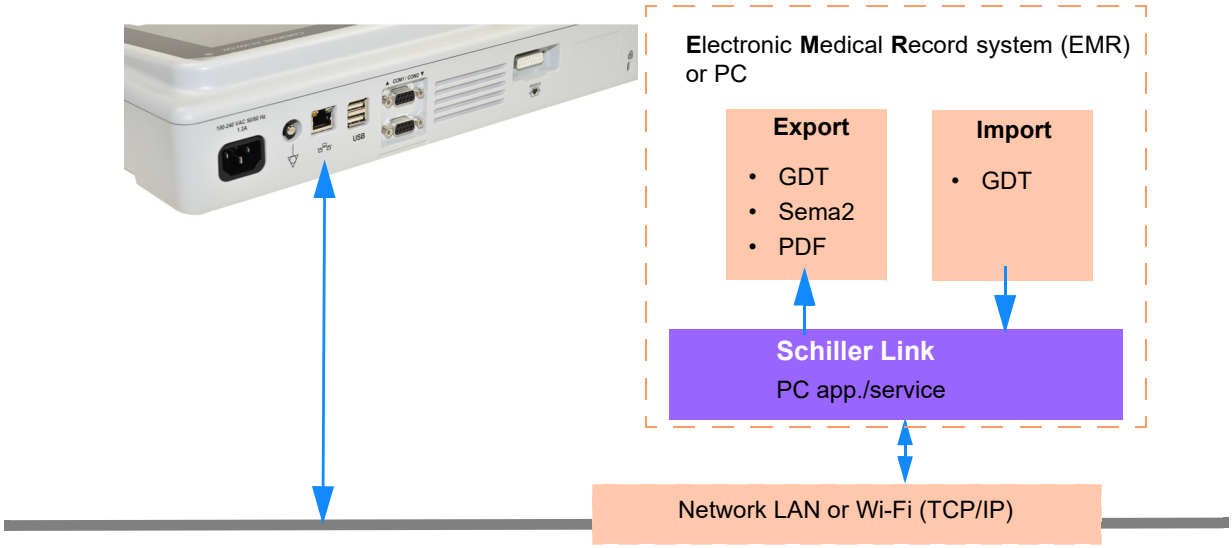
REF: 2.511462 Rev A / CAT: 070-3063-00 Rev A

9.1.4 Schiller Link

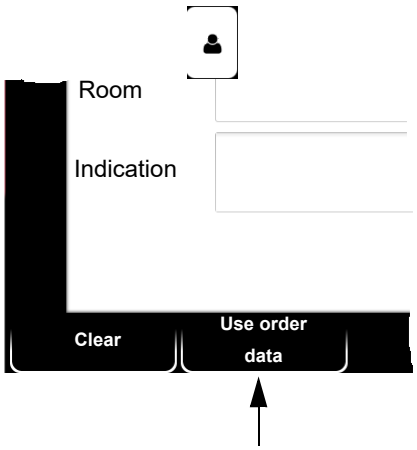
Schiller Link is a PC application/service which communicates between the EMR system and the CardioPulse Prime.

➜ To activate this communication, set Schiller Link in the menu **Connectivity > EMR integration** (see page 72).

➜ Integration in the network is automatic, provided the CardioPulse Prime is part of the same network as the EPA system



Procedure with EMR system



1. Enter/select a patient in the EMR system
2. Generate a new order for this patient
3. Upload the GDT file into the import folder of the Schiller Link service
4. Start and check the order incl. patient data on the CardioPulse Prime. Should no patient data be displayed, press the function key "Use order data". The order data will be loaded and displayed.
5. Perform the recording on the CardioPulse Prime.
6. Store the recording and export it automatically or manually to the export folder.
7. The EMR system imports the recording for review in the EMR system.

Procedure without EMR system

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

REF: 2.511462 Rev A / CAT: 070-3063-00 Rev A

9.1.5 Retrieving data from the Schiller Server

Patient data can automatically be retrieved from the Schiller Server to the CardioPulse Prime. This is called patient data query (PDQ). To do this, the Patient or Visit ID is entered in the patient data screen manually or via a barcode reader (see Page 30).

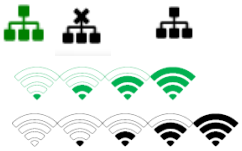
- For PDQ, the Server must be installed on the remote system.
- The server name, URL, TCP/IP address etc. as well as all other transmission settings are defined in the system settings (see Page 72).

9.1.6 Failed data transmission

Should the network not be available, recordings that have not been transmitted are displayed with the symbol .

1. With the icon “EPA export “, the number of failed transmissions is displayed.
2. Recordings can be sent manually from the memory. See section 6.2.2 Transmitting and deleting stored recordings, page 54.

If no data can be transmitted, check the following:



- ➜ Network settings (see Page 72)
- ➜ Network connection WLAN or LAN
- ➜ Encryption settings on the server
- ➜ Settings in the Schiller Link.

REF: 2.511462 Rev A / CAT: 070-3063-00 Rev A

10 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 authorized by Spacelabs Healthcare.

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.

10.1 Maintenance interval table

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 91, 10.8 Inspection Report) – Function key test – Keyboard test – Cables and accessories – AC power cable • Functional tests according to the instructions (see page 91, 10.8 Inspection Report)	➜ User
Every 12 months	• Safety test according to IEC/EN 62353	➜ Qualified service personnel

10.2 Service/Shelf life

Self life-Service Life The shelf life and service-life of the CardioPulse Prime is based on the battery since it has the shortest shelf life and service life than the components and accessories of the CardioPulse Prime. The other components and accessories of the CardioPulse Prime are durable and have a low likelihood of time-dependent product degradation.

Shelf Life The battery has a shelf life of 1 year when charged at 70%. After 1 year the battery needs to be charged to protect the battery from “deep-discharge” during storage. Deep discharge may reduce the battery’s service life.

Service Life The battery has a service life of 4 years based on an estimated 500 charging cycles under normal use.

REF: 2.511462 Rev A / CAT: 070-3063-00 Rev A

10.3 Visual inspection

Visually inspect the unit and cable assemblies for the following:

➜ Device casing (not damaged or cracked)
➜ LCD screen (not damaged or cracked)
➜ Electrode cable sheathing and connectors (undamaged)
➜ AC power cable sheathing and connectors (undamaged)
➜ No kinks, abrasion or wear in any cable assembly.
➜ Input/output connectors (undamaged).

In addition to the visual inspection, switch on the CardioPulse Prime, scroll through the menu and test some sample functions. In this way, you can check that:

- the device performs faultlessly
- the display works
- the function keys and the keyboard work

➜ Enter the results in the inspection report (see page 91, 10.8 Inspection Report).

WARNING

▲ Defective units or damaged cables must be replaced immediately.

REF: 2.511462 Rev A / CAT: 070-3063-00 Rev A

10.4 Cleaning the casing and cables

⚠WARNING

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

⚠ CAUTION

▲ Do not autoclave the unit or any accessories.

▲ Do not immerse the device in liquid.

▲ Do not spray liquid onto the device/cable.

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

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

▲ With time, the casing may become less resistant:

– if an alkaline cleaner or a cleaner with a high alcohol concentration is left for a long time on the surface, or

– if a warm disinfectant or detergent is used. Spacelabs Healthcare therefore recommends using only cleaning agents that are adequate for sensitive materials such as plastics, and using them at room temperature (approx. 68°F).

▲ Never use any of the following solutions or similar products to clean the equipment: Ethyl alcohol, acetone, hexane, abrasive or scouring powder or material, any cleaning material that damages plastic.

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

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

Thoroughly inspect the device and the accessories before cleaning.

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

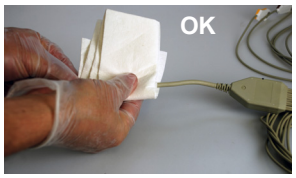
The casing of the CardioPulse Prime and the cable assemblies can be cleaned with a cloth slightly moistened (not wet) on the surface only. If necessary, a domestic non-caustic cleaner or a 50 % alcohol solution can be used to remove grease stains and finger prints. Wipe the equipment with a cloth slightly moistened (not wet) with one of the approved cleaning solutions (see section 10.4.2). Thoroughly wipe off any excess cleaning solution. Do not let the cleaning solution run into or accumulate in connector openings, switches, or gaps. If liquid gets into connectors, dry the area with warm air and check that the device operates properly.

REF: 2.511462 Rev A / CAT: 070-3063-00 Rev A

10.4.1 Cleaning the cable assembly

1. Before cleaning, inspect the cable for damage. Gently bend and flex all parts of the cable. Inspect for splits in the sheathing, damage or extreme wear, exposed wires or bent connectors.
2. Wipe the cable with a cloth slightly moistened (not wet) with one of the approved cleaning solutions listed below.
3. Gently grip the cable with the damp cloth in the center of the cable and slide the cable through the cloth 7.9 inches at a time until clean. Do not clean the whole length in one single action as this may cause ‘bunching‘ of the insulation sheathing.

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



10.4.2 Admissible detergents

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

10.4.3 Non-admissible detergents

Never use products containing the following:

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

REF: 2.511462 Rev A / CAT: 070-3063-00 Rev A

10.5 Disinfection

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

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

10.5.1 Admissible disinfectants

- Isopropyl alcohol 50 %
- Propanol (35 %)
- Aldehyde (2-4 %)
- Ethanol (50 %)
- all products that are suitable for sensitive surfaces, such as:
  - Bacillol® 30 foam/ Bacillol® 30 Tissues (10% Propanol-1, 15 % Propanol-2, 20 % Ethanol)
  - Mikrozid® AF (25 % Ethanol, 35 % 1Propanol-1)

10.5.2 Non-admissible disinfectants

Never use products containing the following:

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

10.6 Cleaning the print head

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

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

REF: 2.511462 Rev A / CAT: 070-3063-00 Rev A

10.7 Battery

- No maintenance is required for the lithium-ion batteries.
- Based on its use, the battery needs to be replaced every 4 years when operation time has fallen under 6 hours.
- Storage and operation conditions outside the temperature range of 59-77 °F 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 1 year (at 70% battery charge), the battery needs to be protected from deep discharge by recharging it; the ideal capacity is 50-70%. If a fully charged battery is stored for a long period of time, this may reduce its service life.

10.7.1 Charging the battery

A totally discharged battery requires approximately 4 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 AC power supply.

1. Connect the device to the AC power supply.
2. The AC power LED lights and the AC power symbol on the screen  is displayed.
3. Charge the battery for at least 4 hours.

10.7.2 Battery disposal

The battery must be disposed of in municipally approved areas or sent back to Spacelabs Healthcare.

⚠WARNING

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

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

REF: 2.511462 Rev A / CAT: 070-3063-00 Rev A

10.8 Inspection Report

▲ The user guide, especially chapter 10, must be read before the inspection.
▲ **Recommended inspection interval:** Every 6 months

Serial no.: _____

Test	Results	Date				
Visual inspection 10.3	• Casing not damaged	❒	❒	❒	❒	❒
➜ External condition	• Electrode connector port not damaged	❒	❒	❒	❒	❒
➜ Availability and condition of accessories	• ECG Electrodes (expiration date and compatibility)	❒	❒	❒	❒	❒
	• User guide	❒	❒	❒	❒	❒
	• AC power and patient cable	❒	❒	❒	❒	❒
Functional test 2.3	• No error message shown in the standard display	❒	❒	❒	❒	❒
➜ ECG test						
➜ Function keys	• Keys function properly	❒	❒	❒	❒	❒
➜ Check the battery	• Battery OK	❒	❒	❒	❒	❒
➜ Printer	• Contrast and line strength	❒	❒	❒	❒	❒
	• Cleaning the thermal print head	❒	❒	❒	❒	❒
Remarks		❒	❒	❒	❒	❒
➜ Recurrent test conducted (every 12 months)		❒	❒	❒	❒	❒
Inspection carried out by:		❒	❒	❒	❒	❒

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

Name: .....
.....

REF: 2.511462 Rev A / CAT: 070-3063-00 Rev A

10.8.1 Lifed-item replacement every 3 - 5 years

Inspection	Results	Replacement				
Internal battery						
➜ Replace internal battery if operation falls substantially under six (6) hours.	• Unit sent to Spacelabs Healthcare service center for accumulator replacement.	❒	❒	❒	❒	❒
	Date of replacement:					
	Inspector:					

REF: 2.511462 Rev A / CAT: 070-3063-00 Rev A

11 Trouble Shooting

11.1 Possible problems

Error	Possible causes and indicators	Error localization and troubleshooting
Unit does not switch on, blank screen	• No power connected; green LED next to the On/Off button is not lit.	➜ Check the AC power cable. ➜ If the AC power indicator is lit, it indicates that power is reaching the unit and the internal power supply should be OK. Press and hold the On/Off key for 10 seconds. Wait a few seconds and switch the device on again.
	• AC power connection OK, but indicator and LED are not lit.	➜ If the battery is faulty, it is possible that the unit cannot be switched on even if the AC power supply is connected. Have the battery replaced by your Spacelabs Healthcare representative. ➜ If the screen is still not lit, it indicates a software error, monitor or internal power supply problem. Call your local Spacelabs Healthcare representative.
QRS traces overlap	• Incorrect settings for patient • Poor electrode contact	➜ Change the sensitivity setting. ➜ Check the electrode contact and re-apply the electrodes. ➜ If the problem persists, call your local Spacelabs Healthcare representative. ➜ Note: Some patients have very high amplitudes and even on the lowest sensitivity settings, the QRS traces can overlap.
"Noisy" traces	• High resistance between skin and electrodes • Patient not relaxed • Incorrect settings	➜ Check the electrode resistance (all leads need to be shown in green) ➜ Re-apply the electrodes. ➜ Ensure that the patient is relaxed and warm. ➜ Check all filter settings (**Menu > Settings > ECG > Filters & formulas**). ➜ Activate the myogram (Low pass) filter and change the cut-off frequency. ➜ Ensure AC power filter is correct for AC power supply. ➜ If the problem persists, call your local Spacelabs Healthcare representative.
No printout obtained after an auto mode recording.	• No paper • Paper incorrectly loaded • Incorrect settings • Battery operation with less than 35% capacity: no printout possible	➜ Ensure that paper is loaded. ➜ Reload paper. ➜ Ensure that the paper has been inserted correctly. ➜ Check that the printout is activated for at least one setting, and that Print after acquisition is activated (see page 66 and 76) ➜ Connect the device to the AC power and charge the battery ➜ If the problem persists, call your local Spacelabs Healthcare representative.

REF: 2.511462 Rev A / CAT: 070-3063-00 Rev A

Error	Possible causes and indicators	Error localization and troubleshooting
Printout fades, is not clear, or the printout is 'patchy'	• Old paper inserted • Dirty print head • Print-head out of adjustment	➜ Ensure that new original paper is inserted. ➜ Note that the CardioPulse Prime 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. ➜ If the problem persists, call your local Spacelabs Healthcare representative.
No printout of interpretation statement, averaged 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 66 section 8.3 and page 41 section 4.11.2,)
Function keys blocked	• Software hangs up • Function keys defective	➜ 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 AC power and switch on. ➜ If the problem persists, call your local Spacelabs Healthcare representative.
Interferences, lines on the display	• Excessive EMC interferences	➜ Check for sources of excessive EMC interferences.
Memory full	• The ECG recording cannot be stored because the memory is full.	➜ Delete old ECG recordings, see page 51.

REF: 2.511462 Rev A / CAT: 070-3063-00 Rev A

11.2 Preventing electromagnetic interferences

"Non ionizing electromagnetic radiation"

The user can help avoid electromagnetic disturbances by keeping the minimum distance between portable and mobile radio frequency (RF) telecommunication devices (transmitters) and the **CardioPulse Prime**. 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 CardioPulse Prime and its cables.
- Use of the CardioPulse Prime adjacent to or stacked with other electric/electronic devices should be avoided - 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

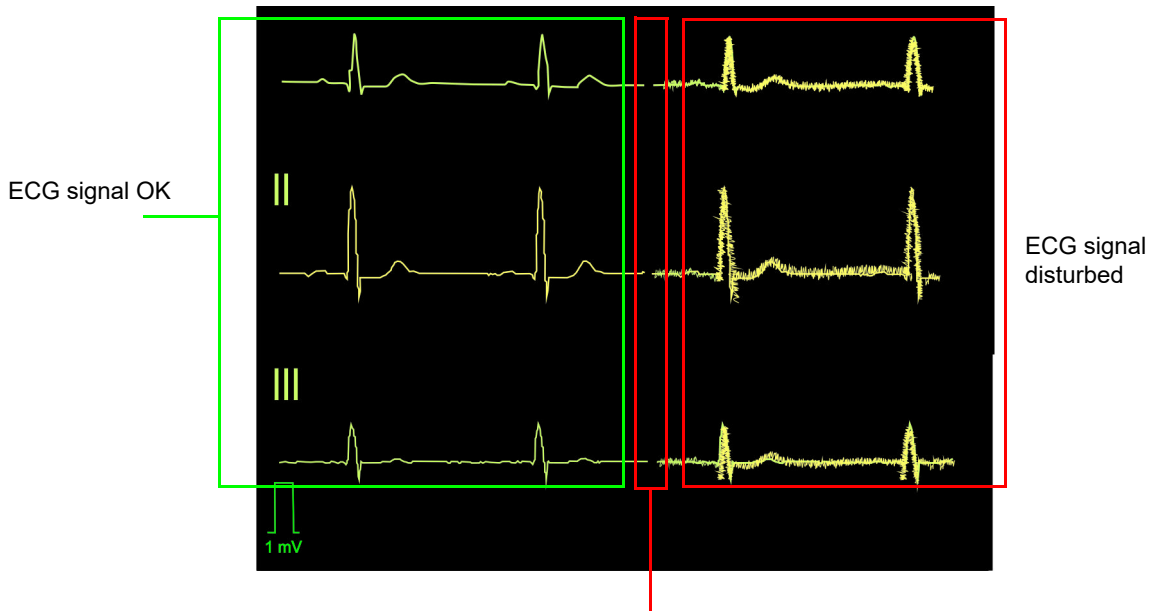
For more information on operation in an electromagnetic environment according to IEC/EN 60601-1-2 see section 12.5 EMC information, page 103.

REF: 2.511462 Rev A / CAT: 070-3063-00 Rev A

11.2.1 Measures to prevent electromagnetic interference

In the case of certain electromagnetic interference, artefact's can occur, which are distinguishable from the ECG signal. The essential performance characteristics of the device are not affected by these artefact's, but the user can take the following measures to prevent electromagnetic interference:

Typical disturbed ECG signal



The user can take the following measures to prevent electromagnetic interference:

- Increase distance to the source[1] of interference.
- Turn off the source of interference.
- Turn the device to change the angle of radiation.
- Connect the device to a different AC power connector.
- Only use original accessories (especially patient cables).
- Immediately replace defective cables, especially patient cables with defective sheathing.
- Make sure the patient cable is securely screwed on.
- Observe the maintenance intervals as stated in section 10.1 Maintenance interval table, page 85.

1. Others non mobiles RF transmitter source of interferences can be: diathermy, electrocautery, RFID, and security systems (e.g., electromagnetic anti-theft systems, and metal detector)

REF: 2.511462 Rev A / CAT: 070-3063-00 Rev A

11.3 Accessories and disposables

WARNING

▲ Always use Spacelabs Healthcare spare parts and disposables or products approved by Spacelabs Healthcare. Failure to do so may endanger life and/or invalidate the warranty.

Your local representative stocks all the disposables and accessories available for the CardioPulse Prime. A comprehensive list of all Spacelabs Healthcare representatives can be found on the Spacelabs Healthcare website (www.Spacelabshealthcare.com). In case of difficulty, contact our head office. Our staff will be pleased to help process your order or to provide information on all Spacelabs Healthcare products.

11.3.1 Patient cables

REF no.:	CAT no.:	Article
2.400175	-	ECG D-SUB C 3.5 x10 IEC 10-wire patient cable IEC, clip-type, 3.5m
2.400178	700-0388-00	ECG D-SUB C 3.5 x10 AHA 10-wire patient cable AHA, clip type, 3.5m
2.400179	700-0389-00	ECG D-SUB B 2.0 x10 AHA 10-wire patient cable AHA, banana plug, 2m
2.400180	-	ECG D-SUB B 2.0 x10 IEC 10-wire patient cable IEC, banana plug, 2m

11.3.2 Electrodes and accessories

REF no.:	Article
2.000041	Electrode kit for adults
2.000052	Electrode kit for children
2.155000	Suction electrodes 24 mm
2.155020	Limb electrodes, adults
2.155030	CARDIO-PREPS (abrasive skin preparation) (50 pieces)
2.155032	Adapter snap/clip for banana plug cables (10 pieces)
2.155034	White Sensor ECG electrodes for resting ECG (500 pieces)

11.3.3 AC power cable and earth cable

REF no.:	CAT no.:	Article
2.310005	161-0279-00	Earth cable for the potential equalisation stud
2.300000	-	AC power cable Switzerland, straight, 2.5m
2.300002	-	AC power cable Schuko Europe, 90° angled, 2.5m
2.300003	-	AC power cable Switzerland, 90° angled, 2.5m
2.300004	-	AC power cable UK, 90° angled, 2.5m
2.300005	-	AC power cable Schuko Europe, straight, 2.5m
2.300011	-	AC power cable UK, straight, 2.5m
2.300012	-	AC power cable USA (hospital grade), straight, 2.5m
2.300014	-	AC power cable China, 90 ° angled, 2.5m

REF: 2.511462 Rev A / CAT: 070-3063-00 Rev A

REF no.:	CAT no.:	Article
2.300016	-	AC power cable Japan, 90 ° angled, 2.5m
2.300024	161-0278-00	AC power cable USA (hospital grade), 90 ° angled, 2.5m
2.300025	-	AC power cable Brazil, 90 ° angled, 2.5m

11.3.4 Thermal chart paper

REF no.:	CAT no.:	Article
2.157050	010-2288-00	Thermal chart paper z-folded 210 x 279.4 mm, number of sheets 100

REF: 2.511462 Rev A / CAT: 070-3063-00 Rev A

12 Technical Data

12.1 Device

Dimensions	15.1 x 12.56 x 3.54 in, approx. 9.92 pound including thermal paper
Ambient conditions	
Operating temperature	• 50 to 104 °F
Relative humidity during operation	• 15 to 95% (non-condensing)
Pressure during operation	• 700 to 1060 hPa
Storage temperature	• 41 to 122 °F
Transport temperature	• 14 to 122 °F
Humidity during storage/ Transport	• 10 to 95% (non-condensing)
Pressure during storage/ Transport	• 500 to 1060 hPa
Power supply	
AC power operation	100 - 240 VAC, 1.3 - 0.7 A, 50/60Hz
Battery	AC power-independent operation with built-in rechargeable battery
Power consumption	max. 64 VA
Display	• Backlit LCD screen for graphic and alphanumeric representation • Resolution: 1024 x 768 dots, 8 “
Battery	
Capacity	• Lithium-Ion 10.8 V, 6.9 Ah • 8.5 hours (normal use with printing every 15 minutes, 2 pages), without Wi-Fi or network operation
Battery life	Under normal operating conditions, 4 years
Recharging time	100 %: approx. 4 hours when the device is switched off
Printer	High-resolution thermal head printer; 8 dots/mm (amplitude axis); 40 dots/mm (time axis 25 mm/s)
Chart paper	Thermo-reactive, Z-folded, 210 x 279.4 mm, number of sheets 100
Speed	• 5/12.5/ 25/ 50 mm/s
Sensitivity	• 5 / 10 / 20 mm/mV
Resting ECG review	Display on a grid of 88 x 152 mm with different layouts.
Speed	• 12.5/ 25/ 50 mm/s
Sensitivity	• 5 / 10 / 20 mm/mV
Rhythm ECG review	Display on a grid of 95 x140 mm with different layouts.
Speed	• 6.25 or 12.5 mm/s
Sensitivity	• 2.5 or 5 mm/mV

REF: 2.511462 Rev A / CAT: 070-3063-00 Rev A

Interfaces	• ECG cable interface • Potential equalisation • Network connection (1Gbit) • 2 USB • 2 RS-232 port is not intended for US market
Memory	Memory for at least 350 ECG recordings, 100 resting rhythm recordings

REF: 2.511462 Rev A / CAT: 070-3063-00 Rev A

12.2 ECG

Patient input	• Fully floating and isolated, defibrillation-protected (only with original Spacelabs Healthcare patient cable)
Lead configuration	• Standard 12-lead • Right precordials • Standard C4r • Left Posterior • Nehb • Pediatric • Balanced
Display	
Leads	• 6- to 12-channel display of the selected leads – Paper speed of 12.5/ 25/ 50 mm/s – Amplitude of 5 /10 / 20 mm/mV
Status	• Filter status • Power source • Leads • Electrode contact status • Heart rate (HR) • Date and time • Patient name and number • LAN / WLAN transmission status
Filter	
Myogram filter (muscle tremor)	• Set to 25, 40, 150, 250 Hz (250 Hz = Filter Off)
Notch filter	• Distortion-free suppression of superimposed AC 50 or AC 60 Hz sinusoidal interferences by means of adaptive digital filtering
Data record	• Patient data • Listing of all ECG recording data (date, time, filter) • ECG measurements results (intervals, amplitudes, electrical axes) • Averaged complexes • Guidance on interpreting adult and pediatric ECGs
ECG amplifier	Complies with IEC 60601-2-25 and ANSI/AAMI EC11

REF: 2.511462 Rev A / CAT: 070-3063-00 Rev A

12.3 Safety Standards

Safety standard	IEC/EN 60601-1 IEC/EN 60601-2-25
EMC	IEC/EN 60601-1-2 The device can be exposed to the following source of interference without impairment of the essential performance: • Static discharges up to 15 kV • Field strength up to 10 V/m in the radio frequency range of (80...2700 MHz, 1kHz modulated) • Magnetic fields of 100 A/m, 50/60 Hz
Protection class	Device as a system: Class I according to 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)

12.4 WLAN standards

Modules	WL1837MOD
FCC ID **IC ID**	Z64-WL180DBMOD 451I-WL18DBMOD
Transmission standards	IEEE 802.11 a, b, g, n
Safety/encryption	WPA2-PSK Enterprise with EAP-TTLS, EAP-TTL or PEA
Frequency range	Dual-band 2.4 GHz and 5 GHz
Max. power output 2.4 GHz (1DSSS)	+16.5 dBm
Max. power output 5 GHz (OFDM6)	+18 dBm

REF: 2.511462 Rev A / CAT: 070-3063-00 Rev A

12.5 EMC information

The unit meets the Collateral Standards of Electromagnetic compatibility – Requirements and tests IEC/EN 60601-1-2 the limits and methods of measurement of electromagnetic disturbance characteristics of industrial, scientific and medical radio frequency equipment.

Medical electrical equipment is subject in regard to the electromagnetic compatibility (EMC) and its special precautionary measure.

The unit must in reference to the mentioned EMC-hints in the accompanying documents be installed and operated.

This medical device is intended for use in the electromagnetic environment specified in the following tables. The user of this device should ensure that it is used in such an environment.

Electromagnetic emissions

Emission	Test Compliance	Electromagnetic environment guidance
RF emissions CISPR 11/32	Group 1	This device uses RF energy only for its internal function. Therefore its RF emission are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The device is suitable for use in all establishments, including those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/Flicker emissions IEC 61000-3-3	Complies	

Immunity

Immunity Test	IEC 60601-1-2 Test level	Compliance Level	Electromagnetic environment guidance
ESD IEC 61000-4-2	±8kV Contact ±15kV Air	±8kV Contact ±15kV Air	Floors should be wood, concrete or ceramic tile. If floors are synthetic, the relative humidity (RH) should be at least 30%.
EFT IEC 61000-4-4	±2kV Power supply lines ±1kV I/O lines	±2kV Power supply lines ±1kV I/O lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1kV line to line ±2kV line to ground	±1kV line to line ±2kV line to ground	Mains power quality should be that of a typical commercial or hospital environment.
Voltage Dips/Interupptions IEC 61000-4-11	0 % UT; 0,5 cycle At 0°, 45°, 90°, 135°, 180° 225°, 270° and 315° 0 % UT; 1 cycle 70 % UT; 25/30 cycles h) Single phase: at 0° 0 % UT; 250/300 cycle	0 % UT; 0,5 cycle At 0°, 45°, 90°, 135°, 180° 225°, 270° and 315° 0 % UT; 1 cycle 70 % UT; 25/30 cycles h) Single phase: at 0° 0 % UT; 250/300 cycle	Mains power quality should be that of a typical commercial or hospital environment.
Power Frequency 50 or 60Hz Magnetic Field IEC 61000-4-8	30 A/m	100 A/m	Power frequency magnetic fields should be that of a typical commercial or hospital environment.
NOTE U_T is the AC mains voltage prior to application of the test level.			

Immunity Test	IEC 60601-1-2 Test Level	Compliance Level	Electromagnetic environment guidance
			Portable and mobile communications equipment should be used no closer to any part of this device, including cable, than the recommended separation distance (d) calculated from the equation applicable to the frequency of the transmitter **Recommended separation distance:**
Conducted RF IEC 61000-4-6	3 Vrms outside ISM band 6 Vrms in the ISM & amateur radio band 150 kHz to 80 MHz	$[V_1]$ = 10 Vrms $[V_1]$ = 10 Vrms	$d = \frac{3.5}{V_1} \times \sqrt{P}$
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2700 MHz	$[E_1]$ = 10 V/m 80 MHz to 2700 MHz	$d = \frac{3.5}{E_1} \times \sqrt{P}$ for 80 MHz to 800 MHz $d = \frac{7}{E_1} \times \sqrt{P}$ for 800 MHz to 2.7 GHz
Proximity fields from RF wireless communications equipment IEC 61000-4-3	see section 12.5.1 Immunity to proximity fields from RF wireless communications equipment, page 105	section 12.5.1 Immunity to proximity fields from RF wireless communications equipment, page 105	The recommended separation distance for this tested frequency is 0.3 m.
			where P is the maximum power in watts and d is the recommended separation distance in meters. Field strengths from fixed transmitters, as determined by an electromagnetic site[a] survey, should be less than the compliance[b] levels (V_1 and E_1). Interference may occur in the vicinity of equipment marked with following Symbol  “non ionizing radiation”
Note 1 At 80 MHz and 800 MHz, the higher frequency range applies. Note 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			

a Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast ant TV broadcast cannot be predicted theoretically with accuracy. To access the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the device is used exceeds the applicable RF compliance level above, the device should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocation the device.

b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than $[E_1]$ V/m.

REF: 2.511462 Rev A / CAT: 070-3063-00 Rev A

12.5.1 Immunity to proximity fields from RF wireless communications equipment

Test frequency [MHz]	Band[a] [MHz]	Service	Modulation	max. power P [W]	Distance d [m]	Immunity level [V/m]
385	380-390	Various transmitting services (TETRA 400)	Pulse modulation[b] 18 Hz	1.8	0.3	27
450	430-470	- Walkie-talkie (FRS) - Rescue, Police Fire brigade, Maintenance (GMRS)	FM [c] ±5 KHz ±1 KHz sine	2	0.3	28
710 745 780	704-787	L TE Band 13/17	Pulse modulation 217 Hz	0.2	0.3	9
810 870 930	800-960	- GSM800/900 - LTE band 5 - Mobile phone CT1+, CT2,CT3	Pulse modulation 18 Hz	2	0.3	28
1720 1845 1970	1700-1990	- GSM1800/1900 - DECT (mobile phone) - LTE Band 1/3/4/25 - UMTS	Pulse modulation 217 Hz	2	0.3	28
2450	2400-2570	- Bluetooth, WLAN 802.11b/g/n - LTE Band 7 - RFID 2450 (active and passive Transponder and reader)	Pulse modulation 217 Hz	2	0.3	28
5240 5500 5785	5100-5800	WLAN 802.11a/n	Pulse modulation 217 Hz	0.2	0.3	9

a.For some services, only the uplink frequencies are included.
b.The carrier shall be modulated using a 50 % duty cycle square wave signal.
c.As an alternative to FM modulation, 50 % pulse modulation at 18 Hz may be used because while it does not represent actual modulation, it would be worst case.

REF: 2.511462 Rev A / CAT: 070-3063-00 Rev A

Blank page

REF: 2.511462 Rev A / CAT: 070-3063-00 Rev A

13 Index

REF: 2.511462 Rev A / CAT: 070-3063-00 Rev A

Blank page

REF: 2.511462 Rev A / CAT: 070-3063-00 Rev A

14 Appendix - Symbols

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

	Identification of the manufacturer
	Identification of the manufacturing date
	Identification of the distributor
	Identification o070-3062-00f the importer
MD	Medical device
SN	Serial number
REF	Reference number
LOT	Batch code
GTIN	Global Trade Item Number
CAT	Catalogue number
QTY	Quantity
UDI	UDI: unique device identification as QR code machine readable and human readable as number (e.g  (01) 0 7613365 00210 2 (21)xxxx.xxxxxx)
	Number of pieces in the packaging
EC REP	Authorised European representative
CE XXXX	Notified body (e.g CE 0123 marking notified body TÜV SÜD)
CE	CE marking, affirms its conformity with European standards

	Regulatory Compliance Mark for the Australian standards
	The device is recyclable
	Symbol for the recognition of electrical and electronic equipment. Device must not be disposed of in the household waste.
	Symbol for the recognition of a battery. Battery must not be disposed of in the household waste.
	The packaging is made in low density polyethylene and can be recycled.
	Federal law (USA) restricts this device to sale by or on the order of a physician
	Non ionising electromagnetic radiation. To indicate that the device contains a Radio Frequency (RF) transmitter to transmit data (e.g Bluetooth or WiFi)
	Contains a Bluetooth module
	Do not reuse
	Latex-free
	Use-by date (expiry date of battery, electrodes or other consumables)
	Temperature range for storage or transport, respectively
	Pressure range for storage or transport, respectively
	Humidity range for storage or transport, respectively
	Consult instruction for use (indicates the need for the user to consult the instructions for use)
	Use within X days after opening (electrodes or other consumables)
	Keep dry (store in a dry location)

REF: 2.511461 REV A / CAT: 070-3062-00 REV A

	Keep away from sunlight (protect from direct sunlight)
	Fragile, handle with care
	Transport upwards (this way up)
	Do not use hooks
	EIP = electronic information product (dos not contain any toxic and hazardous substances or elements above the maximum concentration values (product can be recycled and re-used).

REF: 2.511461 REV A / CAT: 070-3062-00 REV A

Blank page