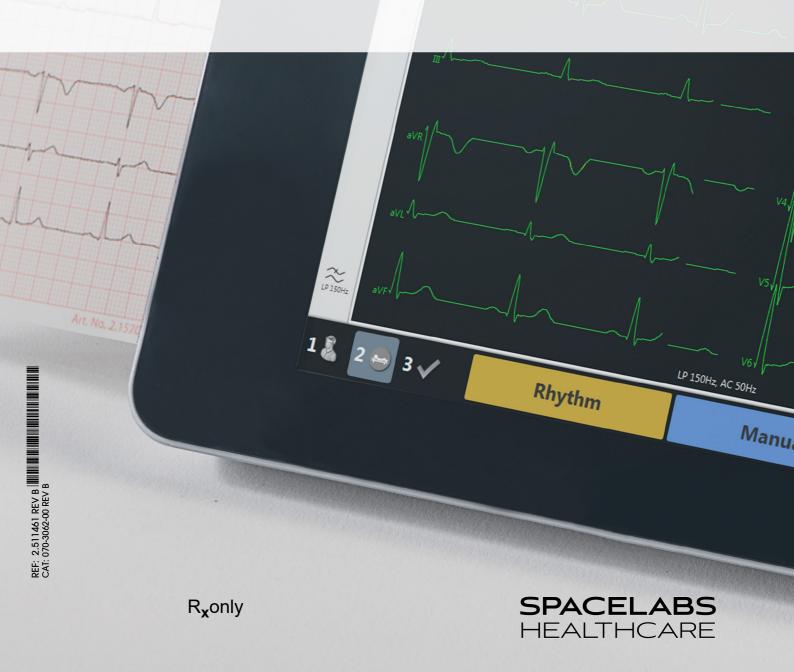


# CardioPulse Go

**Operating manual** 



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- 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.



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## Manufactured by:

SCHILLER AG Altgasse 68 CH-6341 Baar, Switzerland

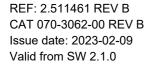


The **CardioPulse Go** (Type CARDIOVIT FT-1) bears the CE-0123 mark (Notified Body TÜV-SÜD Produkte Service GmbH, Ridlerstr. 65, 80339 Munich, Germany), indicating its compliance with the essential requirements of the Annex I of the Medical Device Directive 93/42/EE regarding safety, functionality and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



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









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# **Safety Notes**



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

### **Intended purpose** 1.1



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

### **Indications**

**User Guide** 

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

## Intended users

The CardioPulse Go is intended to be used by trained operators under supervision of a licensed healthcare practitioner.

### Patient target group

- The CardioPulse Go is intended to be used for adult and paediatric patients.
- There are no restrictions regarding height, weight, gender or ethnicity of the patients.
- Paediatric patients are defined as follows:
  - Neonates: from birth through the first 28 days of life
  - Infants: 29 days of age to less than two years of age
  - Children: Two years of age to less than 12 years of age
  - Adolescents: 12 years of age through 21 years of age (up to, but not including, the twenty-second birthday)
- Subgroups:
  - Transitional Adolescent B: 18 through 21 years of age BUT no special considerations compared to adults



### Affected body regions

▲ The CardioPulse Go is not in direct contact with the patient.

### Context of use

- ▲ The CardioPulse Go is intended for indoor use in healthcare facilities.
- ▲ The CardioPulse Go needs to be operated according to the technical data (see Technical data).
- ▲ The CardioPulse Go is portable. The CardioPulse Go is transportable by means of a trolley (optional).

## 1.2 Contraindications



### **System**

- ▲ The CardioPulse Go is not indicated:
  - for sterile use
  - for use in areas where there is any danger of explosion or in the presence of flammable gases such as anaesthetic agents
  - for direct cardiac application
  - for use in an MRI suite
  - for outdoor use
  - for use as a vital signs physiological monitor
  - for use with high frequency surgical units

### **Patient**

No known contraindications for resting ECG.

# 1.3 Responsibility of the User



- ▲ The CardioPulse Go must only be used by qualified physicians or trained medical personnel.
- ▲ The numerical and graphical results as well as any interpretation suggested by the device must be examined with respect to the patient's overall clinical condition and the quality of the recorded data.
- ▲ The responsibilities of the personnel for the operation and maintenance of the device must be specified.
- ▲ Ensure that the personnel have read and understood this user guide,. in particular this section **Safety Notes**.
- ▲ Damaged or missing components must be replaced immediately.
- ▲ The safety, reliability and performance of the device can only be guaranteed when the maintenance intervals as stated in the section Maintenance are observed.

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### **Organizational Measures** 1.4

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

### **Packaging**

- Do not use the device and disposables if the packaging is damaged or has been unintentionally opened before.
- Do not use the device if the packaging is exposed to environmental conditions outside of those specified (section 12.1 Device, page 101) and contact SCHILLER.

### 1.5 **Safety-Conscious Operation**



- Make sure that the staff have read and understood the operating instructions, in particular this section Safety Notes.
- Only operate the device in accordance with the specified technical data.
- The device is CF classified. It is defibrillation protected only when the Spacelabs Healthcare original patient cable is used. However, as a safety precaution, remove the electrodes before defibrillation, if possible.
- Do not touch the unit casing during defibrillation.
- To ensure patient safety, none of the electrodes, including the neutral electrode, nor the patient or any person with simultaneous patient contact, must come in contact with conductive parts, even when these are earthed.
- Immediately report any changes that impair safety (including operating behavior) to the person responsible.
- Do not place any liquids on the unit. If liquid is spilled on the device, immediately disconnect the device from the mains and wipe it. The device must be serviced before reusing.
- Only connect the original Spacelabs Healthcare patient cable to the patient
- ▲ 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.

# 1.6 Safety facilities



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

## 1.7 Operation with other Devices



- ▲ The CardioPulse Go may be connected/combined with other medical devices such as:
- ECG:
  - Patient cables and electrodes
  - ECG suction pump
- · Thermal paper
- CARDIOVIT CS-104
- Trolley
- ▲ Accessory equipment connected to the analogue and digital interfaces must be certified according to the respective IEC standards (e.g. IEC/EN 60950 for data processing equipment and IEC/EN 60601-1 for medical equipment). Furthermore, all configurations shall comply with the valid version of IEC/EN 60601-1. Everybody who connects additional equipment to the signal input part or signal output part configures a medical system and is therefore responsible that the system complies with the requirements of the valid version of IEC/EN 60601-1. If in doubt, contact the technical service department or your local representative.
- Any other equipment used with the patient must use the same common earth as the CardioPulse Go.
- ▲ 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 and to reduce the risk of burns in case of a lack of potential equalisation. However, the stimulation units should only be used at a sufficient distance from the electrodes and both devices must be connected to the same potential equalisation. If in doubt, the patient should be disconnected from the device.
- ▲ This device can safely be used with pacemaker patients.
- ▲ There is no danger when using this device simultaneously with electrical stimulation equipment.
- ▲ If the device is part of a medical system, only the original Spacelabs Healthcare patient cable must be used with, and connected to, the CardioPulse Go.
- ▲ 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 99).

1



### **Network safety** 1.8



When the CardioPulse Go 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.

### **Maintenance** 1.9



- Danger of electric shock! Do not open the device. There are no serviceable parts inside. Refer servicing to qualified technicians authorized by Spacelabs Healthcare only.
- Before cleaning and to isolate the AC power supply, switch the unit 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.

### 1.10 Serious incidents



If any serious incident occurs in relation to the CardioPulse Go, such incident needs to be reported to Spacelabs Healthcare as well as the competent national authority of the country in which the user and/or patient is established.

### 1.11 **Terms of Warranty**

Your CardioPulse Go is warranted against defects in material and manufacture, as stated in the Terms and Conditions. Excluded from this warranty is damage caused by an accident or as a result of improper handling. The warranty entitles to free replacement of the defective part. Any liability for subsequent damage is excluded. The warranty is void if 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 device if:

- assembly operations, extensions, readjustments, modifications or repairs are carried out by persons authorized by him, 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.

### 1.11.1 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.



- 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.



### 1.12 Safety Symbols and Pictograms

#### 1.12.1 Symbols used in this document

**User Guide** 

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



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



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



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



For general safety notes as listed in this chapter.



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



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



Reference to other instructions.

### **Touch-sensitive areas**

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



Touch (to open/close menus and perform functions)CardioPulse Go



Move up or down.



Move to the right or left



Scroll up or down using two fingers

General used symbols see 14 Appendix - Symbols.

Note: All other symbol used for operating elements and connectors are described in chapter 2.3, 2.4 and 2.5



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



Attention: consult accompanying documents.



Warning: Projectile Hazard. Keep outside MRI scanner.



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!



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



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.



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

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

- Increase the distance between the disturbed device and the CardioPulse Go. A minimum distance of 20 cm must be kept between the device and a pacemaker.
- Turn the device to change the angle of radiation.
- · Connect the device to a different AC power connector.

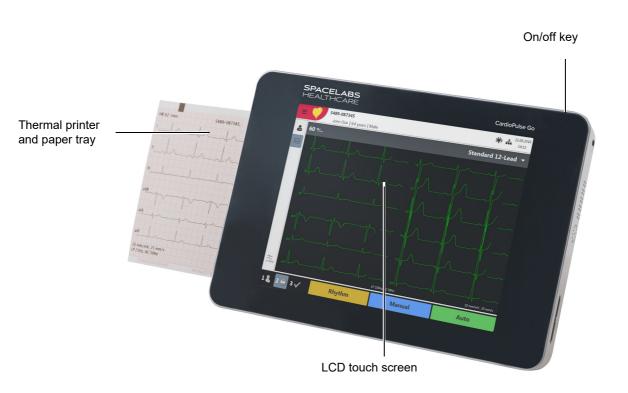
For more details, see page 97.

# 2 Introduction

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

The CardioPulse Go has the following features:

## 2.1 Main components of the CardioPulse Go



## 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

## 2.1.2 Options

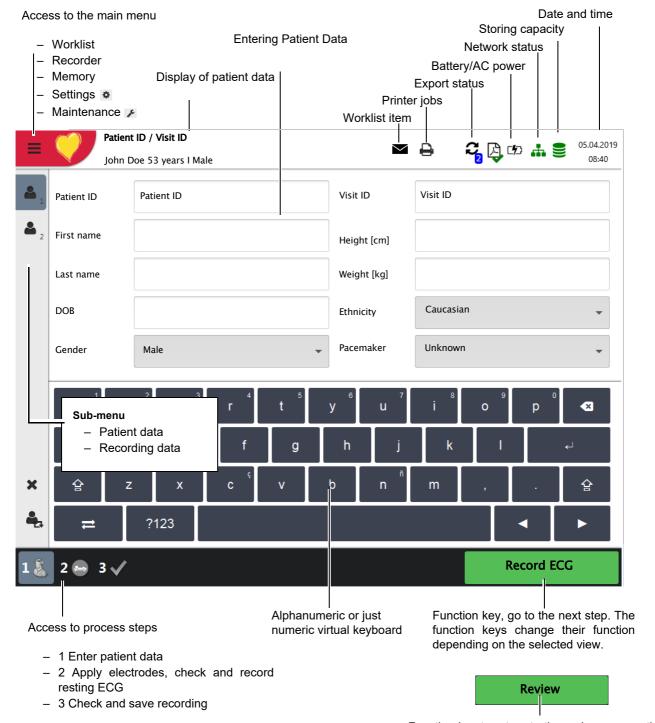
- · Interpretation
- Worklist

## 2.2 Connections

- RJ-45 Ethernet connector (network)
- 2 USB interfaces for software updates with a USB stick and connection of a Barcode reader
- USB type B interface (is not intended for the US market)
- · Kensington lock

CardioPulse Go

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

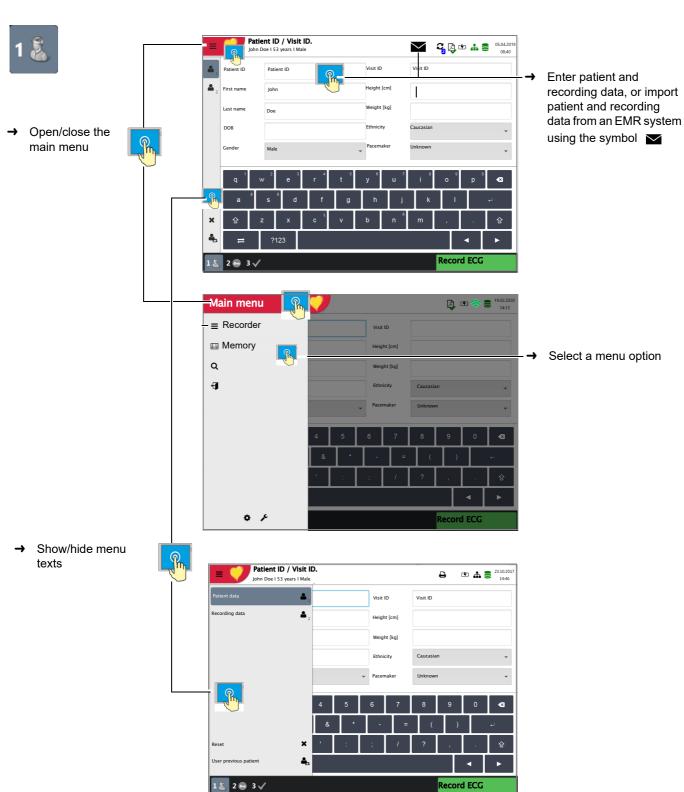


Function key to return to the review screen; this is only available when the recording has not yet been accepted.

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

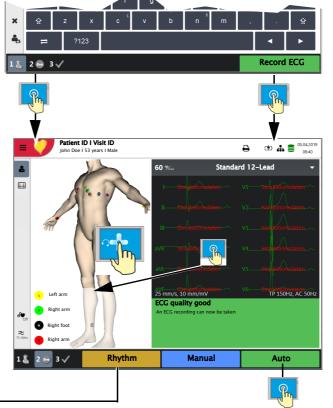
# 2.4 Multi-touch screen operation

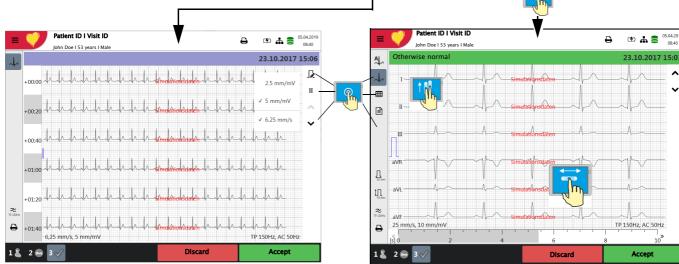
The touch-sensitive areas of the screen are located as follows:





- Prepare ECG recording
  - Determine electrode positions and apply electrodes
  - Check the signal quality





**User Guide** 

- To edit patient data or record an emergency ECG, press the key 18 before accepting the recording, and edit/enter the Review to return to the review screen. patient data. Press
- The recorded ECG is displayed and can be reviewed.
- Rotate leads I...V6: scroll up or down and along the time axis.
- Display 4 average values, results and measurements.
- Set filter for display to 25/40/150 Hz or Off.
- Accept the ECG (i.e. save), print, or discard.

### **Rhythm ECG**

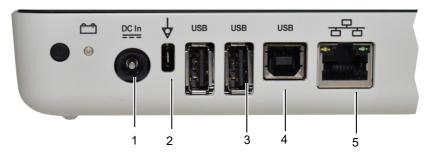
→ Press lead and to set the amplitude, press to select the lead and to move along the time axis.

### 2.5 **Connection panel**



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.

### 2.5.1 **Back panel**



(1) Power input 15 VDC



- (2) Potential equalisation stud. The potential equalisation stud is used to equalise the ground potential of the unit to that of any nearby AC-powered equipment. Use the hospital or building common ground for all AC-powered units.
- (3) USB interfaces for the Barcode scanner and USB memory sticks.
- (4) USB type B interface is not intended for the US market
- (5) RJ-45 Ethernet LAN connection (Local Area Network)

#### 2.5.2 Right hand side panel





- The patient cable as well as the connector comply with the safety standard CF **I** I e.g. they are fully floating and isolated and defibrillation protected.
- The unit is only CF rated and defibrillation protected if used with the original patient cable see 11.3.1 ECG CablePatient cables.



# **Operation**

**User Guide** 

### 3.1 **Start-up and Preparation**



Danger of electrical shock. 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 Go must not be placed in the vicinity of X-ray or diathermy units, large transformers or electric motors.

### 3.1.2 Connection of external cable assemblies and ancillary equipment

- 1. Connect the external power supply unit to the AC power.
- Connect the external power supply unit's output to the back panel. The AC power indicator lamp is lit.
- Leave the CardioPulse Go connected to the AC power for 8 hours to fully charge the battery (see page 23).
- Connect the potential equalisation cable.
- Connect the patient cable (side panel).
- Connect any ancillary and optional equipment (see page 20). 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 Go to that of all AC-powered equipment in the vicinity. Use the hospital or building common ground. A yellow/green ground cable is supplied as an option (CAT no.: 161-0280-00).



Danger of triggering ventricular fibrillation! If the CardioPulse Go 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.



### 3.2 Switching on / off



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

#### 3.2.1 Login and Logout / Emergency ECG



**SPACELABS** 

**HEALTHCARE** 

() Shutdown

User name:

Password:

**Emergency ECG** 

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 8.5.1 Setting user name and password for access control, page 82)

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

### Login

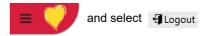
Enter the user name (administrator) and password (administrator) and press "Login" to log in.

### **Emergency ECG**

- Select "Emergency ECG" to bypass the login procedure and to perform an emergency ECG.
- You are automatically logged off when the ECG recording is accepted.

## Logout

Open the main menu





Login 🕟

- If Emergency ECG is selected, the login is bypassed for one acquisition. The Login 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.

3

3.3

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## 3.3 **Power supply**

**User Guide** 





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

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

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



## Half full





## **Battery capacity**

The internal battery provides power for up to four 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.

### **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.

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

#### 3.3.2 Isolating the device from the AC power supply

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

### **System and ECG settings** 3.4



- The system settings (time, date, device ID etc.) and other general settings are described on page 72.
- Resting ECG settings (auto format, user defined leads, print options, interpretation, rhythm lead definition, etc.) are described on page 52.

### Overview Menu > Settings

Menu Settings	Sub-menu
	Leads & cable
	Filters & formulas
ECG	<ul> <li>Views &amp; layouts</li> </ul>
(Page 72)	<ul> <li>Additional leads</li> </ul>
	<ul> <li>Interpretation</li> </ul>
	Rhythm ECG
	General
Reports	Manual printout
(Page 75)	Resting ECG
	Rhythm ECG
	EMR integration
Connectivity	Update server
(Page 78)	Ethernet
	• WLAN
	Date & time
Pagianal	<ul> <li>Keyboard</li> </ul>
Regional (Page 79)	• Language
	• Units
	Patient ID system
	• Info
	Power management
	Station
General	• Update
(Page 80)	Manage licenses
	Mandatory fields
	Workflow
	Access control
	Printer



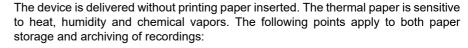
## CardioPulse Go

### 3.5 Changing the printing paper



## **Important**





Before use, keep the paper in its original cardboard cover. Do not remove the card-



board 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 a plastic cover.
- Certain glues can react with the paper. Therefore, do not use glue to attach the printout onto a mounting sheet.

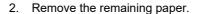
Good printouts can only be achieved when original chart paper or chart paper of the same quality is used.

If different paper is used:

- The operator is solely responsible for making sure that the printing quality is flaw-
- The printing quality needs to be checked before the device is used for patient recordings
- Pull out the paper tray.









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

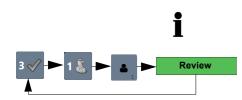


5. Push the paper tray home until it locks into place.

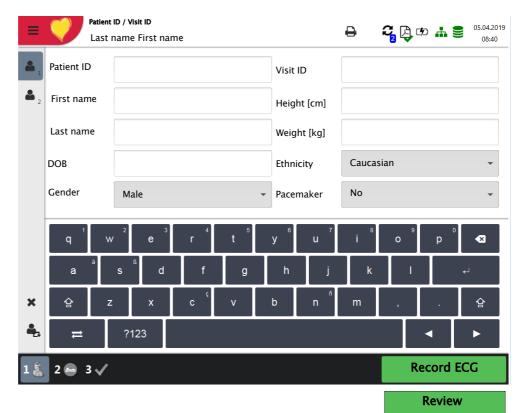


### 3.6 Patient / recording data

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



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



With the data of the current patient, you can:

- · edit it directly in the entry fields
- obtain the data from the server by entering the Patient or Visit ID (configuration: see page 78)
- press X to reset the data and enter a new patient
- to use the previous patient data
- read the Patient ID with a Barcode scanner.
  - Use the alphanumeric keyboard (shown) to enter the patient data.
  - For numeric entry fields, only the numeric keypad is displayed.
  - Press the key **?123/ABC** to display special characters.
  - Use the **Shift** key to switch the keyboard to capitals.
  - To select special characters from the keyboard, press and hold the key and select the special character.





## Patient data - left entry fields

**Patient ID** Enter the patient's identification number.

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

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

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

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

## Patient data - right entry fields



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.

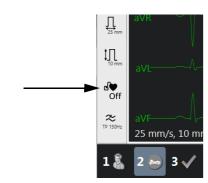
Weight Enter the patient's weight.

**Ethnicity** Select one of the following:

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

**Pacemaker** 

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



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



## Recording data - left side

Room Examination room

**Medication** Digitalis

Indication Reason for medication

## Recording data - right side

Referring physician Referring physician

Attending physician Attending physician

Remarks about the patient/recording

Deleting entered patient data.

×

The previous patient data is entered again.



All fields (except for Medication) can be set as Mandatory fields: **Menu > Settings > General > Mandatory fields**, see section 8.5 General, page 80. For worklist recordings, defined mandatory fields are not taken into account.

## 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**.

Patient data query is possible as follows:

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

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

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

These settings along with other transmission settings are detailed in the system settings (see page 70).

### PDQ with Barcode reader

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



Barcode scanner configuration: see document 2.510721.

## 3.6.2 PDQ in the worklist



If you use the "Worklist" workflow, you can search/enter patient data in the same way (see page 65).

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

### 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 Go as described on the previous page.

i

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

# Placing the electrodes



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CardioPulse Go

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 acces-
- 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.
  - 1When 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.

<sup>1.</sup> 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 incorpo-

<sup>2.</sup> Dedicated abrasive cleaning gel gives very good results in reducing the skin-electrode resistance.

## 4.2 Electrode Identification and Color Code

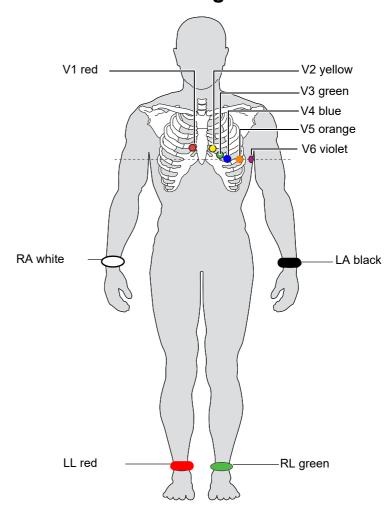
The electrode color codes in the following sections correspond to Code 1 (IEC) for the graphics and to Code 2 (AHA) in the tables

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

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

CardioPulse Go

### Standard 10-lead resting ECG 4.3

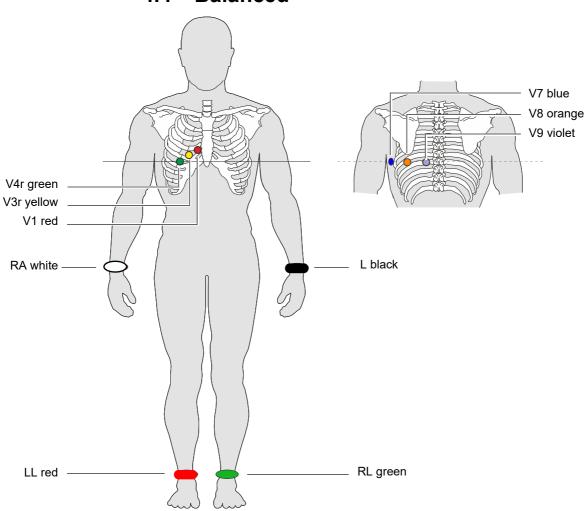


### Electrode placement for standard leads 4.3.1

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

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

# 4.4 Balanced

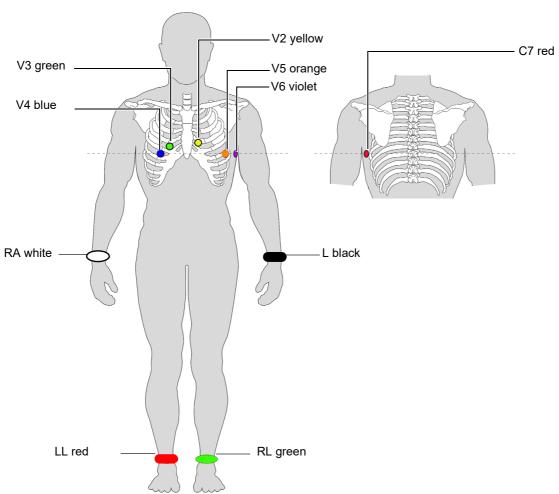


## Balanced, 10-wire cable

AHA label	Electrode placement
V1 brown / red	→ Fourth intercostal space at the right sternal border.
V3r brown / yellow	→ Left of the mid-scapular line at the level of C3
V4r brown / green	→ Left of the mid-scapular line at the level of C4
V7 brown / blue	→ Left axillary line at the level of C4.
V8 brown / orange	→ left posterior axillary line opposite C4
V9 brown / violet	→ Left axillary line at the level of C4, opposite C3
LA black	→ Left arm
RA white	→ Right arm
LL red	→ Left foot
RL green	→ Right foot

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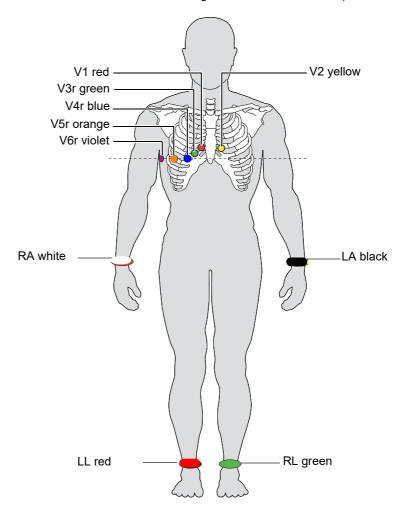


AHA label	Electrode placement		
V4 brown / blue	→	Fifth intercostal space on the mid-clavicular line.	
V3 brown / green	$\rightarrow$	Fourth intercostal space, above C4r	
V2 brown / yellow	→	Fourth intercostal space at the left sternal border	
V5 brown / orange	$\rightarrow$	Anterior axillary line on the same horizontal level as C4	
V6 brown / violet	→	Mid-axillary line on the same horizontal level as C4	
V7 (V1 brown / red)	<b>→</b>	Left posterior axillary line at the level of C4.	
LA black	→	Left arm (resting ECG)	
RA white	→	Right arm (resting ECG)	
LL red	$\rightarrow$	Left foot (resting ECG)	
RL green	→	Right foot (resting ECG)	



# 4.6 Right precordials (V3r-V6r)

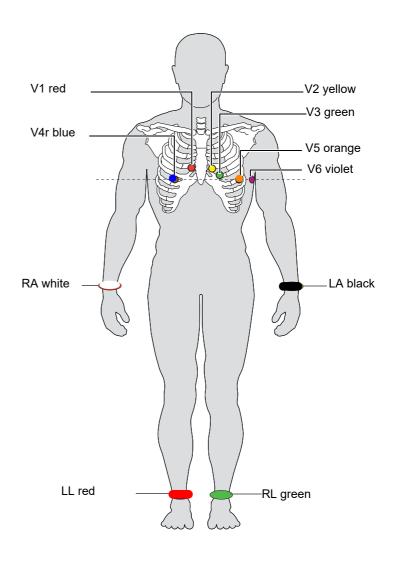
Since the treatment of an infarction might depend on the influence of the right ventricle, it is suggested to perform additional recordings with right precordial leads in the case of an acute infarction of the right ventricle's inferior wall (Circulation 2007).



AHA label		Positioning
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	→	Designated point halfway between V1 and V4r.
V4 brown / blue	$\rightarrow$	Fifth intercostal space on the mid-clavicular line.
V5 brown / orange	→	Anterior axillary line on the same horizontal level as V4r.
V6 brown / violet	$\rightarrow$	Mid-axillary line on the same horizontal level as V4r.
LA black	→	Left arm
RA white	$\rightarrow$	Right arm
LL red	→	Left foot
RL green	<b>→</b>	Right foot

# 4.7 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.

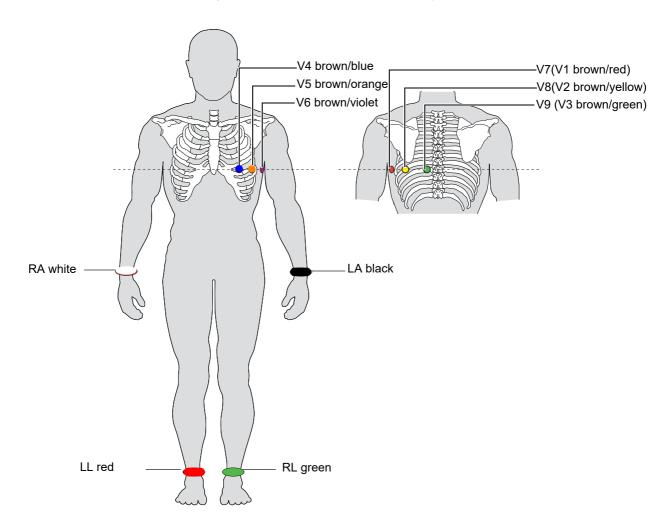


AHA Label		Electrode placement
V1 brown / red	→	Fourth intercostal space at the right sternal border.
V2 brown / yellow	$\rightarrow$	Fourth intercostal space at the left sternal border.
V3 brown / green	→	Midway between V2 and V4.
V4 brown / blue	$\rightarrow$	Fifth intercostal space on the mid-clavicular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



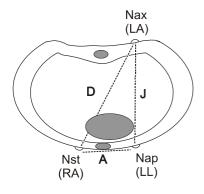
# 4.8 Left posterior V7-V9

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

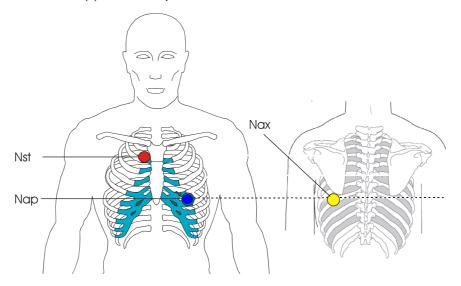


AHA label		Positioning
V7 (V1 brown / red)	→	Left posterior axillary line at the level of V4.
V8 (V2 brown / yellow)	<b>→</b>	Left of the mid-scapular line at the level of V4.
V9 (V3 brown / green)	<b>→</b>	Left paravertebral line at the level of V4.
V4 brown / blue	<b>→</b>	Fifth intercostal space on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

#### 4.9 **Nehb leads**



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



Place the electrodes as follows:

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

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

#### Skin/Electrode Resistance 4.10

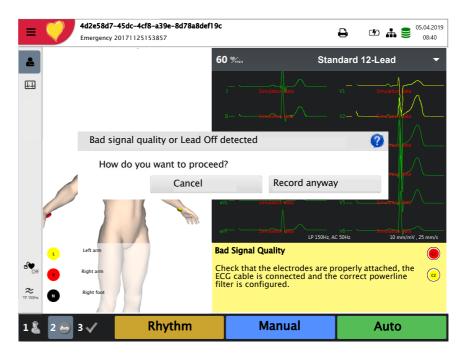
#### 4.10.1 Electrode and patient cable check

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
  - AC power 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.

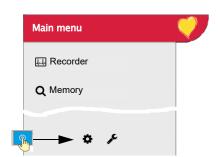
. If F (LL) or N is not connected or has come off, the electrode resistance cannot be measured and all leads are marked red.





# 4.11 Lead sequence/lead view

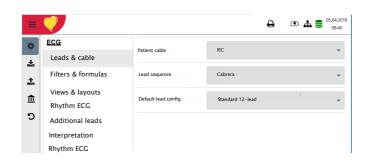
### 4.11.1 Setting Standard or Cabrera lead sequence



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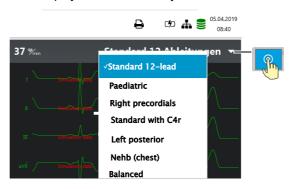
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- → The lead sequence is defined in the settings. (Menu > Settings > ECG > Leads & cable).
- → In the Lead menu, select between Standard and Cabrera.



### 4.11.2 Select the lead view (Standard or other settings)

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



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

# Important

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

# **Resting ECG**



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



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



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

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

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

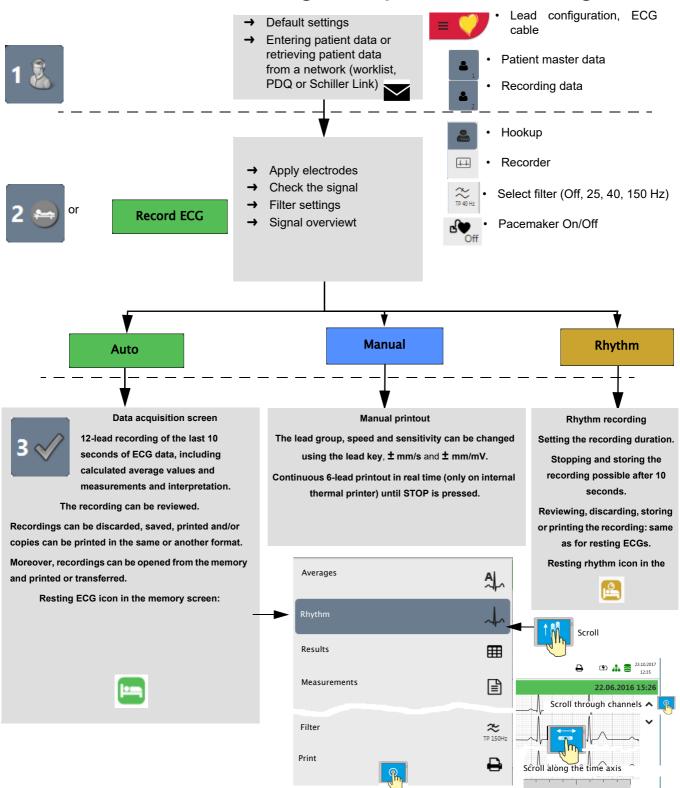
- · Lead configuration
- Filter

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

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# 5.1 Resting ECG - procedural flow diagram



5

#### 5.1.1 Printing, saving and transferring automatically

### Menu > Settings > General > Workflow

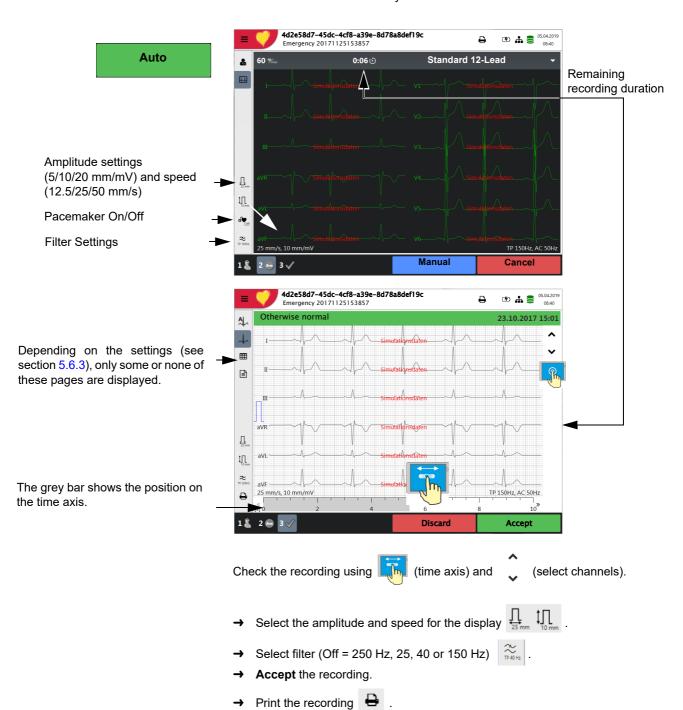
Activate Print after acquisition, Transmit after acquisition and Delete after transmission to automatically print and transmit a saved recording or to delete recordings after transmission.

- The transmission settings are detailed in the section Settings (see page 78).
- Further ECG settings are described later in this section (see page 52).
- Printing and transfer from the memory is described in the section Memory (see page 62).
- The settings are saved automatically. The settings can be exported (see page 71).

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### 5.2 **Automatic resting ECG recording**

To take an automatic ECG recording, press the **Auto** key. After approx. 10 seconds, the recording is 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.



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.

5

5.2

### 5.2.1 Automatic printout

The printout gives the following:

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

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

### Patient data

#### Result

- · Interpretation
- · Intervals & axis

### Measurements

Detailed measurement table

#### Rhythm

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

#### **Averages**

Averaged cycles with markings

SPACEL

# 5.3 Manual rhythm printout

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



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

### 5.3.1 Starting manual printout

Manual

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

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



### Select lead sequence

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

The Standard and Cabrera lead sequences are as follows:

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

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

### Select speed

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

### Select sensitivity

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

### Stopping the printout

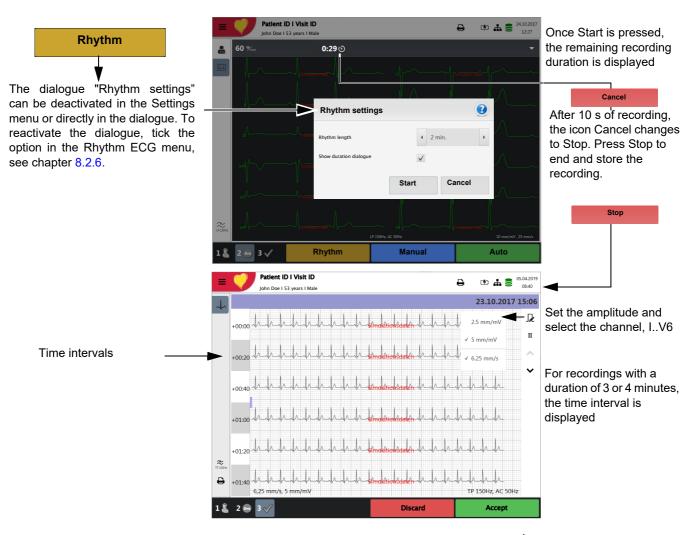
→ To stop the manual recording (printout), press the **Stop** key.

The printout provides the following information:

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

#### 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.



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

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



### 5.4.1 Automatic printout

The printout gives the following:

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

# 5.5 Changing the ECG preview layout

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

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

### 5.5.1 Display

Leads

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

The Standard and Cabrera lead sequences are as follows:

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

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

- · Standard 12-Lead
- Pediatric
- · Right precordials
- · Standard C4r
- · Left posterior
- Nebh (chest)



#### 5.5.2 Myogram filter (Low pass filter)

**User Guide** 

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, LP 25 Hz, LP 40 Hz or LP 150 Hz is displayed.



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



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

#### 5.5.3 Other filters

The following additional filters are available:

### Baseline filter

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

### Notch filter

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

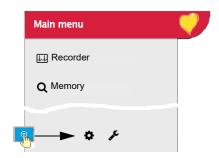


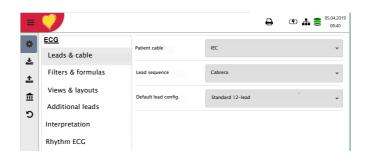
· The filters are activated/deactivated or changed in the ECG settings (see following description).



### **ECG** settings 5.6

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





### Overview Menu > Settings

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



Changed settings are saved automatically. In Menu > Import, settings from another device can be imported, or a backup of the settings can be restored (see page 71).

#### 5.6.1 Leads & cable

Menu	Parameter	Description / selection
Leads & cable	Patient cable	IEC or AHA
Leaus & Cable	Lead sequence	Standard or Cabrera
	Default lead config.	<ul> <li>Standard 12-lead</li> <li>Pediatric</li> <li>Right precordials</li> <li>Standard C4r</li> <li>Left posterior</li> <li>Nebh (chest)</li> <li>Balanced</li> </ul>

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### 5.6.2 Filters & formulas

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

### 5.6.3 Views & layouts

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

Preview	RECG review	Rhythm ECG
---------	-------------	------------

### **Preview**

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

Order of preview views in Step 2



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



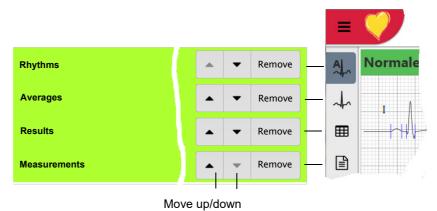


Preview	RECG review	Rhythm ECG

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

View and order in Step 3 of the Review





### **Rhythm ECG**

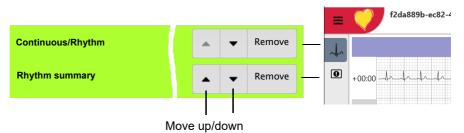
These settings apply to current resting rhythm recordings and recordings from the memory. Therefore, saved ECGs can be displayed with different settings at any time.

Preview	R-ECG review	Rhythm ECG

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

View and order in Step 3 of the Review





#### 5.6.4 **Additional leads**

Default leads per lead configuration

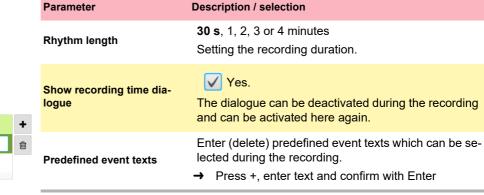
These settings apply to the current resting rhythm recording, recordings from the memory, and the printout. Therefore, saved ECGs can be displayed or printed with different settings at any time.

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

#### 5.6.5 Interpretation

Menu	Parameter	Description / selection
	Print interpretation	Yes/No
Interpretation	Display interpretation	<b>Yes</b> /No

#### 5.6.6 Resting rhythm





### 5.6.7 Reports

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

### General

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

### **Manual printout**

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

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



# **Resting ECG**

**User Guide** 

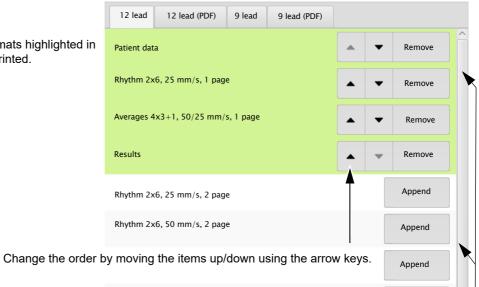
These settings apply to current resting ECG recordings and recordings from the memory. Therefore, saved ECGs can be printed with different settings at any time.



• The order listed below can vary.

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

Printout formats highlighted in green are printed.



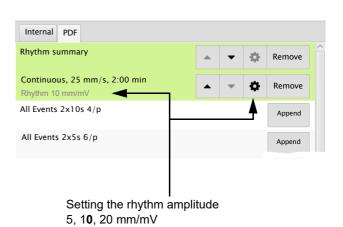
Add/remove print formats by pressing Append or Remove.

### **Rhythm ECG**

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

Menu D	Description / selection
•	
•	
Internal •	0 41 00 4 00 T
·	
•	HR trend
•	Rhythm summary
•	Continuous 25 mm/s, 2:00 min Rhythm 5, 10, 20 mm/mV
•	All events 2x10s, 6 pages Rhythm 5, 10, 20 mm/mV
•	All events 2x5s, 6 pages Rhythm 5, 10, 20 mm/mV
•	Continuous 12.5 mm/s, 5:20 min Rhythm 5, 10, 20 mm/mV
PDF .	Continuous 6.25 mm/s, 10:40 min Rhythm 5, 10, 20 mm/mV
•	Manual events 10s,1/2 page Rhythm 5, 10, 20 mm/mV
•	Manual events 10s, 1 page Rhythm 5, 10, 20 mm/mV
•	Rhythm 10s/page Rhythm 5, 10, 20 mm/mV
•	Rhythm 20s/page Rhythm 5, 10, 20 mm/mV





# 6 Memory

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

Approx. 350 resting ECGs and 100 resting rhythms can be stored on the CardioPulse Go. Recordings are stored manually after completion of the acquisition.

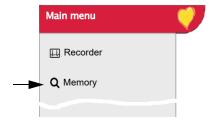




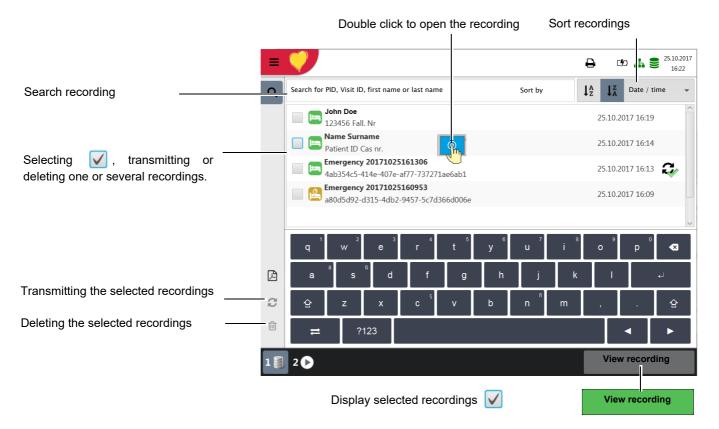


Memory capacity is indicated by the icon . A green icon means Memory OK, a yellow icon means Memory almost full, a red icon means Memory full, no recording possible. Chapter 6.1.2 describes how to delete recordings.

# 6.1 Editing the memory



- → When Menu > Memory is selected, stored recordings are displayed
- The recordings are listed by date/time; however, different listing criteria can be selected and recordings can also be searched via the search function.



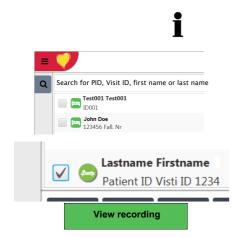
# 6.1.1 Opening the print preview from the memory and printing a recording

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

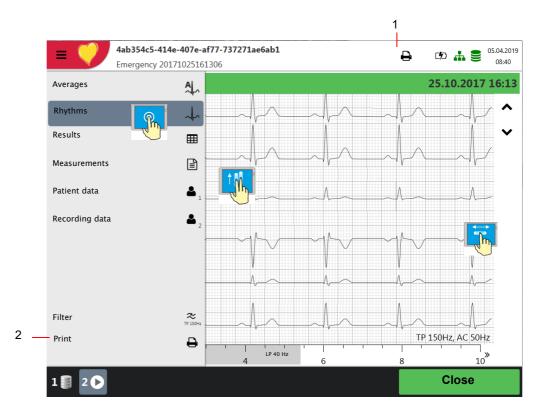
If the recording cannot be printed (e.g. no paper), the printout can be generated again by pressing the icon (1) A Print jobs in the status bar at the top.

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

- 1. Search and select the desired recording.
- 2. Press the key View recording.
- → The recording is displayed according to the settings in Menu > Settings > Resting ECG > Vies & layouts > RECG Review, and the layout can be changed for the displayed recording at any time.
- 3. Press (2) to print the recording in the selected format, see section 8.2.7 Reports, page 75.



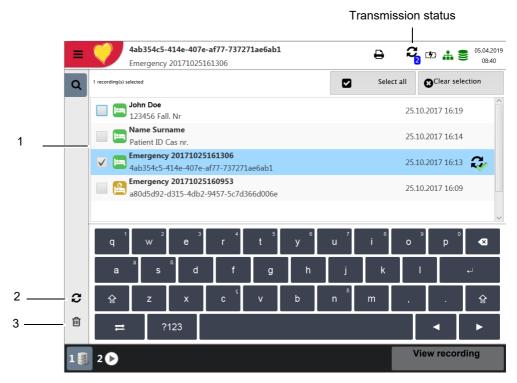
Example: resting ECG





### 6.1.2 Transmitting and deleting stored recordings

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



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

If the selected operation cannot be carried out due to an error, an error message is issued (see page 87) and the following symbols/buttons are displayed for each recording:



Indicates faulty recordings or recordings that have not been transmitted.



Indicates recordings that have not been transmitted.



Exported recordings.

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The transmitting options are detailed in the section System settings (see page 83).

# 7 Worklist (Option)

#### 7.1 **General information**

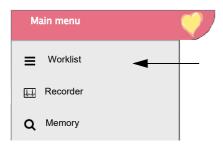
The Worklist function enables a doctor / administrator to define a worklist of patients that require recordings to be made. The doctor can define the patient, room / department, and specify the type of recording to be made. The worklist is defined directly from the Hospital information system (HIS) (e.g.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

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

- To be able to use the worklist function, the unit must be set up to communicate with Server (see page 78).
- The Server user guides describes how to define worklists from Server.

The server has options to send a worklist to a specific unit or to all units on the system. To receive a specific worklist from server, the unit identification of the CardioPulse Go (device ID in the system) must be the same as the one defined for the 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

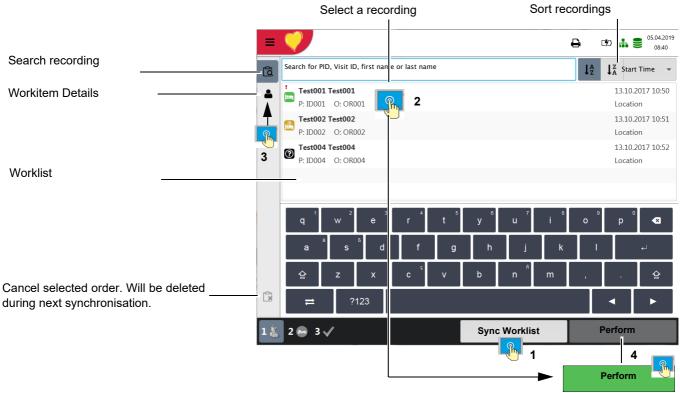


If worklists are to be used, the workflow can be adapted accordingly. To do so, set the Default workflow in Menu > Settings > General > Workflow to Worklist. In this way, the worklist is shown directly after power-up. However, worklist can also be selected manually from the menu.

#### 7.2 Receiving a worklist

To open the worklist proceed as follows:

1. Press Menu > Worklist.



Sync Worklist Sync Worklist 12:35:11

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

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

### **Recording status:**

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



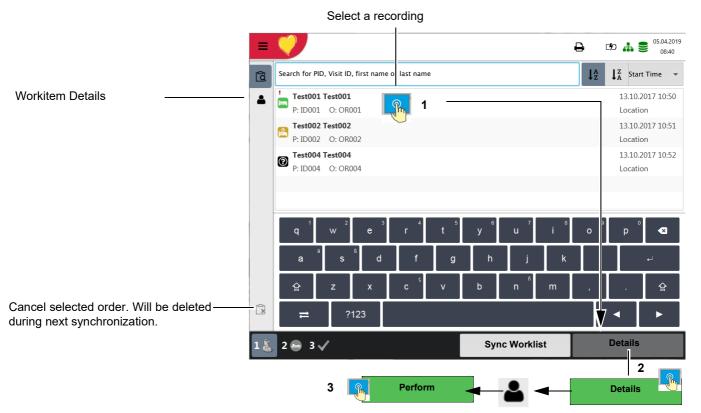
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CardioPulse Go

- · This procedure corresponds with the worklist mode "Record from worklist", see setting section 8.5 General, page 80, Workflow.
- · Patient data provided by the HIS cannot be edited (except for height and weight).
- If you have selected an incorrect work item, use the key  $\bigcirc$  (and **not**)  $\bigcirc$  to cancel the selected work item. 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 \( \rightarrow\$** to check the work order or to complement patient data.
- 3. Press the Perform key.
- 4. The corresponding recording acquisition screen (resting ECG or resting rhythm) is opened. If no recording type has been defined, both options are available.
- to return to the worklist without performing the recording (last chance to Press do so).
  - 5. Take the recording:
    - Resting ECG (see page 45)
    - Resting rhythm (see page 48)

### 7.2.2 Performing a recording from work order details

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- This procedure corresponds with the worklist mode "Record from work order details", see setting section 8.5 General, page 80, Workflow.
- Patient data provided by the HIS cannot be edited (except for height and weight).
- If you have selected an incorrect work item, use the key (and **not**) to cancel the selected work item. Select the new work item from the list, or use the Search field.
- 1. Prepare the patient and select a work item.



- 2. Select **Details (2)** to check the work order or to complement patient data.
- 3. Press **Perform (3)** in the "Work item details" view 🚨 .
- The corresponding recording acquisition screen (resting ECG or resting rhythm) is opened. If no recording type has been defined, both options are available.
- Press to return to the worklist without performing the recording (last chance to do so).
  - 5. Take the recording:
    - Resting ECG (see page 45)
    - Resting rhythm (see page 48)

#### 7.2.3 Sending worklist recordings to the HIS



It is possible to automatically send performed worklist recordings; alternatively, you can have the unit prompt you to manually send worklist items. This is defined in system settings (Menu > Settings > General > Workflow page 80).



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



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



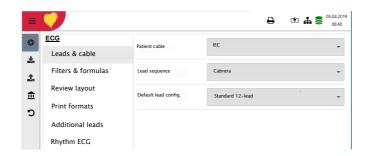
Canceled work items (red background) are deleted from the worklist during the next synchronization.

# 8 General and system settings

# 8.1 System settings

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

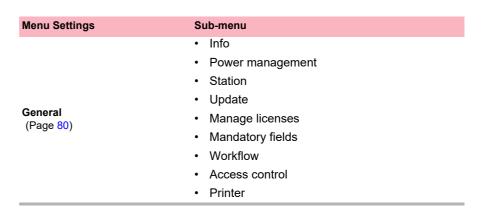




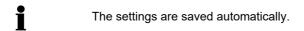
### Overview Menu > Settings

Menu Settings	Sub-menu
ECG (Page 72)	<ul><li>Leads &amp; cable</li><li>Filters &amp; formulas</li><li>Views &amp; layouts</li><li>Additional leads</li><li>Interpretation</li><li>Rhythm ECG</li></ul>
Reports (Page 75)	<ul><li>General</li><li>Manual printout</li><li>Resting ECG</li><li>Rhythm ECG</li></ul>
Connectivity (Page 78)	<ul><li>EMR integration</li><li>Update server</li><li>Ethernet</li><li>WLAN</li></ul>
Regional (Page 79)	<ul><li>Date &amp; time</li><li>Keyboard</li><li>Language</li><li>Units</li><li>Patient ID system</li></ul>

Reset to factory settings



#### 8.1.1 Saving and restoring settings



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

Export settings **1** Select Export and Export target USB and enter a file name to save the settings.

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

# 8.2 ECG

The default settings are printed **bold**.

### 8.2.1 **Leads & cable**

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

### 8.2.2 Filters & formulas

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

**ECG** 

## 8.2.3 Views & layouts

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

## **Preview**

_		
Preview	RECG review	Rhythm ECG

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

## **RECG Review**

Preview	RECG review	Rhythm ECG
11011011	INEGO IOVION	<b>y</b> 200

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

## **Rhythm ECG**

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

Preview	R-ECG review	Rhythm ECG

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

## 8.2.4 Additional leads

Default leads per lead configuration

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

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

## 8.2.5 Interpretation

Menu	Parameter	Description / selection
	Print interpretation	<b>Yes</b> /No
Interpretation	Display interpretation	<b>Yes</b> /No

## 8.2.6 Resting rhythm

Parameter	Description / selection	
Rhythm length	<b>30 s</b> , 1, 2, 3 or 4 minutes Setting th€	
Show recording time dialogue	Yes. The dialog and can be	
Predefined event texts	Enter (delete) predefined lected during the recordir hich can be selected during the recording hick can be selected as a selected during the recording hick can be selected as a selected during hick can	

ECG 8.2



## 8.2.7 Reports

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

## General

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

## **Manual printout**

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

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

## **Resting ECG**

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

i

• The order listed below can vary.

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

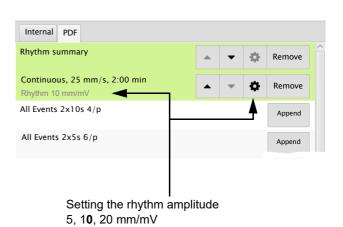


## **Rhythm ECG**

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

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

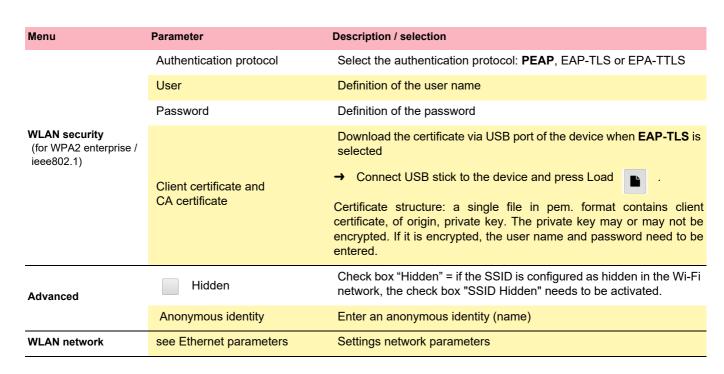




## 8.3 Connectivity



Menu	Parameter	Description / selection
EMD integration	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)
EMR integration Server settings	Host	Name of the server
	SSL cert. validation	No/Yes 🗸
	Port	Port address
	User	User name
	Password	Password
Update server	Host	Schiller Update server
Opuate Server	Port	Port address and key Test connection
	Use DHCP	Active or Not active. If this is not activated, the following parameters need to be entered:
Ethernet	IP address	Identifier address of the device in the TCP/IP network.
Ethernet	Subnet mask	E.g.: 255.255.255.0
	Standard Gateway	Gateway IP address.
	DNS server	Domain name of the server
	Wi-Fi enabled	Active Not active
	SSID Hidden	SSID = Enter network name.  Check box "Hidden" = if the SSID is configured as hidden in the Wi-Fi network, the check box "SSID Hidden" needs to be activated.
WLAN general	Wi-Fi security	<ul> <li>Selection of the encryption protocol</li> <li>WPA/WPA2 personal         SSID + key + (encryption = AES + authentication)</li> <li>WPA2 enterprise / ieee802.1 (additional settings see *)         SSID + certificate + (encryption = AES + authentication)         SSID + user name &amp; password + (encryption = AES + authentication)</li> </ul>
WLAN security (for WPA/WPA2 personal)	Password	Enter password for WPA/WPA2 protocol



## 8.4 Regional settings

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



#### 8.5 General

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

Menu	Parameter	Description / selection						
	Transmit after acquisition	ECG data is transmitted after acquisition and storage of the recording						
	PDF to USB after save	Yes, $\ensuremath{\text{No}}$ . After saving, the PDF is automatically exported to the USI stick						
	Delete after transmission	ECG data is deleted once it has been successfully transmitted from the memory.						
	Print after acquisition	ECG data is printed once it has been stored.						
Workflow	PDQ mode	PDQ by <b>Patient ID</b> PDQ by Visit ID None (PDQ is not started, even if <b>EPA integration</b> has been selected)						
	Default workflow	Worklist Recorder						
	Worklist mode	Record from worklist						
	(only if option has been activated)	Record from work order details						
	Auto sync worklist	Yes, <b>No</b> . Worklist is synchronized every minute.						
	Access control mode	<ul> <li>Basic         Login when switching on the device and/or accessing the Settings menu requires a password</li> <li>Local (Default factory setting)         Definition of users, passwords and privileges locally on the device</li> <li>Schiller Server         Access control is defined via the Schiller Server.</li> </ul>						
	Basic							
	Device login active	✓ If activated, the login dialogue is displayed at switch-on.						
Access control (automatic logout when	Device password	Defining the password (default)						
access control is activated, see menu "Automatic logout" next page)	Settings Login Active	If this is activated, the login dialogue is displayed when the settings are opened						
Important! These set- tings must only be per-	Settings Password	Defining the password (admin)						
formed by trained personnel.	Local							
	User name	Administrator (additional users can be created)						
	Password	Enter the password ("administrator" is used as password if no other password is entered)						
	Retype Password	Confirm password						
		Selecting the privileges:						
	Privileges	Adjust system settings; Analyze recordings (from memory); Create recordings.						
	Schiller Server	This requires a working EMR connection and Schiller Server administrator rights. Access control is defined on the Schiller Server						

trator rights. Access control is defined on the Schiller Server.

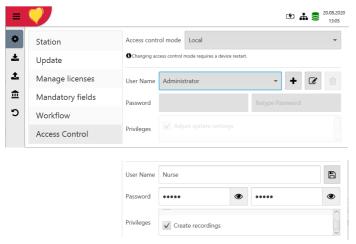


Menu	Parameter	Description / selection
Automatic logout (Is only displayed if Access control is activated)	Automatic logout enabled	✓ Yes/No
	Logout timeout [s]	300
Print setting	Contrast	1-10 (5)
	Line width	Thin, <b>normal</b> , thick

## 8.5.1 Setting user name and password for access control



- ▲ 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.



- 1. Choose the "Access control" menu. The Access control mode "Local" is by default activated.
- Select one of the predefined "User Name" (Nurse, Physician) by pressing the key.
- 3. Use the buttons + 🗷 🛍 to add, edit or delete users.
- → User privileges can be selected or deselected with the check boy ✓. The "Adjust system settings" privilege cannot be disabled for the administrator.
- 4. Select the button 🗈 to save the settings.

# 9 Transmission - Overview



- 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 Go network from other networks
  - defining access authorization for the configuration of the host system, incl. CardioPulse Go, 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 anti virus/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 Go'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 Go, transmission is possible via a network or Wi-Fi. The transmission options are as follows:



- ▲ When a non-medical device is connected to the interface, ensure that both units are securely connected to the same earth potential.
- An external device must only be connected using the original interface cable assembly.



▲ The transmission of ECG data via WLAN can disturb other devices, including pacemakers. Therefore, keep a distance of at least 20 cm from the patient while an ECG is transmitted.

#### LAN

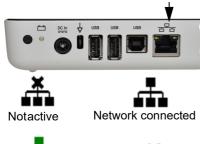
data transmission via local LAN network (Ethernet) to the EMR system. For an Ethernet (network) connection, connect the cable assembly to the RJ-45 connector.

#### LAN or WLAN not active/active

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

Green = connection to network/server established

Black = no connection to network/server







#### Wifi

If Wifi is activated, the following symbols are displayed



- Green symbol: connected to the Wifi network and the Server.
- · Black Symbol: connected to the network but no connection to the Server
- · Signal strength is displayed with 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 78).

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

## Schiller Server/Schiller Gateway

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

### PDF export

Simple export of a recording as PDF to a memory 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 80).

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 64)

#### 9.1.3 PDF export

## **Data integrity**



USB stick

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

## **Settings**



Activate PDF export in the Menu > Settings > Workflow > PDF to USB after save. If PDF export is active, the recordings from the memory are transmitted as soon as

a USB stick is connected. The symbol 🏚 PDF export is displayed when data has successfully been transferred to the memory stick.

## Caution

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



## Manual PDF export from memory



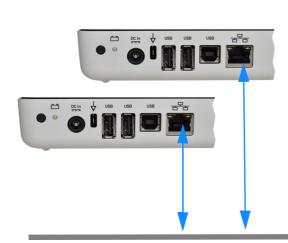
An individual recording can be exported to a USB stick from the memory if the setting above "Delete after transmission" has been selected.

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

#### 9.1.4 Schiller Link

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

- To activate this communication, set Schiller Link in the menu Connectivity > EMR integration (see page 78).
- Integration in the network is automatic, provided the CardioPulse Go is part of the same network

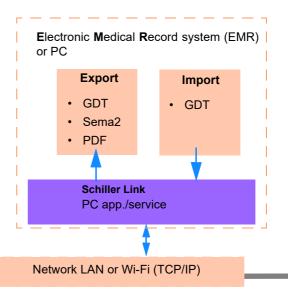


Start

**Recording Order** 

Height [cm]

An order for a new recording has been received.



## Procedure with 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 Go.
- 5. Perform the recording on the CardioPulse Go.
- 6. Store the recording and export it automatically or manually to the export folder.
- The EMR system imports the recording for review in the EMR system.

## **Procedure without EMR system**

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

#### 9.1.5 Receiving data from server

Patient data can be received from a server and automatically entered on the CardioPulse Go. 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).



- · Patient data query requires the Server being available via network.
- The server name, URL, TCP/IP address etc. as well as all other transmission settings are defined in the system settings (see page 78).



in the status bar.



- 1. The blue figure indicates the number of failed transmissions.
- 2. Data that was not transmitted can be resent from the memory. See section 6.1.2 Transmitting and deleting stored recordings, page 64.

If no data can be transmitted, check the following:

- → Network settings (see page 78)
- → Network connection WLAN or LAN
- → Encryption settings on the server
- → Settings in the Schiller Link.





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

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

Interval	Maintenance step	Responsible
Before each use	Visual inspection of the device and ECG electrodes	→ User
Every 6 months	<ul> <li>Visual inspection of the device (see page 93, 10.6 Inspection report)</li> <li>Touch screen test</li> <li>Cables and accessories</li> <li>Power supply unit and AC power cable</li> <li>Functional tests according to the instructions (see page 93, 10.6 Inspection report)</li> </ul>	→ User
Every 12 months	Safety test according to IEC/EN 62353	→ Qualified service personnel

#### 10.1 **Visual Inspection**

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

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

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

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



Defective units or damaged cables must be replaced immediately.



#### 10.2 Cleaning the casing and cables

**User Guide** 



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.



- Do not autoclave the device and accessories.
- Do not immerse the device in liquid.
- Do not spray liquid onto the device/cable.
- The use of detergents with a high acid content or detergents that are otherwise unsuitable can damage the device (i.e. cracks and wear of the plastic casing).
- Always follow the usage instructions provided by the manufacturer of the cleaning solution.
- With time, the casing may become less resistant:
  - if an 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.

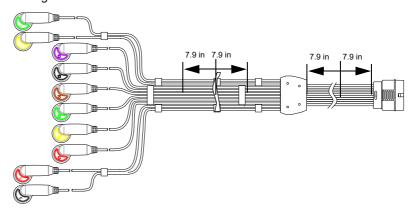
- Look for any signs of damage and make sure that the keys and connectors work correctly
- Gently bend and flex cables, inspecting them for damage or extreme wear, exposed wires, and bent connectors.
- Confirm that all connectors engage securely.

The casing of the CardioPulse Go and the cable assemblies can be cleaned with a cloth slightly moistened (not wet) on the surface only. If necessary, a domestic noncaustic 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 10.2.2). Thoroughly wipe off any excess cleaning solution. Do not let the cleaning solution run into or accumulate in connector openings, switches, or gaps. If liquid gets into connectors, dry the area with warm air and check that the device operates properly.

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## 10.2.1 Cleaning the cable assembly

- 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.
- 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.







## 10.2.2 Approved cleaning solutions

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

## 10.2.3 Non-admissible detergents

Never use products containing the following:

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

Maintenance
User Guide Maintenance
Disinfection

## 10.3 Disinfection

Disinfection removes certain bacteria and viruses.

Use commercially available disinfectants intended for clinics, hospitals and medical practices. Please refer to the information of the manufacturer's disinfectants for the application.

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

## 10.3.1 Approved disinfectants

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

## 10.3.2 Non-admissible disinfectants

Never use products containing the following:

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

## 10.4 Cleaning the thermal print head



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

- 1. Open the paper tray and remove the paper. The thermal print head is located directly above the pressure roller (when the paper tray is closed).
- 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.

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10.3

## 10.5 Battery

- No maintenance is required for the lithium-ion polymer batteries.
- Replace the battery approximately every 4 years (depending on the application) when the battery running time falls substantially under one hour.
- Storage and operation conditions outside the temperature range of 59 77 °F will reduce the service life of the battery!
- Make sure that the batteries remain charged during storage. If the device is not used for more than 3 to 4 months, the battery needs to be protected from deep discharge by recharging it; the ideal capacity is 50-80%. If a fully charged battery is stored for a long period of time, this may reduce its service life.

## 10.5.1 Charging the battery

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

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

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

## 10.5.2 Battery disposal



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



- ▲ Explosion hazard! The battery must not be burned or disposed of in domestic waste.
- ▲ Acid burn hazard! Do not open the battery.

**User Guide** 

Maintenance Inspection report

10 10.6

## 10.6 Inspection report

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▲ The user guide, especially chapter 10, must be read before the inspection.

▲ Recommended inspection interval: Every 6 months

Serial no.:	

Test			esults	Date					
Vis →	ual inspection 10.1 External condition	•	Casing not damaged	o	□				
		•	Electrode connector port not damaged						
<b>→</b>	Availability and condition of accessories	•	ECG Electrodes (expiration date and compatibility)						
		•	User Guide	_			□		
		•	AC power and patient cable						
Fun →	ectional test 2.3 ECG test	•	No error message shown in the standard display	٥	О	О	٥	□	
<b>→</b>	Multi-touch screen test	•	Touch screen works						
→	Check the battery	•	Battery OK	□			□	□	
<b>→</b>	Printer	•	Contrast and line strength						
		•	Cleaning the thermal print head	٥	□		٥	٥	
Ren	narks								
→	Recurrent test conducted (every 12 months)				□		О		
Ins	pection carried out by:								

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

| Name:  | <br> |  |
|--------|------|------|------|------|------|------|------|--|
| Phone: | <br> |  |

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## 10.6.1 Lifed-item replacement every 3 - 5 years

Ins	pection	Results	Replaceme	ent			
Inte	ernal battery						
<b>→</b>	Replace internal battery if operation falls substantially under one hour.			o	o	o	О
		Date of replacement:					
		Inspector:					

# 11 Trouble shooting

## 11.1 Possible problems

Error	Possible causes and indicators	Error localization and troubleshooting
Unit does not switch on; blank screen	<ul> <li>No AC power supply; green AC power indicator on the power supply unit is off.</li> <li>AC power connection OK, bu indicator  and LED are no</li> </ul>	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.  Check / change the battery. If the battery is faulty, it is possible that
	lit.	<ul> <li>→ If the screen is still not lit, it indicates a software fault, monitor problem or internal power supply. Call your local Spacelabs Healthcare representative.</li> </ul>
	Incorrect settings for patient.	→ Change sensitivity setting.
		→ Check electrode contact and reposition the electrodes.
QRS traces overlap	Bad electrode contact.	→ 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.
	<ul> <li>High resistance between skir and electrodes</li> </ul>	green)
		→ Re-apply electrodes.
"Noisy" traces	<ul><li>Patient not relaxed</li><li>Incorrect settings</li></ul>	<ul> <li>→ Ensure that the patient is warm and relaxed.</li> <li>→ Check all filter settings (Menu &gt; Settings &gt; ECG &gt; Filters &amp; formulas).</li> </ul>
Noisy traces		<ul> <li>→ Activate the Myogram (Low pass) filter and change the cut-off frequency.</li> </ul>
		→ Ensure mains filter is correct for AC power supply.
		→ If the problem persists, call your local Spacelabs Healthcare representative.
	No paper	→ Ensure that paper is loaded.
	<ul> <li>Paper incorrectly loaded.</li> </ul>	→ Reload paper.
No printout obtained after an auto mode		→ Ensure that the paper has been inserted correctly with the black mark at the top.
recording.	Incorrect settings	→ Check that the printout is activated for at least one setting, and that Print after acquisition is activated (see page 58 and 80)
		→ If the problem persists, call your local Spacelabs Healthcare representative.



Error	Possible causes and indicators	Err	or localization and troubleshooting
	Old paper inserted.	<b>→</b>	Ensure that new Spacelabs Healthcare paper is inserted.
		<b>→</b>	Note that the CardioPulse Go 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.
Printout fades, is no			
clear or the printou is 'patchy'.	Dirty print head	<b>→</b>	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.
	<ul> <li>Line width/contrast setting in- correct</li> </ul>	. →	Set the line width, contrast, printer, see page 82.
	Print-head out of adjustment.	→	If the problem persists, call your local Spacelabs Healthcare representative.
No printout of interpretation	<ul> <li>Incorrect settings</li> </ul>	_	Check that the interpretation and measurement options are en-
statement, average cycles or measurements		7	abled for the printout and that the lead sequence is set to Normal (see page 58 section 5.6.7 and page 41 section 4.11.2,
	Software hangs up	→	Switch off and on again after a few seconds.
Multi-touch screen	n	<b>→</b>	Press and hold the On/Off button for 10 seconds to force the device to switch off. Reconnect AC power and switch on.
is blocked		→	If the problem persists, call your local Spacelabs Healthcare representative.
Multi-touch screen responds in an		<b>→</b>	Check for sources of excessive EMC interferences.
irregular way			
Not able to star	Memory full		
ECG recording		<b>→</b>	Delete old ECG recordings, see page 62.



## 11.2 Preventing electromagnetic interferences



"Non ionising electromagnetic radiation"

The user can help avoid electromagnetic disturbances by keeping the minimum distance between **portable** and **mobile** HF telecommunication devices (transmitters) and the CardioPulse Go. The distance depends on the output performance of the communication device as indicated below.

HF source Wireless communications devices	Transmitter frequency [MHz]	Testing fre- quency [MHz]	Max. power P [W]	Distance d [m]
Various radio services (TETRA 400)	380-390	385	1.8	0.3
<ul><li>Walkie-talkies (FRS)</li><li>Rescue service, police, fire brigade, servicing (GMRS)</li></ul>	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
<ul> <li>Bluetooth, WLAN 802.11b/g/n</li> <li>LTE Band 7</li> <li>RFID 2450 (active and passive transponders and reading devices)</li> </ul>	2400-2570	2450	2	0.3
WLAN 802.11a/n	5100-5800	5240/5500/ 5785	0.2	0.3



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

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

d = recommended minimum distance in meters

P = transmitting power in Watts



For more information on operation in an electromagnetic environment according to IEC/EN 60601-1-2 see section For fixed installed HF-Transmitters (for example, Radio and TV transmitters) the following minimum distance to the transmitter can be calculated as follows:., page 108.

## 11.2.1 Measures to prevent electromagnetic interferences

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

- Increase distance to the source of interference.
- Turn the device to change the angle of radiation.
- · Connect the potential equalisation cable.
- · Connect the device to a different 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 Maintenance, page 88.



#### 11.3 Accessories and disposables



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

Your local representative Spacelabs Healthcaree stocks all the disposables and accessories available for the CardioPulse Go. 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 **ECG CablePatient cables**

**User Guide** 

REF no.:	CAT no.:	Label	Description
2.400175	-	ECG D-SUB C 4.6/4.25 x10 IEC	10-wire patient cable IEC, clip type, 4.6/4.25 m
2.400178	-	ECG D-SUB C 4.6/4.25 x10 AHA	10-wire patient cable AHA, clip type, 4.6/4.25 m
2.400179	-	ECG D-SUB B 3.1/2.55 x10 AHA	10-wire patient cable AHA, banana plug, 3.1/2.55 m
2.400180	-	ECG D-SUB B 3.1/2.55 x10 IEC	10-wire patient cable IEC, banana plug, 3.1/2.55 m
2.400226	-	ECG FS P 2.1/1.6 x10 IEC	10-wire patient cable, IEC, push-button, 2.1/1.6 m
2.400227	700-0386-00	ECG FS P 2.1/1.6 x10 AHA	10-wire patient cable, AHA, push-button, 2.1/1.6 m
2.400330	-	ECG FS B 2.1/1.6 x10 IEC	10-wire patient cable, IEC, banana plug, 2.1/1.6 m
2.400331	00-0387-00	ECG FS B 2.1/1.6 x10 AHA	10-wire patient cable, AHA, banana plug, 2.1/1.6 m

#### **Electrodes and ECG consumables** 11.3.2

REF no.:	CAT no.:	Label	Description
2.000041	-	ECG KIT	Electrode kit for adults (metal) including electrode gel
2.000052	-	ECG KIT	Electrode kit for children (metal) including electrode gel
2.155020	-	Set of 4 clamp electrodes	Limb electrodes, adults (metal)
2.155000	-	Suction chest electrode	Suction electrodes chest, 24 mm, set of 6 pieces
2.310317	-	ECG FS D-SUB 0.25 x10 AC	Suction pump adaptor
2.155025	-	Ambu® BlueSensor R	Blue Sensor electrodes for exercise ECG (500 pieces)
2.155032	-	Ambu® Snap Clip	Adapter for banana plugs (10 pieces)
2.155034	-	Ambu® WhiteSensor 0415M	White Sensor electrodes for resting ECG (500 pieces)
2.157055	010-2281-00	ECG Recording Paper Fanfold	Thermal chart paper, box of 10 (60 sheets each)

#### AC power cable, Power supply and potential equalisation 11.3.3

REF no.:	CAT no.:	Article
2.310320	161-0280-00	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



REF no.:	CAT no.:	Article
2.300012	-	AC power cable USA (hospital grade), straight, 2.5m
2.300014	-	AC power cable China, 90 ° angled, 2.5m
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
2.200136	161-0281-00	Medical-grade power supply unit, 100-240 VAC, 1.0 -0.6 A, 50/60Hz, 15 VDC 30 Watts (replacement of the 2.200126)

## 11.3.4 Other accessories

REF no.:	CAT no.:	Article
2.310317	700-0399-00	D-SUB to FT-1 ECG cable connector adapter
2.000147	-	Barcode scanner set including barcode scanner (2.200208 // LS2208-SR20001R-UR) and SCHILLER User guide "Barcode scanner for use with SCHILLER units" (2.510721)

## 11.3.5 Trolley

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

# HEALTHCARE CardioPulse Go

SPACELABS

## 12 Technical data

## 12.1 Device

**Dimensions** 

**Display** 

Power supply with:

· external power supply unit

Input

Output to CardioPulse Go

Battery

Power supply device

**Battery** 

Capacity

Battery life Charging time

**Printer** 

Frequency range Chart paper Speed

Sensitivity

**ECG** review

Speed Sensitivity

**Interfaces** 

Memory

230 x 160 x 30 mm, approx. 1.1 kg incl. thermal paper

- · Multi-touch Backlit LCD screen for graphic and alphanumeric representation
- Resolution: 1200 x 768 dots, 8 "

Medical grade switching power supply, protection class I

(Note: because the protective earth (PE) ends in the power supply, the protective earth test does not need to be performed.)

100 - 240 VAC, max. 1.0 A (100 V) - 0.6 A (240V), 50-60 Hz

15 VDC, max. 2 A

Operation with built-in rechargeable battery

15 VDC 30 VA

- · Lithium-ion polymer 11.1 V, 2.4 Ah
- · 4 hours normal use without printing and WLAN

Under normal operating conditions, 4 years

100 %: approx. 3 hours when the device is switched off

High-resolution thermal head printer; 8 dots/mm (amplitude axis); 20 dots/mm (time axis) @ 25 mm/s

0 to 250 Hz (IEC/AHA)

Thermo-reactive, Z-fold, 114 mm wide, optimal positioning on 150 mm

- 5/12.5/ 25/ 50 mm/s (5 /12.5 mm/s only available for manual printouts), for resting rhythm: 6.25 mm/s
- 5 /10 / 20 mm/mV, for resting rhythm: 2.5/5 mm/mV

Display of the ECG on an area of 118 x 192 mm with different layouts.

- 12.5 / 25 / 50 mm/s, for resting rhythm: 6.25 mm/s
- 5 /10 / 20 mm/mV, for resting rhythm: 2.5/5 mm/mV
- · ECG cable connection
- Potential equalisation
- Network connection (1Gbit)
- · 2x USB type A
- · 1x USB type B is not intended for the US market

Memory for at least 350 ECG recordings and 100 resting rhythm recordings

### **Ambient conditions**

Operating temperature

Relative humidity

Pressure during operation

Storage temperature

Transport temperature

Humidity during storage/transport

Pressure during storage/transport

• 50 to 104 °F

• 15 to 95% (non-condensing)

• 700 to 1060 hPa

• 41 to 122 °F

• 14 to 122 F

• 10 to 95% (non-condensing)

500 to 1060 hPa

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## 12.2 ECG

## **Patient input**

Fully floating and isolated, defibrillation protected (only with original Spacelabs Healthcare patient cable)

## Lead configurations

- · Standard 12-lead
- Paediatric
- Right precordials
- · Standard C4r
- Left posterior
- Nehb
- Balanced

## Display

Leads

- Display of the selected leads, 2x6 or 4x3 leads (configurable)
  - Chart speed 12.5, 25 or 55 mm/s (configurable)
  - Amplitude 5, 10 or 20 mm/V (configurable)

Status

- Filter status
- Power source
- Leads
- · Electrode contact status
- · Heart rate (HR)
- Date and time
- · Patient name and number
- · WLAN transmission

## Filter

Myogram filter (muscle tremor)

Notch filter

Set to 25, 40, 150, 250 Hz (250 Hz = Filter Off)

Distortion-free suppression of superimposed AC 50 or AC 60 Hz sinusoidal interferences by means of adaptive digital filtering

Data record

- Patient data (name, age, height, weight, BP, device ID, MTA ID)
- Listing of all ECG recording conditions (date, time, filter)
- ECG measurement results (intervals, amplitudes, electrical axes)
- Average complexes
- · Guidance on interpreting adult and pediatric ECGs

With optional interpretation (C) program

## **ECG** amplifier

Complies with IEC 60601-2-25 and ANSI/AAMI EC11

## 12.3 Safety standards

Safety standard IEC/EN 60601-1

IEC/EN 60601-2-25

**EMC** IEC/EN 60601-1-2

Protection class Device as a system: Class I in accordance with IEC/EN 60601-1

Conformity/classification CE/lla 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
 Z64-WL180DBMOD

 IC ID
 451I-WL18DBMOD

**Transmission standards** IEEE 802.11 a, b, g, n

Safety/encryption WPA2 enterprise /ieee802.1, WPA2-PSK, WPA-PSK, WEP64/128/256, TKIP, AES

Frequency range Dual-band 2.4 GHz and 5 GHz

Max. power output 2.4 GHz (1DSSS) +16.5 dBm

Max. power output 5 GHz (OFDM6)

+18 dBm

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12.5



**SPACELABS** 

#### 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.

#### 12.5.1 **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 these
Harmonic emissions IEC 61000-3-2	Class A	The device is suitable for use in all establishments, including those directly connected to the public low-voltage power supply network
Voltage fluctuations/Flicker emissions IEC 6100-3-3		that supplies buildings used for domestic purposes.

#### 12.5.2 **Immunity**

Immunity Test	IEC 606101 Test level	Compliance Level	Electromagnetic environment guidance
ESD	±8kV Contact	±8kV Contact	Floors should be wood, concrete or ceramic tile. If floors are synthetic, the relative humidity (RH) should be at least 30%.
IEC 61000-4-2	±15kV Air	±15kV Air	
EFT	±2kV Power supply lines	±2kV Power supply lines	Mains power quality should be that of a typical commercial or hospital environment.
IEC 61000-4-4	±1kV I/O lines	±1kV I/O lines	
Surge	±1kV differential mode	±1kV differential mode	Mains power quality should be that of a typical commercial or hospital environment.
IEC 61000-4-5	±2kV common mode	±2kV common mode	
Voltage Dips/Dropout IEC 61000-4-11	$< 5\% \ U_T$ (> 95% dip in UT) for 0,5 cycle $40\% \ U_T$ (60% dip in UT) for 5 cycles $70\% \ U_T$ (30% dip in UT) for 25 cycles $< 5\% \ U_T$ (> 95% dip in UT) for 5 s	$< 5\% \ U_T$ (> 95% dip in UT) for 0,5 cycle $40\% \ U_T$ (60% dip in UT) for 5 cycles $70\% \ U_T$ (30% dip in UT) for 25 cycles $< 5\% \ U_T$ (> 95% dip in UT) for 5 s	Mains power quality should be that of a typical commercial or hospital environment. The unit shutoff during the >95% for 5 second disturbance. If the user of the HT300-series meter requires continued operation during power mains interruptions, it is recommended that the HT300-Series meter be powered from an uninterrupted power supply or battery.
Power Frequency 50/60Hz Magnetic Field IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be that of a typical commercial or hospital environment.

NOTE U<sub>T</sub> is the AC mains voltage prior to application of the test level.



## 12.5.3 Emissions equipment and systems

Immunity Test	IEC 606101 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 <sub>1</sub> ] = 10 Vrms	$d = \frac{3.5}{V_1} \times \sqrt{P}$
Radiated RF IEC 61000-4-3	10 V/m 80 MHz to 2700 MHz	[E <sub>1</sub> ] = 10 V/m 80 MHz to 3000 MHz	$d = \frac{6}{E_1} \times \sqrt{P}  \text{for 80 MHz to 3000 MHz}$
Proximity fields from RF wireless communications equipment IEC 61000-4-3	see section 12.5.4 Immunity to proximity fields from RF wireless communications equipment, page 107	proximity fields from RF wire-	$\label{eq:def} \text{d} = \frac{6}{E_1} \times \sqrt{\text{P}} \qquad \text{for tested frequencies}$ Tested Frequency see section 12.5.4 Immunity to proximity fields from RF wireless communications equipment, page 107
			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 <sup>a</sup> survey, should be less than the compliance <sup>b</sup> levels (V <sub>1</sub> and E <sub>1</sub> ).  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  $[V_1]\ V/m$ .

# 12.5.4 Immunity to proximity fields from RF wireless communications equipment

Test frequency [MHz]	Band <sup>a</sup> [MHz]	Service	Modulation	max. power P [W]	Distance d [m]	Immunity level [V/m]
385	380-390	Various Transmitter devices (TETRA 400)	Pulse modulation <sup>b</sup> 18 Hz	1.8	0.3	27
450	430-470	<ul> <li>Walkie-talkie (FRS)</li> <li>Emergency services, Police,</li> <li>Fire, Maintenance (GMRS)</li> </ul>	FM <sup>c</sup> ±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 - Funktelefon CT1+, CT2,CT3	Pulse modulation 18 Hz	2	0.3	28
1720 1845 1970	1700-1990	- GSM1800/1900 - DECT (mobile telephone) - LTE Band 1/3/4/25 - UMTS (Universal Mobile Telecommunications System)	Pulse modulation 217 Hz	2	0.3	28
2450	2400-2570	<ul> <li>Bluetooth, WLAN 802.11b/g/n</li> <li>LTE Band 7</li> <li>RFID 2450 (active &amp; passive transponder and readers)</li> </ul>	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



## 12.5.5 Recommended separation distances

For fixed installed HF-Transmitters (for example, Radio and TV transmitters) the following minimum distance to the transmitter can be calculated as follows:.

Maximum Power Output [Watts]	Separation distance according frequency of the transmitter [m]		
	150 kHz to 80 MHz	80 MHz to 3000 GHz	
	$d = \frac{3.5}{V_1} \times \sqrt{P}$	$d = \frac{6}{E_1} \times \sqrt{P}$	
0.01	0.04	0.06	
0.1	0.11	0.19	
1	0.35	0.6	
10	1.1	1.9	
100	3.5	6	

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts [W] according to the transmitter manufacturer.

Note 1 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.



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# 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 )
5	Number of pieces in the packaging
EC REP	Authorised European representative
<b>(€</b> ××××	Notified body (e.g <b>( 6</b> 0123 marking notified body TÜV SÜD)
(€	CE marking, affirms its conformity with European standards

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	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.
LDPE	The packaging is made in low density polyethylene and can be recycled.
R <sub>C</sub>	Federal law (USA) restricts this device to sale by or on the order of a physician
(( <u>`</u> ))	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
<b>②</b>	Do not reuse
TATEX	Latex-free
$\subseteq$	Use-by date (expiry date of battery, electrodes or other consumables)
	Temperature range for storage or transport, respectively
( <del>+</del> ) • ( <del>+</del> )	Pressure range for storage or transport, respectively
<u>%</u>	Humidity range for storage or transport, respectively
$\triangle$	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)
Ť	Keep dry (store in a dry location)

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

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