CT8000i-2

User guide

Art. no.: 2511406 Rev.: a

seca

Precision for health

Sales and Service Information

The seca sales and service centre network is world-wide. Contact your nearest seca subsidiary to obtain the address of your local distributor. In case of difficulty, a complete list of all distributors and subsidiaries is provided on our internet site:

sales@seca.co.uk
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CH-6341 Baar, Switzerland

CE 0123

The CT8000i-2 (Type CARDIOVIT AT-1 G2) bears the CE-0123 mark (Notified Body TÜV-SÜD Produkte Service GmbH, Ridlerstr. 65, 80339 Munich, Germany), indicating its compliance with the essential requirements of the Annex I of the Medical Device Directive 93/42/EE regarding safety, functionality and labelling. The requirements apply to patients, users and third persons who come into contact with this device within the scope of its intended use.

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SW > 1.1.0

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1 Safety notes

1.1 Intended Use

▲ The CT8000i-2 is a 12-lead ECG device intended to be used by trained medical professionals in healthcare facilities for cardiological diagnosis in adult and paediatric patients.

▲ ECG analysis is complemented with algorithms that provide measurement results, data, graphic presentation and interpretation for review by the user.

1.2 Indications for use

▲ The CT8000i-2 is a 12-lead ECG device intended to acquire ECG signals from body surface electrodes and record, analyse, display and print ECGs for cardiological diagnosis in adult and paediatric patients.

1.3 Contra-indication

▲ The unit is not intended for:

- sterile use.
- use in potentially explosive areas or in the presence of flammable gases such as anaesthetic agents.
- direct cardiac application.
- use in an MRI suite.

1.4 Responsibility of the User

▲ The CT8000i-2 must only be used by qualified medical personnel.

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

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

▲ Ensure that the personnel have read and understood this user guide. In particular this section **safety notes** must be read and understood.

▲ 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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1.5 Organisational Measures

- ▲ Before using the device, ensure that a medical product representative has explained its functions as well as the safety requirements.
- ▲ Keep this user guide in an accessible place for reference purposes. Make sure that it is always complete and legible.
- ▲ Observe the operating and maintenance instructions.
- ▲ These operating instructions do not override any statutory or local regulations, or procedures for occupational safety and environmental protection.

1.6 Safety-conscious Operation

- ▲ Only operate the device in accordance with the specified technical data.
- ▲ The device is CF classified. It is defibrillation protected only when the seca original patient cable is used. However, as a safety precaution and if possible, remove the electrodes before defibrillation.
- ▲ Do not touch the unit during defibrillation.
- ▲ To ensure patient safety, none of the electrodes including the neutral electrode, nor the patient or any person with simultaneous patient contact, must come in contact with conductive parts, even when these are earthed.
- ▲ Immediately report any changes that impair safety (including operating behaviour) to the responsible person.
- ▲ Do not place any liquids on the unit. If liquid is spilled on the device, immediately disconnect the device from the mains and wipe it. The device must be checked before reusing.
- ▲ Only connect the original seca patient cable to the patient socket.
- ▲ If the patient cable should become defective after defibrillation, an electrode becomes displaced, or an electrode resistance is too high, a lead-off indication is displayed in the upper right part of the screen (see section 4.5.1 Electrode and patient cable check, page 25).
- ▲ Only use accessories and disposables recommended or supplied by seca. The use of third-party accessories (including disposables) may result in injury, inaccurate information due to electromagnetic interferences and/or damage to the device.

1.7 Safety facilities

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

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1.8 Operation with other Devices

- Accessories connected to the analogue and/or digital interfaces must be certified according to the corresponding IEC standards (e.g. IEC/EN 60950 for data processing equipment and IEC/EN 60601-1 for medical equipment). Furthermore, all configurations shall comply with the valid version of IEC/EN 60601-1. Everyone who connects additional equipment to the signal input part or signal output part configures a medical system and is therefore responsible that the system complies with the requirements of the valid version of IEC/EN 60601-1. If in doubt, contact the technical service department or your local representative.
- Any other equipment used with the patient must use the same common earth as the CT8000i-2.
- Special care must be exercised when the unit is used with high-frequency equipment. Use the special high frequency seca patient cable to avoid possible signal interference during ECG acquisition. However, the stimulation units should only be used at a sufficient distance from the electrodes and both devices must be connected to the same potential equalisation. If in doubt, the patient should be disconnected from the device.
- There is no danger for patients with a pacemaker.
- There is no danger when using this unit simultaneously with electrical stimulation equipment.
- If the patient cable should become defective after defibrillation, a lead-off indication is displayed on the screen (see page 25).
- Portable communication devices, HF radios and devices labelled with the  symbol (non-ionic electromagnetic radiation) can affect the operation of this device (page 54).

1.9 Maintenance

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

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1.10 Terms of warranty

Your CT8000i-2 is warranted against defects in material and manufacture, as stated in the Terms and Conditions. Excluded from this warranty is damage resulting from negligence or improper use. The warranty entitles to free replacement of the defective part. Any liability for subsequent damage is excluded. The warranty is void if unauthorised or unqualified persons attempt to make repairs.

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

- assembly operations, extensions, readjustments, modifications, or repairs are carried out by persons authorized by the manufacturer, and
- the seca 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. Seca makes no warranty of merchantability or fitness for a particular purpose with respect to the product or parts thereof.

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1.11 Symbols and Pictograms

1.11.1 Symbols used in this document

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

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

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

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

For general safety notes as listed in this chapter.

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

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

Reference to other instructions.

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1.11.2 Symbols used on the device

Potential equalisation.

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

Manufacturer symbol, manufacturing date.

The device is IP20-classified and is not protected against the ingress of liquids. Keep dry.

Symbol for the recognition of electrical and electronic equipment

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

The unit/component can be recycled

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Attention: consult accompanying documents.

Consult the user guide.

Consult the Instruction for use.

Mains LED.

Battery charging LED (for details, see section 3.4.1 Mains and battery indicators, page 18).

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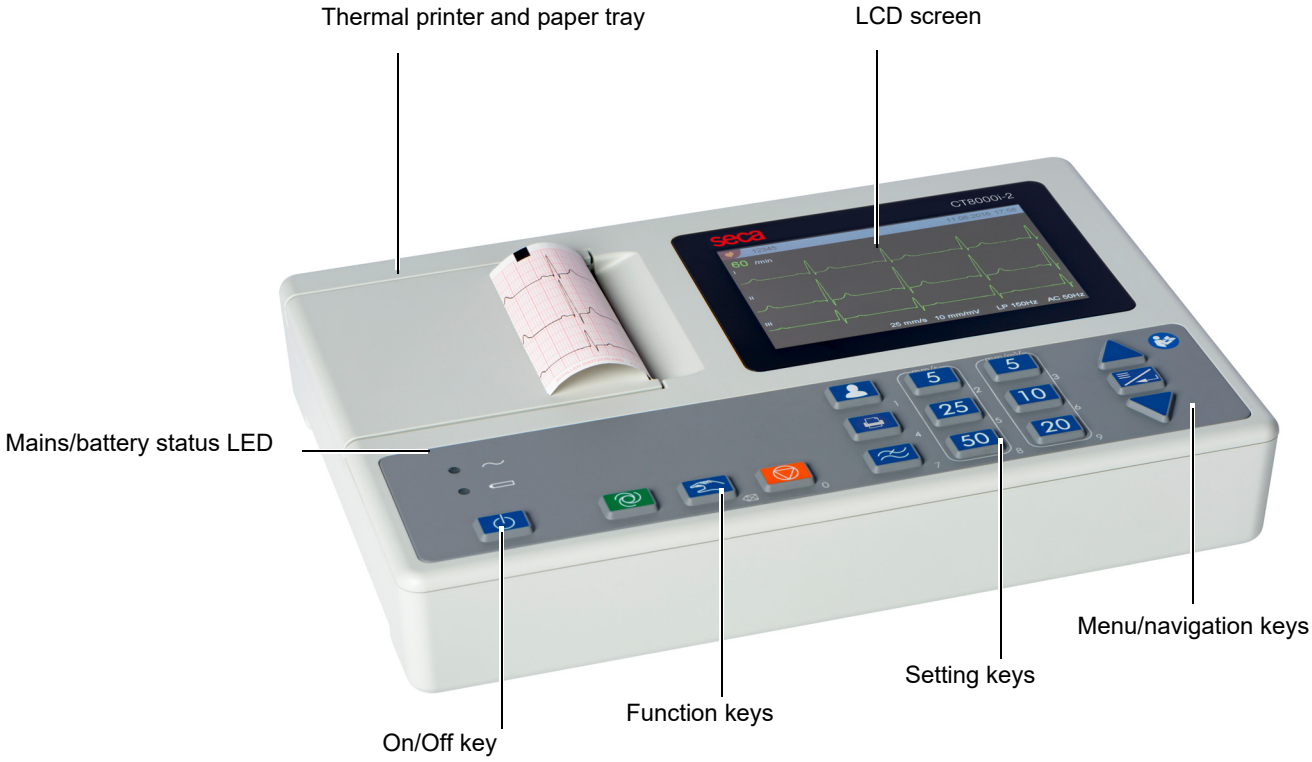
2 Overview

The CT8000i-2 is a 12-channel ECG unit designed to record, display and measure resting ECGs. The display and keyboard enable easy and intuitive operation to efficiently enter patient data, record ECGs and adjust device settings.

The CT8000i-2 has the following features:

2.1 Main Components of the CT8000i-2



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 print formats
- Measurements
- Display of all 12 channels (4x3)
- Display of reversed electrodes
- Recording review
- PDF export to USB stick

2.1.2 Options

- Interpretation
- CCAA

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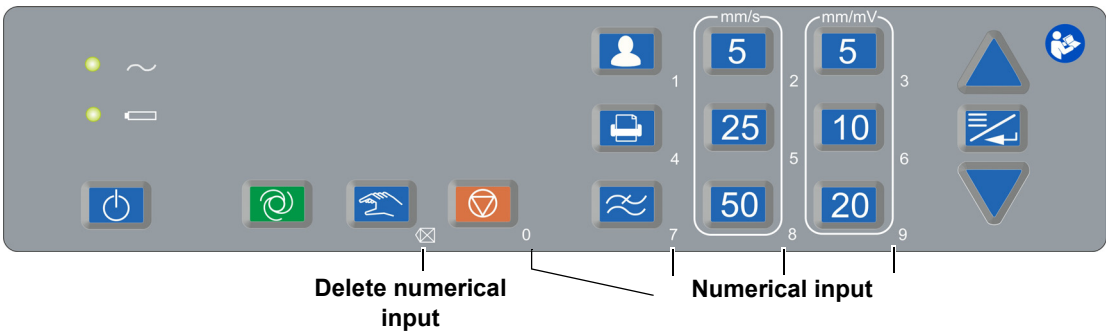
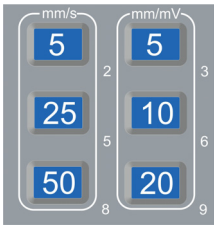
2.2 Keyboard



2.2.1 Description of keys

	Switching the device on/off
	Starting an automatic resting ECG
	Starting a manual resting ECG For numerical input: delete (backspace ⌫)
	• Stopping printout of an automatic/manual ECG • Closing the menu
	Entering patient information. If the key is pressed twice, the previous patient's data is retrieved.
	Printing an ECG from the Preview screen. Unless new patient data has been entered, additional printouts (copies) can be generated.
	Changing the myogram filter (Off, 25, 40 or 150 Hz). Once the recording is completed, the filter is reset to the value programmed in the menu "Filter & formulas" (see page page 41).
	Setting the ECG chart speed and amplitude.
 **(.)** **(-)**	Menu/Enter key and Up/down keys (▲▼). To enter a dot **(.)** or dash **(-)** as part of the patient ID, use the arrow keys (▲▼).
 etc.	During numerical input, the numbers associated with the keys as well as Backspace are automatically active.

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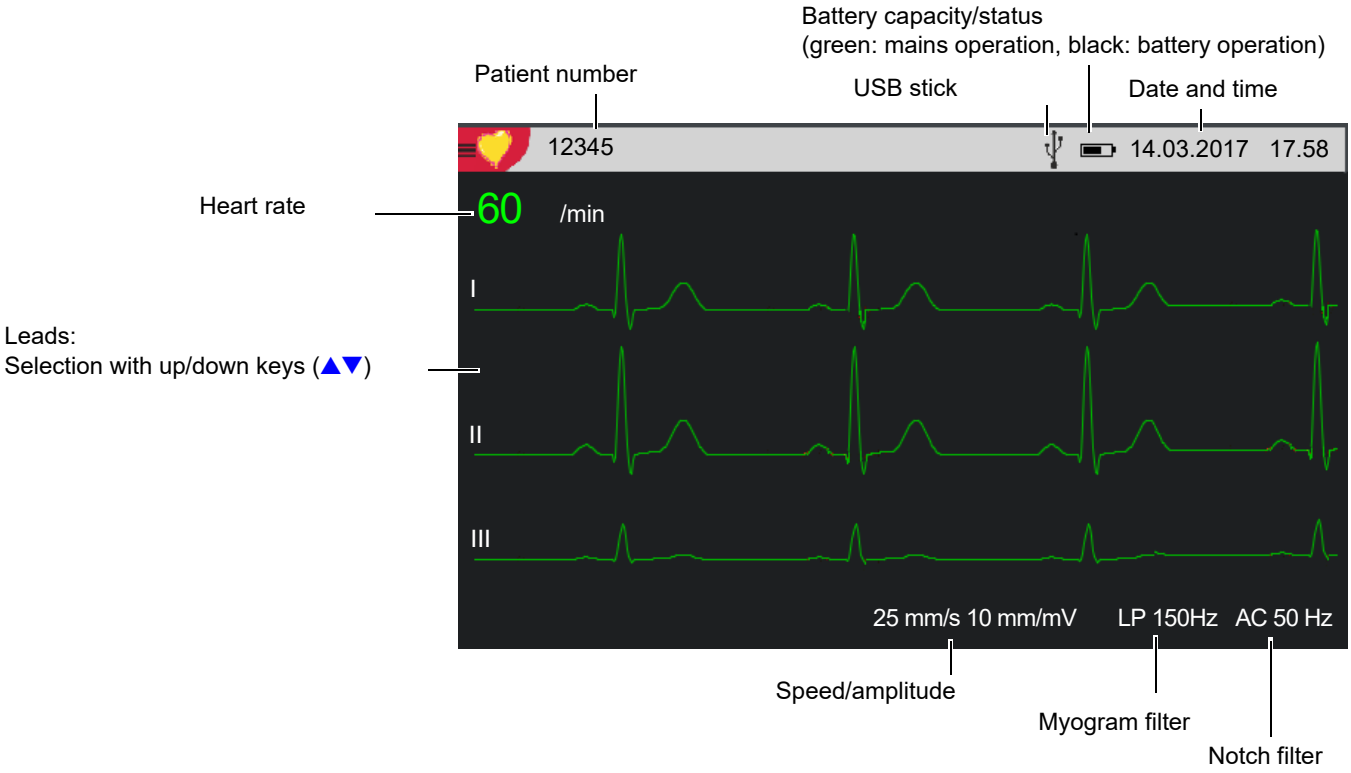
2.3 Display

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



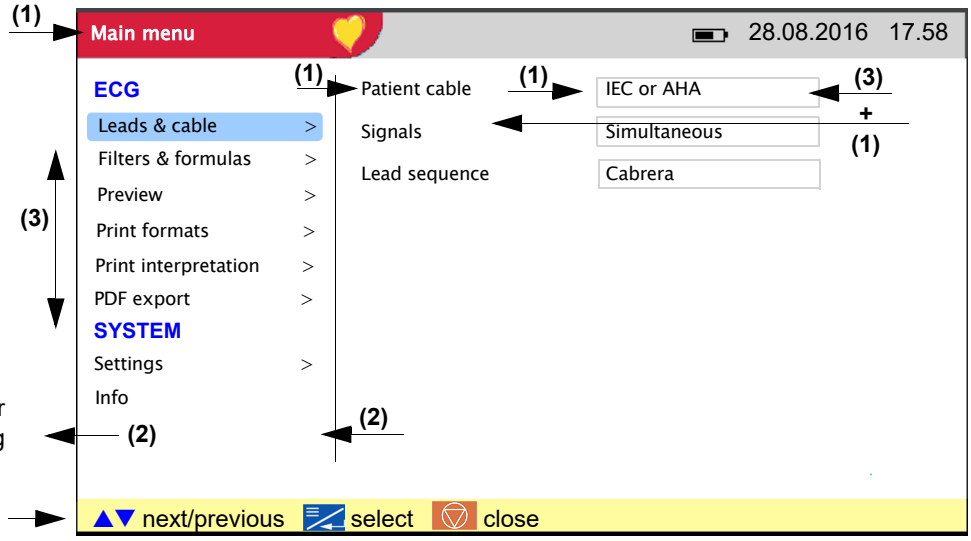
Menu display and navigation

(1)
Menu/Enter key to open main menu/parameter

(2)
Stop key to exit a sub-menu (back) and to close the main menu.

(3)
Use the Up/down keys to scroll up or down and select a sub-menu/setting

Navigation help



▲▼ next/previous select back
▲▼ change confirm
0..9 input confirm & close menu

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3 Operation

3.1 Initial operation

DANGER

▲ Electrical shock hazard. Do not operate the unit if the earth connection is suspect or if the power supply unit/mains lead is damaged or suspected of being damaged.

3.1.1 Location

- Do not keep or operate the unit in a wet, moist or dusty environment. Avoid exposure to direct sunlight or heat from other sources.
- Do not allow the unit to come into contact with acidic vapours or liquids.
- The CT8000i-2 should not be placed in the vicinity of X-ray or diathermy units, large transformers or electric motors.

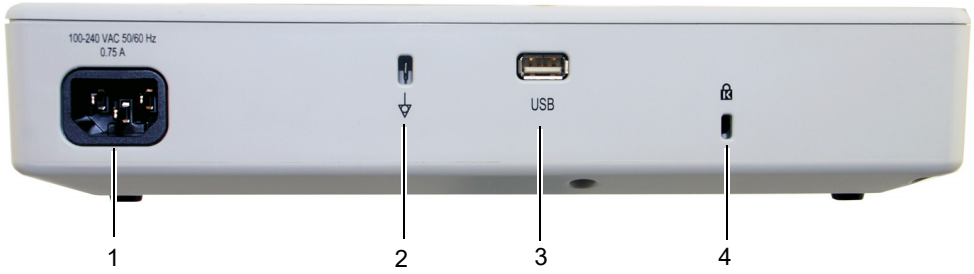
3.2 Connections

CAUTION

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

▲ Position the device so that the mains connection (1) is easily accessible at all times.

3.2.1 Back panel



(1) Mains connection 100...240 VAC

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

(3) USB interface for USB memory stick.

(4) Kensington lock

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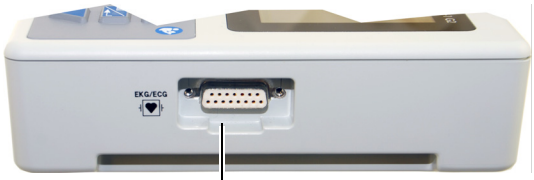
3.2.2 Right-hand side panel

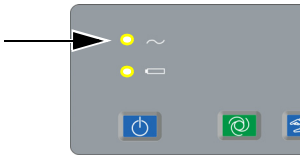


ECG patient cable connector

CAUTION

- ▲ The patient cable as well as the connector comply with the safety standard CF ⊣♥⊢, 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 SCHILER patient cable.
- ▲ In order to prevent disturbance of the ECG signal caused by electromagnetic interferences:
  - – only the original seca patient cable may be used.
  - – the patient cable needs to be screwed on to ensure a secure connection.

3.2.3 Connection of external cable assemblies



1. Connect the mains cable to the mains.
2. Connect the mains cable at the rear of the unit. The mains indicator LED is lit.
3. Leave the CT8000i-2 connected to the mains for 3 hours to fully charge the battery.
4. Connect the potential equalisation cable.
5. Connect the patient cable (side panel).

3.2.4 Potential equalisation

The potential equalisation stud at the back of the unit is used to equalise the ground potential of the CT8000i-2 to that of all mains-powered equipment in the vicinity. Use the hospital or building common ground. A yellow/green ground cable is supplied as an option (article number 2.310320).

WARNING

- ▲ Danger of triggering ventricular fibrillation! If the CT8000i-2 is used together with devices that are designed for direct cardiac application, both devices must be connected to the hospital/building common ground (potential equalisation) to prevent equalising currents between different device potentials.

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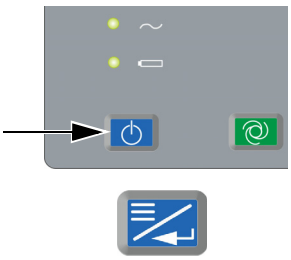
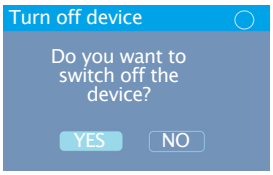
3.3 Switching on / off



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

To switch the device off, confirm the dialogue by pressing the Enter key.

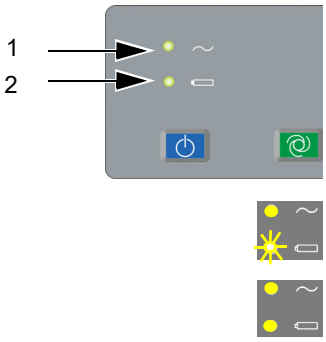


The device switches itself off automatically if it has not been used for 11 minutes. After 10 minutes, a dialogue is displayed in which switching off can be cancelled by pressing  .

3.4 Power supply

3.4.1 Mains and battery indicators

The unit can either be operated by the mains supply or by the built-in rechargeable battery. Battery charging is indicated by the LED next to the battery symbol.



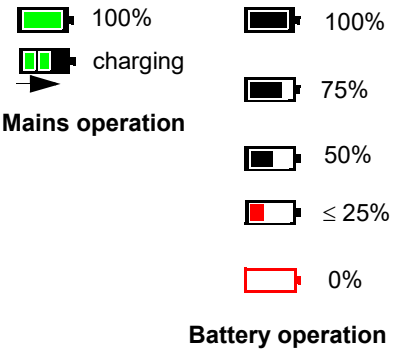
(1) When the mains supply is connected, the mains LED is lit.

(2) The battery LED is blinking when the battery is being charged, and it is lit when charging is complete.

➜ During battery operation (no mains connected), both LEDs are off.

The status is indicated as follows:

- Battery LED is blinking: the battery is being charged.
- Battery LED is lit: the battery is fully charged.



Battery capacity/charging status on the LCD

- **Symbol during mains operation**
  - Green symbol, filling: battery is being charged
  - Green symbol: battery fully charged
- **Symbol during battery operation**
  - Black symbol
  - Black/red symbol: battery operation, capacity ≤ 25%
  - Red symbol: battery empty

3.4.2 Isolating from the mains

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

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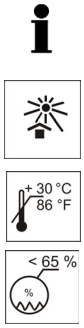
3.5 Changing the Printing Paper



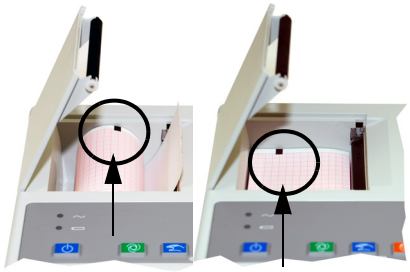
Important

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

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

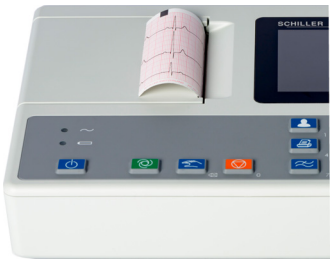
seca can only guarantee perfect printouts when original seca chart paper or chart paper of the same quality is used.

1. Open the paper tray.



2. Remove the remaining paper.

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.



4. Pull out the first page as shown on the left.
5. Close the paper tray.

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3.6 System and ECG settings

- The system settings (time, date, device ID etc.) and other general settings are described on page 41.
- The ECG settings are described on page 41.

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4 Electrode placement

WARNING

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

4.1 Basics

Careful application of the electrodes and good electrode contact is important for a good recording (see electrode positioning on pages 23 - 25).

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 seca (see accessories)
2. Before using disposable electrodes, check that the expiration date has not yet passed.
3. To increase the electrode's conductivity and adherence:
   - Shave the areas where the electrodes are to be placed, if necessary.
   - Thoroughly clean the areas with alcohol or soapy water.
   - Let the skin dry before applying the electrodes.
   - [1]When applying the electrodes, ensure that a layer of gel is between the electrode and the skin.
4. Check the electrode resistance as described in the section 4.5.
5. If the electrode resistance is higher than the acceptable level:
   - Remove the electrode and use an abrasive cleaning pad or abrasive cleaning gel [2] to remove the uppermost layer of epidermis.
   - Apply the electrode. Always use a new disposable electrode.
6. Ensure that the patient is warm and relaxed before you start the recording.
7. After the recording, remove the electrodes. Clean the suction or vacuum electrodes according to the manufacturer's instructions.

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

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4.2 Electrode Identification and Colour Code

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

The patient cable (type IEC or AHA) is set in the menu General and System Settings, see chapter 9.

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4.3 Resting ECG with 10-lead patient cable

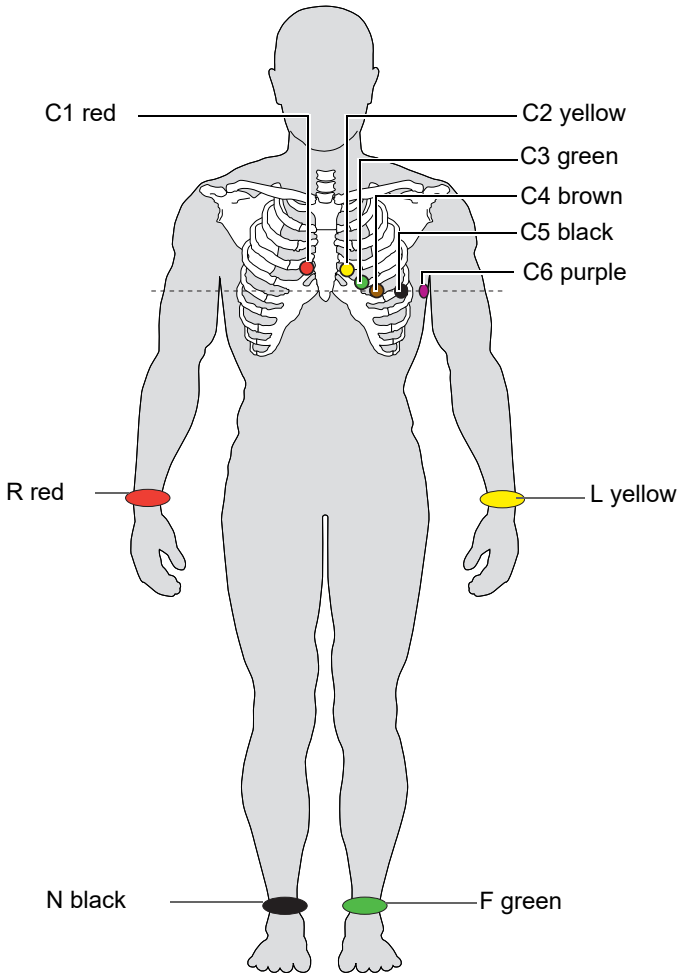

Fig. IEC labelling

4.3.1 Electrode placement for standard leads

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

The electrode resistance can be checked in the electrode test screen (see page 25).

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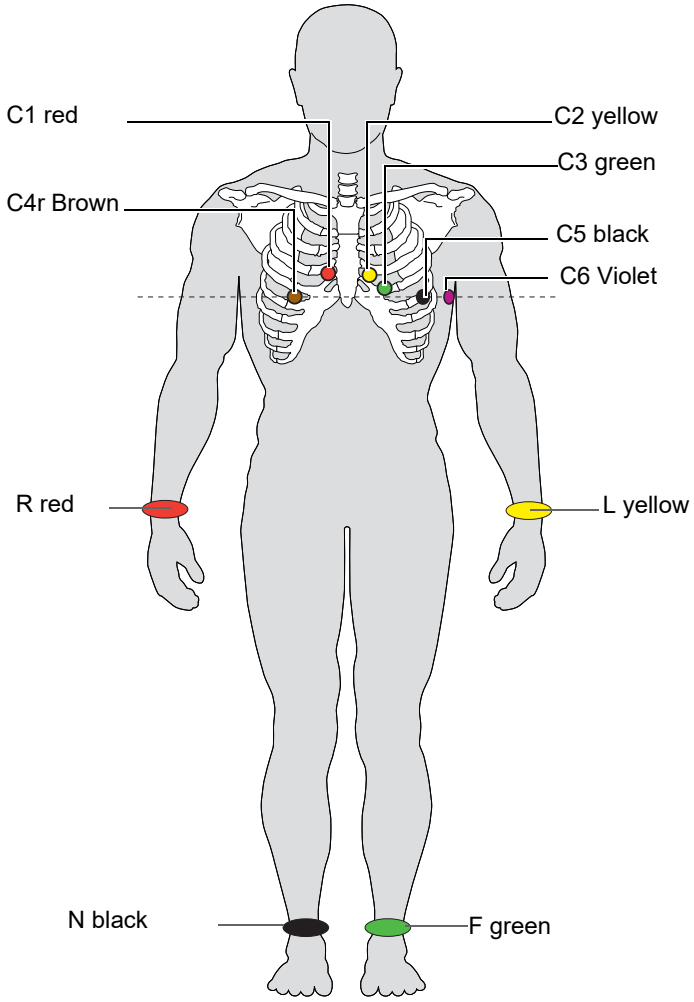
4.4 Standard with C4r for CCAA recordings

ACC/AHA guidelines recommend examining patients suffering from a myocardial infarction with inferior ST elevation for possible RV ischaemia or RV infarction; this examination should be performed with a right precordial C4r lead. (See section 7.1.2 Starting the CCAA analysis, page 37)



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

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4.5 Skin/Electrode Resistance

4.5.1 Electrode and patient cable check

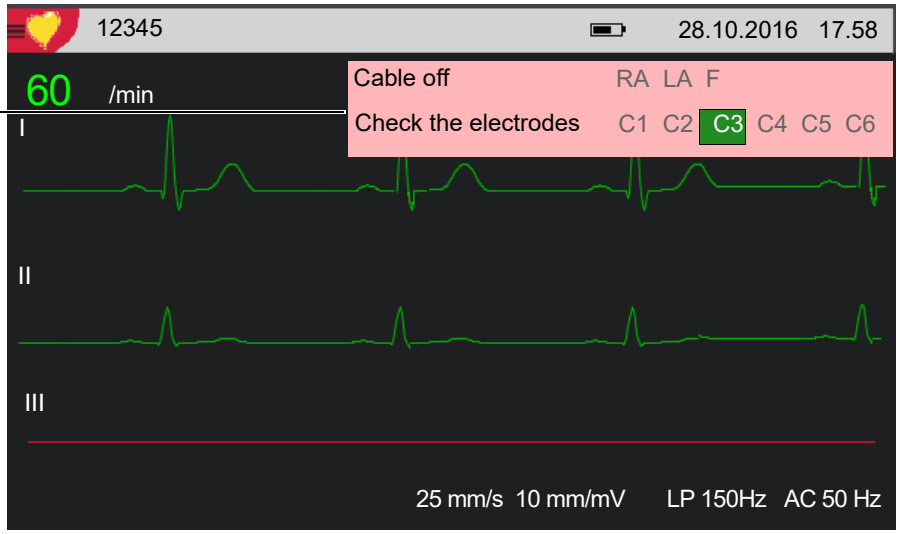
The electrode check is performed before the start of an ECG recording. The following is checked and displayed:

- Excessive nose (signal noise too high, the electrode is highlighted in colour)
  - due to poor electrode contact
  - due to mains interferences (mains filter not activated)
- Electrodes reversed (electrode is highlighted in colour)
- Electrodes off (electrode is highlighted in colour)

The electrode status is shown in the top right of the screen. If an electrode is displayed in colour, the suspected cause is displayed. The electrode needs to be checked and re-applied, if necessary.

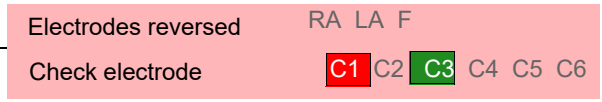
- If F (LL) or N is not connected or has come off, the electrode resistance cannot be measured and all leads are marked red.

Electrode off indication



Indication poor ECG signal quality

Indication of reversed ECG electrodes



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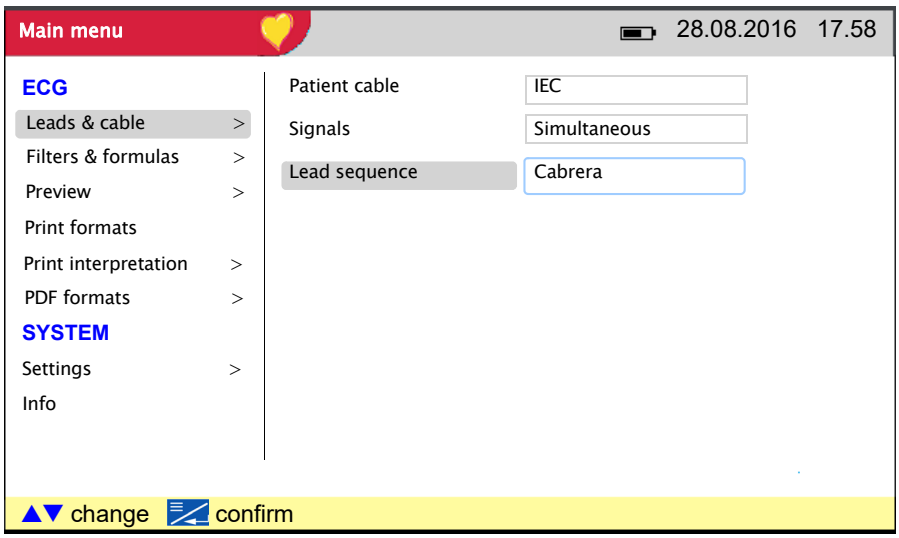
4.6 Lead sequence/lead view

4.6.1 Setting Standard or Cabrera lead sequence

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

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



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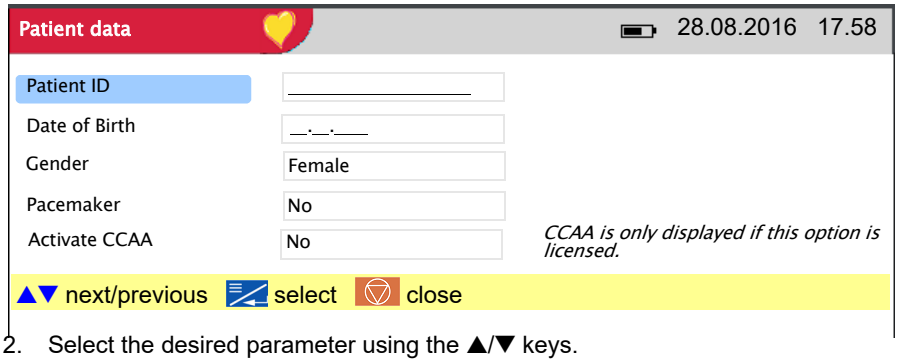
5 Patient data

If no date of birth and gender is entered, the interpretation is performed as if for a 50-year old male patient.

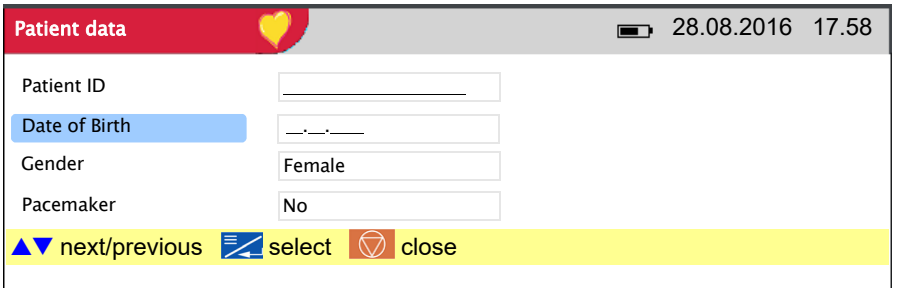
In the patient data screen, new patients can be entered.

1. Press the patient data key. The following is displayed:

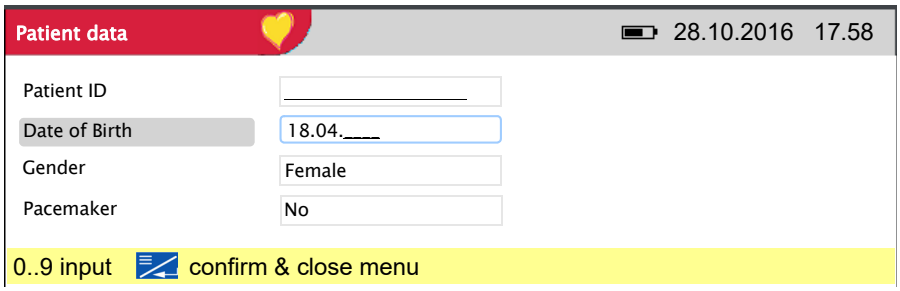


2. Select the desired parameter using the ▲/▼ keys.

To enter a dot **(.)** or dash **(-)** as part of the patient ID, use the arrow keys



3. Press the Menu/Enter key to access the setting.



4. Use the dual-function keys to enter numerical values, or use the ▲/▼ keys to select the correct setting.
5. Press the Menu/Enter key to confirm and access the next setting. Use the Stop key  to exit the patient data menu.

If the key  is pressed twice, the previous patient's data is retrieved.

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Patient ID Enter the patient's identification number (max. 16 characters)

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

Gender Enter the patient‘s gender - Male or Female or Undefined

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.

Activate CCAA (option) Activating a CCAA recording by entering the following:

- Prior Bypass/Stent Yes/No
- Chest pain for [h]

➜ For more details, see section 7 Culprit Coronary Artery Algorithm, page 35.

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6 Resting ECG

WARNING

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

CAUTION

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

▲ The CT8000i-2 device is CF classified ⊣♥⊢. The patient connection is fully isolated. During the ECG recording, ensure that neither the patient nor the leading parts of the patient connection nor the electrodes (including the neutral electrode) come in contact with other persons or conductive objects, even when these are earthed.

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

▲ If the CT8000i-2 is used together with other electronic devices, 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 standard values for the display and thermal printer are **25 mm/s** and **10 mm/mV**.

The displayed lead sequence (Standard or Cabrera) can be selected. The standard settings for amplitude and speed can be changed in the ECG menu.

For the ECG display, the following parameters can be changed using the keyboard (before the start of the recording):

- Filter[a]
- Speed
- Amplitude
- Lead group

The definition of the print formats is described on page 42.

a. Once the recording is completed, the filter is reset to the value programmed in the menu "Filter & formulas" (see page 41).

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6.1 Resting ECG - Procedural Flow Diagram

→ Basic settings

- Lead configuration, ECG cable

→ Enter the patient data
→ Apply the electrodes

- Patient data
- Activate CCAA (option)

Record ECG

→ Check the signal ▲▼
→ Filter settings

Select the speed/amplitude

- Select filter (Off, 25, 40, 150 Hz)

Auto

Resting ECG recording

12-channel recording of the last 10 seconds of ECG data, including calculated average values, measurements and interpretation.

The recording can be checked using the keys ▲▼ .

The recording can be printed and saved internally as PDF, or it can be discarded.

Manual

Manual printout

Use the keys ▲▼

5, 25, 50 mm/s and 5, 10, 20 mm/mV to change the lead sequence, speed and amplitude.

Continuous real-time printout of 3 channels until STOP is pressed.

Discard the recording

The recording is printed and stored internally as PDF. A PDF is only stored when “PDF export“ is activated, see section 9.2.6 PDF formats, page 42.

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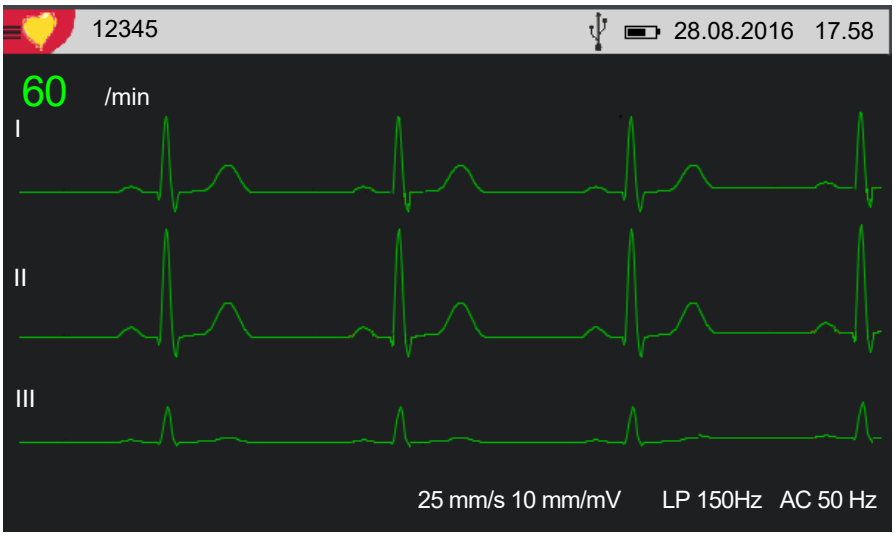
6.2 Automatic resting ECG recording

To take an automatic ECG recording, press the **Auto** key. After approx. 10 seconds, the recording is analysed and the result displayed. The recording can be checked and printed.

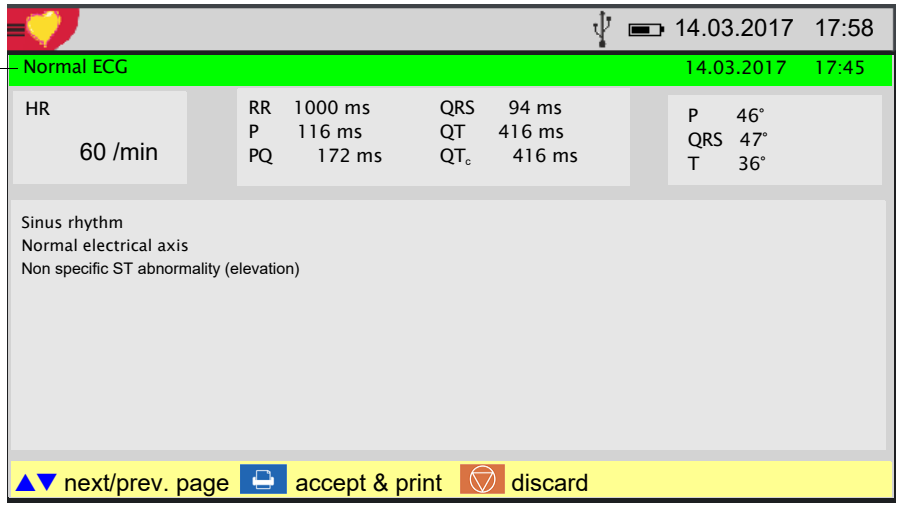
Auto



Review

The recording can be reviewed. Use the keys ▲▼ to toggle between the following 6 pages:

- Rhythms I, II, III
- Rhythms aVL, aVL, -aVR
- Rhythms V1, V2, V3
- Rhythms V4, V5, V6
- Interpretation
- Measurements



Colour code for classification:

Blue = undefined

Red = abnormal ECG

Orange = otherwise normal ECG (or) possibly abnormal ECG

→ Use the keys ▲▼ to review the recording, pages 1 - 6

→ Print the recording and check/complete the patient data on the printout. (Depending on the settings, not all pages are printed as shown on the display.)

→ Press to exit the review screen without printing. The patient data is not deleted.

- When the ECG has been printed, the patient data is deleted; however, the patient data is again activated if the key is pressed twice.

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6.2.1 Printout

The printout gives the following:

- Date and time
- Name (needs to be written by hand)
- Patient ID
- Date of Birth
- Gender
- Pacemaker Yes/No
- Height (needs to be written by hand)
- Weight (needs to be written by hand)
- Blood pressure (needs to be written by hand)
- Medication (needs to be written by hand)
- Remark (needs to be written by hand)
- Speed
- Sensitivity
- Filter
- Device ID
- Device serial number
- Software version

And any combination of the following (for printout settings, see page 42):

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

Averaged cycles
- Averaged cycles with markings

Interpretation

Measurements
- Detailed measurement table

Result
- Intervals, axis & LVH criteria

Patient data

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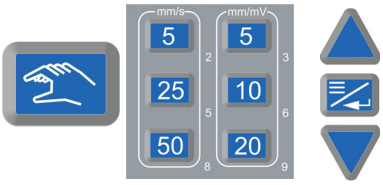
6.3 Manual Rhythm Printout

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.

6.3.1 Starting manual printout



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

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

The following settings are performed via direct keys or via the menu:

Select lead sequence

➜ To change the lead sequence for the printout (Standard I, II, III, aVR, aVL, aVF), press the key ▲▼.

The Standard and Cabrera lead sequences are as follows:

Lead sequence	Lead group 1	Lead group 2	Lead group 3	Lead group 4
Standard	I, II, III	aVL, aVF, -aVR	V1, V2, V3,	V4, V5, V6,
Cabrera	aVL, I, -aVR	II, aVF, III	V1, V2, V3,	V4, V5, V6

The default lead group is defined in the ECG settings (see page 41).

Select speed

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

Select sensitivity

➜ To change the printout amplitude (5, **10** and 20 mm/mV), press the corresponding key.

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 (if entered)
- Name (written by hand on the printout)
- Date and time
- Speed
- Sensitivity
- Filter
- Device name
- Device serial number
- Software version

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6.4 Changing the ECG display

The ECG display is optimised for one column of 3 channels and cannot be changed. The amplitude and speed can be changed at any time with the direct keys. The standard values for the display and thermal printer are **25 mm/s** and **10 mm/mV**.

6.4.1 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	Lead group 3	Lead group 4
Standard	I, II, III	aVL, aVF, -aVR	V1, V2, V3,	V4, V5, V6,
Cabrera	aVL, I, -aVR	II, aVF, III	V1, V2, V3,	V4, V5, V6

6.4.2 Myogram filter

The myogram 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 , **LP 150** Hz or OFF is displayed.

The cut-off frequency is user-defined at LP 25 Hz, LP 40 Hz or **LP 150** Hz or LP Off (250 Hz) (see chapter 9.2.2, page 41).

6.4.3 Other filters

The following additional filters are available:

Baseline filter

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

Notch filter

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

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

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7 Culprit Coronary Artery Algorithm

7.1 Introduction

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

The closer the occlusion site to the origin of the coronary artery, the larger the size of the area at risk. The algorithm indicates the location of the occlusion site and issues a recommendation based on the ECG data and patient history. The recommendation is based on the following:

- **Prior Bypass/ Stent.** This data is entered before the ECG recording is taken (see section 6.1 Resting ECG - Procedural Flow Diagram, page 30). If the patient has had prior bypass or stent, the ECG is not analysed further and the advice **Go to PCI centre (P**ercutaneous **C**oronary **I**ntervention) is given.
- **ST Score**. The sum of the absolute ST deviations in mm in 12 leads (excluding V4r). That is the total ST deviation (mm) of all leads (I, II, III, aVR, aVL, aVF, and all leads V1 to V6).
- **Occlusion Site.** The calculated occlusion site.

The site of occlusion is determined by the following:

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

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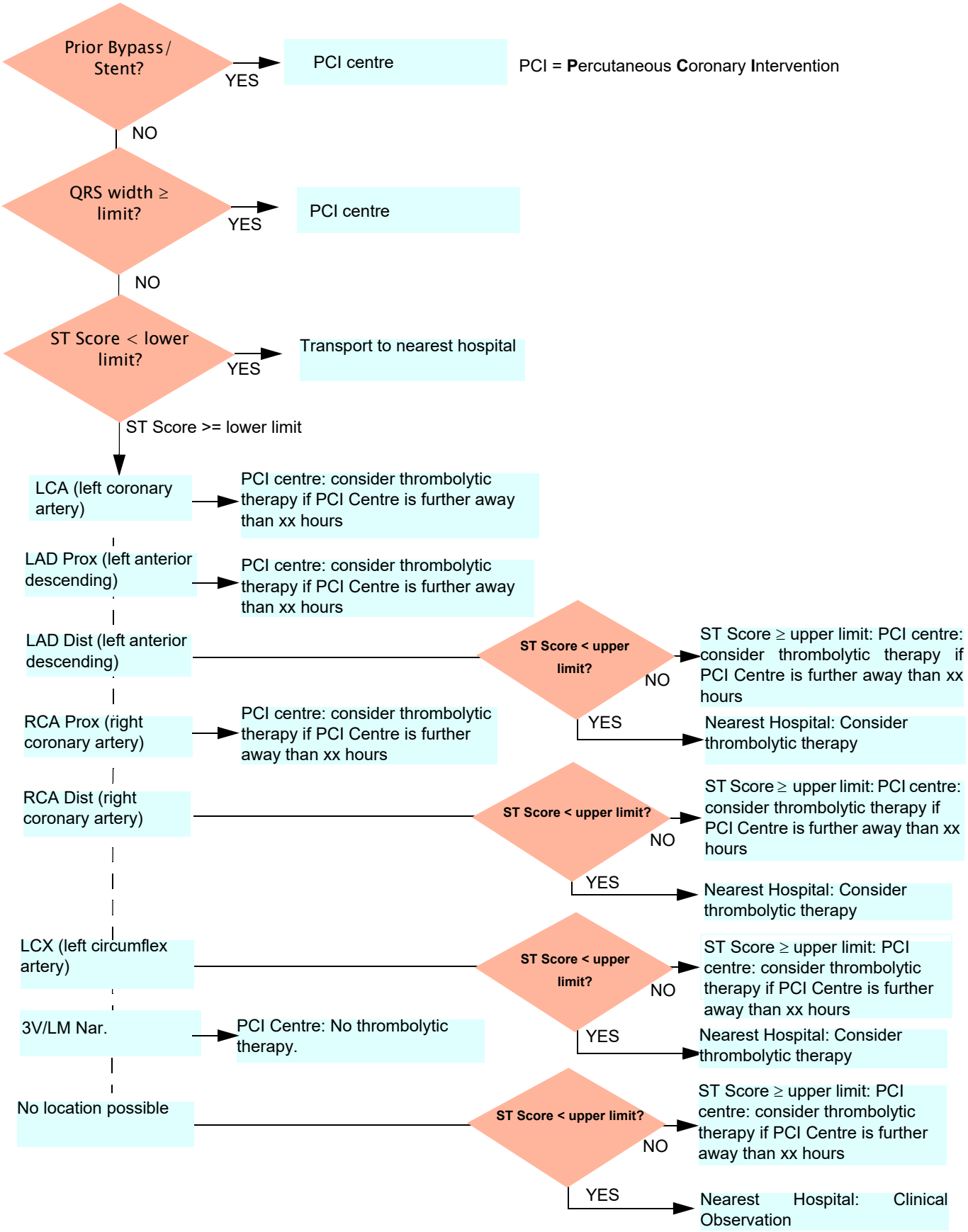
7.1.1 Culprit Artery Algorithm Decision Overview



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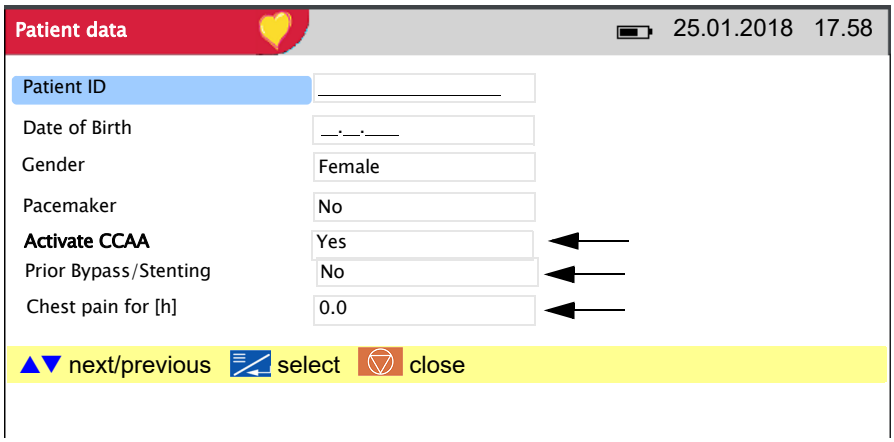
7.1.2 Starting the CCAA analysis

When the CCAA analysis option is activated, make sure that the C4 electrode is attached in position C4r (precordial), see section 4.4 Standard with C4r for CCAA recordings, page 24.

Procedure

1. Enter the patient data.
2. Activate **CCAA** by selecting “Yes”.



3. Enter the additional parameters Bypass/stenting and time since chest pain started.
4. Check the electrode placement (V4r) and record the ECG.

The data is shown in the print preview. The recording can be checked, accepted and further printouts obtained in different formats, and it can be exported as PDF.

All other settings and features (saving, printing etc.) are the same as described in section 6.2 Automatic resting ECG recording, page 31.

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7.1.3 CCAA information on print preview/printout

Information on LAD (left anterior descending)

▲ For men under the age of 40 showing early repolarisation in the anterior leads, false LAD diagnoses may occur.

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

Manual entry before the start of the recording:

– Previous bypass or stenting (Yes/No)
– Time since chest pain started, in hours

Measured values:

- QRS width (averaged) [ms]
- ST score (averaged) [mm]

Assessed area of an occlusion:

– LCA (left coronary artery)
– LAD Prox (left anterior descending)
– LAD Dist (left anterior descending)
– RCA Prox (right coronary artery)
– RCA Dist (right coronary artery)
– LCX (left circumflex artery)
– 3V/LM narrowing (all three vessels or left main is affected)

Advice:

Recommendations based on the ST score and additional information:

- Transport to PCI centre
- Transport to nearest hospital
- Consider thrombolytic therapy if PCI centre is further away than 1.5 hours.
- Consider thrombolytic therapy
- No thrombolytic therapy

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8 PDF export

8.1 Data integrity

⚠ CAUTION

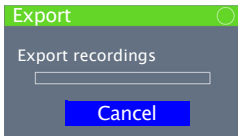
▲ When exporting patient data to a USB stick, the operator needs to take appropriate security measures to protect the data:
- Make sure that only authorised persons have access to the USB stick.
- After data transmission from the USB stick to a secure system, delete all data from the USB stick.
- Deactivate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

Activate **PDF export** in **Menu > PDF formats**. If **PDF export** is active, the ECG is automatically stored on the device, see section 9.2.6 PDF formats, page 42. The PDF's content can be defined in the same menu.

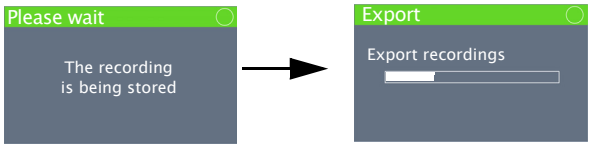
8.2 Export procedure

1. Connect the USB stick on the back of the device.

If there are any stored recordings, these are automatically exported to the USB stick. This procedure can be cancelled by pressing the **Menu** key.



2. When a recording is confirmed by pressing the **"Accept & print"** key, the saving dialogue is displayed, followed by the export dialogue.



- Exported recordings cannot be exported a second time.
- Max. 100 ECG recordings can be stored on the internal memory.
- Active memory management (deleting and re-printing from the memory) is not available.

8.2.1 Deleting ECG data stored on the device

1. Connect the USB stick on the back of the device. Not yet exported data is transmitted and deleted from the device.
2. Delete data stored on the USB stick via PC.

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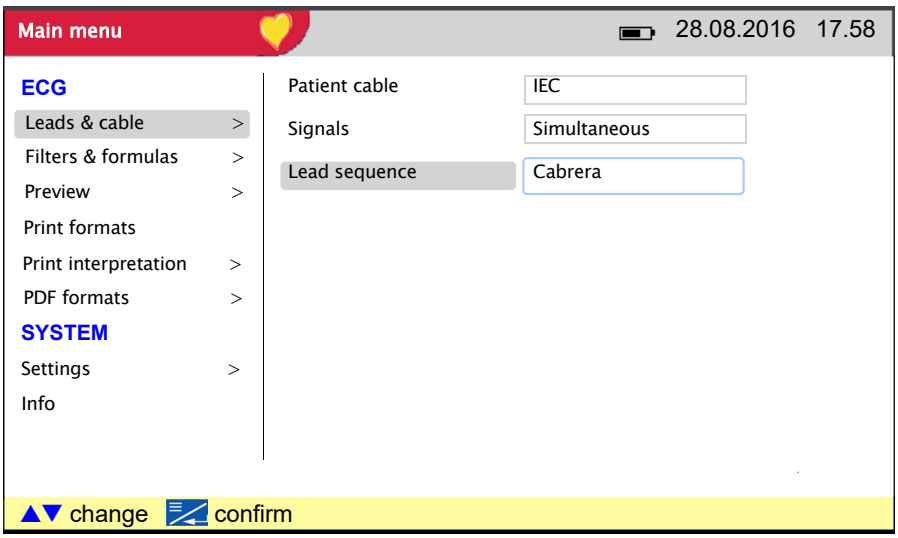
9 General and System Settings

9.1 System settings

The system settings are saved when the main menu is closed.

When the Menu key is pressed, the main menu is displayed. The following illustration gives an overview of all available settings.



1. Press the Menu/Enter key .
2. Select the desired parameter using the keys ▲▼ (next/previous)
3. Press the key (select) to access the sub-menu.
4. Press the key (select) to access the setting.
5. Use the dual-function keys to enter numerical values, or use the keys ▲▼ (change) to select the correct setting.
6. Press the key (confirm) to get to the next parameter.
7. Press the key (back) to return to the main menu.
8. Press the key (close) to return to the ECG screen; the settings are saved.

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9.2 ECG

The default settings are printed **bold**

9.2.1 Leads & cable

Menu	Parameter	Description / selection
Leads & cable	Patient cable	IEC or AHA
	Signals	Simultaneous or **Sequential.** If Sequential is selected, consecutive time segments are used for the individual lead groups (this applies for printouts). If Simultaneous is selected, the same time segment is used for all lead groups (this applies for printouts). If a print format with a rhythm lead is defined, Sequential is used, even if you have selected Simultaneous.
	Lead sequence	Standard or Cabrera

9.2.2 Filters & formulas

Menu	Parameter	Description / selection
Filters & formulas	Notch filter	Off/ **AC 50**/AC 60 Hz
	Myogram filter	LP 25 Hz / LP 40 Hz/ LP 150 Hz / **Off** (250 Hz)
	QTc calculation	**Bazett**, Fridericia, Framingham, Hodges

9.2.3 Display

Standard settings for ECG display.

Menu	Parameter	Description / selection
Preview	Lead group	**For Standard:** **I / II / III**, aVR / aVL / aVF, V1 / V2 / V3, V4 / V5 / V6 **For Cabrera:** **aVL / I / -aVR,** II / aVL / III, V1 / V2 / V3, V4 / V5 / V6
	ECG speed	5 / **25** / 50 mm/s
	ECG sensitivity	5 / **10** / 20 mm/mV

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9.2.4 Print formats

The stored recordings can be printed in different formats.

Menu	Display	Description
Print formats	ECG printout	**4 pages (25 mm/s),** 8 pages (25 mm/s) 8 pages (50 mm/s) Off
	Average cycles	Off 4x3 (25 (mm/s) 4x3 (50 (mm/s) **6x2 (50 (mm/s) + 1 rhythm (25 mm/s)** 12x1 (25 (mm/s) + 2 rhythms (25 mm/s)
	Rhythm lead 1	I, **II**.....V5, V6
	Rhythm lead 2	I, II.... V5, **V6**
	Markings	**On** / Off
	Measurements	**On** / Off

9.2.5 Interpretation

Menu	Display	Description
Interpretation	Interpretation	On / **Off**
	Unconfirmed report	**On** / Off
	Abnormal ECG	**On** / Off

9.2.6 PDF formats

Menu	Display	Description
PDF formats	PDF export	On / **Off**
	ECG printout	**4x3 + 1 (25 mm/s), 1 page** 2x6 (25 (mm/s), 1 page 2x6 (50 (mm/s), 1 page Off
	Rhythm lead 1	I, **II**.....V5, V6
	Average cycles	Off 4x3 (25 (mm/s) + 2rhy. (25 mm/s) 4x3 (50 (mm/s) + 2rhy. (25 mm/s) **6x2 (50 (mm/s) + 2 rhythm leads (25 mm/s)** 12x1 (25 (mm/s) + 2 rhythms (25 mm/s)
	Rhythm lead 1	I, **II**.....V5, V6
	Rhythm lead 2	I, II.... **V1...** V6
	Markings	**On** / Off
	Measurements	**On** / Off

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9.3 System

9.3.1 Settings

Menu	Parameter	
Settings	**Language**	Select a language
	Date format	dd.mm.yyyy, yyyy-mm-dd or mm/dd/yyyy.
	Date	Enter the date
	Set Time (24h)	Enter the time

Displaying the parameter “Simulation ECG” to activate simulated ECGs is described in the service manual and only serves demonstration purposes.

9.3.2 Info

Software and hardware versions are displayed.

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10 Maintenance

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

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

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

Interval	Maintenance step	Responsible
Before each use	• Visual inspection of the device and ECG electrodes	➜ User
Every 6 months	• Visual inspection of the device (see page 49, 10.6 Inspection Report) – LCD display – Cables and accessories – Power supply unit and mains cable • Functional tests according to the instructions (see page 49, 10.6 Inspection Report)	➜ User
Every 12 months	• Safety test according to IEC/EN 62353	➜ Qualified service personnel

10.1 Visual inspection

Visually inspect the unit and cable assemblies for the following:

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

In addition to the visual inspection, switch on the CT8000i-2, scroll through the menu and test some sample functions. In this way, you can check that:

- the device performs faultlessly
- the display works
- the keyboard works

WARNING

▲ Defective units or damaged cables must be replaced immediately.

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10.2 Cleaning the casing and cables

⚠WARNING

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

⚠ CAUTION

▲ Do not autoclave the unit or any accessories.

▲ Do not immerse the device in liquid.

▲ Do not spray liquid onto the device/cable.

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

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

▲ With time, the casing may become less resistant:

– if an alcaline 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. Seca therefore recommends using only cleaning agents that are adequate for sensitive materials such as plastics, and using them at room temperature (approx. 20°C).

▲ 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 CT8000i-2 and the cable assemblies can be cleaned with a cloth slightly moistened (not wet) on the surface only. If necessary, a domestic non-caustic cleaner or a 50 % alcohol solution can be used to remove grease stains and finger prints. Wipe the equipment with a cloth slightly moistened (not wet) with one of the approved cleaning solutions (see section 10.2.2). 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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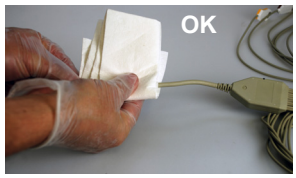
10.2.1 Cleaning the patient cable

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

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



10.2.2 Admissible detergents

- 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

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10.3 Disinfection

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

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

10.3.1 Admissible disinfectants

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

10.3.2 Non-admissible disinfectants

Never use products containing the following:

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

10.4 Cleaning the print head

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

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

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10.5 Battery

- The lead gel battery does not require any maintenance.
- Replace the battery approx. 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 15-25 °C will reduce the service life of the battery!
- Make sure that the battery remains charged during storage. If the device is not used for more than 3 to 4 months, the battery needs to be protected from deep discharge by recharging it; the ideal capacity is 50-80%. If a fully charged battery is stored for a long period of time, this may reduce its service life.

10.5.1 Charging the battery

A totally discharged battery requires approximately 4 hours to be 90% charged (when the unit is switched off). It is possible to use the unit when the battery is being charged; however, the charging time may be longer.

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

1. Connect the device to the mains supply.
2. The blinking battery LED indicates that the battery is being charged.
3. Charge the battery for at least 4 hours.

10.5.2 Battery disposal

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

⚠WARNING

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

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

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10.6 Inspection Report

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

Serial no.: _____

Test	Results	Date				
Visual inspection 10.1	• Casing not damaged	r	r	r	r	r
➜ External condition	• Electrode connector port not damaged	r	r	r	r	r
➜ Availability and condition of accessories	• ECG Electrodes (expiration date and compatibility)	r	r	r	r	r
	• User guide	r	r	r	r	r
	• Mains and patient cable	r	r	r	r	r
Functional test 2.2	• No error message shown in the standard display	r	r	r	r	r
➜ ECG test						
➜ Keyboard test	• Keyboard is working	r	r	r	r	r
➜ Check the battery	• Battery OK	r	r	r	r	r
➜ Printer	• Contrast and line strength	r	r	r	r	r
	• Cleaning the thermal print head	r	r	r	r	r
Remarks						
➜ Recurrent test conducted (every 12 months)			r		r	
Inspection carried out by:						

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

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

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10.6.1 Lifed-item replacement every 3 - 5 years

Inspection	Results	Replacement				
Internal battery						
➜ Replace Internal Accumulator if operation falls substantially under one hour.	• Unit sent to seca service centre for accumulator replacement.	❒	❒	❒	❒	❒
	Date of replacement:					
	Inspector:					

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10.7 Accessories and disposables

WARNING

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

Your local representative stocks all the disposables and accessories available for the CT8000i-2. A comprehensive list of all seca representatives can be found on the seca website (www.uk.secashop.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 seca products.

Art. no.:	Article
2.310320	Earth cable for the potential equalisation stud
2.400175	10-wire patient cable, IEC, 3.5 m, push-button
2.400178	10-wire patient cable, AHA, 3.5 m, push-button
2.400180	10-wire patient cable, IEC, 2 m, banana plug
2.400179	10-wire patient cable, AHA, 2 m, banana plug
2.000041	Electrode kit for adults
2.000052	Electrode kit for children
2.155025	Blue Sensor disposable ECG electrodes
2.155031	Biotabs Ag/AgC electrodes for resting ECG
2.155032	Adapter snap/clip for banana plug cables (10 pieces)
2.157058	Thermal chart paper, Z-folded
2.300003	Mains cable AC Swiss 90° angled
2.300004	Mains cable UK, 90° angled
2.300005	Mains cable Schuko Europe, 90° angled
2.300014	Mains cable China
2.300016	Mains cable Japan
2.300024	Mains cable USA hospital grade
2.300025	Mains cable Brazil

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11 Trouble Shooting

11.1 Possible problems

Error	Possible causes and indicators	Error localisation and troubleshooting
Unit does not switch on, blank screen	• No mains supply; mains indicator on the device is off. • Battery empty/defective	➜ Check the mains cable and connection ➜ If the mains indicator is lit, it indicates that power is reaching the unit and the internal power supply should be OK. Press and hold the On/Off key for 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 the unit cannot be switched on even if the mains supply is connected. ➜ If the screen is still not lit, it indicates a software error, monitor or internal power supply problem. Call your local seca representative.
QRS traces overlap	• Incorrect settings for patient • Poor electrode contact	➜ Change the sensitivity setting. ➜ Check the electrode contact and re-apply the electrodes. ➜ If the problem persists, call your local seca representative. ➜ Note: Some patients have very high amplitudes and even on the lowest sensitivity settings, the QRS traces can overlap.
"Noisy" traces	• High resistance between skin and electrodes • Patient not relaxed • Incorrect settings • Electromagnetic interferences	➜ Check the electrode resistance (all leads need to be shown in green) ➜ Re-apply the electrodes. ➜ Ensure that the patient is relaxed and warm. ➜ Check all filter settings (**Menu key > Filter & formulas**). ➜ Activate the myogram filter and change the cut-off frequency. ➜ Ensure mains filter is correct for mains supply. ➜ If the problem persists, call your local seca representative. ➜ Specific devices labelled with the symbol  may interfere with the ECG signal. Switch such devices off and/or generally maintain a sufficient distance to other electric/electronic devices (see chapter 11.2).
No printout obtained after an auto mode recording.	• No paper • Paper incorrectly loaded • Incorrect settings	➜ Ensure that paper is loaded. ➜ Reload paper. ➜ Ensure that the paper has been inserted correctly with the black mark at the top. ➜ Check that the printout is activated for at least one setting, and that Print after acquisition is activated (see page 42 and 43) ➜ If the problem persists, call your local seca representative.
Printout fades, is not clear, or the printout is ‘patchy‘	• Old paper inserted • Dirty print head • Print-head out of adjustment	➜ Ensure that new seca paper is inserted. ➜ Note that the CT8000i-2 thermal paper is heat- and light-sensitive. If it is not stored in its original seal, stored in high temperatures or is simply old, print quality can deteriorate. ➜ Over a period of time, the printing ink from the grid on the paper can form a film on the thermal print head. Clean the thermal print head. ➜ If the problem persists, call your local seca representative.

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Error	Possible causes and indicators	Error localisation and troubleshooting
No printout of interpretation statement, averaged cycles or measurements	• Incorrect settings	➜ Check that the interpretation and measurement options are enabled for the printout. (See page 42 sections 9.2.4 and 9.2.5.)
Keyboard blocked	• Software hangs up	➜ Switch off and on again after a few seconds. ➜ Press and hold the On/Off button for 10 seconds to force the device to switch off. Reconnect mains and switch on. ➜ If the problem persists, call your local seca representative.

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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 **CT8000i-2**. The distance depends on the output performance of the communication device as indicated below.

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

⚠ CAUTION

- ▲ **Portable** HF telecommunication devices must not be used within a radius of 0.3 m from the **CT8000i-2** and its cables.
- ▲ Do not place the **CT8000i-2** 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, please consult the service manual.

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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 mains 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 44.

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12 Technical Data

12.1 Device

Dimensions	285 x 189 x 61 mm, approx. 1.94 kg incl. thermal paper
Display	• Colour LCD • Resolution: 800 x 480 dots, 5 “
Power supply	100 - 240 VAC, max. 0.75 A (115 V) - 0.4 A (230 V), 50/60Hz Mains-independent operation with built-in rechargeable battery
Power consumption	max. 30 W
Battery	
Capacity	• Pb gel battery 12 V, 2.0 Ah • 4 hours normal use without printing
Battery life	Under normal operating conditions, 4 years
Recharging time	90%: approx. 4 hours when the device is switched off
Printer	High-resolution thermal head printer; 8 dots/mm (amplitude axis); 20 dots/mm (time axis) @ 25 mm/s
Frequency range	Complies with IEC 60601-2-25 and ANSI/AAMI EC11
Chart paper	• Thermo-reactive, Z-folded, 80 mm wide
Speed	• 5 / 25 / 50 mm/s; (for resting ECG: 25 / 50 mm/s)
Sensitivity	• 5 /10 / 20 mm/mV (for resting ECG: 10 mm/mV)
ECG display	ECG is displayed on an area of 108 x 65 mm
Speed	• 5/ 25/ 50 mm/s;
Sensitivity	• 5 /10 / 20 mm/mV;
Interfaces	• ECG cable interface • Potential equalisation • 1 USB
Internal memory	• 100 ECGs in PDF format (only for export to USB stick)
Ambient conditions	
Operating temperature	• 10 to 40 °C
Relative humidity	• 20 to 90% (non-condensing)
Pressure during operation	• 780 to 1060 hPa
Storage temperature	• 5 to 50 °C
Transport temperature	• -10 to 50 °C
Humidity during storage/ Transport	• 10 to 95% (non-condensing)
Pressure during storage/ Transport	• 500 to 1060 hPa

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Environmental conditions EMC	• IEC/EN 60601-1-2 • CISPR 11/32 Group 1, class B The **CT8000i-2** can be exposed to the following interferences without any impairment of the essential performance features: • static discharge up to ±8 kV contact, ±15 kV air • radio frequency range up to 10 V/m (80 to 3000 MHz) • near fields of wireless HF telecommunication devices 9 to 28 V/m (385-5785 MHz), for more details, see table on page 54. • Magnetic fields of 30 A/m, 50 Hz

12.2 ECG

Patient input	Fully floating and isolated, defibrillation-protected (only with original seca patient cable)
Lead configurations	• Standard 12 channels
Display	
Leads	• Display of selected leads (3 x4)
Status	• Filter status • Power source • Leads • Electrode contact status • Heart rate (HR) • Date and time • Patient number
Filter	
Myogram filter (muscle tremor)	Set to 25, 40, 150, 250 Hz (250 Hz = Filter Off)
Notch filter	Distortion-free suppression of superimposed AC 50 or AC 60 Hz sinusoidal interferences by means of adaptive digital filtering
Data record	• Listing of all ECG recording data (date, time, filter)
With optional interpretation ETM	• ECG measurements results (intervals, amplitudes, electrical axes) • Averaged complexes • Guidance on interpreting adult and paediatric ECGs
ECG amplifier	Complies with IEC 60601-2-25 and ANSI/AAMI EC11

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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/IIa in accordance with directive 93/42/EEC
Protection	This device is not designed for outdoor use (IP 20)

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