ECG-EXPERT

User Manual

MD CE
0318

V 1.2 *date: 10/10/25*

List of Contents

1. Safety Information

Read and obey all safety information in this chapter before using the ECG-EXPERT.

For assistance or to report any adverse events, please contact:

Custom Software & Electronics, S.L.
Sant Pau Art Nouveau Site
Sant Antoni Maria Claret, 167
08025 Barcelona - Spain.
www.medicalcse.com
Phone: (+34) 722-613-269
Email: service@medicalcse.com

See www.medicalcse.com for details of authorized dealers near you.

In this manual, a **warning** identifies conditions and actions that may result in operational difficulties or ECG expert malfunction that may result in incorrect measurements.

⚠ **A Precaution** identifies scenarios and actions that may result in harm to the ECG expert or viewing equipment, or cause data loss.

2. Introduction

The ECG-EXPERT is a compact, portable, microprocessor-controlled, wireless Bluetooth, 12-lead, standby ECG system powered by a long-lasting lithium polymer battery.

The system consists of a main transmit and receive unit, electrodes (supplied by the user), cables, charger with micro USB connector and the ECG-EXPERT measurement software application for installation on a user-provided computer/mobile platform, e.g. Windows PC/laptop, Apple iOS device or Android device. The data is stored on the computer device for further analysis by qualified medical personnel. The data may also be sent by email for analysis or information to third parties.

In addition, ECG-EXPERT incorporates defibrillator protection and is safe to use in patients with pacemakers.

2.1 Safety Warning:

- The analysis and diagnosis of ECG-EXPERT data should only be carried out by qualified and trained medical personnel.
- ECG-EXPERT is not intended to be used as a vital signs monitor.
- U.S. Federal Law Restrictions:
  - The ECG-EXPERT is sold with a prescription or order from a licensed physician.
  - Sale and use without a prescription is prohibited.

2.2 Help & Support

For general and product-related comments, questions, or concerns, please contact Medical CSE directly.

Report any injuries or adverse events to Medical CSE using any of the contact methods listed below.

Sant Pau Art Nouveau Site
Carrer Sant Antoni Maria Claret, 167
08025 Barcelona- Spain.

Phone (+34) 722-613-269
Email: service@medicalcse.com

Frequently Asked Questions and Product Information: www.medicalcse.com
Local Distributor: www.medicalcse.com

Technical Support: (+34) 722-613-269
Email:service@medicalcse.com

3. Intended Use

3.1 Intended Use

Electromedical equipment intended to be used by a healthcare professional in a clinical setting to measure electrical potentials on the body surface, record the electrical activity of the heart and display it in the form of a graph, in order to assist the physician in assessing the electrical physiology of the heart in the body. The duration of use is usually 5 to 10 minutes

The service life of the device is 10 years from the date of manufacture.

3.2 Directions for use

The product is designed to perform basic ECG measurements on patients for diagnostic examination and follow-up purposes. The product needs a computer (tablet PC, smartphone or PC with Bluetooth) to display and store the information for further analysis by a medical specialist.

3.3 Intended Users

Specialist physician (cardiologists and electrophysiologists) or health professional trained for use as nurses and medical technicians.

3.3.1 Population/patient group

Healthy or asymptomatic adults undergoing health checkups or screening for cardiovascular disorders.

Patients experiencing symptoms related to heart disease or who have already been diagnosed with a heart problem.

3.4 Clinical indications

The product is designed to perform basic ECG measurements on patients for diagnostic examination and monitoring purposes. The product requires a computer (tablet PC, smartphone, or PC with Bluetooth) to display and store the information for subsequent analysis by a medical specialist.

3.5 Measurement

The expected user has basic knowledge of ECG measurements and can place the electrodes on the patient's body, as well as be able to verify that these connections are correct and can initiate data collection. See Chapter 13.4.

ECG-EXPERT measures 6- or 12-lead electrocardiograms. The data can be analysed by a qualified doctor via the ECG-EXPERT app and/or sent for further analysis by a qualified doctor.

3.6 Analysis

The expected user for the analysis of the reports generated by the ECG expert is a doctor with experience in the analysis of ECG signals.

4. Side Effects

None were detected.

5. Contraindications

ECG-Expert should not be used by patients with known skin reactions to the electrode material.

ECG-Expert should not be used in areas where there are open wounds, rashes or lesions on the patient's torso where it comes into direct contact with the skin.

6. Warnings

- Modification of equipment is not permitted.
- Do not use the product if it is damaged or its cables are damaged or its insulating cover is defective.
- Do not replace cords with cords other than those provided with the equipment.
- The equipment must be closed and its internal parts must be inaccessible at all times.
- Avoid exposing the equipment to direct sunlight for extended periods of time.
- Remove the connecting wires with the electrodes that are not needed to perform data capture.
- Do not use the product near explosive gases or vapors, or in damp or wet environments. Protect equipment from water, wet, saline, and sulfuric environments.
- Do not use the product if it is not working properly.
- Do not connect the product to a patient and simultaneously charge the battery of the product.
- Read the Safety Information section before using the product.
- Examine the product box before use. Check that there is no damage to the product. Look closely at the insulation around the product terminals and the electrode connection wires.
- Do not use sharp objects to operate the equipment.
- Verify that the terminals of the equipment and the equipment are not in contact with any conductive surfaces.
- Do not use the equipment near high-frequency (microwave) sources that are running.
- Make sure that no conductive part of the equipment (terminals, cables, electrodes) comes into contact with any conductor. (Cables, metal surfaces, metal conduits or plugs)
- Do not use the equipment in an operating room or during surgery.
- Any serious incident involving the product must be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient are established

7. Patient Privacy

The privacy of patient health information may be protected by U.S. (state, federal), European, or international/foreign laws governing how such information may be used, stored, transmitted, and disclosed.

The ECG-EXPERT system employs security features that comply with U.S. HIPAA policies.

Third parties may be prohibited from accessing such information without obtaining written permission from the patient. The user is fully responsible for understanding and following all laws regulating the storage, transmission, and disclosure of any electronic patient data through the use of software.

If the user is unable to comply with a law or restriction that applies to the use and disclosure of such data, the user should not proceed to collect or store such information.

The ECG-EXPERT request may require the entry of individually identifiable health information in order to function. Records are stored and retrieved through the use of the patient's name, date of birth, and/or patient ID number. By entering this information, the user assumes any and all risks and liabilities incurred with the use or transmission of such information.

8. Certifications

The ECG-EXPERT complies with the following standards:

ECG Device:

- EN/IEC 60601-1
- EN/IEC 60601-1-2
- EN/IEC 60601-2-25
- EN/IEC 60601-2-49

Bluetooth Module:

- EN 60950-1
- EN 62311
- EN 300-328
- EN 301-489-1
- EN 301-489-17
- 47 CFR Part 15 Subpart C

9. Equipment supplied in the Box

The following items are supplied in the box:

- ECG-EXPERT biomedical signal capture device.
- 10 electrode connection cables
- 1 cable USB a micro USB
- 1 unique ID card with QR code for Bluetooth pairing.

10. Identification of the ECG-EXPERT parts

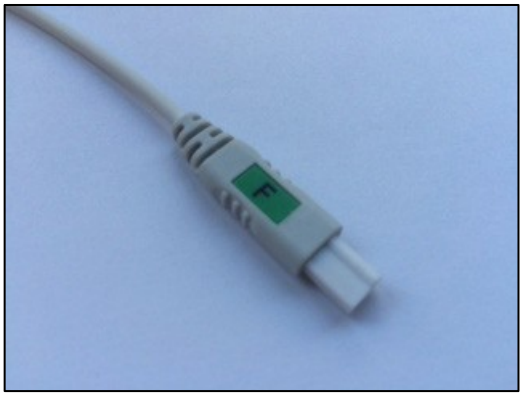
The device has a simple interface. The elements are indicated in the following figure:

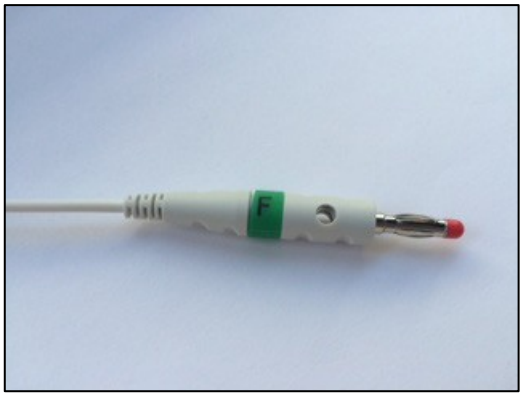
1. Cables de electrodos
2. Cable plugs
3. Status LEDs for Cables and Electrodes
4. Battery status indicator
5. On/off button
6. Bluetooth Link LED (Blue)
7. Micro USB battery charging port

Warning:

To avoid connection errors, each cable is uniquely labeled with its corresponding plug ID on the ECG-EXPERT (standard code N, R, C1 or V1, C2 or V2, C3 or V3, C4 or V4, C5 or V5, C6 or V6, L, F).

Make sure each wire is plugged into an outlet with the same code.





End of the cable to be connected to the ECG-EXPERT End of the cable to be connected to the electrodes

11. System Requirements

11.1 Minimum System Requirements

The display device must support, at a minimum:

a) Bluetooth 2.1. Contact Medical CSE for versions later than Bluetooth 4.0.
b) Exclusive Bluetooth link with the ECG expert.
c) Any of the following operating systems
    i. Android: 5.0 o posterior
    ii. iOS: 9.3 or later
    iii. Windows 7.0 or later
    iv. MacOS Capitan o posterior.
d) Minimum communication data rate of 115.2 kbps, ideally 230.4 kbps
e) ECG-EXPERT Application

11.2 Email settings

To exploit the full potential of our ECG-EXPERT, we recommend having the e-mail service (Mac mail, Windows mail, Gmail, etc.) installed on the same device used as the viewer, i.e. where the ECG-EXPERT application is installed.
The visualization application uses this service to send emails with the ECG reports attached.

11.3 Precautions⚠

As with other wireless systems, the Bluetooth data link can be affected by several

factors. Some of them are described below.

a) Any evolution of the Bluetooth protocol (greater than 4.0).
b) Any additional devices used in the Bluetooth link (multi-device link).
c) Any device removed in the Bluetooth link (multi-device link).
d) Updating the operating system or related software on the display device.

The Bluetooth data link between the display device and the ECG-EXPERT is unique, point-to-point, i.e. one Bluetooth channel for each ECG-EXPERT unit.

Do not share the Bluetooth link with another device.

The user should check that the ECG expert has not been affected by the above factors before their next use. Chapters 13, 14 and 15 describe how to use the ECG-EXPERT and its expected behaviour. In case of abnormal behavior, contact MedicalCSE.

If the Bluetooth data link is lost during operation, the ECG-EXPERT is immediately switched off and waits 60 seconds for a new data link. If there is no new link, it will be automatically turned off. At the same time, the ECG-EXPERT app on the display device is also switched off and data collection is terminated. However, it continues to run in the background, waiting for the start of a new Bluetooth connection, initiated by the user.

12. Charging the ECG-EXPERT device

Connect the supplied micro USB cable to the ECG-EXPERT and the supplied universal power adapter (110/120 VAC or 220/240 VAC). Connect it to an AC power source to charge the ECG-EXPERT.

It is fully charged in less than two hours from a fully discharged state. When fully charged, the battery status LED turns green when the power button is pressed.

13. ECG-EXPERT Configuration

To use the ECG-EXPERT, download the ECG-EXPERT app on the display device and pair it with the ECG-EXPERT. Then plug the wires and electrodes into the correct sockets.

13.1 Download the ECG-EXPERT App

Download the app from the relevant store (Google Play Store or Apple Store) if you use portable devices (smartphones or tablets) or from the link provided by MedicalCSE for Windows and MacOS. Install it on the display device and configure it (see the next chapter).

13.2 Bluetooth pairing

ECG-EXPERT uses a Class 2.1 Bluetooth and LTE wireless data link.

Precaution: ⚠
The Bluetooth range will be reduced when there are objects (walls, furniture, people, etc.) between it and the display device. To improve the Bluetooth connection, reduce the distance and/or allow a line of sight between the ECG-EXPERT and the display device.

Follow the steps below for mobile devices:

- See section 13.5. Turn on the device by pressing the on/off button
- Scan the supplied QR card with the display device's camera

Follow the steps below for Computers:

- See section 13.5. Turn on the device by pressing the on/off button
- Turn on Bluetooth on your computer
- On the Bluetooth tab, search for a new Bluetooth device. When a device named CSExxxx is found, select it and pair.

13.3 Electrode Specifications and Selection

The cables supplied with the device are designed for use with PIN type electrodes or with commercially available adapters for this type of connection.

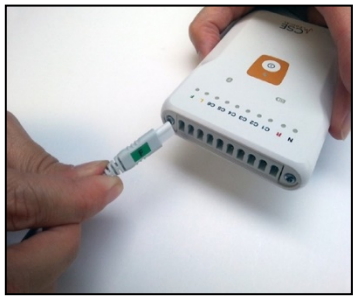
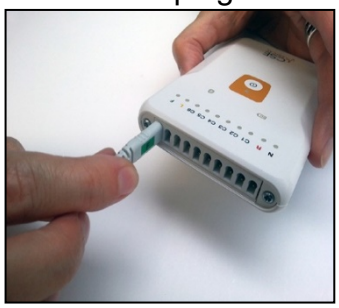
Precaution: ⚠
The use of pregelled, Ag/AgCl, latex-free electrodes that meet the following specifications is recommended:

- Impedance (typical): 650 ohms
- DC Compensation Voltage (Typical): 0.2 mV
- Recovery from a defibrillation load (typical): 9.9mV
- Polarization Potential Variation: 0.2mV/s

13.4 Connecting and Positioning the Electrode Wires

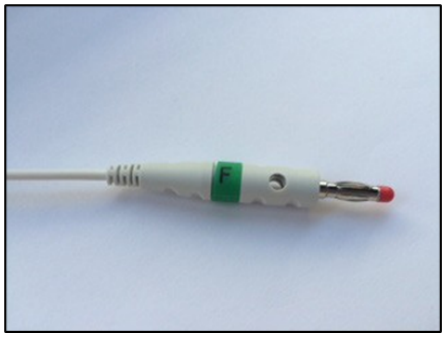
The electrode wires have different one-way connection terminals. The terminal end of the ECG-EXPERT device of the cable is shown in the following images.

Each cable terminal and its corresponding socket on the ECG-EXPERT device is encoded with a letter and a color. The pictures show the green wire F inserted into the plug identified

with the green letter F. Connect the remaining wires in the same way, matching the letters and colors.

The electrode end of the wire is shown below. It is also coded with a letter and color that helps identify the correct position of the electrode on the patient's body (see also Chapter 13.5). A standard ECG electrode may be attached to it.



Warning:
Before using the ECG-EXPERT, make sure that all cables are properly connected and secure in your accessories.

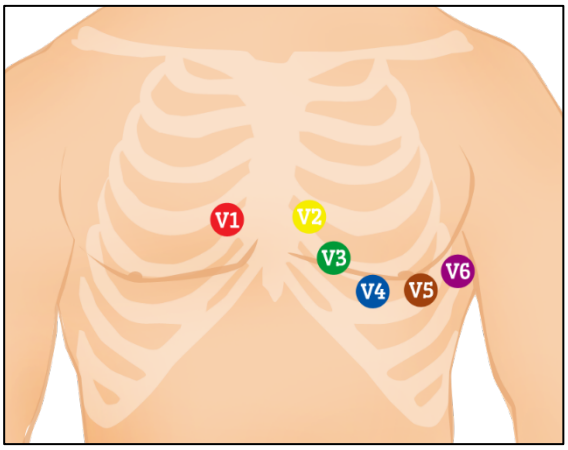
13.5 Electrode Positioning

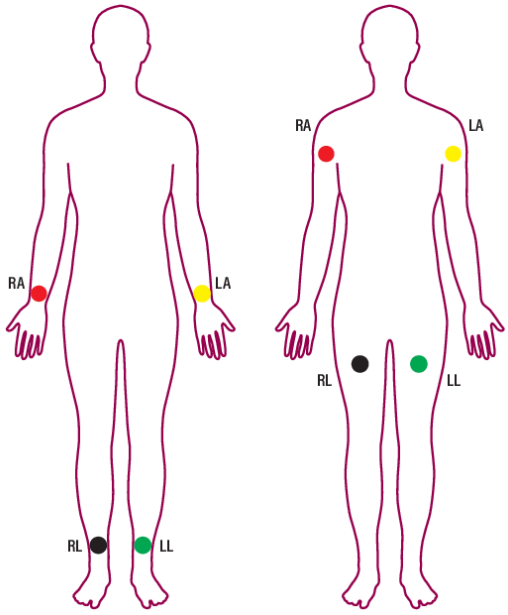
The following diagrams show the general positions of the electrodes for ECG data measurement.

Warning:

It is the user's responsibility to ensure correct positioning. It is recommended that the User practice correct positioning with a qualified and experienced medical professional before taking ECG measurements.

Precordial PositioningPositioning of the limbs





13.6 Switching on the ECG-EXPERT device

Precaution: ⚠

Before turning on the ECG-EXPERT:

- Make sure that all leads are correctly connected to the ECG-EXPERT and that the electrodes are correctly positioned on the patient's body.
- Verify that the ECG-EXPERT is not connected via micro-USB to any device.

Press the power button. A flashing red light above the power button indicates that the device is turned on. Immediately afterwards, the battery status LED lights up.

Turn on the device

LED Battery Status Key:

a) **Green** – The battery is fully charged.

b) **Orange**: The battery has enough power (<40%) to measure ECG signals , but it needs to be charged soon.

c) **Red** – The battery needs to be recharged for the device to work in optimal condition.

d) No color: the battery is completely discharged. It can be fully charged in 2 hours with the supplied charger. If there is no power after 10 minutes, contact Medical CSE for assistance.

The flashing Bluetooth LED (blue) on the right side of the device indicates that the Bluetooth module is on but waiting for the connection.

The connection of the electrodes to the ECG-EXPERT can be done while it is powered without affecting it or the patient or the user.

13.7 Switching off the ECG-EXPERT device

To turn off the ECG-EXPERT, proceed as follows:

a) Press down on the power button. The LED light above the button starts flashing.

b) Press and hold for a few seconds until all the lights turn off, indicating that the device is off.

Turn off your device

During ECG data acquisition, the device cannot be turned off and will not react when pressing the on/off button. Finish the data acquisition process before turning off the device.

13.8 Use with Defibrillator

Warning:
While the ECG-EXPERT has been designed and certified with protection against the action of a defibrillator, it is NOT recommended for use during defibrillation. It is recommended that the ECG expert disconnect from the patient during defibrillation.

13.9 Use with Pacemaker

ECG-EXPERT is designed to detect the presence of implanted stimulator devices, such as pacemakers. The operation of these devices is not affected during ECG-EXPERT operation and ECG data measurement.

If a malfunction is suspected in an implanted device or in the ECG expert, it is recommended to stop the measurement of the ECG data and contact MedicalCSE for assistance.

14. Features of the ECG-EXPERT App

This chapter describes the various functions of the tabs and submenus that can be used in the operation of the ECG-EXPERT. See Chapter 15 for a description on how to use ECG-EXPERT to obtain ECG measurements.

Make sure that the display device has the latest version of your operating system (OS) and the latest version of the ECG-EXPERT app (check the app store or the corresponding medical CSE). Then open the ECG-EXPERT app.

Precaution: ⚠

For compatibility with the various display devices, the functions of the ECG-EXPERT app are customized for iOS/Android devices or MacOS/Windows computers. Make sure that only the relevant procedure for the selected display device is used.

iOS/Android Devices

Go to More and then Settings

14.1 General Tab iOS/Android Devices

- Line Frequency Filter: Select between 50 Hz or 60 Hz depending on the country in which ECG-EXPERT is used. Check out this link for more information on this topic: https://en.wikipedia.org/wiki/Mains_electricity_by_country

- Noise Filter: Select from 0.67 Hz ~ 40 Hz (monitoring), 0.05 Hz ~ 150 Hz (diagnostics), or Unfiltered (raw data)

- Quick Diagnostics: When selected, allows for an initial on-screen diagnostic before saving it as a report.

- Quick Send: When selected, the report saved in PDF or DICOM format will be automatically sent to a user-preconfigured destination email address. This feature is particularly useful when a user wants all ECG reports to be automatically sent to a specific email address, for example, to a doctor or an ECG analysis service. To do this, the user must enter the email address where all reports will be sent. Must be an active email account (Gmail, Yahoo, etc.)

- Classifier: When selected, the saved ECG report is analyzed against a predefined "normal" ECG and presented in percentage terms. Please note that this is only a probability calculation between the saved ECG report and the MedicalCSE ECG database.

14.2 Reports Tab iOS / Android Devices

- Grid: Displays the grid in PDF reports.

- Patient Name: If selected, displays the patient's name in PDF reports. For patient privacy, do not select this option: the name will not appear on PDF reports.

- Age: Show the patient's age rather than date of birth on the PDF report.

- Size and Weight: Displays the size and weight in the PDF report.

14.3 iOS/Android Devices Tab

For pairing and selection of Bluetooth devices.

- Use QR Scanning: QR scanning is a quick one-step Bluetooth pairing method and is the preferred method for initial pairing. Thereafter, the ECG-EXPERT device appears as a pre-paired device. It can be reused if, for some reason, the ECG-EXPERT is not displayed as a previously paired device.

- Select Device: Displays a list of all devices previously paired with this display device. The user can select the ECG expert from here. See Chapter 13.2 for Bluetooth pairing.

- Edit device: To change the device name

- Wipe Device: Deletes all previously paired devices.

14.4 DICOM Tab iOS / Android Devices

- In case the User wishes to integrate the ECG-EXPERT into a system that supports the use of the DICOM protocol, all these fields must be filled in correctly.
- C-ECHO Test: Once all fields have been completed, click here to check if the DICOM configuration has been configured correctly.

14.5 Worklist Tab iOS/Android Devices

- Fill in these fields only when the user is working with the worklist in the DICOM protocol.

14.6 Cloud Tab iOS / Android Devices

MedicalCSE offers cloud storage for ECG reports from ECG-EXPERT. Contact MedicalCSE to set up cloud storage.

- Select Cloud to store all ECG-EXPERT reports in ECG-EXPERT Cloud. Make sure all fields are filled in correctly.

14.7 Log Tab iOS/Android Devices

- Log File: Displays the record of previous ECG-EXPERT activities on the display device.

MacOS/Windows Computers

14.8 MacOS / Windows Computer Devices Tab

Once ECG-EXPERT has been paired (see Chapter 13.2), it should appear in this view (click refresh if the device name is missing).

The device must have a name. This field cannot be empty.

14.9 MacOS / Windows Computer Filters Tab

- Line Frequency Filter: Select between 50 Hz or 60 Hz depending on the country in which ECG-EXPERT is used. Please refer to the following link for more information on this issue: https://en.wikipedia.org/wiki/Mains_electricity_by_country

- Noise Filter: Select from 0.67 Hz ~ 40 Hz (monitoring), 0.05 Hz ~ 150 Hz (diagnostics), or Unfiltered (raw data)

14.10 MacOS / Windows Computer Reports Tab

Options menu:

- Quick Diagnostics: When selected, allows for an initial on-screen diagnostic before saving it as a report.
- Classifier: When selected, the saved report is analyzed against a predefined "normal" ECG and presented in percentage terms. Please note that this is only a probability calculation between the saved ECG report and the MedicalCSE ECG database.
- Log: When selected, the activity log is displayed on the screen.

Departure menu:

- Path: The user can select where to save all reports.
- Use the patient's name in file names (instead of folder names)
- Use the patient's date of birth in file names

Cloud Menu:

MedicalCSE offers cloud storage for ECG reports from ECG-EXPERT. Contact MedicalCSE to set up cloud storage.

- Select Cloud to store all ECG-EXPERT reports in ECG-EXPERT Cloud. Make sure all fields are filled in correctly.

Alternatively, the User can configure the storage with another cloud provider.

14.11 PDF Tab Computers MacOS / Windows

In this tab, the user can configure the format of the PDF file generated after an ECG scan

a) Grid: Simple, Full, or No Grid

b) Fields: Show Patient Name, Show Age Instead of Date of Birth, Show Size

and Weight. The user can add additional fields such as the doctor's name, institution name, and institution email. A page for comments can also be added.

c) Logo: Here you can add the user's logo, e.g. doctor, hospital or analysis service.

14.12 MacOS / Windows Computers Worklist Tab

- Fill in these fields only when the user is working with a worklist in the DICOM protocol.

14.13 MacOS/Windows Computers Storage Tab

MedicalCSE offers cloud storage for ECG reports from ECG-EXPERT. Contact MedicalCSE to set up cloud storage.

- Select Cloud to store all ECG-EXPERT reports in ECG-EXPERT Cloud. Make sure all fields are filled in correctly.

Alternatively, the User can configure the storage with another cloud provider.

15. ECG Data Measurements

This chapter details how to perform ECG measurements and use the functions available in ECG-EXPERT.

iOS/Android Devices

15.1 Basic Settings iOS / Android Devices

a) Open the ECG-EXPERT app on the viewing device.

b) Connect the electrodes to the device using the supplied wires as explained in Chapter 13.4. MedicalCSE recommends keeping the cables connected to the device.

c) Place the electrodes on the patient's body according to the diagrams in Chapter 13.5 or as directed by a qualified medical professional.

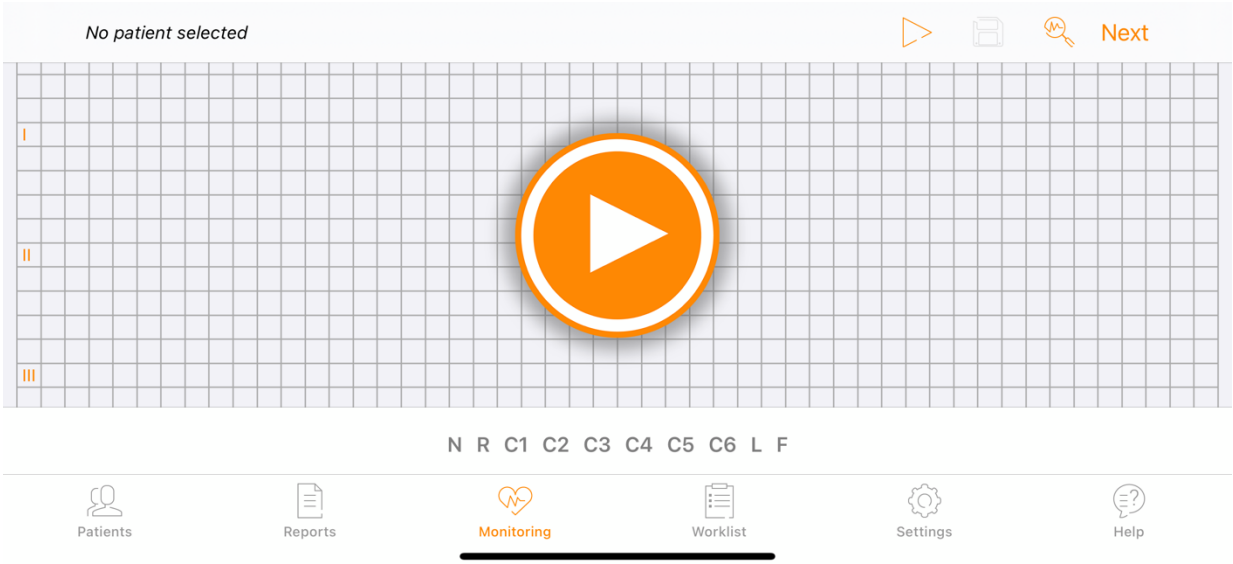
   i. To perform a 6-lead ECG measurement, connect only the limb wires (N, F, L, and R).

   ii. To perform a 12-lead ECG measurement, connect all 10 wires (limbs and chest).

d) Turn on the ECG-EXPERT as explained in Chapter 13.6.

e) If it is not already paired, pair the ECG-EXPERT with the display device (see Chapter 13.2).

f) From the home screen

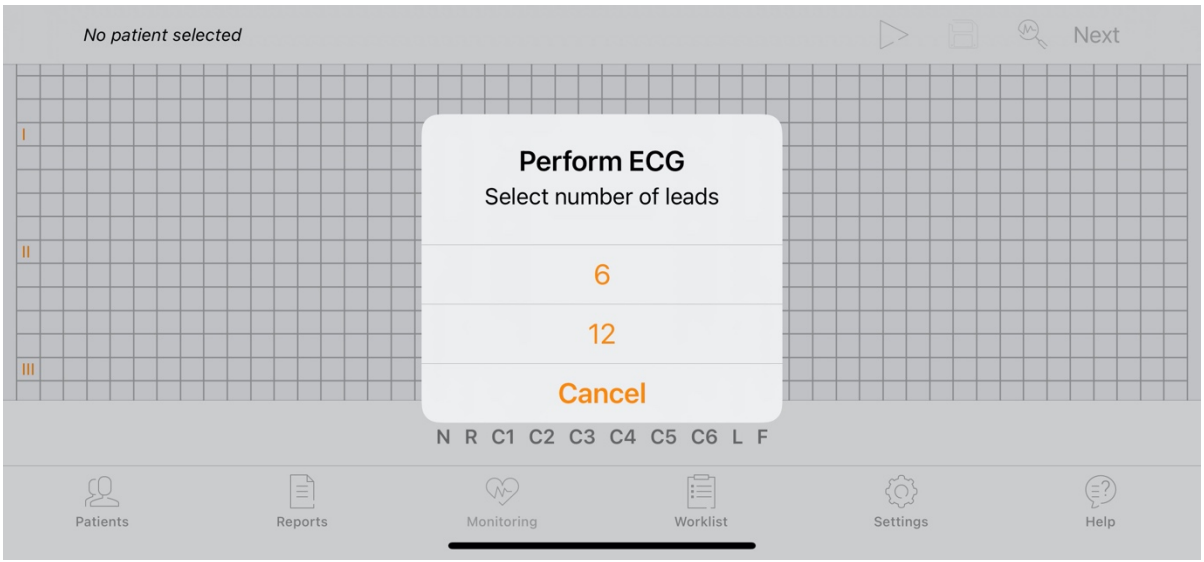


iOS Home Screen

Tapping  selects the desired lead. Use the Next button to switch between leads.

Tap the  play button to start the ECG measurement.

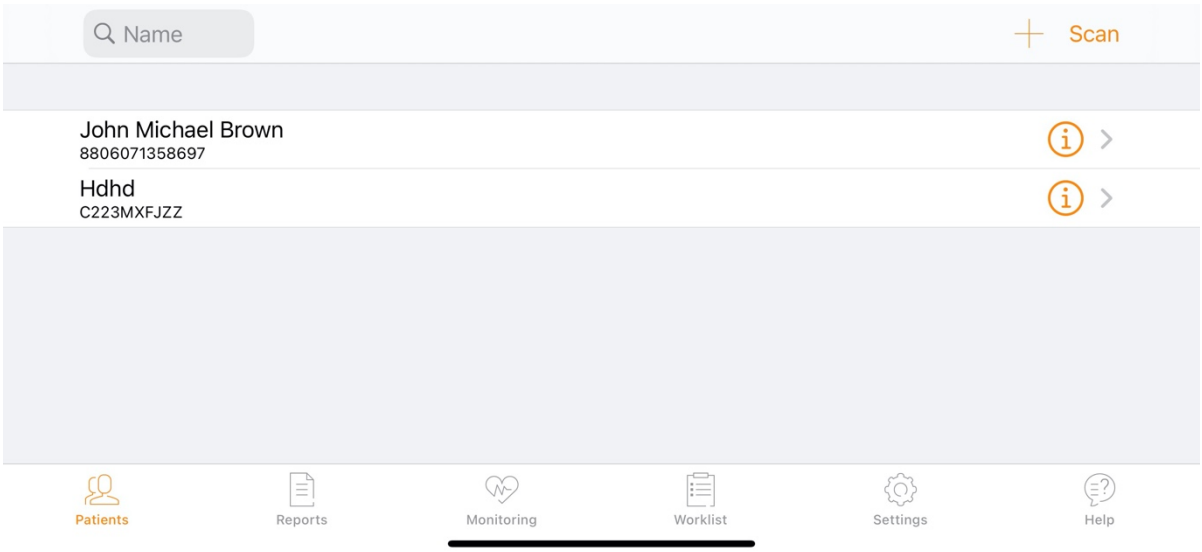
After that, the lead screening screen appears. Select 6 or 12 leads.



iOS Lead Screening Screen

Once the number of leads has been selected, the camera of the iOS/Android device will open to scan the QR card that comes with the ECG-EXPERT device for Bluetooth pairing. This will only happen during the first use of the ECG-EXPERT app. See Chapter 14.3 for more information.

g) To create a patient, select the Patients tab.



iOS Patient Screen

If the patient has a barcode or QR code, simply tap Scan to upload the patient's data to the app. See MedicalCSE for details.

If there is no barcode or QR code associated with the patient, tap (+).

Fill in all required fields (patient name, patient ID, patient gender, and date of birth are the only required fields) and tap the Save button.

To search for a patient, use the search bar.

The patient data created can be edited by tapping the (i) symbol.

h) Select a patient listed in the Patient tab (this can also be done by the user after the ECG measurement is complete).

i) Tap Start to start the ECG measurement.

j) The status of the electrodes is displayed in color on the display while the ECG measurement is being performed. Green indicates that the electrode is connected correctly, while red indicates that there is a poor or no connection.

The same colors should also appear on the status LEDs on the ECG-EXPERT device's cable.

k) Wait until the measurement is finished (depends on the measurement type selected, 10 seconds or tap Stop for Continuous). If the measurement is satisfactory, tap the Save button, otherwise, repeat the measurement, tapping the Home button again.

l) Once the Save button is tapped, a dialog box appears. If a patient X has been previously selected, the dialog box says "Save Report? The report will be kept with patient X."

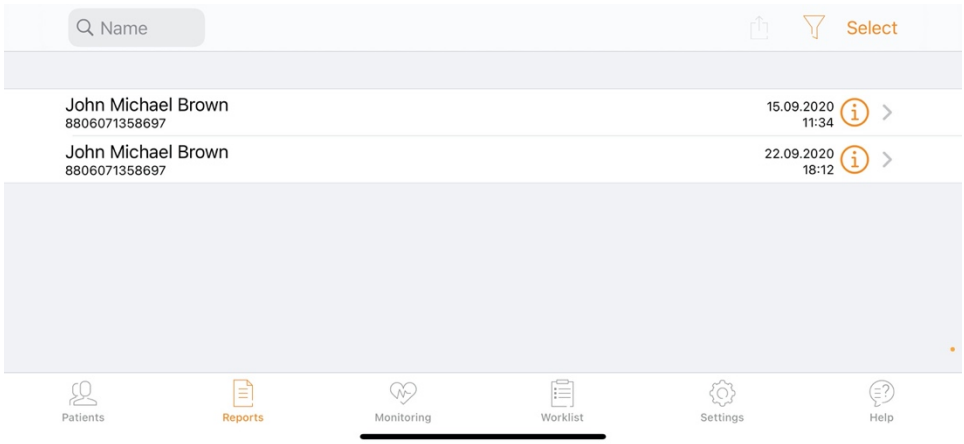
If the selected patient is incorrect, tap Cancel to go to the patient list and select another patient.

If no patient is selected, go to the Patient tab and tap the (+) symbol to create a new patient (see point g)).

m) Saved reports are available on the Reports tab.

iOS Report

15.2 iOS / Android Device Reports



iOS Patient Reports Screen

Lists all reports saved by the patient. From here there are 4 options available:

a) Search by name using the search bar

b) Filter by date or time by tapping the symbol

c) To view the report, select the report with the patient's name (see Chapter 15.3).

d) Use the Select button (see Chapter 15.4).

15.3 iOS/Android Device Reports View

Available features:

- Scroll through all the ECG charts displayed on the screen.
- Turn the ruler on or off to measure directly on the display.
- By tapping the "Annotations/Replies" button, the user can add a comment to the report
- When you tap on the symbol, a pop-up screen appears with the full signal

Measurement.

- By tapping the symbol (zoom), the user can select a lead individually.

- The Next button switches between one lead and the next.

15.4 Selecting Reports iOS / Android Devices

After tapping the "Select" button, the user can select one or multiple reports.

When you select a report or select multiple reports, several options appear along the top edge of the screen bar:

- Erase 
- Export the report to the DICOM server 
- When two reports from the same patient are selected, tapping the "Compare" button displays both reports on the same screen for easy comparison.
- Print button allows printing to any Wi-Fi printer
- Cancel button. Exit to the previous screen

MacOS/Windows Computers

15.5 Basic Configuration Computers MacOS / Windows

a) Open the ECG-EXPERT app.

b) Connect the electrodes to the ECG-EXPERT device using the supplied wires as explained in Chapter 13.4. MedicalCSE recommends keeping the cables connected to the device.

c) Place the electrodes on the patient's body according to the diagrams in Chapter 13.5 or as directed by a qualified medical professional.

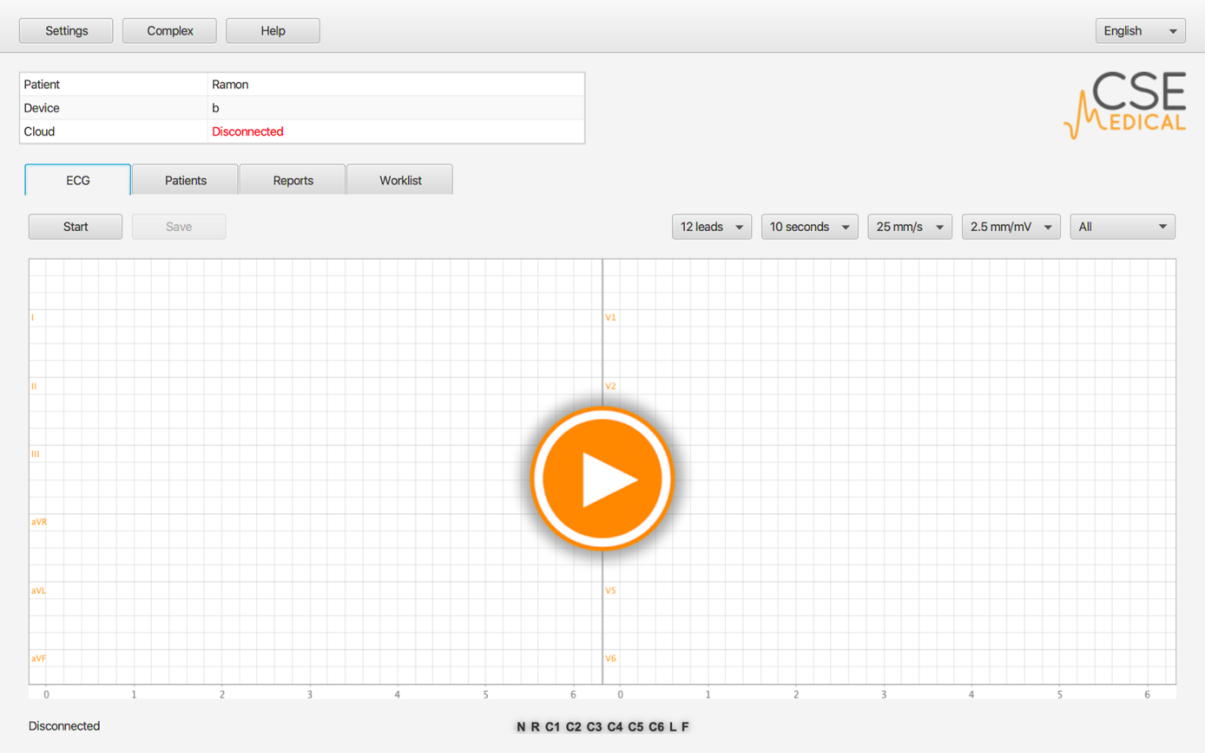
   i. To perform a 6-lead ECG data measurement, connect only the limb wires (N, F, L, and R).

   ii. To perform a 12-lead ECG data measurement, connect all 10 wires (limbs and chest).

d) Turn on the ECG-EXPERT as explained in Chapter 13.6.

e) If it is not already paired, pair the ECG-EXPERT with the computing device (see Chapter 13.2).

The initial (default) screen opens in the ECG tab:



MacOS/Windows Home Screen (ECG)

f) From the home screen (touch ECG tab) configure the settings by selecting between (tabs):
   - 6 or 12 leads
   - 10 seconds or continuous mode
   - 25 mm/s o 50 mm/s (eje horizontal)
   - 2,5 mm/s, 5 mm/s, 7,5 mm/s o 10 mm/s (eje vertical)
   - Different views of leads

g) Once setup is complete, tap the Home or Play button to begin ECG measurement.

h) The status of the electrodes is displayed in color on the display while the ECG data is being measured. Green indicates that the electrode is connected correctly, while red indicates that there is a poor or no connection.

   The same colors should appear on the status LEDs on the ECG-EXPERT device cable.

i) Wait until the measurement is finished (depends on the measurement type selected, 10 seconds or tap Stop for Continuous). If the measurement is successful, tap Save 

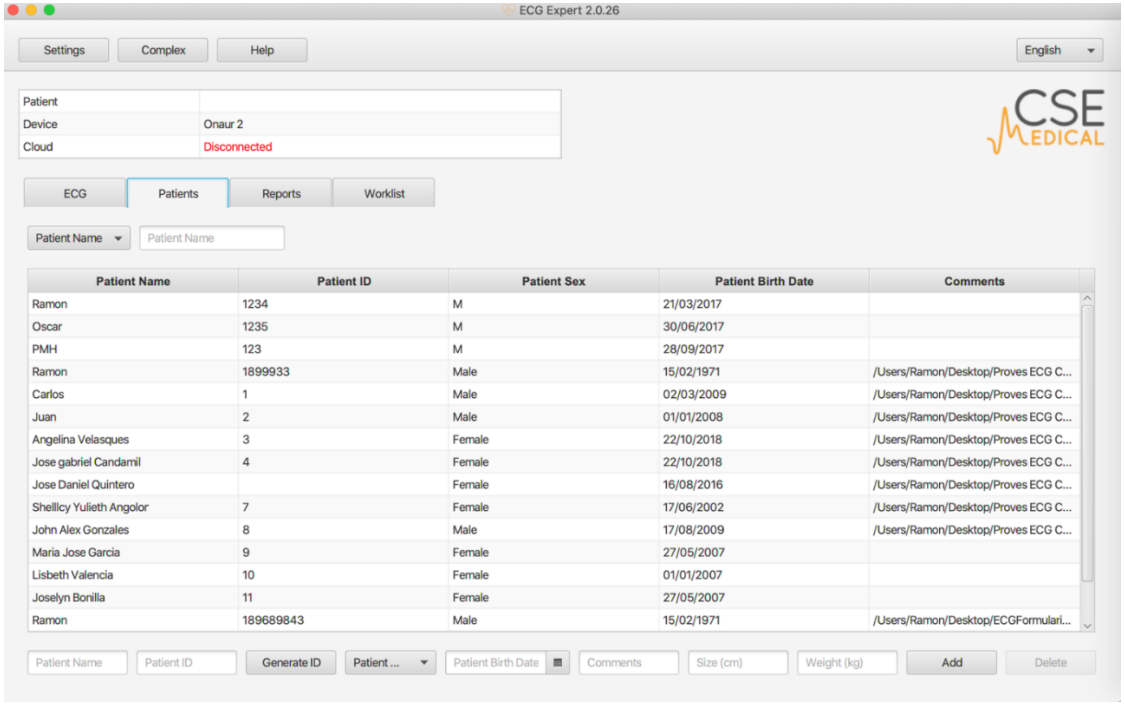
   otherwise, repeat the measurement, tapping the Home button again.

j) Once the Save button is tapped, a dialog box appears. If a patient X has been previously selected, the dialog box says "Save Report? The report will be kept with patient X."

   If the selected patient is incorrect, tap Cancel to go to the patient list and select another patient.

If no patient is selected, go to the Patient tab and tap the (+) symbol to create a new patient (see item (k)).

k) To create a patient, go to the Patients tab. **Important: This step can be performed at any time, before or after the ECG measurement.**



Patient screening

Fill in all required fields (patient name, patient ID, patient gender, and date of birth are the only required fields) and tap the Save button.

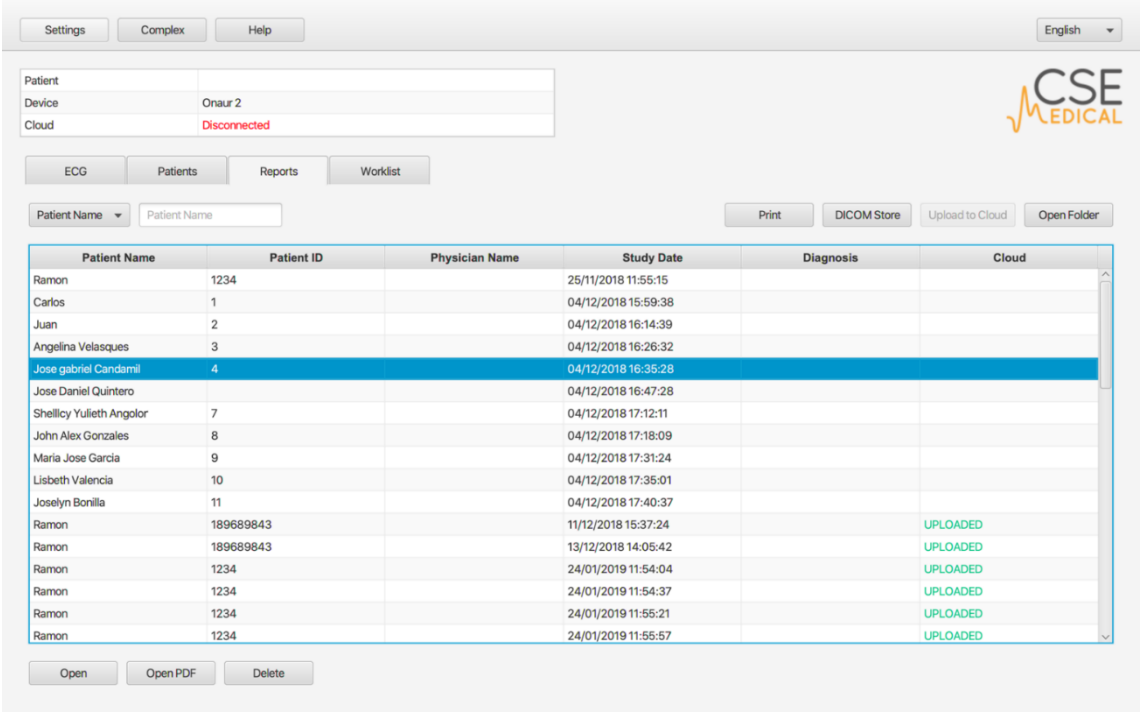
To search for a patient, use the search bar.

The patient data created can be edited by tapping the (i) symbol.

l) Saved reports are available on the Reports tab.

MacOS Report

15.6 MacOS/Windows Computers Reports Tab



Report screen

Use the search bar to search for reports by patient name or patient ID.

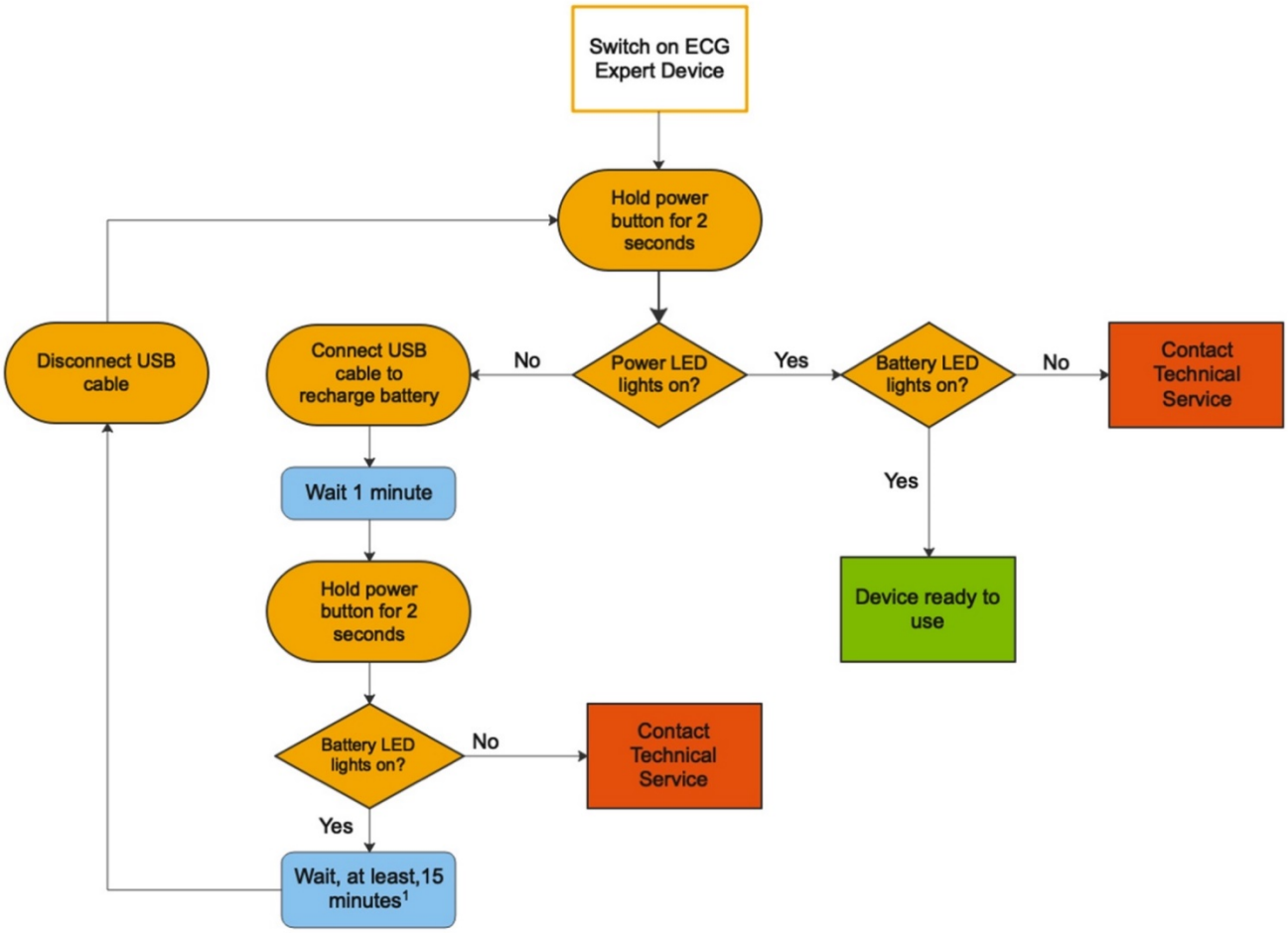
The screen shows all the reports saved on the computer.

When selecting a report, different features are available:

- Open: The report opens in a different window. The ruler, text addition, measurements, and axis can be changed from here.
- Open PDF: The report opens in Acrobat Reader. Once opened, the diagnosis can be performed directly from the PDF file.
- Delete Report
- Impression
- DICOM Store: Send to DICOM Server, if Connected
- Open folder: Go to the folder on the user's computer where all reports are saved (in DICOM and PDF).

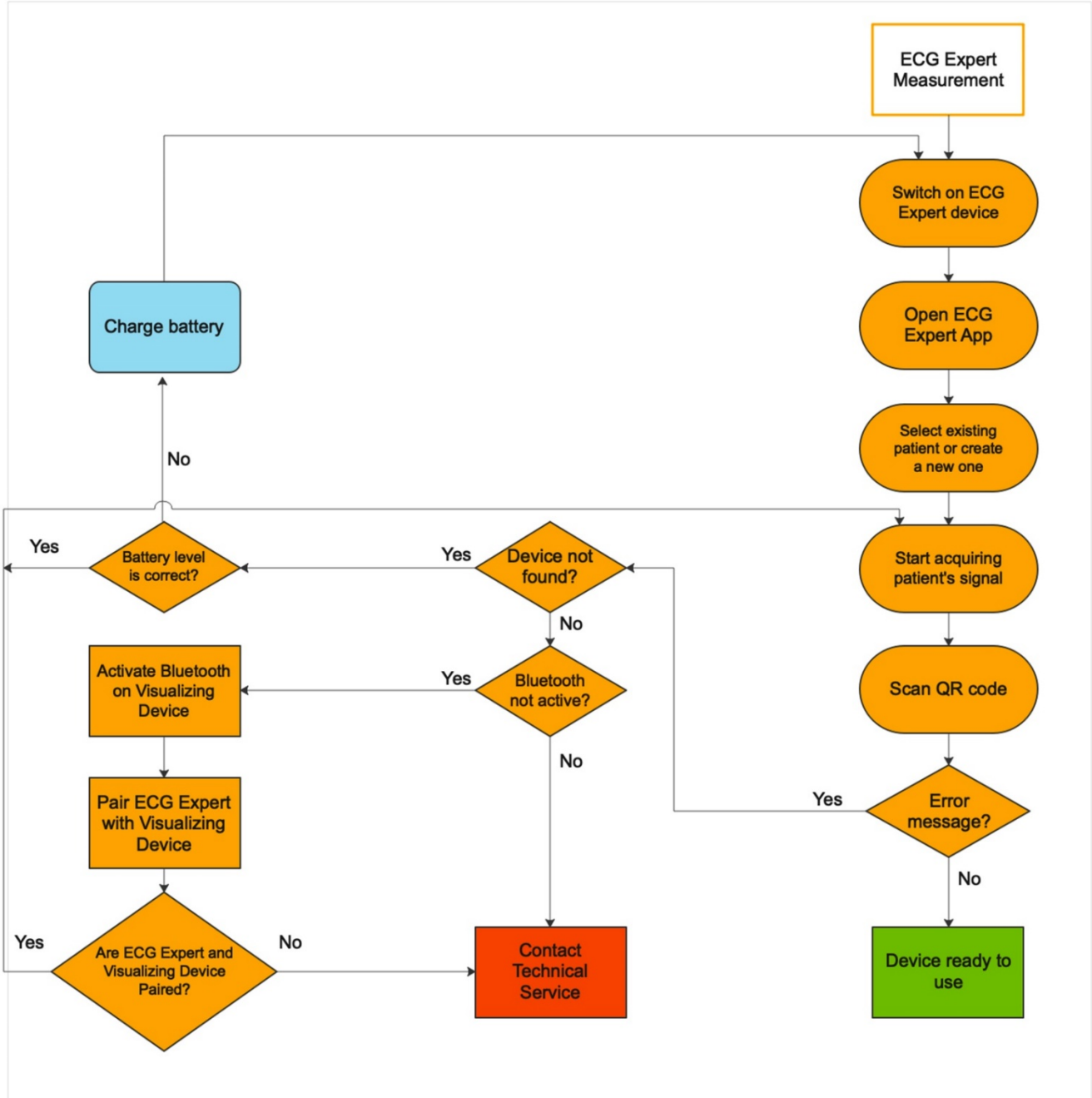
16. Troubleshooting

16.1 Device Initialization

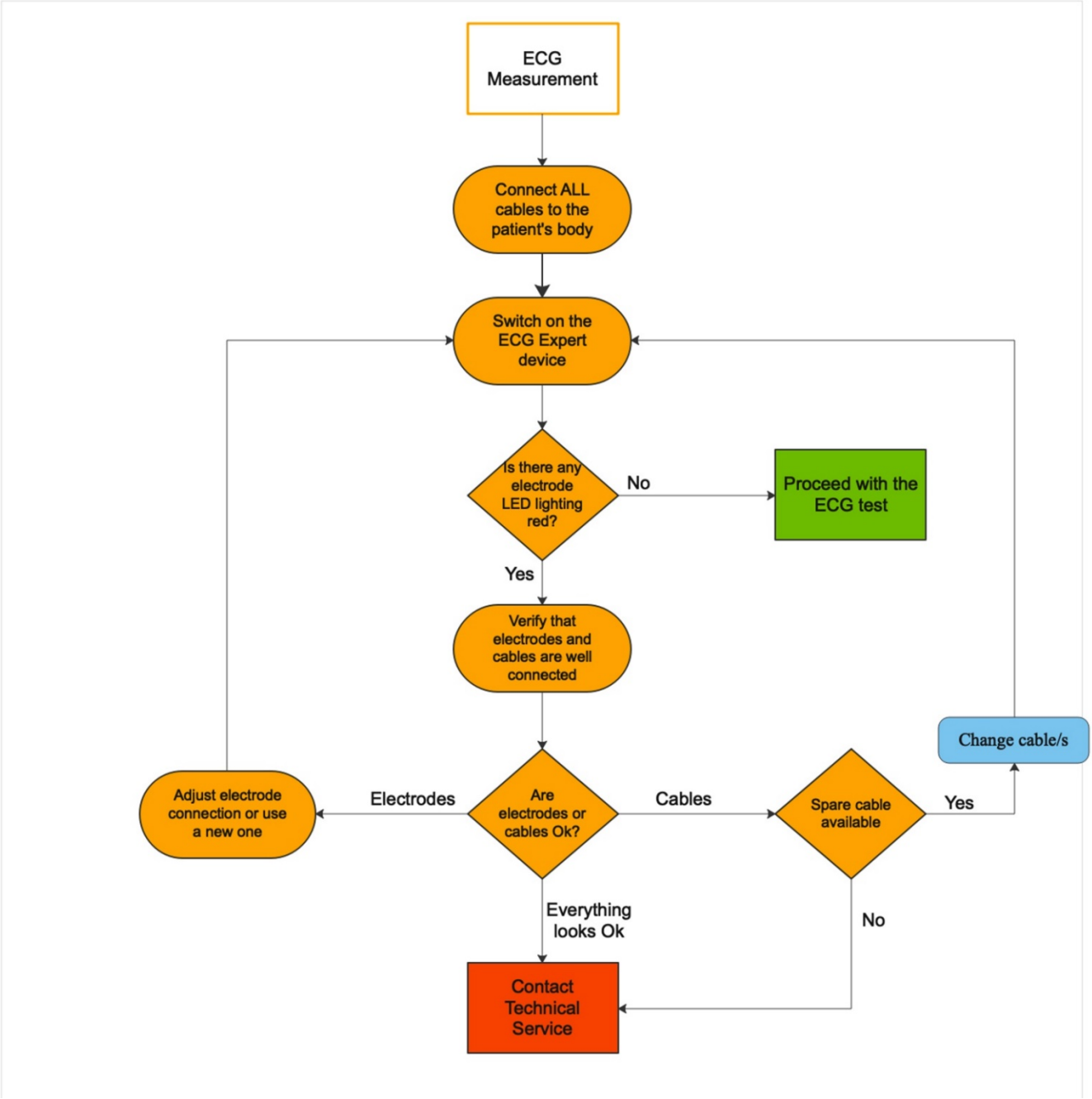


[1]MedicalCSE strongly recommends to charge ECG Expert device at least 30 minutes to achieve full charge. To check if ECG Expert device is fully charged battery LED lights green once you switch on the ECG Expert device

16.2 Bluetooth pairing



16.3 ECG Data Measurements



17. Inspection, Cleaning, Storage and Transport

17.1 Preventive Inspection

A preventive inspection is required before using the ECG device to verify the absence of visible damage to the device or cables that may affect the proper functioning of the device.

Visual inspection should include the device and all cables, to check for damaged or worn areas, including but not limited to breaks, cuts, discoloration, or oxidation of any part or component. If a cable or other accessory shows any of these symptoms, replace it before using the ECG-EXPERT.

17.2 Cleaning

Wipe the outside of the device with a mild solution of dish detergent and water on a soft cloth. Avoid any excessive amount of cleaning solution to prevent liquid from entering through the connectors or slots of the ECG device. If necessary, use a water solution with low-alcohol sterilizing detergent, such as those used in hospitals.

⚠ **Warning: Check that all equipment, including accessories, is completely dry before use.**

The supplied cables are reusable but are not previously sterilized. To clean and disinfect the equipment, proceed as follows:

a) Disconnect the cable by pulling on the connector.

b) Proceed carefully, avoid pulling with excessive force, twisting or bending the connection cable.

c) Wipe the cables with a soft cloth with sterilizing cleaning solution.

d) Wipe the cable with a soft, dry cloth.

17.3 Storage

To avoid damage to the battery, store the device between -15ºC and 50ºC.

To avoid internal cuts in the cable conductor or damage to the outer insulation, do not overbend the cables.

17.4 Transport

If the ECG-EXPERT or one of its components is to be transported, use the original packaging.

If original packaging is not available, protect items from shock, moisture, dust, and electrostatic discharge (ESD) by using proper padding and ESD-approved sealed packaging.

17.5 Warnings: ⚠

- **DO NOT IMMERSE THE EQUIPMENT IN ANY LIQUID.**
- Strictly follow the cleaning instructions in section 17.2. Do not use any harsh or harsh cleaning products:
- Prolonged exposure to alcohol can affect the mechanical properties of the protective housing and cables.
- N-propyl alcohols or sodium hypochlorite should be avoided as disinfection agents for both the cables and the device.

18. Maintenance

Thanks to its robust, solid-state digital design, the ECG-EXPERT does not need a specific maintenance program.

Precaution: ⚠

However, it is recommended that the ECG expert stay away from hard objects and avoid receiving strong blows, bumps, and falls. Also, make sure that the plugs on the cable connectors are kept covered when not in use. Use caution when using the cables, avoiding "twisting" and handling them roughly.

18.1 Repairs

This should only be done by authorized technical experts if necessary. Contact Medical CSE for more information.

18.2 Security Checks

The safety of the ECG-EXPERT must be checked by an authorized technical expert after any repair, modification or conversion. Contact Medical CSE for more information.

18.3 Electronic Waste and Recycling

This medical device contains electronic components and must be disposed of in accordance with Directive 2012/19/EU on waste electrical and electronic equipment (WEEE). Do not dispose of it with household waste. Take it to an authorized WEEE collection and recycling point.

19. Technical Specifications

19.1 General

General Information	
Name (REF)	ECG-EXPERT
BASIC UDI	8437017782018ECGEXPERTDP
EMDN	Z120503 Electrocardiograph
Manufacturer	Custom Software & Electronics S.L. c/ Sant Antoni Maria Claret, 167 08042 Barcelona- Spain
SRN	ES-MF-000003031
Processing	
Computerized measurements	12-lead analysis
ECG analysis frequency	500 samples per second
Digital sampling rate	8000 samples per channel per second
ECG display	Real-time graphical representation
Acquisition mode	Real-time acquisition on all electrodes (channel delay <10 µs)
Dynamic range	416mV
Resolution	24 bits per channel (<1uV)
Frequency Characteristics	
Low cut-off frequency (–3 dB)	0.02Hz
High cut-off frequency (–3 dB):	Configurable at 40Hz or 150Hz
Adaptive line filter	47–53 Hz (European grid) / 57–63 Hz (American grid)
CMRR	>105dB
Input impedance	>100 MΩ with defibrillation protection
Patient leakage current	<10uA
Heart rate range	20-260pm
Start-up stabilization time	3 secondi
Patient Information	
Supported Patient Information	Name, Patient ID, gender and medical notes
Display	
Display Type	Tablet, PC or smartphone
Resolution	1920 × 1080 pixels (1080p)
Displayed data	Name, patient ID, battery level indicator, gender, medical notes
Printer	
Printer Technology	Depending on User's Printer
Keyboard	
Tipo	Depending on Display Device
Software and Operation	
Resting ECG	Records and prints up to 12 ECG leads at rest
Operation Modes	Continuous and 10s intervals
Multi-language	English, Spanish, Italian
ECG Display Software	
ECG-EXPERT App	ECG-EXPERT Application: available on App Store and Google Play; connected via QR code or installation link for Windows Compatibility: Android ≥5.0, iOS ≥9.3, Windows ≥7.0, macOS El Capitan or later Functions:
Functions	ECG graph capture, , external storage support
Interpretation	Diagnostic assistance (qualified physician required)
Storage	Depending on User Device
Communications	
Bluetooth	Bluetooth: 2.1 Class 1, 2.45 GHz, +8.5 dBm power
Report Format	
	PDF

Electrical Characteristics	
Power Supply	USB 2.0 Standard 4V@500mA max
Battery	Rechargeable lithium-polymer (complies with E062113)
Battery Capacity	3.7 V – 820 mAh
Charging time	<2h
Autonomy	2 hours full charge
Dimensions	
Length	115mm
Width	75mm
Thickness	17mm
Weight	125g
Environmental Conditions	
Operating Temperature	5°C - 38°C
Storage Temperature	-15°C - 50°C
Operating Humidity	25% – 95% (non-condensing)
Storage Humidity	25% – 95% (non-condensing)
Pressure	
Operating pressure	70kPa – 106kPa
Storage altitude	Up to 2000 m
Certifications	
Applied standards	EN 60601-1-2:2015/A1:2021 – EN 60601-2-25:2015 -EN 60601-1:2006/AC:2022-12
European Union	MDR 2017/745 Class IIa, Rule 10 – CE ON0318
United States	FCC Identification RFRMSR
Physical protection	IP5X (dust resistant)
Electrical shock protection	Type BF (IEC 60601-1), defibrillator proof
Water protection: IPX0	

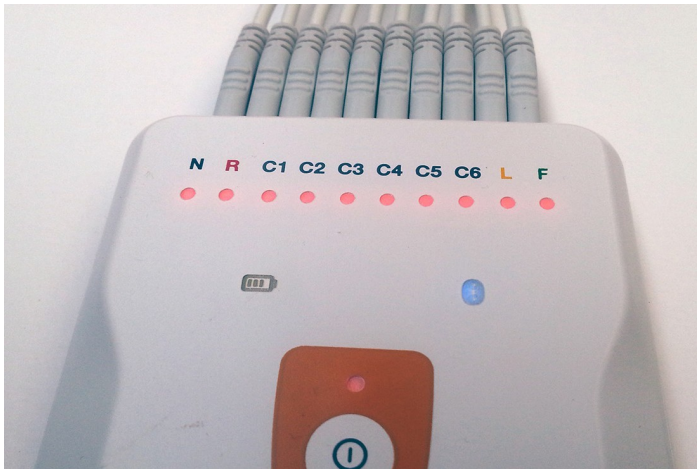
19.2 EMC Information

The ECG-EXPERT complies with the electromagnetic compatibility requirements of EN 60601-1-2 and
IEC 60601-1-2.

The ECG-EXPERT has an intentional radiator (Bluetooth module) that complies with ETSI EN 301-489-17, ETSI EN 301-489-1 (Europe) and 47 CFR Part 15 Subpart C (USA) approved under FCC ID RFRMSR.

This device must not be modified without the written consent of the manufacturer, Medical CSE. Unauthorized modifications may void the authority granted by the European Commission and the rules of the U.S. Federal Communications Commission that allow the operation of this device.

Guide and Statement from the Manufacturer - Electromagnetic Emissions			
This device must only be used under the electromagnetic environment specifications described in this document.			
Emission Test	**Compliance**	**Guide**	
RF Emissions CISPR 11	Group 1	ECG Expert uses RF only for its internal operation resulting in very low RF emission which is not likely to cause any interference with surrounding electronic equipment.	
RF Emissions CISPR 12	Class B	The device is suitable for operation in all kind of facilities, including domestic (non industrial) buildings and, also, in those with direct connection to a public low-tension electrical grid such as in buildings for domestic use.	
Harmonic Emissions IEC61000-3-2	Class A	The device is suitable for operation in all kind of facilities, including domestic (non industrial) buildings and, also, in those with direct connection to a public low-tension electrical grid such as in buildings for domestic use.	
Power fluctuation/Flickers IEC61000-3-3	Compliant	The device is suitable for operation in all kind of facilities, including domestic (non industrial) buildings and, also, in those with direct connection to a public low-tension electrical grid such as in buildings for domestic use.	
Immunity Test	**IEC60602 Standard Test Level**	**Compliance Level**	**Reference Electromagnetic Environment**
Electrostatic discharge IEC61000-4-2	±6kV by contact, ±8kV aerial	±6kV by contact, ±8kV aerial	Floors should be conductive (wood, concrete or ceramic tiles). If the floor is covered with a synthetic material, relative humidity must be over 30%.
Transient / Fast flashes IEC61000-4-4	±2kV far power supply lines from public grid, ±1kV far input / output lines	±2kV far power supply lines from public grid, ±1kV far input / output lines	The power grid quality must be as good as in a standard commercial environment or as in a hospital
Shock Wave / Surge IEC61000-4-5	±1kV in line to line; ±2kV in line to ground line	±1kV in line to line; ±2kV in line to ground line	The power grid quality must be as good as in a standard commercial environment or as in a hospital
Power cuts, interruptions or voltage variation in power feed lines IEC61000-4-11	< 5% U_T(drop > 95% of U_T) for 0.5 cycles , <40% U_T(drop > 60% of U_T) for 5 cycles , <70% U_T(drop > 30% of U_T) for 25 cycles	< 5% U_T(drop > 95% of U_T) for 0.5 cycles , <40% U_T(drop > 60% of U_T) for 5 cycles , <70% U_T(drop > 30% of U_T) for 25 cycles	The power grid quality must be as good as in a standard commercial environment or as in a hospital. If continuous operation is required, the device has to be powered by a continuous power source.
Magnetic field at grid frequencies (50/60 Hz) IEC61000-4-8	3 A/m	3 A/m	The magnetic fields at grid frequencies must be between the typical values from a typical commercial or hospital environments



19.3 Electrical and Electromagnetic Interference Mitigation

As with any electronic device, external electromagnetic fields may affect the normal operation of the device or any electromagnetic fields generated within the device may interfere with other devices.

In order to avoid these interferences, the device has been robustly designed to avoid alterations in the ECG electrode signals by external electromagnetic fields in standard environments (away from high-voltage power lines or electromagnetically noisy equipment such as washing machines, power generators, microwaves or operating televisions).

Due to the nature of the radio link between the equipment and the display equipment (smartphone, tablet or computer) it is possible that an intense electromagnetic field may affect the connection speed between these two devices, lengthening the waiting time to obtain a complete biometric measurement. Under extreme electromagnetic conditions, the communication link between these two devices may break, but it does not affect the quality or shape of the signal obtained.

To avoid unwanted effects, it is important to ensure that the device operates within an electromagnetic field of less than 3 V/m and 3 A/m. It is NOT recommended to operate the device:

a) Less than 10 m from a high-voltage power line
b) Less than 2.5 m from industrial equipment, microwaves or televisions in operation.

If the device is experiencing interference from the power grid of the country where the ECG measurement is performed, refer to Chapter 14.1 of this manual for instructions on how to minimize such interference.

20. Symbols and Labels

20.1 Symbols

The following symbols are used in this product:

			
CE Medical Device ON certification	CF-type equipment, protected against	Instructions	Caution
			
Date of manufacture	Maker	Protect from sunlight	Direct current
			
Serial Number	E-Waste/Electrical Waste	Serial connection	Prescription only (USA)
			
Bluetooth	Medical Device	Unique device identification	Manual reading required

21. Contact

Custom Software & Electronics
Recent Modernist Sant Pau
Sant Antoni Maria Claret, 167
08025 Barcelona
Spain

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