

CHIS_001_B.1_Instructions for Use (EN)

Applicable to
CardioHis

Change control

Rev.	Modifications
1	Original document, first digital version
2	EMC Information update
3	SGS review
4	Format update
5	User Interface (0.31 (47)) update
6	AEMPS presentation update
7	User Interface (0.93 (56)) update
8	User Interface (0.95 (58)) update
9	Intended use update
10	App installation update
11	App and hardware included in the integrated system
12	NB first round assessment
13	NB second round assessment
14	ECG cable model change
15	Compatible ECG electrodes update

Publication date: February 25, 2025



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1. User responsibilities

CardioHis will operate in accordance with the information contained in this User Manual, the device label, and other documents that may be attached to the device. The device must be set up, operated and cleaned in accordance with the instructions provided by the manufacturer.

CardioHis is to be used ONLY in accordance with the Intended Use contained in this manual (section 6.1). Do not use this unit for other purposes not specified by the manufacturer.

CardioHis must be checked periodically by qualified personnel. If the device is faulty, broken, or mechanically deformed, turn it off and do not use it for clinical activities.

Do not use disposables other than those recommended by the manufacturer. If any part of the device, or a disposable, is damaged, contaminated, or defective, replace it immediately.

In the event that it is necessary to repair or replace the device, it must be communicated to the technical service and it must be repaired only by qualified personnel authorized by CardioHis SL

Consult the regional legislation or the restrictions that must be applied to the sale or use of this device.

Users of this product are responsible for any malfunction resulting from improper use, faulty maintenance, incorrect repair, damage or alteration by any person or entity other than CardioHis SL or authorized by this manufacturer.

NOTE: The user is RESPONSIBLE for informing the manufacturer and the competent authority of the Member State in which the user and/or patient is established of any serious incident that occurs related to this device.

2. Symbols

Symbol	Description
Note	Provides additional information or clarification.
	Indicates how to use the device correctly and those conditions that may damage it
WARNING	Represents a hazardous situation with respect to the procedures or operating conditions mentioned in this manual that can result in injury or death to the user or patient if the operation is not performed correctly
	Consult the instruction manual
	Manufacturer
	Lot Number
	Serial number
	Defibrillation-proof type CF applied part
	Storage and transport pressure limit; indication on the packaging.
	Storage and transport relative humidity limit; indication on the packaging.
	Temperature limits; indication on the packaging.
	Product type (medical device)

3. Safety warnings

- Read and follow all cautions, warnings and troubleshooting.
- Please read this manual before using CardioHis.
- The device must be used only with accessories approved by the manufacturer. The use of accessories and cables not specified by CardioHis SL may cause an increase in radio frequency (RF) emissions or a decrease in the immunity of the device.
- CardioHis is designed to be used by trained healthcare professionals only.
- CardioHis requires special precautions regarding electromagnetic compatibility (EMC) and must be installed and put into service in accordance with the EMC information provided.
- Portable and mobile RF communications devices may affect the device.
- CardioHis should not be used in close proximity to other devices. In case it is strictly mandatory, it must be verified that the device works as expected in the configuration to be used.
- If the device's MEAN WELL / GSM25E05-P1J external power supply adapter fails, do not replace it or other internal components yourself. Do not use the unit and call specialized technical support for assistance.
- Do not open the unit if you have not been previously trained for technical support by the manufacturer of the product. Never touch the internal electronic cards without adequate protection against electrostatic discharges.
- It is recommended to disconnect the CardioHis device from the patient in case of use of defibrillation pulses. Despite CardioHis has been designed and tested according to the basic safety of the harmonised standard EN/IEC 60601-2-25, essential performance tests of the harmonised standard EN/IEC 60601-2-25 has not been executed because CardioHis does not have essential features. In case of CardioHis fails, the ECG signals will be continued acquired with the pacemaker programmer used together to the device.

4. Definitions and abbreviations

Abbreviation	Description
ECG	Electrocardiogram
V	Volts
mV	millivolts
ms	milliseconds
A	Amps
Hz	Hertz
W	Watts
EMC	Electromagnetic compatibility
RF	Radio frequency

5. Introduction to this Manual

This manual describes the Instructions for Use of the CardioHis device and CardioHis app model, 01. This manual includes the essential aspects to be able to use CardioHis safely, the intended use and the different operating modes of the device.

It is very important to read this manual before using CardioHis. Images and diagrams are included to facilitate the use of the device. This document is subject to periodic revision.

For any questions about this manual or about the use of CardioHis, please contact us:

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C/ Daniel Balaciart 4, Oficina 8
46020. Valencia. Spain
Email: info@cardiohis.com
www.cardiohis.com

6. General Description of the Device

CardioHis is a medical device used to manually measure the left ventricular activation time (LVAT) parameter using ECG signals.



Figure 6.1: CardioHis Device

CardioHis device connects via Bluetooth with the Apple device (iPad Air 64gb 4th generation recommended), where ECG signals are displayed on the same screen and the user can change visualization parameters such as trace speed and zoom of the signals.

Figure 6.2 shows a front view of the device.



Figure 6.2: Front view of the device

- **Green led:** Indicates whether the system is ON or OFF.
- **Blue led:** Indicates the status of the device's Bluetooth connection. When the acquisition device is not connected to the Apple device and during the wireless connection procedure, the led will flash blue. When the device is connected to the external device, the led will be fixed in blue color.

The power supply and the connection of the ECG electrodes are made at the rear part of the device. Figure 6.3 shows a rear part view of the equipment.



Figure 6.3: Rear part view of the device

6.1. CardioHis app

CardioHis application runs on the Apple device. The Apple device could be supplied separately and must meet with the following characteristics:

- A14 Bionic chip with 64-bit Neural Engine architecture
- iPadOS 15 operating system
- Memory: 64GB
- Screen: 10.9-inch multi-touch
- Resolution: 2360x1640
- Bluetooth 5.0

CardioHis app needs to connect via Bluetooth to the CardioHis device in order to be executed. Otherwise the application will never enter the main screen and cannot be used.

Once paired the CardioHis app and the CardioHis device, this CardioHis device cannot be connected to the CardioHis app executed in another Apple device at the same time.

The CardioHis app can never be used with a device other than the CardioHis device.

6.1.1 CardioHis app installation

The CardioHis application runs only in iOS system and must be installed in the Apple device.

To install the Cardiohis app, the user must download it from the Apple Store. Once installed, the

Cardiohis app icon  will appears in the main screen of the Apple device.

The app will be updated automatically every time its developer makes significant changes. The Apple device must be connected to internet to perform the update successfully.

6.2. Intended use

CardioHis is a medical device used to manually measure the left ventricular activation time (LVAT) parameter using ECG signals.

CardioHis must be used ALWAYS in conjunction with a pacemaker programmer. CardioHis will be used ALWAYS to assist the physician in the study. The physician will NEVER make the final clinical decision using only the information shown on the CardioHis.

CardioHis has not been clinically tested in patients under 18 years old and in pregnant women. Both groups of patients should be excluded from using the device.

6.3 Expected benefit when using the device

CardioHis could be used to assist the physician to define the patient's rhythm and left bundle branch pacing using the LVAT measures, in different medical situations in which it may be necessary to record an ECG.

6.4. Operation principle

CardioHis is a novel medical device that has been designed to manually measure the left ventricular activation time (LVAT) parameter using ECG signals.

CardioHis is an active medical device that needs software (CardioHis app), intended to be used in combination with the hardware.

The software allows the ECG signals to be viewed simultaneously in the Apple device (4th generation iPad Air 64 GB recommended). It also allows manual measurement of several non-vital parameters: QRS width, Heart Rate or LVAT measures through the use of manual calipers.

CardioHis uses 10-lead surface ECG signals: LA, RA, RL, LL, V1, V2, V3, V4, V5 and V6. The acquired 10-lead ECG signals are filtered in the first stage and amplified by analogue upfront products. Then, the 10-lead signals are converted into 12 surface ECG leads (I, II, III, aVR, aVL, aVF, V1, V2, V3, V4, V5 and V6).

Once acquired, the signals are further processed and transmitted to the Apple device via Bluetooth wireless technology. The user-friendly CardioHis app allows the user to change visualization parameters such as trace speed and zoom of the signals and to generate the report of the patient study.

The product configuration is very simple and intuitive. The following figure shows the general installation of the product:

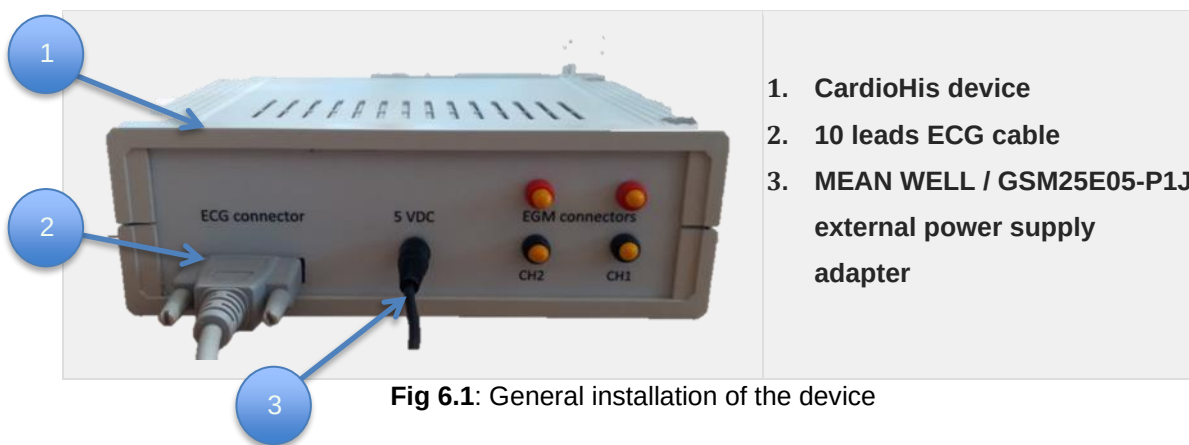


Fig 6.1: General installation of the device

NOTE: EGM connector's ports will not be used in this version of CardioHis.

CardioHis will be used in conjunction with a pacemaker programmer. CardioHis will ALWAYS be used to assist the physician in the study. The physician will NEVER make the final decision using only the information shown on the CardioHis.

The product must be connected to an external 5V DC power supply. It is not necessary to connect this unit to a server. The product should only be used with accessories approved by the manufacturer.

The product should only be installed by trained personnel. Furthermore, the product could be connected in combination with other medical devices, such as CPAP or ventilators. The device software must be updated locally or remotely under the supervision of qualified technical personnel.

6.5. Intended users

Device shall be used by trained health care personnel, as healthcare professional.

6.6. Intended patient population

CardioHis could be used to assist the physician to define the patient's rhythm and left bundle branch pacing using the LVAT measures, in different medical situations in which it may be necessary to record an ECG.

There are no differences in gender or race.

6.7. Contra-indications

- Allergy to the adhesive used to affix the leads.

- CardioHis has not been clinically tested in patients under 18 years old and in pregnant women. Both groups of patients should be excluded from using the device.

6.8. Compatible ECG cable in CardioHis device

The compatible ECG cable in CardioHis device is listed next:

- **CH004:** ECG cable, 10 leads IEC Pinch/Grabber, European standard connector

WARNING: Do not use or connect ECG cables not specified by the manufacturer.

6.9. Compatible ECG electrodes

The compatible electrodes for use with the ECG cable and CardioHis device are listed next:

- **BlueSensor L (Ref: VL-00-S/25). Manufacturer: Ambu**
- **BlueSensor L (Ref: L-00-S/25). Manufacturer: Ambu**

WARNING: Do not use or connect ECG electrodes not specified by the manufacturer.

6.10. Compatible external power supply in CardioHis device

The compatible external power supply in CardioHis device is listed next:

- **MEAN WELL / GSM25E05-P1J**

WARNING: Do not use or connect external power supply not specified by the manufacturer.

7. Unpacking the device

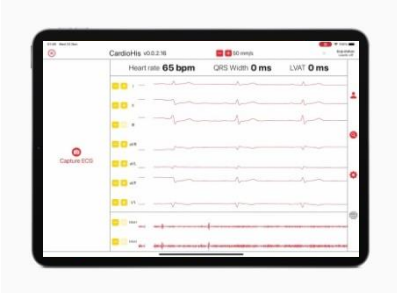
Unpack the product and check that it contains the following items:

- CardioHis Device
- Apple device (optional)
- 10-lead ECG cable
- MEAN WELL / GSM25E05-P1J external 5V power supply adapter

Note: It is recommended to save the device package in case you need to move the device later

8. Parts and accessories

WARNING: Do not use or attach items not specified by the manufacturer.

Image	Reference	Description
CardioHis Device		
	CH001	CardioHis Device
ACCESSORIES:		
Apple Device		
	CH002	Apple device (iPad Air 64GB 4th generation recommended). Optional.
Power supply adapter		
	CH003	MEAN WELL / GSM25E05-P1J. External 5V power supply adapter. Medical grade.
APPLIED PARTS:		
10-lead ECG cable		
	CH004	ECG cable, 10 leads IEC Pinch/Grabber, European standard connector.

8.1. Single and multiple use

The device itself is a reusable medical device. There is no need to clean the device between patients and no special processing is required. The device cannot be sterilized.

WARNING: Do not use the CardioHis device and/or the Apple device if are damaged during the cleaning process.

9. Device connection

1. Connect the ECG cable

Unpack the ECG cable, connect the ECG cable to the back of the device under the label indicating ECG CONNECTOR, and fix the ECG cable with the two screws available for this purpose.



2. Connect the MEAN WELL / GSM25E05-P1J external power supply adapter

Unpack the MEAN WELL / GSM25E05-P1J external power supply adapter, make sure the external power supply is not turned on, and plug the MEAN WELL / GSM25E05-P1J external power supply adapter cable into the back of the device under the label indicating 5V DC.



WARNING: Disconnect the external power supply from CardioHis If the ECG signals totally loss or loss in quality occurs in the pacemaker programmer when turned on the CardioHis device.

10. Initial setup

10.1. Before turning on

Make sure that all connections have been made as described in section "9. Device connection".

Check that the device and its accessories are not damaged or misconnected.

WARNING: If the devices, or parts, are broken, deformed, or visibly contaminated, the device must not be used.

10.2. Initialize the device

10.2.1 Apple device power ON

Press the power button for more than 5 seconds to turn on the Apple device.



WARNING: If Apple device does not power on properly, check the battery charge

WARNING: If Apple device power OFF accidentally or tactile function does not work properly, repeat the power ON procedure again

ADVERTENCIA: Si después de repetir el procedimiento de encendido los problemas detectados no se resuelven, no utilice el dispositivo Apple y sustitúyalo.

10.2.2 Turn on device

Turn ON the external power supply.

10.2.3 Enter the Apple device password

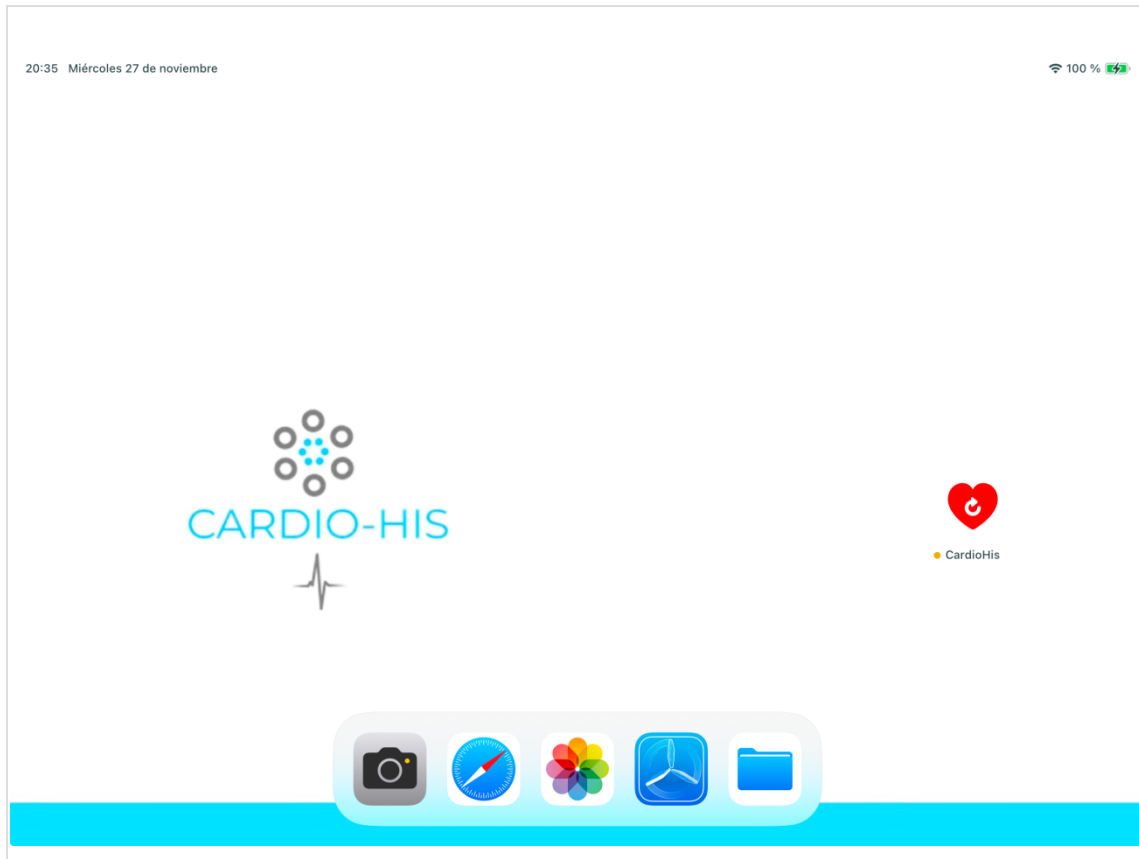
The password to access the Apple device was provided in the CardioHis training course.

The password may be requested from the person designated as responsible for CardioHis in the training course.

WARNING: CardioHis S.L. is not responsible for any safety issue related to unauthorized personnel accessing the iPad device.

10.2.4 Starting the CardioHis application

- Open the CardioHis app 



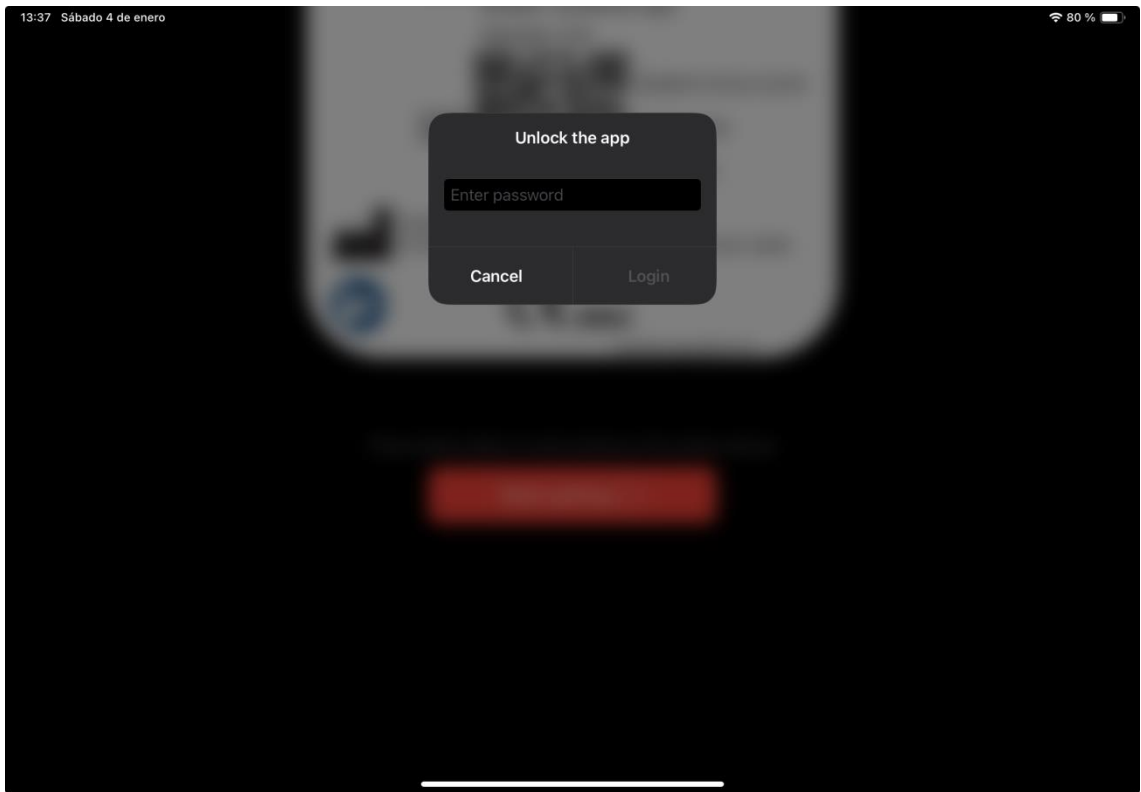
WARNING: The distance between the Apple device and CardioHis must be 5m or less.

WARNING: The CardioHis app needs to connect via Bluetooth to the CardioHis device in order to be executed. Otherwise the application will never enter the main screen and cannot be used.

Once paired the CardioHis app and the CardioHis device, this CardioHis device cannot be connected to the CardioHis app executed in another Apple device at the same time.

The CardioHis app can never be used with a device other than the CardioHis device.

- Enter the CardioHis app password

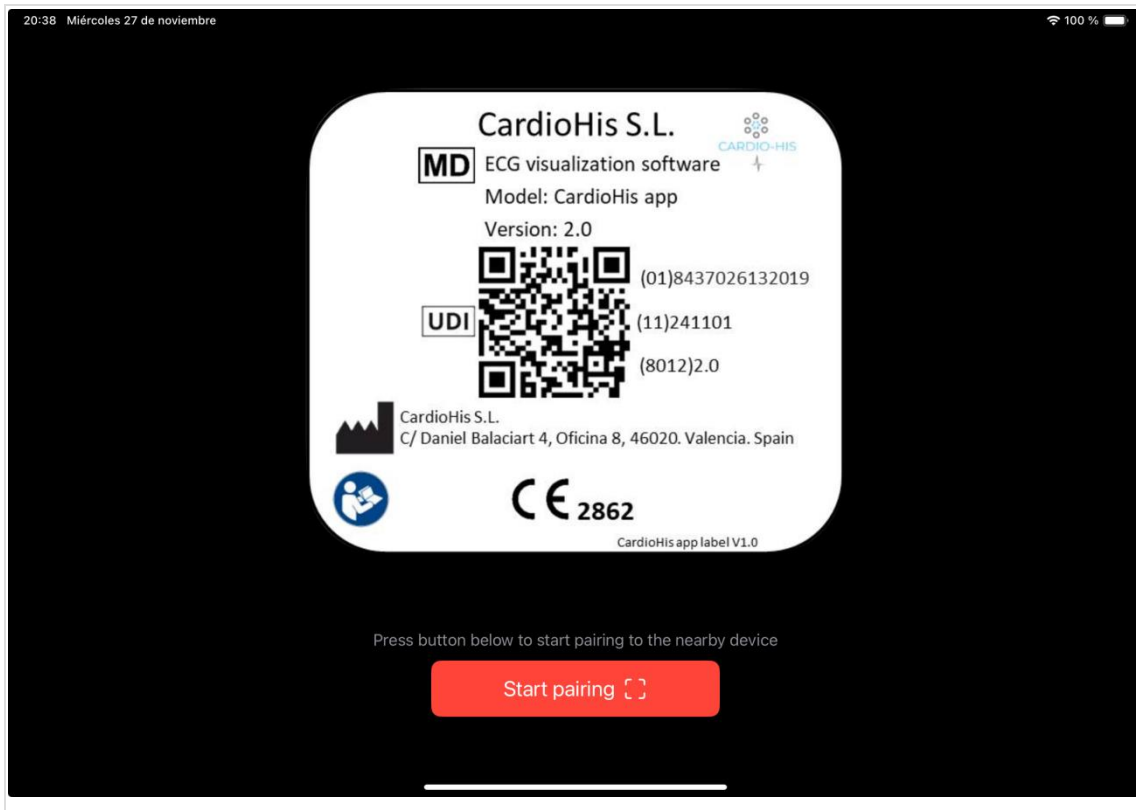


The password to access the CardioHis app was provided in the CardioHis training course.

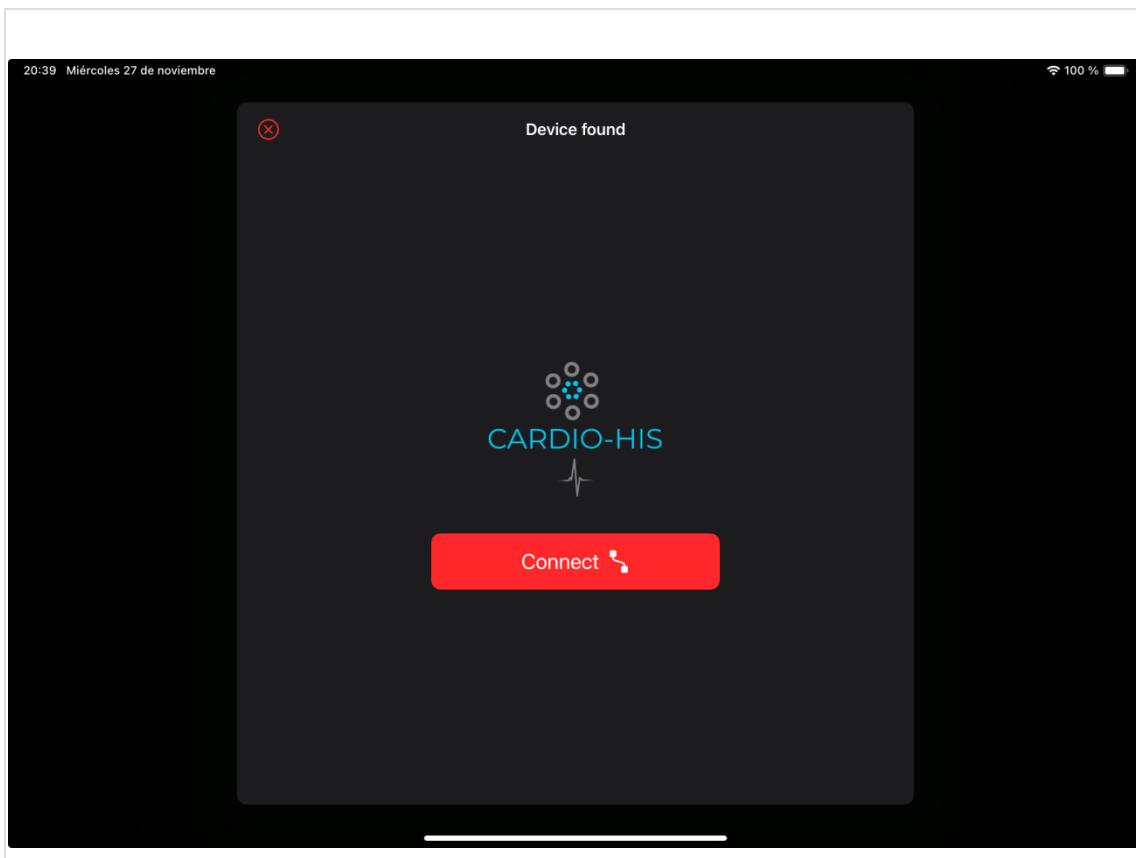
The password may be requested from the person designated as responsible for CardioHis in the training course.

WARNING: CardioHis S.L. is not responsible for any safety issue related to unauthorized personnel accessing the CardioHis app.

- Select Start pairing. The application will find the CardioHis device and the following screen will be displayed.



- Press the Connect button



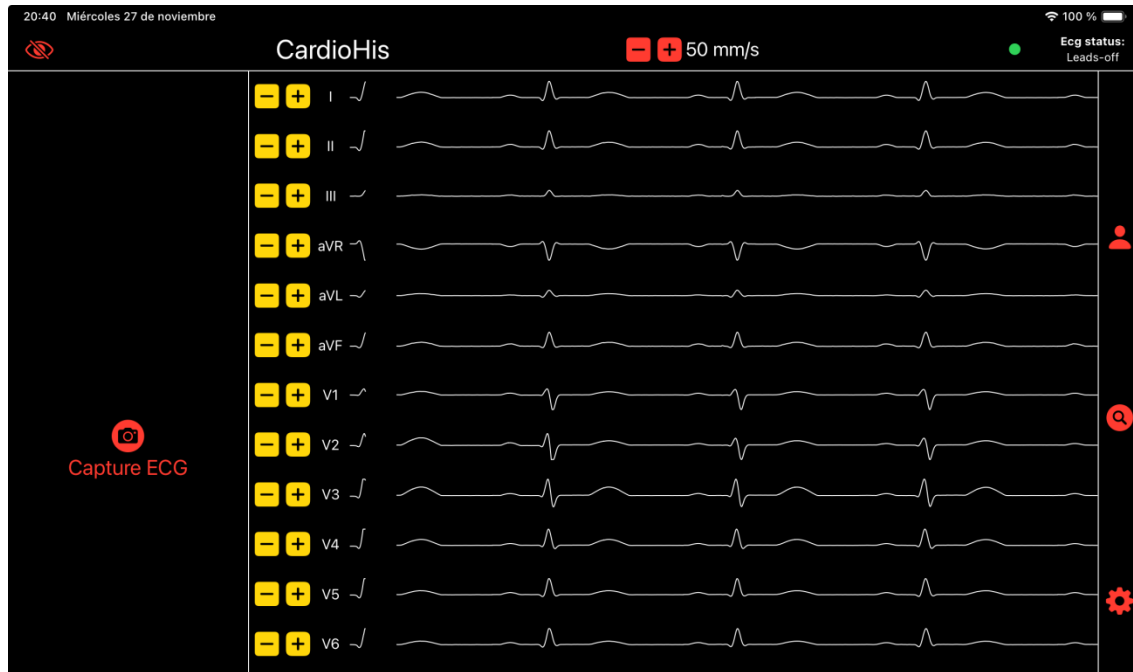
WARNING: The user is responsible for troubleshooting any detected issues before starting to use the device on a patient.

If one of the above steps fails, the device cannot be used. In this case, please restart the device (Power OFF and Power ON) and repeat the previous steps.

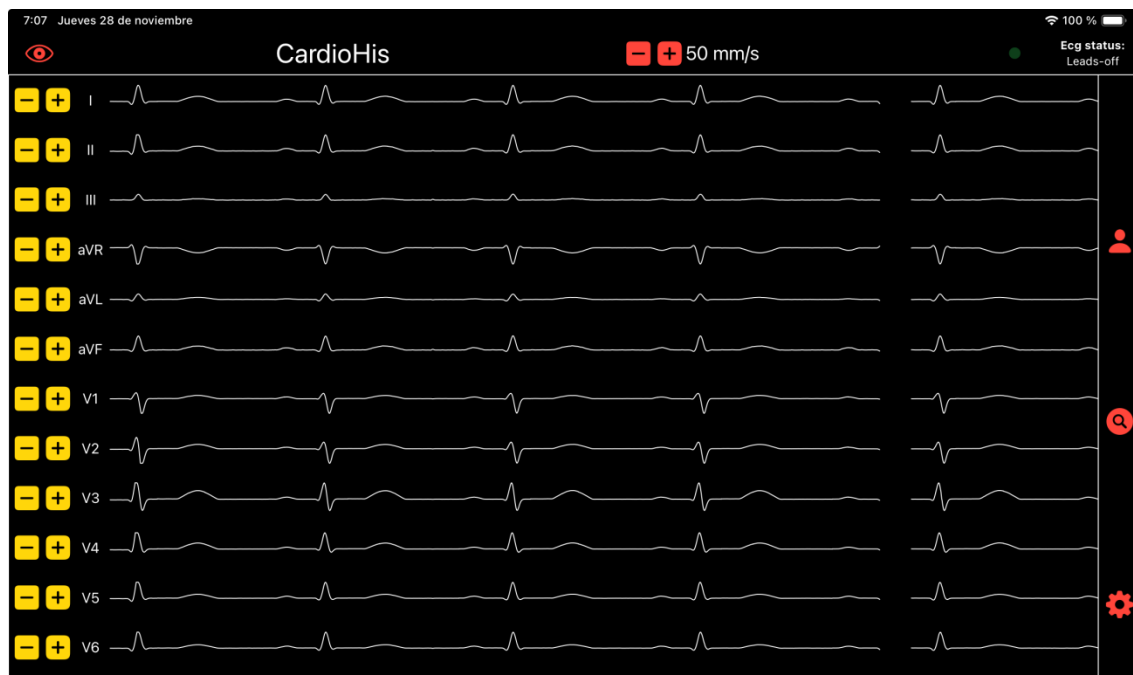
WARNING: If the errors found cannot be solved by restarting the system, do not use the device and contact the technical service.

11. General user interface

The main screen of the user interface displays the ECG signals simultaneously. The user interface must be operated by the touch screen.



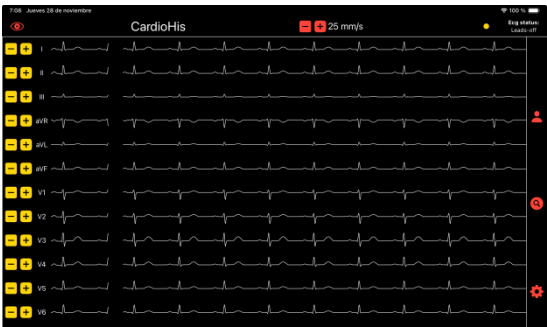
To view the signals in full screen, the user can press the icon . To return to the main screen, the user must press the icon .

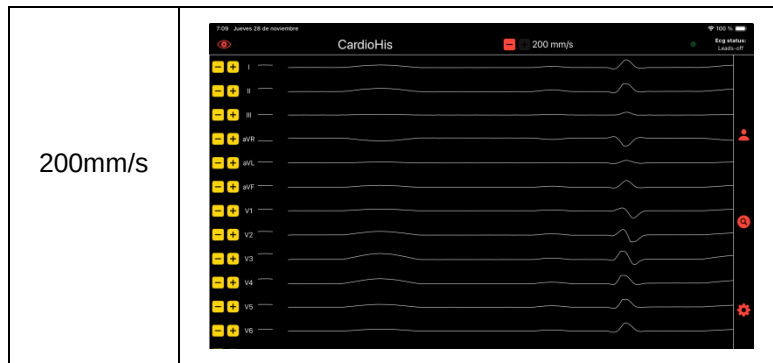


The functionalities of the main screen window are described in the following table:

Symbol	Function	Description
	Drawing speed	The rate at which the system displays a trace. The value is displayed in mm/s.
	Bluetooth connection status.	Bluetooth connection status. Flashing green circle indicates a good connection; the flashing orange circle indicates a medium strength connection and the flashing red circle indicates a poor connection.
Ecg status: Leads-off	ECG status	Status of ECG signals. OK will indicate that all leads have been detected and Leads-off will indicate that the system has not detected at least 1 lead
	Signal zoom	To zoom in and out each ECG signal.
 Capture ECG	ECG capture	Capture the displayed signals to use as reference signals.
	Procedure data	Enter the procedure ID information.
	Analyze window	To switch to the analysis window.
	Settings	To open the settings window.
	Print report	To save or print the final report of the current patient.

The following table shows different examples of plotting speeds:

25mm/s	
50mm/s	

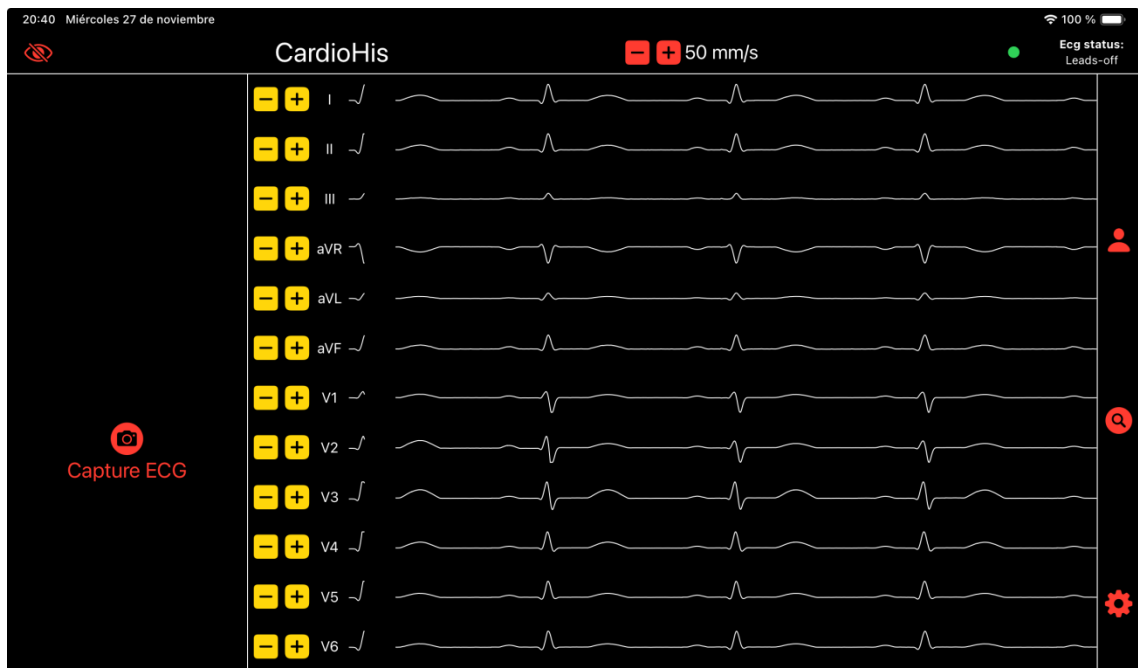


In addition, the main screen will display automatic real-time non-vital measurements such as heart rate, QRS width, and LVAT.

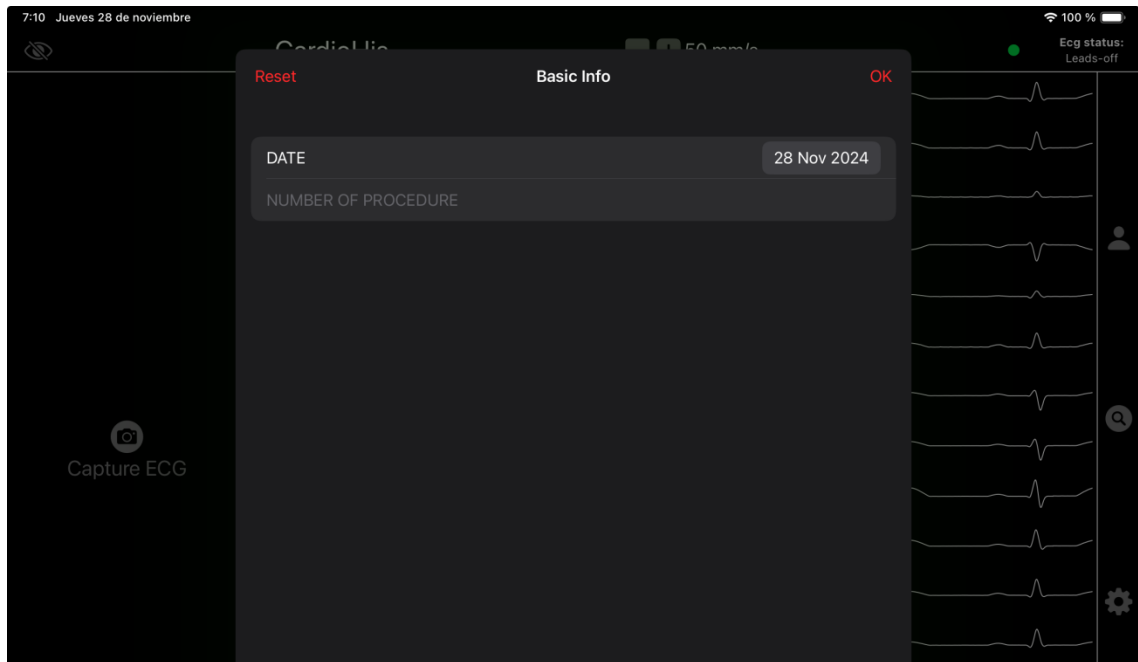
WARNING: CardioHis will ALWAYS be used to assist the physician in the study. The physician will NEVER make the final decision using only the information shown on the CardioHis.

11.1. Enter procedure data

To enter the procedure data, the user must select the patient option  on the main screen.



In the procedure information window, the user can enter a unique code to identify the current procedure. No personal information must be entered in this field.

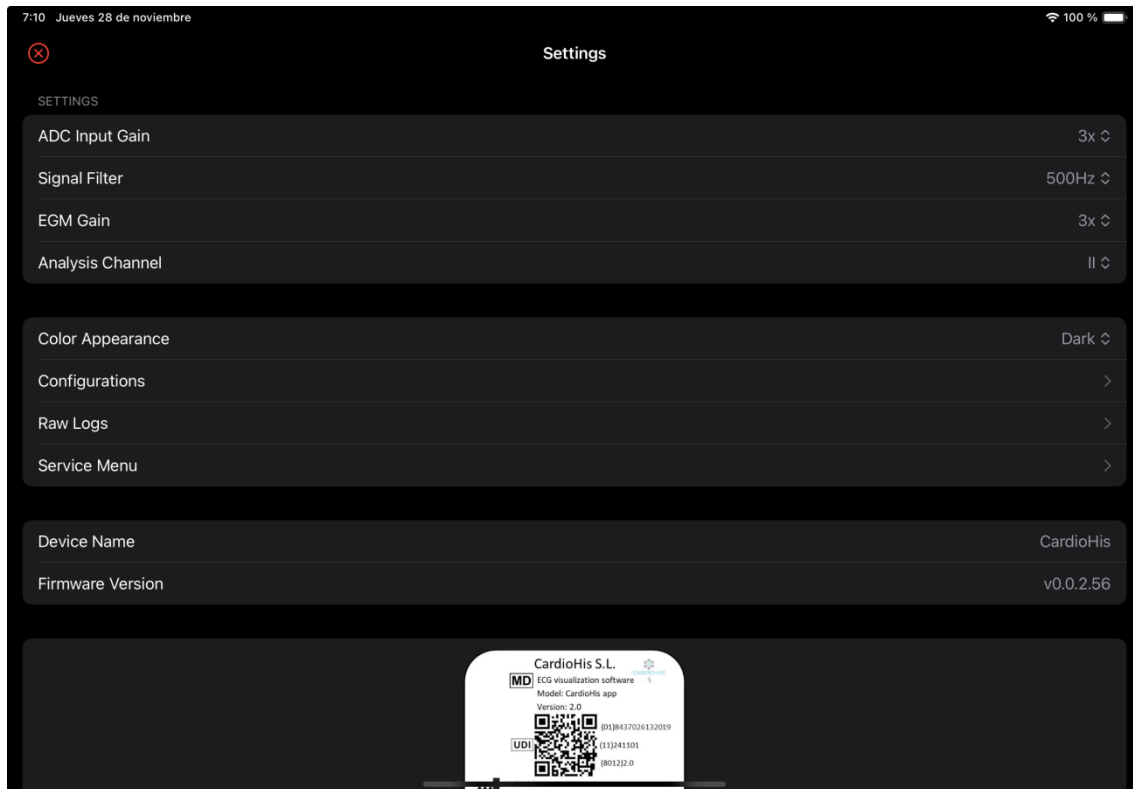


WARNING: CardioHis S.L. is not responsible for any safety issue related to access to patient personal data.

Finally, press the Reset button to reset the entered data if necessary or press the OK button to save the entered data and return to the main screen.

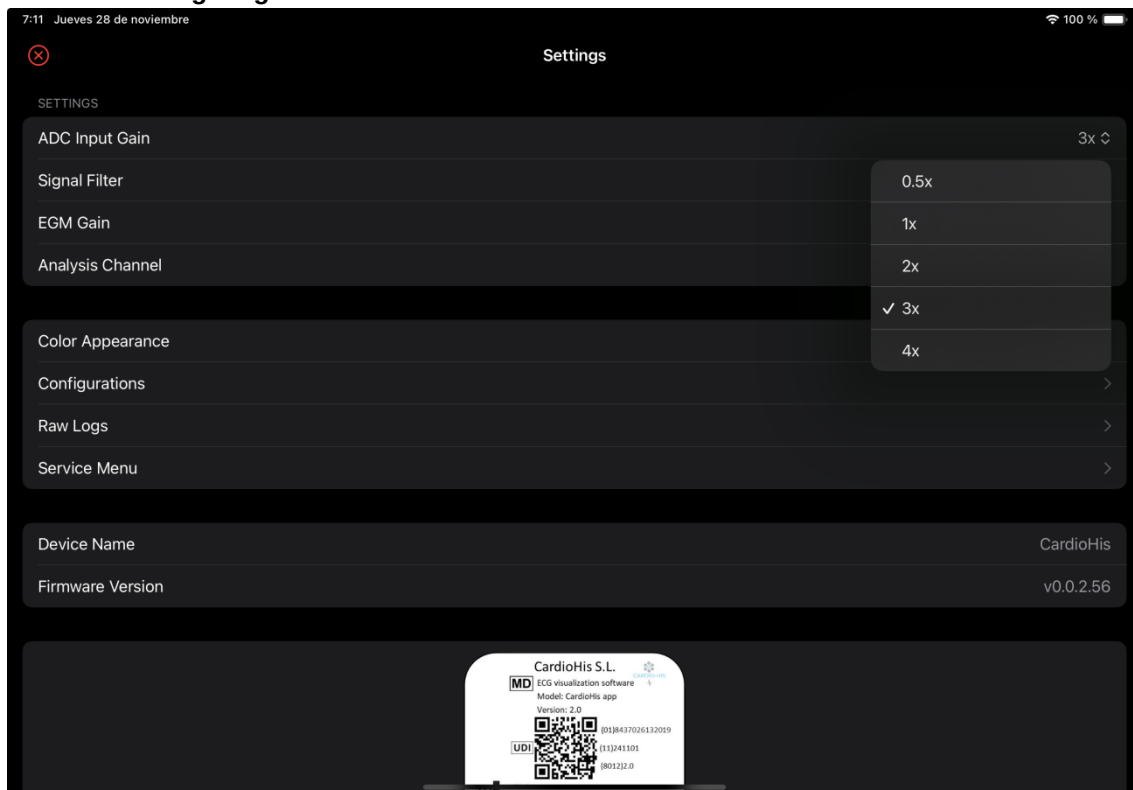
11.2. Adjustment

To configure the CardioHis acquisition and display parameters, the user must select the configuration option  on the main screen. The configuration window will open:

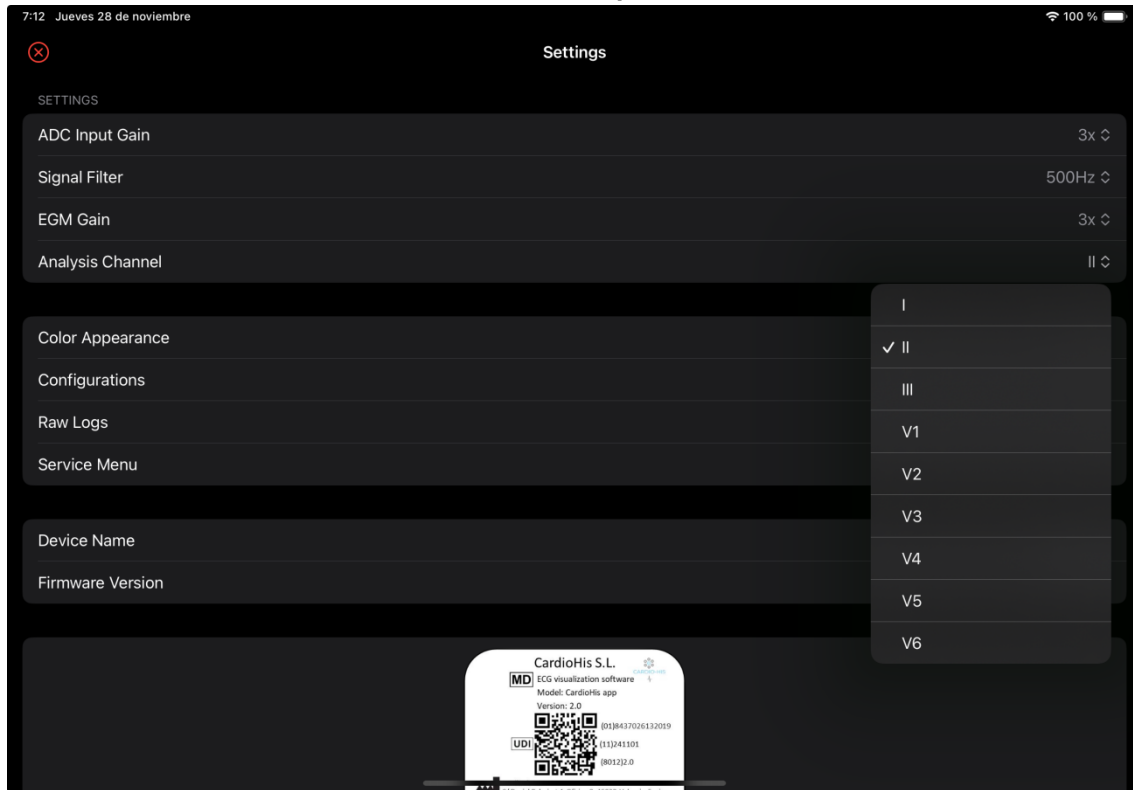


In this window, the user can adjust the following signal processing parameters:

- **ECG signal gain:** From 0.5x ECG to 4x ECG:

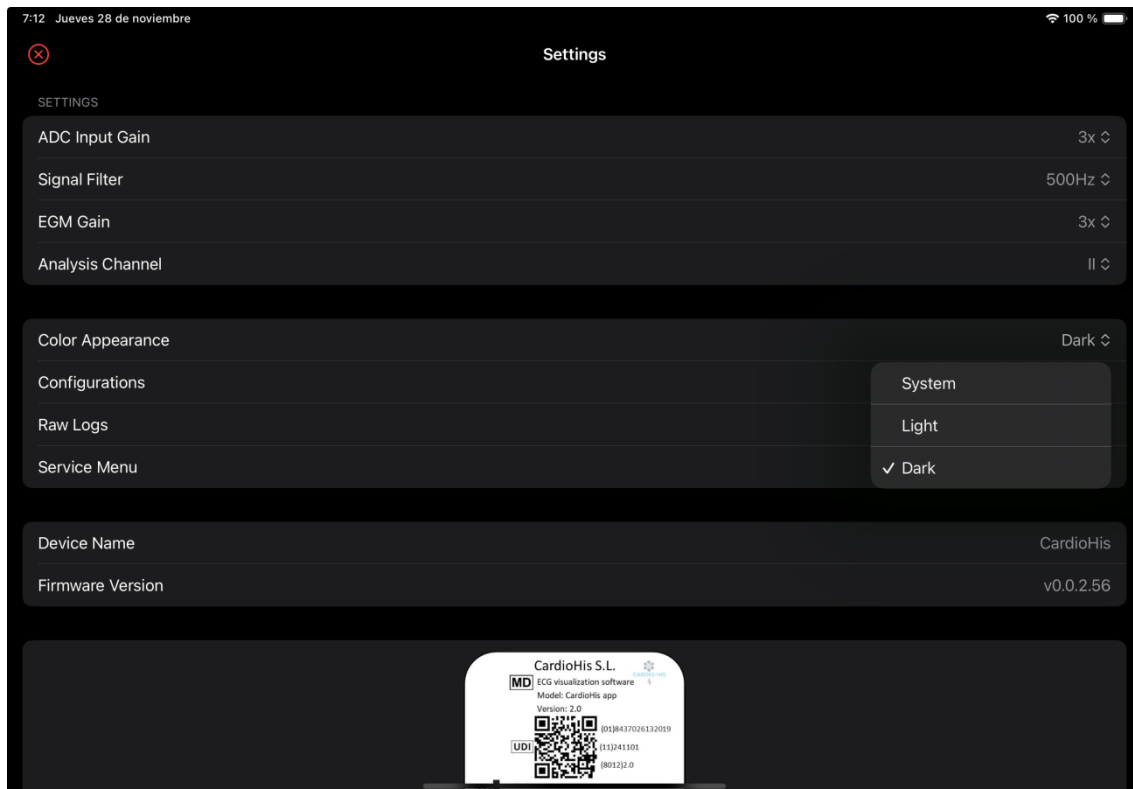


- Select the channel used to calculate the parameters

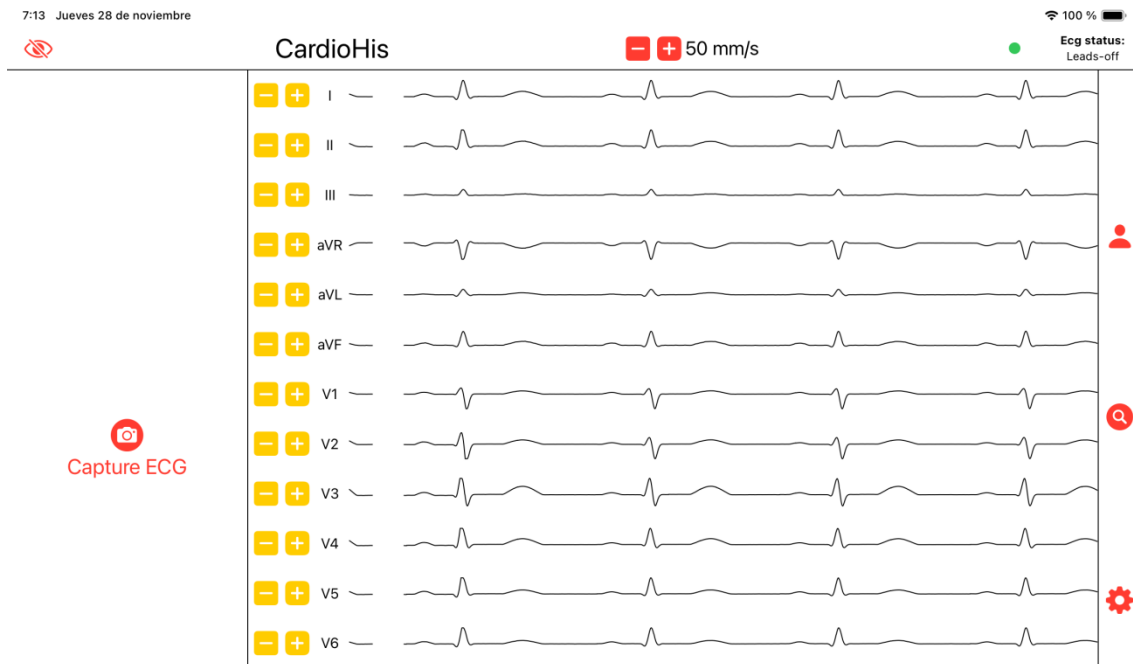


- Select the background color: dark, light or system

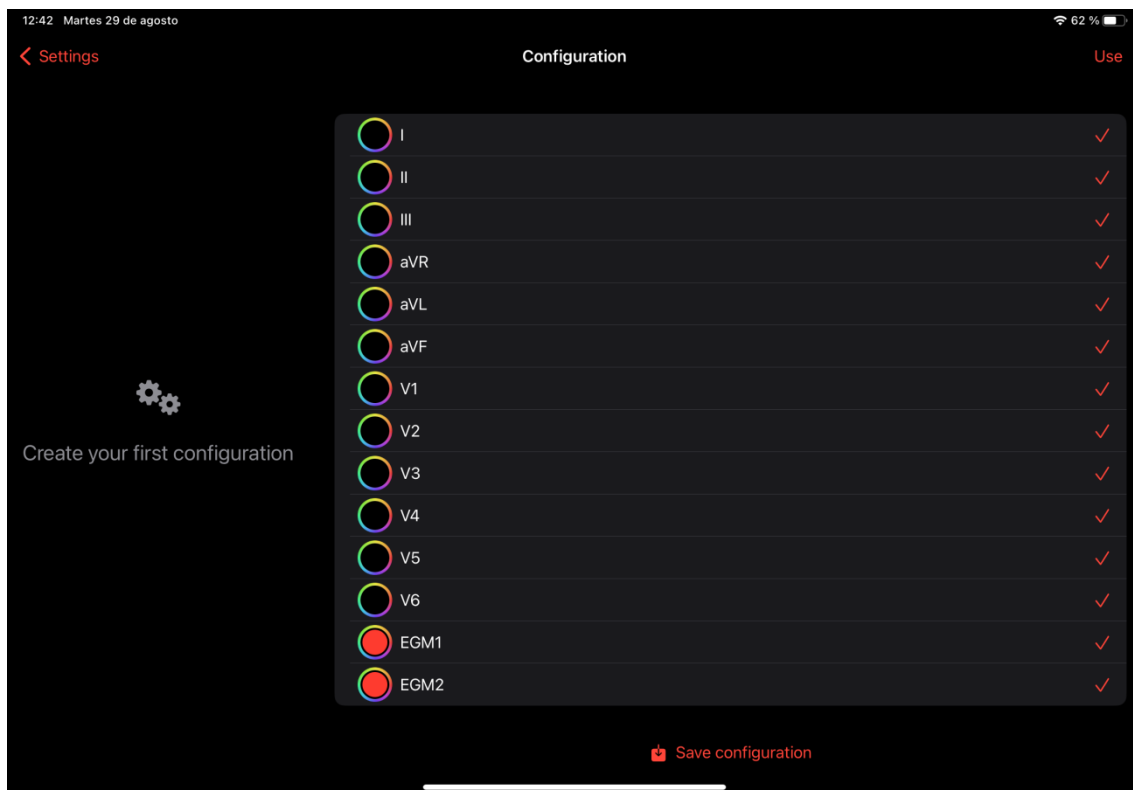
Dark:



Light:

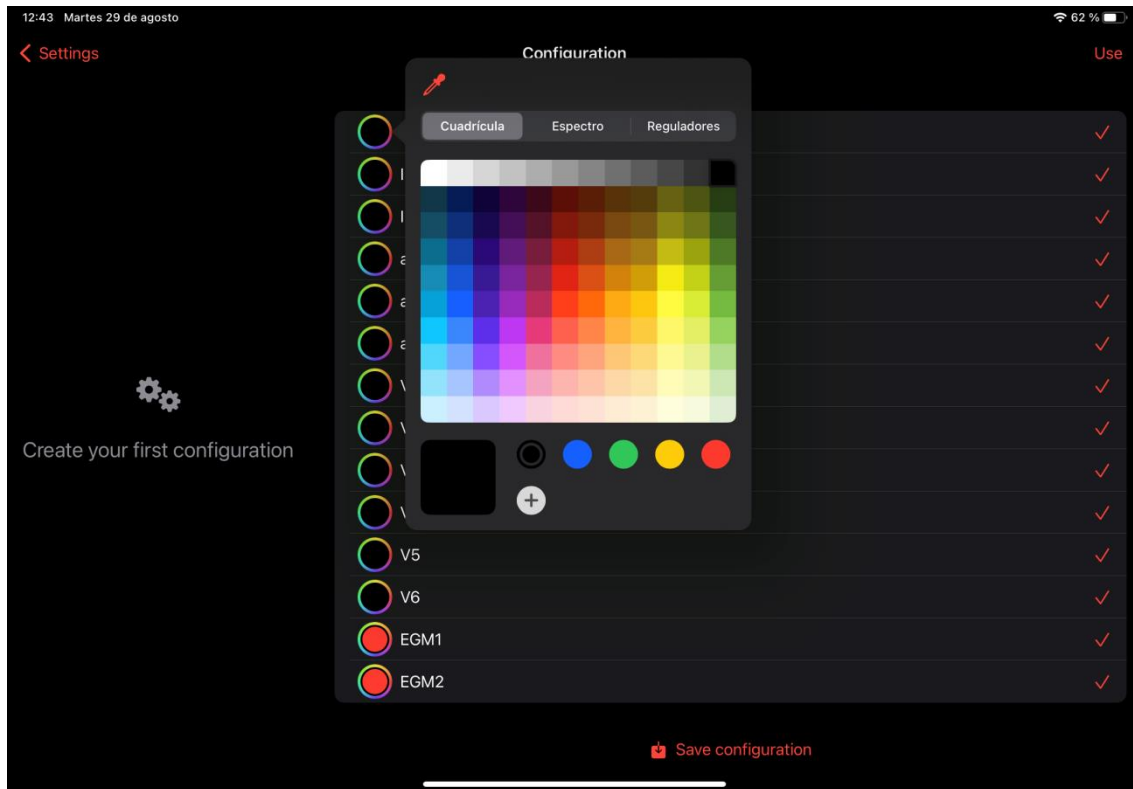


In addition, the user can select the signals to be displayed on the main screen, load a previous saved configuration and update the changes applied to the current one through the Configurations option. If necessary, the user could create a new configuration:

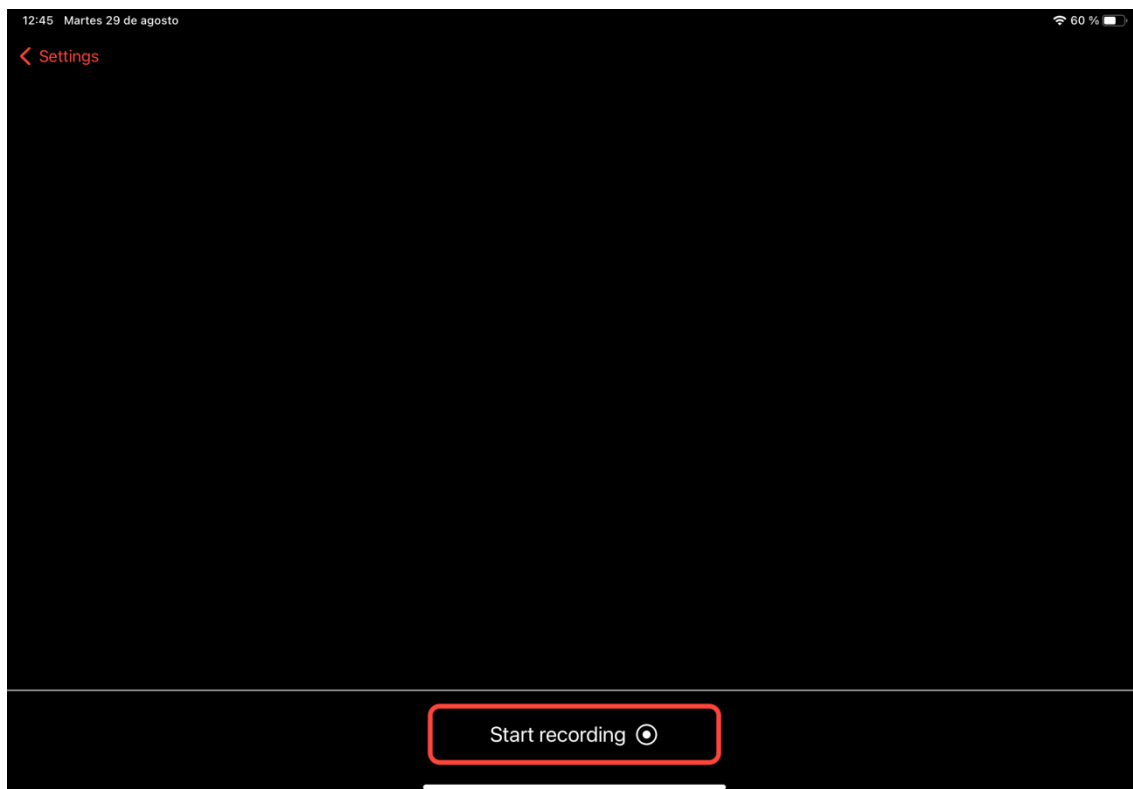


Press the Use button to apply the selected parameters, or the close button  to discard the changes.

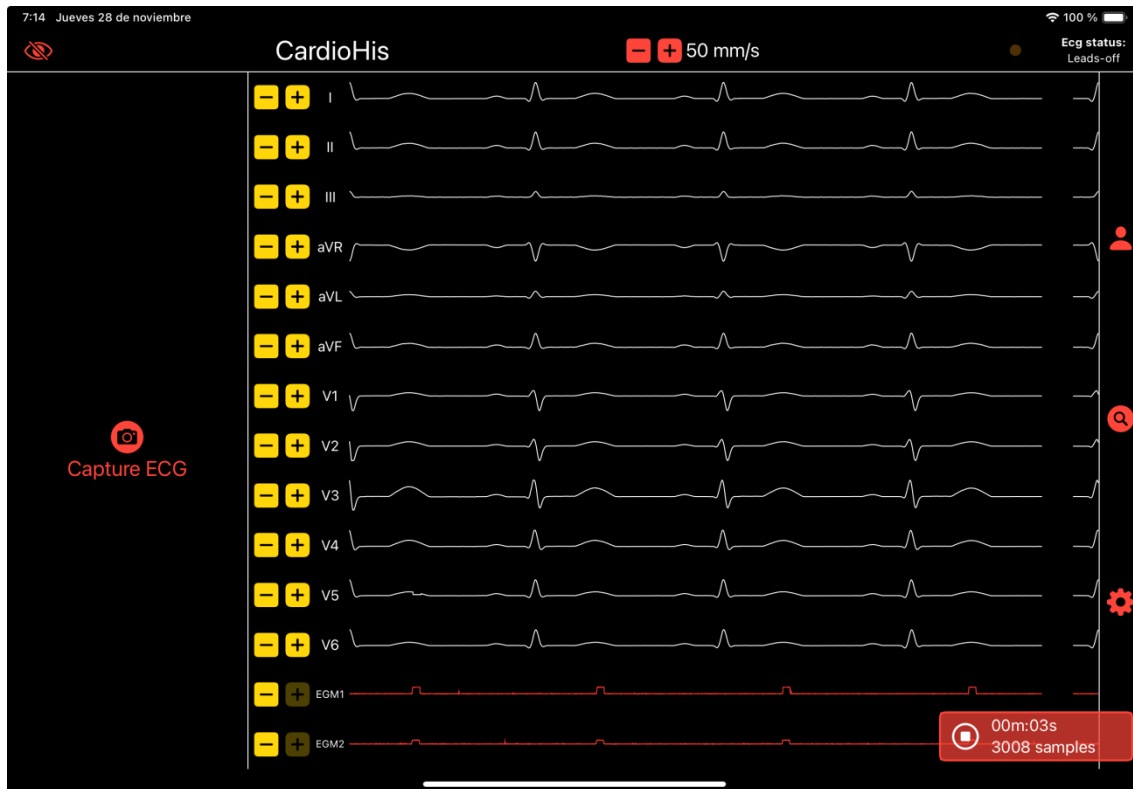
In the configuration window, the user can select the graphic color for each signal. Simply click on the circle located before the name of the signal to change:



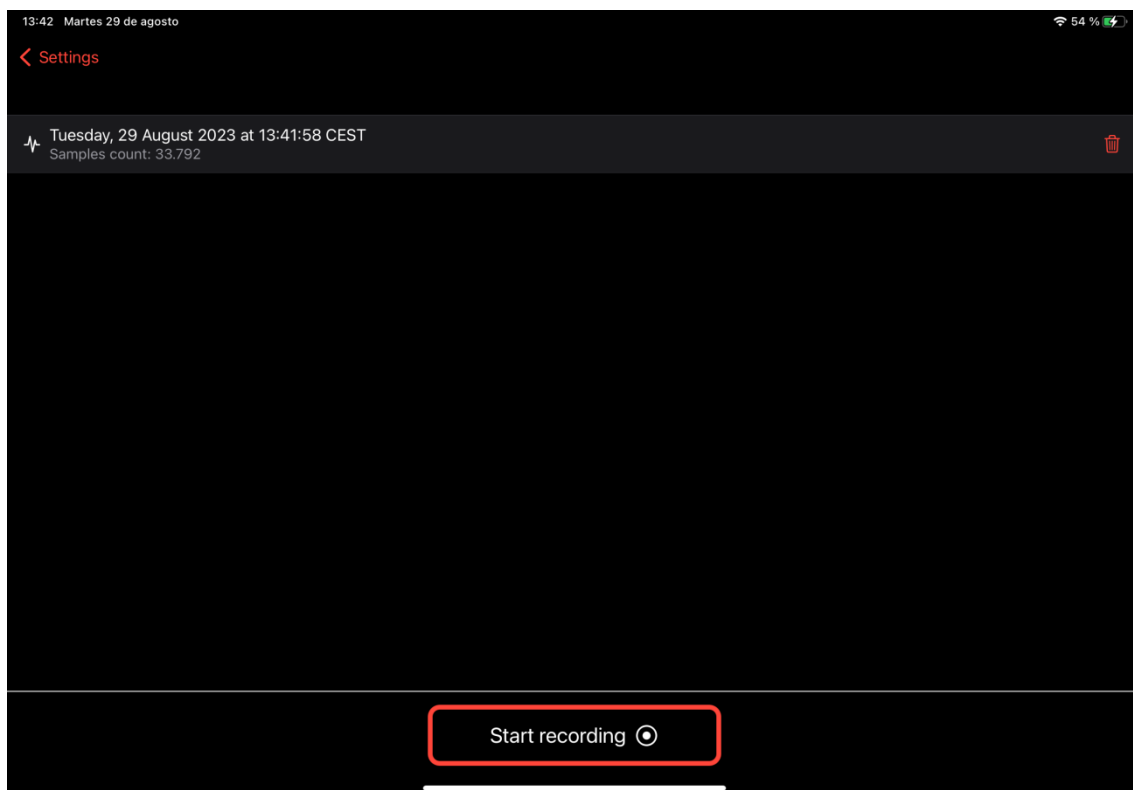
The Raw Logs option allows the user to save the acquired signals in text format:



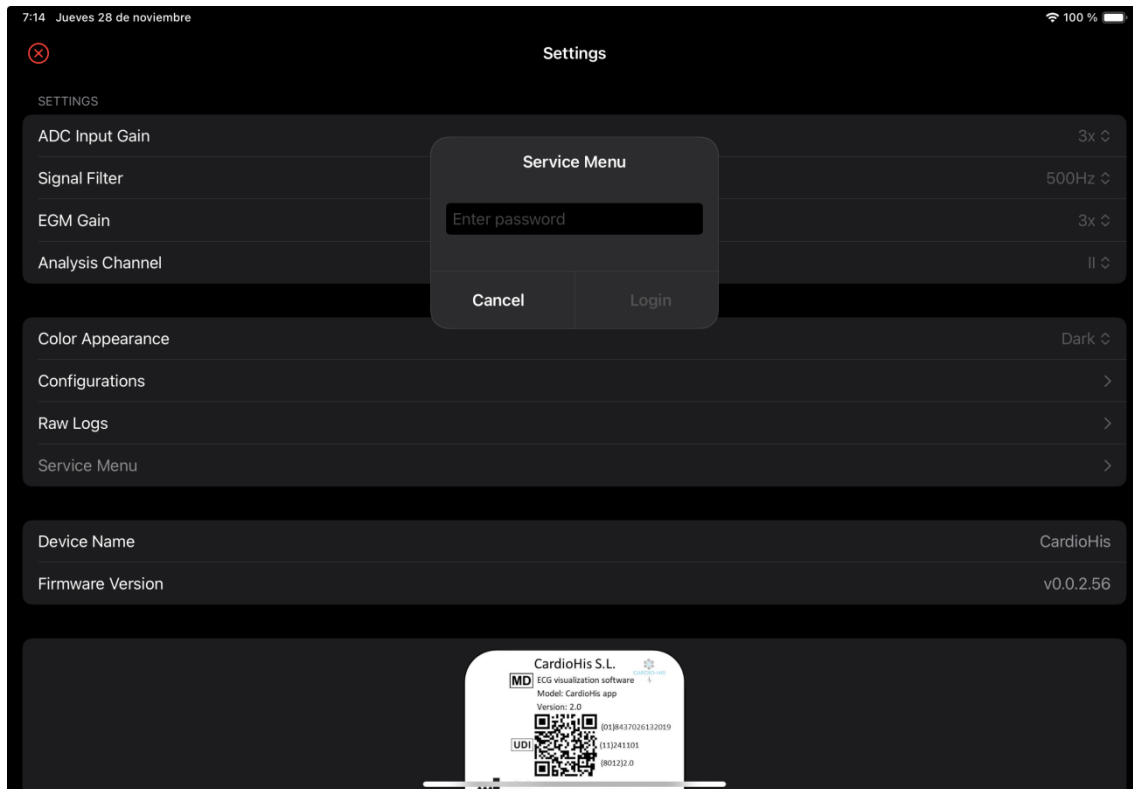
Pressing the Start recording button will start recording the data. To stop recording the user must press the Stop button at the bottom right of the screen:



The list of saved data can be seen on the Raw logs screen. The user may export said data for further analysis:

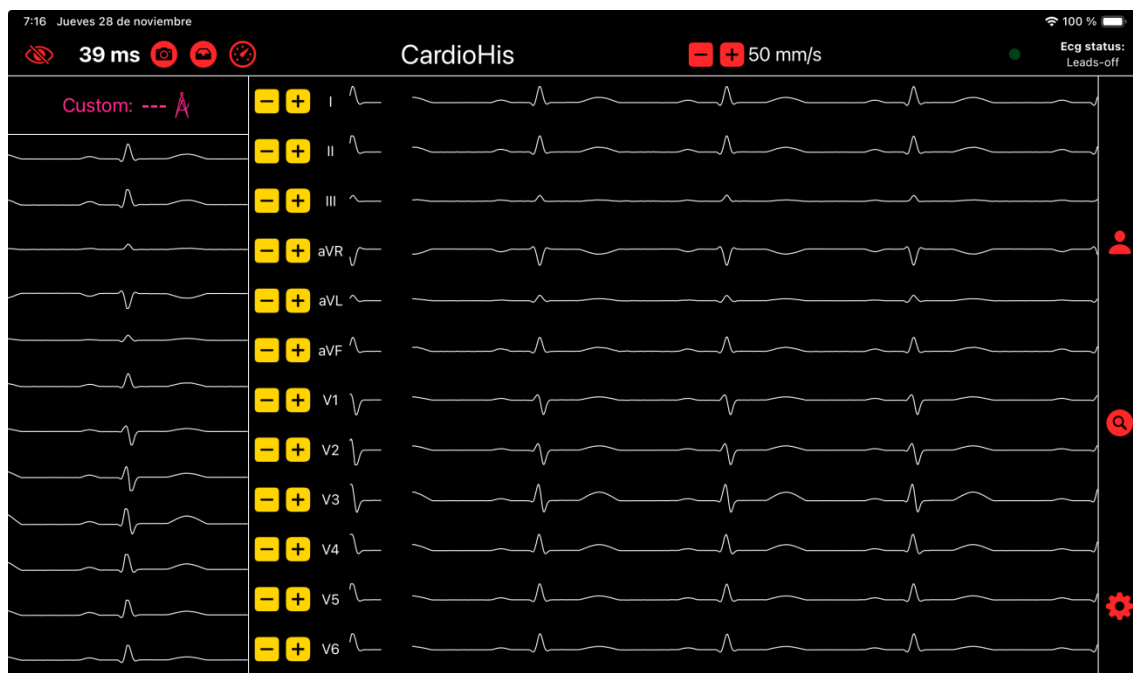


The Service Menu option allows access to the Technical Services/Manufacturing mode. This mode can only be accessed through a password that will be in the possession of the technical services group of CardioHis S.L.

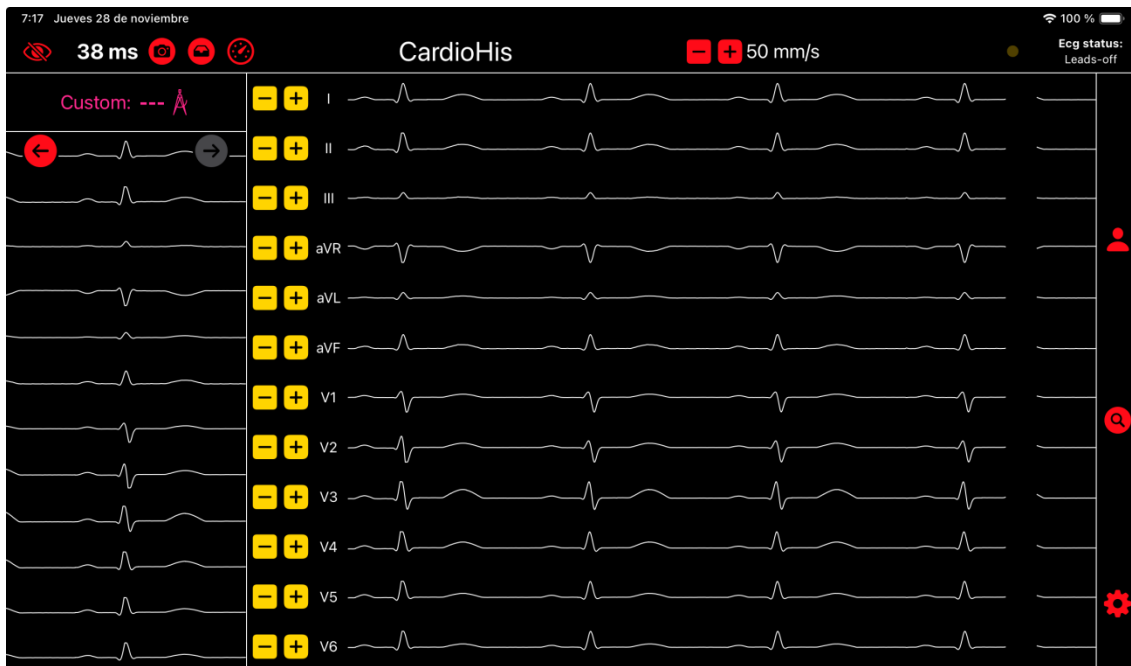


11.3. ECG capture

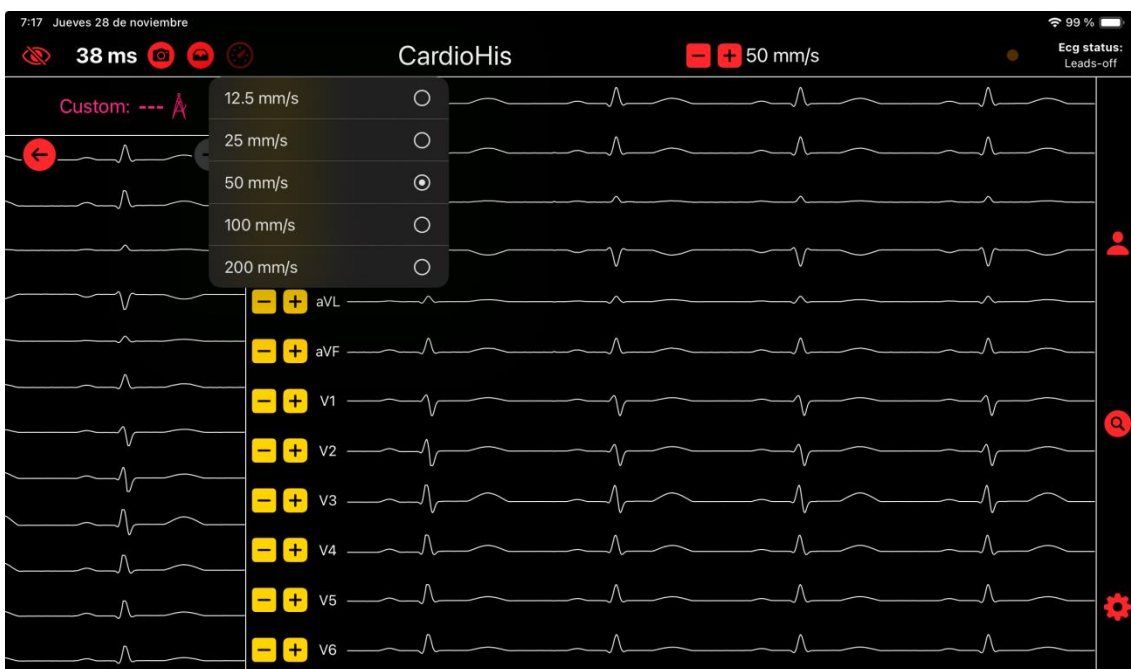
Pressing the Capture ECG button  on the main screen, the user can take a picture of the displayed signals to use for comparison purposes. The created image will be displayed in the Capture ECG area of the main screen:

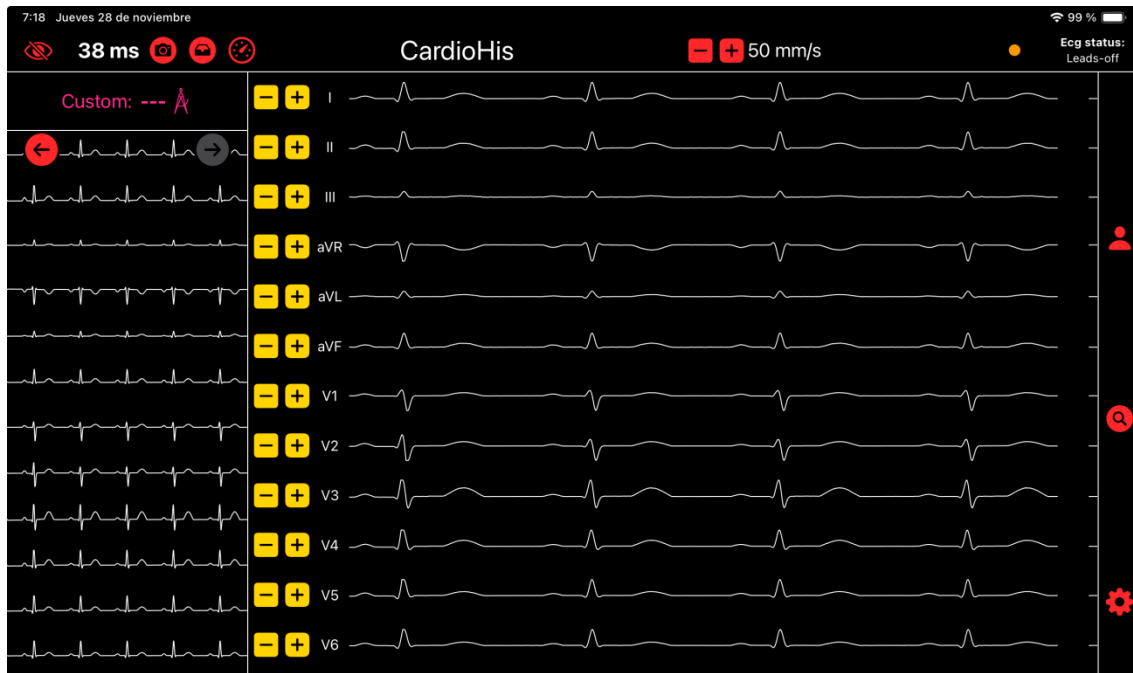


In this way, the user can take as many images as he needs using the image icon . To move between the acquired images, the left and right arrows of the ECG capture area must be used:



In addition, the user can select the desired trace speed of the captured ECG using the trace speed icon :





Captured images can be saved as references using the save references icon .

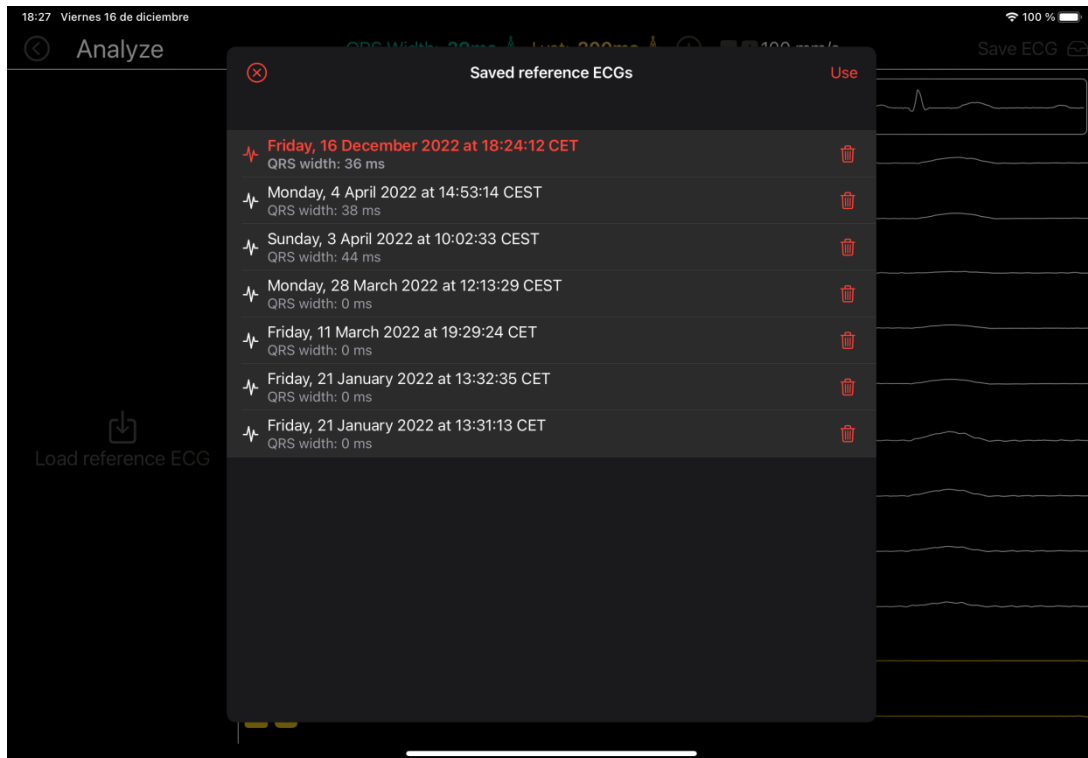
11.4. Analyze data

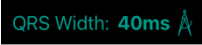
To switch to the Analyze window, press the Analyze button  on the main screen:

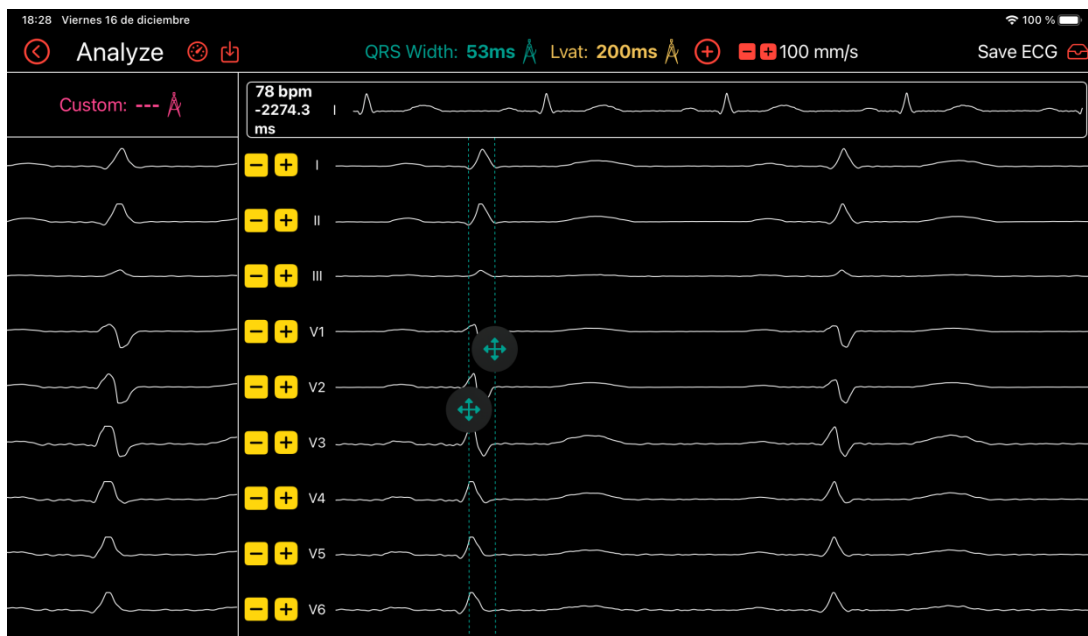


In this window the user can execute the following actions:

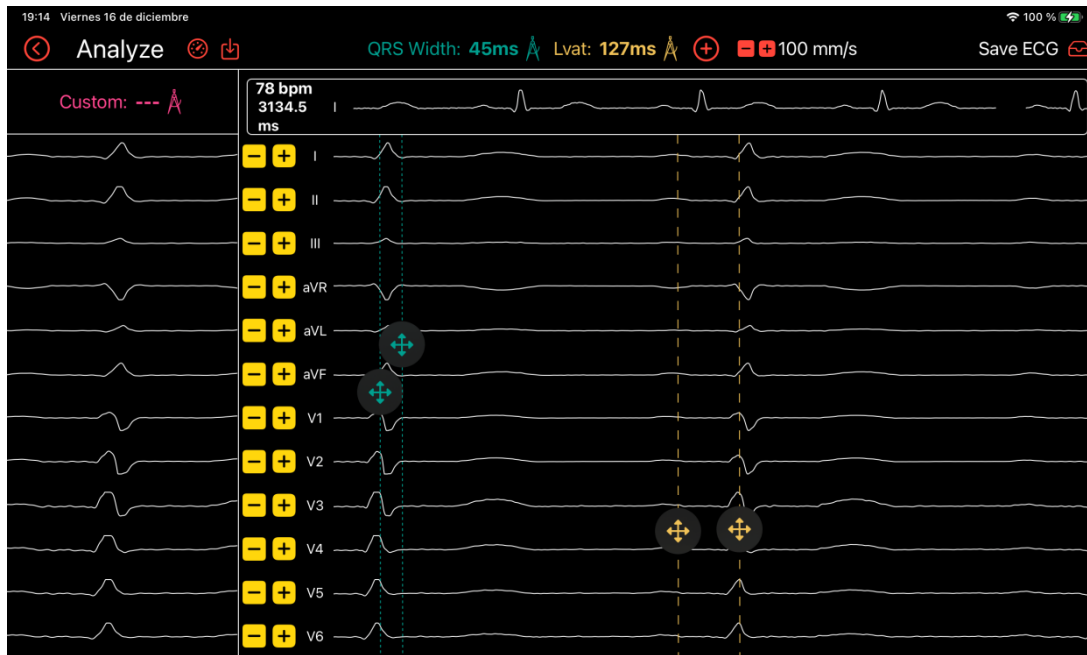
- Load saved reference images to the ECG capture window on the main screen: Press the Load Ref icon. 



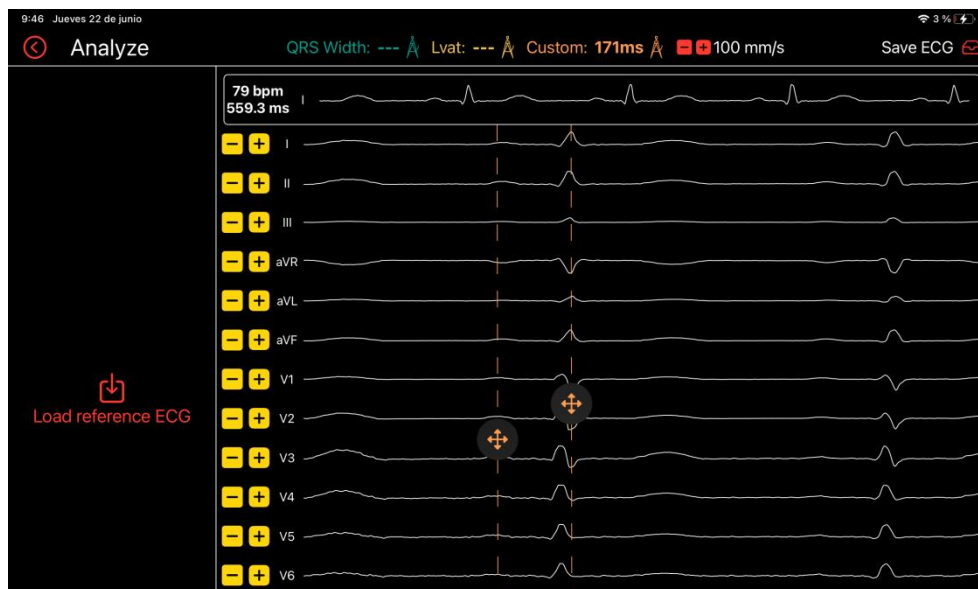
- Measure QRS Width manually: Press the QRS width edit icon . While measuring the QRS width, the QRS width text will be displayed in green color and 2 dashed lines will allow the user to select the start and end point of the QRS interval. The new measured value will be displayed.



- Measure LVAT manually: Click the LVAT edit icon . While measuring LVAT, the LVAT text will be displayed in yellow and 2 dashed lines will allow the user to select the start and end point of the LVAT interval. The new measured value will be displayed.



- If necessary, press the icon  to generate a new calibrator. The Custom text will be displayed in orange and 2 dashed lines will allow the user to select the start and end point of the new measurement. The value resulting from the measurement will be displayed.



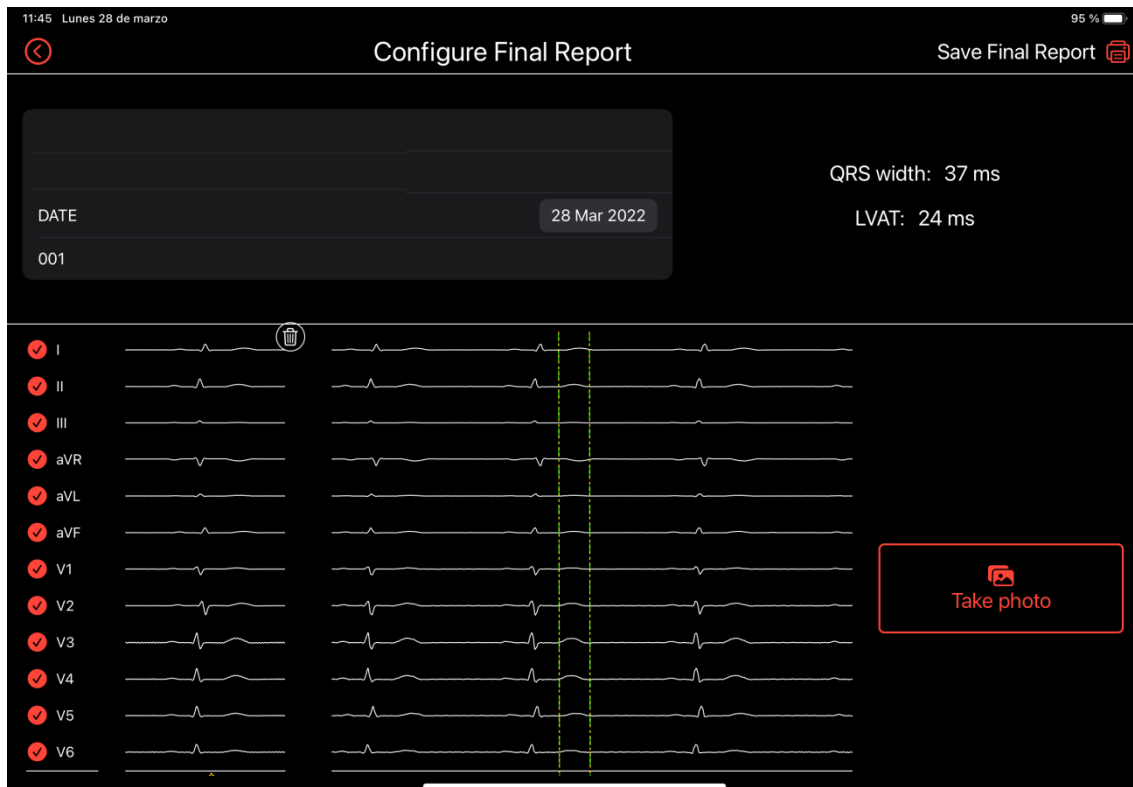
WARNING: CardioHis will ALWAYS be used to assist the physician in the study. The physician will NEVER make the final decision using only the information shown on the CardioHis.

- Save ECG: Press the Save ECG icon . The signals and measurements in the analyze window will be saved in the CardioHis Apple device as images in jpg format. After saving, the CardioHis application will automatically return to the main screen and the print icon will appear.  icon will be displayed in red.

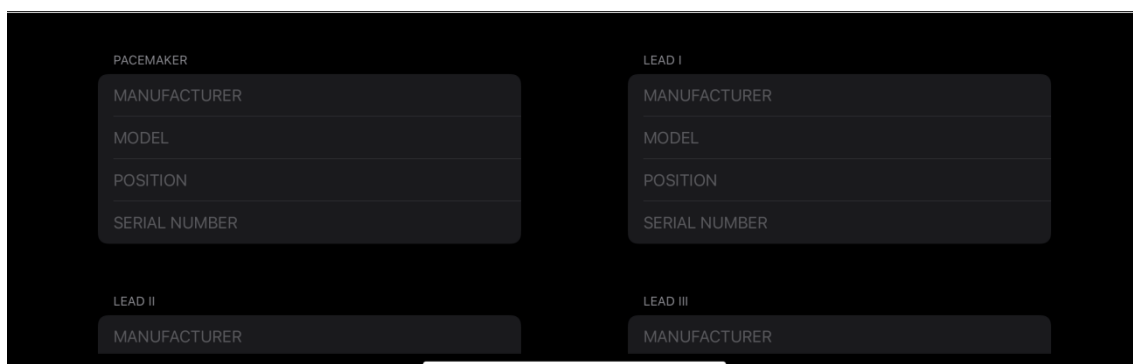
If necessary, tap the back arrow icon  in the analysis window to return to the main screen.

11.5. Print report

After saving the signals in the analysis window, the user can save or print the final report of the current patient. Press the print icon  on the main screen. The report print window will be displayed:



If necessary, the technical parameters of the cables used in the study can be entered:



You can add the name, address and telephone number of the hospital where the study was performed:

11:47 Lunes 28 de marzo

94 %

Configure Final Report

Save Final Report

SERIAL NUMBER

SERIAL NUMBER

LEAD II

MANUFACTURER

MODEL

POSITION

SERIAL NUMBER

LEAD III

MANUFACTURER

MODEL

POSITION

SERIAL NUMBER

CABLES

DETECTION

IMPEDANCE

THRESHOLD

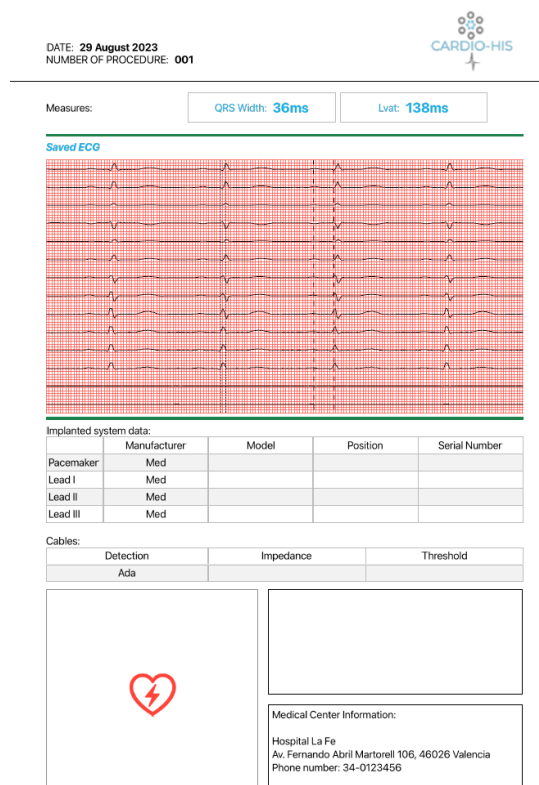
NOTES

MEDICAL CENTER INFORMATION

Hospital La Fe de Valencia
Av. Fernando Abril Martorell 106, 46026 Valencia
Phone number: 5555555555

In addition, the user can take some photos of the operating room, fluoroscopy images, etc. using the Take Photo icon.

To generate the final report in pdf format, use the Save Final Report icon in the upper right corner of the screen. Below is an example of a generated report:



12. Device disconnection

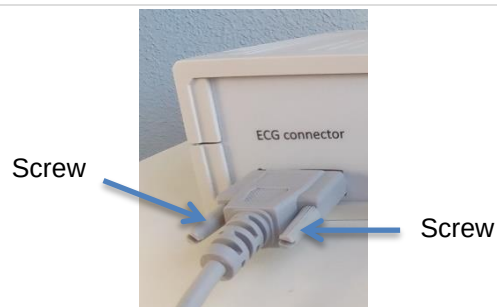
1. Disconnect the MEAN WELL / GSM25E05-P1J adapter from external power supply

Disconnect the MEAN WELL / GSM25E05-P1J external power supply adapter cable at the back of the device under the label indicating 5VDC.



2. Disconnect the ECG cable

Disconnect the ECG cable using the two screws available for this purpose and disconnect the ECG cable at the back of the device under the label indicating ECG CONNECTOR.



13. Training courses required for the use of CardioHis

Some initial and periodic training is required for the use, marketing and servicing of CardioHis. The description of the courses, the duration, the frequency, the objective and the target user profiles are summarized in the following table:

Training Course	Frequency	Duration	Expected use	user profile
Clinical training	Annual	3 hours with practical test	Use of CardioHis in patients, wiring installation, application, safety regulations	clinical staff
Technical formation	Annual	4 hours with practical test	Wiring installation, periodic review, general verification of the device, application, safety regulations.	Technical staff with experience in ECG studies

14. Warranty

CardioHis SL guarantees this product against any manufacturing or material defect for one year from the date of purchase.

The guarantee includes the repair, replacement or exchange of the product and/or components without charge to the customer, including labour and materials. Transportation costs are not included.

This guarantee does not include disposable elements, consumables or accessories such as ECG cables (included in the maintenance contract, see conditions).

This guarantee will not be valid under the following conditions:

- When the use and care of the device have not been in accordance with the instructions contained in this manual.
- When the failure is due to incorrect use of the equipment.
- When the product has been opened or maintained by unauthorized personnel or companies formed by CardioHis SL

15. Cleaning

WARNING: Before cleaning the device, turn it off and disconnect it from the mains.

Clean the acquisition device with a damp cloth soaked in a mild detergent. It is important to dry the device after cleaning. Use standard wipes to disinfect surfaces and clean the body of the unit, terminals and appliances. The Apple device touch screen can be cleaned with ammonium wipes for better disinfection.

WARNING: ECG cable must be checked and cleaned if required between patients.



Do not sterilize the device or accessories in a steam or liquid autoclave.



Do not use fats or oils for cleaning.

15.1. Disposing devices and kits

Devices must be disposed of in accordance with the European Directive for Waste Electrical and Electronic Equipment (WEEE). Please consult local authorities to proceed.

Disposable kits must be disposed of in accordance with hospital recycling guidelines. Take into account the possible contamination of the components of the kits to be discarded.

16. Technical specifications

16.1. Physical specifications

Dimensions (height x width x length)	CardioHis	220x190x80mm
	iPad device	250x170x5mm
Weight	CardioHis	1 kilogram
	iPad device	0.5kg
Materials	ABS	
IP rating	20	

16.2. Operating and storage conditions

	Temperature	Humidity	relative pressure
Operating conditions	10 – 35°C	15 - 90%	65.0 - 102 kPa
Storage conditions	-10 – 60°C	15 - 90%	50.0 - 102 kPa

16.3. ECG signals measuring specifications

ECG signals amplitude range	0.5mV-2mV
ECG signals Heart rate range	30 BPM-240 BPM
Manual measuring accuracy	≥ 95%
Manual measuring variation between devices	≤4%
Manual measuring drift over time (after 24 hours turned on and acquiring signals)	≤4%

16.4. Electric specifications

Power supply	100 – 240 V AC, 50 – 60 Hz, 2 A max.
	MEAN WELL / GSM25E05-P1J external 5V 0.4A power adapter.
	The adapter meets the following parameters: <ul style="list-style-type: none"> • Euro Connector, class II • Medical grade (2 × MOPP) EN 60601-1 • Short circuit protection
	Device designed for continuous operation

Normative	EN 60601-1-2:2015
	EN 60601-1:2008 + A12:2015
	EN 60601-2-25:2016 (Basic safety)
Classification	Class IIa

16.5. Software and Firmware Specifications

Software version	2.0
Firmware version	2.0
Important Software Safety Considerations	<ul style="list-style-type: none"> - None of the PROGRAMMABLE ELECTRONIC SUBSYSTEMS (PESS) provide the functionality required for BASIC SAFETY FOR ESSENTIAL PERFORMANCE - Firmware or software failures do not create an unacceptable RISK

16.6. Radio Frequency Electromagnetic Specifications

Reception frequency band	2.4-2.483GHz (<i>Bluetooth 5.0</i>)
Reception frequency band	2.4-2.483GHz (<i>Bluetooth 5.0</i>)
Receiver Sensitivity	-98dBm (at 1Mbps)
Effective Radiated Power (ERP)	+3dBm to -20dBm (programmable)

16.7. Essential performance and basic safety

Essential performance: The equipment does not have essential features.

Basic safety: CardioHis is designed to prevent physical harm to patients and operators in the event of:

- Electrostatic discharges and other high energy pulses.
- Chassis leakage currents.
- Mechanical risks.
- Defibrillation pulses.

WARNING: CardioHis has been designed and tested according to the basic safety of the harmonised standard EN/IEC 60601-2-25. Essential performance tests of the harmonised standard EN/IEC 60601-2-25 has not been executed because CardioHis does not have essential features.

WARNING: All EMC instructions in this manual must be followed to maintain basic safety for the life of the equipment.

16.8. Electromagnetic and RF Specifications

Guidance and manufacturer's declaration - electromagnetic emissions		
CardioHis is intended for use in the electromagnetic environment specified below. The user of the CardioHis must ensure that it is used in a safe environment.		
Emission test	Accord ance	Electromagnetic environment - Guidance
RF emissions CISPR 11	Group 1	CardioHis uses radio frequency energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic devices.
RF emissions CISPR 11	A class	CardioHis is suitable for use in all locations other than those assigned in residential settings and those directly connected to a low voltage power supply network that powers buildings used for domestic purposes.

WARNING: Portable RF communication equipment (including peripherals such as antenna cables and external antennas) should not be used closer than 12 inches (30 cm) to any part of the CardioHis, including cables specified by the manufacturer. Failure to do so may result in performance degradation of this equipment.

NOTE! The EMISSIONS characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If used in a residential ENVIRONMENT (for which CISPR 11 class B is normally required), this equipment may not provide adequate protection for radio frequency communication services. The user may need to take mitigation measures, such as relocating or reorienting the equipment."

Guidance and manufacturer's declaration - electromagnetic immunity		
CardioHis is intended for use in the electromagnetic environment specified below. The user of the CardioHis must ensure that it is used in a safe environment.		
Immunity test	Standard or test method	Compliance level
Electrostatic discharge (ESD)	IEC 61000-4-2	±8kV per contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air
Radiated RF electromagnetic fields	IEC 61000-4-3	3 V/m, 80 MHz – 2.7 GHz, 80% AM at 1 kHz
Wireless RF proximity fields. Communication equipment	IEC 61000-4-3	See reference in the following table
Rated Power Frequency Magnetic Fields	IEC 61000-4-8	30 A/m, 50Hz or 60Hz
Conducted disturbances induced by RF fields	IEC 61000-4-6	3V, 0.15 – 80MHz 6V in ISM bands between 0.15 – 80 MHz 80% AM at 1kHz
NOTE: UT is the AC supply voltage before application of the test level. Interference may occur		

in the vicinity of devices marked with the following symbol:



Recommended distances between portable or mobile RF communication devices and CardioHis

CardioHis is intended for use in an electromagnetic environment in which RF radiation is controlled. The user can help prevent electromagnetic interference by maintaining a minimum distance between portable or mobile RF communication devices (transmitters) and the CardioHis as recommended below, according to the maximum output power of the communication devices.

Maximum output power of the transmitter(W)	Distance according to transmitter frequency(meter)		
	150kHz to 80MHz	80MHz to 800MHz	800MHz to 2.5GHz
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.74
1	1.2	1.2	23
10	3.8	3.8	7.3
100	12	12	23

For transmitters with a maximum output power not listed above, the recommended distance d in meters (m) can be determined using the equation applicable to the frequency of the transmitter, where P is the manufacturer's maximum output power in watts (W) of the transmitter.

NOTE 1: At the frequencies of 80 MHz and 800 MHz, the distance applies for the higher frequency range.

NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

Specifications for cabinet port immunity to RF wireless communication equipment

Test frequency (MHz)	Band (MHz)	Service	Modulation	Max power (W)	Distance (m)	Immunity level (V/m)
385	380 - 390	TETRA 400	18Hz pulse modulation	1.8	0.3	27
450	430 - 470	GMRS 460, FRS 460	FM $\pm$ 5kHz deviation 1kHz sinusoidal	2	0.3	28
710	704 - 787	LTE band 13, 17	217 Hz pulse modulation	0.2	0.3	9
745						
780						
810	800 - 960	GSM 800/900, TETRA 900, iDEN 820, CDMA 850, LTE band 5	18 Hz pulse modulation	2	0.3	28
870						
930						
1720	1700 -	GSM 1800, CDMA	217 Hz pulse	2	0.3	28

1845	1990	1900, GSM 1900, DECT, LTE band 1, 3, 4, 25, UMTS	modulation			
1970						
2450	2400 - 2570	Bluetooth, WLN 802.11 b/g/n, RFID 2450, LTE band 7	217 Hz pulse modulation	2	0.3	28
5240	5100 - 5800	WLN 802.11 a/n	217 Hz pulse modulation	0.2	0.3	9
5500						
5785						

WARNING: The expected life of the unit will be compromised if the electromagnetic environment is not suitable.

17. Troubleshooting

Problem	ID	Solutions
ECG signal problems	Low quality ECG signal	<ul style="list-style-type: none"> Check the ECG cable and connections are correct. Check the connection of the electrodes on the patient. Use gel to improve contact with the skin and preferentially select areas without hair. Keep ECG cables as far as possible from power cables (220V), the floor and metal surfaces (especially the surgical table).
Communication between CardioHis and Apple device problem	CardioHis and Apple device disconnection	<ul style="list-style-type: none"> Bring the Apple device and CardioHis closer (5m or less). Restart the CardioHis app (Close and Open).
CardioHis turn On problem	CardioHis does not turn ON	<ul style="list-style-type: none"> Check the MEAN WELL / GSM25E05-P1J external 5V 0.4A power adapter connection. Substitute the MEAN WELL / GSM25E05-P1J external 5V 0.4A power adapter.
CardioHis app does not open, closes or frozen unexpectedly or the Apple device turn off unexpectedly	Apple device powered Off abruptly or the signals are not properly displayed.	<ul style="list-style-type: none"> Restart the Apple device (Power OFF and ON). Restart the CardioHis app (Close and Open).
Power outage	CardioHis device turned off suddenly	<ul style="list-style-type: none"> Acquire the ECG signals with another ECG signals acquisition devices.
General failure of the device	CardioHis device turned off suddenly	<ul style="list-style-type: none"> Acquire the ECG signals with another ECG signals acquisition devices.

WARNING: If the problems found cannot be solved by indicated solutions, contact the technical service and do not use the CardioHis device.