

INSTRUCTIONS FOR USE



SOFTWARE VERSION

1.0.0



PLEASE READ THIS DOCUMENT CAREFULLY BEFORE USING VR-CARDIO



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PATENT NOTICE: This system is covered by the following patent register: European Patent Office. No. 23 382 800.3



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List of acronyms

| Abbreviation | Meaning |
|--------------|---|
| A/D | Analog to digital |
| AF | Atrial Fibrillation |
| ΑΡΙ | Application Programming Interface |
| AR | Augmented Reality |
| AEMPS | Spanish Agency of Medicines and Medical Devices |
| CPU | Central Processing Unit |
| DICOM | Digital Imaging and Communications in Medicine |
| ECG | Electrocardiogram |
| ECGi | Electrocardiographic imaging |
| EP | Electrophysiology |
| FZM | Fibrillation Zones Map |
| FPS | Frames Per Second |
| GPU | Graphics Processing Unit |
| GUI | Graphical User Interface |
| ID | Identity |
| PC | Personal Computer |
| VR | Virtual Reality |



1. Introduction

VR-CARDIO is a clinical-use system focused on improving cardiac care by offering the ability to aid in the diagnosis and visualization of cardiac arrhythmias. It uses a non-invasive external data acquisition system, going beyond traditional, invasive catheter-based methods. It accurately depicts transmembrane and cardiac action potentials from the electrocardiogram, showing the origins of cardiac arrhythmias in precise detail. By employing advanced stereoscopic Virtual Reality (VR) and 360° Augmented Reality (AR) visualization, which can also be holographic, it enables near real-time monitoring of the heart's electrical activity, improving the efficiency of cardiac care procedures. This innovative approach marks a significant advance in efficient and non-invasive cardiac treatment.

The user will find detailed information on the technical specifications of the system, operating instructions, safety protocols, methods for accurate data interpretation and practical examples. IFU is not only an essential tool to take full advantage of VR-CARDIO's innovative capabilities but also ensures compliance with the regulations established by the Spanish Agency of Medicines and Medical Devices (AEMPS). VR-CARDIO is aimed at cardiologists, electrophysiology technicians and other professionals in the sector, and this document is key to effectively use and implement VR-CARDIO, thereby improving the efficiency of cardiac care procedures and raising the standard of care for patients.

1.1 Intended use

VR-CARDIO family is intended for use by electrophysiologists and cardiology specialists outside the operating room as an aid to real-time visualization and interpretation of three-dimensional electro anatomical maps of cardiac electrophysiology. It provides an immersive, three-dimensional stereo-scopic view of the electrical behavior of the heart, enhancing non-invasive mapping capabilities during the evaluation of conditions such as atrial fibrillation and other arrhythmias.

The system enables the analysis, visualization and informative interpretation of cardiac electrophysiological data, aiding in the understanding of complex arrhythmias and guiding preliminary assessments. It is beneficial in assisting and treating patients at risk of or being evaluated for cardiac arrhythmias.

Its use is intended to assist traditional diagnostic methods and to deepen the understanding of arrhythmia mechanisms in order to develop non-invasive management strategies.

The VR-CARDIO family consists of two main components:

• VR-CARDIO Explore (Ref. VR-CARDIO-01) is a web page that receives the raw data, stores it, launches the algorithms to process the data and uploads it to the database so that the VR-CARDIO VHET360 can access it.

• VR-CARDIO VHET360 (Ref. VR-CARDIO-02) is a software system designed for the real-time visualization and interpretation of three-dimensional electroanatomical maps of cardiac electrophysiology. It assists cardiology specialists in diagnosing and treating arrhythmias such as atrial fibrillation.

2. Symbols and indications

2.1 Symbols

| | Warning: this symbol is used to warn the user of a potential hazard related to the use of the software that could have consequences for the safety of the patient or the user. |
|------------|---|
| | Caution: this symbol is used to indicate that caution is necessary when using the software, without consequence to patient or user safety. |
| i | Consult instructions for use or consult electronic instructions for use. |
| CG-MA-WWWW | Name of manufacturer: YYYYY-MM-DD corresponds to date of manufacture |
| REF | Software reference: indicates the manufacturer's batch code in order to identify a specific medical device. |
| SN | Software serial number |
| MD | Medical Device |
| UDI | Unique Device Identifier |

| D Only | Caution: Federal (US) law Part 21 CFR 801 Subpart D restricts this device to sale by |
|---------------|--|
| K Only | or on the order of a physician, only under prescription. |

2.2 User profile characterization

VR-CARDIO is intended for use by electrophysiologists and cardiology specialists outside of operating room settings. Usage typically occurs during patient consultations or follow-up visits, where detailed cardiac data is necessary to make informed decisions about patient care.

VR-CARDIO is specifically designed for integration into various non-surgical areas within hospital environments, catering to the distinct needs of each setting to enhance patient diagnostics and care management.

2.3 Patient population characterization

VR-CARDIO is intended for use on individuals who are undergoing electrophysiological (EP) procedures. VR-CARDIO is intended to be used on individuals undergoing EP procedures from 18 years of age.

3. Warnings

The use of VR-CARDIO medical device includes various types of warnings, as follows:

3.1 VR-CARDIO Explore warnings





Credentials are unique and private. They should not be shared with any third party to prevent any privacy breach of the collected data.

Incorrect patient registration or data acquisition may lead to inaccurate results.



Internet connection loss may result in data loss.



The ECG signal displayed in real time is subject to timely interpretations, it is advised that a diagnosis is not made until the signal has been completed and processed.

3.3 VR-CARDIO VHET 360 warnings





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4. Technical characteristics

4.1 Minimum requirements for VR-CARDIO VHET360

4.1.1 Minimum screen resolution

Display resolution and aspect ratio: Minimum Full HD (1080p) resolution. Only landscape orientation is supported. Aspect ratios supported: 16:9. Mobile devices are not supported. Minimum resolution 1920x1080.

4.1.2 Minimum network requirements

Minimum required for an 8MB/s dedicated link (QoS) to use the streaming device for each device.

In the medical center there must be one 12 MB/s dedicated link for every three devices accessed simultaneously with a maximum latency of 50 ms, only applicable to shared sessions.

| antity | 1 | |
|-----------------------|-----------------------|---------------------------|
| inection | To be connected to o | one of the network points |
| mory | 8 GB or more | |
| k Space | Minimum of 2GB free | space |
| U | Intel Core i7-1260P 2 | 2.1 GHz (16 CPU) |
| U | NVIDIA T550 Mobile | GDDR6 4 GB |
| quired infrastructure | network point or pr | ivate Wi-Fi |
| erating system | Windows 10 or highe | r - 64Bits |
| talled applications | A web browser and \ | R-CARDIO VHET360 |
| | | |
| | | |
| | 1 | |

4.1.3 Minimum computer requirements

To be connected to one of the network points

4.1.4 Minimum VR or holographic computer requirements

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Windows 10 or higher - 64Bits

A web browser and VR-CARDIO VHET360 4.1.5 Virtual reality device

Option 1 Viewfinder Model: HP Reverb Professional Edition VR 1000

Connection type: USB A and Mini DisplayPort

Software: Windows Mixed Reality

Option 2 Viewer model: Meta Quest 2

Connection type: USB C to A

Software: Oculus Meta Quest Link

4.1.6 Holographic display

Hologram model: Mirror portrait

Connection type: USB C and HDMI.

Software: Looking Glass Bridge

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4.2 IT-security measures

4.2.1 Access to VR-CARDIO

- To prevent unauthorized access, a login with registered credentials is required.
- Users must create strong passwords.
- In case of authentication failures, use the password reset function or contact technical support.

4.2.2 Data protection

- All patient data is encrypted during transmission and storage.
- User consent must be obtained before processing patient data.
- To prevent unauthorized data sharing, audit logs track all access and modifications.

4.2.3 Session security

- Sessions are secured with dynamic tokens that change periodically to prevent interception.
- Dynamic security tokens refresh every 5 minutes to prevent interception.
- Even if data is intercepted, it remains in a proprietary format and is unreadable without decryption keys.

4.2.4 Session security

- Patient data cannot be lost; all records are stored in a redundant database with daily backups.
- For critical data (e.g., ECG signals), the system validates file integrity before processing.



4.2.5 System update

- Install all software updates promptly to ensure security and performance. Notifications will appear when updates are available.
- Unauthorized software is blocked; only approved versions can interact with VR-CARDIO.

4.3 Usability measures

4.3.1 Image and signal accuracy

- Images and signals are diagnostic aids only. Clinicians must correlate outputs with clinical findings.
- Poor resolution/noisy signals may indicate improper electrode placement or device malfunction. Discontinue use and contact support if anomalies persist.

4.3.2 Data uploads

• Ensure stable internet connectivity during uploads. The system will display confirmation upon success.

4.3.3 Troubleshooting

- Authentication Issues: Use password reset or contact support.
- Session Errors: Restart the application and log in again. Persistent errors must be reported.

5. Accessories

For optimal performance and compatibility with the holographic display and VR applications, several accessories are recommended, where the device has been fully tested.

Please find below a list of the recommended accessories. The use of any accessories not included in this list is the user's responsibility.

- HP Reverb Professional Edition VR 1000 viewfinder, which connects via USB A and Mini DisplayPort and uses Windows Mixed Reality software.
- Meta Quest 2 viewer, which connects through a USB C to A cable and operates with Oculus Meta Quest Link software.
- To enhance the holographic display experience, the Mirror Portrait hologram model is the recommended one. It requires a connection via USB C and HDMI and utilizes Looking Glass Bridge software.
- A computer that fulfills the minimum requirements specified above is also required.

6. Device Description

VR-CARDIO is an advanced system designed to help in the detection and analysis of cardiac arrhythmias. This medical software provides detailed and accurate visualization of the heart's electrical activity, helping doctors make an accurate diagnosis and more effective treatment planning. It is intended for use by a cardiac signal specialist, as electrophysiologists and cardiology specialists may be.

Specific clinical applications include:

- 1. Electro-anatomical mapping and advanced visualization of electrical signals: through the collection of cardiac signals, VR-CARDIO can perform an electro-anatomical reconstruction of the heart. Thanks to its three-dimensional (3D), holographic, stereoscopic 360° visualization of a model of the patient's cardiac geometry and temporal activation maps. This advanced visualization provides the clinician with a deeper understanding of the patient's cardiac conditions and facilitates clinical decision-making.
- II. Help in Arrhythmia detection: VR-CARDIO is specifically designed to help in the identification of various types of cardiac arrhythmias, both atrial and ventricular. By external acquisition systems that collect signals from multiple points on the patient's torso, the device records electrical signals from the heart, allowing a detailed analysis of the heart rhythm. VR-CARDIO provides information on the mechanistic basis of arrhythmias and the location of the origin of the arrhythmia, whose objective is to help in the diagnosis and targeted treatment planning.
- III. Complementing conventional cardiac navigation systems: VR-CARDIO stands out for its advanced visualization, offering a significant complement to conventional cardiac navigation systems. While the latter relies on invasive technologies and often radiation exposure, VR-CARDIO uses an external acquisition system that collect signals from multiple points on the patient's torso for electro-anatomical mapping and arrhythmia detection without the risks associated with invasive procedures. Its ability to provide three-dimensional and holographic visualizations overcomes the limitations of two-dimensional visualizations, facilitating deeper analysis and a better understanding of the structure and function of the heart.

VR-CARDIO is composed of software elements.

The electrical signal collected from the subject's torso by external acquisition systems that collect signals from multiple points on the patient's torso, is sent for processing, analysis and visualization in VR-CARDIO (VR-CARDIO Explore and VR-CARDIO VHET360).

6.1 VR-CARDIO Explore

Web page that manages the connection with an external acquisition system and manages the data, receiving the raw data, storing it, launching the algorithms to process the data, and uploading it to the database to be able to access it through the VR-CARDIO VHET360 desktop application. On this website, data from recorded sessions with an external acquisition system such as patient data or electrode signals can be seen.



Figure 1. VR-CARDIO Explore logo

6.2 VR-CARDIO VHET360

Visualization software which contains a series of tools for the visualization and management of the data collected with an external system. This application is connected via an API to the database where VR-CARDIO Explore stores the processed data. This software has different ways of visualizing the data; 2D display, VR glasses and holographic display, all in an online room to interact with other users.

7. Use of VR-CARDIO

7.1 Previous information

7.1.1 General safety and operational requirements

To ensure correct and safe operation of the software and to avoid serious personal injury or damage to property, it is recommended to read the user's instructions for use in its entirety and to pay special attention to this section before using the software. The user must observe detailed safety precautions to avoid risks during the use of the software.

7.1.2 Potential device benefits

Current diagnosis of arrhythmias through electro-anatomical mapping generally requires invasive electrophysiological study using catheterization and cardiac navigators.

7.1.3 Additional considerations

- Procedure for reporting adverse events: for any problems or inquiries that may arise, it is recommended that users directly contact the Spika Tech support team. This can be done by sending an email detailing the situation to the following contact email: contact@spikatech.com.
- Possibility of follow-up: the use of this software does not require additional visits or followup. Should there be a need to review an existing case later, it can be done through VR-CARDIO Explore and VR-CARDIO-VHET360-Visualization using the automatically generated Session ID or Patient ID.

7.2 VR-CARDIO Explore 7.2.1 Data acquisition

With the patient ready, the next step is data acquisition. It requires logging in at https://www.VR-CARDIOexplore.com , filling in the fields with the corresponding credentials.



WARNING: Credentials are unique and private. They should not be shared with any third party to prevent any privacy breach of the collected data.

| • | → SPIKA [™] TECH |
|-------------------|------------------------------|
| CARDIO Explore | |
| LOGIN | |
| Password | |
| LOGIN | |

Figure 2. Login page interface of VR-CARDIO Explore

7.2.2 Patient registration



WARNING: Incorrect patient registration or data collection may lead to inaccurate results.

If this is the first time a patient uses an external acquisition system, registration as a new patient is mandatory. This can be done by accessing the VR-CARDIO section of the profile.





And enter the "Patients" section.



Figure 4. Patients section icon

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Figure 5. The "Add patient" icon permits to create a new patient profile

The fields required for patient registration are:

- First name
- Last name
- Date of birth (mm/dd/yyyy) Please note that the date format is dependent on the PC's language.
- Gender
- Height (cm)
- Weight (kg)
- Body somatotype
- Abdominal circumference (cm)
- Pectoral perimeter (cm)
- Physical condition
- Previous pathologies
- Previous treatments

7.2.3 Recording of the session



WARNING: Loss of internet connection may result in data loss

To start recording the session, it is necessary to go to the Sessions section.

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Figure 61. "Sessions" section icon

And click on the "Add session" button, a form will open with different informative fields. Only the fields marked as mandatory are to be filled in, being them the device, which corresponds to the external acquisition system identification number, and patient, which corresponds the patient who has the external acquisition system on.

Figure 72. "Add session" icon. This icon opens different informative fields

| Device* | Device |
|-------------------------|----------------------|
| User * | ✓ |
| Notes | Notes |
| Previous pathologies | Previous pathologies |
| Previous treatments | Previous treatments |
| Position | Seated ~ |
| Size | XS ~ |
| Fit | Tight ~ |
| | |
| | SAVE |

Figure 8. Informative fields. The fields marked as mandatory must be filled out

After creating the session, a confirmation will be requested to view the session live, if accepted, the session will start to be displayed.





WARNING: The electrocardiogram signal displayed in real time is subject to timing interpretations, it is advisable not to make any inferences until the signal is finished and processed



Figure 9. Signal recording

To stop the session, click on the pause icon.



And prompts will be displayed to stop recording and process the data







Figure 12. Prompt confirming if you want to start the pipeline

7.3 VR-CARDIO VHET 360 7.3.1 Installation

To start using VR-CARDIO VHET360, unzip the VR-CARDIO-VHET360-Visualization-v1.0.0.zip file, navigate to the VR-CARDIO-VHET360-Visualization-v1.0.0 folder and run the file named VR-CARDIO-VHET360-Visualization-v1.0.0.zip file is available to download from the VR-CARDIO website or provided by Spika Tech in a pen drive, included with the device purchase. For complete guidance on using VR-CARDIO VHET360, please refer to this document, which details each section of the application.

7.3.2 Home screen

As soon as the application is launched, the credentials required to access the account will be entered. These credentials are the same as those previously entered on the VR-CARDIO Explore website.



WARNING: Credentials are unique and private. They should not be shared with any third party to prevent any privacy breach of the collected data.



Figure 13. VR-CARDIO app Login

When running the application, the first thing the user encounters is the home screen, which is the main page of the application. This home screen contains three main buttons, each with a specific function. The 'CE Label' button allows to display the CE Label. On the footer, the corresponding medical device label is displayed.

When entering an account to the application, the first button encountered is the "Online" button, which allows the user to network with other users of the application and share patient case information. Clicking this button initiates a connection to the application server that allows the user to share information with other users in real time.



WARNING: The medical professional who creates a virtual room is responsible for the individuals with whom the room joining code is shared, since personal data will be shared with third parties

The second button is the "Offline" button, where the user can access all the functionalities of the application, although he/she will not be able to share information with other users in real time. For the scope of this user's instructions for use, it will be the button to be pressed to move forward.

The third button is the "Logout" button, that allows you to log out of your account and go to the previous screen.

Finally, the fourth button is the "Exit" button, which is used to close the application completely. Pressing this button closes the connection with the server, saves the changes made and closes the application securely.



Figure 14. VR-CARDIO Online/Offline menu



WARNING: The user is responsible for the directory where the downloaded cases are set, as it could cause a security problem.

If the user has a virtual reality system, the "VR Mode" button must be selected. Likewise, if the user has a holographic display and wishes to use it, the "Hologram Mode" button should be pressed. However, for the scope of this guide, it will not be necessary since the data will be visualized on the computer screen.

Finally, once the necessary configurations have been made, press the "Start" button to enter the application in offline mode.

As in the other modes of the application, the "Back" and "Exit" buttons are available to return to the home screen and exit the application, respectively.



Figure 15. If you press "Exit" button, you'll be sent to home screen again

Upon entering the application, either in online mode (where the room code will appear in the lower right corner) or in offline mode, the user will encounter an interface that presents a series of panels organized by default. The panels allow the user to access the application's functionalities, such as loading cases, viewing graphs... To access the cloud panel and load the cases stored there, the user must go to the 4 buttons in the upper right corner (if accessing Offline mode there are only three) of the screen. From top to bottom, the first one is for exit the application. The second one, identified as a folder icon, is the cloud button, which allows the user to load the cases stored in the cloud.



Figure 16. VR-CARDIO room interface. "Load cases" Icon

When the Cloud button is clicked on the main screen of the application, a panel opens showing the cases available in the Cloud. The third one is the Panel and Workspace button, that allows the user

to move, hide and display panels, as well as load and modify workspaces as desired (A workspace is a specific colocation of the panels). The fourth one is the online user button, which only appears when entering the application in online mode and allows the user to see, give permissions and mute the users that join the room.

| | | $\langle \rangle$ |
|----------|---------------------------------|---|
| | 5C7B3DB76ECE60389 | 112E20A51564B4 📆 |
| £ | Description | Previous pathologies |
| CARDIO | Previous treatments | Target Pathologies |
| | READY | |
| 23 | 3601313AD7270F57EA | F2A384CB10796 |
| H | Description | Previous pathologies |
| CARDIO | Previous treatments | Target Pathologies |
| CARDIO | Description Previous treatments | Previous pathologies Target Pathologies |
| | 508B81459B22C88E09 | 994D69961C3F2 |
| CARDIÓ | Previous treatments | Target Pathologies |
| CARDIO | 3A4AEDE5066EBC33B | CCFD031C0DFA Previous pathologies Target Pathologies |

Figure 17. Cloud panel

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Figure 18. User information of each external acquisition system recorded session

- 1. Case icon: icon that loads the case, this icon has three stages. One stage is when the icon has a white filter, indicates that this case is not downloaded. The second stage is when the icon has a green stage, indicates that this case is downloaded and can be shown in the application. The third stage is when the icon has no filter, this indicates that the case is shown in the application.
- 2. Case name: the name under which the case has been saved.
- 3. Download/Delete button: this button is used to download a case from the cloud or delete a case locally. The icon changes depending on the status. During the download of a case, a progress bar is displayed along with the percentage downloaded, and when the download is complete, the word "Complete" is displayed to indicate completion.
- **4.** Information area: in this section there is 4 buttons that display specific information from the patient when pointing on it:
 - a. **Description:** general description of the case.
 - b. Previous pathologies: information about previous pathologies the patient has had.
 - c. **Previous treatments:** information on previous treatment the patient has had.
 - d. Target pathologies: information about the specific pathologies or medical conditions that are the focus of the current treatment or diagnosis.
- **5. Ready information:** just additional information that shows when a case is ready for display in the application.





WARNING: The algorithm can predict if the user has an arrhythmia, but by no means does replace a professional diagnosis. In the stance arrhythmia prediction is launched by the system, it must be validated by a medical professional, thanks to the help of VR-CARDIO VHET360.



Figure 19. Visualization scene

8. Detailed information

8.1 VR-CARDIO Explore 8.1.1 Profile

The profile is the central space for accessing the user's private information and personalized content on the website. Given the type of user, different levels of access are offered, categorized into two main roles:

- Administrator
- Professional

These roles allow each user to explore and manage specific areas within the profile, adapting to their needs and functions on the platform and are further developed on section 8, 'profiles'.

8.1.2 Language selection

There are three official languages available for VR-CARDIO Explore: Spanish, English and Arabic. You can select your preferred language using the menu located in the top left corner.



Figure 30. VR-CARDIO Explore language selection

8.1.3 User registration



WARNING: Credentials are unique and private. They should not be shared with any third party to prevent any privacy breach of the collected data.

To access the profile section, the user must complete a registration process with the required personal data on the platform. This step is done by accessing the registration page, accessible through the link (<u>https://VR-CARDIOexplore.com/#/signup</u>).

| VR-Cardio Explore | |
|---|--|
| VRCardio Interactive-images Real cases Cardio 3D ECGs Atlas | |
| | CREATE NEW ACCOUNT Pret News Pret News Lest News |

Figure 41. Registration page interface for VR-CARDIO Explore

8.1.4 User login

Once the user has registered, the login can be done, using his/her credentials on the corresponding page (<u>https://VR-CARDIOexplore.com/#/login</u>).



Figure 52. Login page interface for VR-CARDIO Explore

In this interface, the necessary data to access the user's profile and personal space can be entered.

8.1.5 User password recovery

If the user wishes to access the personal area but faces difficulties in accessing the profile due to credential problems, he/she can go to the password recovery page (<u>https://VR-CARDIOex-plore.com/#/resetpassword</u>).



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In this space, the e-mail address associated with the inaccessible account must be provided. A temporary access code will then be sent to this address, enabling the creation of a new password.

8.1.6 Calendar

By logging into the profile, users have access to a calendar that highlights relevant activities on the web platform.

| | | | | | | 4 , R |
|------------|-----|-----|-----|-----|-----|--------------|
| March 2024 | • | | | | | |
| Sun | Mon | Tue | Wed | Thu | Fri | S |
| 25 | 26 | 27 | 28 | 29 | 1 | : |
| 3 | 4 | 5 | 6 | 7 | 8 | |
| 10 | 11 | 12 | 13 | 14 | 15 | 1 |
| 17 | 18 | 19 | 20 | 21 | 22 | 2 |
| 24 | 25 | 26 | 27 | 28 | 29 | 3 |
| 31 | 1 | 2 | 3 | 4 | 5 | 1 |

Figure 24. Calendar. Relevant activities are highlighted

8.2 Connection to VR-CARDIO Explore8.2.1 Introduction to the data collection

The external acquisition system captures the wearer's cardiac signals. This collects vital information related to cardiac activity. This entire data set is processed by VR-CARDIO Explore platform. This process enables seamless integration of the collected cardiac signals into the immersive experience provided by VR-CARDIO Explore, thus offering a comprehensive and accurate view of the user's cardiac health.

8.3 Data collection

8.3.1 Patient creation



WARNING: Incorrect patient registration or data collection may lead to inaccurate results.



Before starting to capture user data using an external acquisition system, it is essential to create a patient profile in VR-CARDIO Explore. In this way, all the cardiac signal data associated with that specific user can be effectively stored and organized. To carry out this process, access the Patients section, as detailed above. This step is essential to ensure proper information management and to provide a personalized, user-centric experience in the VR-CARDIO Explore environment.



Figure 25. Patient section icon

In this section, it is imperative to go to the "Add Patient" area, located at the top left of the screen. Here, all the fields necessary for the creation of the patient profile should be completed, ensuring that the relevant information is captured comprehensively and accurately. This step facilitates the organization and tracking of cardiac data associated with each patient in VR-CARDIO Explore, contributing to efficient and personalized management of clinical information.

| My patients | | | | | |
|-------------|------------------------------|------------|---|----------|--|
| + Ac | d patient | | | n Return | |
| Nam | e | Patient id | | Q | |
| 0 | agm-19 | ۲ | ľ | Û | |
| 0 | ajy-13 | ۲ | Ø | Û | |
| 0 | alejandro,gonzález garcia | ۲ | Ø | Û | |
| ۲ | ana maria,estarellas de haro | ۲ | Ø | Ô | |
| • | anaisa,amaran coma | ۲ | 6 | Û | |
| 0 | andreea, filote petrescu | ۲ | Ø | Û | |
| ٥ | andres,giraldo donado | ۲ | Ø | Û | |

Figure 26. "My patients" home page. Click "Add patient" to create a new patient. The names in the images are fictitious to be used as an example in the application.

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| | | 1.0 |
|-----------------------------|--------------------|----------|
| Add patient | | ← Return |
| Name: * | Name | |
| Surname: * | Surname | |
| Age: * | dd/mm/aaaa | |
| Sex: * | Other 🗸 | |
| Height (cm): * | Height | |
| Weight (kg): * | Weight | |
| Body type: * | Endomorph | |
| Abdominal diameter (cm): | Abdominal diameter | |
| Pectoral diameter (cm): | Pectoral diameter | |
| Physical state: * | Normal 🗸 | |

Figure 27. Patient information fields. The fields marked as mandatory must be filled out

8.3.2 Session creation



WARNING: Loss of internet connection may result in data loss.

Once the patient profile has been created, the next step involves setting up a session to start data acquisition. To do this, it is essential to go to the "Sessions" section, as explained above. This process allows the patient-specific session to be configured and activated, thus preparing for the capture and recording of cardiac data associated with that specific session in VR-CARDIO Explore.

| | | | an ana |
|-------------------------|--|-------|---------------------------|
| Stearenda Internidan | an a | en en | en begeten Kortu etten |
| (N | ESSI IEW D | | 5 () 10001 (M |
| n carri | VISI | Т |) ²⁷¹ |

Figure 28. Sessions section icon

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In this section, it is essential to go to the "Add Session" area, located at the top center of the screen. Here, all the fields necessary for the creation of the session must be completed, ensuring an accurate and detailed configuration. By providing this information, a specific session is established for the patient, allowing the effective capture of cardiac data associated with that precise session within VR-CARDIO Explore. This step facilitates an organized and structured process for data acquisition.

| Му | My sessions | | | | | | |
|-------|-------------------------------|---------------------|---|---|------------|-------------|--------|
| Downl | pad all sessions 👗 | | | | | ÷ | Return |
| • A | ctive sessions | + Add session | | | Patient id | | Q |
| | Name | Creation date | | | | | |
| ٥ | alejandro, gonzález garcía | 2/8/2024, 9:15:55 | ۲ | ٥ | ~ | an | ŵ |
| ۲ | ana maria, estarellas de haro | 2/16/2024, 10:34:51 | ۲ | ۰ | ~ | <u>.ut</u> | ŵ |
| ٥ | ana maria, estarellas de haro | 2/16/2024, 10:37:19 | ۲ | ۰ | ~ | <u>.ut</u> | ŵ |
| ٥ | anaisa, amaran coma | 2/16/2024, 10:50:39 | ۲ | ٥ | ~ | <u>1.01</u> | â |
| ٥ | anaisa, amaran coma | 2/16/2024, 10:48:11 | ۲ | ۰ | ~ | <u>1.01</u> | â |
| ٥ | andres, giraldo donado | 2/16/2024, 17:40:17 | ۲ | ٥ | ~~ | <u>lan</u> | ŵ |

Figure 29. "My sessions" home page. Click " Add session" to create a new session. The names in the images are fictitious to be used as an example in the application.

Add session

| | ← Return |
|-------------------------|----------------------|
| Device * | Device |
| User * | ~ |
| Notes | Notes |
| Previous pathologies | Previous pathologies |
| Previous treatments | Previous treatments |
| Position | Seated v |
| | SAVE |
| | |

Figure 30. Informative session fields. The fields marked as mandatory must be filled out

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Once the session is established, data collection is initiated by the acquisition device. After a short wait of 40 seconds, the collected cardiac signals begin to be displayed in real time within VR-CARDIO Explore. This process ensures an immediate and dynamic experience, allowing the user to interact and analyze in real time the cardiac signals captured in the virtual environment.



WARNING: The ECG signal displayed in real time is subject to timely interpretations, it is advised that a diagnosis is not made until the signal has been completed and processed.

Session data



Figure 61. Signal recording

To stop the recording, click on the pause icon (top left) or on the return button. If pausing the recording with the icon, the option to process the data collected by an external acquisition system will be given for later review.



8.3.3 Visualization of collected data

After completing all cardiac signals collection, a global display of the signals can be achieved by accessing the viewing section of the newly recorded session in VR-CARDIO Explore. However, for

more detailed and complete information, it is essential to access the VR-CARDIO VHET360 visualization tool. In this tool, all data is presented in a comprehensive way, with three-dimensional, holographic, stereoscopic 360° visualization of the patient's torso and heart, thus providing a deeper and more detailed visual and analytical experience.



Figure 34. Selecting highest-quality signals from the session



Figure 35. Collected signals with Time in X axis and Amplitude in Y axis

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8.4 Data analysis

The VR-CARDIO system incorporates a module consisting of an algorithm specifically designed to create a heart electrical map. This objective is achieved by solving electrocardiography inverse problem, which requires interpretation of the electrical potentials recorded on the surface of the torso. The procedure begins by addressing the direct problem, establishing a link between the heart electrical activity and the electrical activity observed on the torso.

Once the relationship between the source of electrical activity, the heart, and the observation points, the torso, has been established using discretized bioelectromagnetic equations, sophisticated mathematical techniques are used to solve the inverse problem of electrocardiography. This allows accurate and noninvasive visual maps of the electrical activity of the heart to be produced. These visualizations are essential for the diagnosis of atrial and ventricular arrhythmias, as they provide a visualization of cardiac activity without the need for invasive methods.

Note that the resolution of the inverse problem for the estimation of cardiac activity from signals collected from the torso depends on spatial information, such as distances or geometries of the torso and the heart, as well as parameters such as the conductivity of the torso. Therefore, the VR-CARDIO system was previously composed of modules that at the same time are composed of algorithms mainly based on interpolation, whose result provides the reconstruction of both the torso and the heart. To finalize this process, whose result is the inference of the cardiac activity mapping, an optimization of the heart location is performed according to the direct-inverse problem, giving in turn an improvement of the heart reconstruction.

Finally, once the electrical mapping of the heart has been inferred from the electrical signals collected in the torso, using the inverse problem, the corresponding leads I, II, III, aVF, aVL, aVR of a standard ECG are calculated using the direct problem.

In a standard ECG the twelve leads of the electrocardiogram (ECG) are a graphical representation of the heart's electrical activity obtained from different angles.

They are used to evaluate cardiac function and detect abnormalities such as arrhythmias, heart attacks, and other cardiac conditions.

- Limb leads:
 - I, II, III (bipolar leads, resulting from the combination of augmented unipolar leads)
 - aVR, aVL, aVF (augmented unipolar leads)
- Precordial (chest) leads:
 - V1, V2, V3, V4, V5, V6

In this way, and after characterizing the signals obtained for these leads, a model for detecting arrhythmias is obtained. Note that the characterization of the signals is performed considering both temporal and spectral characteristics focused on the differentiation between different types of



Along with the detection of arrhythmias, the final module of the VR-CARDIO system is composed of an algorithm whose result provides areas located in the atria susceptible to atrial fibrillation ablation. This algorithm is composed of a characterization of the electrical signals inferred in the heart based on frequency entropies.

8.5 VR-CARDIO VHET360 8.5.1 Languages

VR-CARDIO VHET360 is available exclusively in English.

8.5.2 Home screen

Unity provides two main rendering pipelines: HDRP (High-Definition Render Pipeline) and URP (Universal Render Pipeline), each adapted to different needs and platforms. In our case, we have two modes of application: one that uses HDRP for high-fidelity graphics on powerful platforms, and one that uses URP to ensure performance and compatibility with a wider range of devices, including mobile. HDRP offers superior visual quality with advanced features such as physical lighting and complex effects but requires powerful hardware. URP, on the other hand, is more versatile and enables higher performance, although it may lack some of the advanced graphical details offered by HDRP.

The application has a Graphical User Interface (GUI) that is designed to be easy to use and allow the user to access the main functionalities of the application. When running the application, the first thing the user encounters is the home screen, which is the main page of the application. Three buttons are displayed on this screen, each with a specific function.

The first button encountered is the "Online" button, enabling users to connect with others on the application's network to share information about patient cases. When this button is pressed, a connection to the application server is initiated, enabling real-time information sharing among users.

The second button is the "Offline" button, permitting users to access the application without requiring an internet connection. Upon pressing this button, users can utilize all application functionalities, without real-time information sharing capabilities among doctors and other users.

The third button is the "Logout" button, that allows you to log out of your account and go to the previous screen.

Finally, the fourth button is "Exit" button, utilized to completely close the application. Pressing this button closes the connection to the server, saves any changes made, and safely shuts down the application.

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In summary, the application's home screen allows the user to select among several options to access the main functionalities of the application; it also provides an intuitive and user-friendly user experience.



Figure 36. VR-CARDIO app Online/Offline home page

8.5.3 Online connection



Figure 37. Data sharing acceptance.



WARNING: The medical professional who creates a virtual room is responsible for the individuals with whom the room joining code is shared, since personal data will be shared with third parties.

Selecting the "Online" button directs the user to the online mode screen, presenting two options: create a room or join an existing room. To create a completely new room, follow these simple steps:

- Insert a username in the "Username" space, otherwise the system will provide a default one.
- If the user has a Virtual Reality system and wants to use it, the "VR Mode" button must be selected. In the same way, if the user has a holographic screen and wants to use it, the user must press the "Hologram Mode" button.



WARNING: Virtual Reality glasses and a PC with them are required for Virtual Reality viewing.

- Once the previous steps have been completed, the "Create" button can be pressed to create the room.
- When entering the created room, in the lower right corner the room code will be provided, which must be shared through another channel, for example, e-mail, with those users willing to enter the room.



Figure 38. Example of a provided code needed to enter the room

If entering an existing room is desired, proceed as follows:

- Insert a username in the "Username" space, otherwise the system will provide a default one.
- If the user has a Virtual Reality system and wants to use it, select the "VR Mode" button. In the same way, if the user has a holographic display and wants to use it, the user should press the "Hologram Mode" mode.



WARNING: Virtual Reality glasses and a PC with them are required for Virtual Reality viewing.

- Finally, the user will have to contact the room creator to get the room code, which the user will have to write in the "Join Code" space and press the "Join" button to enter the room.

Finally, the "Back" button, located in the upper left corner, is used to return to the home screen and, as before, the "Exit" button will enable the complete application closure.

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Figure 39. Home screen

Other users are visually identified through a distinctive color marker that indicates the direction in which they are pointing their cursor or Virtual Reality (VR) device. This system enables the detection of other user's focus on a specific panel, adjustments to room settings, or interactions with the virtual cavity. In addition, when a user communicates via voice chat, their marker lights up to identify the audio source easier for other assistants.



WARNING: A poor internet connection may influence the real-time position of the pointer of other assistants.



Figure 80. Heart reconstruction using a VR device

8.5.4 Offline mode

The offline mode is a useful feature for those users who need to work with the application without connecting with other users. By selecting the "Offline" button, the offline mode screen is displayed, which allows to access the application without the need of creating an online room. To enter the



- In case the user has a Virtual Reality system, the "VR Mode" button must be selected. Likewise, if the user has a holographic screen and wishes to use it, the user must press the "Hologram Mode" button.



WARNING: Virtual Reality glasses and a compatible PC are required for VR visualization

- Finally, once the necessary configurations have been made, the "Start" button can be pressed to enter the application in offline mode.

As in the other modes of the application, the "Back" and "Exit" buttons are available to return to the home screen and exit the application, respectively.



Figure 41. VR-CARDIO Offline mode home page

Preparing to use VR glasses

- 1. Connect the Virtual Reality device to the computer.
- 2. Make sure the drivers for the Virtual Reality device are updated.
- 3. Start the mixed reality portal if it does not open automatically.
- 4. If it is the first time, proceed with the setup process.

Basic operation with VR

1. Connect the Virtual Reality device to the computer.

2. Interact with three-dimensional elements using the main controller of the Virtual Reality device.

Preparing to use Hologram Display

- 1. Download the installer for the holographic screen manufacturer's drivers here: <u>https://look.glass/bridge-win</u>.
- 2. Run the downloaded file to install the drivers.
- 3. Start the drivers before using the holographic screen.

Basic operation without VR or with Hologram

- 1. Use the mouse to interact with all the screen elements through the left click.
- 2. Hold down the SHIFT key and click on the cavity or any interactive element to pull it closer or push it away by moving the mouse.
- 3. Hold down the CONTROL key and click on the cavity or any interactive element to rotate it on various axes by moving the mouse.
- 4. Hold down the SHIFT and CONTROL keys and click on the cavity or any interactive element to rotate it on the Z-axis by moving the mouse.

8.5.5 Traditional 2D screen

When entering the application, whether on Online (room code will appear in the lower left corner) or Offline mode, the user will encounter an interface that presents a series of panels organized in a predetermined way. These panels allow the user to access the various functionalities of the application, such as uploading cases, viewing graphs...

8.5.5.1 Cloud and User panel

To access the Cloud panel and load the cases stored there, the user must go to the three buttons (four if online) located in the upper right corner of the screen. Cloud button can be found on the second place, represented with a folder icon. It allows the loading of cases stored in the Cloud.



Figure 92. Loading stored cases icon

8.5.5.2 Cloud panel



WARNING: A poor internet connection may make Cloud cases downloading unavailable.

When the Cloud button is pressed on the main screen of the application, a panel opens showing the cases available in the Cloud.



Figure 43. Cloud Panel

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8.5.5.3 Cases

When selecting the button that displays the cases, a list of all available cases will appear. Each item in the list is a file card with the information of a case:



Figure 44. User information of each recorded session.

- 1. **Case icon:** icon that loads the case, this icon has three stages. One stage is when the icon has a white filter, indicates that this case is not downloaded. The second stage is when the icon has a green stage, indicates that this case is downloaded and can be shown in the application. The third stage is when the icon has no filter, this indicates that the case is shown in the application.
- 2. Case name: the name under which the case has been saved.
- 3. Download/Delete button: this button is used to download a case from the Cloud or delete a case locally. The icon changes depending on the status. During the download of a case, a progress bar is displayed along with the percentage downloaded, and when the download is complete, the word "Complete" is displayed to indicate completion. Downloaded cases are stored in a folder previously specified by pressing the "Set Case Directory" button on the online or offline mode screen.
- 4. Information area: in this section there is 4 buttons that display specific information from the patient when pointing on it:
 - a. Description: general description of the case.
 - b. Previous treatments: information on previous treatment the patient has had.
 - c. Previous pathologies: information about previous pathologies the patient has had.

- d. **Target pathologies:** information about the specific pathologies or medical conditions that are the focus of the current treatment or diagnosis. In the stance arrhythmia prediction is launched by the system, it must be validated by a medical professional, thanks to the help of VR-CARDIO VHET360.
- 5. **Ready information:** just additional information that shows when a case is ready for display in the application.



WARNING: The algorithm can predict if the user has an arrhythmia, but by no means does replace a professional diagnosis. In the stance arrhythmia prediction is launched by the system, it must be validated by a medical professional, thanks to the help of VR-CARDIO VHET360.



Figure 45. Downloaded case

8.5.5.4 User panel

When accessing the user panel, all the users present in the room can be observed. In this menu, the user hosting the room (room host) can manage the voice chat permissions of the users, allowing them to mute them or enable their microphone as needed. In addition, as the host, the virtual token that determines who holds the role of room administrator can be managed.



Figure 46. Users present in room. The room host can manage voice permissions

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8.5.5.5 Main scene

When loading one of the cases in the application, the following will be displayed:



Figure 47. Visualization scene

These are the six main interaction panels of VR-CARDIO, which will be detailed below.

Note: The buttons represented with an open eye will be detailed in the Workspace Storage Panel.

8.5.5.6 Display range selector panel



WARNING: The presented maps and heart reconstructions serve as diagnostic support tools and should not be interpreted in isolation. They do not replace the medical judgement of trained professionals in any case.

All the parameters that control the representation of the voltage on the cavity surface can be modified thanks to the Display Range Selector Panel, as well as the selection of the different provided maps, both the temporal map and the static maps.

In descending order, the first thing to be discovered are the selection buttons for the different electrical signal display maps.

1. The first of these is the instantaneous voltage map. In the context of the visual representation of the signals captured by a catheter in a mesh structure, an estimation is carried out by projecting these signals on the mesh. It is assumed that the potential remains constant in the projection over the distance.

However, it is important to note that this estimation introduces some uncertainty, and associated errors may arise. This map is based on a node mapping method that uses the distance between the catheter at the time of measurement and the surface of a regularized grid, as well as a correlation of two shifts. This approach has been designed to improve mapping accuracy within the system. In addition, an improved method called "Bicriterion" has been developed, which adapts and consolidates previous mapping methods with the objective of eliminating far field effects and increasing the effectiveness of the visualization. The result of this visualization is presented in the form of a dynamic map on a threedimensional grid, which allows access to any time instant of the signals and to observe their representation on the surface. This innovative way of visualizing electrograms has several uses, including the validation and improvement of future signal processing algorithms. It may even have applications in the educational field, as it shows the complete signals instead of summaries as in other maps, although it may have a higher level of noise. As more data is obtained and new maps are generated, the aim is to reach a sufficient level of information to make accurate diagnoses.

- 2. The second of the maps is the isochrones map. This map provides a temporal visualization and reconstruction of the classical Local Activation Time (LAT) map, illustrating how the electrical impulse propagates across the heart's cavities. By focusing on local activation times, it highlights the precise moments when the impulse reaches specific areas, stimulating the corresponding tissue. This Map is particularly effective in identifying the flow of propagation, including acceleration, deceleration, or avoidance of certain areas. This is critical not only for pinpointing high-activity and low-activity regions (e.g., areas with altered propagation speeds or impulse avoidance indicative of damaged tissue) but also for offering a global perspective on the heart's functional behavior.
- 3. The third is the max voltage map. This map represents the distribution of maximum amplitudes across all cardiac cavities, providing a means to identify areas of maximum energy accumulation. It is a valuable tool for detecting high-activity regions potentially associated with electrical heart remodeling, as well as low-activity regions that may indicate tissue damage.
 - a. Low voltage areas map: This map extends the functionality of the Max Voltage Map by applying a thresholding process to specifically identify damaged areas. The threshold is guided by medical expertise, typically set at 0.5 mV of recorded real potentials, a commonly used criterion for distinguishing such regions.
- 4. The fourth map is the max slope map. This map highlights the maximum slope observed across the signals, which is closely linked to regions of maximum energy accumulation. While it shares similarities with the Max Voltage Map in terms of the insights it provides, its added value lies in its correlation with action potential amplitudes. This relationship is well-established in the field, making the map particularly useful for analyzing extra potential signals.

5. Finally, the fifth map is the cardio polar map. Cardio polar is an advanced three-dimensional visualization tool designed to enable electrophysiologists to analyze the dynamics of depolarization and repolarization of the heart in real time. This system facilitates the observation of the cardiac activation front through a simplified representation of electrical potential signals, focusing on temporal and spatial aspects for diagnosis.

Below is shown both the icon and the descriptive text of the currently selected map. Continuing down the horizontal bar of color gradients can be seen, which indicates which colors correspond to which voltages in the cavity. In the figure, values of voltages below -1.5 mV would correspond to orange and reddish colors, values around 0 mV would fit greenish and light blue colors and values above 1.5 mV would fit dark blue and purple colors.

On the left of this horizontal bar, a circular arrow icon button can be observed, and can be used to reset all the panel parameters to their default values. On the right, the button represented with the icon of an eye can be found, which is explained in the Workspace Storage Panel.





Below the previous horizontal bar, the color gradient control slider can be appreciated. Dragging the left end to the right will trim the color gradient and, as it can be seen in the figure below, in which the reddish colors have been trimmed. This allows its customization to cater to the user's needs. Dragging the right end to the left will do the same for the blue and purple colors. The button to the left of the slider, represented with a gradient, is the reset button to the default values of the slider, it will only reset the value of the slider to its right.

B87386900, registered in the Mercantile Register of Madrid, in volume 33.500, Folio 200, Page M-603059, Entry. 1, hereinafter THE OWNER.



Figure 49. Color panel sliders customizing

Moving on to the next slider, there is the color range multiplier that increases the voltage range, that is, dragging the center handle to the left will increase the minimum and maximum numerical ranges of voltages. Dragging the handle to the right will do the same by decreasing the range. The button represented by a drop to the left of the slider will reset to the default value.



Figure 50. Color panel sliders final mode

The next slider, the base color shift, allows for adjustment of the voltage ranges mapped to the gradient. Shifting the slider to the left causes the numerical ranges to move to the left, while shifting it to the right moves them to the right. This enables precise selection of the voltage ranges

that correspond to the color gradient. The button to the left of the slider, represented with a gradient and two arrows pointing outward, will have the reset button to the default value of the slider itself.

Continuing with the next slider, the color gradient transparency limits controller is presented, with it, a zone in which those voltages corresponding to the inside of this zone are completely transparent can be seen, providing a better view of what is happening in the back of the cavity.

This transparency zone is reflected both in the horizontal color gradient bar and in the Main Signal Panel, where a green rectangle indicating that the voltages inside it will be completely transparent is displayed.

The button to the left of the slider represented by an "X" resets the slider to its default values.

Finally, the slider to manage the intensity of the normals is displayed. By dragging the central controller to the left decreases the intensity and dragging it to the right increases the intensity.

These normals represent a displacement of the heart mesh in the direction of the surface normal, based on the voltage levels. This provides an alternative, and often more informative, representation of the instantaneous voltage relative to the surrounding surface. The leftmost button, depicted with a sphere inside a mesh, activates a "pseudo normal" algorithm. This algorithm prevents the crossing of mesh triangles in convex areas of the surface, generating a more continuous and accurate representation.

The button on the left closest to the slider represented with a double arrow pointing up and down, is the button to reset the intensity of the normals to their default value.

8.5.5.7 Main signal panel

This panel is designed for in-depth manipulation of a selected signal, offering users precise control over various aspects of signal visualization and interaction. It features multiple controllers and tools to enhance the user experience.

At the top of the panel, there are two buttons and a horizontal slider. The first button resets the horizontal zoom (x-axis) of the signal, allowing users to quickly revert to the original view. The second button, positioned on the right, enables a measurement tool that lets users interact directly with the signal display for detailed analysis. The horizontal slider below these buttons allows users to zoom in or out along the x-axis, providing finer control over the signal's timeline.

On the left side, there is a vertical slider and four buttons. The vertical slider enables users to select a specific signal from the Surface Electrogram Panel, displaying it within this detailed view panel. The four buttons represent different sections of the heart: the overall heart, atria, and ventricles. Pressing any of these buttons masks or unmasks the corresponding cardiac cavity, helping users focus on specific heart regions during signal analysis.



On the right side of the panel, a vertical slider allows users to adjust the zoom on the y-axis, making it possible to amplify or minimize the signal amplitude for easier examination of variations.

Additionally, users can click and drag on the signal display window to navigate through time, offering seamless interaction with different sections of the signal for more comprehensive temporal analysis. This combination of features ensures users can efficiently manipulate and interpret the selected signal with precision.



Figure 51. Main signal panel

8.5.5.8 Time panel

This panel is the focus for most of the interactions related to time management. Although there are a couple of interactions that are not directly related, they do have an indirect connection to this main function.



Figure 102. Time panel

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Figure 53. Time panel with main signal panel

The button, identified with the letter "S", allows activating and deactivating the color representation of the cavity surface.



Figure 54. The "S" icon represents the activation or deactivation of color representation for the cavity surface

Just below the buttons mentioned above, there is the first slider that allows adjusting the autoplay speed. Dragging the slider to the left slows down the playback, while moving it to the right speeds it up.

The next slider, located immediately below, controls manual time playback. Dragging this slider to the left moves it backward in time and moving it to the right moves it forward. The speed of moving

backward or forward in time increases as moving further to the extremes. Next, there are three buttons.

- The center button, with the "Play" symbol, allows to start or stop automatic time playback. On either side of this button, there are two buttons that allow to go backward or forward in time in specific increments. Intuitively, the left button moves backward in time, while the right button moves forward.
- The two hexagonal buttons have a different interaction. To use them, click on them and make circular movements with the corresponding controller, either a mouse or a Virtual Reality controller. The left hexagon is used to zoom the time axis of the signal plots in the main panel and in the Surface Electrogram Pane. The right hexagon is used to scroll on the same time axis.

The bust at the bottom of the panel is a button and at the same time an indicator. It rotates to represent from which direction the cavity is being viewed. Pressing the button resets both its rotation and that of the cavity to its initial rest rotation.



Figure 55. Color panel and main signal panel.

In the virtual reality application, three different viewing modes are offered:

- 1. Large view away from the observer: in this mode, the scene is represented in an enlarged form and away from the observer, allowing a panoramic view of the cavity and its surround-ings. This perspective provides a detailed overview of the structure.
- 2. Mock-up mode, close to the observer: in this mode, the representation of the cavity is shown in a smaller scale and closer to the observer. The perspective is like observing a physical model, allowing for a more accurate examination of details and a closer perception of the structure.

3. The observer enters the cavity and can navigate inside: this mode provides an immersive experience in which the observer can enter the cavity and explore its interior. By using navigation controls, the user can move freely inside the cavity and examine details from different perspectives.

These three virtual realities viewing modes provide varied options for interaction and detailed analysis of the cavity according to the user's needs and preferences.

8.5.5.9 Navigation camera panel

This panel oversees controlling the displacement of a projection system that simulates a camera on the surface of the cavity. This camera allows visualizing the portion of the cavity or the heart located below it and emits ten rays that interact with the surface. These rays access the closest vertices of the mesh where the electrical signal information is stored. These electrical signals are subsequently represented in M Mode Panel, providing a detailed visualization over time of the signals.

The double arrows located in the upper left corner and in the lower right corner rotate the camera in the "z" axis, allowing rotations about the viewing axis itself. To interact with this handler, press the arrows and make circles around the center of the "navigation camera" panel.

The slider on the right side, represented by a pattern of horizontal lines, of the panel manages how close or far the camera is with respect to the cavity. Clicking and dragging upwards will move the camera away from the cavity (up to a certain limit) and dragging downwards will move the camera closer to the surface (up to a certain limit).

Finally, the button at the top right position, represented by four corners, toggles between two sizes for the panel, thus bringing the panel closer to the user and improving its visualization.



Figure 56. Navigation camera panel

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8.5.5.10 Surface electrogram panel

This panel represents the ten signals obtained by the Navigation Camera.

This panel provides a visualization along the time dimension of a series of samples ordered by the projection of a curve, adjusted to the surface. In this way, it allows the specialist to access very quickly the signals of an area of interest.

The horizontal slider regulates the contrast of the signals, dragging the central slider to the left attenuates the contrast of the signals and dragging it to the right increases it.

The vertical slider selects the signal to be displayed in the Main Signal Panel, highlighting in the Surface Electrogram Panel with a brighter color.



Figure 57. Surface electrogram panel

The two buttons to the right of the previous slider provide different panel displays. With both buttons deactivated, the panel is compressed in depth and height. Pressing the upper button will expand in height, while pressing the lower button will expand in depth. With both buttons activated, it will expand in both dimensions.



These different perspectives make it easier for the specialist to compare precisely the tissue under study in spatial-temporal terms, helping to detect fragmented activation fronts, among other features.



Figure 58. Surface electrogram panel compressed along Y and Z axes



Figure 59. Surface electrogram panel compressed along Z axis

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Figure 60. Surface electrogram panel compressed along Y axis

8.5.5.11 ECGs

This panel offers three distinct modes, each designed to provide a different level of interaction and visualization based on the user's needs. These modes are accessible through three dedicated buttons, allowing seamless switching between various data representations.

- **Mode 1:** Display of signals by pressing the first button, the panel displays the signals acquired by an external acquisition system. This mode is ideal for users who need a comprehensive view of all raw signals in real-time, offering a detailed perspective on the data collected.
- **Mode 2:** ECG calculation pressing the second button switches the panel to a mode that presents the calculated ECGs. This mode takes the raw signals acquired by an external acquisition system and processes them into standard ECG waveforms, allowing users to analyze the patient's heart activity more effectively through familiar and clinically relevant patterns.
- **Mode 3:** Torso visualization with electrode mapping by pressing the third button, the panel shifts to a 3D visual representation of the patient's torso, displaying the distribution of the electrodes on the surface. Users can interact with this mode by selecting individual electrodes, which will display the specific signal acquired from the chosen electrode. This mode is particularly useful for spatial analysis, helping users correlate specific signals with their corresponding electrode positions on the torso.

These three modes provide a flexible and intuitive interface, enabling users to switch between

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raw data, processed ECGs, and spatial electrode mapping with ease, enhancing both diagnostic precision and workflow efficiency.



Figure 61. Mode 1: Electrodes signal



Figure 62. Mode 2: ECG calculation

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Figure 63. Mode 3: Point electrodes in torso selector

8.5.5.12 Real time panel

This panel consists of one horizontal controller, two buttons and one subpanel.

The horizontal controller allows the user to zoom in or out along the x-axis on all the signals of the panel. The two buttons switch between the modes of this panel:

- The first one, by pressing the first button shows the real time signals acquired by an external acquisition system.
- The second one, pressing the second button shows the torso of the patient and the distribution of the electrodes on the torso, pressing on an electrode will show the signal being acquired in real time by that electrode.

Finally, the subpanel contains two lists and three buttons. On the patient list displays all the patients that the user has registered. On the boards list displays all the external acquisition systems that the user has. The left button connects to the external acquisition system, the middle button sends the information and displays it in the panel, the right button records the session that is visualized.

This panel provides a versatile interface with tools for signal visualization, patient management, and real-time data interaction. It features a horizontal controller, two mode-switching buttons, and a subpanel with additional functionalities for managing patients and data boards.



Figure 64. Real-time signal display

Zoom and Mode Control

- The horizontal controller allows users to zoom in and out along the x-axis across all signals displayed on the panel, enabling precise analysis of signal details over time.
- The two buttons switch between two distinct panel modes:
 - **Real-time signal display:** Pressing the first button shows the real-time signals acquired by an external acquisition system, offering a comprehensive, live view of all active signals.
 - **Electrode mapping on the torso:** Pressing the second button displays a 3D torso visualization with the electrode positions. Users can interact with this mode by selecting individual electrodes to view the real-time signal being acquired from that specific electrode, making it ideal for spatial correlation and detailed signal tracking.

Subpanel for Patient and Board Management

The subpanel enhances data management by offering two lists and three control buttons:

- Patient List: Displays registered patients, enabling selection and management of recordings.
- **Boards List:** Shows all available external systems that the user can connect to.

The three buttons below these lists control board operations:

- **Left Button:** Connects the selected external system, establishing communication for data transmission.
- **Middle Button:** Instructs the board to send data, displaying the incoming signals on the panel in real time.
- **Right Button:** Records the current session being visualized, allowing users to save and review data later for further analysis or documentation.

This combination of real-time visualization, patient management, and board control makes the panel a powerful tool for both clinical diagnostics and data monitoring, offering a streamlined workflow and enhanced user control.



Figure 65. Electrode mapping on the torso

9. Permissions

VR-CARDIO system is designed to be used by electrophysiologists and cardiology specialists outside of operating room settings to assist in the real-time visualization and interpretation of three-dimensional, holographic, stereoscopic 360° visualization electro-anatomical maps of cardiac electrophysiology.

| | Description | Access |
|---------------|---|---|
| Professionals | This is the user designated to rec- ord new sessions, create new pa- tients for the sessions, visualize already recorded signals and edit any data from the already created patients. Only electrophysiolo- gists and cardiology specialists can have this type of access. | With this access, the user will have access to all the patients and sessions recorded with their profile and be able to visualize and edit specific data on them, for clinical use. (can create content and has access to advanced functionalities). |

| Admin | This is the user responsible for managing user profiles. Only web administrators, who will always be SPIKA TECH's personnel, can have access to this type of access. | With this access, the user has access to all the available tasks and ECG reports with editing and upload permissions for tech- nical support purposes only, excluding clin- ical use, for every user in VR-CARDIO. This type of user can also manage the rest of user types, by managing the information, creating and deleting organizations, and changing their roles' permissions. |
|-------|--|---|
| | | This user profile has only administrative and management tasks, with no operation role according to the intended use of the device. For this reason, those users will be excluded from the test. |

10. Troubleshooting / Residual anomalies

10.1 Connection disruption during data collection

10.1.1 Completion of data collection and display

If the connection is lost while data collection is in progress, data collection will automatically stop, and no action will be required. The data will be displayed on the visualization tool for a brief moment until the data collected until the Wi-Fi disconnection is completely displayed.

10.1.2 Solution

To prevent connection disruptions, ensure both the external acquisition systemand the PC are connected to a stable and secure network for data collection and display.

10.2 Insufficient connection quality 10.2.1 Inability to collect and display data

If the connection is very low, it will not be possible to collect and display data from the device. Session creation is allowed, but if a brief period detects that the data collection process to display them is not working properly due to the connection, no action is needed, the session automatically ends and is deleted from the record as it contains no data.



10.2.2 Solution

To improve the connection, check on your PC if there is a network with better signal quality.

10.3 External data collection device shutdown during data collection

10.3.1 Completion of data collection and display

If the external data collection device is turned off while data collection is in progress, data collection will automatically stop, and no action will be required. Data will continue to be displayed on the visualization tool for a brief moment until all data collected until the external data collection device shutdown is fully displayed.

10.3.2 Solution

To prevent the external data collection device from shutting down during data collection, avoid manipulating the external data collection device until data collection is complete to prevent manual shutdown erroneously.

10.4 Insufficient record quality 10.4.1 Non-optimal record quality detection

If after making a record and visualizing the signal the quality of it is not optimal, it may be due to various factors, such as the patient moving during acquisition or the electrodes not making ideal contact with the body, among other causes.

10.4.2 Solution

To avoid this type of incident, it is essential to check the correct positioning of the external data collection device beforehand and instruct the patient to limit their movement and activities such as talking during the signal acquisition. It may be necessary to repeat the acquisition.

11. Maintenance and monitoring

For maintenance and monitoring of this device, please adhere to the following guidelines:

- **Functional testing:** perform functional tests on the software to ensure all systems are functioning correctly.
- **Software updates:** keep the software up to date by installing any available updates provided. Software updates may include bug fixes, performance improvements, and new features.
- **Data integrity:** verify the integrity of the data acquired by the device during monitoring sessions. Check for any anomalies or inconsistencies in the recorded signals and troubleshoot any issues promptly.
- **User training:** provide adequate training to users on how to properly use, maintain, and monitor the software. Educate users on common troubleshooting procedures and safety precautions.
- **Record keeping:** maintain detailed records of maintenance activities, such as testing. Keep records of software usage and monitoring sessions for reference.
- Spika Tech will conduct annual service activities for the system at the customer's site during the warranty period. These activities will encompass any necessary actions identified by Spika Tech to ensure the system operates properly. Service activities will be scheduled during normal business hours or, if conducted alongside functional maintenance, may be rescheduled.
- The disposal of VR-CARDIO is the responsibility of the user and must be carried out in accordance with local requirements.

12. Frequently Asked Questions (FAQs)

| | If the device is not responding, try the following steps: |
|---|--|
| What should I do if the software is not | Check all connections and make sure they are se- cure. |
| responding | Restart the computer. |
| | If the problem persists, contact technical support for further assistance. |
| How do I contact technical support? | You can contact technical support by <u>con-</u> <u>tact@spikatech.com.</u> |

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| The contact information is typically provided in the user's instructions of use or on the manufacturer's |
|--|
| website. Be prepared to provide your device's model number and a description of the issue. |

13. Manufacturer information



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Patents

This system is covered by the following patent register: European Patent Office. No. 23 382 800.3



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