



T6.3.1 - Digital platform for management of chronic patients -**Output**

Version n. 1 - 12/2023























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T6.3.1 – Digital platform for management of chronic patients

PROJECT NAME: "Promoting eHealth in cb Area by Stimulating local Economies" - ACRONYM: PHASE - PROJECT NUMBER: 365



PROJECT: "Promoting eHealth in cb Area by Stimulating local Economies"

ACRONYM: PHASE

Output



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1. Executive Summary

This document provides evidence of the delivery of the Digital platform for management of chronic patients, developed within the PHASE project as one of the main outputs.

The report envisages an introduction to the PHASE project, detailing its rationale and main objectives, enriched by the identification of the challenges it faces as well as its planned - and implemented - n. 3 pilot actions.

Subsequently, the Digital platform for management of chronic patients is briefly described, and the links to the video tutorials uploaded on Youtube channel providing an explanation of the platform in Italian - English, Albanian and Montenegrin subtitled - are indicated, as well as some screenshots of the mentioned videos. The report also identifies the business and research institutions involved/offering no financial support within the implementation of the platform.

The detailed description and functioning of the platform are included in the dedicated User Manuals, annexed to this document in the English version.

2. Introduction

E-Health is a strategic business sector for European economic development, as mainly reported in EC strategy regarding the "**Digital Transformation of Health and Care in the Digital Single Market**". Significant efforts and investments are demanded to National and local governments in order to align with EU standards, in terms of innovative services organization, digital platforms and sharing services among citizens.

The development of eHealth sector boosts European territories, not only for the improvement of public and private healthcare services, but also by **stimulating competitiveness and innovation** of MSMEs in ICT and digital technologies sector. However, the digital transformation of healthcare sector involves also traditional companies providing social and healthcare services to patients such as nurses, physicians, private clinics and ambulatories, pharmacies and drug stores, gyms and rehabilitation centers, etc. The latter have to improve and innovate the way they provide their services through the use of mobile apps, digital platforms, wearable sensors, personalized data, etc.

Digital technologies such as 4G/5G mobile communication, artificial intelligence or supercomputing offer new opportunities to transform the way we receive and provide health and care services, enabling

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innovative approaches to independent living or integrated health and social care. Furthermore health data and advanced data analytics can help accelerate scientific research, personalized medicine, early diagnosis of diseases and more effective treatments.

Finally, the recent COVID-19 pandemic has furtherly increased the general public sensitiveness on eHealth, stimulating debates and propositions, while policy makers boosted up the efforts and investments (at national and regional scale) to regulate and define standards in the e-health sector.

Starting from these considerations, the **PHASE** project aimed at:

- creating an ecosystem of policies, practices and tools acting as facilitator of competitiveness of MSMEs in healthcare sector and e-health;
- boosting the creation and the development of eHealth digital MSMEs by providing non-financial services
- increasing **competences** in MSMEs, **awareness** in public authorities and **empowerment** in common citizens in CB area about eHealth;
- promoting the CB cooperation among private and public stakeholders through the creation of a transnational network
- improving the overall health and the **quality of life** of citizens in the CB area by using information and communication technologies (ICT) to increase self-management of healthcare and diseases

The PHASE project developed ICT platforms and procedures to address territorial needs (i.e. patient's needs). The approach has been tested and validate in **n.3 different Pilot actions**, addressing 3 different types of clinical needs from patients:

- 1. **Infarct Network**, a territorial network of ICT nodes and equipped ambulances aiming at a prompt and appropriate clinical intervention in early phases of heart-attack (emergency/urgency)
- 2. Management of **Integrated Care Pathways** with specific reference to Neurodegenerative diseases. It is the case for patients requiring multi-specialistic support for their complex disease.
- 3. Remote **monitoring of chronic patients**, for those who requires continuous but low intensity care on the territory, without the need to go to hospitals. It basically extends the healthcare services even to patients' house.

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The PHASE project aimed at creating the right conditions for the boost of eHealth sector in CB area, by providing services and supporting local MSMEs as well as increasing competence and awareness in public authorities and empower patients and caregivers. The project posed the base for the development of common shared open protocols and digital tools, a crucial aspect to guarantee interoperability among different platforms and increase the efficiency of the processes. The digital eHealth ecosystem of services promoted by PHASE project has the potential to contribute to the implementation of the most advanced models of eHealth in the world such as the territorial Virtual Hospital.

3. Output T6.3.1: Objectives

The purpose of this report, which represents one of the PHASE Project main outputs, is **providing evidence of the implemented Digital platform** at the heart of the pilot action n. 3, **for management of chronic patients**, especially those affected by chronic cardiovascular diseases, needing frequent reassessments for the prevention of complication or the treatment of exacerbations. Moreover, the business and research institutions involved/offering no financial support within the implementation of the platform are identified.

4. The Digital platform for management of chronic patients

The Digital platform for management of chronic patients is based on the **Helis Chronical** software, dedicated to the diagnosis of patient's state of health in various areas, and which is compatible with all existing browsers.

The specific use of the application is identified in the medical environment, and its use must be carried out by **qualified and suitably trained personnel** and in compliance with the instructions contained in the User Manual (both for caregivers and physicians).

The access to the platform is therefore restricted to qualified personnel equipped with specific credentials.

The platform enables health providers to remotely monitor their chronic patients and allows to create new clinical events within which it is possible to make one or more requests for examinations and consultations, with the aid of diagnostic devices.

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It also allows to request a **second opinion**: from the login screen is possible to modify the language setting (English, Italian, Albanian and Montenegrin) end enter the login credentials; with the start button the caregiver can proceed with the identification of the event code and the insertion of the patient's personal data (ID Code, username, date of birth, gender end ethnic group).

Once the personal data are saved, the anamnestic data (weight and height) must be entered.

In the "annotations" section is also possible to enter other data related to the patient that can be useful to the cardiologist in reporting the exam, as the screenshot below shows.



Figure 1. The annotation box on which to enter any useful data of the patient.

The operator/caregiver, in the section form of the method to be sent, assigns **priority** via a drop-down menu. Within the PHASE project the methods used are "**Second opinion**" and "Electrophysiology exam".

In case of "second opinion" the operator, via "acquisition of other exam", selects the attachment item in the drop-down menu and uploads the pdf extract of the implantable application to be sent.

In this way the exam is sent to the referring doctor.

The latter logs in to the Helis Chronical application and displays the "second opinion" tests to be reported on the main screen.

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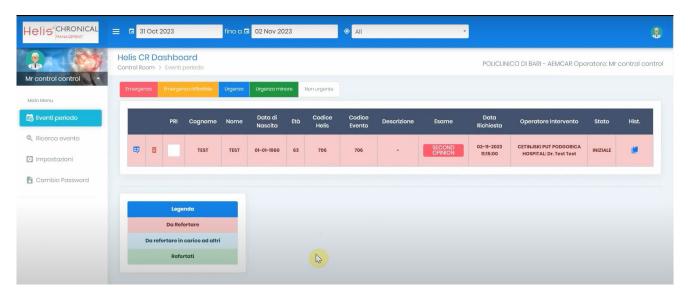


Figure 2. Helis CR Dashboard and the second opinion section.

To take charge of the event he clicks on the button on the left and, in this way, he can view all the **patient's episodes**, in the tracking log on the right, as shown below.

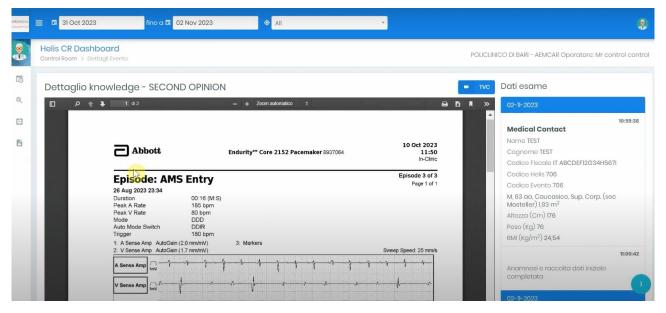


Figure 3. The patient's episodes in the tracking log, viewed by the reporting doctor.

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He can also find all the information that the caregiver entered when requesting the exam, and then reports the second opinion.

Completed the report, the doctor is directed to the confirmation page and previews the report in pdf format; entering his password can confirm the report and finalize it.

At this point, the caregiver in the event list can see that the report for which he requested the second opinion is available. He clicks on the name of the patient, followed by "clinical health data" and "second opinion report available" in green, and pressing on "confirm" he can view the final version of the report.

In case of **caregiver electrophysiology exam**, the caregiver on the same patient selects "Proceed with electrophysiology exam" by clicking on "next", and then the order is sent to the EBIT SuitEstensa application.

On EBIT SuitEstensa the doctor reports the service that was requested by the Montenegrin, Albanian and Italian caregiver, displays the request made by the caregiver and associates it with the patient.

At this point he can check all the events sent by the programmer including serial **numbers and parameters**, and proceeds with the reporting.

To confirm, he enters the password and finalize the report.

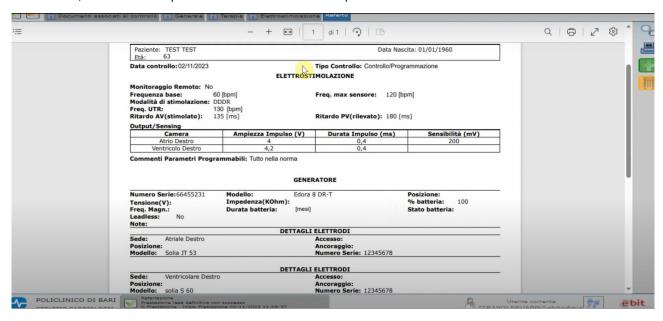


Figure 4. The patient's electrophysiology exam final report.

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Once the report is confirmed by the doctor, it is available for viewing by the caregiver. The latter can click on the "electrophysiology report available" followed by confirm, so notifying the doctor that the report

has been viewed. Then he can open the pdf with the report performed on the EBIT SuitEstensa application and decide to close the event.

He can also search for a report in a closed state using different available filters (nationality, personal code, Helis code, intervention data, surname and name), at any time.

The **video tutorial** including the explanation of the platform, from which screenshots and partly the texts above are taken, is uploaded on Youtube, English, Montenegrin, Albanian subtitled, all available on the link below: https://www.youtube.com/@Policlinico_Bari

- Albanian subtitles: https://www.youtube.com/watch?v=t4aAQu9O7Lw
- Montenegrin subtitles: https://www.youtube.com/watch?v=xx3PPBZFSq8
- English subtitles: https://www.youtube.com/watch?v=LtpCw_SYHk

5. Business and research institutions involved/offering no financial support

The stakeholders who have been involved in the implementation of the platform, ensuring its stability, reliability, security and full functionality, by providing scientific or technical support based on their specific competences, are the following:

- All the PPs involved, namely University Hospital Consortium Corporation Polyclinic of Bari; University Hospital Ospedali Riuniti di Foggia; Molise Region; Ministry of Health and Social Protection of Albania, National Center of Medical Emergencies of Albania, Union of Chambers of Commerce and Industry of Albania, Clinical Center of Montenegro, Ministry of health of Montenegro, Chamber of Economy of Montenegro;
- ARESS Puglia, Regional Agency for Health and Social Affairs of Puglia;
- ASL (Local Health Authority) of Foggia, Brindisi, Bari;
- University of Studies of Bari UNIBA;
- University of Foggia;
- Giovanni Paolo II Cancer Institute Bari;I
- RCCS Casa Sollievo della Sofferenza-San Giovanni Rotondo;

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- ARTI Puglia (Regional Agency for Technology and Innovation);
- Tecnolopolis PST (Technological Scientific Park);
- Confindustria;
- Unioncamere Puglia;
- Regional Department of Health Puglia Region;
- Polytecnic University of Bari;
- Maugeri Bari Scientific Institute;
- AiSDeT (Italian Association of Digital Health and Telemedicine);
- SIC Society of Cardiology (SIC)
- Polytecnic of Torino.

The company **CONSIS**, which offers products and services in the field of ICT, information systems, consultancy, and training, developed this platform and is responsible in case of malfunctions detected or errors received during the execution of the program; in fact, as the User Manuals clarify, the users are requested to notify the CONSIS Helpdesk of any malfunction and / or defect, and the company undertakes to resolve any problems not arising from misuse by the user as quickly as possible from receipt of the report. Moreover, the company **EBIT Ltd.** also played a crucial role, by providing Fysicon, the interface application which provides the opportunity to monitor all the data coming from different implanted devices from a single access point.

6. Annexes

Annex 1. Referring Medical Manual - Helis Chronical Management

Annex 2. Caregiver Manual – Helis Chronical Management

Annex 3. Requests and integrations with third parties. Helis Chronical.net

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Italy - Albania - Montenegro PHASE The state of the sta

This project is co-financed by the European Union under the Instrument for Pre-Accession Assistance (IPA II)



6.1. Annex. 1. Referring Medical Manual – Helis Chronical Management

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Referring Medical Manual Helis Chronical Management

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1 Introduction

This manual provides the User with all the information necessary for the correct operation of the **Helis Chronical** software.

All rights are reserved.

1.1 How to read the manual

This manual contains detailed instructions on using the **Helis Chronical** online reporting system. The most important notes are highlighted in bold.

1.2 Destination of use

Helis Chronical it is intended for the diagnosis of the patient's state of health in various areas.

The specific use of the application is identified in the medical environment. Use must be carried out by qualified and suitably trained personnel and in compliance with the instructions contained in the User Manual.

1.3 License terms

By using the software, you agree to the terms and conditions described below.

The program and accompanying documentation may not be modified, copied, merged with other programs or made available to any third party.

The user is held responsible for any damage resulting from non-compliance with copyright, or from violation of the conditions set out in this agreement.

1.4 Information and recommendations relating to safety of use

Helis Chronical software is compatible with all existing browsers.

1.5 Warnings

Should users detect malfunctions or receive errors during the execution of the program, users are requested to notify the CONSIS Helpdesk of any malfunction and / or defect.

CONSIS undertakes to resolve any problems not arising from misuse by the user as quickly as possible from receipt of the report.



2 Helis Chronical access

The platform allows you to create new clinical events within which it is possible to make one or more **requests** for *examinations* and consultations, with the aid of diagnostic devices.

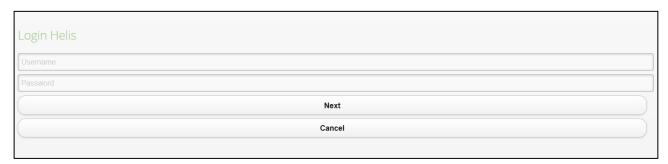
The user in charge of the request will be able to create events and request exams and consultations for the same patient within them.

To start the application, the user starts the Browser, through the specially created link on the Desktop, recognizable by the Helis Chronical software logo.



Link Helis Chronical

The login mask requires login credentials: username and password. The doctor will enter your username and password, then click the **NEXT** button to log into the system. It is possible to cancel the operation by clicking on the **CANCEL** button. Once pressed on **NEXT**, the user will be redirected to the main screen.



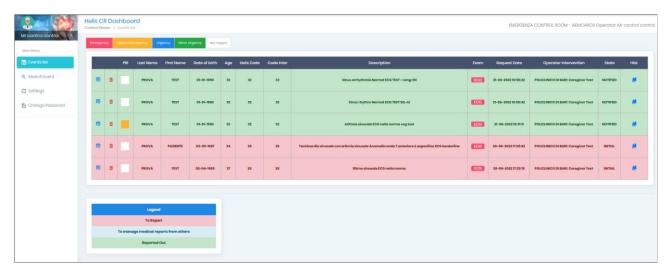
Login Helis Chronical



3 Medical functionality

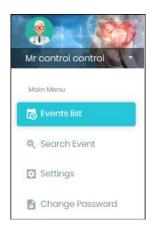
3.1 Initial Screen

After logging into the system, the physician will be shown the main screen of the Helis Chronical system.



Helis Chronical Main Screen

From this screen, the doctor can carry out various operations that can be selected from the menu on the left side of the screen.



Dettaglio Menù



3.1.1 Events Period

By clicking on this menu item, the doctor will be able to manage the list of events in the system. You can also filter the list of interventions by selecting a date range from the appropriate fields located at the top of the screen. The list of interventions will show the doctor only and exclusively the interventions of the type of method assigned to him (ECG, ECHO. Tele consultation, etc...).



Detail Selection Dates Interventios

In the first field the doctor will select the start date and in the second the end date of the interval. Whenever a date is selected, the system will automatically update the list of interventions on the screen. The interventions presented in the list will be differentiated from each other based on their status. After the list of interventions there is a legend that will allow the doctor to distinguish the different states based on their color.



Detail Legend

- TO BE REPORTED: it is possible to take charge of the event for reporting
- TO BE REPORTED IN CHARGE TO OTHERS: the event is in the reporting phase taken over by another
 doctor
- **REPORTED:** the event reporting has already been submitted for this event



3.1.2 Event Priority Display

In the Control Room part, the Doctor / Specialist / Technical Operator / Monitoring Operator will be able to notice, at the upper left, immediately before the Events List, a *Legend* indicating the **Priority** levels and the relative assigned colors.

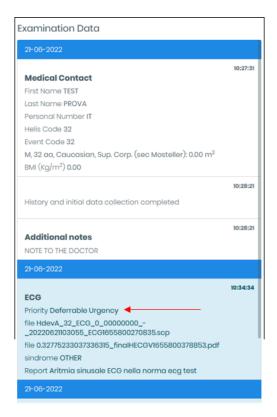
The Priority Level Assigned to the single event by the POC / POCT Operator, for convenience and easy consultation, is displayed in the **PRI** (Priority) column as a colored square.



Priority in the Event List

This information is also visible when the Doctor / Specialist carries out the evaluation of the exam: *the Priority Level assigned to the Even*t is shown in the *Priority* data in the Tracking Log that contains the Clinic.

An illustrative image follows:



Priority in the Tracking Log

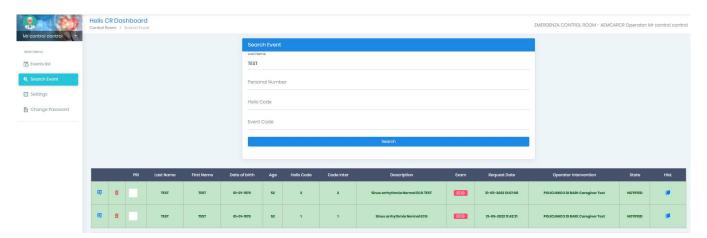


3.1.3 Event search

From this section the doctor can carry out research on specific tracks. The search parameters are: Surname, Tax Code, Helis Code (unique code of the event created by the mobile station) and the Event Code.

Just enter one of these parameters and click on search and the result will be returned in a few moments.

The list will contain both interventions already notified and interventions that have yet to be reported.

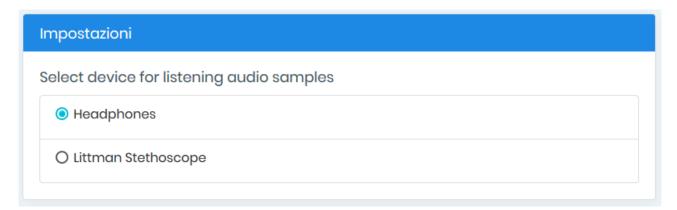


Event Search

Once the search has been carried out, it will be possible to manage the interventions from the list. If already notified, it will be possible to access the event to view the reports already submitted previously; if the interventions are to be reported, it will be possible to access the reporting phase.

3.1.4 Settings

From the settings menu, the doctor can select the device from which he will listen to any audio samples for Phonendoscopy present during the reporting phase or during a teletext consultation.



Select Audio Settings

By selecting **HEADPHONES**, the user can use simple headphones connected to the PC. It is advisable that the headphones connected are equipped with a microphone, in this way the doctor can communicate during a tele consultation. Otherwise, he can only listen.

By selecting **LITTMAN STETHOSCOPE**, the doctor can use a stethoscope configured and connected via Bluetooth to the PC. Through the use of this tool, the doctor will be able to listen to any audio samples present during the reporting or can use the same tool to produce the same samples that will be loaded within the event. This functionality will be described in detail in the following chapters.



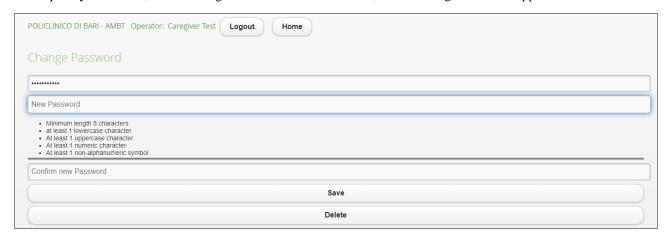
4 Change Password

By accessing this section, the doctor can change the password of his account. In order to change the password, the password used to access Helis Chronical must be entered in the first available text field.



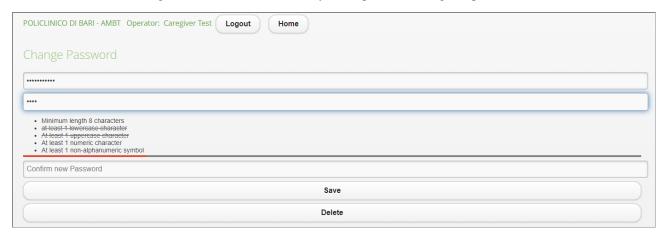
Change Password

Subsequently to the user, after clicking on the New Password field, the following screen will appear:



Complexity Criteria New Password

The user will be presented with a list of minimum complexity criteria that must be respected when composing the new password. By creating the new password, if the criteria are met, they will be removed from the list and the gray bar at the end of the list will change color to indicate the security of the password being composed.

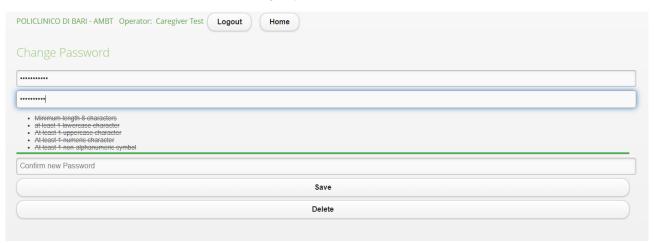


Complexity Criteria New Password





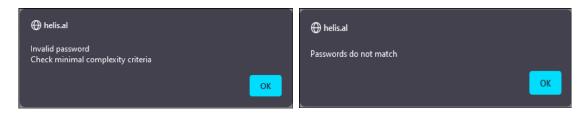
Complexity Criteria New Password



Complexity Criteria New Password

When all the minimum password complexity criteria are met, the user will have to rewrite the password just composed in the **Confirm New Password** field and once the compilation has been completed, by pressing "**Save**" the password change will be confirmed and the operator will be redirected to the screen principal.

In the event that the user does not comply with the minimum complexity criteria or the passwords entered in the two fields do not coincide, upon saving confirmation, the system will notify the changes to be made using pop-ups in order to correctly confirm the change.

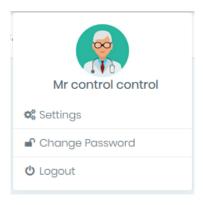


 $Error\ Messages$



4.1.1 Logout

In order to log out, the doctor must click on the user icon at the top right of the screen and press **LOGOUT**. From here the doctor can also access the settings and change password section.



Menù log out



5 Types of exams

5.1 Electrocardiographic examination

The receipt of an event will be notified by an acoustic signal that will alert the referring physician of the arrival of an ECG.



List of interventions

From here the user will have a first summary of the main information regarding the patient and the event such as:

- PRIORITY
- SURNAME and NAME of the patient
- DATE OF BIRTH
- AGE
- HELIS CODE
- EVENT CODE
- **DESCRIPTION**: An automated report performed by the Software using the Glasgow algorithm which gives the doctor an initial (approximate) evaluation of the ECG. In the presence of multiple ecgs, this self-report will give the doctor the opportunity to evaluate the severity of the ecg in order to give precedence to any emergencies that require an immediate event.
- EXAM: The type of exam: whether it is ECG, SECOND OPINION or TELEVIDEO CONSULTTO
- **REQUESTED DATE**: Date and time of sending the request
- INTERVENTION OPERATOR: The operator or position that sent the request
- **STATUS**: The status of the event that may be
 - INITIAL (RED): the ECG has been received and has yet to be taken over by the referring physician
 - INITIAL (GREEN): the ECG was taken over by another referring doctor and is being reported
 - TO BE NOTIFIED: the ECG report has been sent to the requesting station and is being read.
 - **NOTIFIED**: the station read the ECG and confirmed the acknowledgment.
- **HISTORY**: clicking on the button the complete list of all tests performed for the same patient will be displayed in correspondence with the event. In this way, the doctor will have the opportunity to compare the exam just received with any other tests received for that patient.

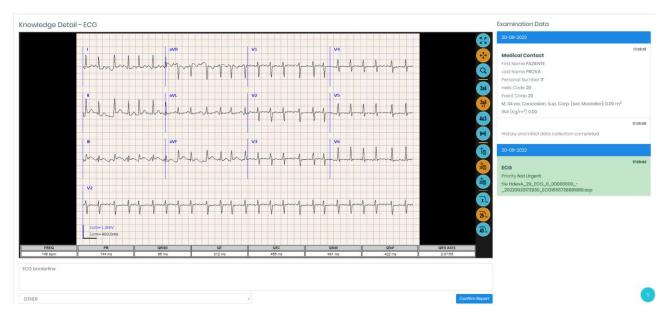
The doctor will use the appropriate buttons to interact or take delivery of the ECG:

- ECG. If the ECG is taken over by another doctor, the button will be replaced by this padlock indicating that the ECG is blocked and is being reported.
- Example 2: by pressing this button, the doctor will be able to delete the event if the workstation no longer needs the report.



5.1.1 Reporting Tool

Once the ECG has been taken over, the screen that will appear will be the following.



Reporting Tool

5.1.1.1 General description

The ECG Reporting Tool allows you to view two-dimensional traces in DICOM format. The display panel is divided into five sections:

- In the upper part of the screen there is the patient data
- In the immediately lower part, the ECG trace
- In the lower part, the measurements taken and the text box in which the doctor will write the report
- On the side of the ECG, the side menu with all the functionality of the reporting tool (Described in detail in the next section)
- On the right side all the information on the event, the clinical data and the measurements made by the station that started the event. This list gives specific information about the patient's status in order to make reporting by the physician easier and more accurate



5.1.1.2 Reporting Tool Functionality

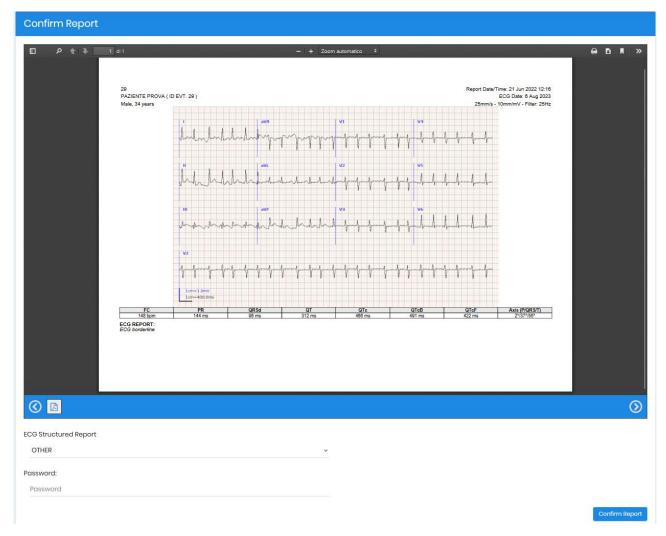
The following table groups and describes all the functions present in the reporting tool. Features that help the doctor in an easier and faster interpretation of the trace.

ICON	TOOLTIP	FUNCTIONALITY
	Fit to screen	Modify the display scale of the selected exam in order to adapt the size of the images to the panel that contains them.
•	Move	If this function is activated, it allows you to move the ECG on the screen so that you can focus on a specific area of the track. (if enabled, it disables the zoom function)
Q	Zoom	It allows you to zoom to view certain areas of the ECG with more precision for easier understanding (if enabled, it disables the move function)
3x4 3x4 4x3 6+6	Display layout	Allows you to view the leads with different layouts: - 3 x 4 - 3 x 4 plus the long track - 4 x 3 - 6 + 6
7 mm 5 mm 10 mm 20 mm	Vertical scale	Allows you to decide the values of the vertical scale in mm / mV (5, 10 or 20 mm / mV)
25 Hz	Filter	Allows you to enable or disable a 25/40 Hz filter.
Confirm Report	Send Report	Once the report field has been filled in, the report can be sent to the requesting station. The user password will be requested again to confirm the sending
⇔	Print Report	Allows the clinician to print the report
Ď.	Export Report (PDF)	Allows you to export and save the report in PDF format



5.1.1.3 Confirm Report

Once the report is completed, the user will be directed to the confirmation page where he will have to manually re-enter his password (password corresponding to the one with which he logs in on the Helis portal) and click on confirm report. The password request upon confirmation of the report is made as an additional security measure: if the doctor were to leave the workstation, entering the password would prevent someone else from sending incorrect reports that could compromise the event in progress.



Confirmation Report

5.1.1.4 Measures

In the lower part of the screen, you can see the box in which the doctor will write the report and immediately above a set of temporal measurements that represent the distances between:

- PR
- QRSD
- QT
- RR
- ST
- QRS AXIS

These measures are expressed in MS.

In addition, the tool automatically provides two derived measurements:

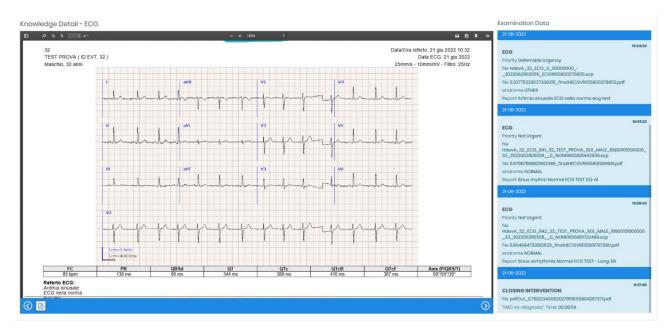
- FREQUENCY: expressed in BPM (beats per minute) and calculated as (1000 / RR) * 60
- QTc: expressed in ms and calculated as QT / sqrt (RR)



5.1.2 Final Report View

Once the POC has read the report and has concluded the event, the final event report will be available for both the POC and the doctor. This report will contain all the electrocardiographic reports performed on the patient including the complete tracking log.

To view the final report, simply access an event in the list and select the last item present from the tracking log, or **INTERVENTION CLOSURE**. The screen that will appear will be the following:



Final Report View

Through the tracking log, the doctor as well as viewing the final report will be able to access all the exams uploaded and the reports previously submitted. Just scroll through the tracking log and press on the exam / report you want to view. Furthermore, for the individual reports and for the final report, the doctor, using the buttons located on the upper part of the screen, can search the document, zoom in as well as print or save the pdf files of all the available reports in the local memory of the computer.

To return to the list of medical interventions, just click on **EVENTS PERIOD** located in the menu on the left of the screens in order to proceed with the reporting of the next event.



5.2 Second Opinion and Teleconsulting Consultancy

The receipt of an event will be notified by an acoustic signal that will alert the referring physician of the arrival of a **SECOND OPINION** or **TELE CONSULTO** event.

The doctor for SECOND OPINION AND TELECONSULTATION events in the list of events will be able to see only and exclusively the events assigned to him and within his competence.



Event Reception

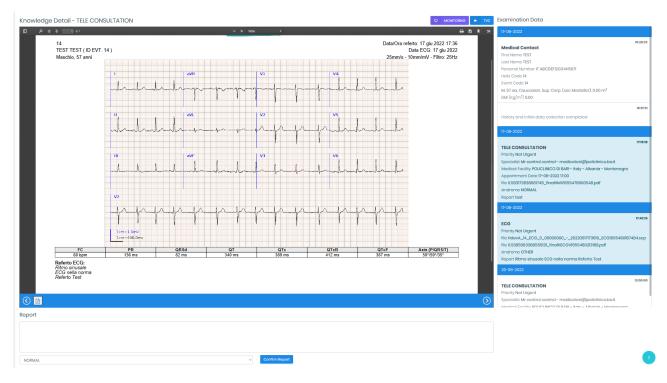
<u>N.B.</u>

The functions that we will describe in the next chapters will be considered valid for both types of interventions. The differentiation between the two types of event requests is that for the **SECOND OPINION** the date indicated in the requested date field is the date on which the POC station awaits the reporting of the event, instead in the case of **TELE CONSULTO** it will be the date and the time of the appointment that the POC has selected to carry out the teletext consultation with the patient.

As regards the **SECOND OPINION** event, the POC station will have time until the date entered on the requested date to upload all the tests and measurements that the doctor will view and for which he will have to issue the report. Instead, for **TELE CONSULTO**, uploading documents and entering any measurements can take place live during the video call with the patient.

5.2.1 Introduction

Using the button the doctor logs in to the event and the screen that will appear will be the following:



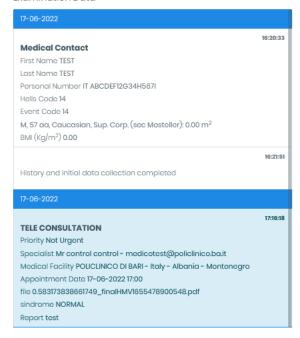
Second Opinion / Teleconsultation Reporting Tool

On the right of the screen we will have the **TRACKING LOG** of the event, or the complete list of data that the POC has entered when creating the Helis event. Each single field will have the precise date and time of entry, in order to have a chronological tracking of the operations performed on the event.

To scroll the tracking log and view all the data entered, the doctor can use the mouse wheel or the scroll bar located on the right side of the table.



Examination Data

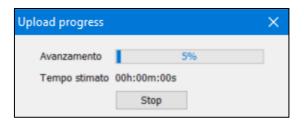


Second Opinion / Teleconsultation Reporting Tool

Whenever the POC will carry out data entry operations on the event, the tracking log will automatically update, presenting the new data entered to the doctor.

For example, if the workstation inserts the patient's vital parameters measurements, they will be added to the tracking log and can be viewed and taken into consideration for the evaluation of the exams included in the event.

When the PC loads a new exam, the doctor will see a loading window in the center of the screen. This window indicates that a new exam is being uploaded.



Loading Exam

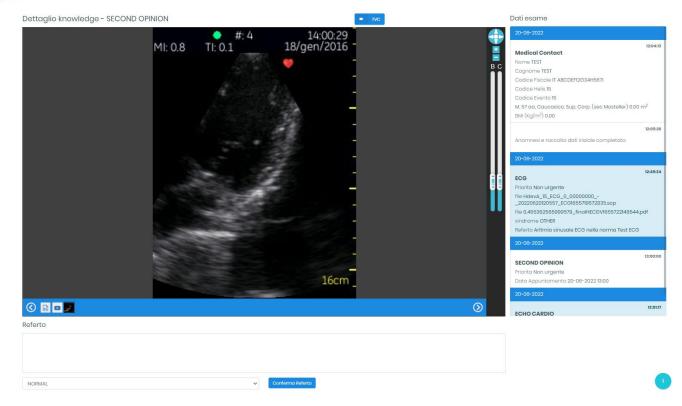
Once the upload has been completed, the doctor receives a **GREEN** notification banner at the top of the screen that will warn him that a file has been uploaded.



Exam Upload Notification

The page will automatically reload and the reporting tool will show the doctor the exam just loaded.



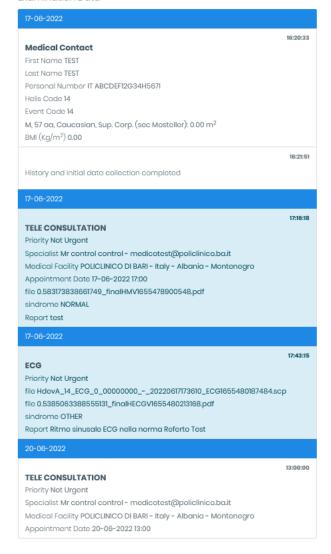


New Exam

Each time a new exam is entered, a new entry will correspond to the tracking log, always correlated with the date and time of entry. Within the tracking log it is possible to note that the loaded exams have a different color from the simple event data or vital parameters. The tracking log indicates the name of the exam and the name of the file uploaded within the event.



Examination Data



Tracking Log detail

You can switch from one exam to another by simply clicking on the exam you want to analyze; the reporting tool will automatically show the selected exam in the center of the screen.

In the next chapter we will analyze more specifically the functionality of the reporting tool.

5.2.2 Reporting Tool Functionality

5.2.2.1 Image analysis

We will now see in detail the tools of the reporting tool that the doctor will use for a correct analysis of the reports in image format. The screen that will appear will be the following:





Exam Image

This table describes the tools of the reporting tool in detail.

ICON	TOOLTIP	FUNCTIONALITY	
	MOVE AND CENTER IMAGE	Using these commands, the doctor can (after zooming in on the image) move to a section of the image to analyze it better. By pressing the central button, the image will be restored to its initial status.	
* -	ZOOM	Using these commands, the doctor can zoom in on the image to better analyze specific sections of the image	
B C COLL COLL COLL COLL COLL COLL COLL C	BRIGHTNESS AND CONTRAST	Using these commands, the doctor can change the brightness (B) and contrast (C) values to better analyze the image.	
	IMAGE NAVIGATION	If the examination includes several images, using these commands the doctor can move from one image to another, either by directly pressing the image icon or by pressing the arrow keys on the sides of the tool.	

5.2.2.2 Video exam analysis

We will now see in detail the tools of the reporting tool that the doctor will use for a correct analysis of the reports in video format. The screen that will appear will be the following:





Exam Image

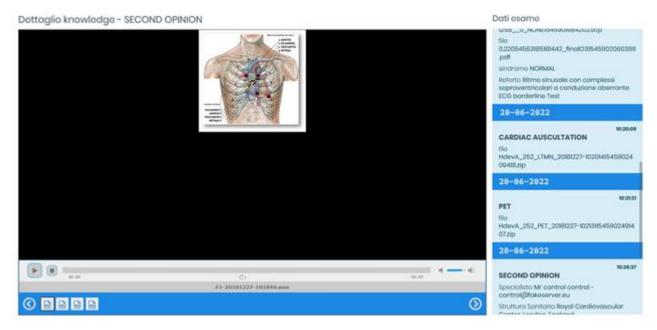
This table describes the tools of the reporting tool in detail.

ICON	TOOLTIP	FUNCTIONALITY
	PLAY/PAUSE/STOP	Using these buttons, the doctor can start and stop the video. You can also use the navigation bar to move through the video track and pause on a specific point.
#\$	→ → VOLUME	
	REPEAT VIDEO	By activating this button, the doctor will set the automatic repetition of the video. This will automatically repeat the video once it has finished playing. The video will continue playing until the doctor stops it.
	VIDEO NAVIGATION	If the exam includes multiple video tracks, using these commands the doctor can move from one video to another: either by directly pressing the video icon or by pressing the arrow keys on the sides of the tool.

5.2.2.3 Audio exam analysis

We will now see in detail the tools of the reporting tool that the doctor will use for a correct analysis of the audio samples for Phonendoscopy. The screen that will appear will be the following:





Exam Image

To access the analysis of the audio samples, the doctor must go to the tracking log and scroll to **CARDIAC AUSCULTATION**. Once clicked, the reporting tool screen will load. This table describes the tools of the reporting tool in detail.

ICON	TOOLTIP	FUNCTIONALITY
	PLAY/PAUSE/STOP	Using these buttons, the doctor can start and stop the video. You can also use the navigation bar to move through the video track and pause on a specific point.
#(VOLUME	From here the doctor can adjust the volume of the video track.
	REPEAT VIDEO	By activating this button, the doctor will set the automatic repetition of the video. This will automatically repeat the video once it has finished playing. The video will continue playing until the doctor stops it.
	AUDIO TRACK NAVIGATION	Using these commands, the doctor can select the various audio tracks by pressing directly on the icon or by pressing the arrow keys on the sides of the tool.
F1-20220620-101844.WAV	AUDIO TRACK NAME	Immediately below the repeat audio button will be the name of the file being played. The first two characters of the file name (F1-F2-F3-F4) identify the 4 different foci that are analyzed in cardiac auscultation.

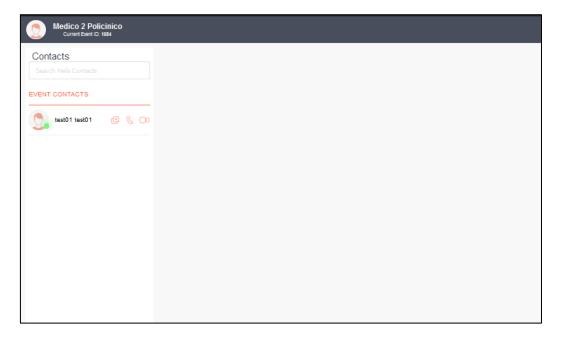
5.2.2.4 Televideo Consultation

Regardless of whether the method selected for the event is **Second opinion** or **Tele Consultation**, the doctor will be able to carry out a Tele Video Consultation, in Video Conference, with the POC who booked it on the predetermined

date and time. Just click on the button

Helis Chronical will open a video conference form in another browser page as shown in the following image:



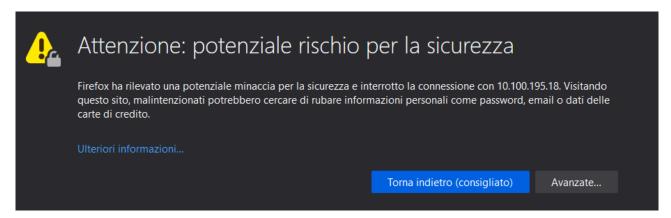


Exam Image

In the upper part of the screen, the name of the doctor who is in charge of the event report will be indicated, while the POC who forwarded the teletext consultation request will be shown in the contact list. To start the video conference for the doctor, just click on the icon.

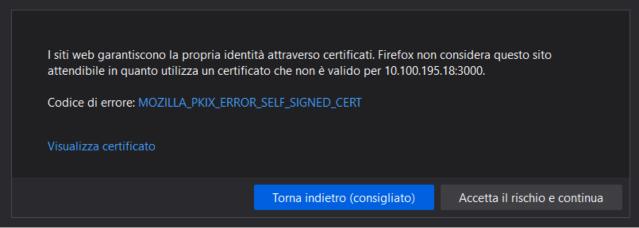
<u>N.B.</u>

If the video conference you are trying to start should be the first call ever made, the browser will block the start of the call and will present the following message:



Video Conference Block 1

In order to continue with the video conference, the doctor must click on "Advanced" and click on "Accept the Risk and Continue".



Video Conference Block 2



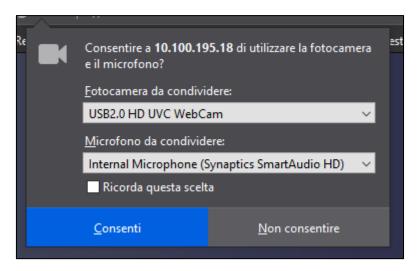
And then on "Retransmit", the page of the video conference module will be reloaded.

Per visualizzare questa pagina Firefox deve ritrasmettere le informazioni già inviate. Questa operazione ripeterà qualsiasi azione eseguita in precedenza, ad esempio una ricerca o una conferma d'ordine.

Ritrasmetti Annulia

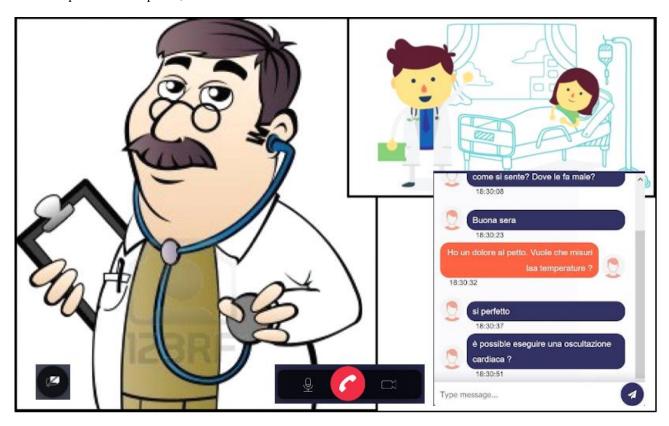
Resend Screen

The doctor will try again to start the video conference from the appropriate button and as a last step will have to authorize the browser to access the computer's microphone and webcam. Just click first on "Remember this choice" and then on "Allow".



Audio/Video Device Permissions

Once this process is completed, the video conference will start.



Tele Conference



During the video conference (if the POC does not have a microphone) it will be possible to use a chat integrated in the video conference system to be able to communicate with the doctor. Just press the button



to open the chat window.

It is important for the doctor to know that everything written in the chat of the videoconferencing system is recorded, reported in the event tracking log and also in the final report generated upon notification of the report being read by the POC.

During the tele-conference it will be possible for the POC (if it had not done so previously) to upload any tests that the doctor can view on the Helis Chronical page as described in the chapter on reporting the event in second opinion. In addition, the doctor will be able to help the POC operator in the detection of any vital parameters or in the positioning of the stethoscope for correct detection of the audio samples that will be loaded into the Helis event and that the doctor can analyze during the video conference.

5.2.3 Monitoring

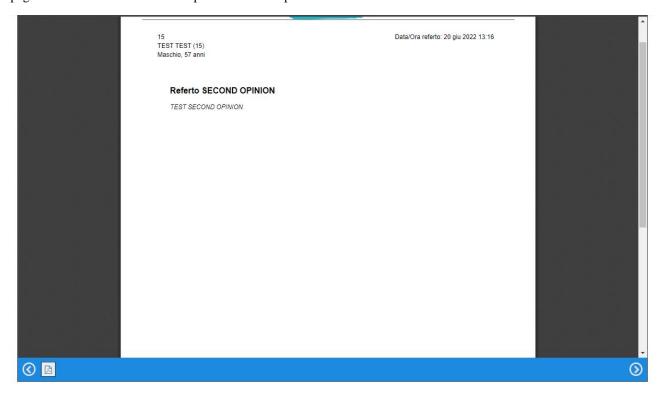
In the Knowledge detail, we find the button at the top right access the portal, which collects all patient information relating to the implanted device.

5.2.4 Confirm Report

Once the video conference has been completed or the analysis of the exams present in the **Second Opinion or Tele Consultation** event has been completed, the doctor will proceed to draw up the report in the appropriate text box at the bottom of the reporting tool.



Once the report has been filled in, the doctor, after clicking on **CONFIRM REPORT**, will be directed to the summary page where the doctor will have a preview of the report that the POC station will receive.



Report Preview



To definitively confirm the report, the doctor must enter the password he uses to log in to the Helis Chronical system in the field immediately below the preview of the report and press **CONFIRM REPORT** again.

Password:	
Password	
	Confirm Report

Confirm Password

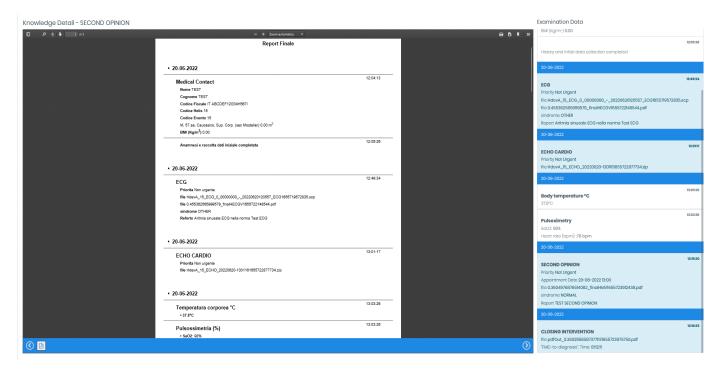
The password request upon confirmation of the report is made as an additional security measure: if the doctor were to leave the workstation, entering the password would prevent someone else from sending incorrect reports that could compromise the event in progress.



5.2.5 Final Report View

Once the POC has read the report and has concluded the event, the final event report will be available for both the POC and the doctor. This report will contain all the reports of all the types of event requested, the exams uploaded, the complete tracking log and the history of the chat used during the remote consultation..

To view the final report, simply access an event in the list and select the last item present from the tracking log, or **INTERVENTION CLOSURE**. The screen that will appear will be the following:



Final Report View

Through the tracking log, the doctor as well as viewing the final report will be able to access all the exams uploaded and the reports previously submitted. Just scroll through the tracking log and press on the exam / report you want to view. Furthermore, for the individual reports and for the final report, the doctor, using the buttons located on the upper part of the screen, can search the document, zoom in as well as print or save the pdf files of all the available reports in the local memory of the computer.

To return to the list of medical interventions, just click on **EVENTS PERIOD** located in the menu on the left of the screens in order to proceed with the reporting of the next event.



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6.2. Annex 2. Caregiver Manual – Helis Chronical Management

T6.3.1 – Digital platform for management of chronic patients

PROJECT NAME: "Promoting eHealth in cb Area by Stimulating local Economies" - ACRONYM: PHASE - PROJECT NUMBER: 365

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Care Giver Manual Helis Chronical Management

rel. 1.0 – 30.06.2022



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1 Introduction

This manual provides the User with all the information necessary for the correct operation of the **Helis Chronical** software.

All rights are reserved.

1.1 How to read the manual

This manual contains detailed instructions on using the **Helis Chronical** online reporting system. The most important notes are highlighted in bold.

1.2 Destination of use

Helis Chronical it is intended for the diagnosis of the patient's state of health in various areas.

The specific use of the application is identified in the medical environment. Use must be carried out by qualified and suitably trained personnel and in compliance with the instructions contained in the User Manual.

1.3 License terms

By using the software, you agree to the terms and conditions described below.

The program and accompanying documentation may not be modified, copied, merged with other programs or made available to any third party.

The user is held responsible for any damage resulting from non-compliance with copyright, or from violation of the conditions set out in this agreement.

1.4 Information and recommendations relating to safety of use

Helis Chronical software is compatible with all existing browsers.

1.5 Warnings

Should users detect malfunctions or receive errors during the execution of the program, users are requested to notify the CONSIS Helpdesk of any malfunction and / or defect.

CONSIS undertakes to resolve any problems not arising from misuse by the user as quickly as possible from receipt of the report.



2 Helis Chronical access

The platform allows you to create new clinical events within which it is possible to make one or more **requests** for *examinations* and consultations, with the aid of diagnostic devices.

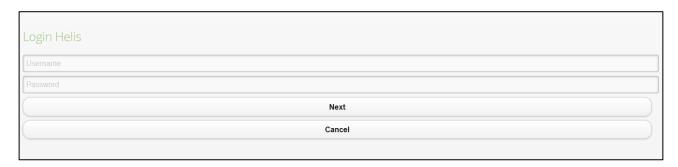
The user in charge of the request will be able to create events and request exams and consultations for the same patient within them

To start the application, the user starts the Browser, through the specially created link on the Desktop, recognizable by the **Helis Chronical** software logo.



Link Helis Chronical

In the first phase, the Operator must enter the credentials to access the platform.



Login Helis Chronical

After logging in, the Operator must indicate the environment code to be used. The environment code identifies the requesting operating unit.



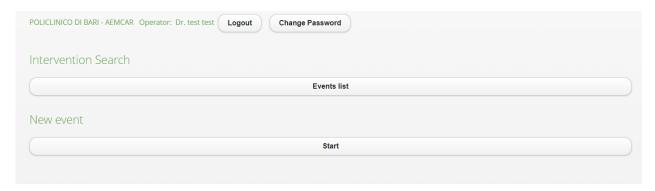
Entering the Environment Code



3 Applicant functionality

3.1 Event list and history search

After entering the room code, the Operator can select the operation to be carried out.

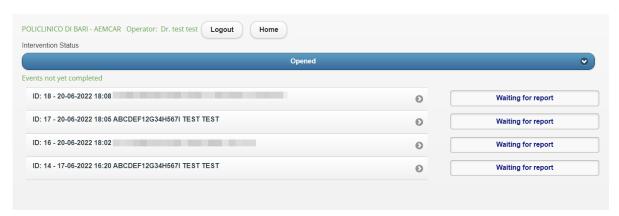


Operation Helis Chronical Choice

Events list: Allows the Operator to search for a previously created Event regardless of the status (open or closed) **Start**: Allows the Operator to make a new event.

3.1.1 List of open events

By accessing the "Events List" section, the operator can directly view the list of open events, regardless of the exam required and its status.



Open Events List

The states can be:

- Cancel: for an open event for which no examination or visit request has been made;
- Pending reporting: it is an event for which at least one exam was requested between ECG, ECO, SECOND OPINION and TELECONSULTO;
- Report Available: which indicates the presence of at least one exam in the reported status;
- Concluded or closed: it is a finished event.

3.1.2 Event Search

The Operator can search for a **CONCLUDED** event at any time through the Events List section. Just select the status of **CLOSED** interventions from the appropriate drop-down menu.

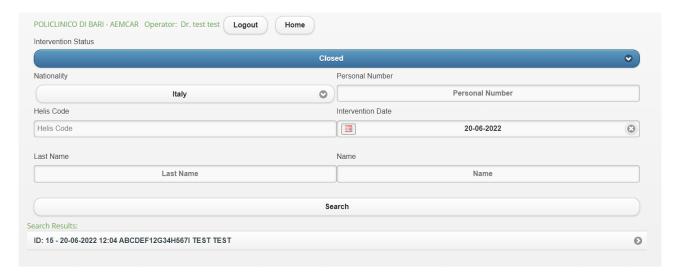


Event Status Menu



The operator will be directed to the event search screen. To search, you must fill in at least one field and click on search.

After searching for the exam, you will need to click on the reference line to download the Final Report.



Research Section



3.2 Initial phase of a New Event

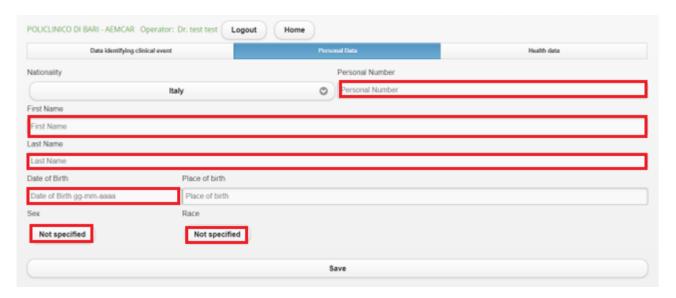
After clicking on the "Start" button, the Operator starts the execution of a new event which consists in the request for one or more exams and / or teleconsultation.

The preparation is divided into three steps.



New Exam - Step 1

The Operator enters the identification code of the event to be carried out in the "**Event Code**" field. Helis Chronical assigns a unique progressive number to the event in progress (which cannot be changed by the Operator).



 $New\ Exam-Step\ 2$

By clicking on "**Personal Data**", the Operator will pass to the insertion of the patient's personal data, if not automatically populated as a result of additions implemented in the particular installation domain.

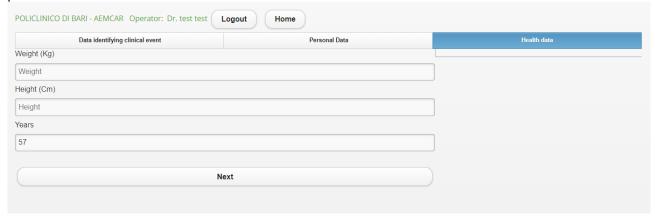
In the event that some data during the request entry phase should be incorrect, the operator can modify each single field. In order to continue, the operator must make sure that he has filled in all the mandatory fields marked in red. By clicking "Save" the program will automatically go to the next screen containing the message "Saving done".



Confirm Save



By clicking on "OK" the program automatically allows access to the third and last step of entering data relating to the patient "Clinical Health Data".

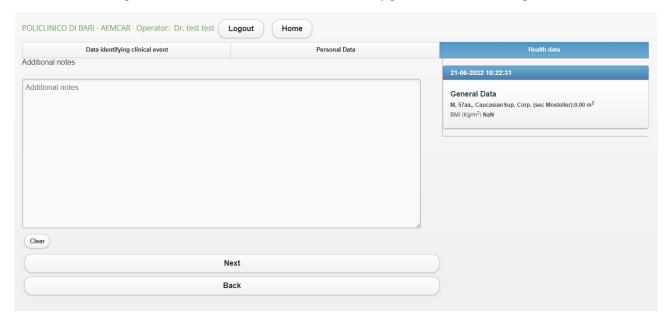


New Exam - Step 3

If he deems it necessary, the operator can enter the weight and height of the patient, otherwise he can continue with the subsequent screens by clicking on the "**Next**" button. The patient's age is automatically calculated by the program based on the date of birth entered in the personal data.

3.2.1 Notes

In this section, the Operator will have a text box in which to enter any personal notes about the patient.



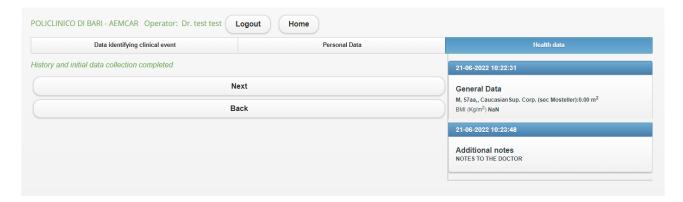
Annotations

Once you have finished filling in the text, just press **NEXT** to save and continue to the next screen. If, on the other hand, you want to completely clean up the text field, just press **CLEAR** and all the typed text will be permanently deleted.



3.2.2 Exam selection

After finishing the interview with the patient, the operator can press "Next" to start with the selection of the operation to be performed otherwise he can press "Back" to return to the previous screens and possibly correct the data entered for the event. The user will always have available on the right side of the screen a complete summary of all the data entered during the event, complete with date and time of entry for each single field.

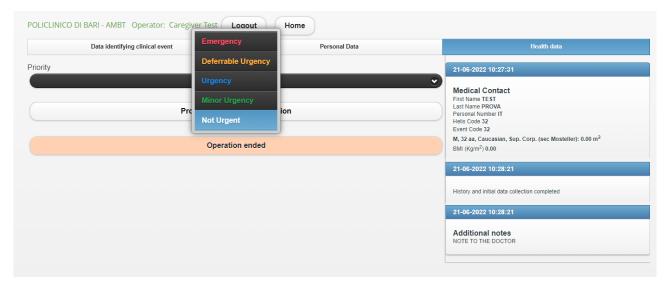


Event Confirmation

3.2.3 Event Priority Allocation

In the form for selecting the examination method to be performed (see image below), the operator has the possibility, using a drop-down menu at the top, to assign a priority to the reporting request he is about to perform.

The default mode is **Not-urgent**.



Levels of Priority

By clicking on the drop-down menu, you will be able to select the Priority Level from the following:

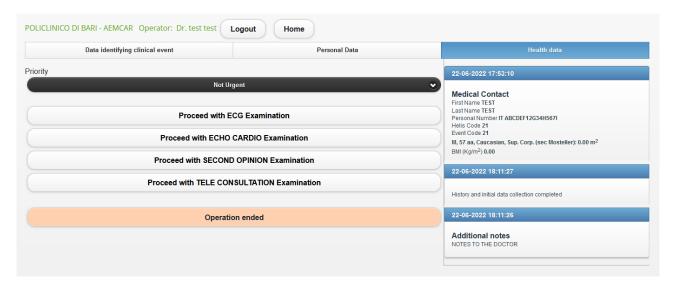
- Emergency;
- Deferrable emergency;
- Urgency;
- Minor urgency;
- **Not urgent** (default value);

Once the priority has been chosen, the operator can proceed, as usual, with the execution of the exam.



3.2.4 Exam preparation

From this screen, the operator can perform a series of tests that can be selected from the menu below.



Exam Selection

It is possible to request several **ECG**, **ECHO CARDIO** type exams at the same time, while requests for **SECOND OPINION or TELECONSULTO** inhibit other types of requests. In the sense that it will not be possible to request other exams until they are reported.

3.2.5 Conclusion of an exam and of the whole event

Each time he returns to this screen, the operator can decide to terminate the event or request other exams among those made available by the system. It is possible to proceed with the request for other types of exam.

The choice "**End of Intervention**", on the other hand, puts an end to the event and allows the system to produce the final report of the entire clinical event. From that moment on, the event will only be available in the Events List section, by selecting the "**Closed**" event history".



4 Types of exams

4.1 Second Opinion or Teleconsultation advice

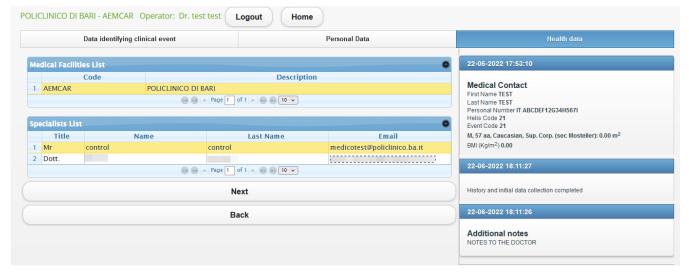
4.1.1 Consultancy planning

The Operator can schedule the booking of a consultation in Second Opinion or a Teleconsult for further diagnostic investigations or as a first clinical choice.

In the first instance, the Operator will select whether to perform a consultation in Second Opinion or schedule a consultation via video conference by selecting one of the two options in the list of exams available on the platform.



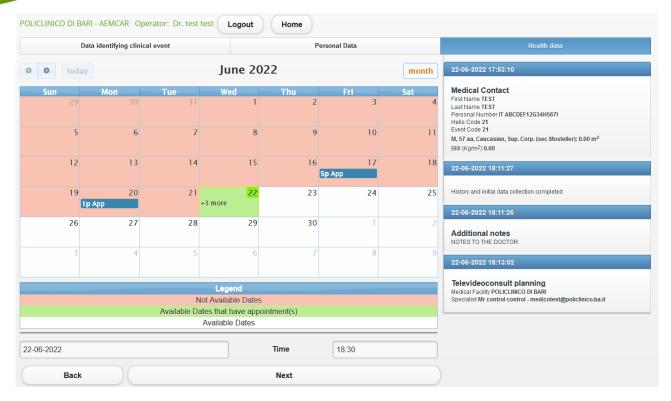
By selecting the teleconsultation, the operator must select the facility and the doctor associated with the facility with whom the video conference visit will be performed. Once the facility has been selected from the list, it will immediately appear under the list of doctors belonging to that facility. Once both have been selected by pressing the "Next" button, the operator will go to the following screen.



Teleconsultation facility and doctors list

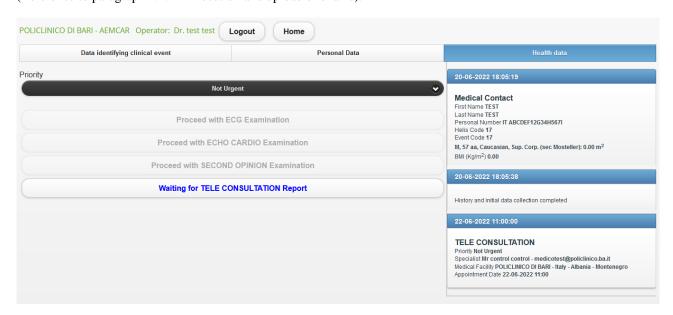
For both the Second Opinion and the Teleconsultation, the operator must select the date and time from the calendar by clicking on the corresponding day and modifying the date in the field provided. In the case of a second opinion, this will be the date by which the reporting is expected. In the case of teleconsultation, the date and time of the appointment with the patient. After selecting, click on **Next**.





Programming Second Opinion and Teleconsulting

You will be prompted for further confirmation, and then you will be redirected to the exam list screen again. Until the consultation report is received, it will not be possible to perform further types of exams for this event. Instead, it will always be possible to access the dedicated section on "**Pending SECOND OPINION or TELECONSULTATION Reporting**" in order to perform a series of data uploads and reports useful for consulting. (Reference to paragraph 4.1.2 - Execution and upload of exams).

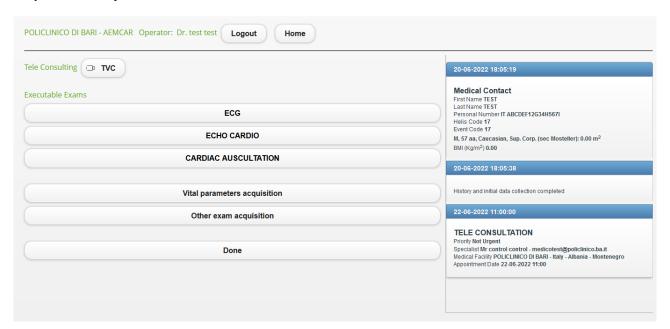


Teleconsulting



4.1.2 Executing and uploading exams

Once a second opinion or teleconsultation has been started, after accessing the section by clicking on "**Pending SECOND OPINION or TELECONSULTATION Report**", the system opens a new section in which it is possible to carry out various operations.



Select Operation Second Opinion or Teleconsultation

The Operator has the possibility to perform the following exams:

- Ecg
- Echo Cardio
- Perform a Cardiac Auscultation
- Carry out new measurements of the Vital Parameters
- Acquire New Exams (upload external reports)
- Carry out a Tele Video Consultation (TVC)

These operations must be done in advance in the event of a second opinion, before the date and time indicated at the time of reporting.

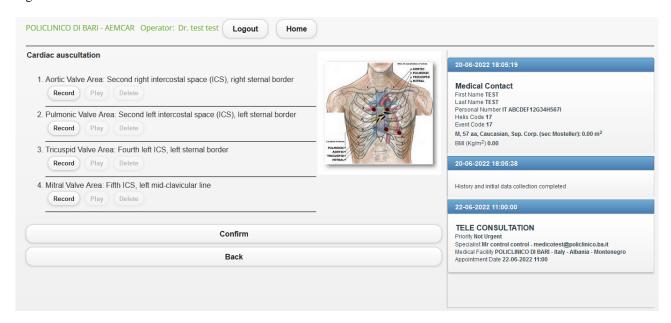
For the teleconsultation, data collection can be carried out both before and during the video call with the consulting specialist.



4.1.2.1 Cardiac auscultation

The Operator, in the presence of specific equipment provided by the writer, will be able to record the heart tones so as to make them available to the Doctor who is in charge of the examination.

Registration is foreseen on the four outbreaks indicated by the international Scientific Literature; can be performed in the desired number of steps (one or more at a time or all together), the image facilitates the identification of the heart regions consulted for auscultation.



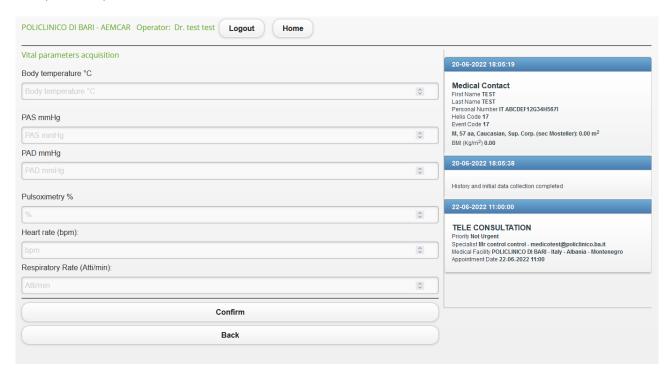
Cardiac Auscultation

The Operator can perform, stop and listen to the recording and, if it is not optimal, can delete and repeat it using the appropriate "**Record**", "**Play**" and "**Delete**" buttons. After pressing the **CONFIRM** button, the current exam is closed and sent to the Helis Platform.



4.1.2.2 Vital Parameters Acquisition

In the **Vital Parameters Acquisition** section, the Operator will be able to detect the current values of Body Temperature, Systolic and Diastolic Pressure (PAS / PAD), Pulse Oximetry (SpO2), Heart Rate (HR) and Respiratory Rate (Acts / min).

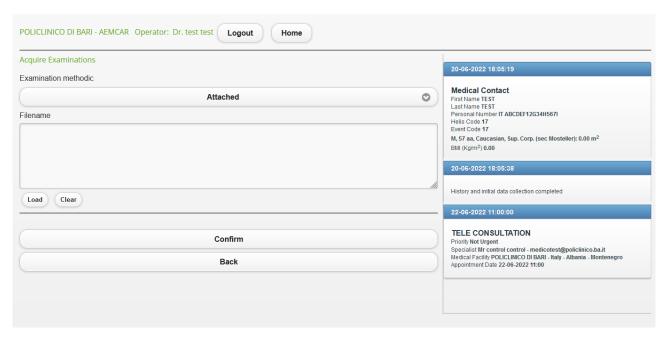


Acquisition of Vital Parameters

The **CONFIRM** button completes the operation.

4.1.2.3 Other Exams Acquisition

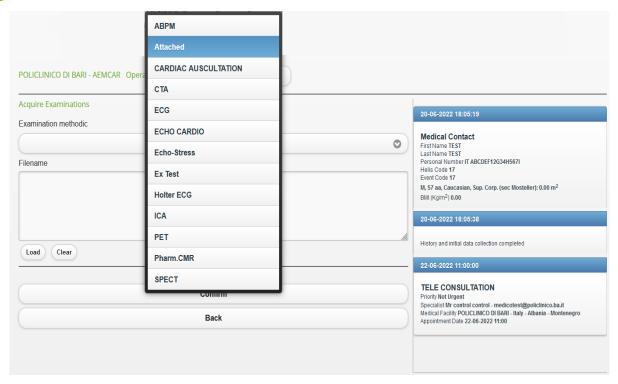
By selecting Acquisition of Other Tests, the Operator can upload any Reports carried out at other Diagnostic Centers.



Acquisitions Other Exams

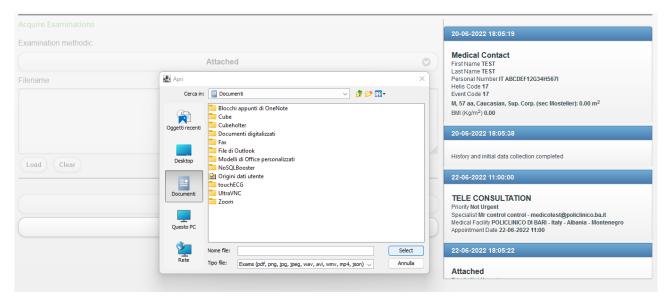
By clicking on the **Exam Method** button, the Operator can select, from a popup list, the Exam Method he wants to upload.





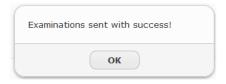
Methodical Selection

After selecting the Exam Method to upload, the Operator can click on **LOAD**: a mask will be displayed that allows you to select the file directly from the PC.



Select File

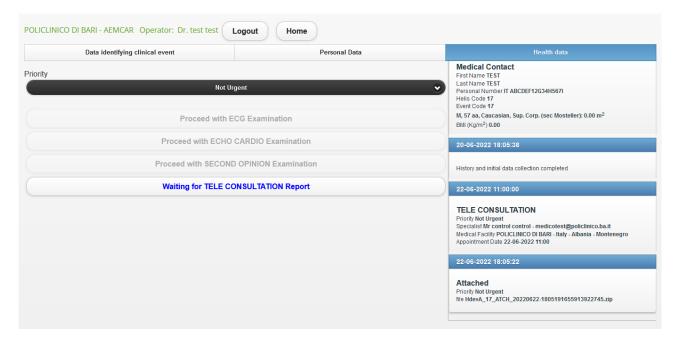
It will be possible to upload image files only in **JPG** and **PDF** format, **WAV** and **MP4** for videos. To finish the file upload operation, simply click on **CONFIRM**, a message will indicate the upload status.



Confirmation

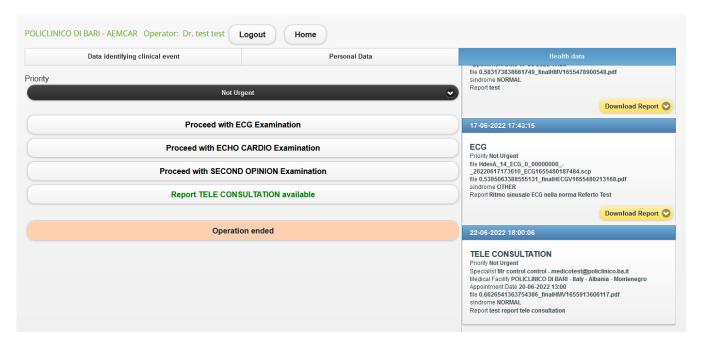
From this moment on, the operator will have to wait for the referring doctor to view all the shared exams and patient data and issue the report. The operator can check the presence of the report from the list of exams in the main screen of the Helis event.





Waiting for Report

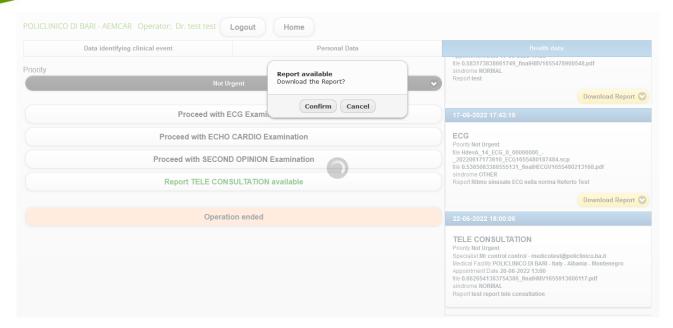
In correspondence with the Teleconsultation exam, the operator will read **Pending Reporting TELE CONSULTO** or if Second Opinion will read **Pending Reporting SECOND OPINION**. The operator will have to wait until the indication corresponding to the exam is **GREEN TELE CONSULTO Report Available or SECOND OPINION Report Available.**



Report Available

It will mean that the doctor in the control room will have forwarded the report. To access the report, simply click on "**Download Report**" and download the report





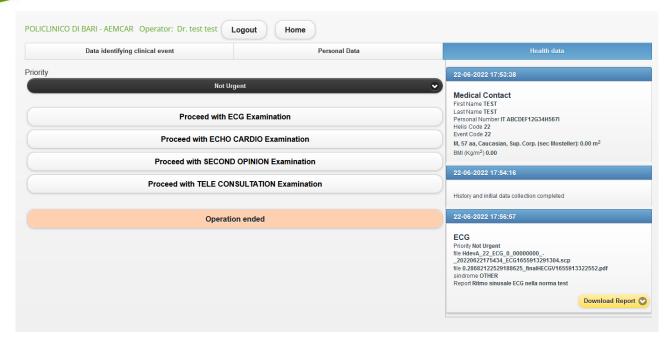
Confirm Download Report



 $Teleconsultation \ Report$

Automatically, upon confirmation of download of the report, the patient report will be notified on the medical report screen. After viewing the PDF Report, the operator, returning to Helis Chronical, will be able to decide, depending on the indications provided by the referring physician who prepared the Report, whether to schedule a further examination or proceed with closing the event on Helis Chronical. As long as the event is not closed it will always be possible to consult the exam report from this section.



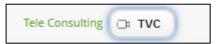


Download Report - Tracking Log

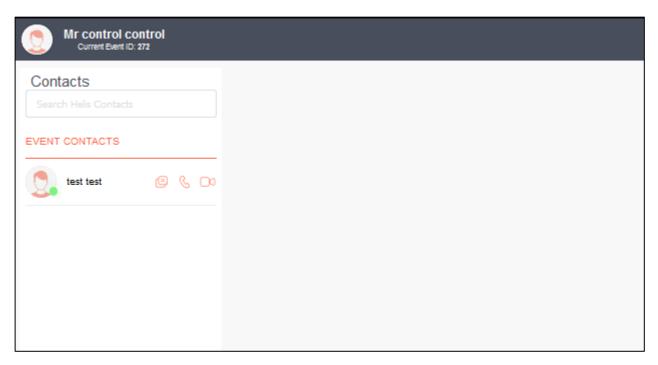
From now on the operator will be able to access the report of the second opinion or teleconsultation, whenever he wants by simply clicking on **Download Report** present on the tracking Log.

4.1.2.4 TVC – Teleconferencing and chat function

If the method chosen is teletext consultation, the Operator can carry out a Tele Video Consultation (TVC), in Video Conference, with the Doctor / Specialist booked and enabled for the service by simply clicking on the button



HELIS Chronical will receive an audio / video communication in real time with the doctor



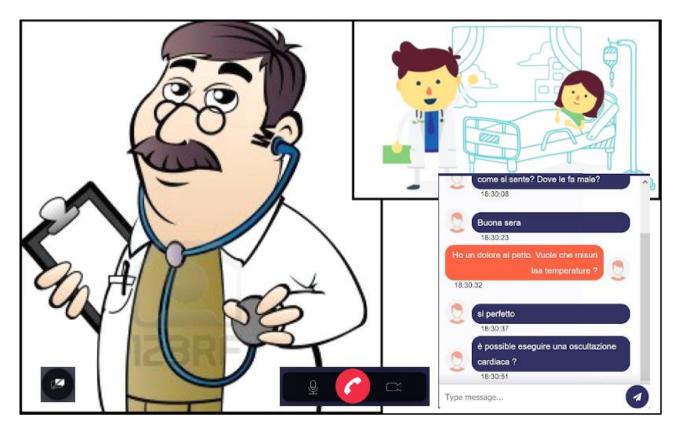
TVC HELIS Chronical

The doctor in charge of the examination report will be displayed in the column on the left of the screen. By clicking on the camera button you will be able to establish the connection.

It is necessary to grant the browser the permissions to use the audio / video devices.

The TVC icon is also present for the second opinion method in case of need.





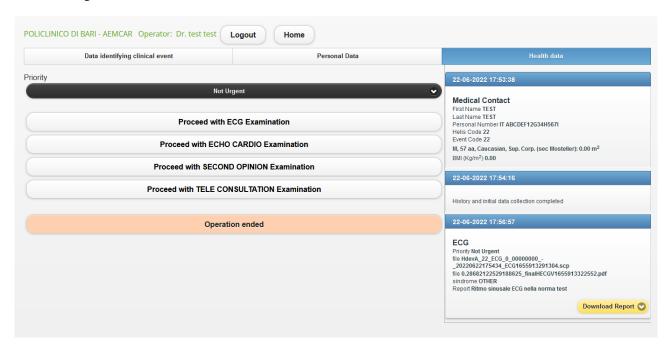
Demo TVC HELIS Chronical

It is important for the doctor to know that everything written in the video conferencing system chat is recorded, reported in the event tracking log and also in the final report.



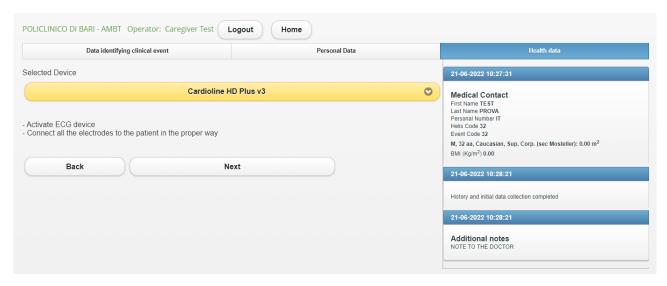
4.2 Electrocardiographic examination

By selecting **Proceed with ECG examination**, the operator will start with the execution of the 12-lead electrocardiogram.



Proceed with ECG Examination

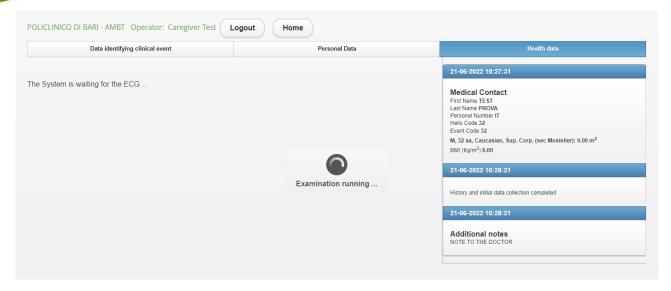
Some preparatory instructions will appear on the screen that the operator must follow before carrying out the ECG examination. Once finished, just press forward to go to the next step.



ECG Preparation

By pressing "Next" the operator will prepare the Helios system to receive the ECG and the screen will display the message "The system is waiting for the Trace".





Waiting for execution of ECG trace

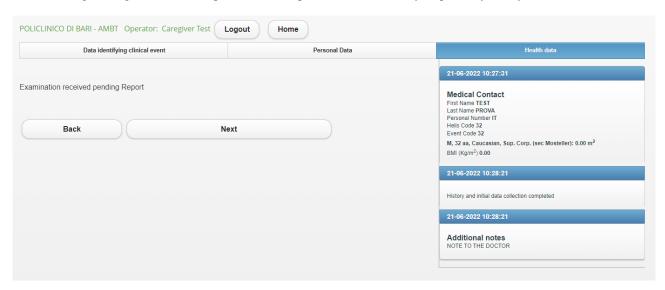
Once the message "Examination in progress ..." appears, the operator will be able to proceed with the execution of the electrocardiographic trace.

4.2.1 Acquisizione ECG

Refer to Appendix A - "Chronical Exam Request Appendix Manual" for details on the requests enabled for your Helis Chronical installation.

4.2.2 Waiting for Report

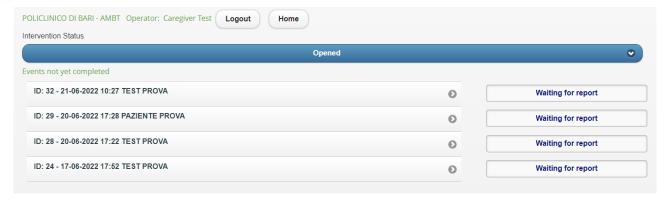
The following message informs the Operator that the path has been correctly acquired by the System.



Confirm ECG Forwarding

By clicking on **NEXT**, the Operator concludes this part of the Patient Visit and is directed to the open events page waiting to receive the ECG report just sent. In fact, he will read, in correspondence with the event, "**Pending Report**".

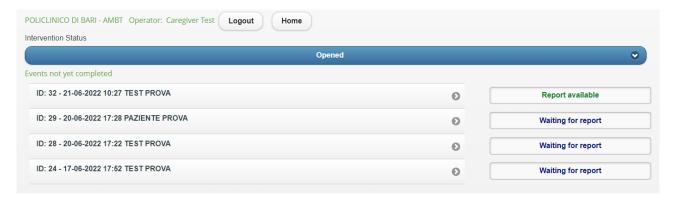




Open Events Summary

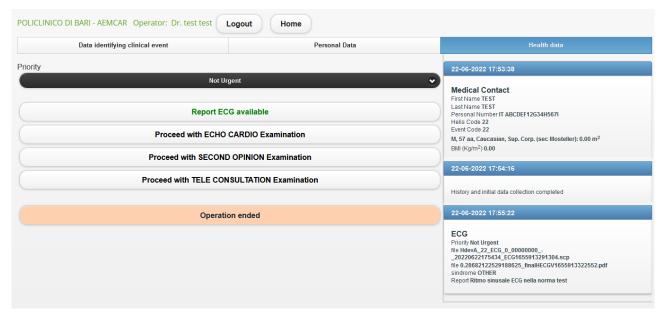
4.2.3 Report View

When the report is available, corresponding to the event, the message "Waiting for Report" will change to "Report available" colored GREEN and the operator will be able to access the part that allows viewing by clicking on the line containing the Patient's name



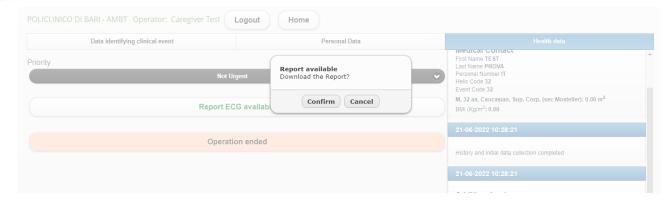
Report Available

By clicking on "Clinical Health Data", the operator will see the list of exams screen. After clicking on "ECG Report Available", which will be colored GREEN, a Pop-up window will appear asking if you are sure to proceed with the download of the report. To do this, simply click on "Confirm" and then on "Download Report" to download the pdf file of the report, while just click on "Cancel" to cancel the download operation



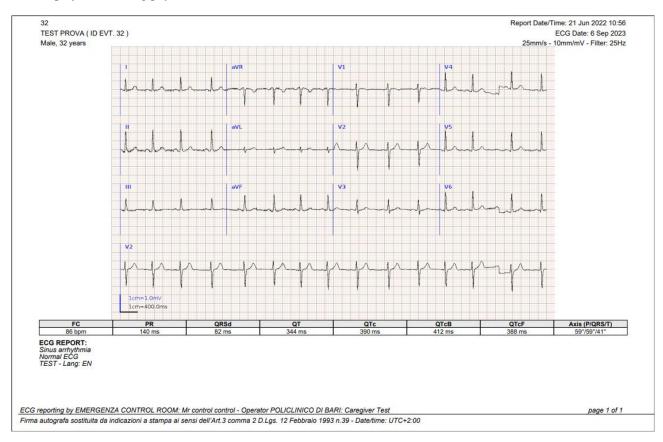
ECG Report Available





Download Report

This function allows you to download a PDF file on your PC containing the electrocardiographic trace and the Report drawn up by the referring physician.



Example ECG Examination

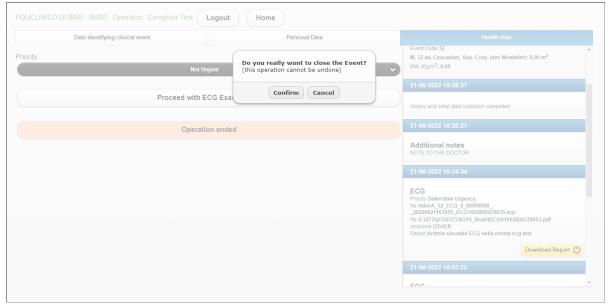
Automatically, upon confirmation of download of the report, the patient report will be notified on the medical report screen. After viewing the PDF Report, the operator, returning to Helis Chronical, will be able to decide, depending on the indications provided by the referring physician who prepared the Report, whether to schedule a further examination or proceed with closing the event on Helis Chronical. As long as the event is not closed it will always be possible to consult the exam report from this section.

5 Event Closure

The choice "**End of Intervention**", on the other hand, puts an end to the event and allows the system to produce the final report of the entire clinical event.

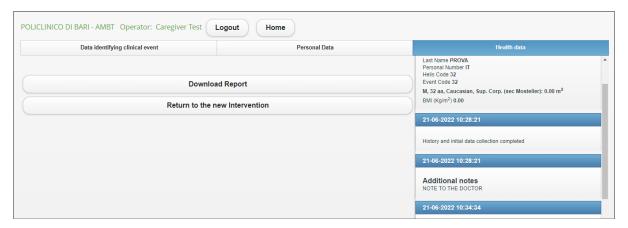
To do this, just click on "**End of Action**", a Pop-up window will appear asking whether to proceed with the closure and then click on "**Confirm**", while just click on "**Cancel**" to cancel the Closing operation.





Event Closure Confirmation

After closing, the event will be closed and it will be possible to download the report in pdf format. The same can only be consulted in the **Events List** section, by selecting the "**Closed**".



Download Report

By clicking on "Back to new intervention", you will return to the Home where you can start a new event or view the Events List.

6 Change Password

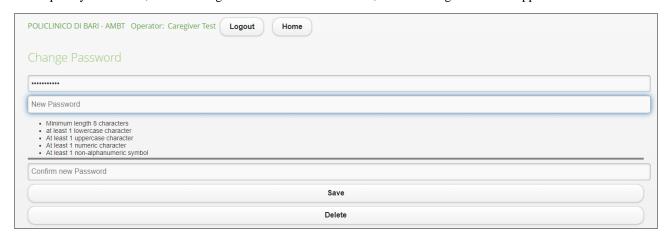
By clicking on "Change Password" on the main screen, the operator can access the screen to change their password. In order to change the password, the user must enter the password used to access Helis Chronical in the first available text field.



Change Password

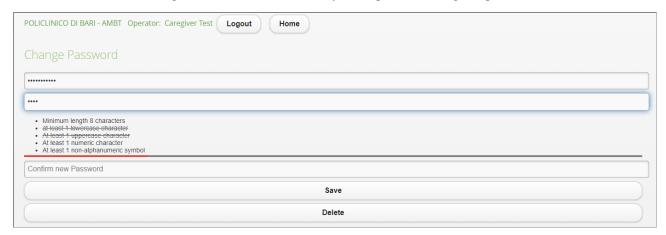


Subsequently to the user, after clicking on the New Password field, the following screen will appear:

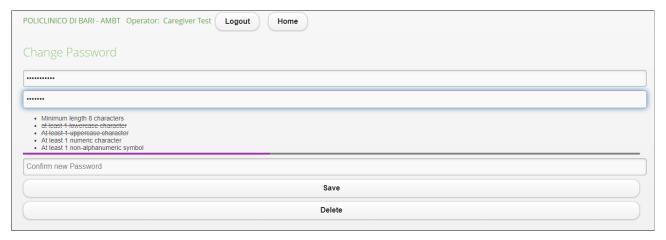


Complexity Criteria New Password

The user will be presented with a list of minimum complexity criteria that must be respected for the composition of the new password. By creating the new password, if the criteria are met, they will be removed from the list and the gray bar at the end of the list will change color to indicate the security of the password being composed.

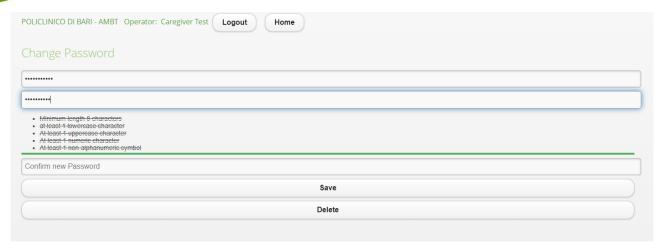


Complexity Criteria New Password



Complexity Criteria New Password

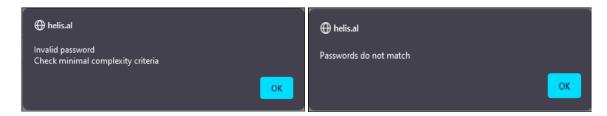




Complexity Criteria New Password

When all the minimum password complexity criteria are met, the user will have to rewrite the password just composed in the **Confirm New Password** field and once the compilation has been completed, by pressing "**Save**" the password change will be confirmed and the operator will be redirected to the screen principal.

In the event that the user does not comply with the minimum complexity criteria or the passwords entered in the two fields do not coincide, upon saving confirmation, the system will notify the changes to be made using pop-ups in order to correctly confirm the change.



Error Messages



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6.3. Annex 3. Appendix A. Requests and integrations with third parties - Helis Chronical.net

T6.3.1 – Digital platform for management of chronic patients

PROJECT NAME: "Promoting eHealth in cb Area by Stimulating local Economies" - ACRONYM: PHASE - PROJECT NUMBER: 365

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Requests for exams and integrations with third parties

Helis Chronical.net

rel. 1.1 - 18.09.2023



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1 Introduction

This Appendix provides the User with all the information necessary for the correct functioning of the integrations with third parties and the list of exams that can be requested on the **Helis Chronical** software.

All rights are reserved.

1.1 How to read the document

This appendix contains detailed instructions on integrations in place on the **Helis Chronical** online reporting system for installation domain.

The most important notes are highlighted in bold.

1.2 Destination of use

Helis Chronical it is intended for the diagnosis of the patient's state of health in various areas.

The specific use of the application is identified in the medical environment. Use must be carried out by qualified and suitably trained personnel and in compliance with the instructions contained in the User Manual.

1.3 License terms

By using the software, you agree to the terms and conditions described below.

The program and accompanying documentation may not be modified, copied, merged with other programs or made available to any third party.

The user is held responsible for any damage resulting from non-compliance with copyright, or from violation of the conditions set out in this agreement.

1.4 Information and recommendations relating to safety of use

Helis Chronical software is compatible with all existing browsers.

1.5 Warnings

Should users detect malfunctions or receive errors during the execution of the program, users are requested to notify the CONSIS Helpdesk of any malfunction and / or defect.

CONSIS undertakes to resolve any problems not arising from misuse by the user as quickly as possible from receipt of the report.



2 Exam Requests Available

For this installation of **Helis Chronical** it will be possible to request only and exclusively the following exams:

- 1. TWELVE LEADS ELECTROCARDIOGRAM
- 2. ECHO CARDIO
- 3. ELECTROPHYSIOLOGY DATA

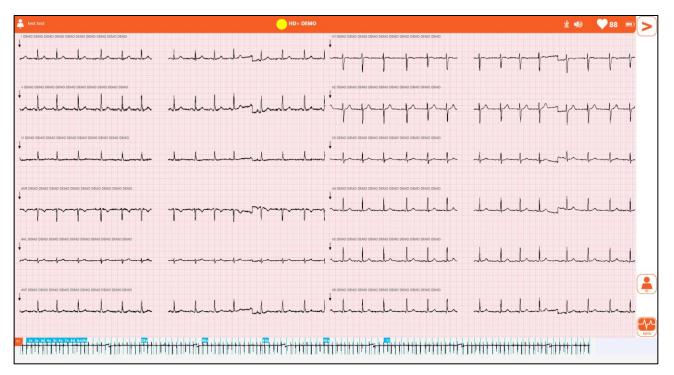
3 ECG acquisition

 $To \ register \ the \ electrocardiographic \ trace, \ the \ Operator \ will \ use \ the \ \textbf{Cardioline TouchECG} \ software.$

The software opening is managed directly by Helis Chronical.

When the Operator displays the reception waiting screen, Helis Chronical will start the software automatically by automatically filling in the necessary patient data.

The operator must place the electrodes on the patient and press the orange button located on the ECG device. The led of the device will start flashing and will automatically connect to the tablet $/ \, pc$.



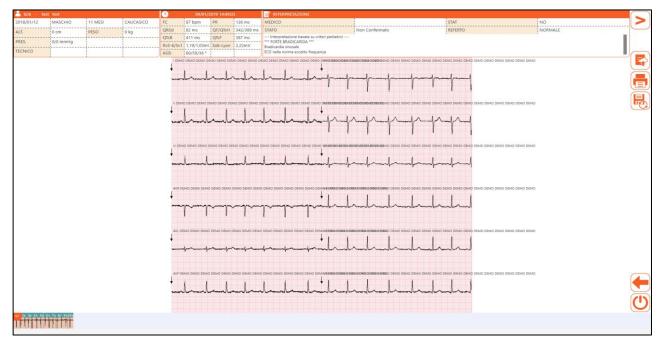
TouchECG Cardioline

Communication takes place using Bluetooth technology, so the distance between the two devices (tablet and HD \pm) cannot exceed 5 m.

When he has verified that the traces are stable and free of artifacts, the Operator can acquire the trace by clicking on the

button located at the bottom right of the screen.





ECG display

Once ECG acquisition is complete, the Operator must click on the button to return to Helis Chronical. The electrocardiographic device will turn off at the end of the exam.

4 Acquisition of an Echo Cardio

By selecting **Proceed with Echo Cardio examination**, the operator will start with the execution of the cardiac ultrasound.



List of available methods

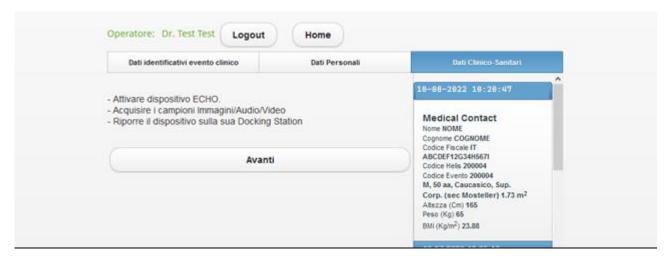
The GE Vscan Extend device will be used to perform cardiac ultrasound.

The procedure for use is briefly followed:

- a) Using the GE-VScan Extend device, perform the ultrasound exam on the patient as usual;
- b) If during the "round of visits" exams are performed on several Patients, it is necessary to write down the six-digit numeric ID of the exam performed: this is because the instrument, without the aid of optional external proprietary software, does not transfer / store exportable information of the Patient;
- c) On the Helis Chronical subsystem, open a Report Request for the current Patient;



Selecting "Proceed with Echo Cardio exam" the following form will appear:



ECHO CARDIO Exam

Click "Next" to start with the acquisition of the Echo Cardio by the Helis Chronical software.

Connect the GE-VScan Extend device to the PC using the appropriate USB cable. The following Box will appear on the device:



GE - VScan Extend Screen

Click on "ALLOW". The message "Connected to PC. Please wait" will appear on the device; After about 5/30 seconds the device will be recognized by the PC





GE - VScan Extend Screen

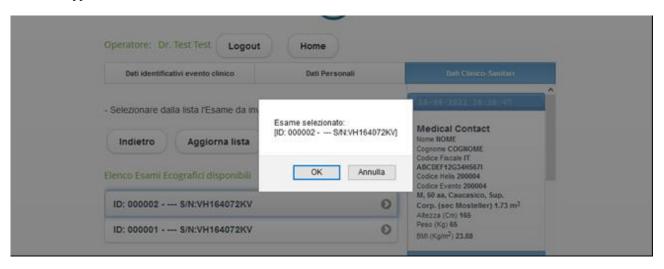
Go back to the Helis Chronical subsystem and click "Next"

If the device has been mounted correctly, a list will be shown containing all the exams contained. If the list is not displayed, the device may not have been mounted correctly yet; wait a few more seconds, then press the "**Refresh list**" button.



Echo Cardio Exam List

In the Exams list, locate the Exam with the ID previously noted for the Patient and click: a confirmation box for the exam will appear; click on "**OK**" to confirm the selection.



Echo Cardio Confirmation of exam selection



After confirmation, the exam will be sent to the Helis Chronical subsystem Server for subsequent reporting;



Confirmation Receipt of Echo Cardio Exam

The operator can click on "Next" to conclude the sending phase of the exam.

If there are no other ECHO exams to send then disconnect the USB cable. After about 30/120 seconds the device will be operational again for the execution of any further tests.

5 Littmann 3M Model 3200 BT stethoscope configuration

Switch on the device from the central power button.



Device Littmann 3M 3200 BT

If the flashing Bluetooth symbol does not appear, the device needs to be configured so that it can automatically connect to Helis





Littmann 3M 3200 BT Stethoscope – Bluetooth OFF

Press the M key; by pressing the [-] key, reach the SETUP option



 $Littmann\ 3M\ 3200\ BT\ Stethoscope-Setup\ Option$

Press the menu key ${\bf M}$ again; by pressing the [-] key, reach the ${\bf BT.}$ COMM option





Littmann 3M 3200 BT Stethoscope – Option BT.COMM

Press the menu key M again; by pressing the [-] key, select the AUTO option



Littmann~3M~3200~BT~Stethoscope-Option~AUTO

Press the menu button M again to confirm the option. The configuration is complete. The device will show its usual screen with Bluetooth flashing.



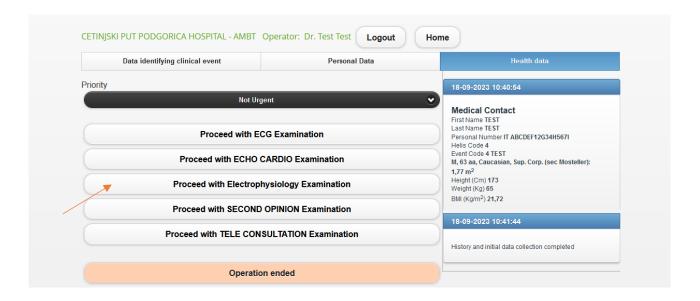


Littmann 3M 3200 BT Stethoscope - Ready to use

6 Acquisition of the Electrophysiology data

6.1 Request by a POC/POCT Operator

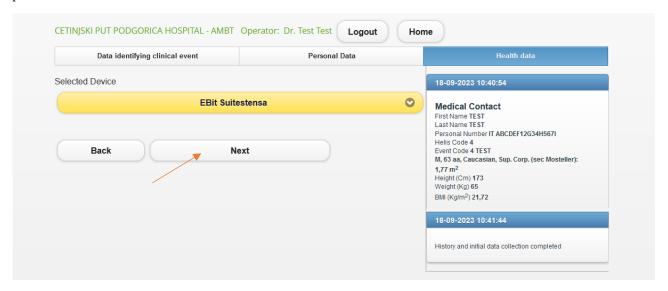
By selecting **Proceed with Electrophysiology Examination**, the POC/POCT Operator will ask, for the current Patient, the recent acquired Electrophysiology data got from its implanted device.



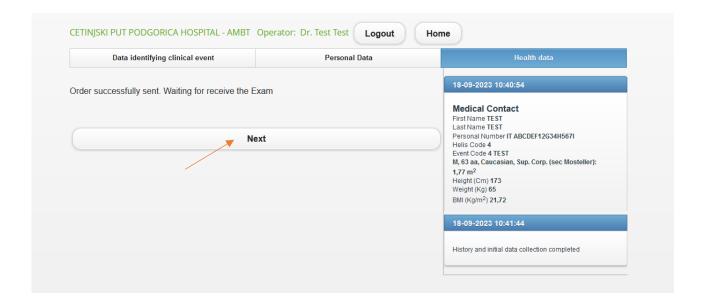


List of available methods

The operator will get the list of configured platforms used for acquire Electrophysiology data, select the available, then press on button **Next**

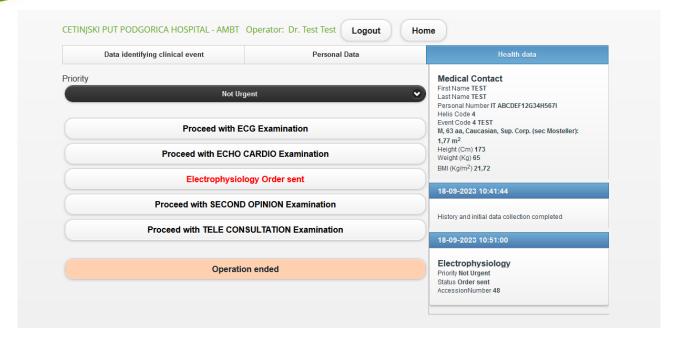


Helis will send a request for Electrophysiology data toward the selected platform:



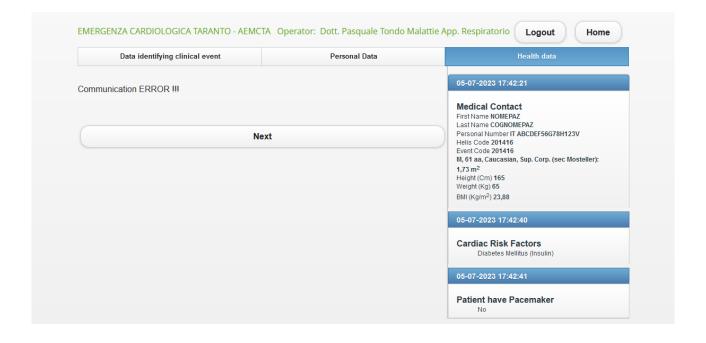
The Operator will, press the **Next** button and will be reconducted to the Methodic List. Current request will appear in status *Electrophysiology Order Sent*





6.2 External Electrophysiology Platform is not available

In case the remote Electrophysiology Platform results not available for placing Orders, Helis will show an error.

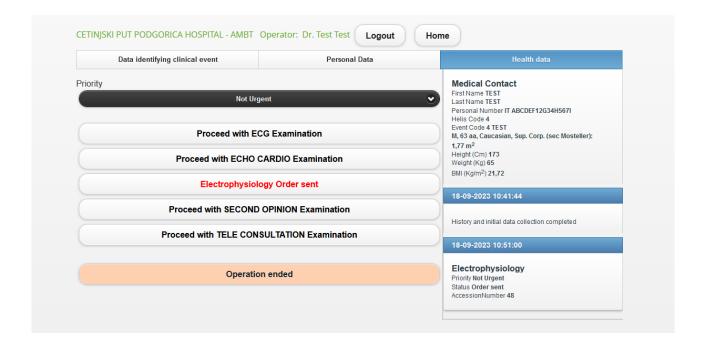


After pressing the button **Next**, it will be possible to execute a new Electrophysiology data request, following the steps shown above.

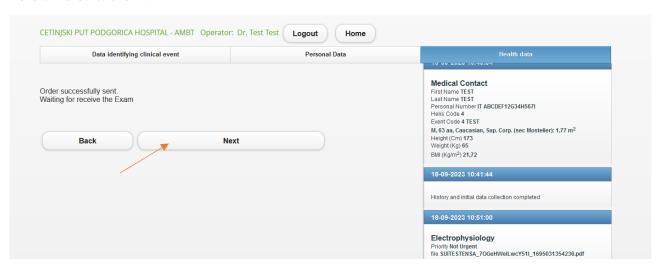


6.3 Cancel a previously placed request

If the POC/POCT Operator wants to cancel a previously placed Electrophysiology Data Order Request, he should go on Methodic List and click on **Electrophysiology Order Sent** button:



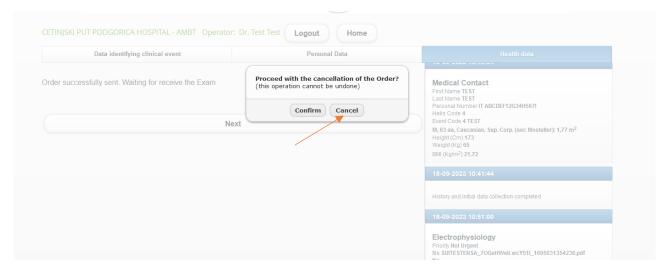
Helis will show this form:



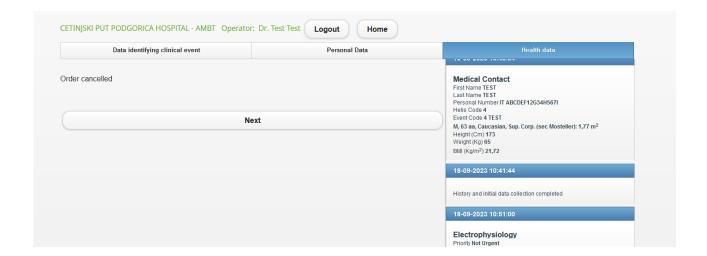
If Operator is sure to cancel this Order he will click on Next Button.



Helis will ask for a confirmation (this operation cannot be undone):



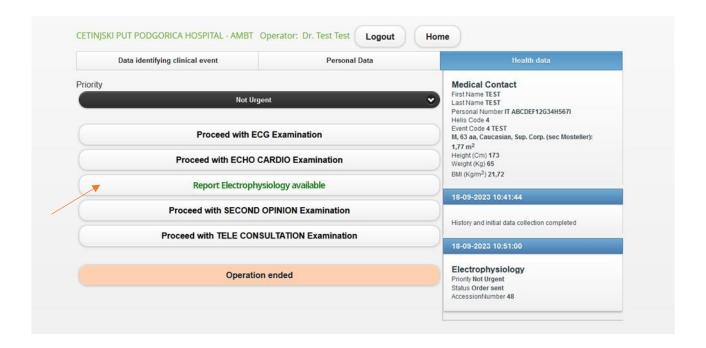
If Operator will click on **Cancel** button, no operation will be executed and will be shown the **Methodic List**; otherwise, if he will click on **Confirm**, the Electrophysiology Request data Order will be cancelled:



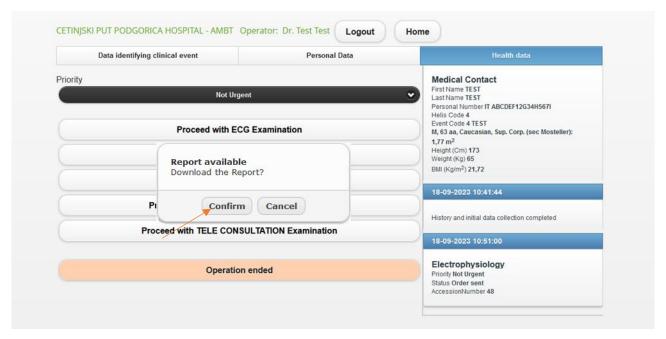


6.4 POC/POCT side: Electrophysiology Report reception

When the external platform will send the Report data, the request will change its status and it will appear in status: **Report Electrophysiology available**



Clicking on this button will appear a confirm dialog: click **Confirm** for download the Report:





The received report will be shown on the screen:



Azienda Ospedaliero-Universitaria Consorziale Policlinico Bari U.O.C. CARDIOLOGIA OSPEDALIERA

"Luigi Colonna"

Direttore: Dr. Carlo D'Agostino

Segreteria: 080/5592083 - Fax: 080/5575729 - Sala Medici: 080/5592424

CONTROLLO PM/ICD/CRT

Paziente: TEST TEST Data Nascita: 01/01/1960 63 Età:

DETTAGLI VISITA Data controllo: 07/09/2023

Tipo Controllo: Controllo/Programmazione

Note Terapia in Atto: terapia in atto Note Terapia Consigliata: terapia consigliata

Elettrostimolazione

Monitoraggio Remoto: No

Malfunzionamenti:

Frequenza base: 120 [bpm] Frequenza massima sensore: 55 [bpm]

Modalità di stimolazione: DDD

Outnut/Sensing

Output/ Sensing					
Camera	Ampiezza Impulso (V)	Durata Impulso (ms)	Sensibilità (mV)		
Atrio Destro	111	10	200		
Ventricolo Destro					
Ventricolo Sinistro					
AS-VP					
AS-VS					
AP-VP					
AP-VS					
AP					
VP					

Generatore

Modello: abbot pm

Numero Serie: 12345 Impedenza(KOhm): Durata Prevista batteria: Tensione(V): 150 30 [mesi] 98 [%] Stato batteria: BOS % batteria:

Leadless: No

Commenti Diagnostica : pacemaker inserito correttamente

Commenti e Conclusioni: commenti e conclusioni paziente test

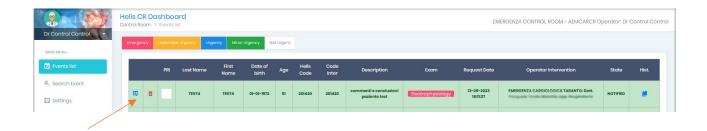
Compilatore: Ebit Admin



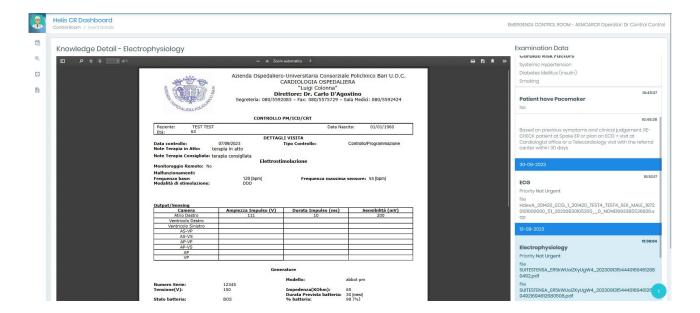
6.5 Control Room side: Electrophysiology Report evaluation

In the same time the report is sent by the external Electrophysiology Platform, this will result available on the Control Room side of Helis Platform, in the worklist of the enabled Doctor/Specialist.

He will immediately get evidence of it:



Opening the event, the Doctor/Specialist will be able to evaluate this exam and take a look to the other ones executed in the same Event Request.







CONSIS

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