TPL-0054 Instructions for Use

1. Document approval

1.1 Prepared by

- Complete and correct content
- Formal, correct design

Role	Date	First and Last Name	Signature
QM	2026-05-08	Lucas Greulich	Signiert von: Lucas Greulich 8144B461C7C34C9...

1.3 Approver

- The document objective is fulfilled.
- The preparation and review are completed.
- Where applicable, detailed criteria are fulfilled (see annex, if applicable)

Role	Date	First and Last Name	Signature
CEO	2026-05-08	Jörg Ströbel	Signiert von: D9A2528D41634C8...

1.4 Document change history

Version	Change Date	Author	Description of the change
1.0	2025-12-30	Lucas Greulich	First version
2.0	2026-05-08	Lucas Greulich	Updating for clear understanding, that CorLector is a system (article 22)

2. Meta-information

2.1 Purpose

The document is intended to create an instruction for use and should serve the following purposes:

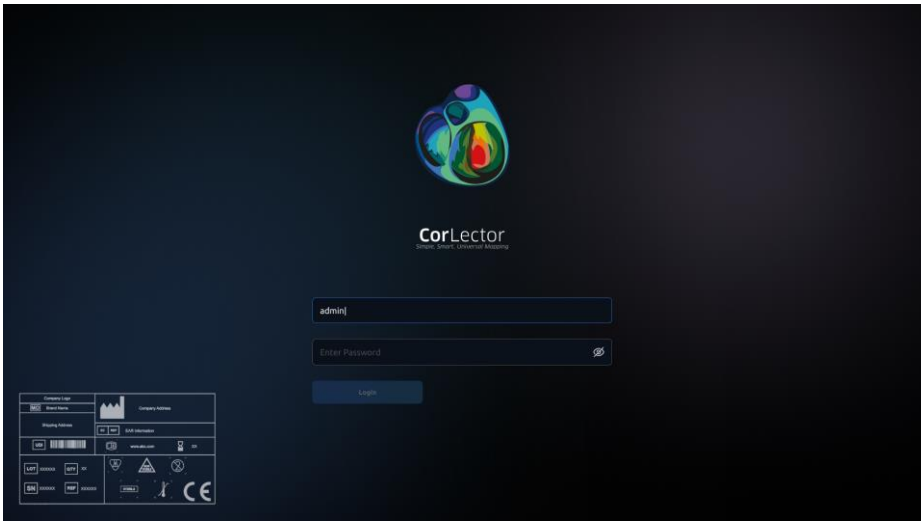
- meet the IFU requirements of the MDR, as well as those of IEC 82079-1:2019, ANSI Z535, AAMI TIR49:2013, and FDA Guidance on Medical Device Patient Labeling;
- create the content of an IFU document in a systematic way (with a focus on the textual content);
- create a useful information architecture that users find logical.

CorLector
Simple, Smart, Universal Mapping

Instructions for use

CorLector

Software



Language version(s):

EN

Date of issue (of last revision) 2025-12-30

CE 0123

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Foreword and important information

Thank you for purchasing this device CorLector System from CorLector GmbH. The CorLector System is supplied by CorLector GmbH as a pre-configured system, including the CorLector software pre-installed on a dedicated workstation in a validated configuration.

Your device is intended for non-invasive analysis of cardiac electrophysiological activity based on standard 12-lead ECG data. It generates 3D electrical activation maps to support clinical assessment and decision-making in electrophysiology.

WARNING! Incorrect handling and improper use can pose hazards and cause damage. We therefore ask you to carefully read these instructions for use and follow them meticulously. Always keep them close at hand. Please observe the safety instructions to avoid personal injury and damage to property.

Please contact us if you have any questions regarding these instructions for use or the use of the device.

To request additional copies of this manual, including the printed (paper) version, please contact CorLector GmbH. using the contact details provided. Kindly note that the estimated delivery time for the paper format is seven (7) days from the date the request is received.

Should you wish to consult the electronic version of this manual, please access the dedicated cloud platform at https://www.corlector.com. Upon entering the website, navigate to the appropriate section and select the specific device version for which you intend to review the corresponding manual.

Your CorLector – Team

Version of the instructions for use

Version : 1.0

Date of issue : 2025-12-30

You can request all versions of the instructions for use from us:

<URL to electronic instructions for use>

The paper version of the IFU can be provided by request.

Scope

These instructions for use apply to the following devices as well as to device versions and variants:

Device	Device version	Software Version
CorLector	-	1.0.0

Contact details of the manufacturer

CorLector GmbH
Blütenstraße 39
90480 Nürnberg
Germany
+49 (0) 176-633 29 314
info@corlector.com
www.corlector.com

Table of Contents

1 Information on how to use these instructions for use

1.1 Explanation of the warnings in these instructions for use

Signal Word	Description
DANGER! 	An immediate hazardous situation exists, and serious harm or death is possible
WARNING! 	Potential hazard that could lead to serious harm or death
	Potential hazard that could lead to slight or medium harm
	Errors committed by the operator can cause damage to the device

1.2 Presentational conventions in these instructions for use

Element	Description
Italic	The italic font indicates cross-references
Bold	The bold font indicates operating elements, controls, switches, window titles, menu elements, functions, etc.
`Courier`	The courier font indicates system outputs, e.g., error messages, prompts, etc.
< >	Angle brackets indicate the required user input
[ ]	Square brackets indicate optional possibilities
|	Vertical bars indicate alternative options (the bar stands for “or”)
<…>	<…>

Should you require additional assistance despite carefully studying the instructions for use and the additional information, please contact your local dealer (or the manufacturer directly).

1.3 Copyright, disclaimer, license terms, warranty, miscellaneous

The information contained in this document is subject to change without notice and does not constitute a commitment by the manufacturer. While every effort has been made to ensure the accuracy of the information, CorLector GmbH assumes no responsibility for errors or omissions.

The CorLector software is provided under a limited license agreement. By using the software, the user agrees to comply with the applicable license terms. Details of the license can be requested from CorLector GmbH.

The warranty for the product is limited to the scope described in the applicable purchase or license agreement. CorLector GmbH disclaims any liability for damages resulting from improper use or modifications of the software outside the intended purpose.

1.4 Feedback on instructions for use

We want to hear from you. Please feel free to tell us your preferences and any criticism on these instructions for use. We will analyze your feedback and take it into account for the next version of these instructions for use.

2 Intended use

2.1 Intended medical purpose

The system is intended for the analysis, display and storage of cardiac electrophysiological data and 3D electroanatomical maps derived from 12-lead ECG signals for use by qualified medical professionals in a clinical setting. It provides noninvasive estimation and visualization of cardiac activation.

2.2 Intended System configuration

The CorLector System is placed on the market as a combined system in accordance with Article 22 of Regulation (EU) 2017/745.

In accordance with Article 22(1) MDR, the system is supplied as a complete unit and is not intended to be assembled, modified or combined by the end user.

The CorLector System is provided by CorLector GmbH as a manufacturer-defined, fixed and validated configuration consisting of medical device software and dedicated hardware. The manufacturer assumes full responsibility for the system configuration and its compliance with the applicable requirements of Regulation (EU) 2017/745.

The validated system configuration includes the following components:

- 1x Dedicated medical workstation

- Manufacturer / Model: Advantech POC-421V3-BTO

- Function: Execution platform for CorLector software in a validated configuration

- 1x Medical-grade keyboard

- Model: Medigenic™ Keyboard Essential

- 1x Medical-grade mouse

- Model: IP68 disinfectable mouse (5-button)

- 1x Dedicated USB storage device

- Model: Swissbit Industrial USB Stick (SFU3008GC1AEZ)

- Function: Secure data import and export of ECG data

- 1x Licensing dongle

- Model: CmStick/B

- Function: Hardware-based license enforcement

The system is delivered with a pre-installed and validated operating system and CorLector software (Version V1.0.0), ensuring a controlled and reproducible system configuration.

The workstation used within the CorLector System includes a CE-marked medical computer that is an independent medical device.

This medical computer is integrated by CorLector GmbH into the CorLector System as part of a validated system configuration in accordance with Article 22 of Regulation (EU) 2017/745.

The medical computer serves as the hardware platform for the execution of the CorLector software. It does not perform the intended medical purpose of the CorLector System independently.

The safety and performance of the complete system are ensured through the validated system configuration defined by CorLector GmbH.

No installation, configuration or combination by the end user is required or permitted.

Only the system configuration supplied and validated by CorLector GmbH is part of the medical device. Any hardware, software or components not explicitly listed above are not part of the system and shall not be used as substitutes or additions.

External ECG acquisition systems are not part of the CorLector System. The system processes ECG data provided by such external devices via approved interfaces (USB) only.

Any deviation from the defined system configuration may compromise safety, performance and regulatory compliance and is therefore strictly prohibited.

2.3 Indication(s) for use

- Atrial and ventricular arrhythmias (ICD-10: I48.x, I49.x)

2.4 Contraindications/exclusions/restrictions

- Complex congenital heart disease (Q20–Q28)
- Dextrocardia (Q24.0)
- Scarring-related arrhythmias
- Unstable coronary artery disease
- Intracardiac thrombus
- Active sepsis
- Acute or life-threatening clinical conditions requiring immediate medical intervention, where delays in diagnosis or treatment could result in serious harm or death
- More than 40% scar tissue on heart

2.5 Patient target group(s)

- Patients with suspected or known arrhythmias
- Complex conditions may require imaging
- No direct patient contact – no application to skin or organs

2.6 Intended users

The CorLector software is intended to be used exclusively by **professional healthcare personnel** with specific qualifications relevant to electrophysiology and clinical ECG interpretation.

Two user groups are defined:

Electrophysiology Physician (EP Physician / Cardiologist)

Primary intended user group

This group includes:

- Board-certified electrophysiologists;
- Cardiologists with advanced training in electrophysiology;
- Physicians experienced in the interpretation of 12-lead ECGs and arrhythmia mechanisms.

Required Skills and Competencies EP Physicians must have:

- Understanding of cardiac arrhythmias, activation patterns, and anatomical orientation;
- Proficiency in interpreting 12-lead ECGs, including recognizing artefacts and conduction abnormalities;
- Familiarity with 3D cardiac mapping systems;
- Ability to correlate ECG signals with activation patterns;
- Training on the CorLector workflow (ECG import, signal-quality verification, segment selection, map metadata, interpretation).

Responsibilities

EP Physicians are responsible for:

- Creating patient cases and entering metadata;
- Importing and validating ECG data;
- Selecting suitable ECG segments;
- Generating electroanatomical maps;
- Interpreting the system generated results in clinical context;
- Exporting and documenting findings.

IT-Administrator (Hospital IT / Clinical Engineering)

Secondary user group non-clinical

Intended exclusively for:

- System setup and configuration;
- Management of user accounts and access rights;
- Cybersecurity compliance.

Required Skills

IT Administrators must:

- Have experience in Windows system administration;
- Understand hospital IT security policies;
- Be trained in the local workstation security concept (USB whitelisting, BIOS lock, offline mode);
- Be authorized by the healthcare institution and CorLector GmbH.

Responsibilities (Non-Clinical)

IT Administrators may perform:

- User account creation, modification, and deactivation;
- Password resets;
- Hardware-level maintenance (keyboard/mouse replacement, system restart);
- Ensuring compliance with access control and cybersecurity measures.

Restrictions

IT Administrators **may not**:

- Interpret ECG data or electroanatomical maps
- Create or analyze patient cases
- Modify validated software configurations
- Install third-party software or connect the system to networks

2.7 Intended use environment(s)

The system is intended to be operated only on the dedicated workstation supplied or approved by CorLector GmbH.

Hospital, clinic, practitioner office (professional healthcare).

Physical Parameters: Normal clinical indoor conditions

Portability: Stationary System

Combinations and Connections: Input from ECG devices using CorLector approved USB device

3 Important safety notes

IMPORTANT! Read all safety notes carefully before using the device. Follow the safety notes to avoid injuries and life-threatening situations.

The safety information below complements the risk control measures derived from the risk management process in accordance with ISO 14971.

3.1 General Warnings and Precautions

- ⚠WARNING The CorLector software must only be used by **qualified EP physicians** or clinicians trained in electrophysiology and 12-lead ECG interpretation.
- ⚠WARNING Incorrect use of the software, including misinterpretation of the results, may lead to incorrect clinical decisions.
- ⚠CAUTION The software is a supporting diagnostic tool and is not intended to replace clinical judgment or other diagnostic methods.
- *NOTE* Ensure that all connected ECG systems and hardware components are functioning properly and are used in accordance with their instructions for use
- *NOTE* CorLector provides **non-invasive visualization** of cardiac activation patterns.
- ⚠WARNING The software must only be operated on the **validated workstation** provided or approved by CorLector GmbH.
- ⚠CAUTION Always verify **patient identifiers** (Case Name, Case ID, Date of Birth, Diagnosis) before importing ECG data or performing analysis.

3.2 Warnings Related to ECG Data and Analysis

ECG File Input

- Only validated 12-lead ECG files in supported formats (EDF, HL7 XML, Physionet) may be used.
- Before confirming ECG import, verify the **ECG preview of all 12 leads**.
- Incorrect ECG selection (e.g., similar file names, wrong patient on USB stick) may lead to incorrect maps and misleading interpretation.

ECG Segment Selection

- Always ensure the selected ECG segment is appropriate (<500ms, stable morphology).
- Selecting the wrong selection may lead to clinically misleading activation maps.

3.3 Warnings Related to Map Interpretation

The 3D map must always be interpreted **in combination with the surface ECG** and clinical context.

Misinterpretation can occur if:

- anatomical orientation is misunderstood (left/right, anterior/posterior);
- color scale legend is not reviewed;
- the wrong map type is selected;
- the ECG segment was incorrect or too short.

Activation maps represent an **estimation**, not a measurement.

Inter-patient anatomical variability, prior surgeries, or conduction abnormalities may affect accuracy.

3.4 Cybersecurity and Data Integrity

⚠WARNING Unauthorized access to the system may lead to data breaches or manipulation.

General Cybersecurity Requirements:

- The workstation is operated **offline**:
  No internet connection, no hospital network, no cloud services.
- Only **authorized users** may log in.
  Strong passwords must be used and updated according to hospital policy.
- Do not attempt to bypass system restrictions, disable security settings, or install additional software.

USB Device Security:

- Only **whitelisted, CorLector approved USB devices** may be used.
  Unauthorized USB devices are blocked automatically.
- Abdicate using private USB devices, smartphones, external HDDs, or cloud-sync drives.

Data Integrity:

- Removing the USB device during read/write may cause **data corruption**.
- Only approved USB devices ensure proper compatibility.
- Always verify that exported files are complete.

Tampering and Unauthorized Access:

If physical or digital tampering is suspected:

- lock the screen immediately;
- disconnect the USB device;
- do not continue analysis;
- inform the IT administrator or CorLector Support;

- document the event.

3.5 Risks Related to Use Environment

- Use only in clinical environments under controlled lighting and ambient conditions.
- Do not operate near strong electromagnetic sources.
- Ensure stable power supply to prevent data interruption or loss.
- Only designated hospital workstations approved by CorLector GmbH may be used.

3.6 Reporting of incidents

Report all serious incidents (harm, injury, infection, etc.) that have occurred in connection with the device to the manufacturer and the competent authority of the EU Member State in which you are domiciled.

The competent authority in Germany is the Federal Institute for Drugs and Medical Devices (Bundesinstitut für Arzneimittel und Medizinprodukte, BfArM). Current contact information can be found on the BfArM website: https://www.bfarm.de.

3.7 Data Privacy and Confidentiality

- All patient data processed in CorLector must comply with applicable data protection regulations (e.g., GDPR).
- Always verify patient identifiers before import, analysis, and export.
- Never export unencrypted patient data.

3.8 Summary of Residual Risks

The following residual risks remain despite risk control measures:

- Incorrect patient selection due to similar case names or user oversight.
- Import of wrong ECG file or wrong ECG segment despite preview.
- Misinterpretation of color scale or anatomical orientation.
- Activation maps not matching true cardiac activation due to:
    - low ECG signal quality
    - corrupted ECG data
    - atypical anatomy or postoperative changes
- User interpreting the map as diagnostic or therapeutic guidance.
- Data loss due to premature USB removal during export.
- Software interruption due to hardware malfunction.

Users must remain vigilant and apply professional judgment at all times.

4 Product description

4.1 Operating principle and process overview

The CorLector System is placed on the market as a combined system consisting of software and dedicated hardware in a manufacturer-defined configuration.

In accordance with Article 22 of Regulation (EU) 2017/745, the system is supplied as a complete unit and is not intended to be assembled or combined by the user.

CorLector GmbH assumes full responsibility for the system configuration and its compliance with applicable regulatory requirements.

The CorLector System is a medical device intended for the non-invasive analysis of cardiac electrophysiological activity. It processes standard 12-lead ECG data to create electroanatomical maps that visualize cardiac activation sequences.

4.1.1 Operating principle

The CorLector System consists of the CorLector software and a dedicated workstation provided in a validated configuration by the manufacturer.

CorLector operates using a sequence of algorithmic steps:

1. **ECG Input**
   The user imports a standard 12-lead ECG recording.
   The software performs:
   - automatic format validation;
   - check for presence of all 12 leads;
   - check for same signal length across leads;
   - check for signal length of 500ms;
   - interpolation of signal sampling rate (SR) to 1 kHz in case it is distinct from this value.
2. **Visualization & User Validation**
   The software displays all 12 leads in the ECG Viewer for manual verification.
   The user reviews the signals and selects an analysis interval.
3. **Segment Selection**
   The user defines a suitable ECG segment (<500ms seconds).
   The selected segment is:
   - visually highlighted across all leads;
   - validated for length and basic signal quality.

   The map-generation button remains disabled until a valid segment is selected.
4. **Map Metadata Definition**
   Before map generation, the user selects:
   - anatomical region (atria/ventricles);

- ECG source;
- map name;
- optional advanced settings.

These metadata ensure traceability and correct interpretation.

5. **Computational Reconstruction**
   The software applies proprietary mathematical models of cardiac conduction to estimate activation times across a generic 3D heart model.
   No CT/MRI data or patient-specific geometries are required.
6. **Visualization of 3D Activation Map**
   The generated map is displayed using:
   - fixed color scale for early/late activation;
   - standardized anatomical orientation markers (AP/PA/LAO/RAO/LL/RL);
   - interactive rotation/zoom;
   - optional preset views.

   A split-view layout shows the ECG segment alongside the 3D map.
7. **Export & Documentation**
   The user can export maps and reports.
   A clear *warning* is shown during USB write operations to prevent data loss.

4.1.2 Process Overview:

The standard CorLector workflow in clinical use consists of:

1. **Case Creation**
   - Entry of mandatory patient metadata and diagnosis;
   - Persistent patient identifiers across all screens).
2. **ECG Import & Verification**
   - File selection;
   - Integrity & compatibility checks;
3. **ECG Segment Selection**
   - Visual inspection and time references;
   - Selection of representative beats.
4. **Activation Map Generation**
   - ECG-to-model computation;
   - Automatic generation of 3D color-coded activation map;
   - User-adjustable visualization options.
5. **Interpretation & Clinical Correlation**

- Review of earliest/late activation zones;
- Comparison with ECG waveforms;
- Consideration of clinical context;

6. **Export or Archiving**
    - Saving to approved USB devices;

The software does not provide therapeutic recommendations or automate diagnoses. Its purpose is to support experienced clinicians in the assessment and treatment planning of arrhythmias.

4.2 Combination with other devices

The CorLector System is delivered as a complete, validated configuration.

No additional hardware components are required from the user for intended operation, except for CorLector-approved ECG data sources and USB devices for data transfer.

Only components supplied or explicitly approved by CorLector GmbH may be used with the system.

4.3 Software overview

The CorLector software provides a structured, workflow-based user interface designed for the import, visualization and analysis of 12-lead ECG data, and the generation of 3D electroanatomical activation maps. The software guides the user through all steps via a clean, intuitive interface optimized for clinical environments.

The user interface consists of several primary screens:

4.3.1 Login Page

This is the entry point of the software and controls user authentication.

Main elements:

- Username field;
- Password field (with masked entry and optional “show password” toggle);
- Login button (activated only when both fields are filled);
- Regulatory identifiers (e.g., CE mark, manufacturer, software version);
- Error messages for incorrect login;
- Shout down button (to close the application).

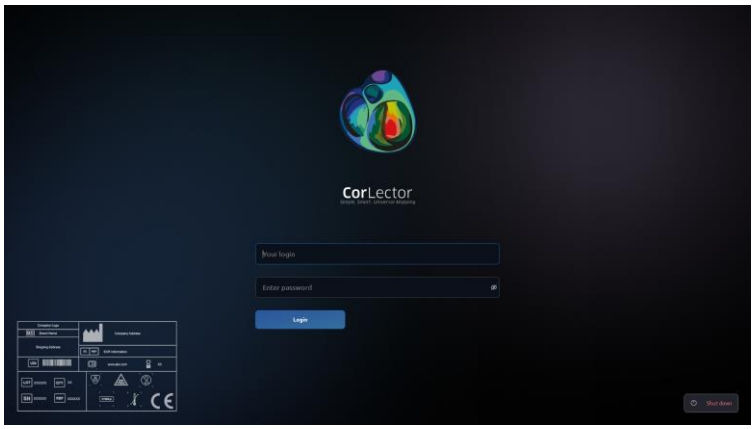


Figure 1 Login page

4.3.2 Home Screen / Case Management Dashboard

After successful login, users see the home dashboard, which provides access to case creation, case search, and recent cases.

Main elements:

- Sidebar with primary actions:
  - **Create New Case**
  - **Import Case**
  - **Close Session (Logout)**
- Table of recently used cases
  - Case Name
  - Diagnosis
  - Gender
  - Age
  - Last edited timestamp
  - Action icons (delete)
- Search bar for quick case filtering
- User menu (active session information)
- Preferences, Help Guide, About.

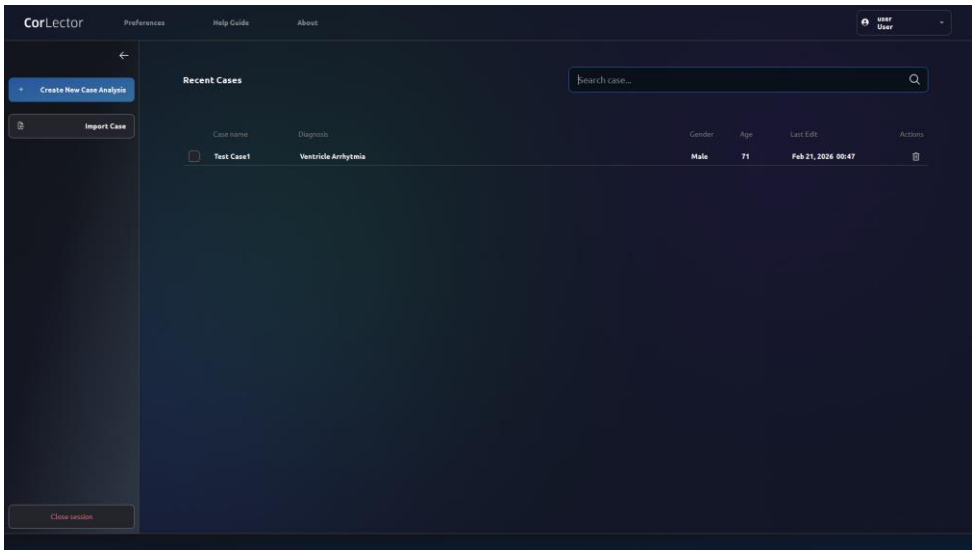


Figure 2 Home Screen / Case Management Dashboard

The image below shows Selection settings. For each recent case there is the possibility to EXPORT and DELETE the case data. If multiple cases are selected, the actions are valid for multiple exports and deletions.

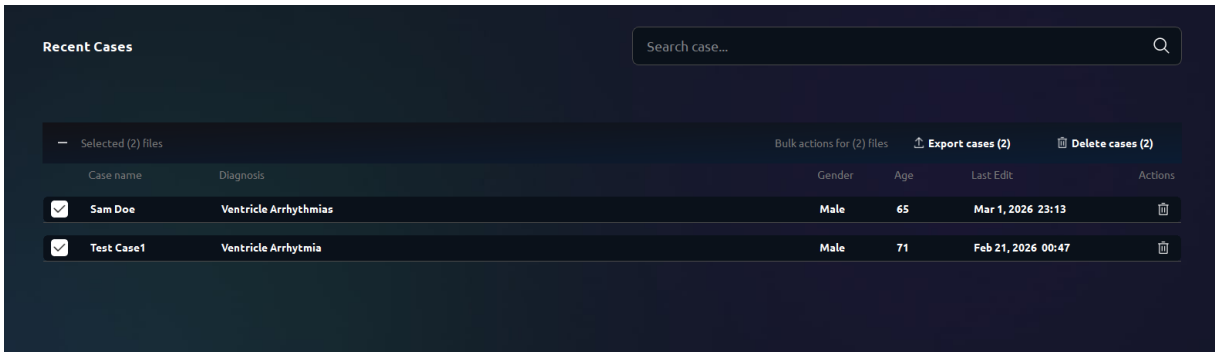


Figure 3 Export cases

4.3.3 Case Creation Dialog

This dialog appears when the user selects “Create New Case Analysis”.

Main elements:

- Mandatory patient metadata fields:
  - Case Name
  - Diagnosis
  - Gender
  - Date of Birth
- Optional notes fields
- Confirmation button
- Cancel button

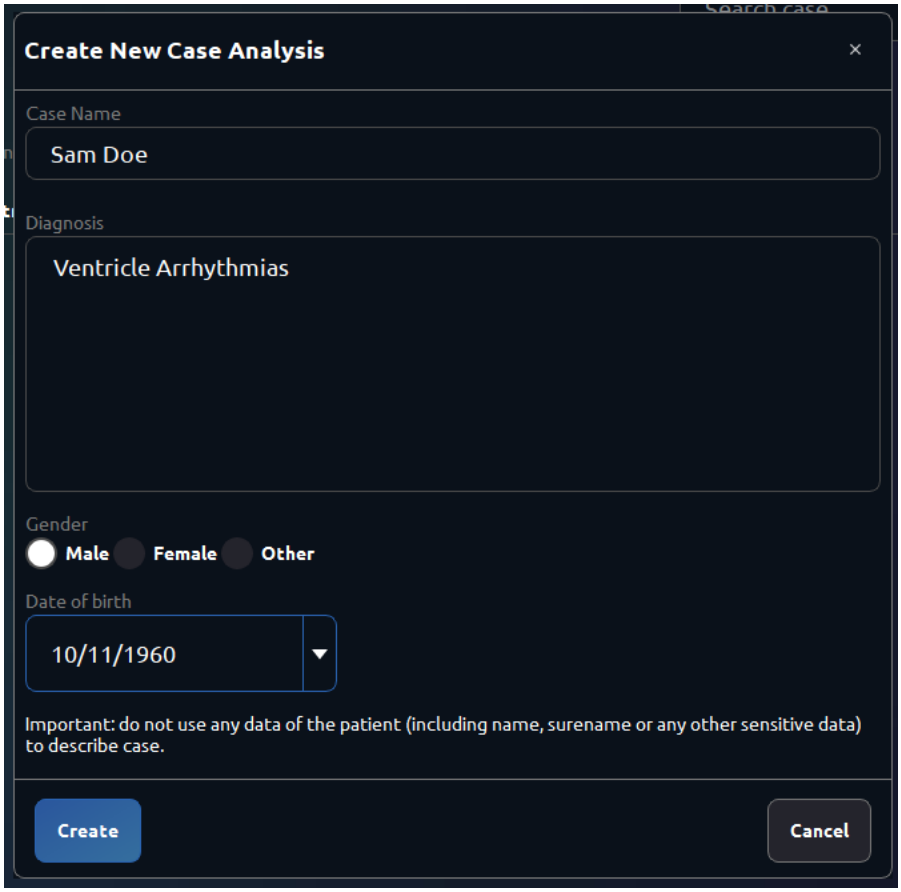


Figure 4 New case widget

4.3.4 ECG Data Viewer & Import Module

Once a case is created, the user imports ECG data. After import, the data viewer opens automatically.

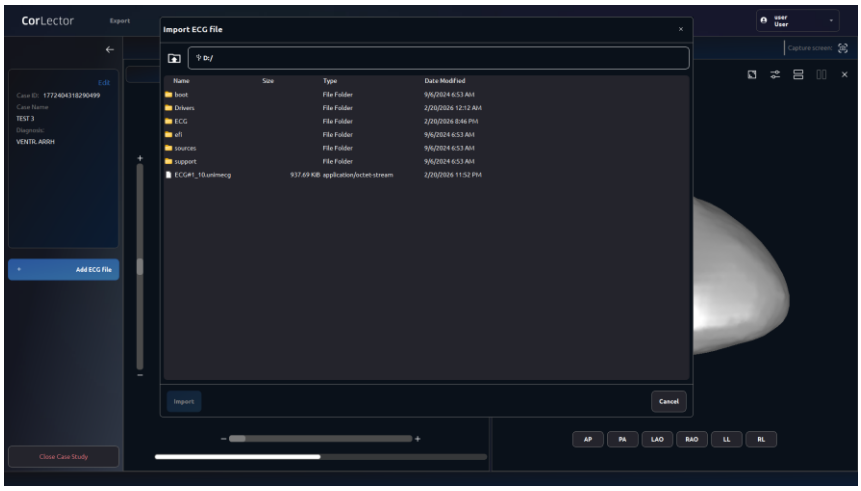


Figure 5 ECG data import dialog

Import data selection. This pop-up window appears after clicking the import ECG button in the case main page.

Main elements:

- File selection window (up Figure)
- Automatic file integrity and compatibility check
- Lead-by-lead visualization
- Scroll & zoom functionality
- Controls for selecting ECG segments
- Highlighting of selected interval
- View settings panel.

Figure 6 Anatomy and ECG preview screen view

Figure 7 ECG Interval selection

ECG view configuration settings. There is the possibility to customize the column number to view the 12 ECG waves.

To select the time interval directly from the ECG wave trace, drag and drop the cursor directly on a preferred lead wave. The interval is highlighted simultaneously and coherently on every ECG wave.

Figure 8 Create AT dialog

Activation map clicked. All possible parameter settings. The interval should be < 500 ms and > 30 ms. Enabling the additional settings, it is possible to select or shift very precisely the time interval in ms.

4.3.5 3D Model & Activation Map Workspace

After selecting a valid ECG segment, the user opens the 3D activation map module.

Main elements:

- Interactive 3D heart model
- Color-coded activation time map
- Fixed-color legend for early/late activation area
- Anatomical orientation markers (AP/PA/LAO/RAO/LL/RL)
- Split view: ECG traces beside the 3D map
- Map metadata panel (map type, source ECG, metadata)
- Export options

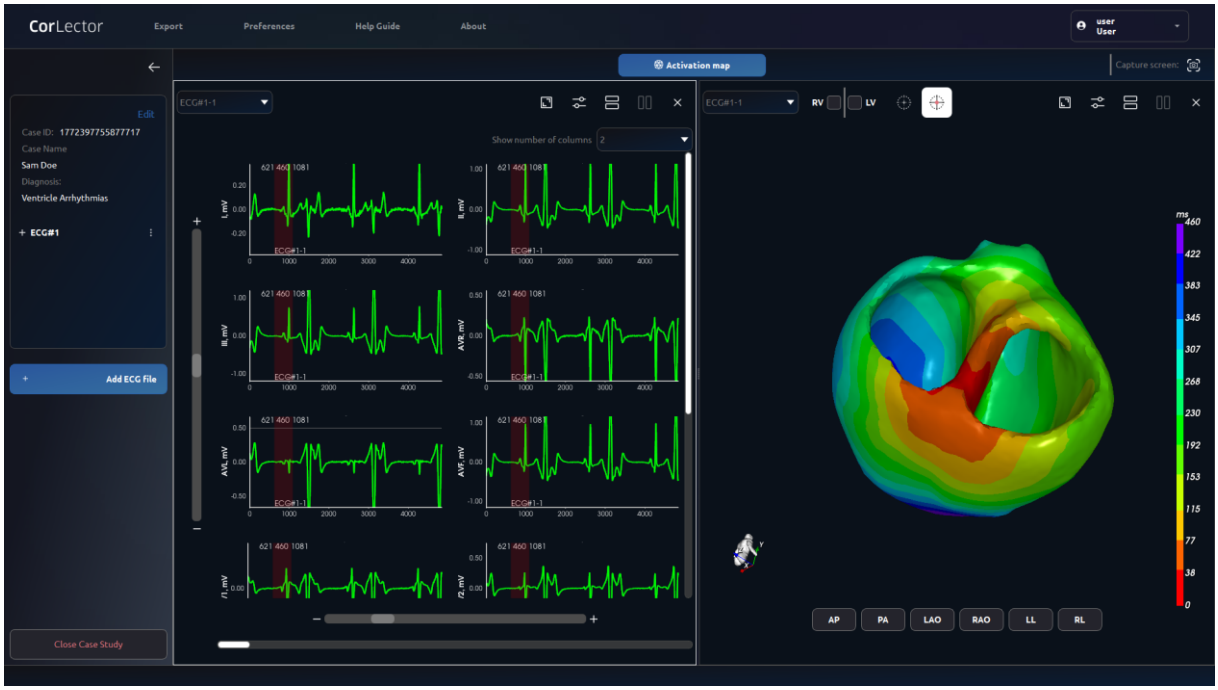
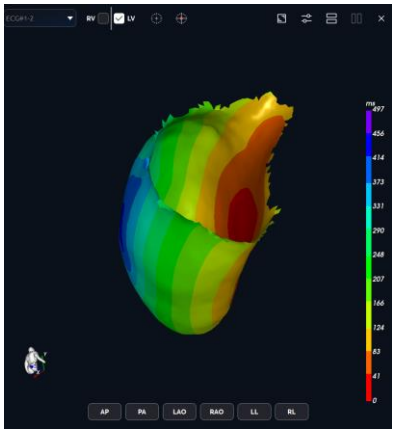
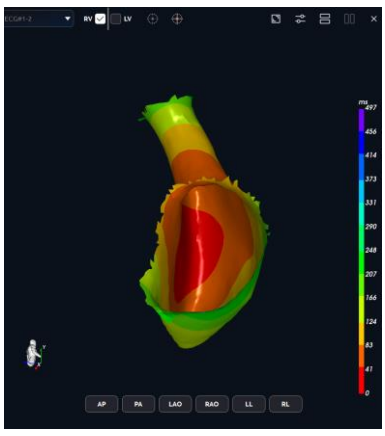


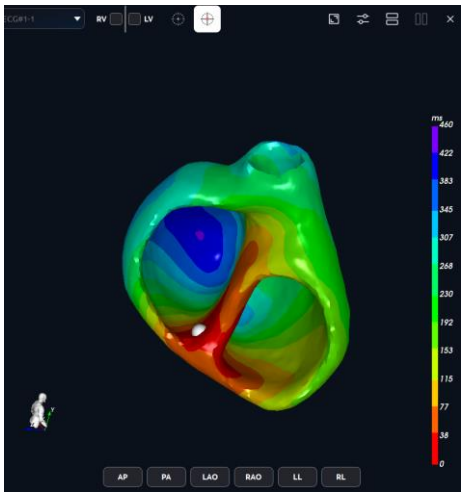
Figure 9 3D Model & Activation Map Workspace

Views and settings

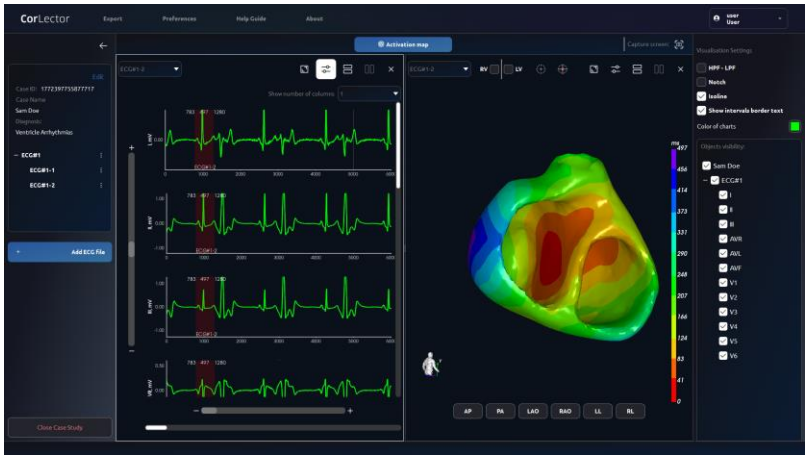




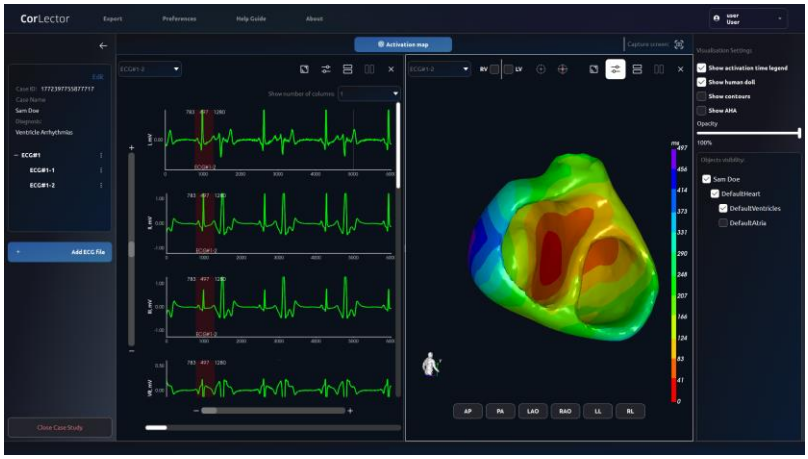
Enabling Left and Right ventricle separated view, with correspondent Electrical Activation Map.



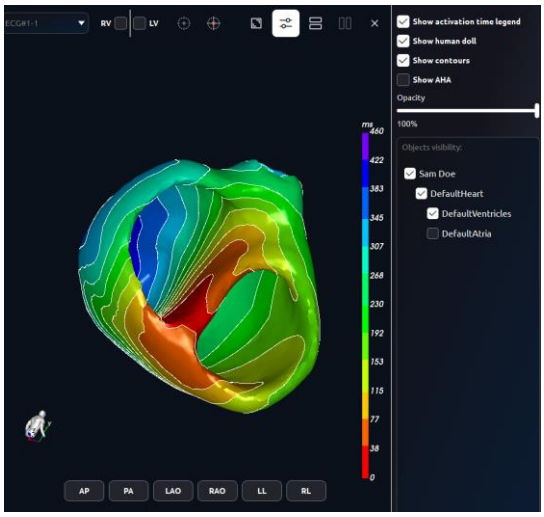
Enabling the target point (White dot) view with the red target button.

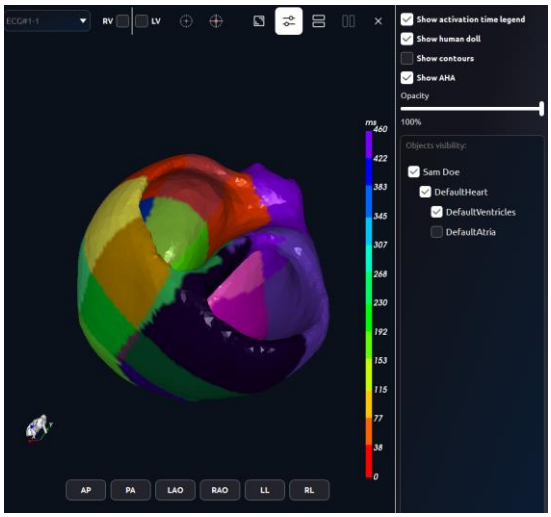


ECG view settings: enabled by ECG related setting button. 12 ECG waves view that can be individually enable/disabled. Band pass ([HPF; LPF]) of 0.05 Hz high pass and 150 Hz low pass filter application; notch filter (50, 60 Hz + harmonics) application; isoline filter (high-pass 0.5 Hz) application. Enable/disable the selected time interval border text view.

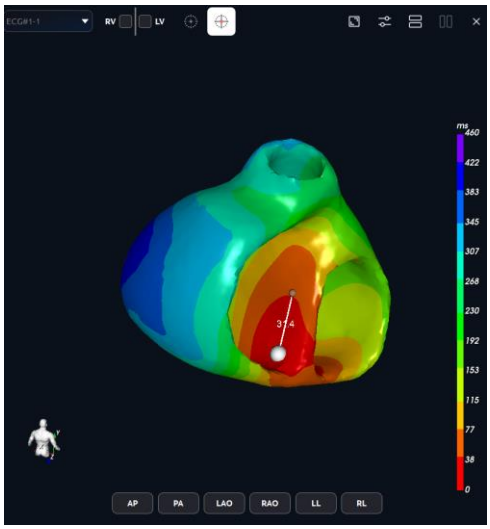


Map view settings menu. Enabled by clicking on map widget's settings button.





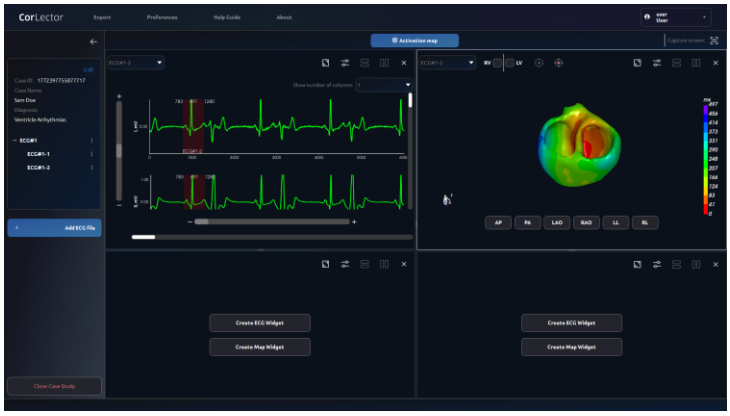
EAM view settings: isoline contouring and AHA colored visualization. The opacity can be set in percentage from 0 to 100%.



Tool for measuring the distance (in millimeters) between the target point and a selected point on the surface.

To enable it, click the grey target and select a point on the heart surface. The user can select multiple targets.

To delete a target, click the target icon and select the target with the right click.

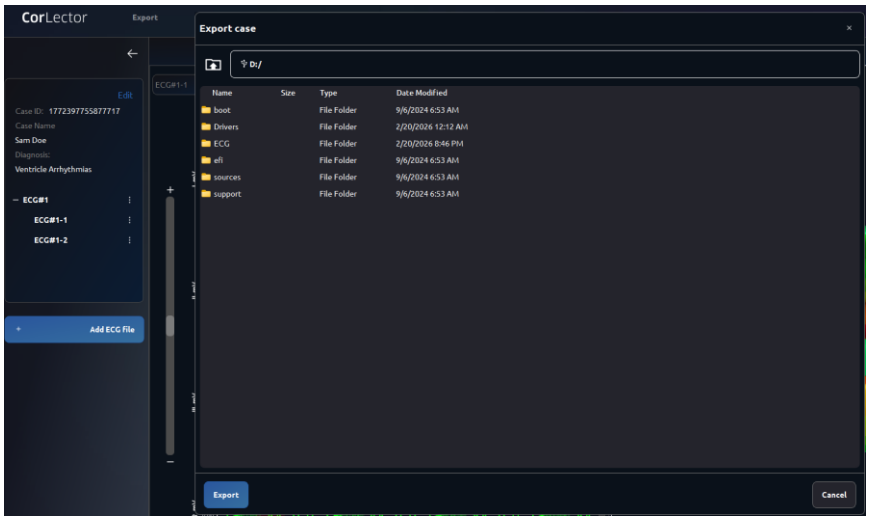


Split the view, to have multi ECG/Maps to compare.

4.3.6 Export

To guarantee a correct export, the user must be sure that a correct USB drive is connected with the system and has the necessary capacity to contain files that have to be exported. Clicking on the export button (in the higher part of the display).

A pop-up window (below) appears showing the export options.



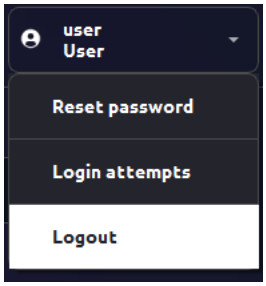
The user is able to select the preferred path for export inside the USB drive.

4.3.7 Users access rights

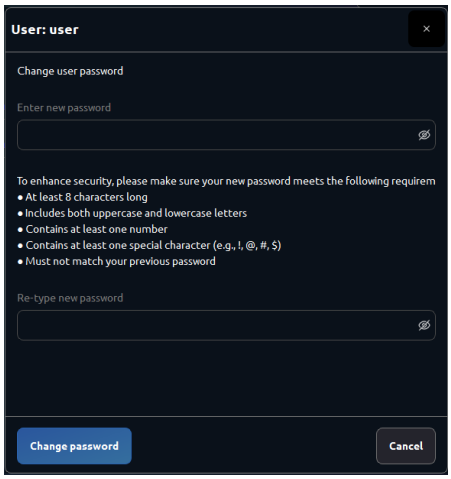
In the upper right corner of the application, User button is present.
This button opens the user menu.

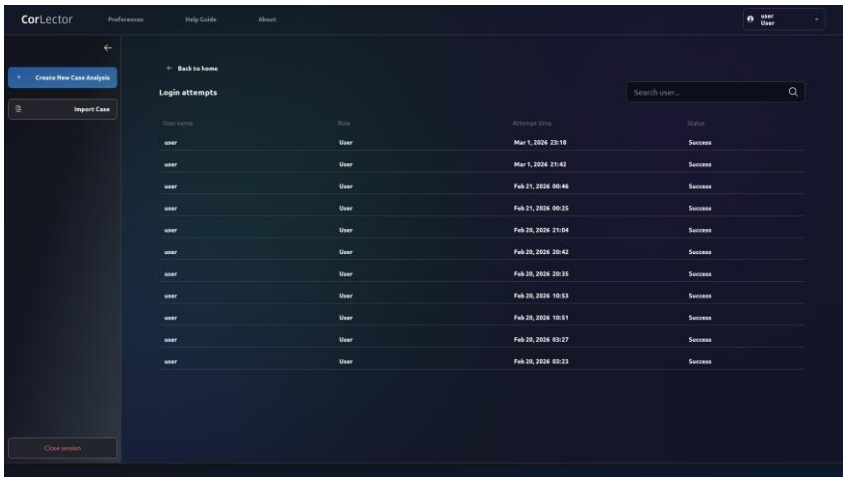
This user menu contains the following functionalities:

- Reset password;
- Login attempts (list of all the user access attempts);
- Logout button (to log out the user).

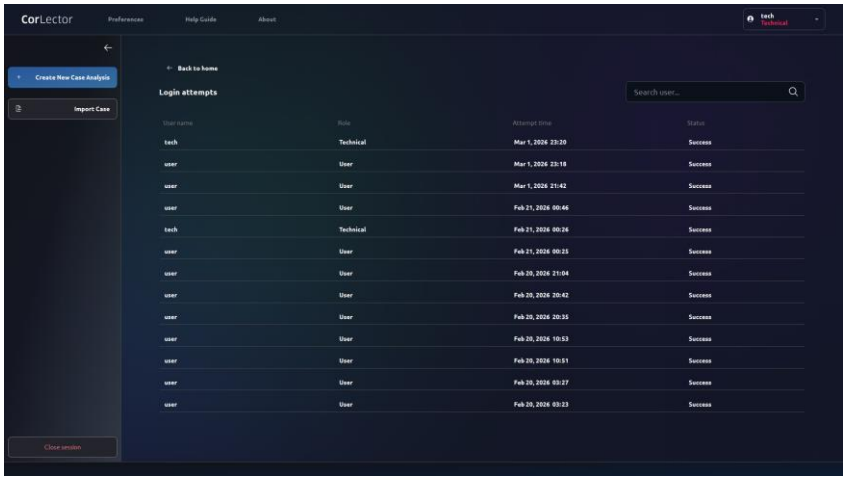


Reset password.
Through this pop-up window, the user is able to change the log-in password.

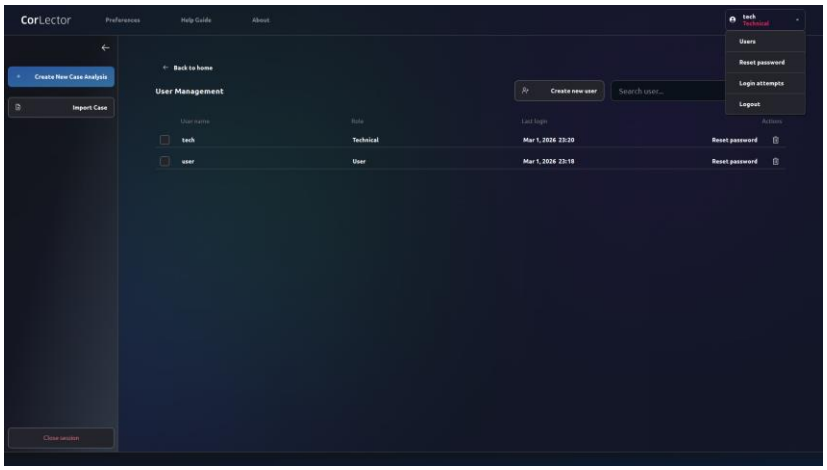




Log in attempts (user view).



Log-in attempts seen by the Admin and Technical users.



User management, only the Technical and the Admin users can access this section. Through this section they can reset other user's password, remove and manage users.

5 Accessories, resources, consumables, spare parts

CorLector is supplied as a pre-configured system including the CorLector software pre-installed on a dedicated workstation and the components required for intended operation.

The system is supplied with all components required for intended use.

Replacement is only permitted with equivalent CorLector-approved components.

The following components are part of the system as supplied by the manufacturer:

- Dedicated workstation with pre-installed CorLector software (Advantech PC)

- Input devices (keyboard, mouse)

- CorLector-approved USB device(s)

6 Installation

CorLector is delivered by the manufacturer as a complete, pre-configured system with the software pre-installed on a dedicated workstation.

The system is not intended to be installed by the user on customer-provided hardware.

The CorLector software is delivered pre-installed on a dedicated and validated medical workstation. No installation or configuration is required by the end user. The workstation is provided in a ready-to-use state and must not be modified, reconfigured, or connected to external networks.

The system is delivered in manufacturer-defined protective packaging ensuring safe transport of the complete system.

6.1 General Notes

⚠CAUTION

End users are not permitted to reinstall, alter, or move the software installation independently.

Installation and system configuration may only be performed by personnel authorized by CorLector GmbH.

End users (EP physicians, technicians, nurses) are not permitted to install, reinstall, alter or relocate the software.

The workstation must remain:

- offline (no Internet, no LAN, no cloud services);
- physically secured against unauthorized access;
- free from any non-approved software.

Hardware and operating system settings (BIOS, Group Policy, USB whitelisting, encryption) must not be modified.

Only IT Administrators authorized by CorLector GmbH may manage user accounts.

⚠WARNING

Any modification to the installation, including changing system settings, connecting to networks, or installing third-party software, may compromise device safety, cybersecurity, and regulatory compliance.

6.2 Installation Scope

The following steps are performed before delivery by CorLector GmbH:

1. Installation of CorLector software on the medical workstation
2. Verification of hardware and OS configuration
3. Setup of cybersecurity controls:
    - Removal of local administrator rights

- BIOS/UEFI password protection
- Disabled external boot (USB, PXE)
- USB device whitelisting (only CorLector approved USB drives are accepted)
- Local encryption and storage policies

4. Validation of the CorLector software build
5. Factory acceptance test (FAT), including:
   - Clean startup
   - ECG import test
   - Map generation test
   - Export and USB handling test
6. Final packaging and shipping in protective materials

Upon delivery to the healthcare institution, the system is ready for operational use.

6.3 Post-Delivery Check

Before using CorLector for clinical cases, the user and/or local IT Administrator must verify the following:

6.3.1 Hardware Verification

- The workstation powers up without abnormalities
- Monitor, mouse, and keyboard are functional
- USB ports detect only approved USB devices

6.3.2 Software Verification

- CorLector launches without errors
- Login screen displays correctly
- Software version matches the documentation or delivery note
- A test case can be created

6.3.3 ECG Import Check (Recommended)

Perform an optional functional check:

1. Insert an approved USB device
2. Import a test ECG file
3. Verify that the ECG preview loads correctly
4. Check that system warnings appear when expected (e.g., unsupported file formats)

6.3.4 Security Verification

- User accounts have been created by IT Administrator
- Unauthorized USB devices are blocked
- System cannot connect to any network
- BIOS password protection is active

If any of these checks fail, contact CorLector Support before clinical use.

6.4 Minimum IT environment requirements (for PES and SW)

As CorLector is supplied as a fully configured system, no minimum IT requirements for customer-provided hardware apply.

The validated hardware and software configuration is defined and controlled by CorLector GmbH.

6.4.1 Network Requirements

- None
- The workstation must remain fully offline
- No Internet, no hospital network, no VPN, no Wi-Fi

6.4.2 Additional Software Requirements

- None
- No antivirus, firewall, or third-party tools may be installed unless pre-approved by CorLector GmbH
- The system already contains all required security controls

6.4.3 Hardware Requirements

The workstation is delivered meeting all validated specifications,

6.4.4 USB Device Requirements

Only CorLector approved USB drives are permitted.

Other USB devices are automatically blocked.

7 Commissioning/preparations

The CorLector software is pre-installed and factory-configured. No additional commissioning steps are required by the end user prior to use. However, the following checks and preparations must be completed before clinical operation:

7.1 Initial Verification

Before using CorLector for the first time, verify:

1. System startup
    - The workstation powers on without unexpected error messages
    - The Windows login screen appears and responds normally.
2. Software startup
    - The CorLector application launches via the desktop icon
    - The login window appears and displays:
        - Username and password fields
        - Software version
        - Regulatory information.
3. Version confirmation
    - Verify that the displayed software version matches the documentation or delivery release note.
4. Unauthorized changes
    - Ensure no additional software has been installed
    - Ensure the workstation remains offline (no network icon, no Wi-Fi).

If any unexpected behavior occurs, do not proceed with clinical use and contact CorLector Support.

7.2 User Access and Licensing

7.2.1 User Accounts

Before clinical operation:

- Required user accounts (EP Physicians, IT Administrators) must be created by a designated, authorized IT Administrator.
- Each user must have:
    - Unique username
    - Secure password
    - Appropriate role / permissions

7.2.2 Access Restrictions

- Only trained EP Physicians may access analysis functions.
- IT-Administrators may only access system and user management.
- Access for unauthorized personnel is not permitted.

7.3 Data Preparation

Before conducting an analysis:

1. Prepare ECG files
    - Ensure the ECG recording has been exported from the hospital ECG system in a supported file format:
        - HL7 XML aECG
        - EDF
        - PhysioNet(HEA, DAT)
    - Ensure the file is complete and not corrupted.
2. USB device preparation
    - Only use CorLector-approved USB devices for data transfer.
3. Patient metadata
    - Prepare the following for case creation:
        - Case name
        - Diagnosis
        - Gender
        - Date of Birth
    - These fields are mandatory for safety and traceability purposes.
4. ECG verification
    - Ensure the recording contains at least 1sec duration and ≥500ms of analyzable rhythm
    - Avoid segments with excessive noise, artefacts, pacing spikes, or telemetry disruptions.

7.4 Functional Test

Although not mandatory, CorLector recommends a brief functional test:

1. Launch the software and log in
2. Create a test case
3. Import a sample ECG file

4. Verify that the ECG preview displays correctly
5. Select a segment and attempt map generation

This test ensures:

- System integrity
- USB functionality
- Correct configuration
- No unexpected behavior

8 Device use

The CorLector software is used to generate 3D electroanatomical maps based on standard 12-lead ECG data. The user interface guides the clinician through a structured workflow.

8.1 Workflow Overview

The standard use of CorLector consists of the following steps:

Step 1 – Create a New Case

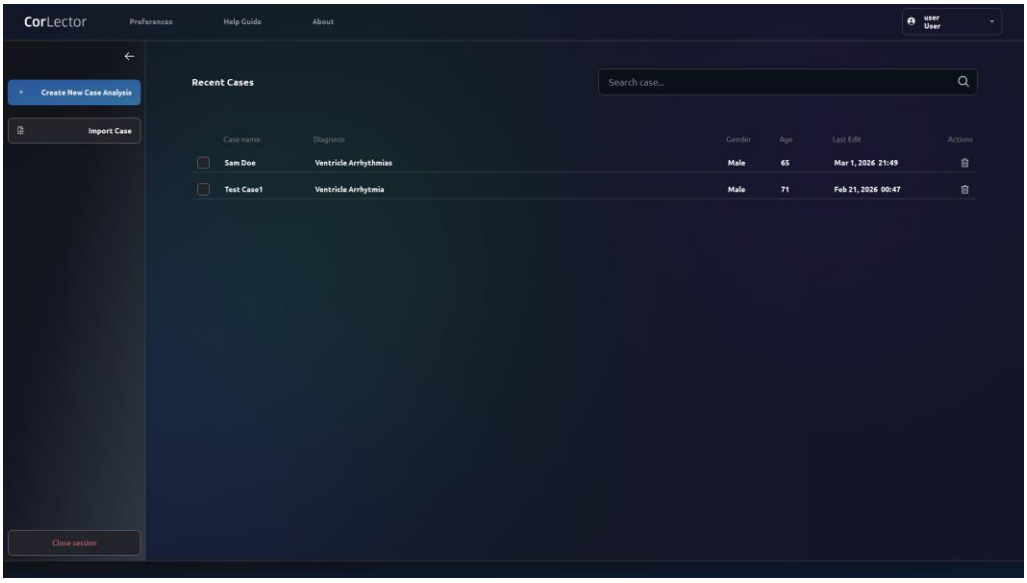
Purpose:
Create a new patient-specific case and enter the required metadata.

Preconditions:

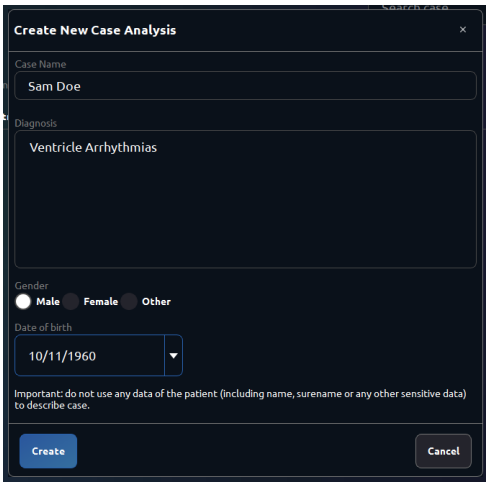
- CorLector is started and the user is logged in.
- The user is an authorized EP Physician.

Step-by-step instructions

1. On the Home screen, click Create New Case Analysis in the main action area or sidebar.



2. In the Case Creation dialog, enter at least the mandatory fields:
   2.1. Case Name
   2.2. Diagnosis
   2.3. Gender
   2.4. Date of Birth (DOB)



3. Carefully verify all patient details.
4. Click Save or Create (depending on final UI label).

System feedback

- A new case is created and appears in the case list.
- Patient identifiers (Case Name, ID, DOB, Diagnosis) are shown persistently in the header left area on all subsequent screens.

Warnings / Notes

- Always verify patient identifiers before proceeding.
- Creating a case with wrong patient data can lead to case confusion and misinterpretation.

Step 2 – Import 12-Lead ECG Data

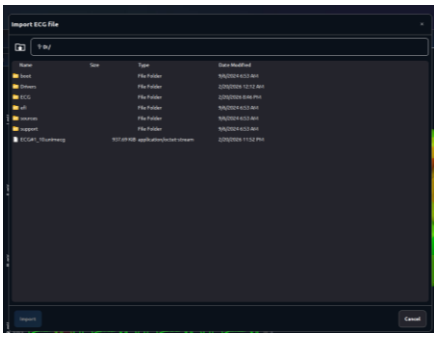
Purpose:
Import the ECG recording for the selected patient case.

Preconditions:

- A patient case has been created (Step 1).
- A supported 12-lead ECG file (EDF, HL7 aECG XML, or PhysioNet) is available.
- An approved, whitelisted USB device with the ECG file is inserted.

Step-by-step instructions

1. Ensure an approved USB device is connected.
2. In the open case, click Import ECG Data (or equivalent menu item).
3. In the file selection dialog Select the desired ECG file.



4. Click Open or Import to confirm the selection.
5. Wait until the integrity and compatibility check is completed.

System feedback

- If the file is supported and intact, the 12-lead ECG Viewer opens and displays all leads.
- If the file is incompatible or corrupted, a clear warning is displayed, and the file is not imported.

Warnings / Notes

- Pay attention to file names and patient identifiers stored in the ECG system.
- Do not ignore “unsupported” or “corrupted file” warnings.
- If the wrong ECG file is imported, immediately cancel and re-import the correct file.

Step 3 – Select the ECG Interval for Analysis

Purpose:
Select a representative ECG segment that will be used for map generation.

Preconditions:

- ECG data has been successfully imported and is visible in the ECG Viewer.

Step-by-step instructions

1. In the ECG Viewer, scroll through the ECG until you identify a segment with:
    - Stable rhythm
    - Sufficient duration (selected interval for map creation should be >30ms and less than 500ms).Acceptable signal quality
2. Use the segment selection tool (drag and drop with the cursor) to set the start marker at the beginning of the desired interval.
3. Drag the end marker to the end of the desired interval.

4. Check that the selected interval visually covers the intended beats across all 12 leads.

System feedback

- The selected segment is highlighted across all leads.
- The Map Generation button remains disabled until a valid segment (length and quality) is selected; it becomes active when requirements are met.

Warnings / Notes

- Avoid segments with artefacts, excessive noise, pacing spikes, or transient conduction changes, unless clinically intentional.
- An incorrect segment can lead to misleading activation maps.

Step 4 – Enter Map Metadata (Mandatory)

Purpose:
Define the key metadata that describe the map and ensure traceability and correct interpretation.

Preconditions:

- A valid ECG segment has been selected and confirmed (Step 3).

Step-by-step instructions

1. Click the Generate Activation Map button (or equivalent).
2. When the Map Metadata dialog appears, fill in the fields:

2.0. ECG used to create the map.
2.1. Select the mapped anatomical region (Atria / Ventricles).
2.2. Confirm or select the ECG source for this map (e.g., ECG #1).
2.3. Enter a Map Name (e.g., “VT Mapping – 2025-11-19”).

3. Double-check that the anatomical region and ECG source are correct.
4. If necessary, adjust the segment boundaries until you are satisfied through the below pop-up window (which appears after clicking EAM button).
5. Click Confirm, OK or Generate to proceed.

System feedback

- The system validates that all required fields are filled.
- If required information is missing or inconsistent, the user is prompted to correct it.
- When validation is successful, CorLector starts the map computation.

Warnings / Notes

- Selecting the wrong anatomical region or ECG source can lead to incorrect clinical interpretation.
- Do not proceed if you are unsure about the selected region or ECG source.

Step 5 – Generate the Electroanatomical Map

Purpose:
Compute and display the activation map based on the selected segment and metadata.

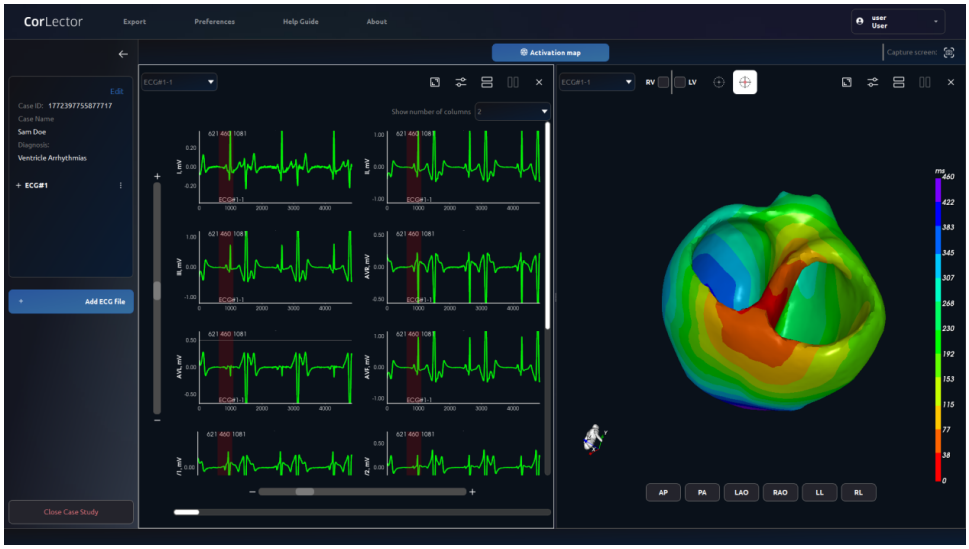
Preconditions:

- ECG segment selected (Step 3).
- Map metadata entered and confirmed (Step 4).

Step-by-step instructions

1. After metadata confirmation, click Generate (if not already triggered in Step 4).

2. Wait while the software processes the ECG data.
3. Do not close the application or remove power during computation.



System feedback

- A progress indicator may be displayed.
- After computation, a 3D activation map appears.
- A fixed color scale legend for early/late activation is shown.
- Anatomical orientation markers (e.g., AP/PA/LAO/RAO/LL/RL) are visible on or near the model.
- In split-view mode, the selected ECG segment is shown alongside the 3D map.

Warnings / Notes

- The generated map represents an estimation based on ECG data and mathematical modeling.
- It does not replace invasive mapping, imaging, or clinical judgement.

Step 6 - Export or Save

- The resulting visualization and data can be saved or exported for clinical documentation.

9 Interpreting results

The CorLector software generates 3D electroanatomical activation maps derived from the selected 12-lead ECG segment. These maps provide a visual estimation of cardiac activation timing to support clinical assessment by trained electrophysiologists.

Interpretation of the results must always be performed by a qualified EP physician and in conjunction with the ECG and the clinical context.

9.1 Understanding the Output

Understanding Key Elements of the Activation Map

Each CorLector activation map consists of the following essential elements:

Color-Coded Activation Pattern

- The map displays estimated activation times using a fixed color legend from early to late activation.
- Early activation = warm colors (e.g., red/yellow)
- Late activation = cool colors (e.g., blue/purple)
- The color scale is standardized to reduce variability in interpretation.

Anatomical Orientation Markers

- Markers such as AP, PA, LAO, RAO, LL, RL are included on the model to guide correct anatomical perspective.
- These ensure the physician can correctly identify anterior/posterior and left/right orientation.

3D Interactive Heart Model

- The model represents a generic heart geometry.
- It can be rotated and zoomed to visualize specific anatomical regions.

ECG Split View

- The simultaneously displayed ECG segment allows direct correlation between electrical signal morphology and reconstructed activation patterns.

9.2 Limitations

- The accuracy of the prediction depends on signal quality and completeness of the ECG data.
- Artifact-laden or noisy recordings may distort the result.
- Differences in individual anatomy, conduction abnormalities, or prior surgeries may affect the interpretation.

9.3 Potential Sources of Misinterpretation

Misinterpretation can occur if:

- The anatomical orientation is misunderstood
- The wrong ECG segment was selected
- The ECG contains noise or artefacts
- The patient's anatomy deviates significantly from normal
- The map is interpreted without ECG correlation
- Only a single view or angle is considered
- Clinical context is not considered.

Physicians should always integrate:

- ECG morphology
- Clinical symptoms
- Prior ablation history
- Imaging (if available)
- Known conduction abnormalities.

10 Operation in exceptional and emergency situations

The CorLector software is intended solely for use under standard clinical conditions. Operation in emergency scenarios or exceptional situations is not supported.

11 IT Security

The CorLector software runs on a dedicated, secured, offline workstation.

IT security is essential to ensure the confidentiality, integrity, and availability of patient data and to maintain the validated system configuration.

This chapter describes the IT security requirements, user responsibilities, and procedures for handling security-related situations.

11.1 IT environment requirements

To maintain cybersecurity and data integrity, the following IT environment requirements must be met:

Offline Operation

- The CorLector workstation must always remain fully offline.
    - No internet connection
    - No hospital network connection
    - No Wi-Fi
    - No VPN
    - No cloud services.

Validated Hardware

- CorLector may only be operated on a validated workstation supplied or approved by CorLector GmbH.
- System must not be installed on alternative hardware or virtual machines.

Operating System Integrity

- The underlying operating system and configuration are part of the validated system.
- The OS must not be updated, modified, replaced, or reconfigured by the user.

Physical Security

- The workstation must be in a secure clinical environment with controlled access.
- Hardware ports must not be tampered with, covered, or modified.

Electromagnetic Safety

- Do not operate the system near strong EM sources (RF ablation generators, MRI rooms).
- Ensure stable and reliable power supply.

11.2 IT security measures to be implemented

11.2.1 Access Control

User Authentication

- Login with username and password is required.
- Strong passwords must be used according to hospital policy.
- Passwords must not be shared between users.

Role-Based Access

Only the following user types exist:

1. EP Physician – Clinical user
    - May create cases, import ECG, select segments, generate maps, export data.
2. IT-Administrator – Technical user
    - Manages user accounts.
    - Responsible for workstation security.

Unauthorized Access Prevention

- Auto-lock activates after 5 minutes of inactivity.
- Users must manually lock the workstation when leaving.

11.2.2 USB Device Security

Only CorLector-approved USB devices may be used.

USB Whitelisting

- Approved USBs are explicitly whitelisted.
- Unauthorized USB devices are automatically blocked.

USB Usage Rules

- Do not connect personal or non-approved USB sticks.
- Smartphones, external HDDs, or cloud-sync USB drives are prohibited.
- USB devices must remain encrypted (AES-256 hardware encryption).

Data Transfer Integrity

- Do not remove USB sticks while the transfer is in progress.
- Always verify export completion messages before ejecting.

11.2.3 System Hardening (Pre-Configured)

The following measures are pre-installed by CorLector GmbH and must not be altered:

- Removal of local administrator rights for all EP users.

- BIOS/UEFI password protection.
- Disabled USB boot and PXE boot.
- Disabled network interfaces (Ethernet, Wi-Fi).
- Application whitelisting (only approved USB Stick may run).
- Restricted Windows services based on the validated configuration.

These configurations must remain unchanged.

11.3 Handling lost or stolen authentication elements

11.3.1 Lost / stolen computer password:

If a password is lost or suspected to be compromised:

1. Do not attempt repeated login attempts.
2. Report the incident to the authorized IT administrator immediately.
3. IT administrator disables the user account.
4. A new password is assigned and user credentials are restored.

NEVER bypass authentication using external tools or local account manipulation.

11.3.2 Lost / stolen USB:

If an approved USB device containing patient data is lost:

1. Immediately report the incident to IT Administration and the Data Protection Officer.
2. Document the event according to hospital policy.
3. CorLector GmbH may be contacted if audit logs are required.

11.4 IT security problems and countermeasures

The following signs may indicate a security issue:

11.4.1 Potential Indicators

- Unexpected login prompts
- Unexpected password changes
- An unapproved USB device being detected
- Altered or missing patient data
- Unexpected system slowdown
- Error messages indicating corrupted files
- Visible signs of physical tampering
- BIOS password suddenly invalid

11.4.2 Required Actions

If any suspicious activity is observed:

1. Stop all work immediately.
2. Lock the workstation (Windows + L).
3. Remove any USB device and secure it.
4. Do not continue the analysis.
5. Report the issue to:
    - Local IT administrator
    - CorLector Support if required
6. Document the incident according to local policy.

11.4.3 If malware or tampering is suspected:

- Disconnect power if safe to do so.
- Do not connect to any network.
- Do not attempt to investigate the issue yourself.

12 Licensing

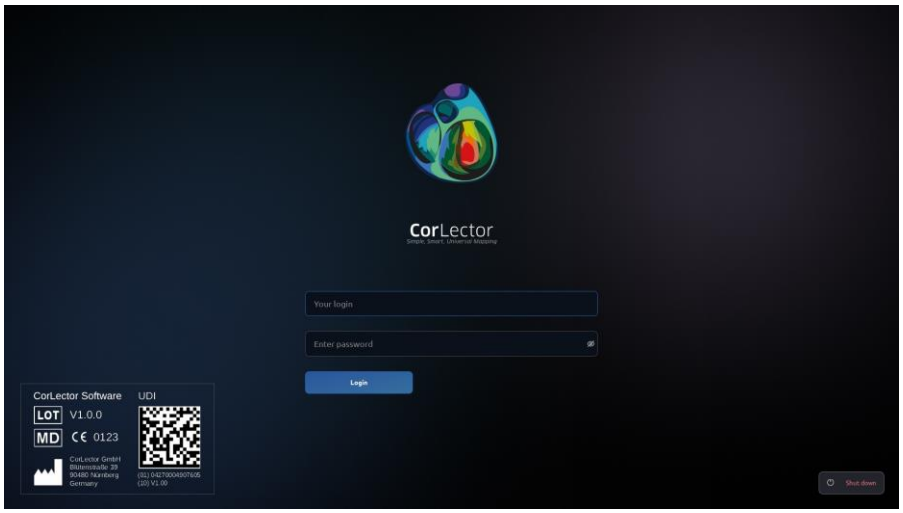
The licencing system allows the user to authenticate in the system correctly to explore all CorLector functionalities.

The CorLector licensing system ensures secure, device-bound authentication, enabling authorized users to access the full suite of CorLector functionalities.

⚠CAUTION **License Activation.** License activation and renewal must be performed by a CorLector-certified technician. This ensures secure device binding and compliance with licensing terms. End-user activation is disabled. Contact CorLector Support to schedule activation after installation or hardware service.

⚠CAUTION Important: Licenses are cryptographically bound to a single device. Activation on a different device will fail unless explicitly re-provisioned by CorLector Support.

⚠CAUTION **Case Entitlement.** Each license entitles the device users to process a predefined number of cases within a predefined time period, as specified in the executed license agreement. This limit is enforced at the device level and cannot be shared or transferred.



12.1 License Status Notification

When the user access with his licence, the system provides the notification of the licence status in the upper right corner of the interface (figure below).

Upon successful case creation with a valid license, the system displays the current license status in the upper-right corner of the user interface (see Figure 10). The indicator provides real-time information regarding license validity and remaining number of cases.

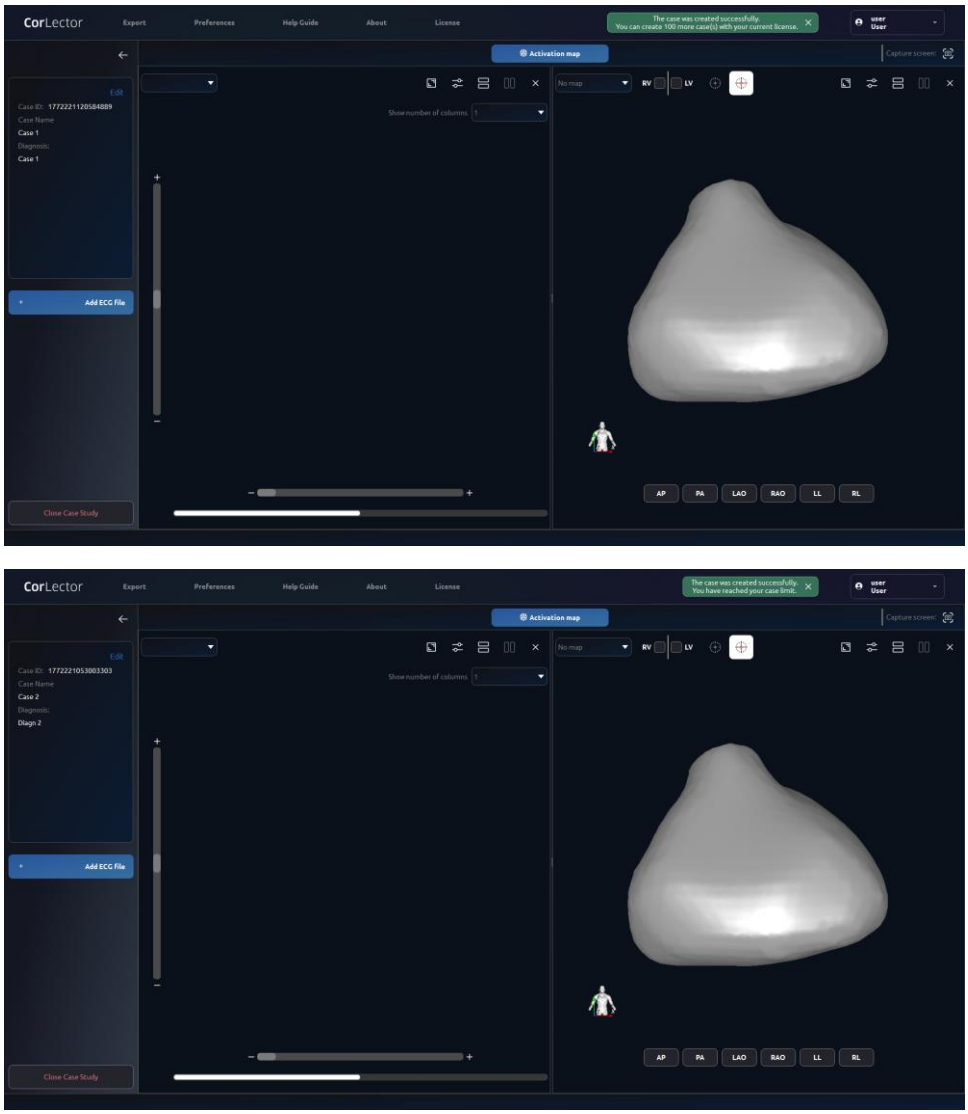


Figure 10 Screenshot with license status

Be careful, the licence is assigned on the device and cannot be shared with other devices.

⚠CAUTION Important: The license is permanently assigned to the specific device on which it was activated. It cannot be transferred, shared, or used concurrently on other devices. Attempting to use the same license on multiple devices may result in access restrictions or license deactivation.

12.2 Expired License Handling

When the licence is expired the system does not provide the access and the user must contact CorLector team.

If the license has expired, the system will deny login and display a notification in the popup window (see *Figure* 11).

⚠CAUTION **Access Restriction:**

The system blocks login entirely. All licensed functionality remains unavailable until a valid license is restored.

Resolution Steps:

To restore access, contact the CorLector Support Team:

- Email: support@corlector.com (replace with actual contact)

Include your device serial number for expedited assistance.

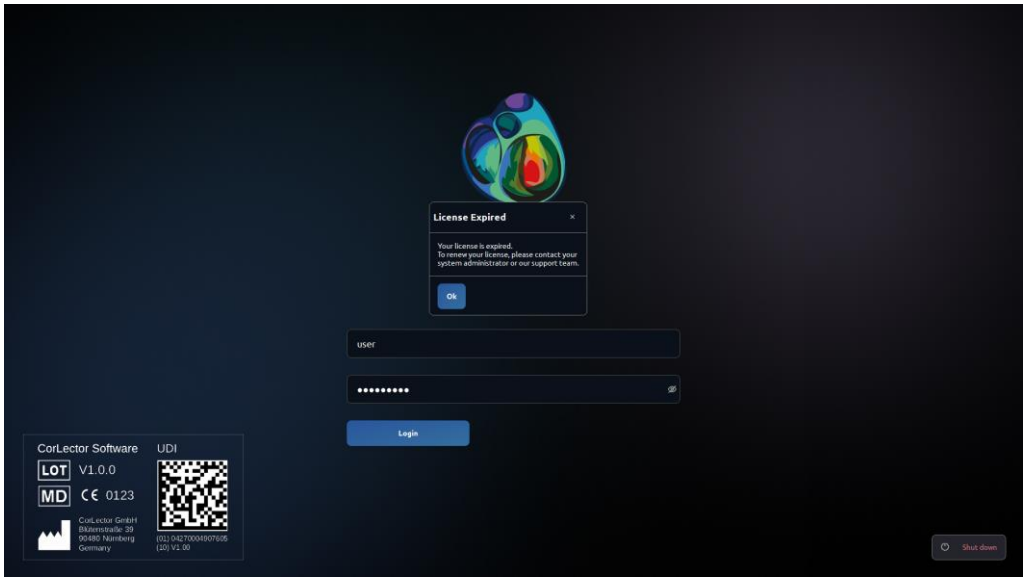


Figure 11*: Screenshot with notification about license expiration*

12.3 Case Limit Restriction

When the maximum number of licensed cases is reached, the system automatically displays a notification dialog box (see Figure 12).

Message Displayed:

"The number of new cases has been exhausted. Please contact us to renew the license."

System Behaviour:

Creation Blocked: Users are unable to create or initiate new cases once the limit is consumed.

Existing Data: Access to previously created cases remains available (read-only), subject to license validity.

Resolution:

To increase your case capacity, contact the CorLector Support Team to renew the license:

Email: support@corlector.com

Required Information: Device serial number

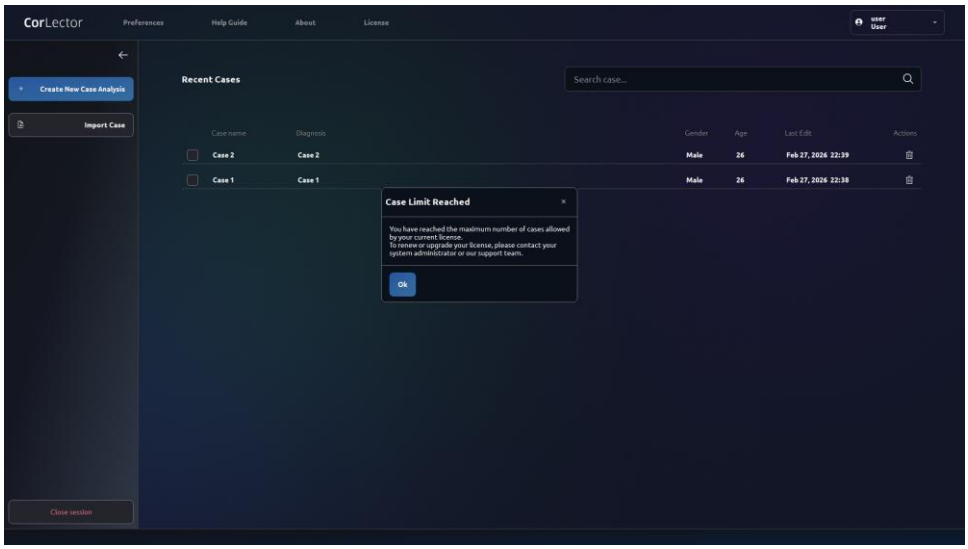


Figure 12 maximum number of licensed has been exhausted

13 Maintenance/Servicing

The CorLector software itself requires no routine maintenance by the end user. However, regular servicing of the underlying IT infrastructure and adherence to update policies are essential to ensure proper functionality and data security.

13.1 Maintenance by End Users

End users are responsible for the following basic maintenance tasks:

Interval	Task	Instruction
Monthly	Ensure sufficient storage space is available	Delete or archive old case data if needed
As needed	Restart the system to ensure optimal operation	Perform reboot if performance degrades

NOTE: Do not modify the software installation, system configuration, or attempt reinstallation. Contact technical support for such operations.

13.2 Maintenance by Authorized Personnel

Only CorLector GmbH or authorized technical service partners are permitted to perform the following actions:

- Software updates or patches
- License renewal or upgrade
- Hardware replacement or reinstallation of the operating system
- System recovery in case of critical failure

Interval	Task	Instruction
As announced	Software update installation	Performed on-site by CorLector
As needed	System restore or reimaging	Only with validated configurations

14 Disassembly, recycling, disposal

As a software product, CorLector itself does not require physical disassembly. However, if the software is provided on a preconfigured workstation or hardware system, the following provisions apply.

14.1 Disassembly

⚠WARNING Disassembly of the hardware system must only be carried out by qualified service personnel.

- Users must not open or modify the hardware system.
- All components must be handled in accordance with applicable electrical and safety regulations.
- Do not attempt to remove the software from the original workstation for installation on another system unless authorized.

14.2 Recycling

The hardware system and accessories (e.g., power supply, monitor) must be recycled according to local electronic waste regulations (e.g. WEEE Directive 2012/19/EU).

Contact CorLector GmbH for instructions on proper recycling or take-back programs.

14.3 Disposal

The hardware system and accessories (e.g., power supply, monitor) must be recycled according to local electronic waste regulations (e.g. WEEE Directive 2012/19/EU).

Contact CorLector GmbH for instructions on proper recycling or take-back programs.

14.4 Data handling during disposal

MPORTANT: Before decommissioning or disposing of the system:

1. Ensure all patient data and case files are securely deleted.
2. Use secure deletion tools or perform certified data wiping.
3. Alternatively, remove and physically destroy the storage medium if required by data protection policies.

15 Troubleshooting

This section provides guidance for identifying and resolving typical issues encountered during the use of the CorLector software. Troubleshooting steps differ depending on whether the issue can be resolved by the user or requires assistance from authorized service personnel.

15.1 Troubleshooting and correction by users

The following table lists common user-level issues and recommended actions:

Issue	Possible Cause	Recommended Action
Software does not start	System not powered or startup failure	Check power supply, restart the system
Error: “Invalid ECG file format”	Incompatible or corrupted file	Check file format; re-import ECG
ECG data are not displayed correctly	Missing leads or signal artifact	Check file format; re-import ECG
3D map is not generated	ECG segment too short or invalid	Check interval selection
System becomes slow or unresponsive	Memory or storage full	Restart system; delete unused case files
License error or expired license	No valid license key	Contact CorLector GmbH for activation support

NOTE: Do not attempt to modify system files or reinstall the software.

16 Repair

The CorLector software is a regulated medical device and may only be repaired or restored by the manufacturer or authorized service personnel. Users are not permitted to perform any repair or modification to the software or hardware components.

17 Device specifications

This section provides the technical specifications and system requirements relevant to the operation of the CorLector software.

17.1 Performance characteristics

Parameter	Specification
Input data	Standard 12-lead ECG (EDF, HL7 aECG XML, PhysioNet)
Output	3D electroanatomical map of cardiac activation (.unimap)
Minimum ECG interval for analysis	≥ 500ms
Supported arrhythmia types	Atrial and ventricular arrhythmias
Export formats	CorLector format

17.2 Device conformity

The CorLector software complies with the following regulatory and technical standards:

- Regulation (EU) 2017/745 on medical devices (MDR)
- ISO 14971:2019 – Application of risk management to medical devices
- IEC 62304:2006 + A1:2015 – Software lifecycle processes
- IEC 62366-1:2015 – Usability engineering
- ISO 13485:2016 – Quality management systems

18 Revision history of the instructions for use

Date of issue	Version number	Change
2025-12.30	1.0	First issue

19 Symbols used on the device and on the labelling

Symbol	Meaning
⚠ DANGER	Danger: an immediate hazardous situation exists, and serious harm or death is possible
⚠ WARNING	Warning: potential hazard that could lead to serious harm or death
⚠ CAUTION	Caution: potential hazard that could lead to slight or medium harm
NOTE	Note: errors committed by the operator can cause damage to the device
	Manufacturer