Instructions for Use
for
XOresearch Cardio.AI™

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Instruction for Use (IFU)
for XOresearch Cardio.AI™

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07/09/2023	**1.0**	Document Creation
13/06/2024	**1.1**	Document update: Smart Actions section added to the document, instructions text has been adjusted.
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07/03/2025	**1.3**	Document update: added sections “Availability of the Instructions for Use”, “Limitations”, legal address of the manufacturer clarified.

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Software Identification:

- Software Name: XOresearch Cardio.AI™
- Software Version: Version 2.5
- Class IIa Software under Rule 11 of MDR (EU) 2017/745
- Intended Use: XOresearch Cardio.AI™ is compatible with legally marketed ECG Holter devices and supports the import of ECG data in EDF and BDF formats through both manual upload and API-based transfer methods. While XOresearch Cardio.AI™ processes data obtained from external devices, it functions as a standalone software and does not directly interact with or control other medical devices in real-time. The annotation and interpretation provided by the software can be reviewed, edited, or confirmed by a physician. The final diagnosis and treatment decisions remain the responsibility of the physician.

Symbols

	Manufacturer

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	Consult instructions for use (IFU)
	Medical device
	CE Mark and the Notified Body number
	Caution
	Catalogue number
	Unique Device Identifier
	Serial Number

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1. Introduction:

Welcome to the Instruction for Use (IFU) for XOresearch Cardio.AI™. This document is provided by XOresearch SIA to assist healthcare professionals in safely and effectively utilizing our clinical decision support software.
The IFU contains essential information about the software's features, its intended use, precautions, and guidance on troubleshooting. Please read this document carefully before using the software.

2. Software Description:

XOresearch Cardio.AI™ is a multipurpose device for automatic annotation and interpretation primarily long, and short (from 7 seconds to 35 days) ECG records with any lead combinations and designed to:
- detect heartbeats, in pre-recorded ECG data; and separate noise from the beats in the data analysed by the device; and
- detect beat and rhythm events for the following rhythms: sinus, atrial, junctional, ventricular; and for the following disorders: pre-excitation syndromes, heart blocks; and for bundle branch blocks; and
- detect PQRST points, ST segment amplitude and direction, T-wave type, HRV, Heart Rate BPM; and
- visualise ECG data along with the other vital signs and patient-related information such as indications, diary events, demographic data; and
- generate an interpretation statement on an ECG data; and
- create a report based on the ECG findings in export it in a PDF format alongside priority indicators labelling; and
- store ECG data in cloud storage; and
- provide temporary or permanent access to ECG data or other vital signs.

The annotation made by the device will be confirmed by the physician and can be edited, or deleted. Platform interpretation results are not intended to be the sole means of diagnosis.

XOresearch Cardio.AI™ is a multipurpose medical device designed by the manufacturer to serve the following clinical purposes:

Automatic Annotation and Interpretation: The primary function of this device is the automatic annotation and interpretation of primarily long and short ECG records, irrespective of lead combinations.
It is specifically developed to:

Detect Heartbeats: Accurately identify heartbeats within pre-recorded ECG data.

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Noise Separation: Distinguish and separate noise from the analyzed heartbeats in the data.
Rhythm Detection: Detect various cardiac rhythms, including sinus, atrial, junctional, and ventricular rhythms.
Disorder Identification: Identify specific cardiac disorders such as pre-excitation syndromes, heart blocks, and bundle branch blocks.
Data Analysis: Analyze critical ECG parameters like PQRST points, ST segment amplitude and direction, T-wave type, Heart Rate Variability (HRV), and Heart Rate in beats per minute (BPM).
Comprehensive Visualization: Display ECG data alongside vital signs and patient-related information, including indications, diary events, and demographic data.
Interpretation Generation: Generate an interpretation statement based on the analyzed ECG data.
Report Creation: Create a comprehensive report summarizing ECG findings, exportable in PDF format, with severity indicators labeling.
Cloud Storage: Store ECG data securely in cloud storage for easy access and retrieval.
Data Accessibility: Provide both temporary and permanent access to ECG data and other vital signs as required.
Please note that while the device offers automatic annotation and interpretation, it is crucial to emphasize that these results are not intended to serve as the sole means of diagnosis. Physicians may confirm, edit, or delete annotations made by the device as part of their clinical practice.

3. Indications for Use:

- XOresearch Cardio.AI™ is intended for use in a hospital or clinical setting, by a physician. XOresearch Cardio.AI™ evaluates the ECG data of ambulatory patients pre-recorded with a legally marketed digital ECG recorder with any lead combinations.
The annotation by the device will be confirmed and may be edited or deleted by the physician. The final decision regarding the treatment of patients is the responsibility of the physician.

4. Contraindications:

XOresearch Cardio.AI™ is not indicated to detect pacemaker, as pacemaker's detection is not part of the current version of the system. XOresearch Cardio.AI™ does not analyse the pacemaker function and threats the signal as is, without any assumptions on presence or absence of the pacemaker, thus should not be used in fully automatic mode without physician attention for patients with a pacemaker.
XOresearch Cardio.AI™ does not support online real time analysis of ECG data. XOresearch Cardio.AI™ processes offline data in post-processing mode.
XOresearch Cardio.AI™ is not intended for real-time patient monitoring.

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5. Patient Population

XOresearch Cardio.AI™ intended to be used on adult patient records (over the age of eighteen) prescribed to undergo electrocardiography.

6. Intended users:

XOresearch Cardio.AI™ is intended for use by medical professionals, such as those who are responsible for deciphering ECG data, analyzing it, and diagnosing the patient on the basis of this data.
Operators of XOresearch Cardio.AI™ must hold recognized qualifications in cardiology or a related discipline, per Directive 2005/36/EC.
All operators of XOresearch Cardio.AI™ should thoroughly read and acknowledge this IFU to ensure safe and effective use. Acknowledgment of the IFU confirms that the user understands the capabilities, limitations, and best practices associated with the software.

7. Precautions/Warnings:

• Ensure that your computer system meets the minimum system requirements specified in the software's documentation. Inadequate hardware or software configurations may result in performance issues or software malfunctions.
• Verify the accuracy of input data, as inaccurate or incomplete data may lead to incorrect recommendations.
• Use the software in a controlled clinical environment with proper lighting and minimal distractions to minimize the risk of errors.
• Always exercise sound clinical judgment when interpreting the software's recommendations. The software is a decision support tool and should not replace the expertise of healthcare professionals.
• Do not rely solely on the software's recommendations for critical or life-threatening decisions. In such cases, seek immediate clinical assessment and intervention.
• Report any software-related issues, errors, or discrepancies to the appropriate personnel or IT support to address and resolve them promptly.
• Ensure that healthcare professionals using the software are adequately trained and competent in its use. Training should cover software operation, data input, result interpretation, and troubleshooting.
• Do not solely rely on the software's recommendations; use clinical judgment.
• Ensure data input is accurate, as incorrect data may lead to incorrect recommendations.
• XOresearch Cardio.AITM is a decision support tool and is not a substitute for the expertise of trained healthcare professionals. Healthcare providers must exercise their clinical judgment when interpreting software recommendations and making medical decisions.
• In cases of urgent or critical medical conditions where immediate clinical assessment and

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intervention are required, do not solely rely on the software's recommendations. Delaying necessary actions can have serious consequences.
• The accuracy of outputs generated by the software depends on the accuracy and completeness of the input data. Users are responsible for verifying the correctness of patient data entered into the system.
• Healthcare professionals are solely responsible for interpreting and acting upon the software's recommendations. Exercise caution and ensure that the recommendations align with the patient's clinical presentation and history.
• Protect patient data and ensure its security during transmission and storage. Unauthorized access or data breaches can compromise patient privacy and confidentiality.
• Report any software-related errors, discrepancies, or unusual behaviors to your organization's IT support or the software provider. Do not attempt to modify or alter the software without proper authorization.
• The software provider and manufacturer disclaim liability for any adverse events or consequences arising from the use of XOresearch Cardio.AITM beyond the extent permitted by law. Healthcare professionals are responsible for their decisions and actions.

8. Performance characteristics of the device

XOresearch Cardio.AI™ has the following performance metrics:

- Accuracy
- Area Under the Curve (AUC)
- F1-Score
- Positive Predictive Value (PPV)
- Sensitivity
- False Negatives
- False Positives

8.1 Accuracy

Accuracy indicates the overall performance of the classification model by calculating the proportion of correctly predicted instances (both positives and negatives) out of the total number of instances. I

Label	Accuracy
Atrial Premature Contraction	**0,999991636**
Aberrated Atrial Premature Beat	**0,9999261919**

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Non-Conducted P-Wave (Blocked)	**0,9975646987**
Left Anterior Fascicular Block Beat (Common)	**0,9999999867**
Bifascicular Block Beat	**0,9999838192**
Intraventricular Conduction Disturbance (Non-Specific Block)	**0,9999999774**
Left Posterior Fascicular Block Beat (Rare)	**0,9999999214**
Junctional (Nodal) Escape Beat	**0,9993236792**
Junctional (Nodal) Premature Contraction	**0,9782229954**
Left Bundle Branch Block Beat	**0,9999975529**
Incomplete Left Bundle Branch Block Beat	**0,9999991992**
Normal Beat	**0,9999999718**
Right Bundle Branch Block Beat	**0,9999856717**
Incomplete Right Bundle Branch Block Beat	**0,9999644693**
Unclassifiable Beat	**0,9992708161**
Ventricular Escape Beat	**0,9896929623**
Ventricular Premature Contraction	**0,999997456**
Fusion Of Ventricular And Normal Beat	**0,997997534**
Noise (No Signal)	**0,9999880832**
Noise Severe	**0,9999361532**
Asystole	**1**
Atrial Ectopic Rhythm	**0,9999947874**
Atrial Fibrillation	**0,9999999825**

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Atrial Flutter	**0,9999981454**
Multifocal Atrial Tachycardia	**0,9999845847**
Paroxsysmal Atrial Tachycardia	**0,9999843906**
AV Dissociation With Interference	**1**
First Degree AV Block	**0,9999996632**
Second Degree AV Block Type I	**0,999301785**
Second Degree AV Block Type II	**0,9999691061**
Third Degree AV Block	**0,9999929647**
Accelerated Av Junctional (Nodal) Rhythm	**0,9999928071**
AV Junctional (Nodal) Escape Rhythm	**0,9999924026**
Junctional Tachycardia	**0,9999897651**
Lown-Ganong-Levine Syndrome	**0,9999950898**
Second Degree SA Block Type I	**0,9998126904**
Second Degree SA Block Type II	**0,9995272605**
Third Degree SA Block	**0,9969650986**
Sinus Arrhythmia	**0,9999012862**
Sinus Tachycardia	**0,9999993796**
Accelerated Idioventricular Rhythm	**0,9996132353**
Ventricular Fibrillation	**0,9729742878**
Idioventricular (Ventricular Escape) Rhythm	**0,9913008829**
Ventricular Couplet	**0,9999870708**
Monomorphic Ventricular Tachycardia	**0,9999958004**
Polymorphic Ventricular Tachycardia	**0,9999190261**
Torsades De Pointes Ventricular Tachycardia	**0,9987499423**

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Wandering Pacemaker From The Sinus Node To (And From) The A-V Node	**0,999995306**
Wolf-Parkinson Type A	**1**
Wolf-Parkinson Type B	**0,9999984975**
Auxiliary Beat	**1**
Artifact	**0,9996820254**
Ventricular Interpolated Beat	**0,9991157064**
Atrial Couplet	**0,9999815924**
Atrial Triplet	**0,9999692744**
Junctional Couplet	**0,9945958893**
Junctional Triplet	**0,9999238543**
Ventricular Triplet	**0,9999449618**

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8.2 AUC

AUC (Area Under the Curve) represents the area under the Receiver Operating Characteristic (ROC) curve, which plots the True Positive Rate (Sensitivity) against the False Positive Rate (1-Specificity) at various threshold levels. AUC measures the model's ability to distinguish between positive and negative classes.

AUC value is **0.9991412278967556**

8.3 F1-Score

F1 score a balanced measure of a classification model's performance. It is especially useful when there is an uneven class distribution or when false positives and false negatives have different consequences.

Label	F1
Atrial Premature Contraction	**0.9834**
Aberrated Atrial Premature Beat	**0.9634**
Non-Conducted P-Wave (Blocked)	**0.9512**
Left Anterior Fascicular Block Beat (Common)	**0.9999**
Bifascicular Block Beat	**0.8854**
Intraventricular Conduction Disturbance (Non-Specific Block)	**0.9986**
Left Posterior Fascicular Block Beat (Rare)	**0.9995**
Junctional (Nodal) Escape Beat	**0.939**
Junctional (Nodal) Premature Contraction	**0.7755**
Left Bundle Branch Block Beat	**0.9808**
Incomplete Left Bundle Branch Block Beat	**0.9992**
Normal Beat	**0.9975**

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Right Bundle Branch Block Beat	**0.8914**
Incomplete Right Bundle Branch Block Beat	**0.9655**
Unclassifiable Beat	**0.9419**
Ventricular Escape Beat	**0.9143**
Ventricular Premature Contraction	**0.9923**
Fusion Of Ventricular And Normal Beat	**0.9189**
Noise (No Signal)	**0.9941**
Noise Severe	**0.9348**
Asystole	**1.0**
Atrial Ectopic Rhythm	**0.9948**
Atrial Fibrillation	**0.9996**
Atrial Flutter	**0.9818**
Multifocal Atrial Tachycardia	**0.959**
Paroxsysmal Atrial Tachycardia	**0.9504**
AV Dissociation With Interference	**1.0**
First Degree AV Block	**0.9941**
Second Degree AV Block Type I	**0.9244**
Second Degree AV Block Type II	**0.9846**
Third Degree AV Block	**0.9965**
Accelerated Av Junctional (Nodal) Rhythm	**0.9964**
AV Junctional (Nodal) Escape Rhythm	**0.9924**
Junctional Tachycardia	**0.9799**
Lown-Ganong-Levine Syndrome	**0.9878**
Second Degree SA Block Type I	**0.9787**

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Second Degree SA Block Type II	**0.968**
Third Degree SA Block	**0.9**
Sinus Arrhythmia	**0.9502**
Sinus Tachycardia	**0.9905**
Accelerated Idioventricular Rhythm	**0.9716**
Ventricular Fibrillation	**0.8571**
Idioventricular (Ventricular Escape) Rhythm	**0.9231**
Ventricular Couplet	**0.9936**
Monomorphic Ventricular Tachycardia	**0.9958**
Polymorphic Ventricular Tachycardia	**0.9248**
Torsades De Pointes Ventricular Tachycardia	**0.7481**
Wandering Pacemaker From The Sinus Node To (And From) The A-V Node	**0.9882**
Wolf-Parkinson Type A	**1.0**
Wolf-Parkinson Type B	**0.9985**
Auxiliary Beat	**1.0**
Artifact	**0.9623**
Ventricular Interpolated Beat	**0.9792**
Atrial Couplet	**0.9907**
Atrial Triplet	**0.9871**
Junctional Couplet	**0.8889**
Junctional Triplet	**0.9913**
Ventricular Triplet	**0.9857**

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8.4 PPV

Positive Predictive Value (PPV) represents the proportion of true positive predictions out of all instances that the model classified as positive.

Label	Precision
Atrial Premature Contraction	0.9754
Aberrated Atrial Premature Beat	0.9527
Non-Conducted P-Wave (Blocked)	1.0
Left Anterior Fascicular Block Beat (Common)	0.9999
Bifascicular Block Beat	0.7946
Intraventricular Conduction Disturbance (Non-Specific Block)	0.9982
Left Posterior Fascicular Block Beat (Rare)	0.999
Junctional (Nodal) Escape Beat	0.9365
Junctional (Nodal) Premature Contraction	0.9048
Left Bundle Branch Block Beat	0.9625
Incomplete Left Bundle Branch Block Beat	0.9996
Normal Beat	0.9981
Right Bundle Branch Block Beat	0.8045
Incomplete Right Bundle Branch Block Beat	1.0
Unclassifiable Beat	0.9625
Ventricular Escape Beat	0.9412
Ventricular Premature Contraction	0.9977

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Fusion Of Ventricular And Normal Beat	**0.8947**
Noise (No Signal)	**0.9912**
Noise Severe	**0.9275**
Asystole	**1.0**
Atrial Ectopic Rhythm	**0.9929**
Atrial Fibrillation	**0.9996**
Atrial Flutter	**0.9646**
Multifocal Atrial Tachycardia	**0.9915**
Paroxsysmal Atrial Tachycardia	**0.9989**
AV Dissociation With Interference	**1.0**
First Degree AV Block	**0.9901**
Second Degree AV Block Type I	**0.9554**
Second Degree AV Block Type II	**0.9811**
Third Degree AV Block	**1.0**
Accelerated Av Junctional (Nodal) Rhythm	**0.9976**
AV Junctional (Nodal) Escape Rhythm	**1.0**
Junctional Tachycardia	**0.9841**
Lown-Ganong-Levine Syndrome	**0.9793**
Second Degree SA Block Type I	**0.9871**
Second Degree SA Block Type II	**1.0**
Third Degree SA Block	**0.9**
Sinus Arrhythmia	**0.9627**
Sinus Tachycardia	**0.9836**
Accelerated Idioventricular Rhythm	**1.0**
Ventricular Fibrillation	**0.75**

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Idioventricular (Ventricular Escape) Rhythm	**1.0**
Ventricular Couplet	**0.9882**
Monomorphic Ventricular Tachycardia	**0.9949**
Polymorphic Ventricular Tachycardia	**0.9295**
Torsades De Pointes Ventricular Tachycardia	**0.6898**
Wandering Pacemaker From The Sinus Node To (And From) The A-V Node	**0.993**
Wolf-Parkinson Type A	**1.0**
Wolf-Parkinson Type B	**0.9975**
Auxiliary Beat	**1.0**
Artifact	**0.9746**
Ventricular Interpolated Beat	**0.9792**
Atrial Couplet	**0.9938**
Atrial Triplet	**0.9894**
Junctional Couplet	**0.9091**
Junctional Triplet	**0.9956**
Ventricular Triplet	**0.9942**

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8.5 Sensitivity

Sensitivity measures the proportion of correctly identified positive instances out of all actual positive instances.

Label	Sensitivity
Atrial Premature Contraction	**0.9916**
Aberrated Atrial Premature Beat	**0.9743**
Non-Conducted P-Wave (Blocked)	**0.907**
Left Anterior Fascicular Block Beat (Common)	**0.9999**
Bifascicular Block Beat	**0.9995**
Intraventricular Conduction Disturbance (Non-Specific Block)	**0.999**
Left Posterior Fascicular Block Beat (Rare)	**0.9999**
Junctional (Nodal) Escape Beat	**0.9415**
Junctional (Nodal) Premature Contraction	**0.6786**
Left Bundle Branch Block Beat	**0.9998**
Incomplete Left Bundle Branch Block Beat	**0.9988**
Normal Beat	**0.9969**
Right Bundle Branch Block Beat	**0.9993**
Incomplete Right Bundle Branch Block Beat	**0.9334**
Unclassifiable Beat	**0.9222**
Ventricular Escape Beat	**0.8889**
Ventricular Premature Contraction	**0.9869**
Fusion Of Ventricular And Normal Beat	**0.9444**

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Noise (No Signal)	**0.9969**
Noise Severe	**0.9422**
Asystole	**1.0**
Atrial Ectopic Rhythm	**0.9967**
Atrial Fibrillation	**0.9997**
Atrial Flutter	**0.9996**
Multifocal Atrial Tachycardia	**0.9287**
Paroxsysmal Atrial Tachycardia	**0.9064**
AV Dissociation With Interference	**1.0**
First Degree AV Block	**0.9982**
Second Degree AV Block Type I	**0.8954**
Second Degree AV Block Type II	**0.9882**
Third Degree AV Block	**0.993**
Accelerated Av Junctional (Nodal) Rhythm	**0.9952**
AV Junctional (Nodal) Escape Rhythm	**0.9849**
Junctional Tachycardia	**0.9757**
Lown-Ganong-Levine Syndrome	**0.9965**
Second Degree SA Block Type I	**0.9705**
Second Degree SA Block Type II	**0.9379**
Third Degree SA Block	**0.9**
Sinus Arrhythmia	**0.938**
Sinus Tachycardia	**0.9974**
Accelerated Idioventricular Rhythm	**0.9448**
Ventricular Fibrillation	**1.0**
Idioventricular (Ventricular Escape)	**0.8571**

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Rhythm	
Ventricular Couplet	0.999
Monomorphic Ventricular Tachycardia	0.9967
Polymorphic Ventricular Tachycardia	0.9201
Torsades De Pointes Ventricular Tachycardia	0.8172
Wandering Pacemaker From The Sinus Node To (And From) The A-V Node	0.9834
Wolf-Parkinson Type A	1.0
Wolf-Parkinson Type B	0.9995
Auxiliary Beat	1.0
Artifact	0.9504
Ventricular Interpolated Beat	0.9792
Atrial Couplet	0.9876
Atrial Triplet	0.9848
Junctional Couplet	0.8696
Junctional Triplet	0.987
Ventricular Triplet	0.9773

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8.6 Specificity

Specificity measures the proportion of correctly identified negative instances out of all actual negative instances.

Label	Specificity
Atrial Premature Contraction	**0.9991001116**
Aberrated Atrial Premature Beat	**0.9983477527**
Non-Conducted P-Wave (Blocked)	**1**
Left Anterior Fascicular Block Beat (Common)	**0**
Bifascicular Block Beat	**0.9643853048**
Intraventricular Conduction Disturbance (Non-Specific Block)	**0.9999749555**
Left Posterior Fascicular Block Beat (Rare)	**0,9989999498**
Junctional (Nodal) Escape Beat	**0,9954999328**
Junctional (Nodal) Premature Contraction	**0,9851924438**
Left Bundle Branch Block Beat	**0,987179429**
Incomplete Left Bundle Branch Block Beat	**0**
Normal Beat	**0,9999965389**
Right Bundle Branch Block Beat	**0,973708448**
Incomplete Right Bundle Branch Block Beat	**1**
Unclassifiable Beat	**0,9974093789**
Ventricular Escape Beat	**0,9697095446**
Ventricular Premature Contraction	**0,9999814086**

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Fusion Of Ventricular And Normal Beat	**0,9622490944**
Noise (No Signal)	**0,998522412**
Noise Severe	**0,99957765**
Asystole	**N/A**
Atrial Ectopic Rhythm	**0,9989795001**
Atrial Fibrillation	**0,9999714194**
Atrial Flutter	**0,9909085154**
Multifocal Atrial Tachycardia	**0,9999840073**
Paroxsysmal Atrial Tachycardia	**0,9999983947**
AV Dissociation With Interference	**N/A**
First Degree AV Block	**0,9997778571**
Second Degree AV Block Type I	**0,9976714034**
Second Degree AV Block Type II	**0,9980773673**
Third Degree AV Block	**1**
Accelerated Av Junctional (Nodal) Rhythm	**0,9995190759**
AV Junctional (Nodal) Escape Rhythm	**1**
Junctional Tachycardia	**0,9986553778**
Lown-Ganong-Levine Syndrome	**0,9989442653**
Second Degree SA Block Type I	**0,9935083226**
Second Degree SA Block Type II	**1**
Third Degree SA Block	**0,9**
Sinus Arrhythmia	**0,9993754609**
Sinus Tachycardia	**0,9997862732**
Accelerated Idioventricular Rhythm	**1**
Ventricular Fibrillation	**0**

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Idioventricular (Ventricular Escape) Rhythm	**1**
Ventricular Couplet	**0,9881996556**
Monomorphic Ventricular Tachycardia	**0,9994307523**
Polymorphic Ventricular Tachycardia	**0,9916427447**
Torsades De Pointes Ventricular Tachycardia	**0,9955232651**
Wandering Pacemaker From The Sinus Node To (And From) The A-V Node	**0,9999280714**
Wolf-Parkinson Type A	**N/A**
Wolf-Parkinson Type B	**0,9974999975**
Auxiliary Beat	**N/A**
Artifact	**0,9983738563**
Ventricular Interpolated Beat	**0,9792**
Atrial Couplet	**0,9997030053**
Atrial Triplet	**0,9988110129**
Junctional Couplet	**0,983608538**
Junctional Triplet	**0,9985289908**
Ventricular Triplet	**0,9995140722**

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8.7 False Negatives

False Negatives (FN) identifies instances where the classification model incorrectly predicts a positive instance as negative.

Label	False Negatives
Atrial Premature Contraction	**0,008471**
Aberrated Atrial Premature Beat	**0,026378**
Non-Conducted P-Wave (Blocked)	**0,102532**
Left Anterior Fascicular Block Beat (Common)	**0,0001**
Bifascicular Block Beat	**0,0005**
Intraventricular Conduction Disturbance (Non-Specific Block)	**0,001001**
Left Posterior Fascicular Block Beat (Rare)	**0,0001**
Junctional (Nodal) Escape Beat	**0,062135**
Junctional (Nodal) Premature Contraction	**0,473596**
Left Bundle Branch Block Beat	**0,0002**
Incomplete Left Bundle Branch Block Beat	**0,001201**
Normal Beat	**0,00311**
Right Bundle Branch Block Beat	**0,000701**
Incomplete Right Bundle Branch Block Beat	**0,071348**
Unclassifiable Beat	**0,084362**
Ventricular Escape Beat	**0,124986**
Ventricular Premature Contraction	**0,013274**

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Fusion Of Ventricular And Normal Beat	**0,058875**
Noise (No Signal)	**0,00311**
Noise Severe	**0,061346**
Asystole	**0**
Atrial Ectopic Rhythm	**0,003311**
Atrial Fibrillation	**0,0003**
Atrial Flutter	**0,0004**
Multifocal Atrial Tachycardia	**0,076768**
Paroxsysmal Atrial Tachycardia	**0,103265**
AV Dissociation With Interference	**0**
First Degree AV Block	**0,001803**
Second Degree AV Block Type I	**0,116816**
Second Degree AV Block Type II	**0,01194**
Third Degree AV Block	**0,007049**
Accelerated Av Junctional (Nodal) Rhythm	**0,004823**
AV Junctional (Nodal) Escape Rhythm	**0,015332**
Junctional Tachycardia	**0,024906**
Lown-Ganong-Levine Syndrome	**0,003512**
Second Degree SA Block Type I	**0,030396**
Second Degree SA Block Type II	**0,066215**
Third Degree SA Block	**0,111111**
Sinus Arrhythmia	**0,066099**
Sinus Tachycardia	**0,002607**
Accelerated Idioventricular Rhythm	**0,058424**
Ventricular Fibrillation	**0**

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Idioventricular (Ventricular Escape) Rhythm	**0,166734**
Ventricular Couplet	**0,001001**
Monomorphic Ventricular Tachycardia	**0,003311**
Polymorphic Ventricular Tachycardia	**0,086841**
Torsades De Pointes Ventricular Tachycardia	**0,223686**
Wandering Pacemaker From The Sinus Node To (And From) The A-V Node	**0,016881**
Wolf-Parkinson Type A	**0**
Wolf-Parkinson Type B	**0,0005**
Auxiliary Beat	**0**
Artifact	**0,052186**
Ventricular Interpolated Beat	**0,021242**
Atrial Couplet	**0,012556**
Atrial Triplet	**0,015435**
Junctional Couplet	**0,149952**
Junctional Triplet	**0,013171**
Ventricular Triplet	**0,023228**

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8.8 False Positives

False Positives (FP) identifiesinstances where the classification model incorrectly predicts a negative instance as positive.

Label	False Positives
Atrial Premature Contraction	**0,02522**
Aberrated Atrial Premature Beat	**0,049649**
Non-Conducted P-Wave (Blocked)	**0**
Left Anterior Fascicular Block Beat (Common)	**0,0001**
Bifascicular Block Beat	**0,25851**
Intraventricular Conduction Disturbance (Non-Specific Block)	**0,001803**
Left Posterior Fascicular Block Beat (Rare)	**0,001001**
Junctional (Nodal) Escape Beat	**0,067806**
Junctional (Nodal) Premature Contraction	**0,105211**
Left Bundle Branch Block Beat	**0,038961**
Incomplete Left Bundle Branch Block Beat	**0,0004**
Normal Beat	**0,001904**
Right Bundle Branch Block Beat	**0,243013**
Incomplete Right Bundle Branch Block Beat	**0**
Unclassifiable Beat	**0,03896**
Ventricular Escape Beat	**0,062473**
Ventricular Premature Contraction	**0,002305**

Fusion Of Ventricular And Normal Beat	**0,117696**
Noise (No Signal)	**0,008879**
Noise Severe	**0,078168**
Asystole	**0**
Atrial Ectopic Rhythm	**0,007151**
Atrial Fibrillation	**0,0004**
Atrial Flutter	**0,0367**
Multifocal Atrial Tachycardia	**0,008572**
Paroxsysmal Atrial Tachycardia	**0,001101**
AV Dissociation With Interference	**0**
First Degree AV Block	**0,009999**
Second Degree AV Block Type I	**0,046681**
Second Degree AV Block Type II	**0,019263**
Third Degree AV Block	**0**
Accelerated Av Junctional (Nodal) Rhythm	**0,002406**
AV Junctional (Nodal) Escape Rhythm	**0**
Junctional Tachycardia	**0,016157**
Lown-Ganong-Levine Syndrome	**0,021137**
Second Degree SA Block Type I	**0,013068**
Second Degree SA Block Type II	**0**
Third Degree SA Block	**0,111111**
Sinus Arrhythmia	**0,038746**
Sinus Tachycardia	**0,016674**
Accelerated Idioventricular Rhythm	**0**
Ventricular Fibrillation	**0,333317**

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Idioventricular (Ventricular Escape) Rhythm	**0**
Ventricular Couplet	**0,011941**
Monomorphic Ventricular Tachycardia	**0,005126**
Polymorphic Ventricular Tachycardia	**0,075849**
Torsades De Pointes Ventricular Tachycardia	**0,449687**
Wandering Pacemaker From The Sinus Node To (And From) The A-V Node	**0,00705**
Wolf-Parkinson Type A	**0**
Wolf-Parkinson Type B	**0,002506**
Auxiliary Beat	**0**
Artifact	**0,026061**
Ventricular Interpolated Beat	**0,021242**
Atrial Couplet	**0,006239**
Atrial Triplet	**0,010714**
Junctional Couplet	**0,099988**
Junctional Triplet	**0,00442**
Ventricular Triplet	**0,005834**

9. Technical Requirements:

XOresearch Cardio.AI™ is accessible through a web browser based on Chromium browser engine: Google Chrome, Microsoft Edge, Opera Browser.
It is recommended to use the latest version of Google Chrome for optimal compatibility and performance.
The minimum required of the last stable version Google Chrome is 116 - when the IFU was produced).
The minimum required of the last stable version of Microsoft Edge is 126, of the Opera - 113.

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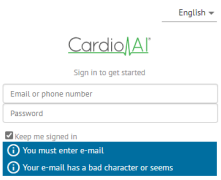
- A stable and high-speed internet connection is essential for accessing XOresearch Cardio.AI™. A minimum download and upload speed of 100Mbit/s is recommended.
- Ensure that network firewall and security settings allow access to the XOresearch Cardio.AI™ web application. It may be necessary to whitelist the following domains to ensure unobstructed access: https://web.cardio.ai/

Operating System: XOresearch Cardio.AI™ is compatible with Windows 11, 22H2, macOS .

Hardware minimal requirements for running Google Chrome to access XOresearch Cardio.AI™ are:
Processor: 1.6 GHz or faster processor (Intel Pentium 4 or later).
RAM: 2 GB (minimum) for normal usage, 4 GB or more recommended for better performance.
Hard Drive: At least 100 MB of free space for browser installation.
Graphics: Graphics hardware acceleration requires a DirectX 9.0c capable video card with WDDM 1.0 or higher driver.

10. Setup:

- The option to access XOresearch Cardio.AI™ is available under the following web link: https://web.cardio.ai/
Software shows the following screen when successful:



The sign in to XOresearch Cardio.AI™ is available under the filling in the **Email or phone number** field > **Password** field > Continue button:

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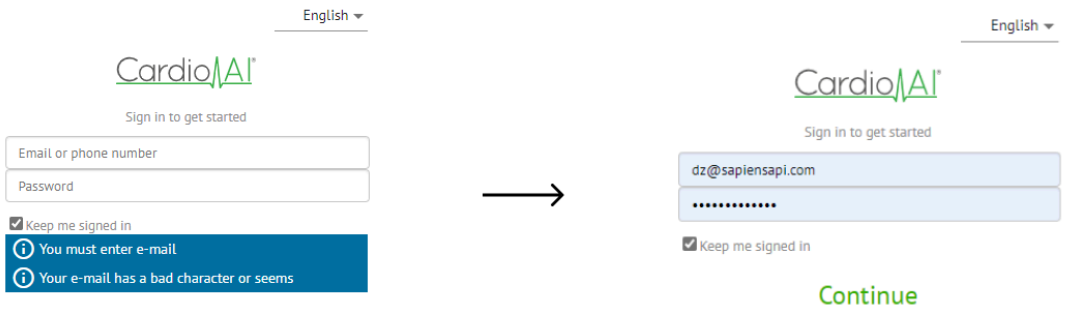
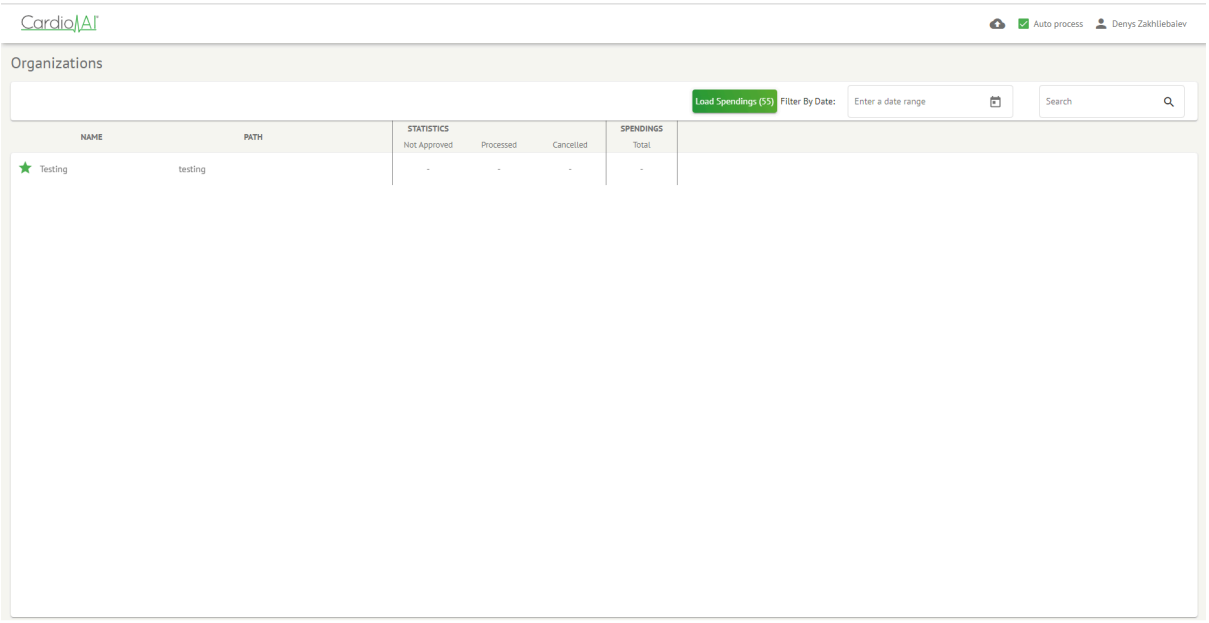


Note: Login credentials are provided by the manufacturer.
XOresearch Cardio.AI™ shows the following screen when successful sign in:



Note. The user is automatically logged out after 10 minutes of inactivity.

11. Software Operation:

11.1 User profile management

The option to access User profile management is available by clicking on the user name:

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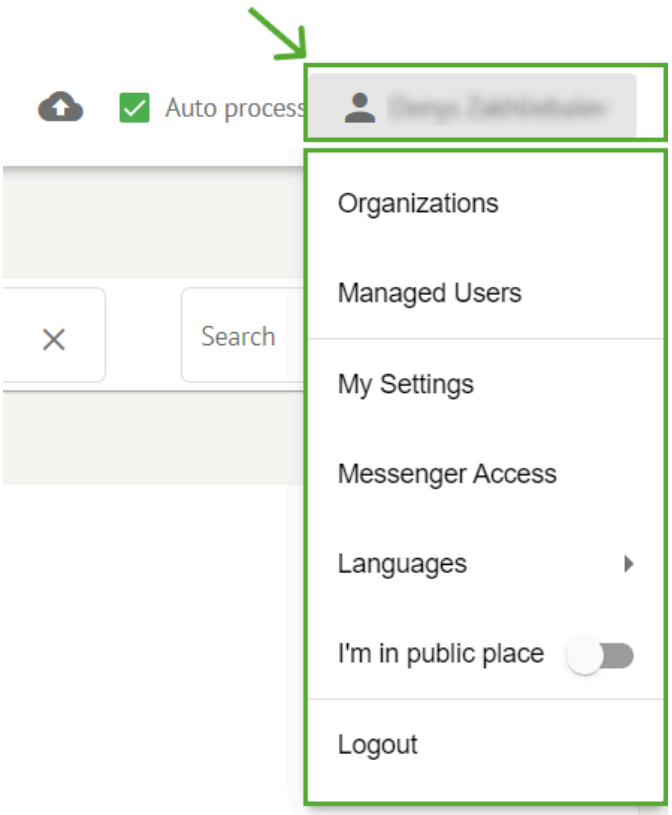
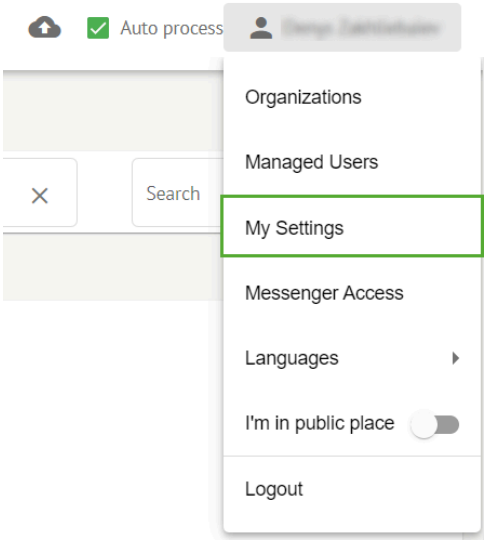


11.1.1 Edit user data

The option to edit user data is available under User profile management menu > My settings:



XOresearch Cardio.AI™ shows the following screen when successful:

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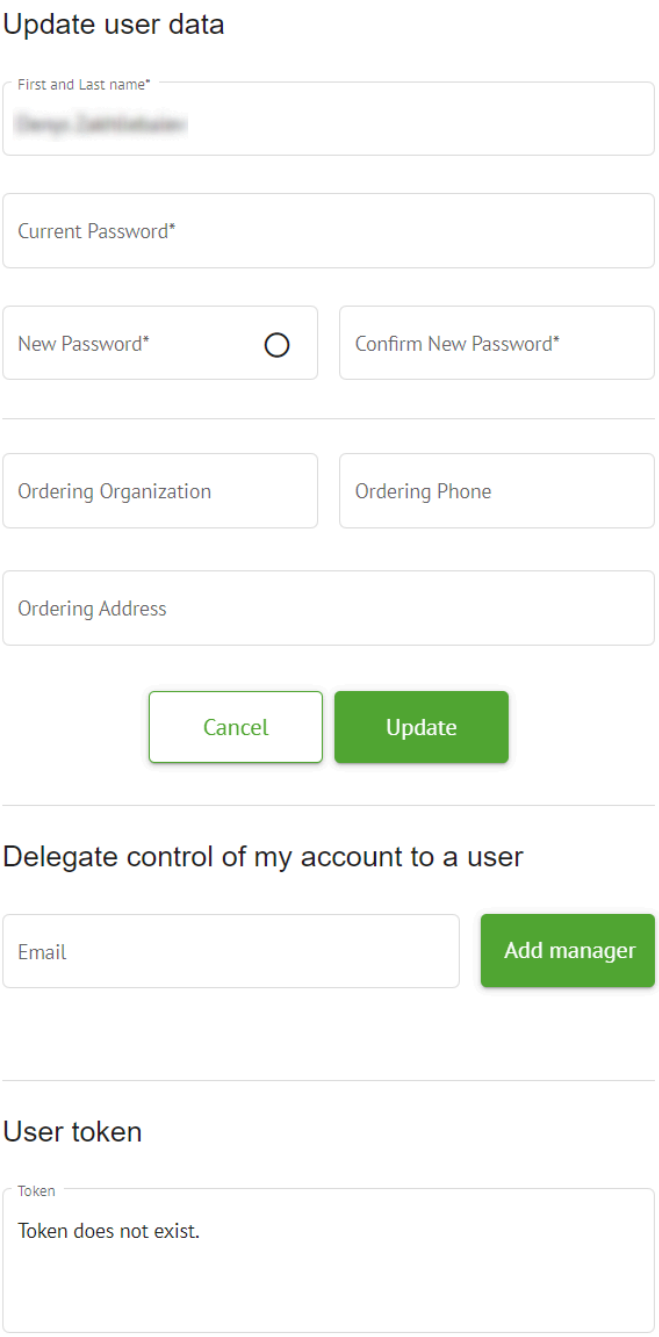

The following sections are presented under the **My settings**:

- Update user data;
- Delegate control of my account to a user;
- User token.

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11.1.2 Update user data

The following settings are available to update under **Update user data** section (All required fields are marked with an asterisk *):

Setting	Description
First and Last name*	Indicates the First and Last name of the user, visible. This field is **required**.
Current password*	Enables to provide the current password in order to change it. This field is **required** when password changing.
New password*	Ipindicates user's password that will be used during the log in process. Password requirements: ● At least 1 special symbol; ● At least 1 lowercase leter; ● At least 1 uppercase letter; ● At least 1 digit; ● Length must be a least 8 symbols. This field is **required** when password changing.
Confirm new password*	This field duplicates the **Password** field and must be filled in identically. This field is **required** when password changing.
Ordering Organization	This field indicates the organization which the user is associated with.
Ordering Phone	This field indicates the phone number which the user is associated with.
Ordering Address	This field indicates the address which the user is associated with.

The option to update the data is available by filling in the data to the correspondent field, and clicking **Update** button. The option to Cancel changes and close the windows is available under the **Cancel** button.

The option to update password is available by filling in the **Current password**, **New password** and **Confirm new password** fields, and clicking the **Update** button.

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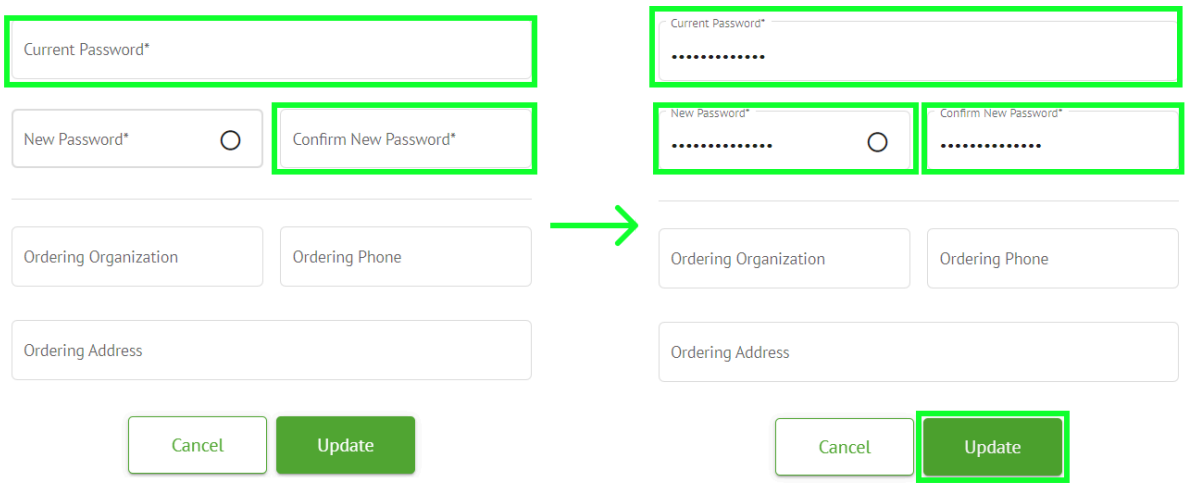
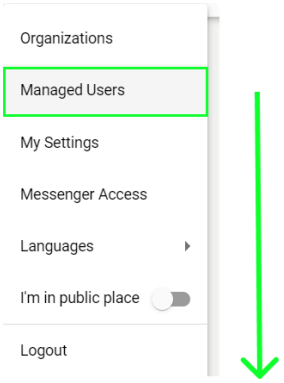


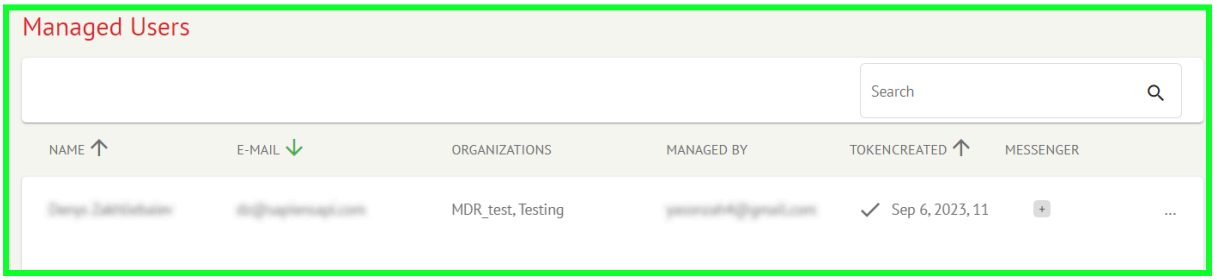
11.1.3 Delegate control of my account to a user

Delegating control of the account to another user enables a user to operate the delegated account by editing the user data, updating the role assignment, configuring the messenger access and deleting the delegated user.

The option to delegate control of the account to another user is available by filling in the 3rd party email address of the user to whom the access should be granted and clicking on the **add manager** button:

The option to browse the managed users is available under User profile management menu > **Managed users:**





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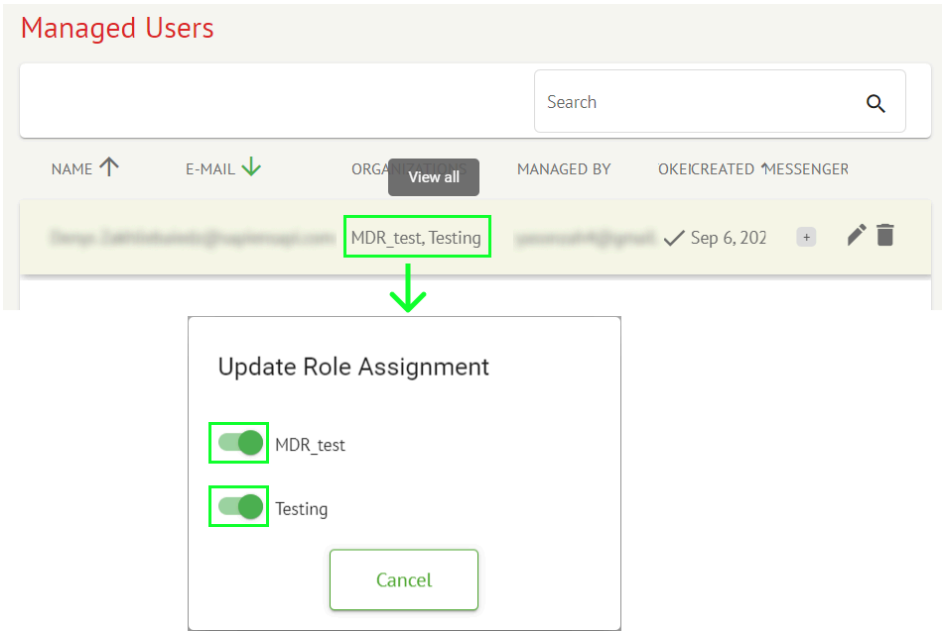
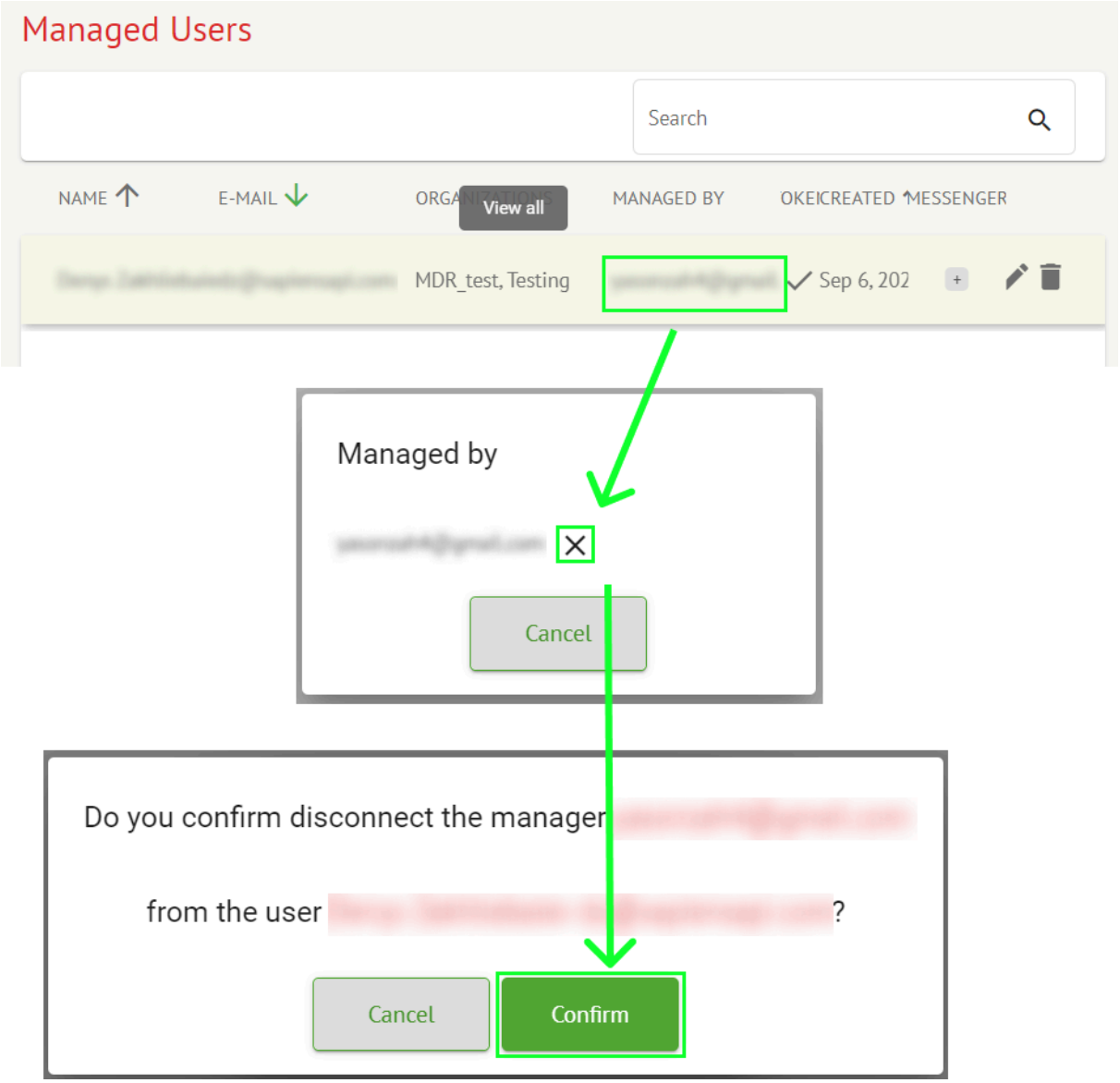
The option to update the managed user presence in the organizations is available by clicking on the available organizations and switching the correspondent organization switch:

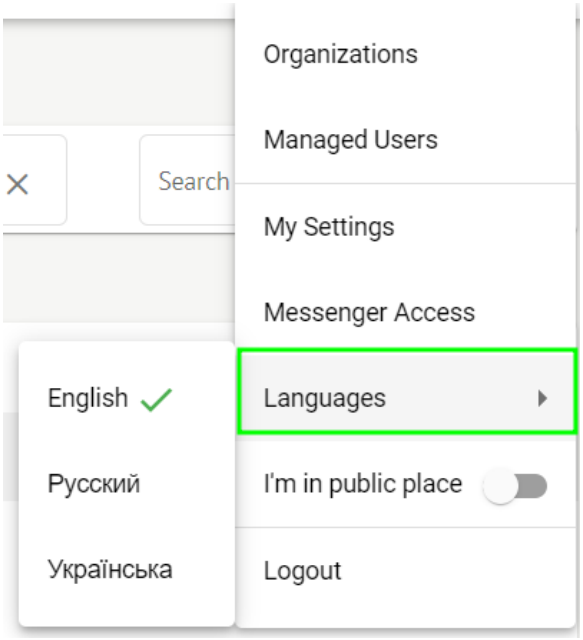


The option to cancel the delegation of the user is available by clicking on the managed by user > Disconnect the manager from the user > Confirm button:



11.1.4 User interface language

The option to change the User interface language is available under User profile management > Languages > select language:

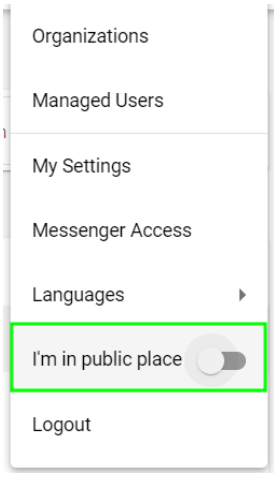


The following languages are available:

- English;
- Ukrainian;
- Russian.

11.1.5 Hiding sensitive information

The option to hide sensitive information (the **patient's** and **uploader names**, **ECG file name** under Tasks section) is available under User profile management > **I'm in public place** switch:



When enabled, all the sensitive information will be blurred during the active session.

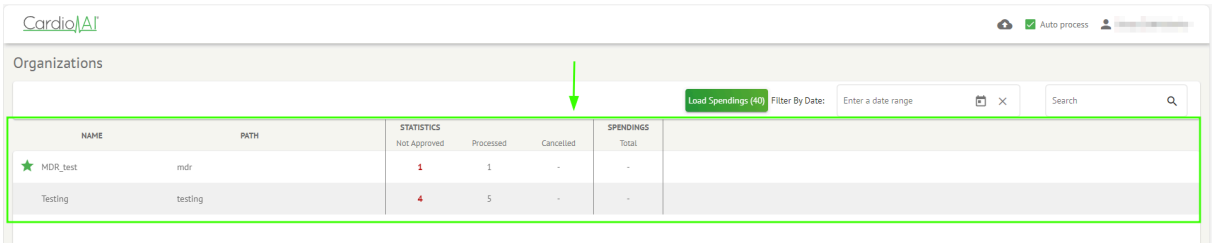
11.2 Organizations overview

The Organization section enables a user to enter the organization in order to perform work with patient data inputting and processing.

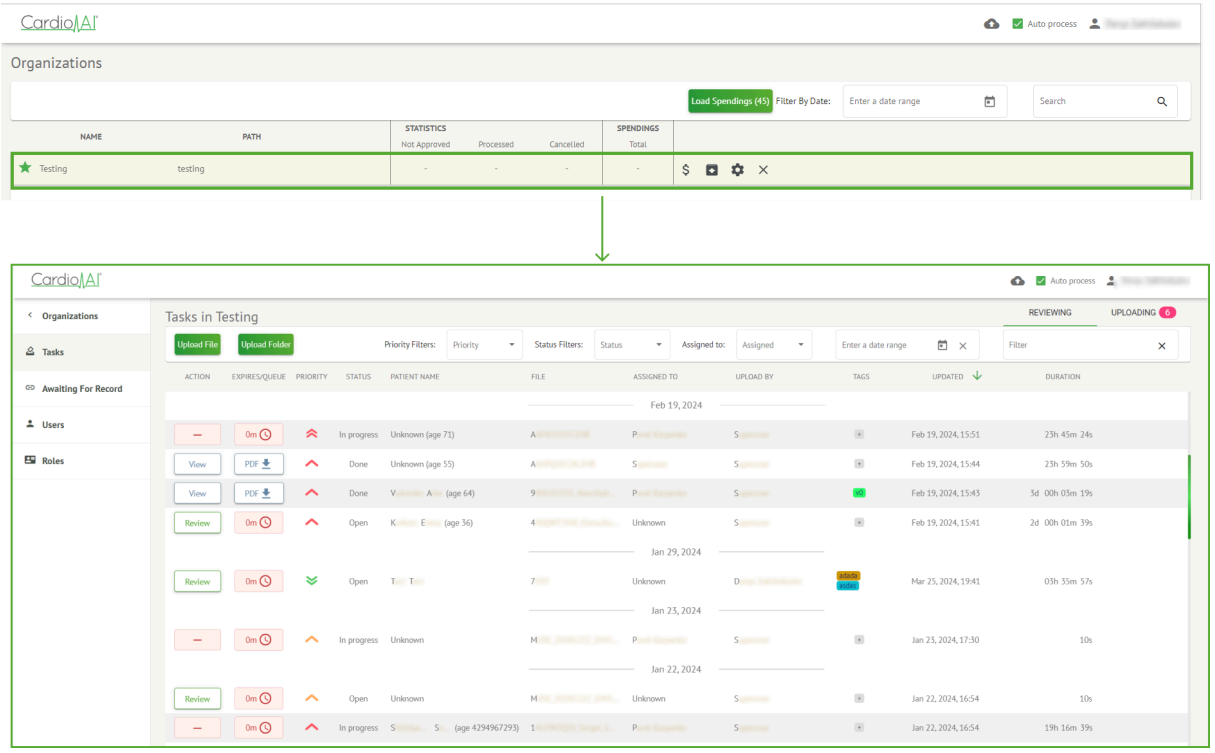
The following information about the organizations is available under the Organizations section:

Setting	Description
General section	
Name	Indicates the name of the Organization
Path	Indicates the path to the Organization available under the URL of the organization.
Statistics	
Not approved	Indicates the number of Not approved (Pre approved) tasks under the organization.
Processed	Indicates the number of the Approved tasks under the organization.
Cancelled	Indicates the number of the canceled tasks under the organization.
Spendings	
Total	Indicates the number of costs the client has spent during working with the software within the organization.

The list of available organizations to user is shown under Organizations screen by the software.

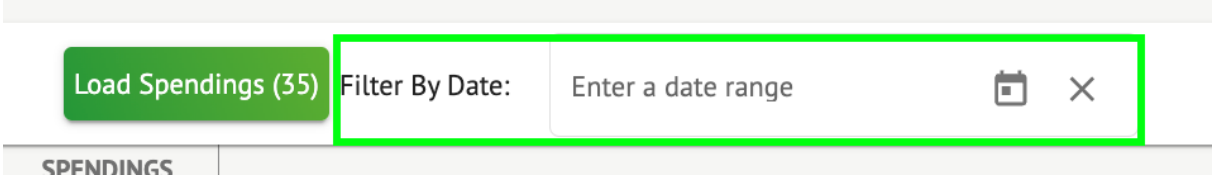


The option to access the organization is enabled by clicking the Organization:



11.2.1 Organizations filters

Under **Organizations**, the user is enabled to filter the organizations by date:



The user is enabled to set up filter by manually entering the date in DD/MM/YYYY format or via the calendar feature:

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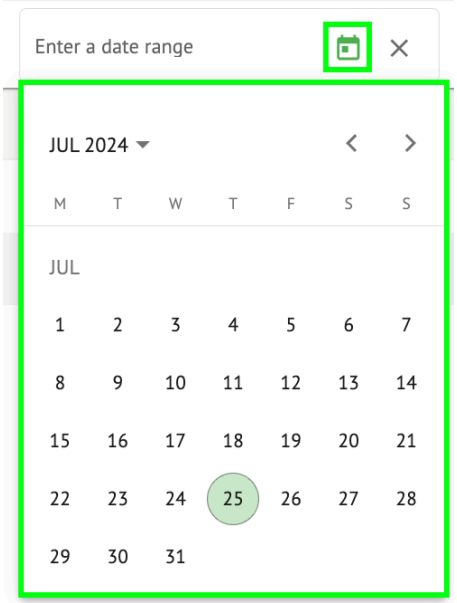
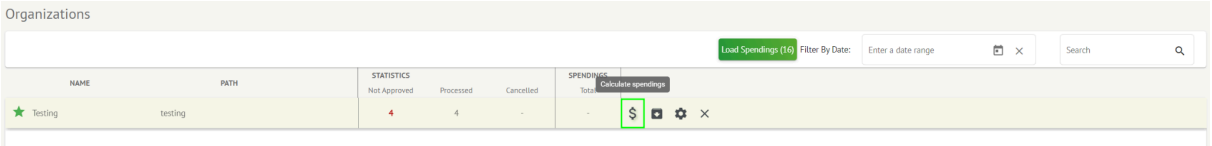
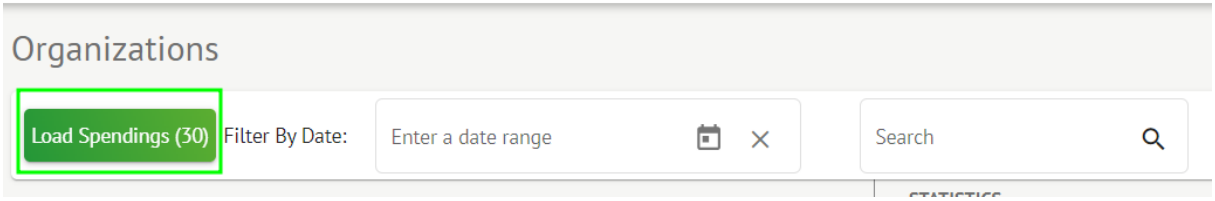


11.2.2 Calculate spendings of the organization

The option to calculate spendings of the organization is available by clicking the **Calculate spendings** button:



The option to calculate spendings within all the available organizations is available under **Load Spendings** button:



Spendings calculation depends on the Date **filter**. By default, the spendings are calculated from the first day of the current month.

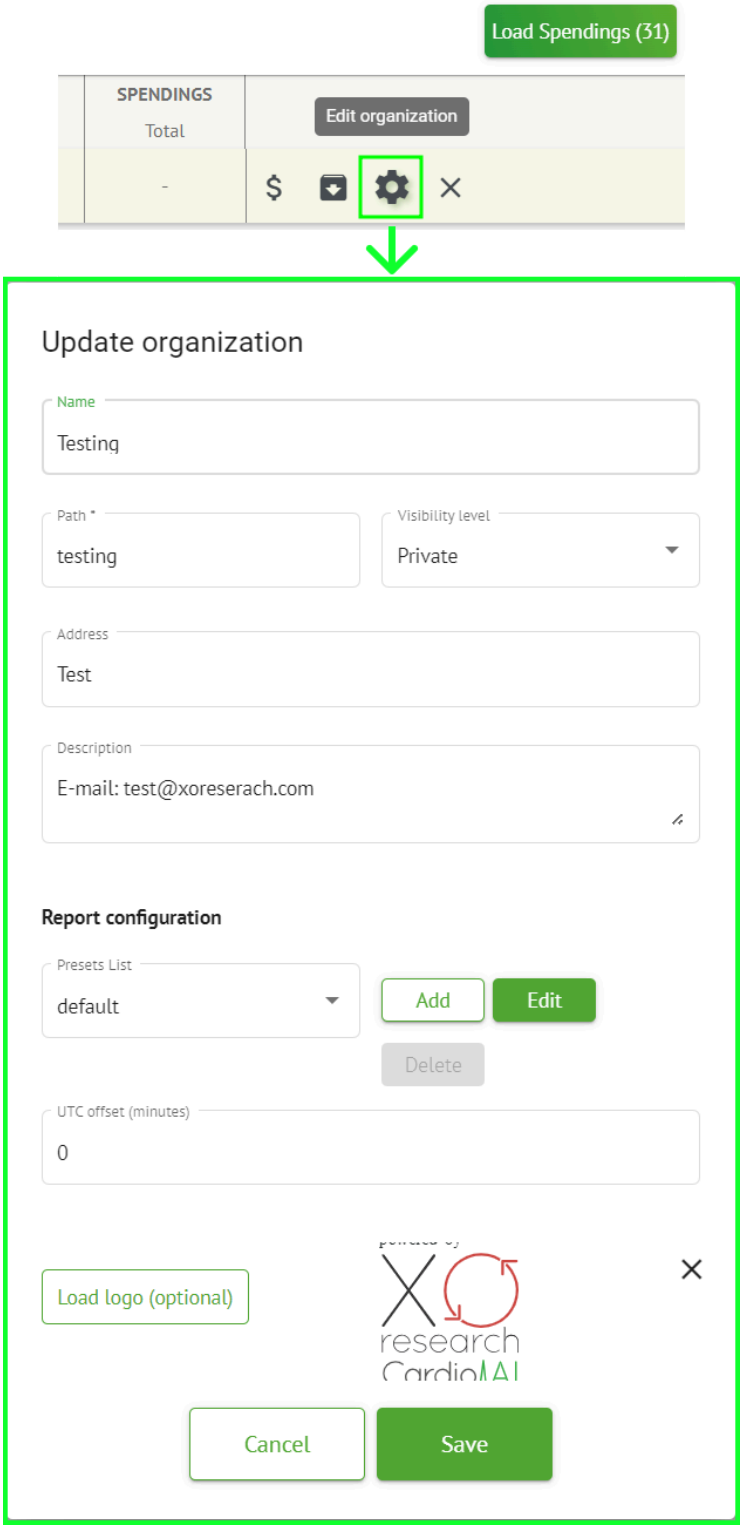
11.2.3 Export spendings into CSV

The option to export spendings into CSV format is available by clicking the **Export spendings into CSV** button:

Note. The option to export spendings becomes available **only** after calculating the spendings. Spendings calculation depends on the Date **filter**. By default, the spendings are calculated from the first day of the current month.

11.2.4 Edit organization

The option to update the organization details is available under the **Edit organization** button:



The following information about the organizations is available to be updated under the Edit organization option:

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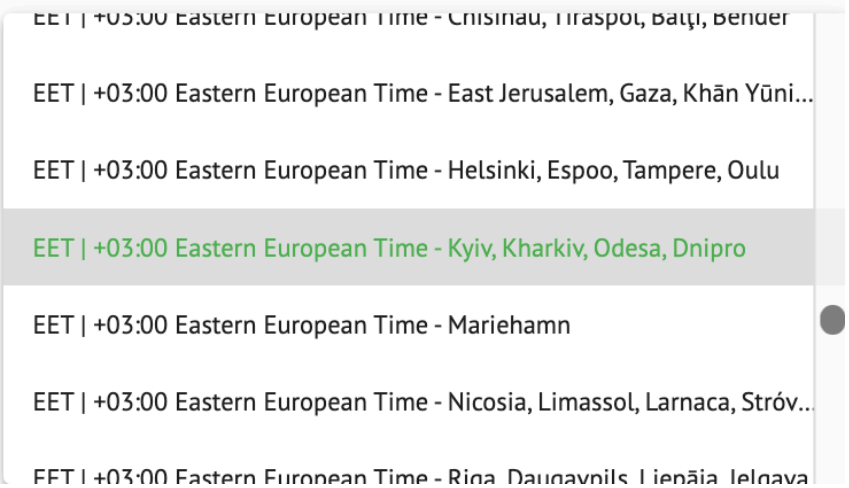
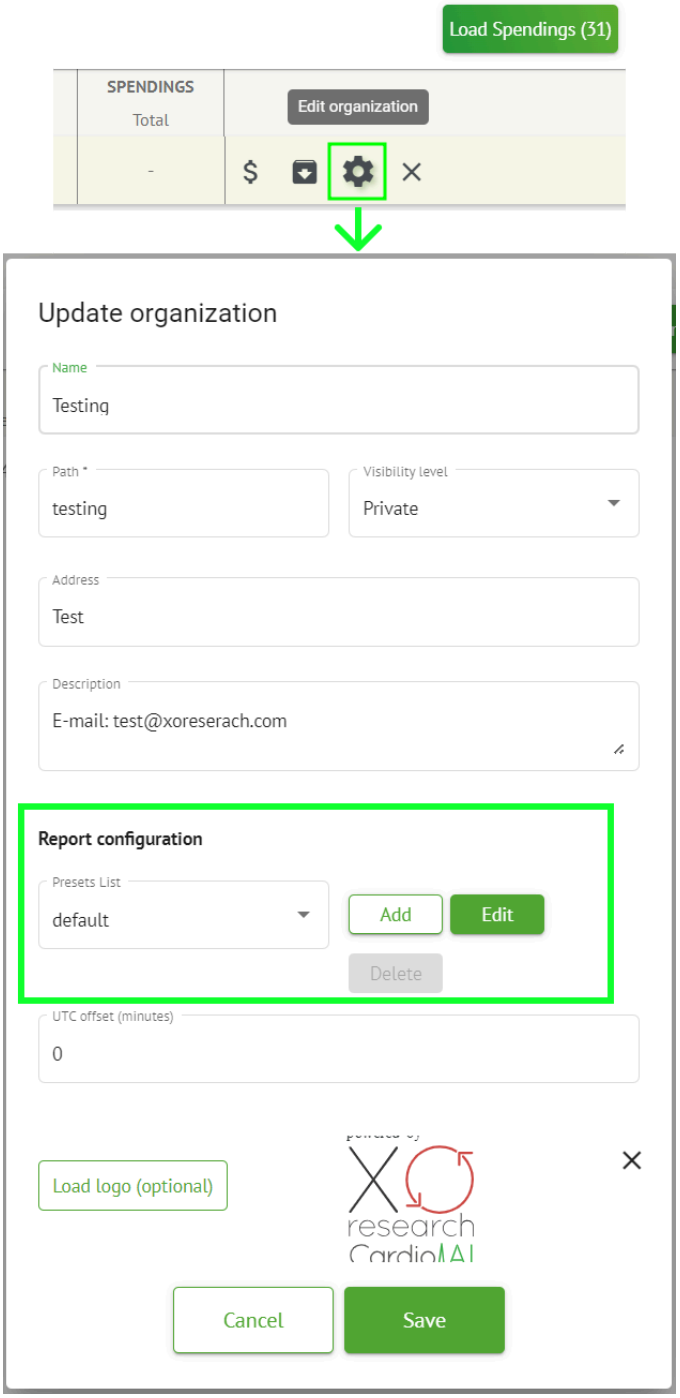
Setting	Description
General section	
Name	Indicates the name of the Organization
Path	Indicates the path to the Organization available under the URL of the organization.
Visibility level	Indicates the visibility status of the organization to the users within the software. The following visibility levels available: ● Public: sets up the path to “pub_*pathname*” and makes the organization available to operate with, without the user authorization. ● Private: makes the organization available to operate with only within the users assigned to the organization.
Address	Indicates the physical address of the organization.
Description	Indicates the description of the organization.
Report configuration	
Presets list	Indicates the preset configuration of the report, generated during the ECG task reviewing. The default value of the preset is **default**. The user is enabled to add, edit and delete the presets.
UTC offset (minutes)	Indicates the timezone of the organization. The option to set the timezone is available by selecting the timezone from the list:  By default, the timezone of the organization is **EET | +03:00 Eastern European Time**
Logo	

Logo	Indicates the logo of the organization. Enables a user to load logo if available, change and remove the existing logo of the organization if needed. The following image formats are applicable: .svg, .png, jpeg, .jpg.

11.2.5 Organization report preset configuration

The option to access organization report preset settings is available under the **Edit organization > Report configuration** section:



The enabled preset for the organization is set under the **Presets list** dropdown:

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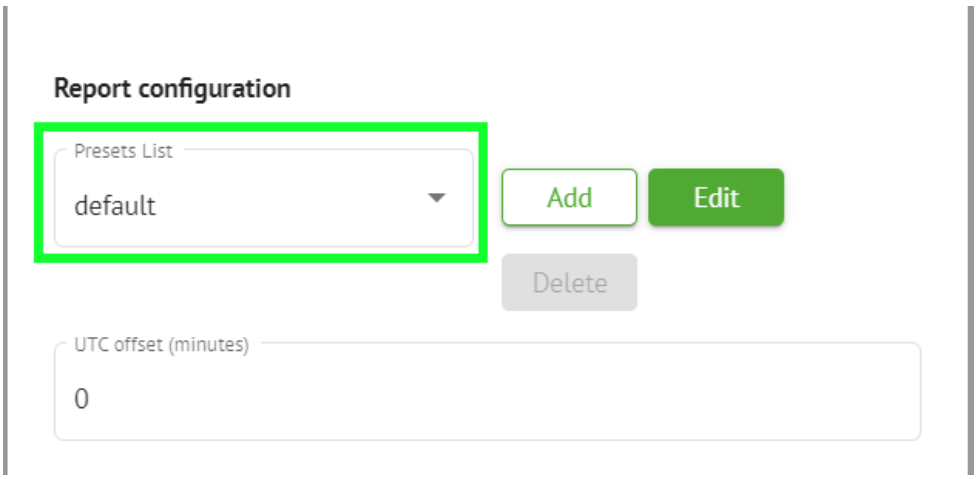
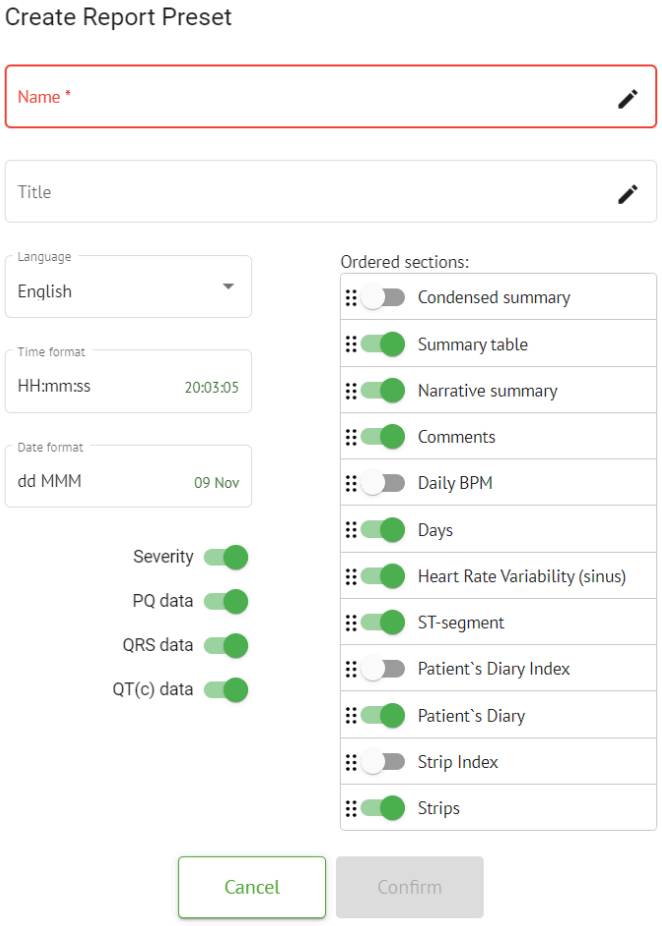


The default value is **default**.

The option to add preset is available under the **Add** button. XOresearch Cardio.AI™ shows the following screen when successful:



The following settings are present under **Add** preset and **Edit** preset sections:

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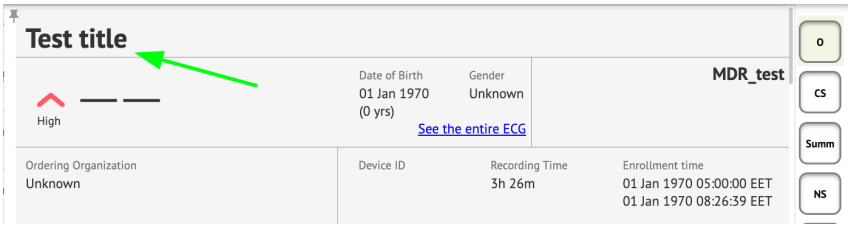
Setting	Description
General section	
Name	Indicates the name of the preset.
Title	Indicates the title of the report preset. When the Title is set, it appears on the first page of the task report: 
Language	Indicates the language of the preset being composed on. The following languages are available: ● English; ● Ukrainian; ● Russian.
Time format	Indicates the time format of the preset. The following formats are available: ● HH:MM:SS; ● H:MM:SS a.m. / p.m.
Date format	Indicates the date format of the preset. The following formats are available: ● DD MMM (e.g., 06 Nov); ● MMM-DD (e.g., Nov-06); ● DD MMMM (e.g., 06 November).
Priority	Indicates the priority of the status. The following priorities available: ● Highest; ● High; ● Medium; ● Low; ● Lowest.
PQ data	Enables to show the PQ interval data with the time between the start of the P wave and the start of the QRS complex
QRS data	Enables to show the QRS complex data with the duration and morphology of each QRS complex.
QT(c) data	Enables to show the QT(c) (Corrected QT interval) data with the

	duration of the QT interval adjusted for heart rate variability.
Ordered sections	Indicates the parts of the report. The order of ordered sections is available to be changed.
Condensed summary	Enables the section which indicates the overall findings and key measurements of the ECG monitoring, including heart rate data, the presence of atrial or ventricular tachycardia, and the burden of ectopic beats.
Summary table	Enables the section which provides a comprehensive overview of key ECG metrics, such as heart rate variability, PQ intervals, and QRS complex durations, summarized in tabular form.
Narrative summary	Enables the section which presents a detailed narrative account of the monitoring period, highlighting significant events, rhythm analysis, and any episodes of bradycardia or tachycardia.
Comments	Enables the section which offers specific observations and insights from the analyzing physician regarding ectopic events, conduction blocks, and other notable findings from the ECG data. This section is a free field to enter the comments during reviewing the ECG analysis.
Daily BPM	Enables the section which charts the daily variations in beats per minute, including maximum, average, and minimum heart rates, as well as occurrences of atrial fibrillation or ventricular blocks.
Days	Enables the section which breaks down the ECG data on a day-by-day basis, allowing for detailed examination of heart rate patterns and ectopic beat occurrences across different times.
Heart Rate Variability (sinus)	Enables the section which displays measures of heart rate variability, offering insights into the autonomic regulation of heart rate during the monitoring period.
ST-segment	Enables the section which visualizes ST-segment deviations and provides analysis on potential ischemic events or abnormalities detected throughout the monitoring duration.
Patient’s Diary Index	Enables the section which indexes significant events or symptoms reported by the patient in the diary, correlating them with ECG findings for contextual analysis
Patient’s Diary	Enables the section which contains entries from the patient regarding symptoms, activities, or any noteworthy events that may correlate with the ECG data analysis.
Strip Index	Enables the section which organizes the ECG strip recordings by time

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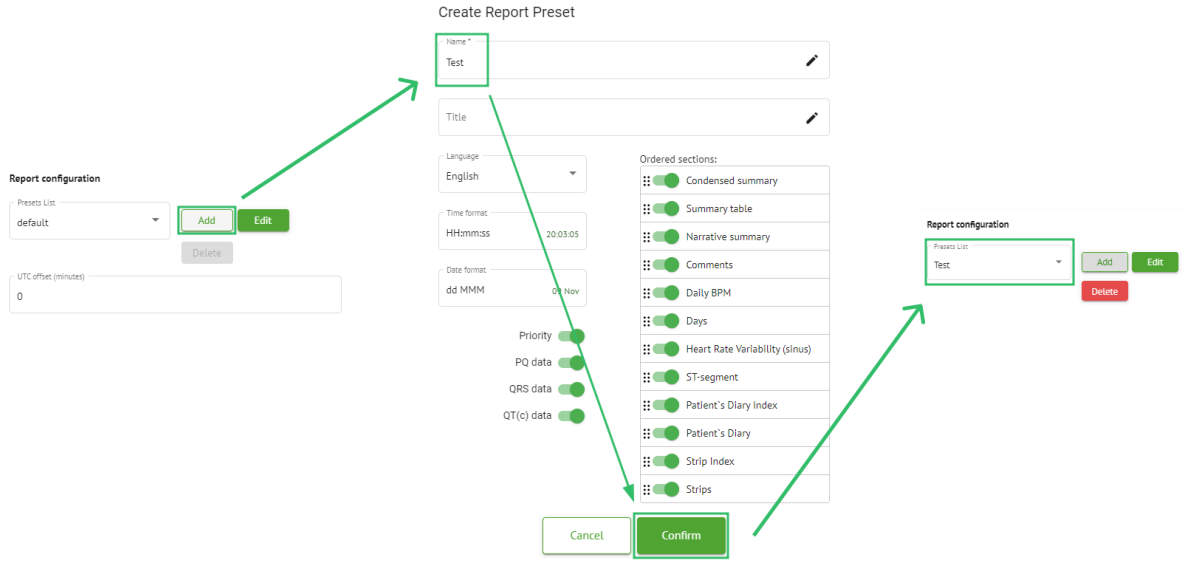
	and type of event, facilitating quick access to specific segments of interest for detailed review.
Strips	Enables the section which presents the actual ECG strips that highlight significant cardiac events or intervals of interest identified during the monitoring period.

The option to add a preset is available by filling the **Name** field and clicking the **Confirm** button.



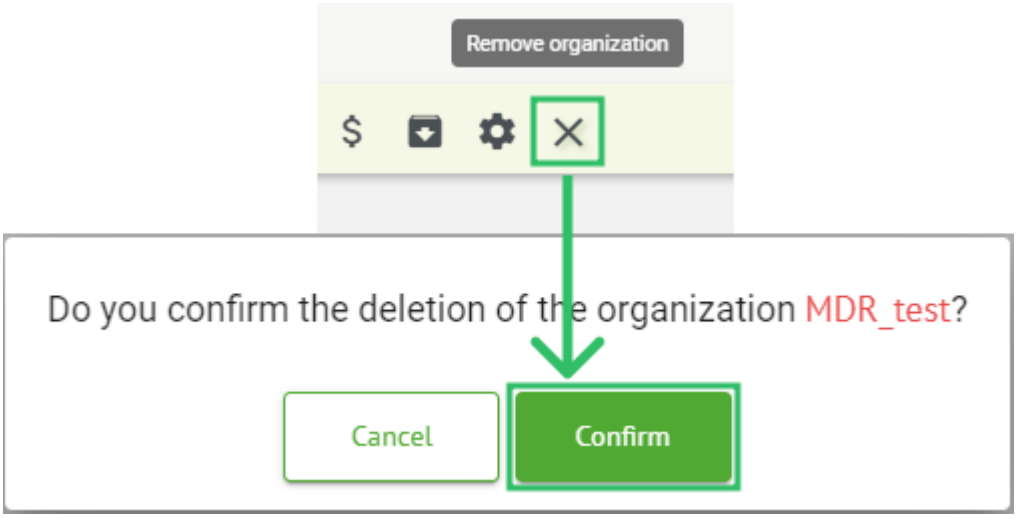
The option to edit preset is available by selecting the preset under the dropdown, clicking the **Edit** button, adding necessary changes and clicking the **Confirm** button**.**

The option to remove the preset is available by selecting the preset under the dropdown, clicking the **Delete** button and clicking the **Confirm** button.

Note. Default preset cannot be deleted.

11.2.6 Remove organization

The option to remove the organization is available under the **Remove organization > Confirm** button:

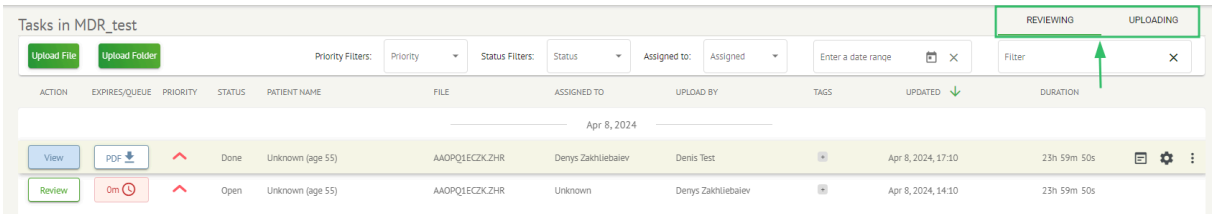


11.3 Tasks section overview

Tasks section enables a user to observe, edit, add and delete tasks, users and roles within the organization.

The Tasks sections is consists of the following subsections:

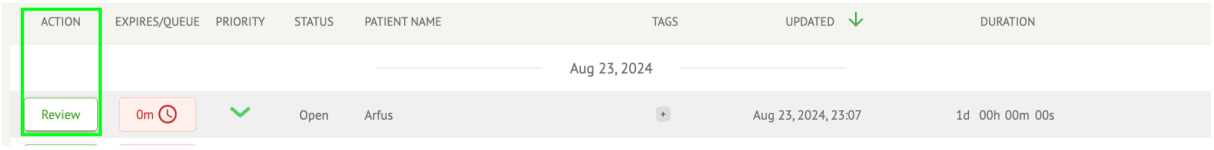
- Reviewing - enables the user to operate available tasks;
- Uploading - enables the user to access the advanced options of ECG uploading.



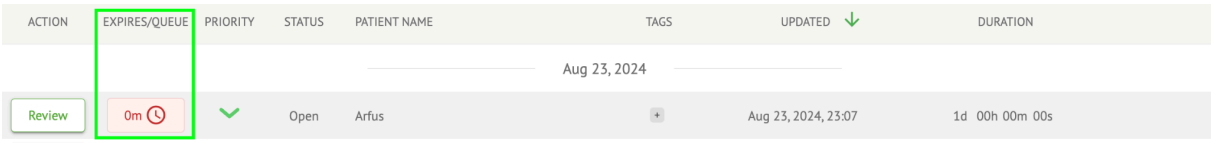
11.3.1 Reviewing subsection overview

Under **Reviewing**, the following information is available for the user:

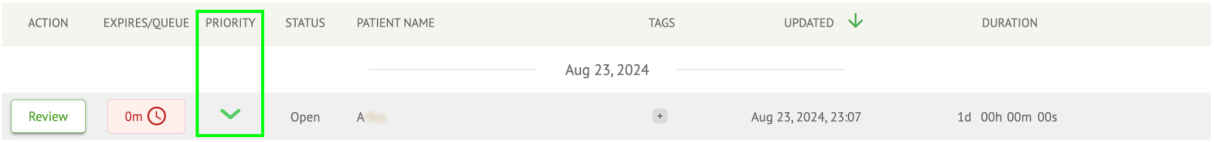
- the available action to operate with tasks. The following actions are:
  - **-** indicates the inability to operate with a task due to technical difficulties.
  - **Review** - enables a user to edit the ECG task.
  - **View** - enables a user to observe the ECG task.
  - **PDF** - enables a user to download the report of the ECG task.



- the expiration time of the task - indicates how many business hours is left for the task to expire. By default, 7 business hours are set for user to process the task.

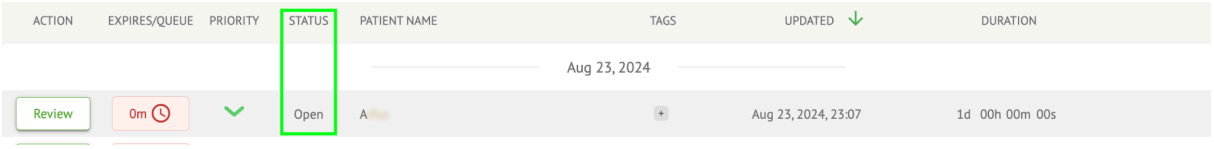


- task priority. Task priority serves a hint for a physician considering the prioritizing of ECG processing. In case the software intelligence detects important abnormalities, it sets the higher priority. The following priorities available: Highest, High, Medium, Low, Lowest, Unknownю



- task status. The following statuses available:

  Open - indicates that the task is available to be edited and no editing actions were applied.
  In progress - indicates that the task is currently in the editing process. The status appears after saving changes to the task editing.
  Pre-approved - indicates that the ECG task is pre-approved and is available for further editing.
  Done - indicates that the ECG report of the task is available to be downloaded and appears after approving the task.
  Canceled - indicates that the ECG task is canceled and is unavailable to be processed.
  Error - indicates that the error appeared during ECG task processing after uploading.



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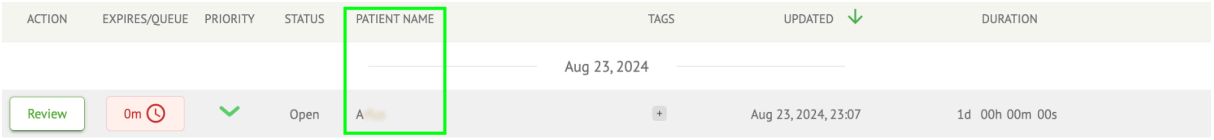
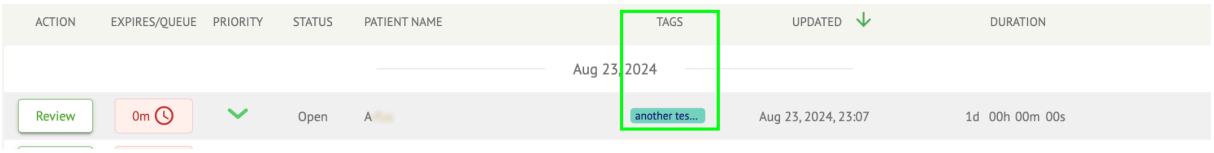
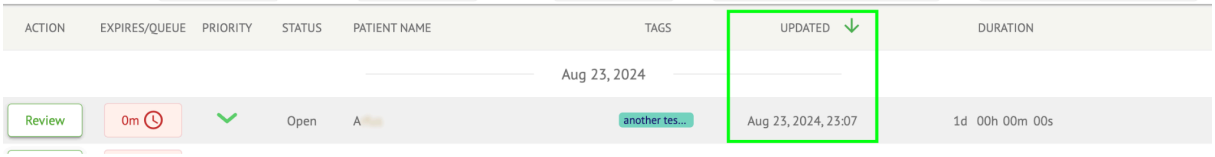
- patient's name,



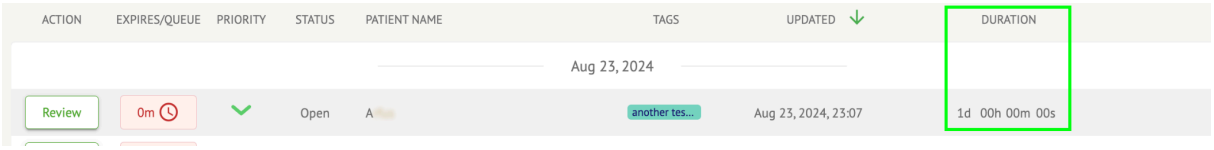
- task tags - indicates the tags of the task (e.g., test), available to be found by task tag filter,



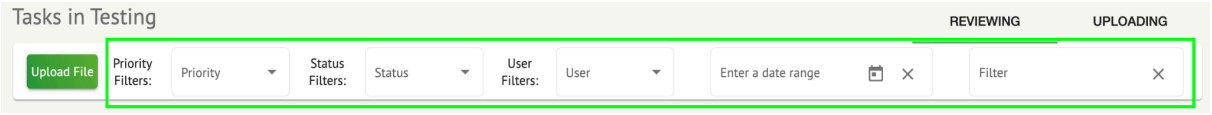
- the date of last task update



- the duration of the record within the task in time format.



The user is enabled to filter the tasks under **Reviewing**. The filter are available above the tasks:



The following filters are available:

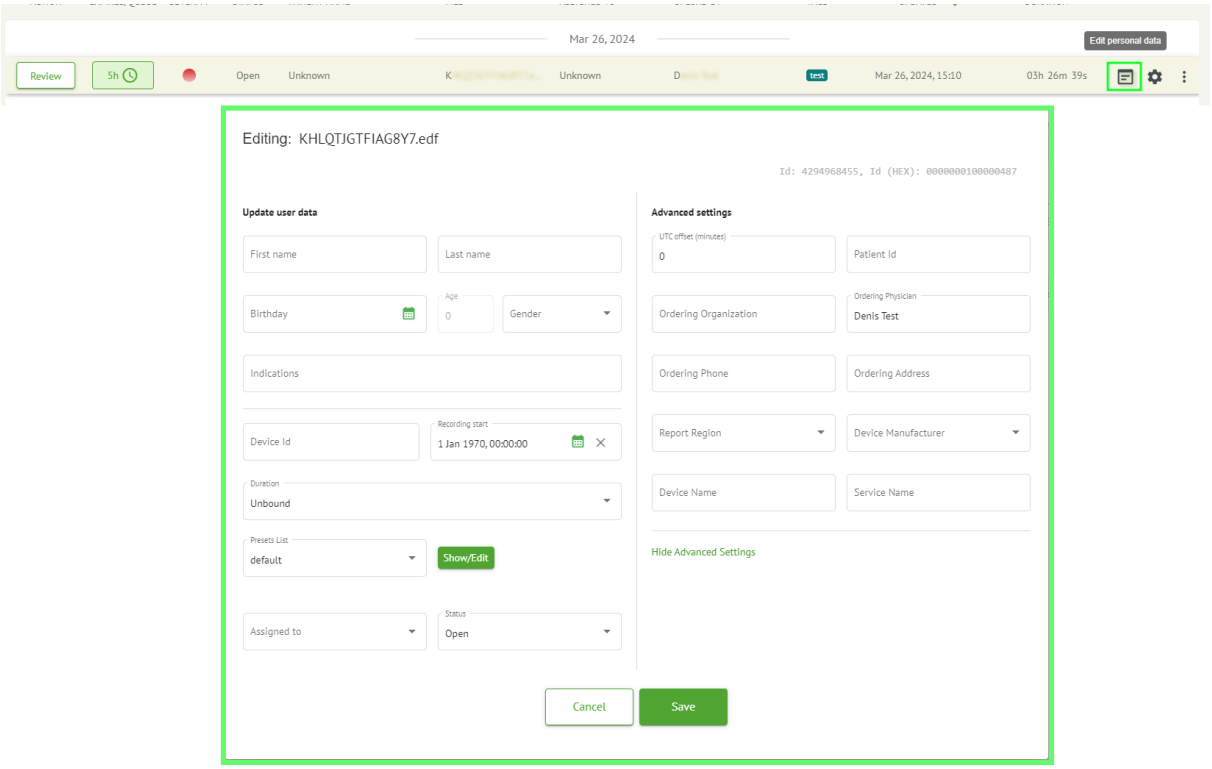
- Priority filters: available under **Priority** dropdown with the following priority filters available: Highest, High, Medium, Low, Lowest, Unknown.
- Status Filters: available under **Status** dropdown, with the following status filters available: Open, In progress, Pre-approved, Done, Canceled, Error.
- Assigned to: available under **Assigned** dropdown with the available users via the organization.
- Date range: available under **Enter date range** calendar input field, with the option to enter dates manually or via calendar menu:
- First/Second name - available under **Filter** input field, with the option to enter First/Second name of the user in the field.

- Event - available under **Filter** input field, with the option to enter the Event in the field, starting with @ symbol.
- Tag - available under **Filter** input field, with the option to enter the Event in the field, starting with # symbol;
- Channel - available under **Filter** input field, with the option to enter the Event in the field, starting with $ symbol;

11.3.2 Reviewing subsection editing

11.3.2.1 Patient data editing

The user is enabled to edit personal data of the patient created with the task under the **Edit personal data** button:



Editing menu consists of the **Update user data** section and **Advanced settings** section.

The following settings available to be edited under the **Editing** menu:

Setting	Description
General section	

First name	Indicates the first name of the patient.
Last name	Indicates the last name of the patient.
Birthday	Indicates the date of birthday of the patient in the DD MMM YYYY format. The user is enabled to select the date of birthday under the Calendar view
Age	Indicates the age of the patient. This field is being modified by the system according to the changes with **Birthday** data.
Gender	Indicates the gender of the patient. The following genders available: ● female; ● male; ● undifferentiated.
Indications	Provides the indications of the patient.
Device Id	Indicates the Device ID of the patient from which the ECG data was obtained.
Recording start	Indicates the date and time of the ECG recording start.
Duration	Indicates the duration of the ECG recording. The following values are available: ● Unbound; ● 1d; ● 2d; ● 3d; ● 5d; ● 7d; ● 14d.
Presets list	Indicates the preset configuration of the report of the task, generated during the ECG task reviewing. The default value of the preset is **default**. The user is enabled to edit the presets.
Advanced settings	
Assigned to	Indicates the user the patient is assigned to. The available users correspond to the users within the organization.
Status	Indicates the status of the task. The following statuses available: ● Open; ● In progress; ● Canceled; ● Done.

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UTC offset (minutes)	Indicates the timezone of the task. The option to set the timezone is available by filling in the field with the time of the time zone other than Greenwich in minutes. For a time zone west of Greenwich, a minus should be set in front of the number. Example: CET - 120.
Patient Id	Indicates the ID of the patient.
Ordering Organization	Indicates the name of the ordering organization of the patient.
Ordering Physician	Indicates the name of the ordering physician of the patient.
Ordering Phone	Indicates the name of the ordering phone of the patient.
Ordering Address	Indicates the address of the ordering organization of the patient.
Report Region	Indicates the region of the report of the task. The following regions available: ● US; ● Canada; ● EU; ● Ukraine; ● Unknown region.
Device Manufacturer	Indicates the manufacturer of the device from which the ECG data was obtained. The following manufacturers available: ● Life Signals; ● Myant; ● Cortrium; ● Unknown Manufacturer.
Device Name	Indicates the name of the device from which the ECG data was obtained.
Service Name	Indicates the name of the service of the patient.

11.3.2.2 Channels editing

The option to edit channels is available under the **Edit channels** button:

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The visibility of the available channels depends on the method of ECG recording and the signal setting.

The following information can be changed under the **Editing channels** menu:

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- Preset name of the leads configuration:

- Proposed preset name field;

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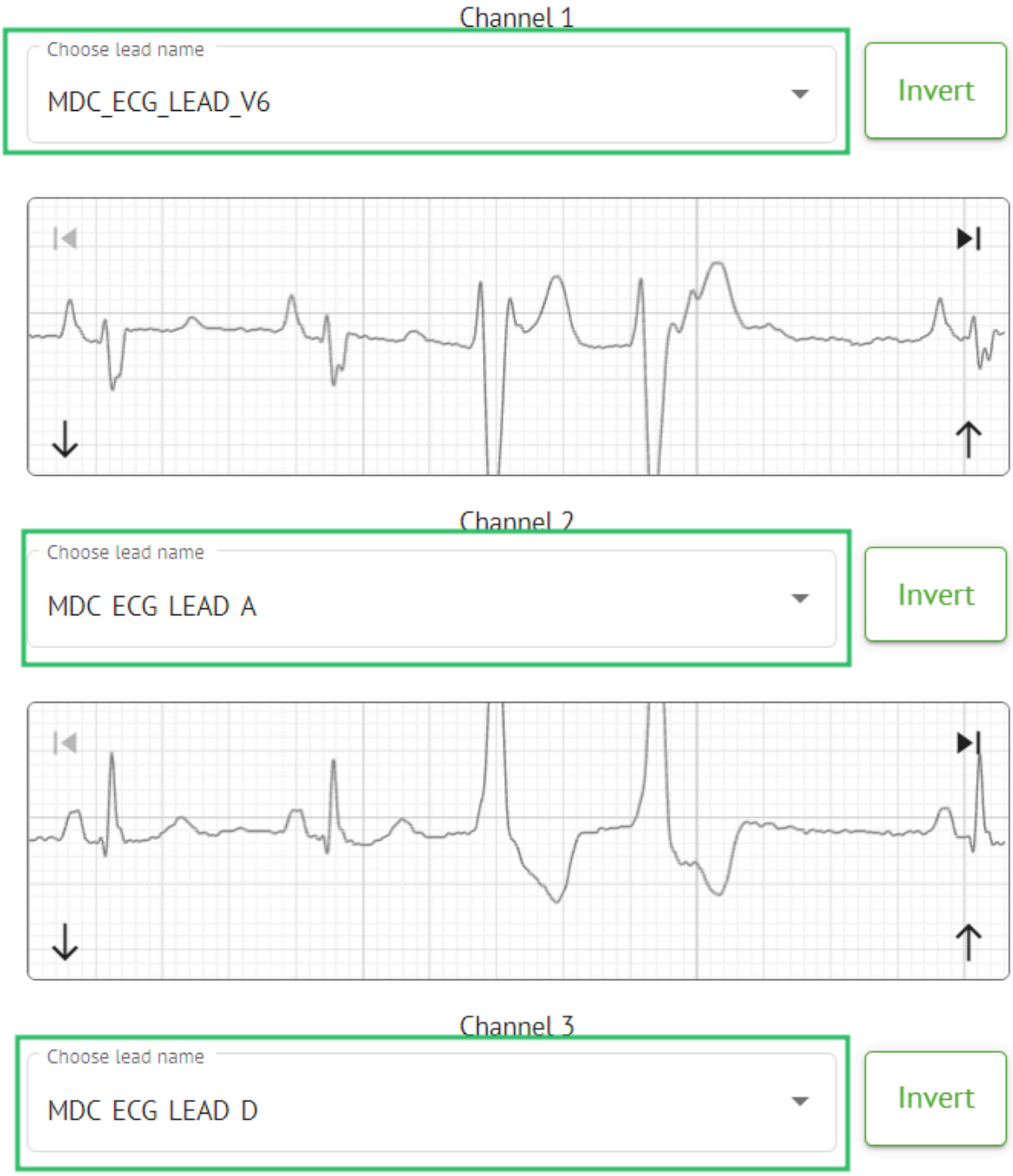
- Name of the channel(s):



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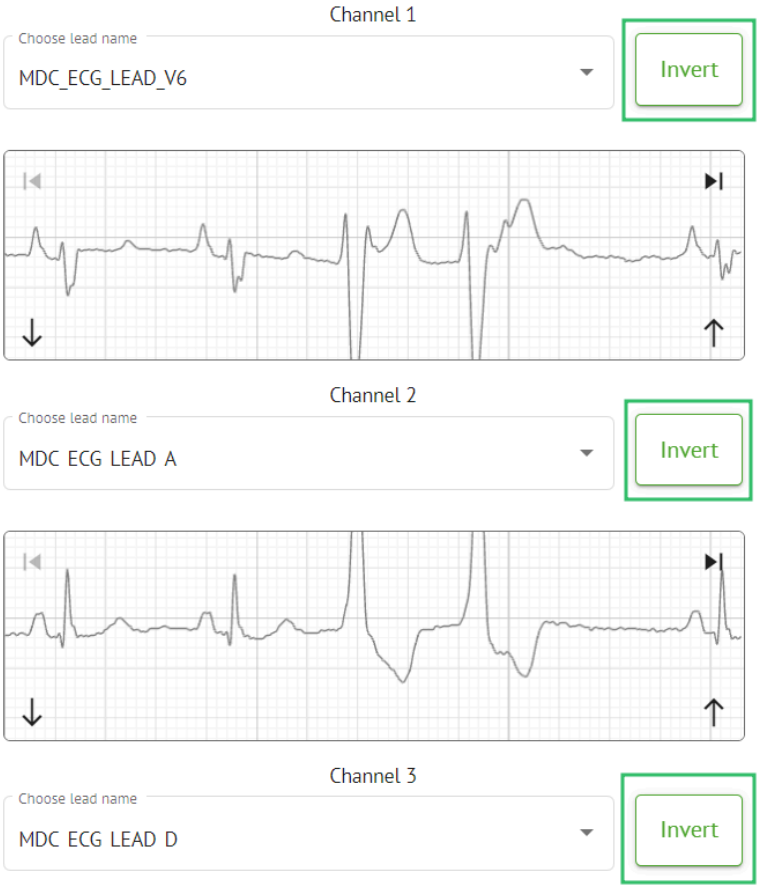
- Inverting the signal of the channel:



The following lead (channel) names available:

- MDC_ECG_LEAD_I;
- MDC_ECG_LEAD_II;
- MDC_ECG_LEAD_III;
- MDC_ECG_LEAD_AVR;
- MDC_ECG_LEAD_AVL;
- MDC_ECG_LEAD_AVF;
- MDC_ECG_LEAD_V1;
- MDC_ECG_LEAD_V2;
- MDC_ECG_LEAD_V3;
- MDC_ECG_LEAD_V4;
- MDC_ECG_LEAD_V5;
- MDC_ECG_LEAD_V6;
- MDC_ECG_LEAD_ES;
- MDC_ECG_LEAD_AS;
- MDC_ECG_LEAD_AI;
- MDC_ECG_LEAD_A;
- MDC_ECG_LEAD_D.

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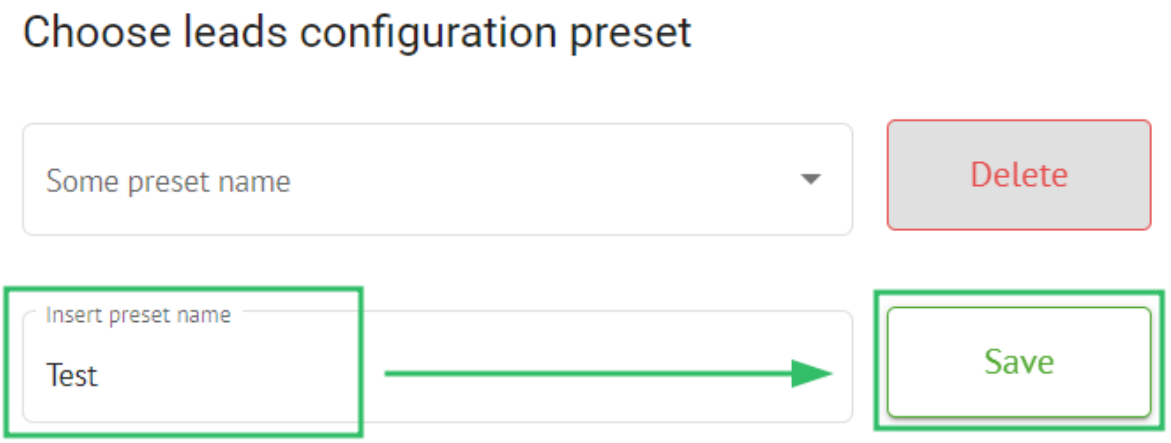
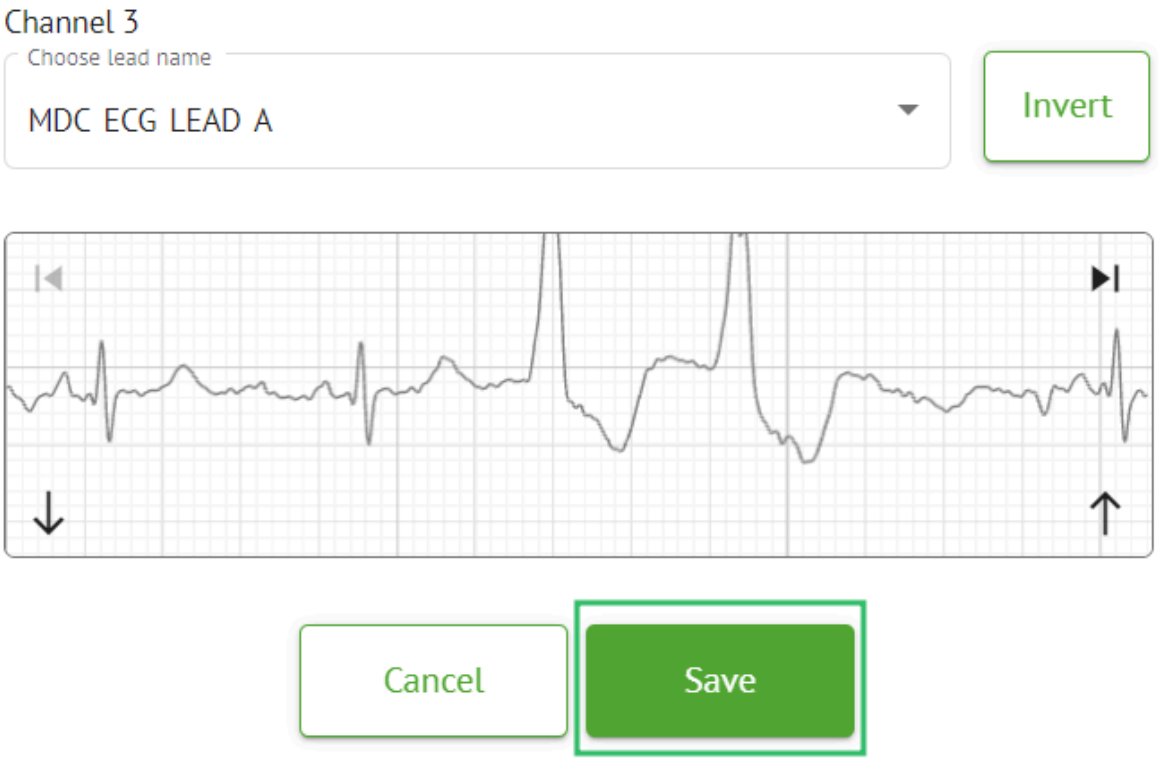
The option to save preset is available by filling the **Preset name** field, making changes and clicking the upper **Save** button:

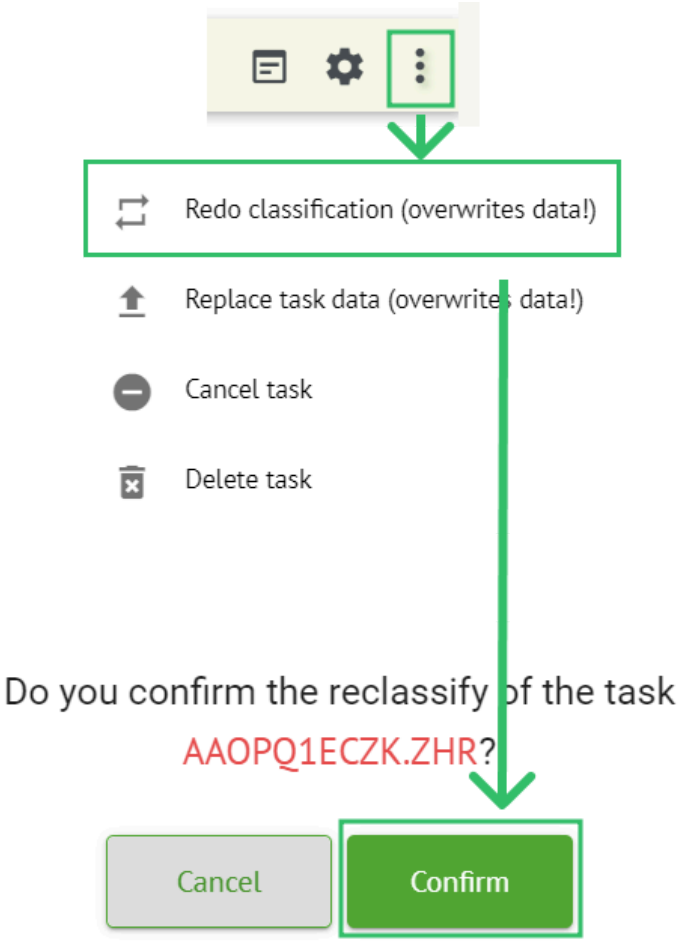


The option to apply changes to the task is available after clicking the lower **Save** button:



11.3.2.3 Task reclassification

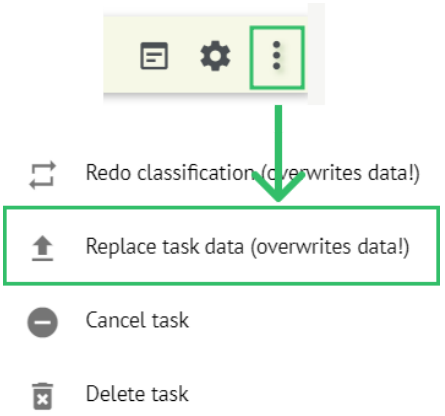
The option to reclassify task is available under task **options** > **Redo classification (overwrites data!)** button > **Confirm** button:



Note. The reclassification process will overwrite the existing data of the task (e.g., setted annotations)

11.3.2.3 Replacing task data

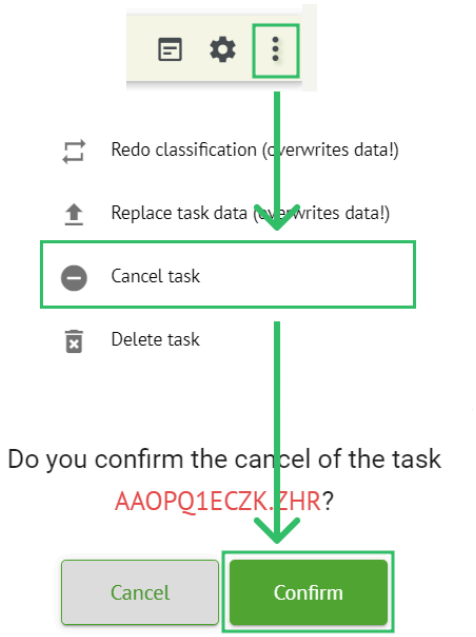
The option to reclassify task is available under task **options** > **Replace task data (overwrites data!)** button > select ECG file:



Note. The replacing process will overwrite the existing data of the task (e.g., setted annotations)

11.3.2.4 Task cancellation

The option to cancel task is available under task **options** > **Cancel task** button > **Confirm** button:



Note. The task cannot be edited after cancellation. The option to revert cancellation is available by **Reclassification** the task.

11.3.2.5 Task deletion

The option to delete task is available under task **options** > **Delete task** button > **Confirm** button:

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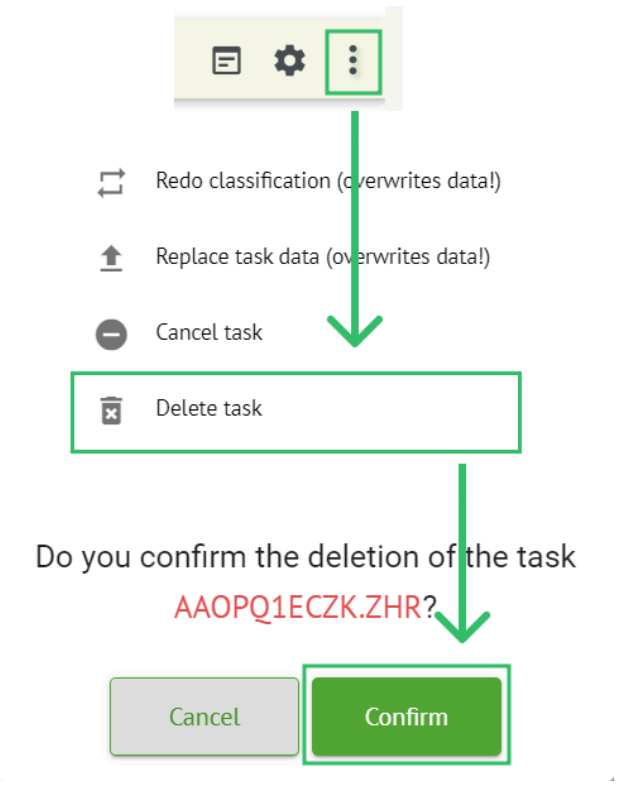


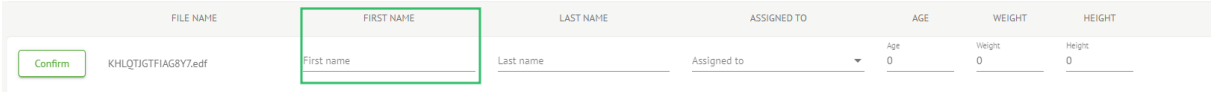
11.3.1 Uploading subsection overview

Uploading subsection is showing the uploadings of the ECG data only if the **Auto-process** function is off:

Under **Uploading** the following information is available to user:

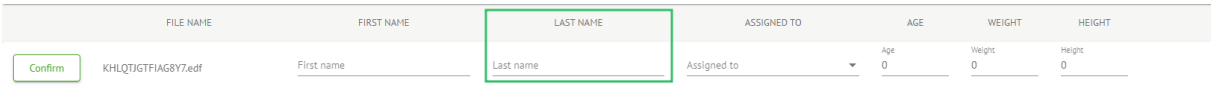
- The name of ECG file:

- The First Name of the patient:



  This setting may be modified before the confirmation step.

- The Last Name of ECG patient:



  This setting may be modified before the confirmation step.
- Assigned To data:

  This setting may be modified before the confirmation step.
- Age data:

  This setting may be modified before the confirmation step.
- Weight:

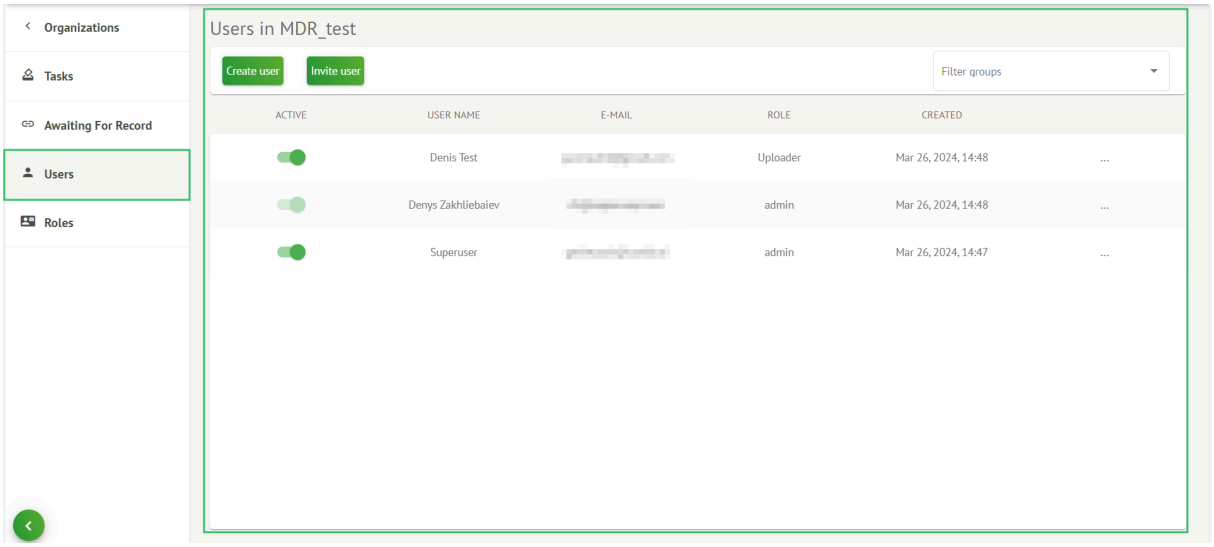
  This setting may be modified before the confirmation step.

11.4 Users section

11.4.1 Users section overview

Users section enables a user to create, invite, manage and delete a user within the organization.

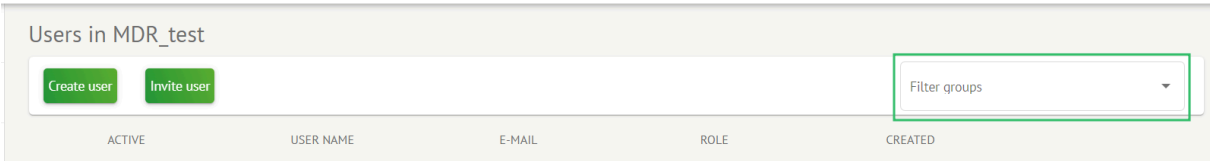
The option to access Users is available under the **Users** tab within the organization:



The following settings are available under the **Users**:

Setting	**Description**
Active	Indicates the user's activation status switch. When active, the user is functioning in the organization.
User Name	Indicates the name of the user.
E-mail	Indicates the email of the user.
Role	Indicates the role of the user. The available roles of the organization correspond to the roles under the **Roles** section. The default available roles are: ● Uploader; ● Editor; ● Admin.
Created	Indicates the date and time of creation of the user.

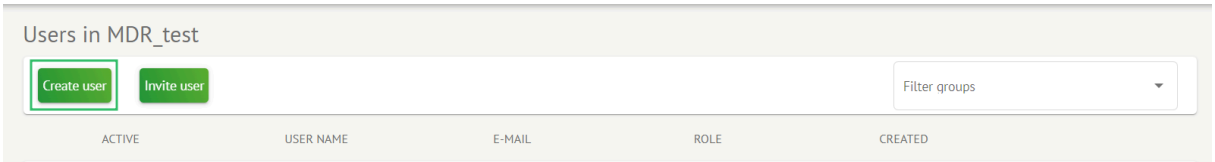
The user is enabled to filter the users' data under the **Users** section by the roles, under the **Filter groups** drop-down:



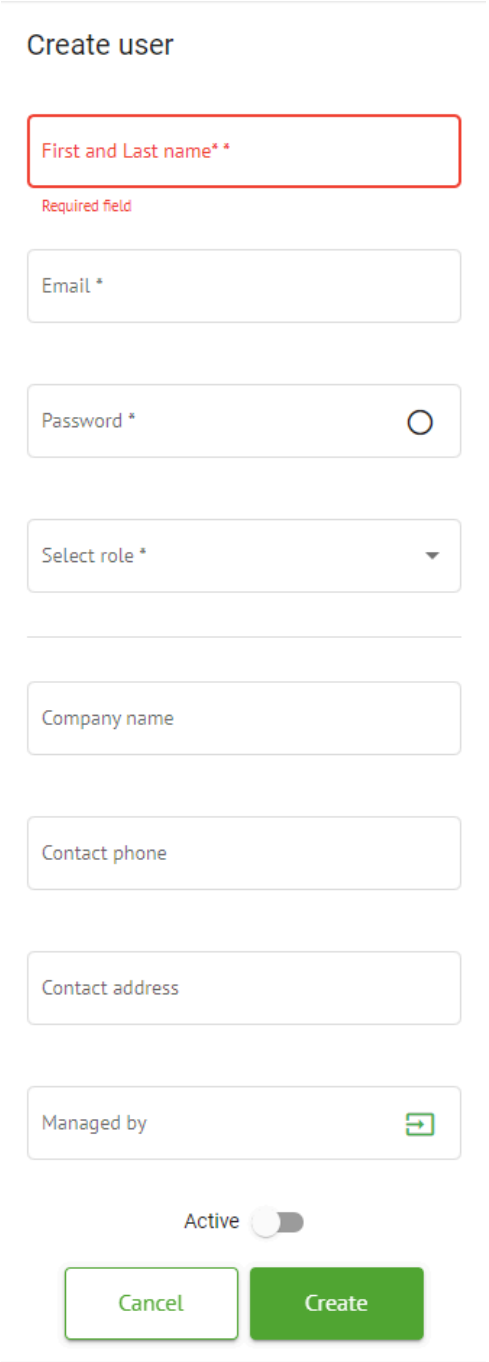
The available filter options correspond to the roles users assigned to.

11.4.2 User creation

The option to create a user within the organization is available under the **Create user** button:



XOresearch Cardio.AI™ shows the following screen when successful accessing:



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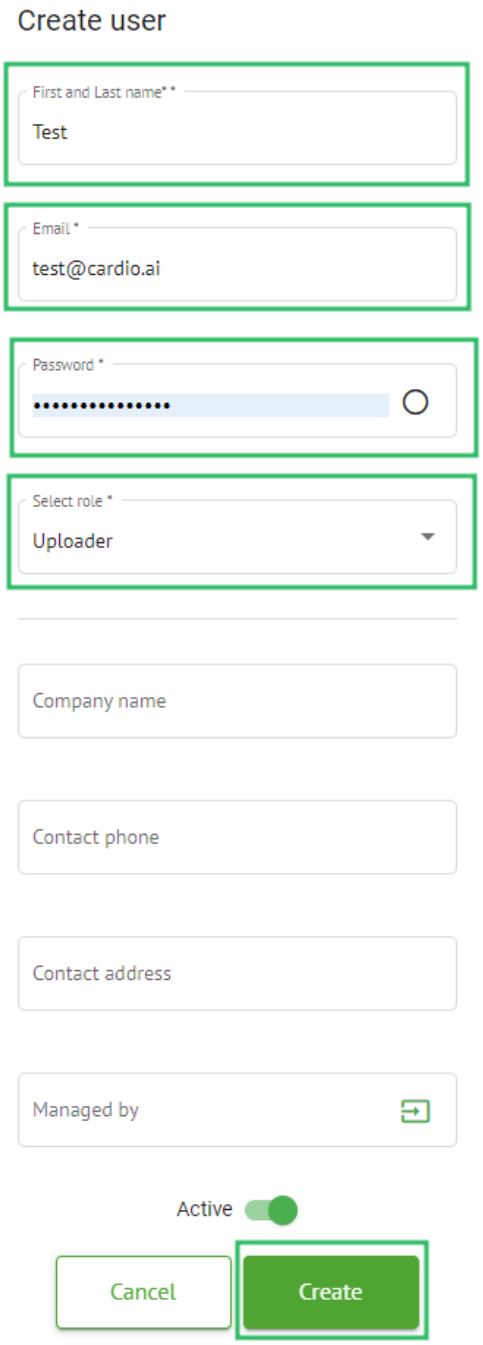
Setting	Description
First and Last Name	Enables to set the First and Last Name of the user. This field is **required**.
Email	Enables to set the email of the user. This field is **required**.
Password	Enables to set the password of the user. The password must include a minimum of 8 characters, comprising special characters, numbers, uppercase letters, and lowercase letters. This field is **required**.
Select role	Enables to set the role of the user. The available roles correspond to roles under the **Roles** section. The default roles are the following: ● Uploader; ● Editor; ● Admin. This field is **required**.
Company name	Enables to set the name of the company of the user.
Contact phone	Enables to set the number of the contact phone of the user.
Contact address	Enables to set the address of the user.
Managed by	Enables to set the manager of the user. The available managers correspond to the users within the organization.
Active	Enables to activate or deactivate the user.

The option to create users is available by filling the required fields and clicking the **Create** button:



11.4.2 User invitation

XOresearch Cardio.AI™ enables the user to invite the user previously created in the system to the current organization. The user is enabled to invite the user by clicking the **Invite user** button > enter email of the user and select the role > **Invite** button:

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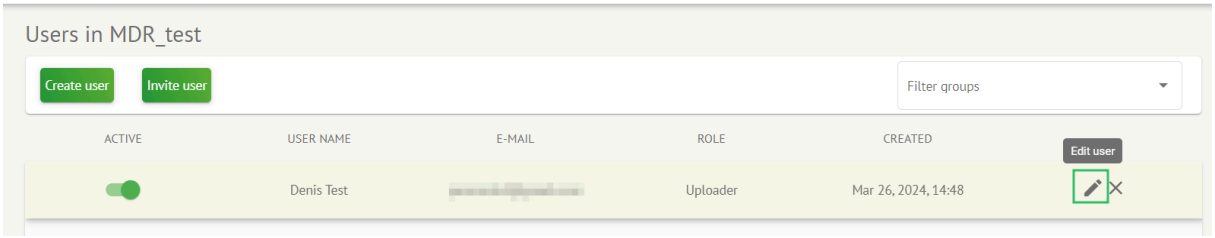
11.4.3 User editing

The option to edit the user is available under the **Edit user** button:



User editing settings correspond to the User creation settings.
Note. The option to setup User management by another user is not available when editing the user.

11.4.4 User role assignment deletion

The option to remove the user from the organization is available by removing the role assignment of the user from the organization. The option to delete the role assignment is available under **Delete role assignment** > **Confirm** button:

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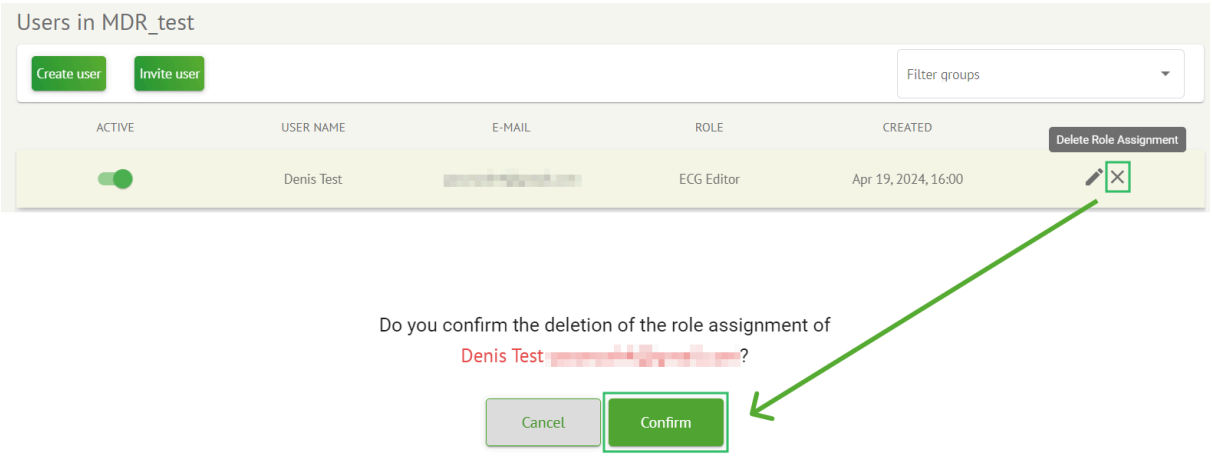
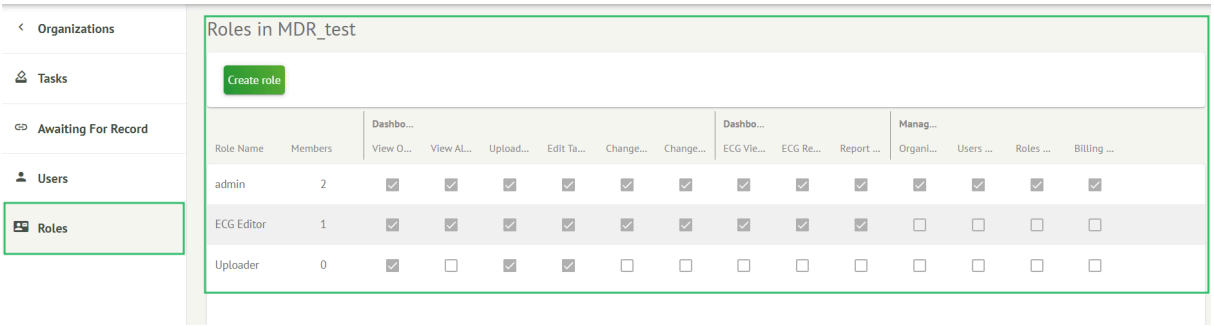


11.5 Roles section

11.5.1 Roles section overview

Users section enables a user to create, manage and delete a role within the organization. The option to access Roles section is available under the **Roles** tab within the organization:



XOresearch Cardio.AI™ creates a predefined set of roles while creating the organization. The default created roles are: Admin, ECG Editor and Uploader.

Roles section dashboard contains the following components:

Setting	**Description**
Role Name	Indicates the name of the role.
Members	Indicates the number of users with the correspondent role.
Dashboard	
View Own Tasks	Enables a user to view the tasks the user uploaded ECG of,

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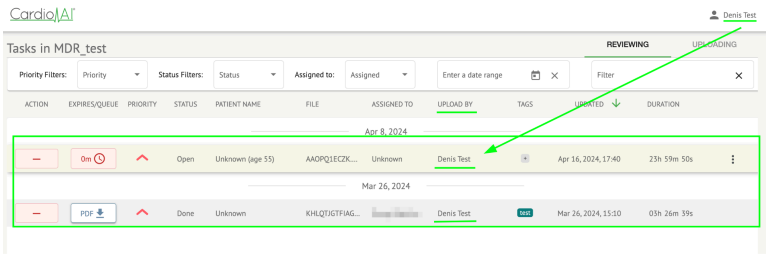
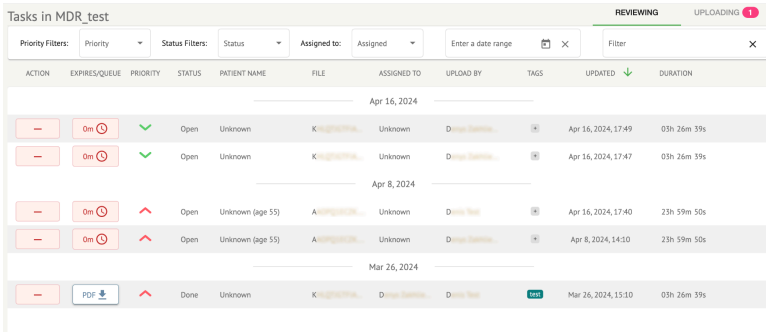
	under the Reviewing subsection of Tasks. 
View All Tasks	 Enables a user to view the tasks initiated by all users within the organization of under the Reviewing subsection of Tasks.
Edit Tasks List	Enables a user to **Edit personal data** of the patient, **Reclassify** and **Reupload** the task data.
Change Reviewer	Enables a user to change **Assigned to** user of the task. under the **Edit personal data** of the patient.

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	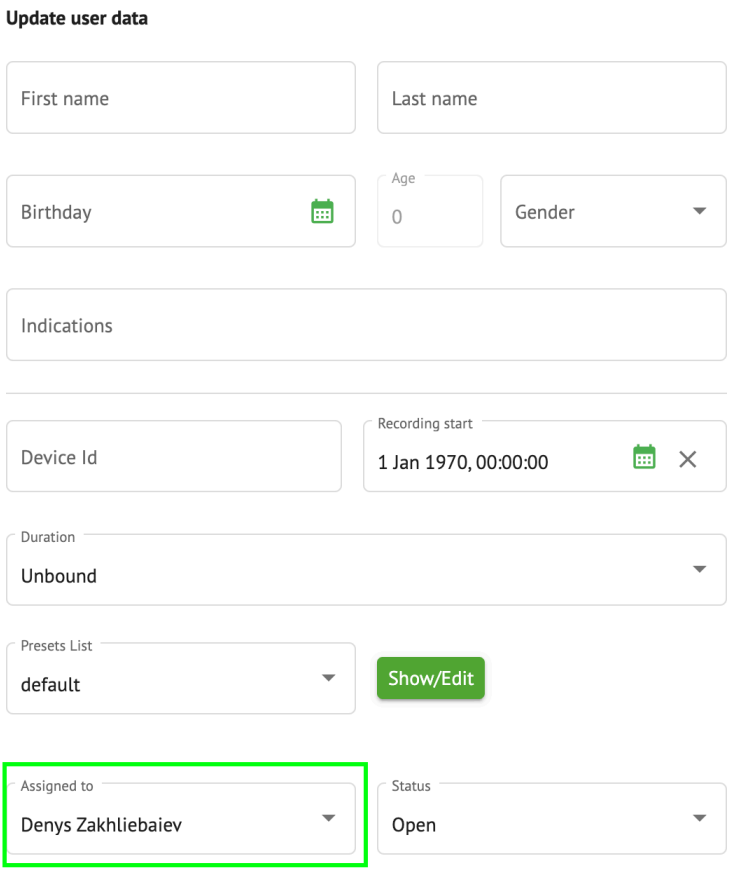
Change Task Status	Enables a user to change **Status** of the task under the **Edit personal data** of the patient.

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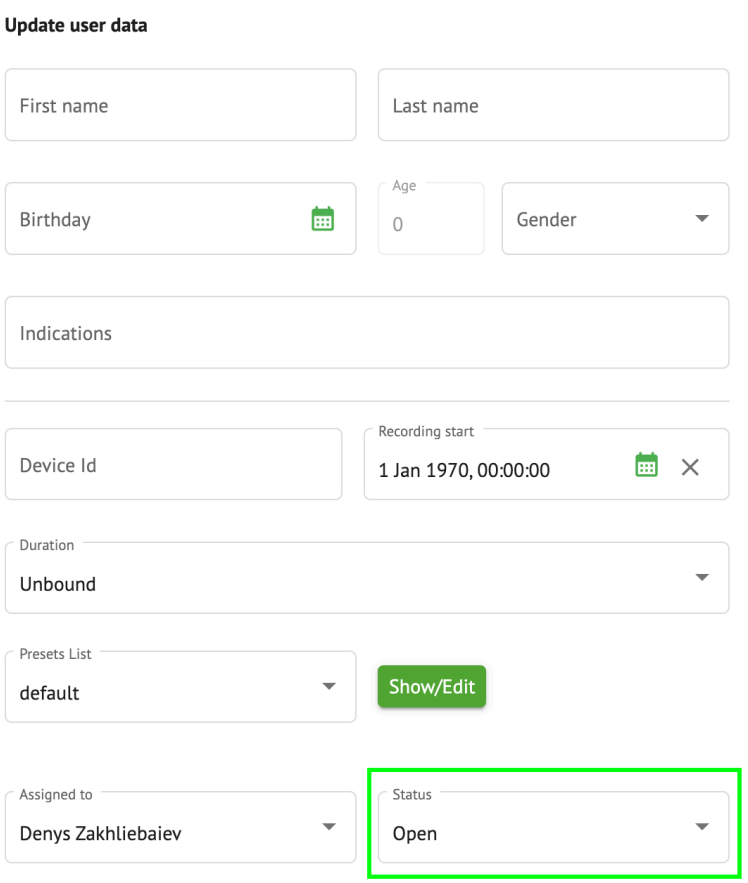
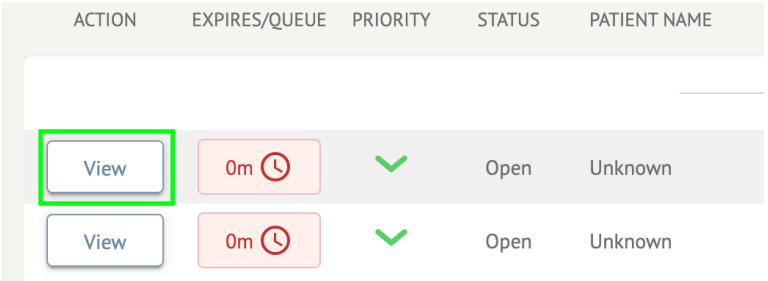
	
Dashboard	
ECG View Access	Enables a user to access ECG task, observe the annotations created by the AI and observe the ECG report. 
ECG Review Access	Enables a user to edit the ECG task data, change the annotations, edit the report, save changes of the task and pre-approve the task. **Note**. Pre-approving the task becomes available after saving changes.

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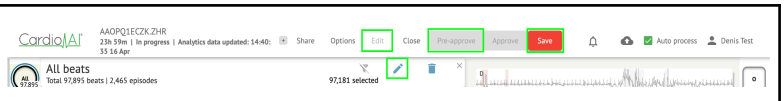
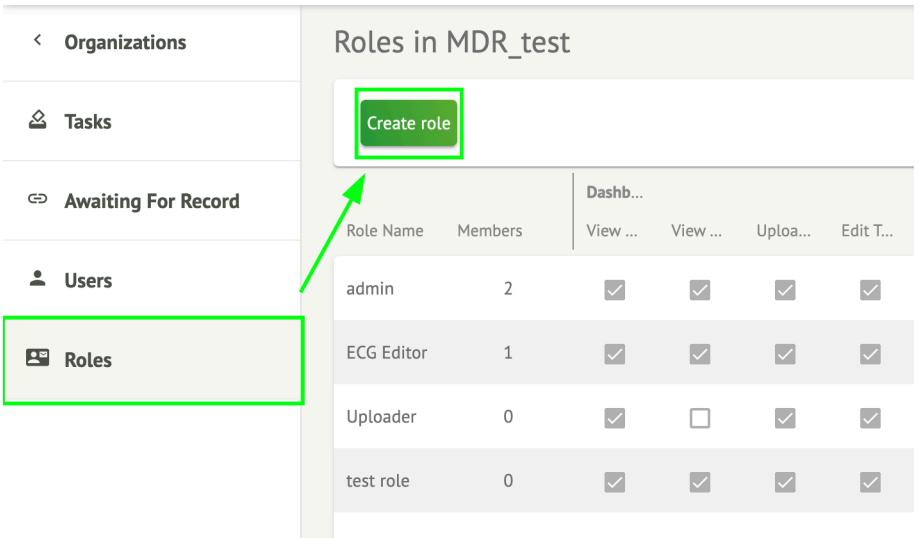
	
Report Final Approve	Enables a user to approve the task, making the report downloadable. 
Management	
Organization's Management	Enables a user to edit and remove the organization.
Users Management	Enables a user to create, invite, manage and remove the users within the organization.
Roles Management	Enables a user to create, manage and remove the roles within the organization.
Billing Management	Enables a user to calculate spendings within the organization.

11.5.1 Role management

The option to create role is available under **Roles** section > **Create role** button:



XOresearch Cardio.AI™ shows the following screen when successful:

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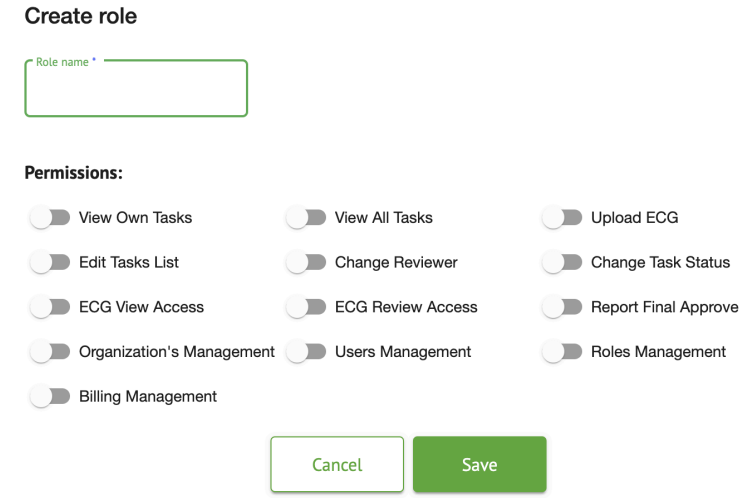
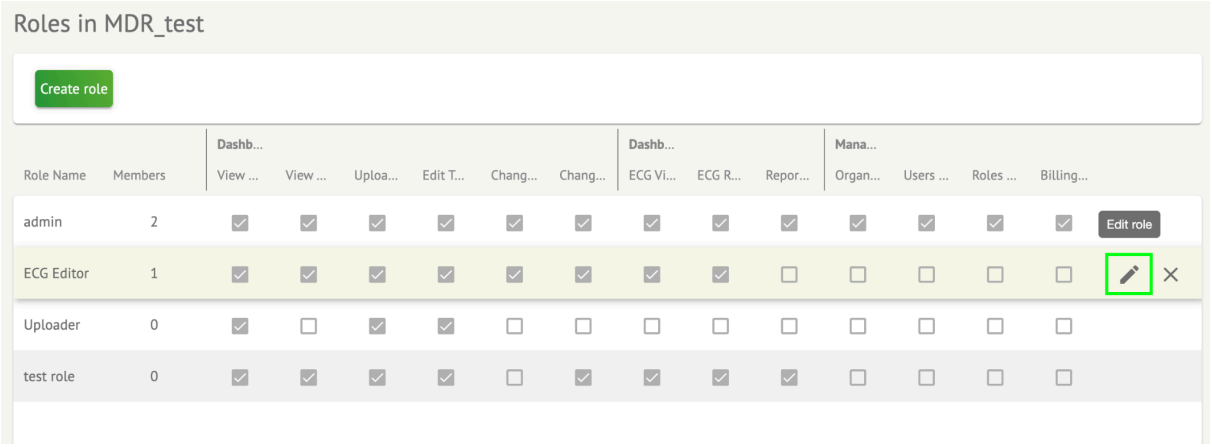
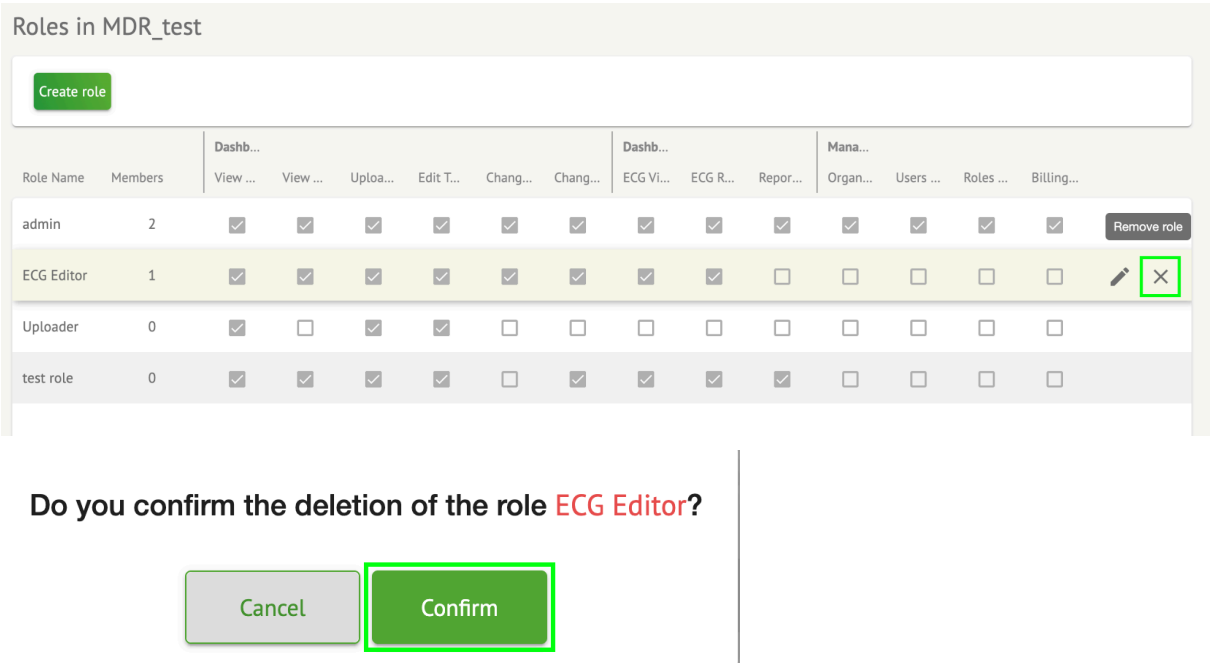


Role becomes created when setting Role name, switching the necessary permissions and clicking the **Save** button.

The option to edit the role is available under **Roles** > select Role > **Edit role** button:

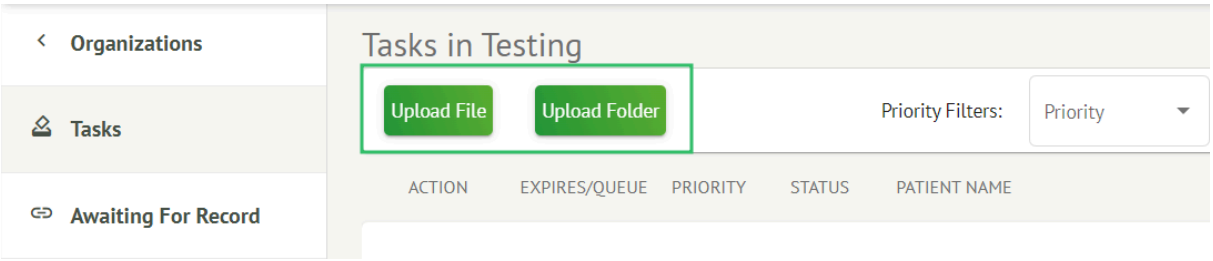


The option to remove the role is available under **Roles** > select Role > **Remove role** button > Confirm button:



11.4 ECG data input

The option to upload pre-recorded ECG is available under **Upload File** button or drag-n-drop. The option to upload several pre-recorded ECG placed in a folder is available under **Upload Folder** button:



XOresearch Cardio.AI™ shows the following screen when successful:

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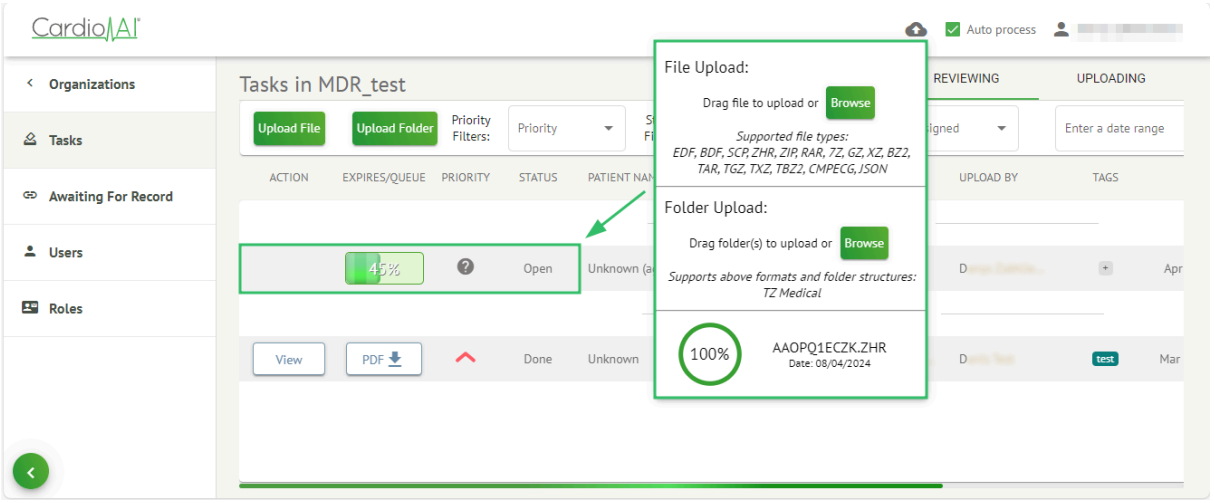
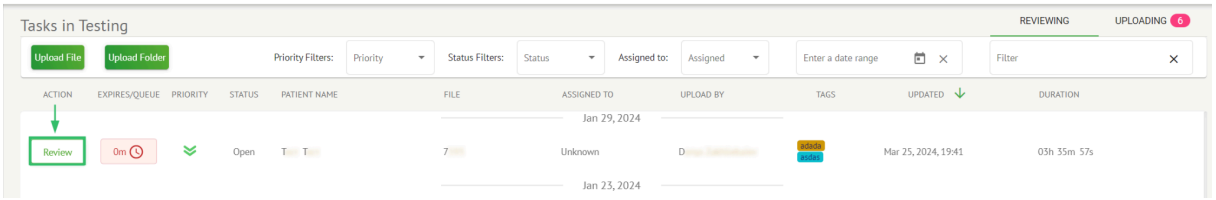


11.5 ECG data analysing

The option to review uploaded ECG is available under the **Review** button.



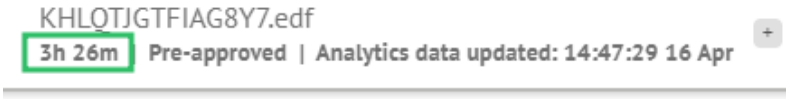
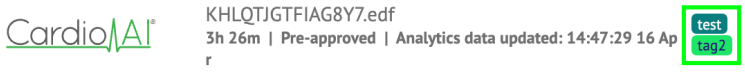
XOresearch Cardio.AI™ shows the following screen when successful:

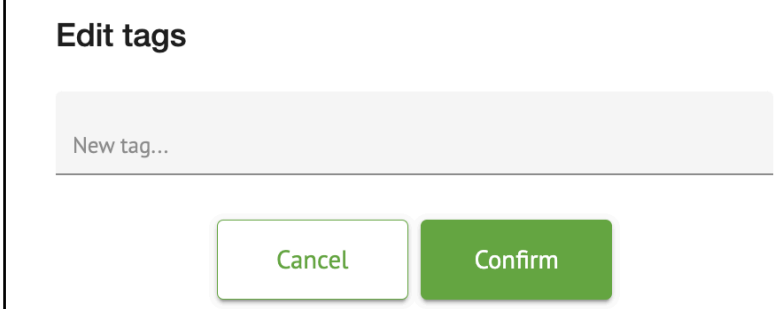
ECG viewer is divided into the following sections:

1. Header section - enables a user to manage ECG viewer options, save and approve the ECG.
2. Side editing bar - enables a user to choose the ECG periods;
3. Detailed ECG data section - enables a user to view and edit ECG;
4. A report section - enables a user to observe, edit and export the ECG report.

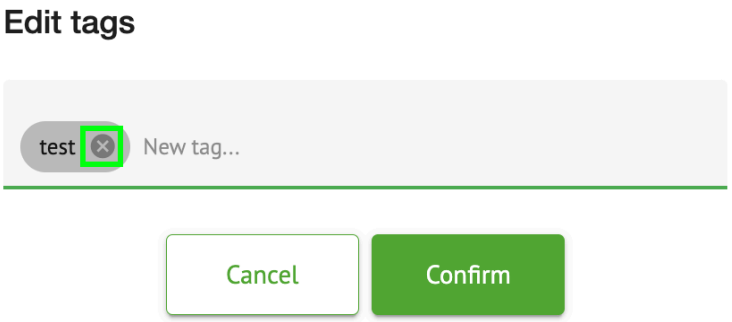
11.5.1 ECG Viewer Header

Header section of the ECG viewer contains the following information:

Setting	Description
Logo	Indicates the logo of the organization: 
ECG file name	Indicates the name of the ECG file. 
Duration of the ECG record	Indicates the duration of the ECG record in days, hours and minutes if applicable. 
Status of the task	Indicates the status of the task: 
Update date	Indicates the time and date of last update of task data: 
Task tags	Indicates the tags of the task:  The option to add tag is available by clicking under **Add tag** button:  Or via clicking the existing tag. Cardio AI shows the following screen when successful:



The option to add a new tag is available by filling the name of the tag under **New tag...** field and clicking the **Confirm** button.
The option to remove existing tag is available by clicking the remove button under existing tag:



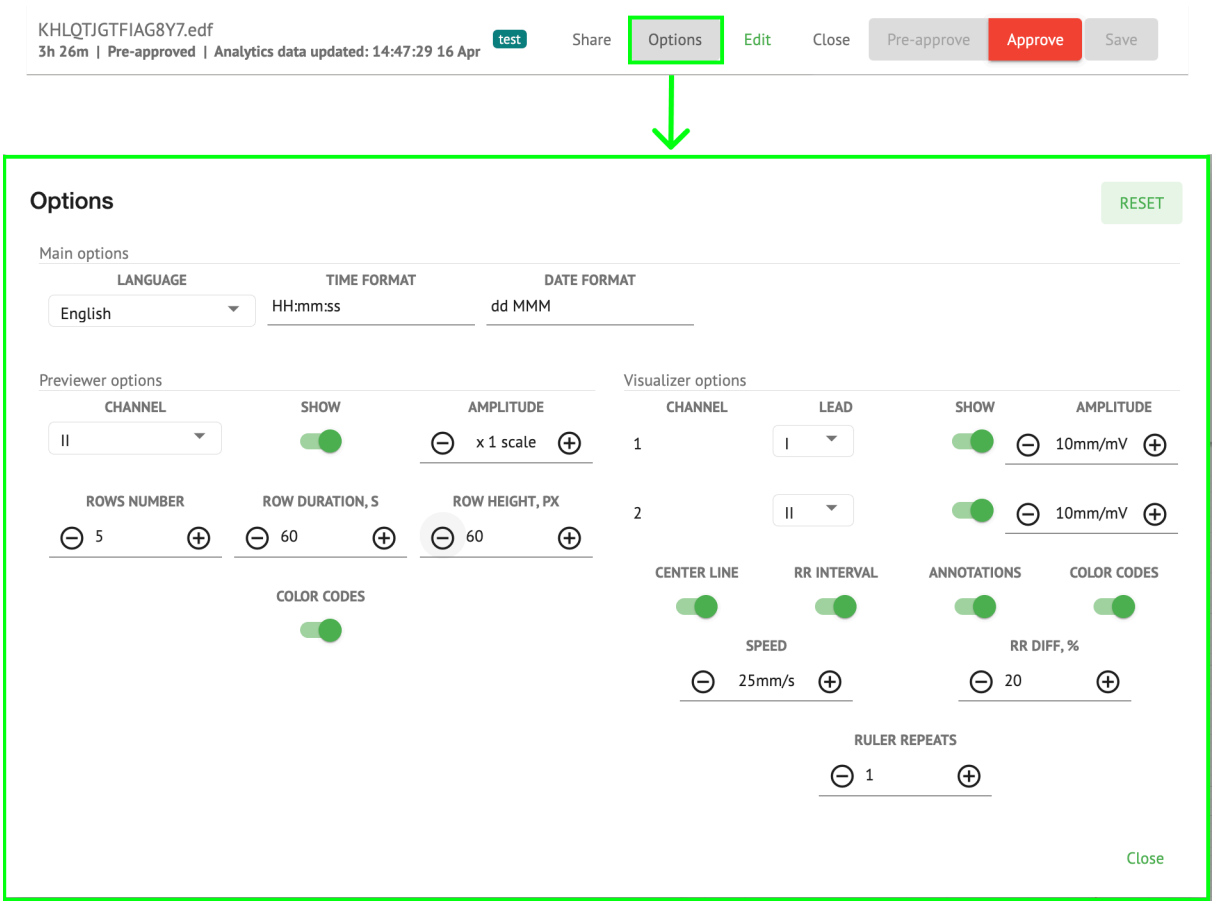
11.5.1.1 Share ECG task

The option to share task is available under **Share** button:

Shareable link will be copied to the clipboard.

11.5.1.2 ECG task options

The ECG task options are available under **Options** button:



Setting	Description
Main options	
Language	Enables to set the language of task viewer. The following languages available: • English; • Russian; • Ukrainian.
Time format	Enables to set the time format of the task data.
Date format	Enables to set the date format of the task data.
Previewer options	
Channel	Enables to select the channel for configuration. The available channels correspond to ECG recording device.
Show	Enables to show or hide the channel.

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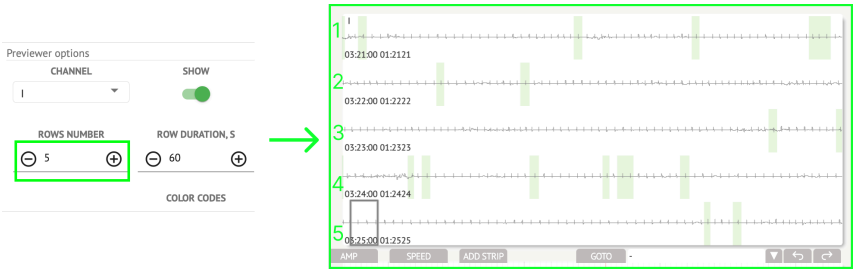
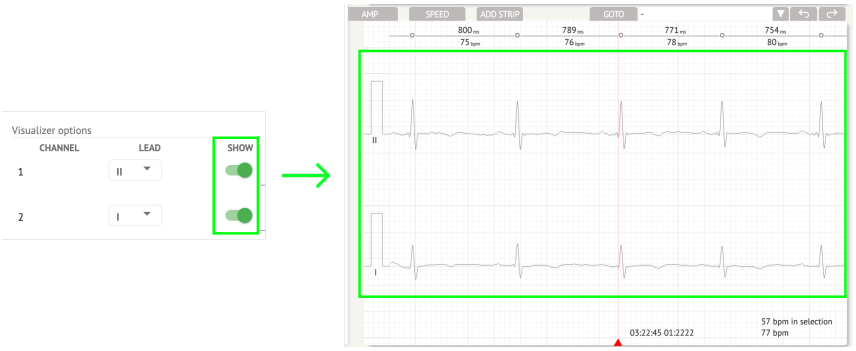
Amplitude	Enables to configure scaling of the amplitude. The available scales are: • x1 scale; • x2 scale; • x3 scale; • x4 scale. The option to change scaling is available under **Plus** and **Minus** buttons.
Rows number	Enables to set the number of rows under **Previewer**. The number of rows available from **1** to **20**. The default value is **5**. 
Row duration, s	Enables to set the duration of rows, in seconds. The following values available: • 30; • 60; • 90; • 120.
Row height, px	Enables to set the height of rows, in pixels. The following values available: • 30; • 40; • 50; • 60; • 70; • 80; • 90; • 100; • 110; • 120.
Color codes	Enables to set the color codes of annotations availability under **Previewer.**
Visualizer options	
Channel	Enables to select the channel for configuration. The available channels

	correspond to ECG recording device.
Lead	Enables to select the channel lead for configuration. The available leads correspond to ECG recording device.
Show	Enables to show the channels under **Visualizer**. 
Amplitude	Enables to set the amplitude of the leads under Visualizer. The following amplitudes available: • 5 mm/mV; • 10 mm/mv; • 20 mm/mV; • 40 mm/mV; • 80 mm/mV; • 160 mm/mV; The option to change Amplitude is available under **Plus** and **Minus** buttons.
Center line	Enables to show the Center line under Visualizer: 
RR interval	Enables to show the time interval between two successive R-waves of the QRS signal under Visualizer:

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Annotations	Enables to show the text codes of annotations under **Visualizer.**
Color codes	Enables to show the color codes of annotations under **Visualizer.**
Speed	Enables to set the speed of the record under **Visualizer.** The following speed options available: • 12.5 mm/s; • 25 mm/s; • 50 mm/s; • 100 mm/s.
RR diff, %	Enables to set the the percentage difference between successive R-R intervals. The following values available from 0 to 100
Ruler repeats	

The option to reset changes is available under **Reset** button.
The option to save changes is available under **Save** button.

11.5.1.3 Edit ECG task

The option to make the Record editable is available under the **Edit** button:

11.5.1.4 Close ECG task

The option to close ECG task and revert to **Tasks** section is available under **Close** button:

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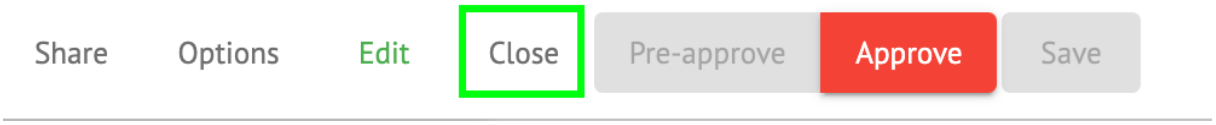


11.5.1.5 Pre-approve ECG task

The option to pre-approve task is available under the **Pre-approve** button:

Note. Task pre-approving is available only after **Saving** the task.

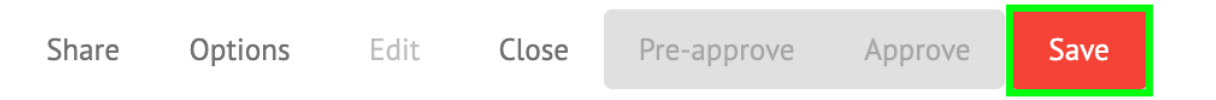
11.5.1.6 Approve ECG task

The option to approve ECG task and download the report in PDF format is available under the **Approve** button:

Note. Task approving is available only after **Saving** the task.

11.5.1.7 Save ECG task

The option to save changes after editing the ECG task is available under **Save** button:



XOresearch Cardio.AI™ shows the following notification when successful:

11.5.2 ECG Viewer Editor

ECG Viewer Bulk Editor consists of the following elements:

1. Side editing bar - contains all and classified beats by annotations;
2. Poincare plot - enables to navigate and select beats;
3. Beats list - enables to bulk select and edit beats

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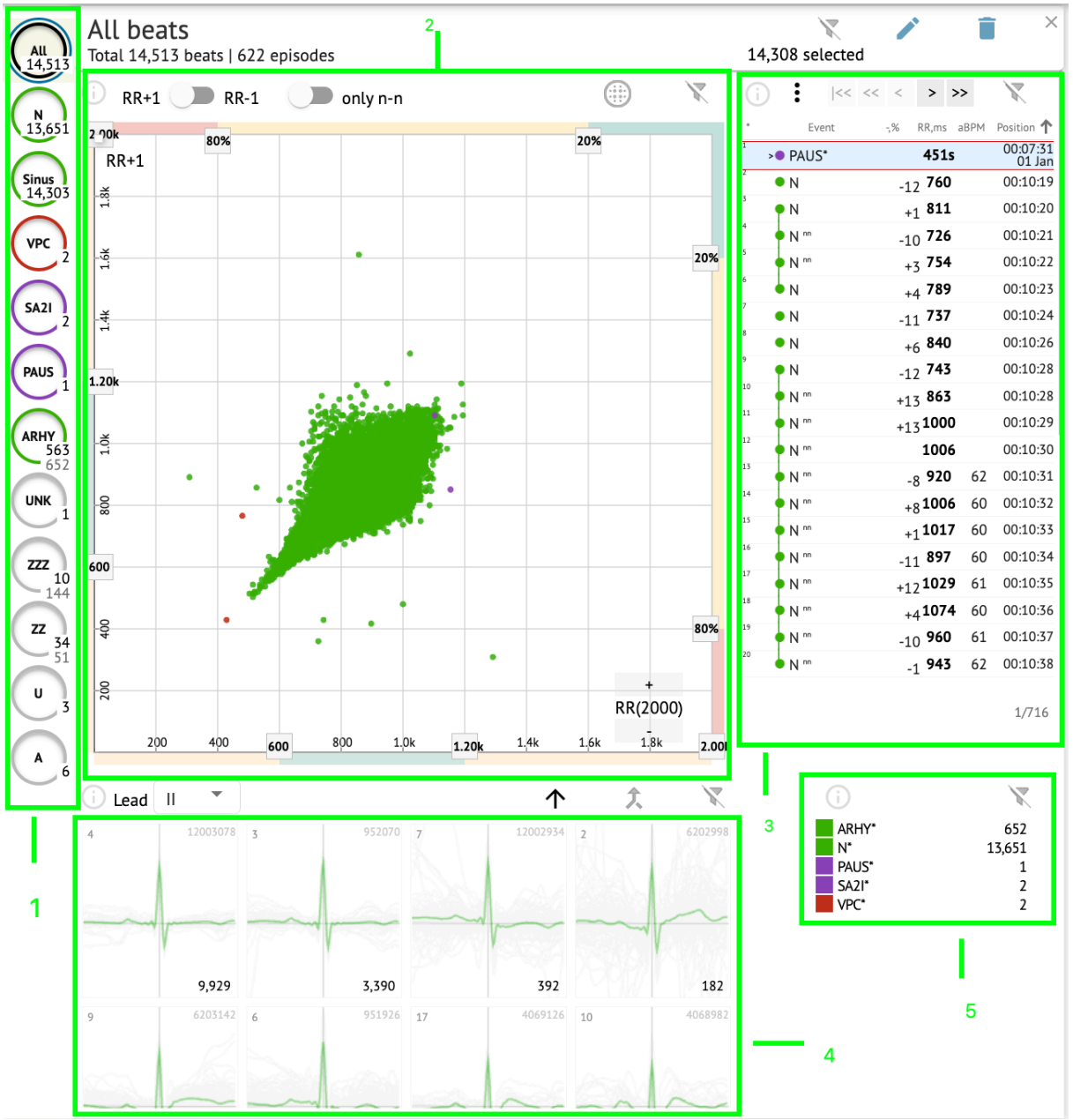
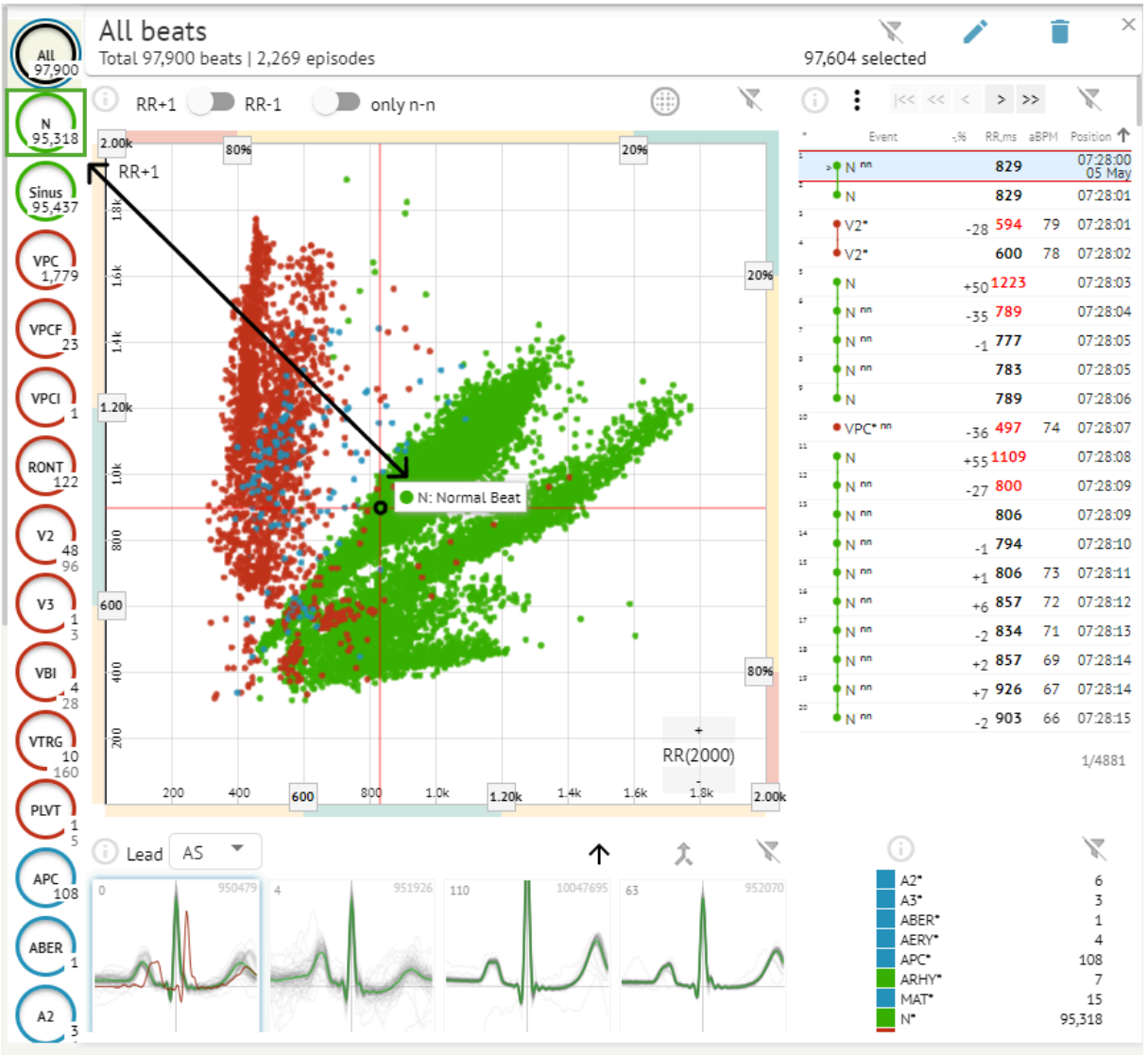
4. Beats cluster panel - enables to compare beats via clusters;
5. Beats cross-annotations list - enables to observe and manage beats with multiple annotations.



11.5.2.1 Side editing bar

Under side editing bar, XOresearch Cardio.AI™ collects and shows all the beats, normal beats and found annotations. All beats highlighted with **black**, normal and sinus beats highlighted with **green**, annotations highlighted with other colors.



The user is enabled to click on the highlighted segments, and software will focus on that selected segment, including a detailed view of the selected segment:

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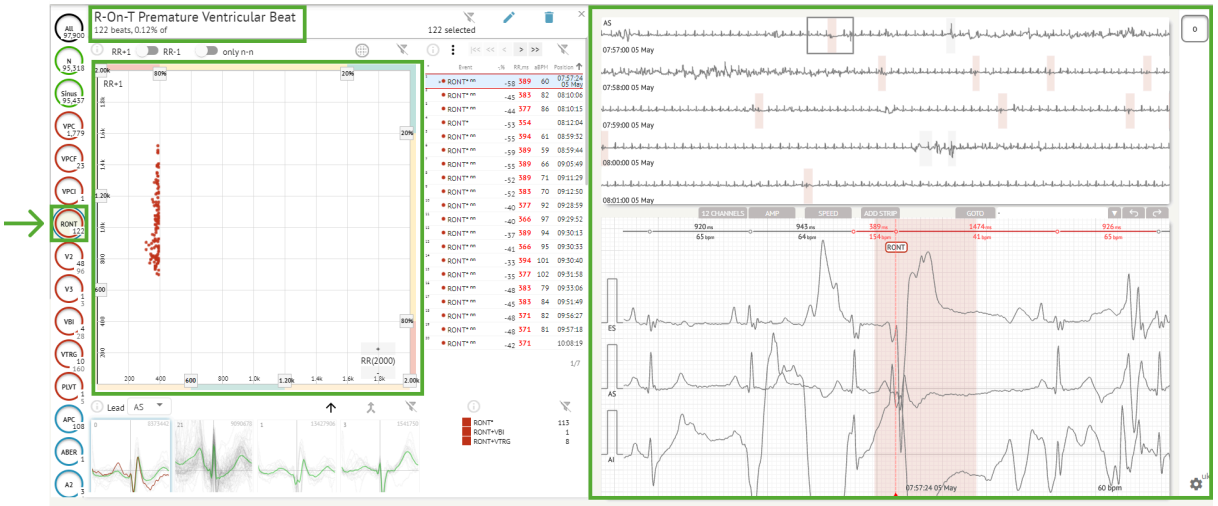
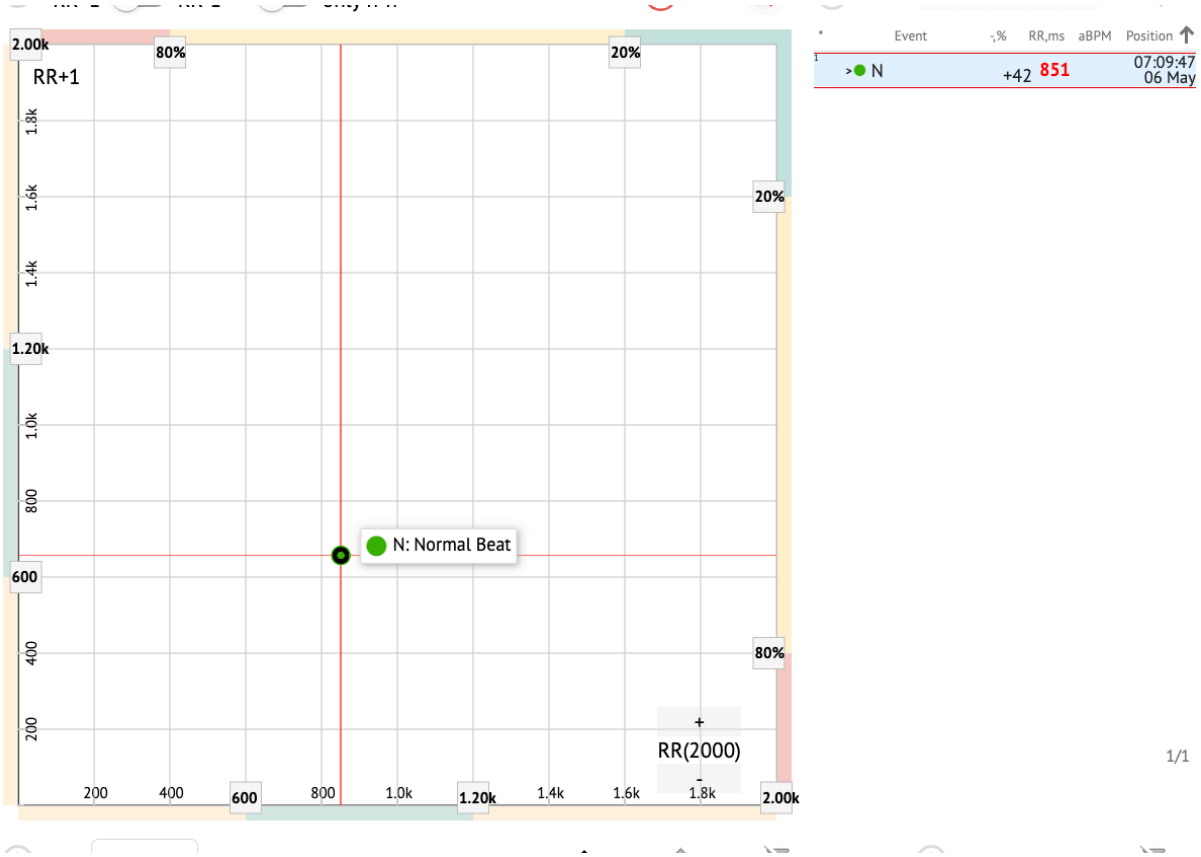


Multi selection of episodes is available via SHIFT or CTRL buttons.

11.5.2.2 Poincare plot

Poincare plot enables a user to review, view and navigate all recorded beats, including normal, and annotations (abnormalities)

The option to navigate to beat is enabled by clicking on the beat:



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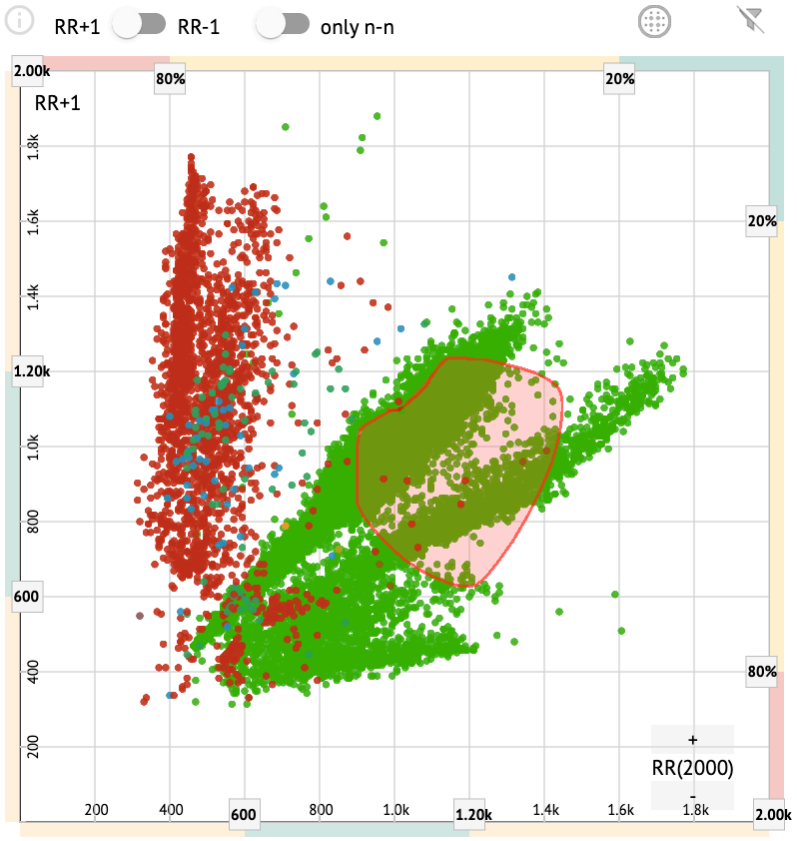
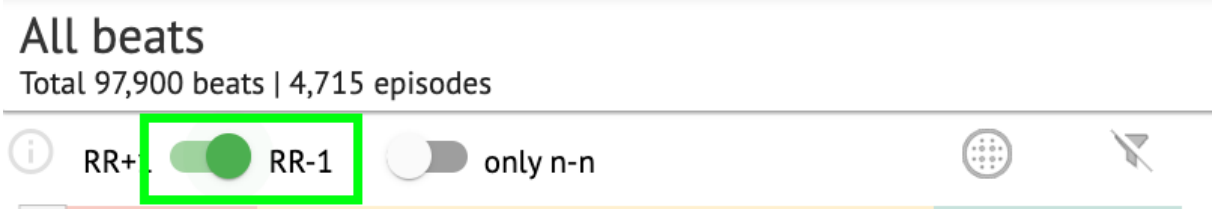
The user has the ability to select multiple bits by drawing an area on the Poincare plot by left-clicking and moving the cursor over the plot:



By default, Poincare plot is shown in the mode RR +1. The option to switch to RR-1 mode is available under the corresponding switch:



The option to show only normal beats to the left and to the right is available under **only n-n** switch:

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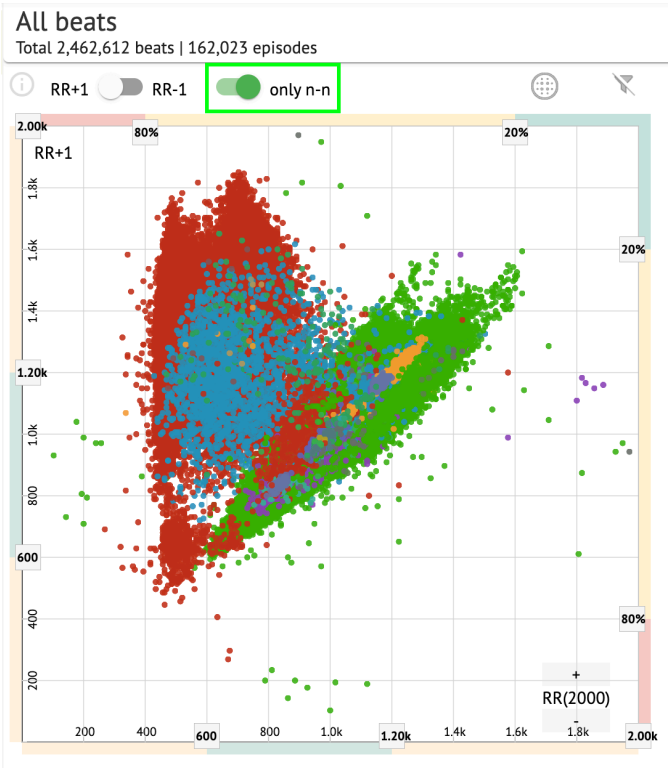

The option to filter beats under Poincare plot is available by clicking on the following filter elements:

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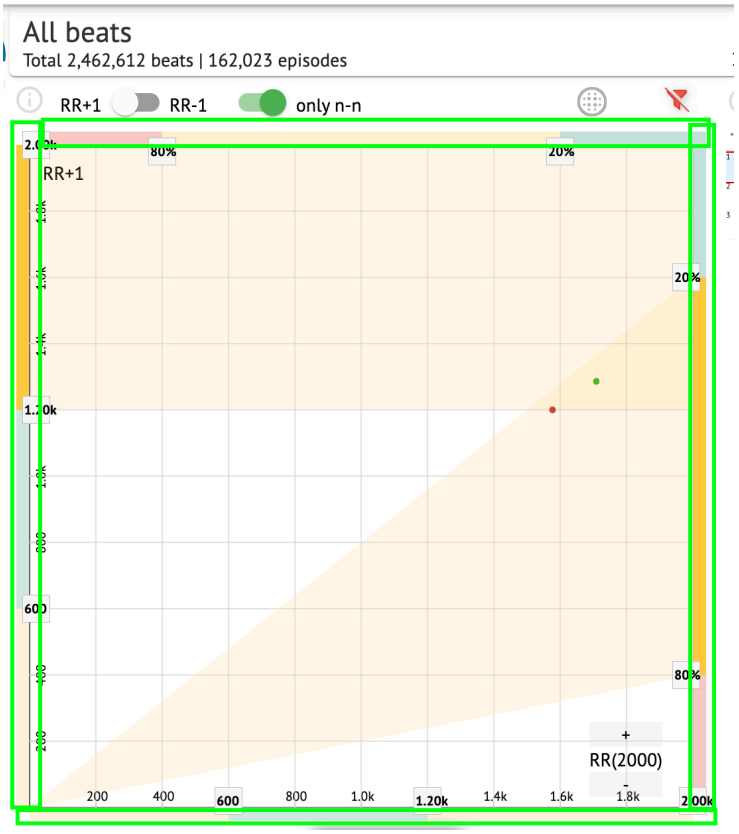
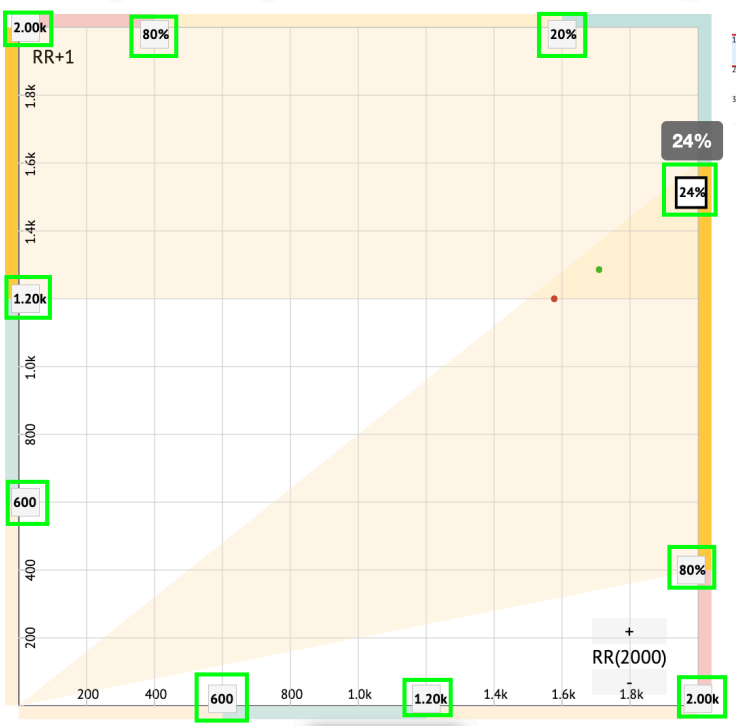


The user is enabled to change the length of filter element by moving the filter elements borders by clicking them and moving the cursor:



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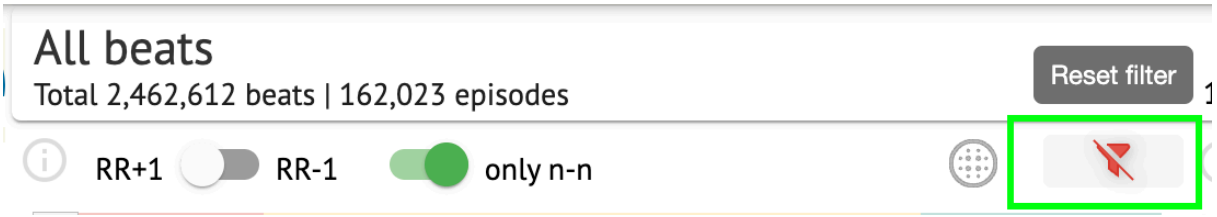
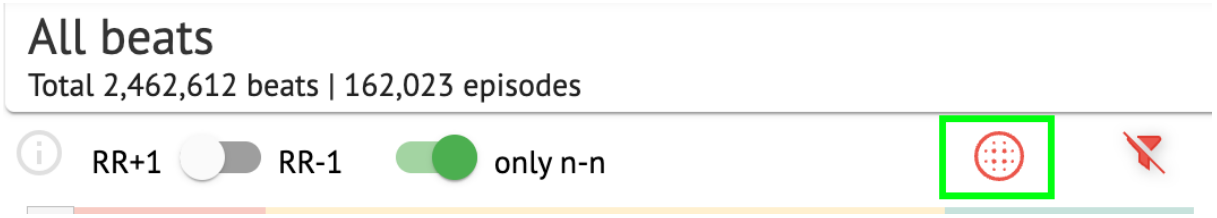
Filtered beats are displayed under the Beats list:

The option to reset filter is available under **Reset filter** button:



When filtered and selecting the single beat, the option to revert to a filter view is available under the following button:



11.5.2.3 Beats list

Beats, selected under the **Side editing bar** or **Poincare plot** are displayed under the Beats list:

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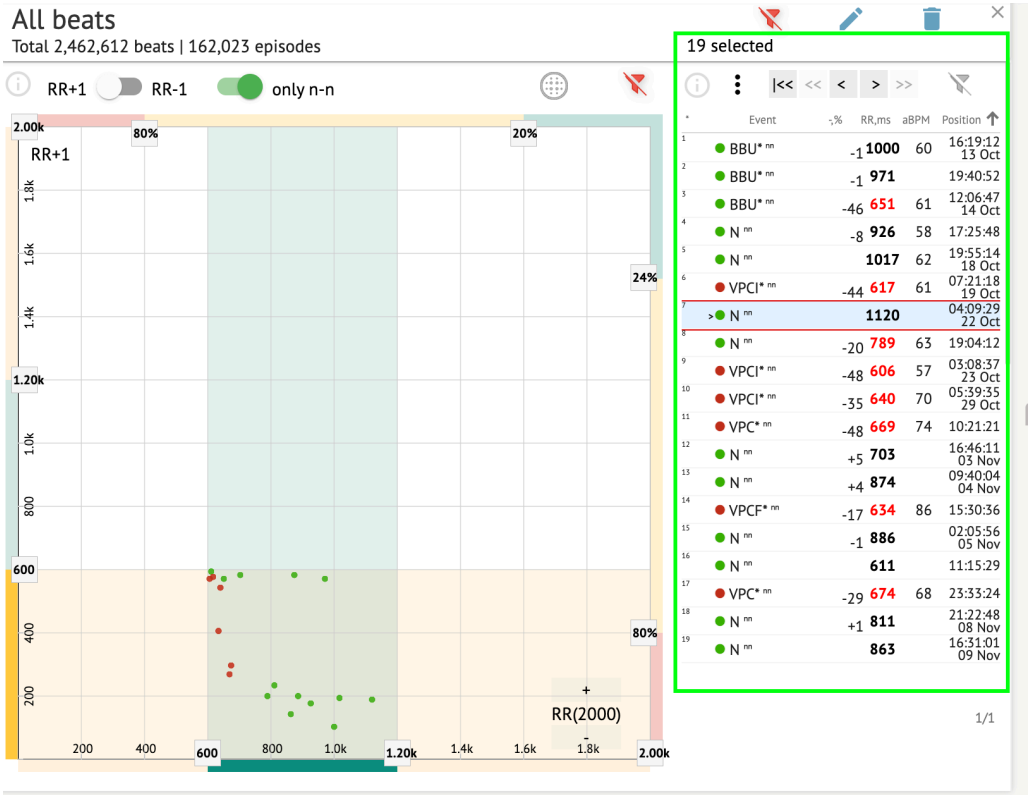

Setting	Description
*	Indicates the number of the beat within the beats under the Poincare plot.
Event	Indicates the name of the annotation correspondent to the beat.
-,%	Indicates the difference in % between the beat and the beat which is left to the beat.
RR,ms	Indicates the distance in ms between the beat and the beat which is left to the beat.
aBPM	Indicates the average BPM of the beat (calculated for the 6 seconds).
Position	Indicates the position (time) of the beat location on the ECG recording

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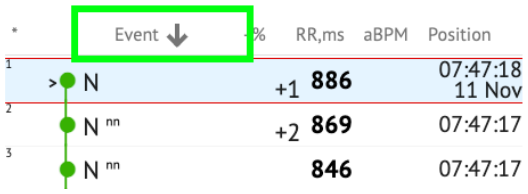
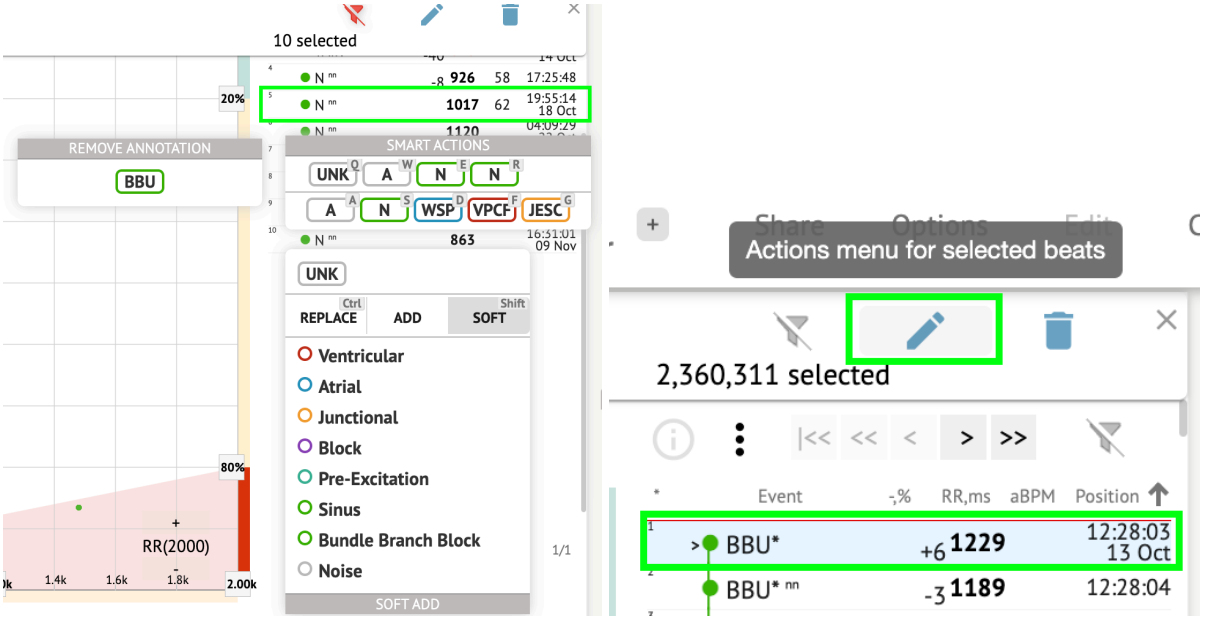
The user is enabled to filter the settings in ascending and descending order by clicking on the setting in the column:



The option to select beat is available by clicking on the beat. The following options available to navigate within beats:

- `>` (Spacebar)- enables to select the next beat;
- `<` (CTRL + Spacebar) - enables to select the previous beat;
- `>>` - enables to select the next twentieth beat;
- `<<` - enables to select the previous twentieth beat;
- `|<<` - enables to select the first beat.

The option to access editing menu of the beats under **Beats list** is available by clicking the right button while selecting the beats, or via **Edit** button:

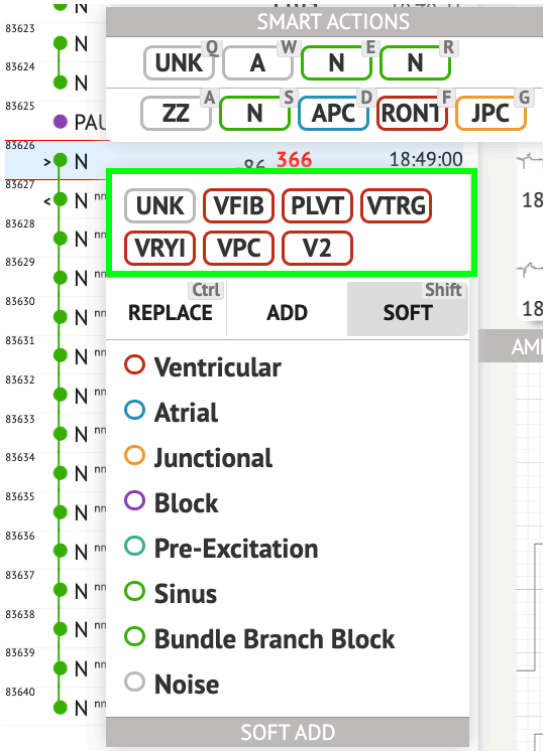


11.5.2.4 Smart actions

Smart Actions - the Editing menu, enables a user to manage beats within the **Viewer** and **Visualizer** sections of **ECG** task.

The following sections available under **Smart Actions** menu:

- Remove annotation - indicates the existing annotation, applied to the beat. When clicking - removes the annotation and classifies the beat as normal. Available only for **abnormal** beats.
- History of **Smart actions**, with the recently applied annotations:



Note. Smart actions history differs within the number of selected beats (1-3, 4+).

- **Replace** - when enabled, allows to replace the beat with another annotation;
- **Add** - when enabled, allows to add the annotation to the beat. When using **Add** option, the added annotation replaces the previous annotation, if applicable. ;
- **Soft** - when enabled, allows to **soft add** the annotation to the beat. When **soft adding**, the added annotation does not replace the previous annotation, if applicable.;

The following annotations available under **Smart actions:**

- **Ventricular** - contains the following annotations:
  VPC - Ventricular Premature Contraction;

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VPCF - Fusion of Ventricular And Normal Beat;
VPCI - Ventricular Interpolated Beat;
RONT - R-On-T Premature Ventricular Beat;
VESC - Ventricular Escape Beat;
V2 - Ventricular Couplet;
V3 - Ventriculat Triplet;
VBL - Ventricular Bigeminy;
VTRG - Ventricular Trigeminy;
VFIB - Ventricular Fibrillation;
VFLU - Ventricular Flutter;
VTDP - Torsades De Pointes Ventricular Tachycardia;
MOVT - Monomorphic Ventricular Tachycardia;
PLVT - Polymorphic Ventricular Tachycardia;
VRYI - Idioventricular (Ventricular Escape) Rhythm;
VAIR - Accelerated Idioventricular Rhythm;

- **Atrial** - contains the following annotations:
  APC - Atrial Premature Contraction;
  ABER - Aberrated Beat;
  NPW - Non-Conducted P-Wave (Blocked);
  AESC - Atrial Escape Beat;
  A2 - Atrial Couplet;
  A3 - Atrial Triplet;
  ABI - Atrial Bigeminy;
  ATRG - Atrial Trigeminy;
  AFIB - Atrial Fibrillation;
  AFLU - Atrial Flutter;
  PAT - Paroxsysmal Atrial Tachycardia;
  MAT - Multifocal Atrial Tachycardia;
  AAT - Automatic Atrial Tachycardia;
  AERY - Atrial Ectopic Rhythm;
  WSP - Wandering Sinus Pacemaker Within The Sinus Node;
  ARYU - Upper Atrial Rhythm;
  ARYM - Middle Atrial Rhythm;
  ARYL - Lower Atrial Rhythm;
- **Junctional** - contains the following annotations:
  JPC - Junctional (Nodal) Premature Contraction
  JESC - Junctional (Nodal) Escape Beat
  J2 - Junctional Couplet;
  J3 - Junctional Triplet;
  JBI - Junctional Bigeminy;
  JTRG - Junctional Trigeminy;
  JT - Junctional Tachycardia;
  RECP - AV Reciprocating Tachycardia;

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RNTR - Reentrant AV Nodal Tachycardia;
WAP - Wandering Pacemaker From The Sinus Node To (And From) The A-V Node;
IRYE - AV Junctional (Nodal) Escape Rhythm;
IRYA - Accelerated Av Junctional (Nodal) Rhythm;

- **Block** - contains the following annotations:
  AV1 - First Degree AV Block;
  AV2I - Second Degree AV Block Type I;
  AV2II - Second Degree AV Block Type II;
  AV3 - Third Degree AV Block;
  AVDI - AV Dissociation With Interference;
  AVDS Isorhythmic AV Dissociation;
  AVDC - Complete AV Dissociation;
  SA2I - Second Degree SA Block Type I;
  SA2II - Second Degree SA Block Type II;
  SA3 - Third Degree SA Block;
  PAUS - Pause;
  AV2 - Second Degree Av Block;
- **Pre-Excitation** - contains the following annotations:
  WPWA - Wolf-Parkinson Type A;
  WPWB - Wolf-Parkinson Type B;
  LGL - Lown-Ganong-Levine Syndrome.
- **Sinus** - contains the ARHY - Sinus Arythmia annotation;
- **Bundle Branch Block** - contains the following annotations:
  BBB - Bundle Branch Block Beat (Unspecified);
  LBB - Left Bundle Branch Block Beat;
  LBBI - Incomplete Left Bundle Branch Block Beat;
  RBB - Right Bundle Branch Block Beat;
  RBBI - Incomplete Right Bundle Branch Block Beat;
  BBLA - Left Anterior Fascicular Block Beat (Common);
  BBLP - Left Posterior Fascicular Block Beat (Rare);
  BBBI - Bifascicular Block Beat;
  BBTI - Trifascicular Block Beat
  BBBL - Bilateral Bundle-Branch Block Beat
  BBU - Intraventricular Conduction Disturbance (Non-Specific Block)
- **Noise** - contains the following annotations:
  UNK - Unclassifiable Beat;
  ZZZ - Noise (No Signal);
  Z - Noise Moderate;
  ZZ - Noise Severe;
  A - Artifact.

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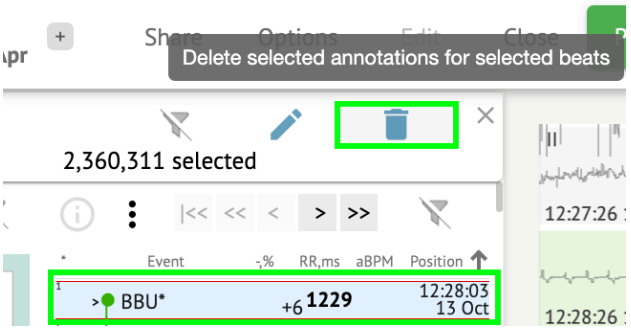
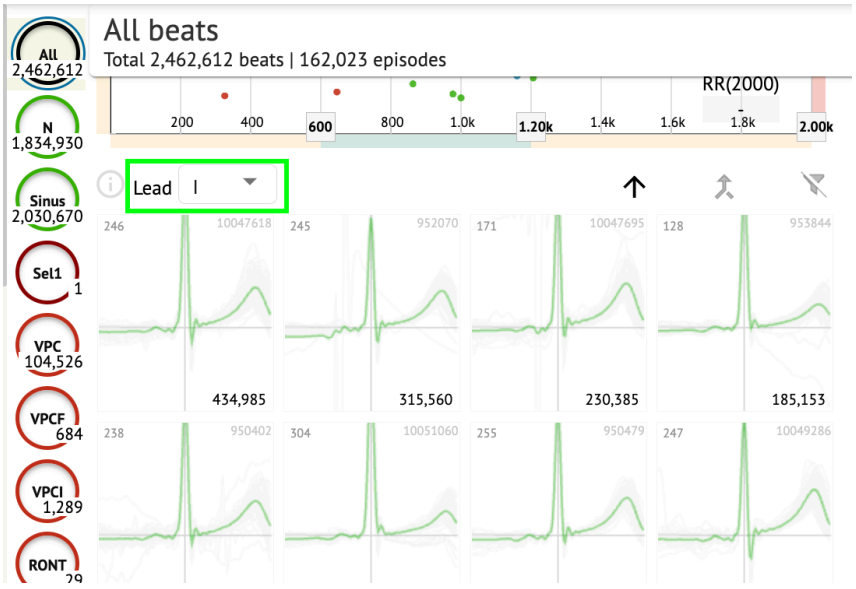
Visualizer: The option to remove annotation is available by selecting the beat > **Delete selected annotations for selected beats** button:



11.5.2.5 Beats clusters panel

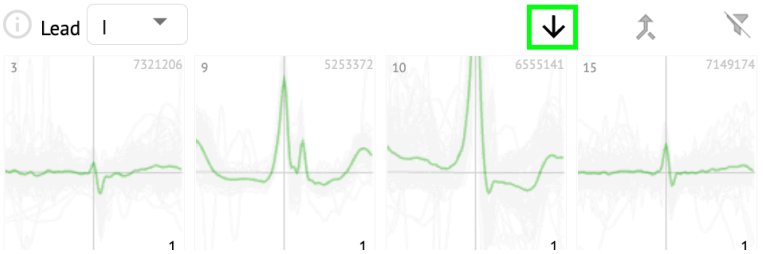
Under the clusters panel, the user is enabled to select clusters of the channels to be displayed the **Poincare plot**.

The option to select channel is available under the **Lead** dropdown:

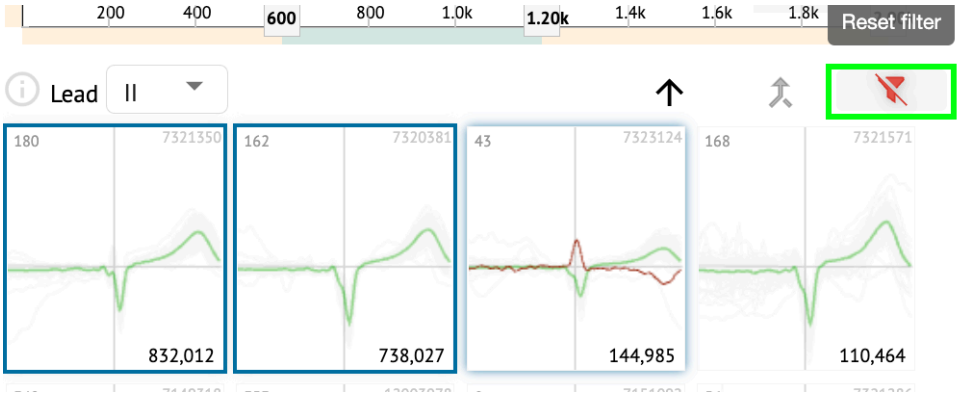


The option to select cluster is available by clicking on the available cluster:

The number on cluster indicates the number of beats within the cluster.
The user is enabled to filter clusters by the beat number under the following button:

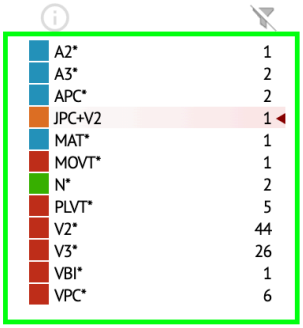


The user is enabled to multi select the cluster by clicking SHIFT and selecting the clusters.
The option to reset the selection filter of the clusters is enabled under the **Reset filter** button:

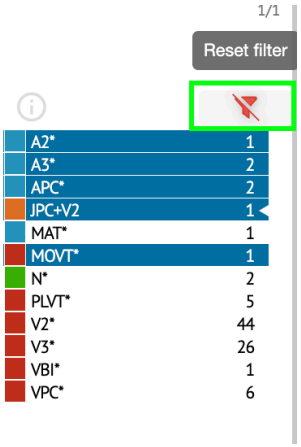


11.5.2.6 Beats cross annotations list

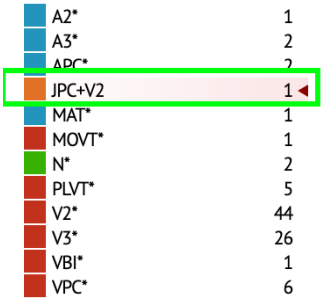
Under the **cross annotations list**, beats are grouped by the events (annotations), and the quantity:



The user is enabled to select the events by clicking on them. The option to reset the selection is available under the **Reset filter** button:



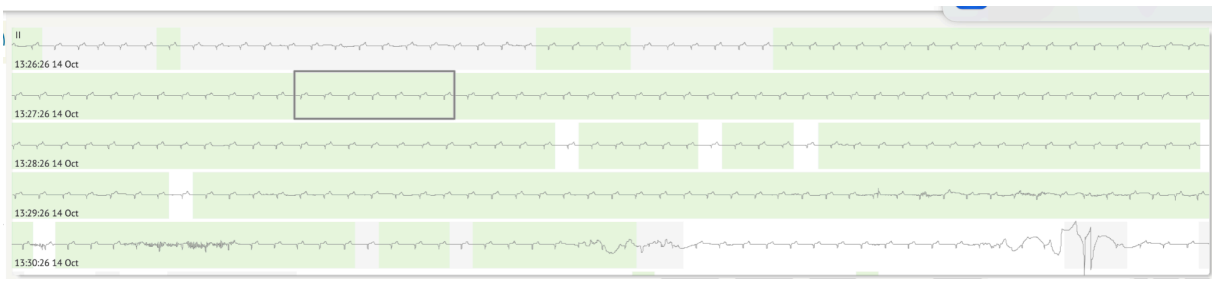
XOresearch Cardio.AI™ indicates the cross-annotations with the following indication:



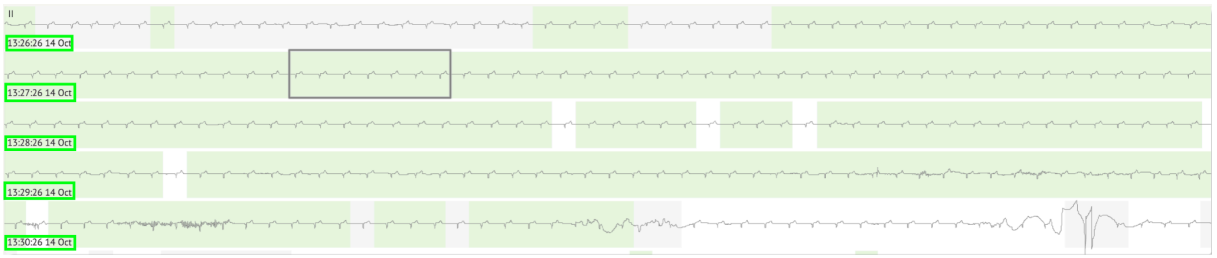
The cross-annotations must be reviewed by the healthcare professional.

11.5.3 ECG Viewer Previewer

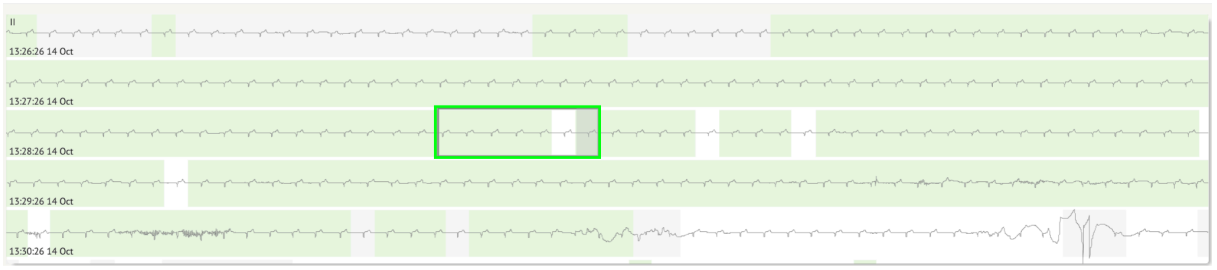
Previewer of the ECG viewer displays the area in which multiple hearts beats are included:



When enabled in options, Previewer includes the color coded annotations.
The left side of each row displays the date and time of the recording section:



The user is enabled to navigate via the Previewer by clicking on row area:



11.5.4 ECG Viewer Visualizer

Under ECG Viewer Visualizer, the user is able to observe and manage beats and annotations correspond to Previewer and Editor.

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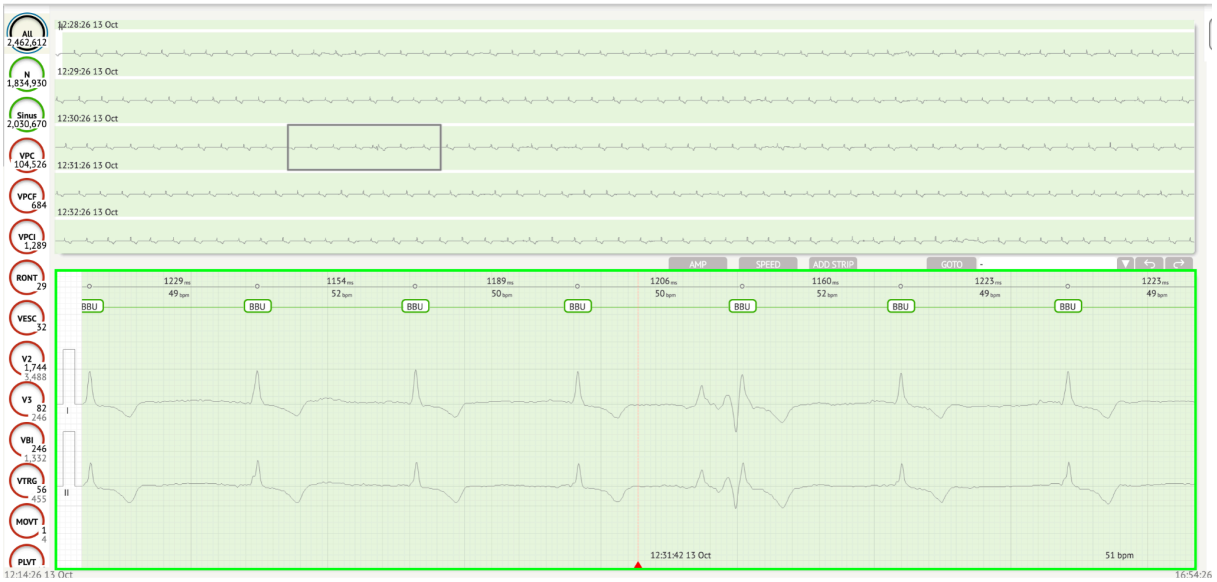

Detailed ECG data section contains the preview section of the ECG divided into parts for each minute of the ECG recording for the whole ECG recording period:

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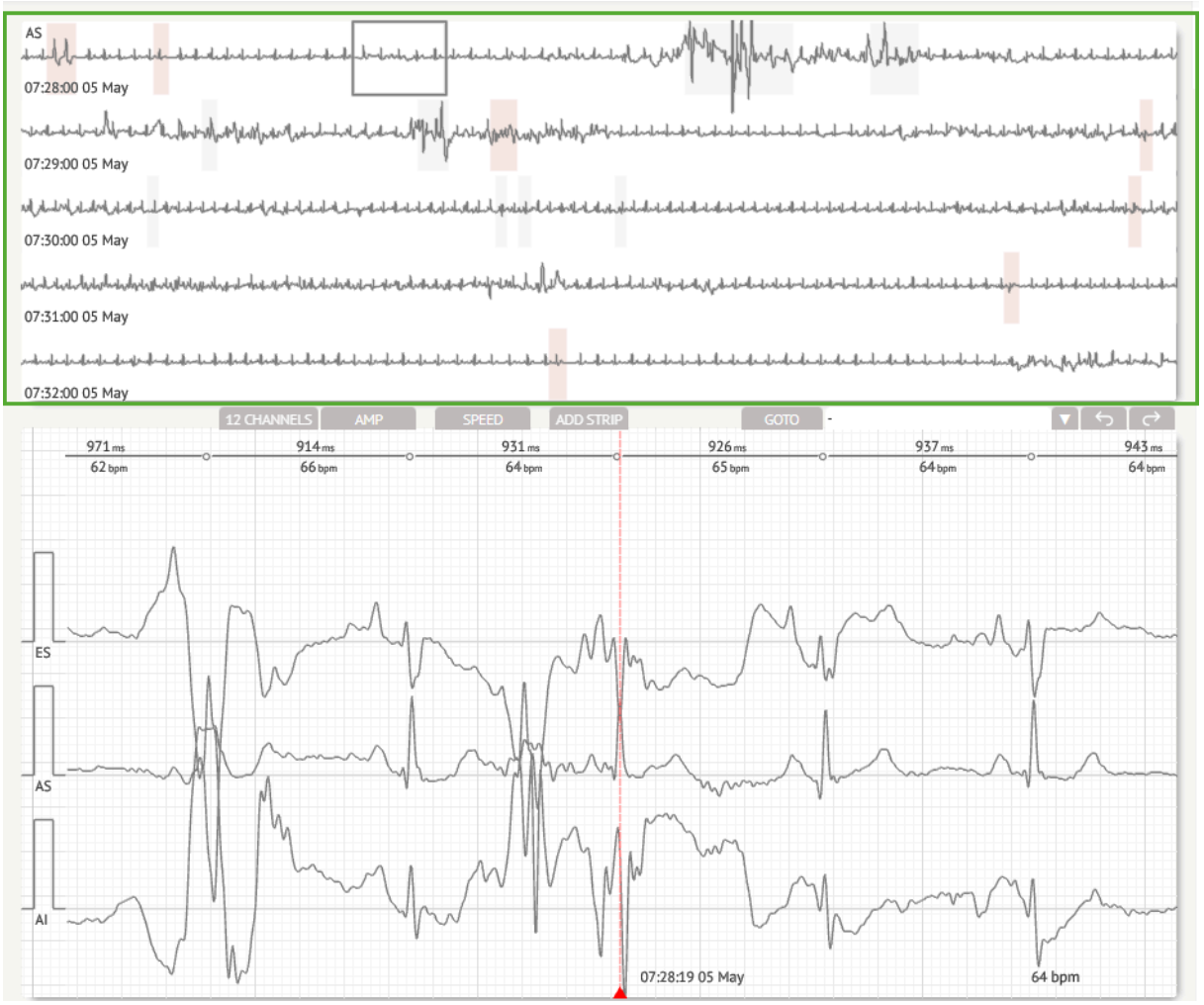

The user is enabled to choose the period by scrolling and choosing the required period. Chosen period is highlighted at the bottom detailed viewer section:

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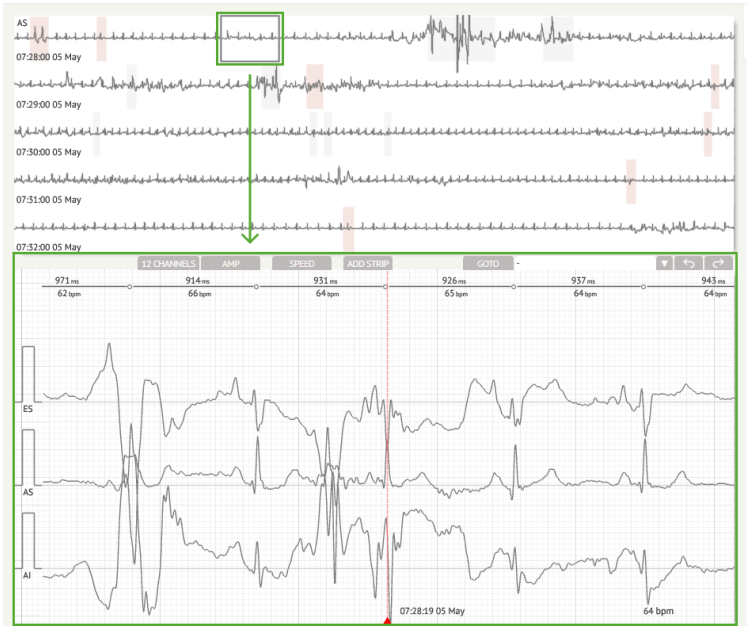
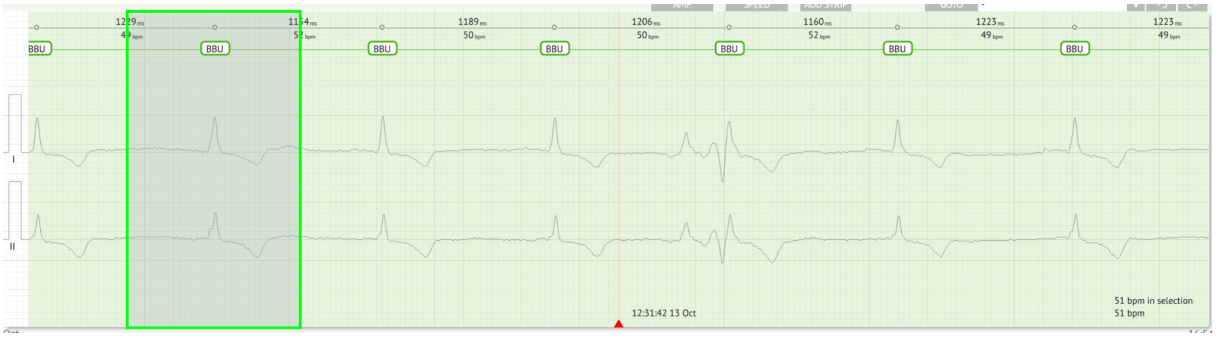


The option to select a beat is available by clicking on the beat



The applicable annotation to the beat set by XOresearch Cardio.AI™ is available at the upper side of the beat, and shows the name by hovering the cursor above:

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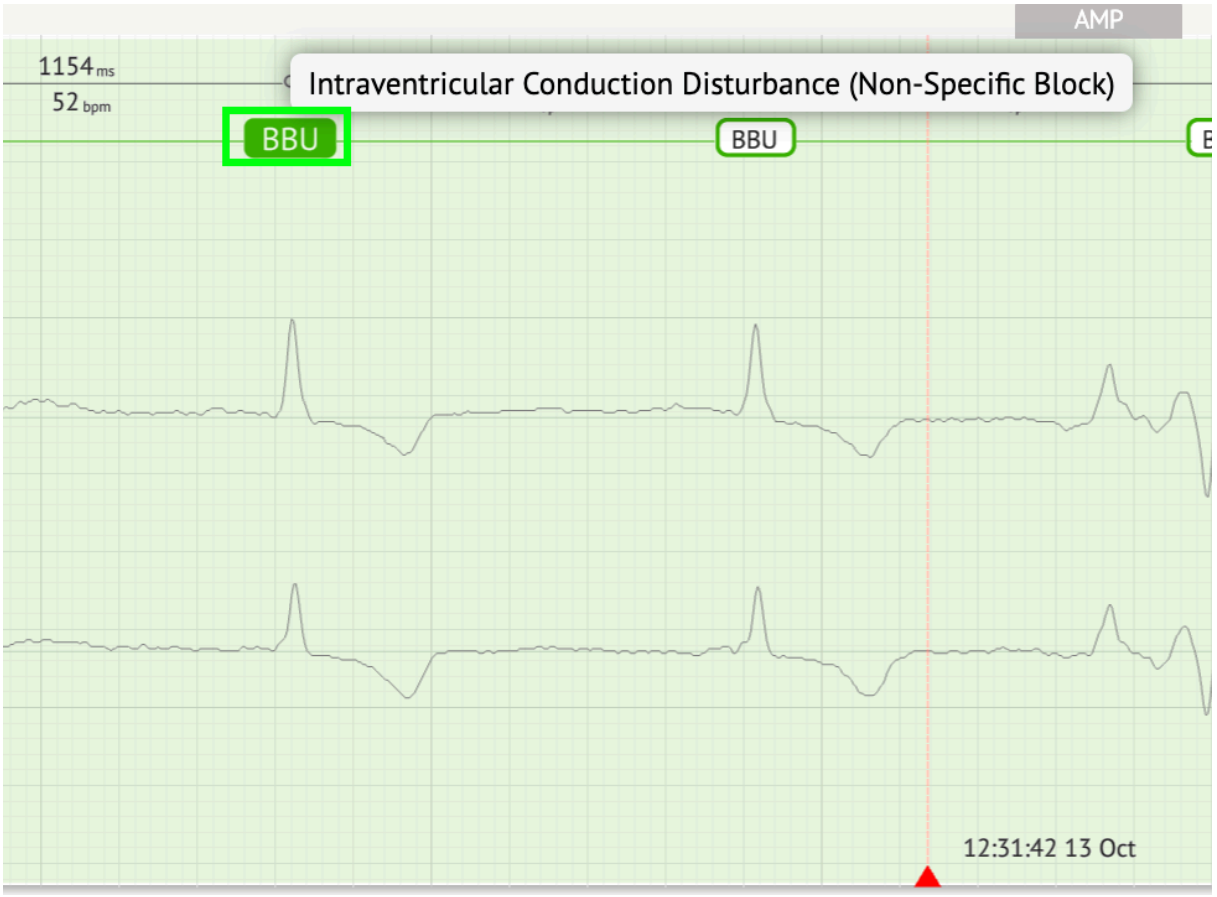

At the visualizer, there is a line at the top: a parameter at the top of the line indicates the distance between the beat and the one on the left; a parameter at the bottom indicates the average BPM:

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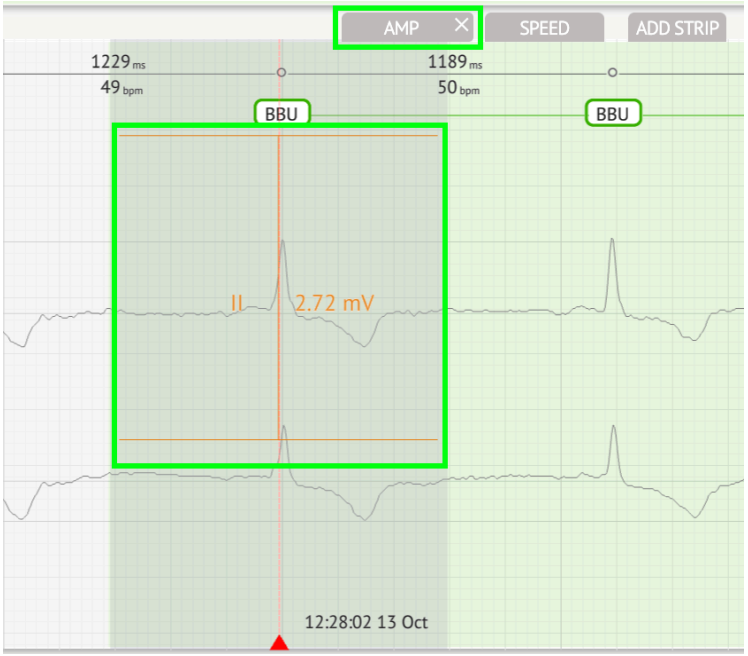
Under Visualizer, the user is enabled to measure the AMP by clicking the beat **>** clicking **AMP** button > Click the left mouse button on the Visualizer beat and swipe the cursor up or down:



The user is applicable to set up several AMP measurements. The option to remove AMP measurements is enabled by clicking the X button under **AMP** button.

Under Visualizer, the user is enabled to measure the speed by clicking the **Speed** button > Click the left mouse button on the Visualizer beat are and swipe the cursor left or right:

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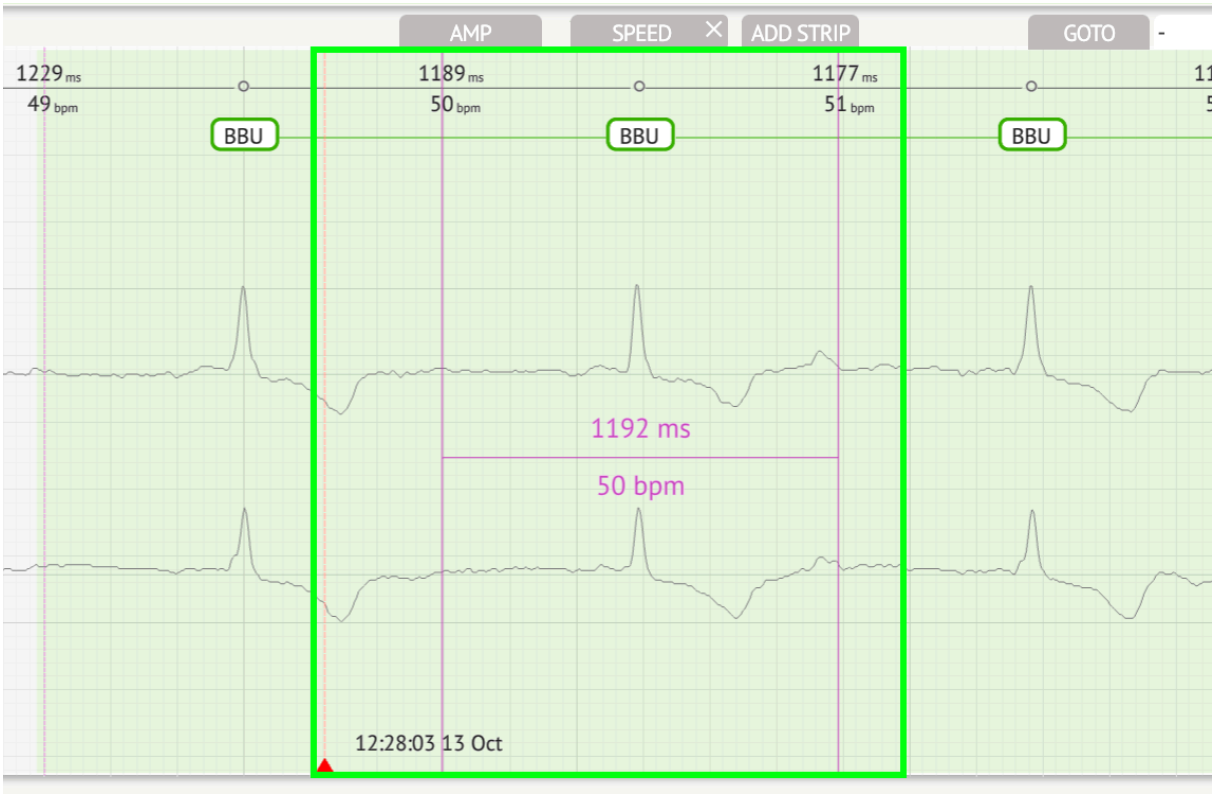
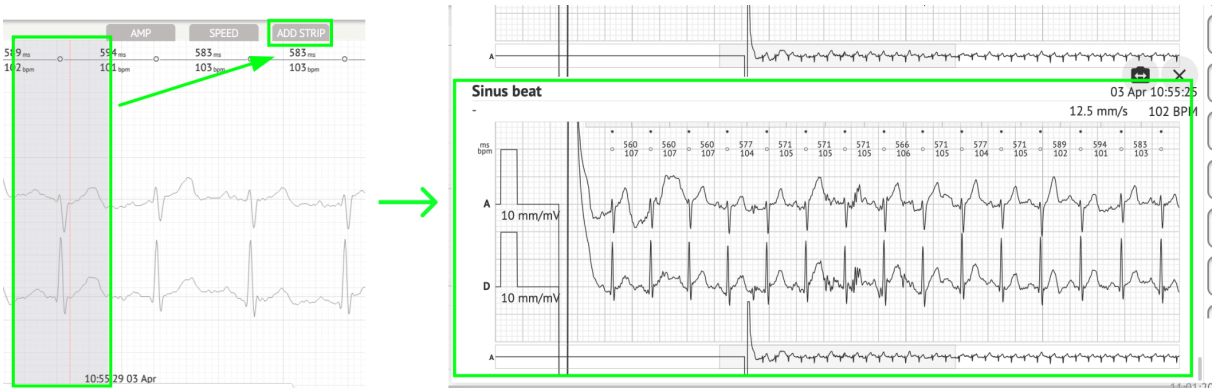


The user is applicable to set up several speed measurements. The option to remove Speed measurements is enabled by clicking the X button under **Speed** button.

The user is enabled to add a strip of the beat to the report by selecting the **beat** > **Add stip** button:



The option to navigate to a certain time / sample is available under **Goto** button > Select **Date** and **Time** > Enter the **Sample** number > **Go** button:

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The option to view PQRST measures recognised by AI is available by double clicking on the beat:

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The option to access Editing menu is available by clicking on the right button at the beat:

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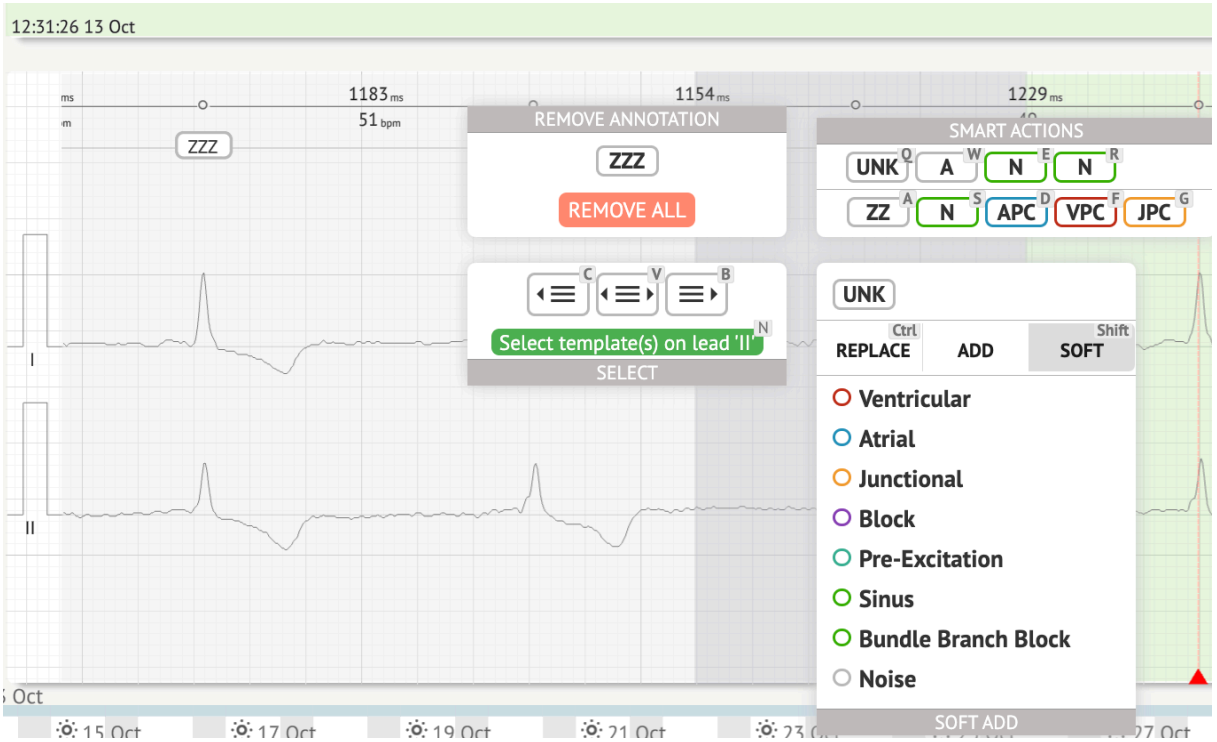

Under Editing menu, the user is enabled to select the beats by the rhythm regularity. The following actions available:

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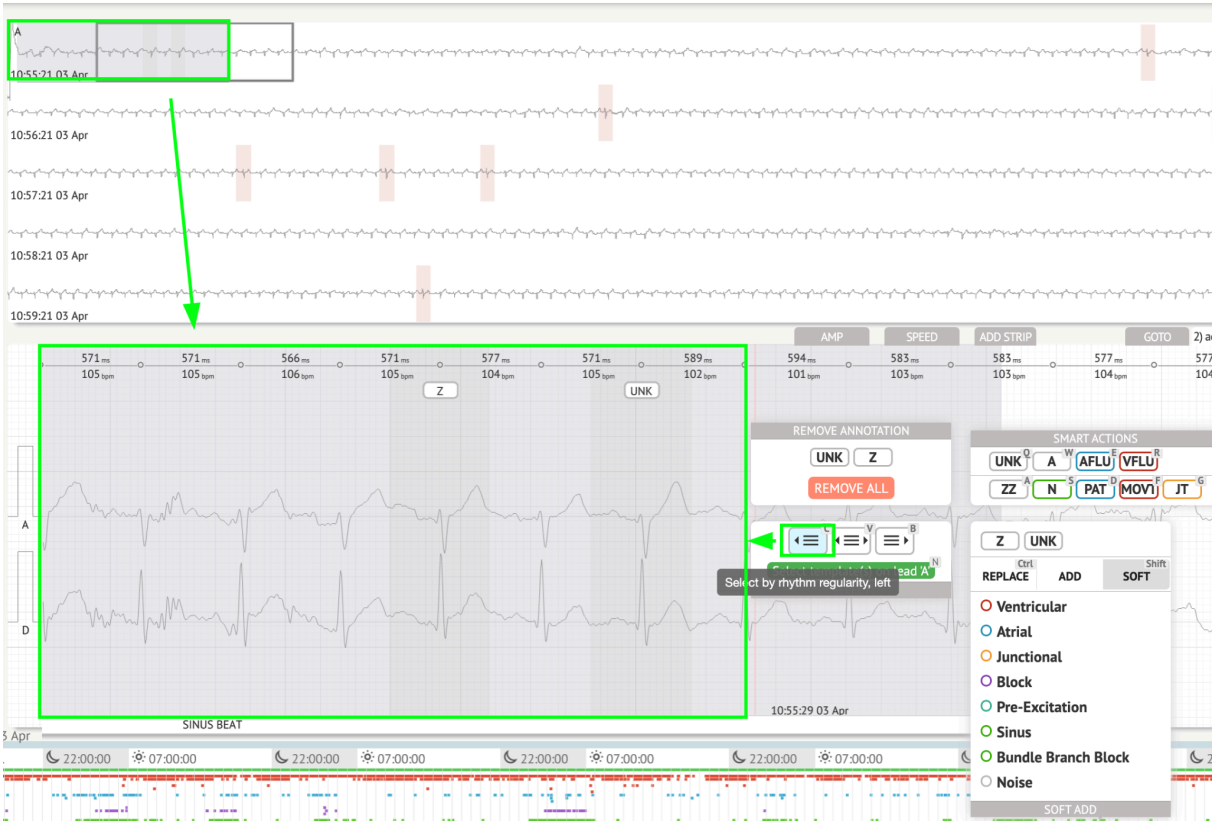
- Select by rhythm regularity, left:



- Select by rhythm regularity:

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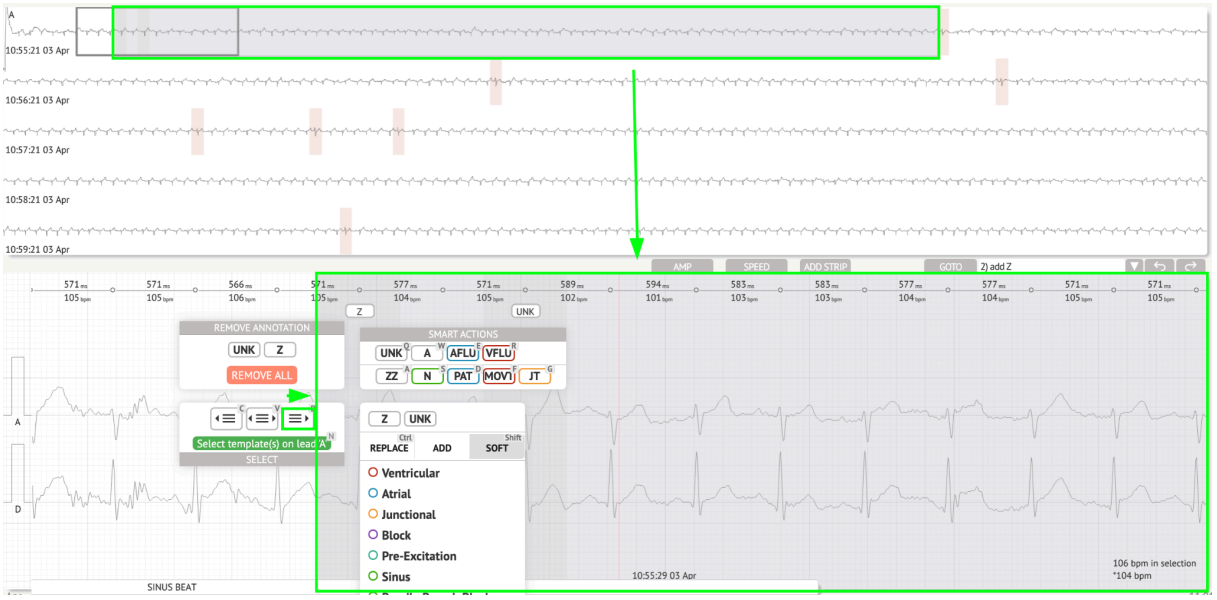
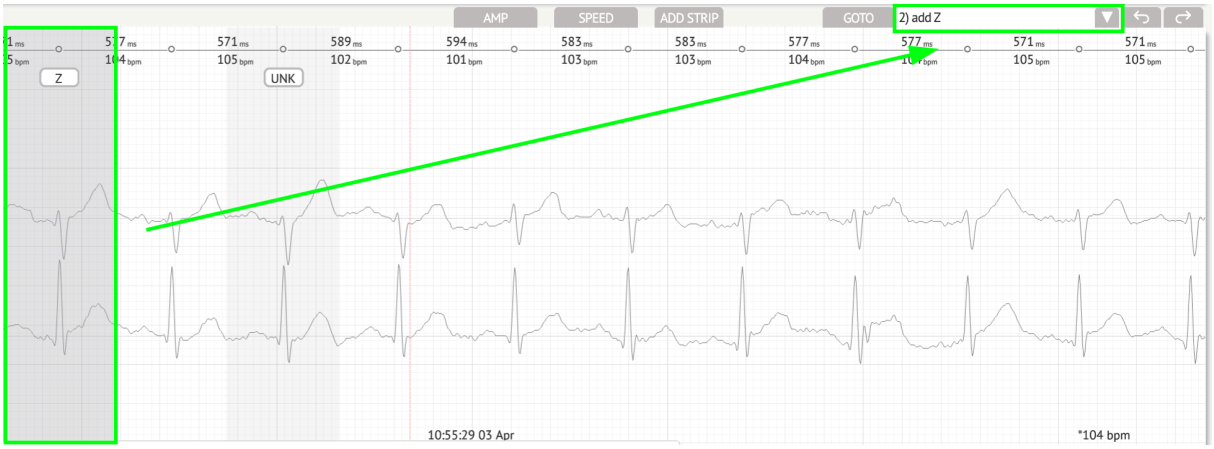
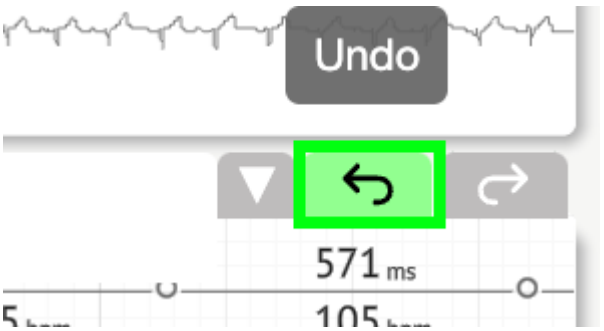
- Select by rhythm regularity, right:



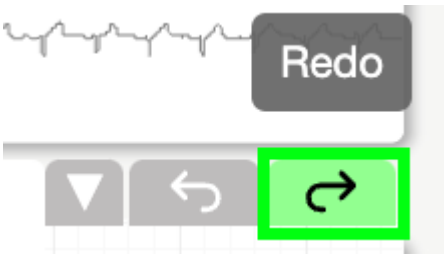
The user is enabled to browse the history of recent actions under the following field:



The option to undo changes is available under **Undo** button:



The option to redo changes is available under **Redo** button:



11.5.5 ECG Viewer bird view

XOresearch Cardio.AI™ enables a user to check and navigate to the events during the recorded ECG day and night periods via bird view:

Time appears above the bird view section when hovering over the selected fragment.

11.6 ECG data report

11.6.1 ECG data report overview

The option to view report of the ECG is available under Overview button:

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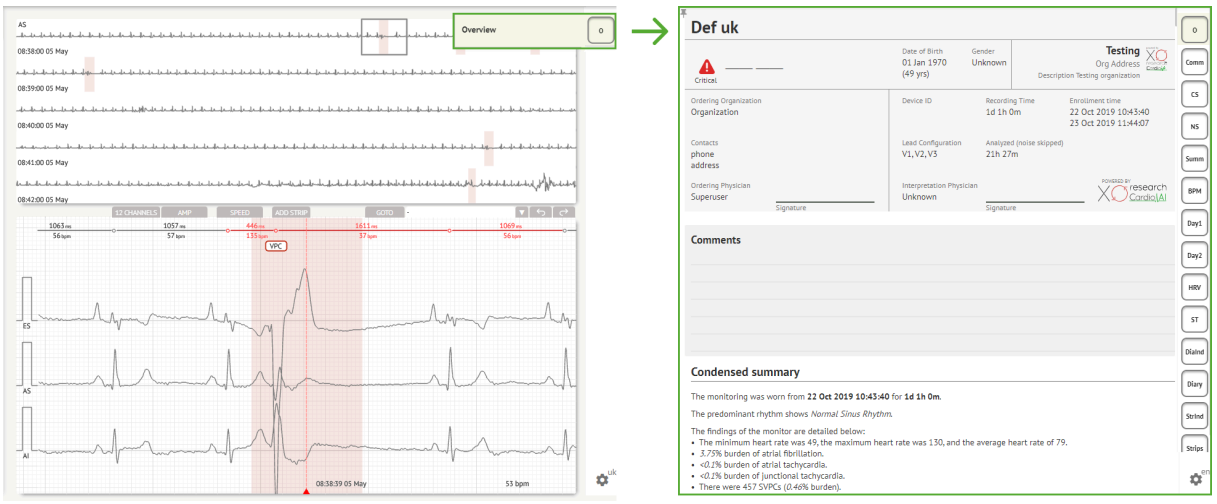

Report is divided into the following sections:

- Personal data section - contains the following information of patient: date of birth, gender, ordering organization, contacts, ordering physician, signature, device id, lead configuration, interpretation physician, recording time, amount of analyzed time, enrollment time;
- Comments section - contains the optional comments; The option to write comments is available by clicking on the **Comments** field and entering the text:

- Condensed summary - provides a concise overview of key monitoring data for quick reference. It includes essential information about the monitoring duration, predominant rhythm, heart rate statistics, and major findings, such as ectopic beats, blocks, and tachycardia events. The purpose is to offer a high-level snapshot of the monitoring results for easy comprehension.
- Narrative summary - offers a detailed and chronological account of the monitoring session. It presents a comprehensive analysis of the data, including specific events, their durations, and their timestamps. The purpose is to provide healthcare professionals with a thorough understanding of the patient's cardiac activity during the monitoring period, allowing for more in-depth evaluation and decision-making. It also highlights notable episodes and deviations from normal rhythm and presents relevant metrics and measurements.

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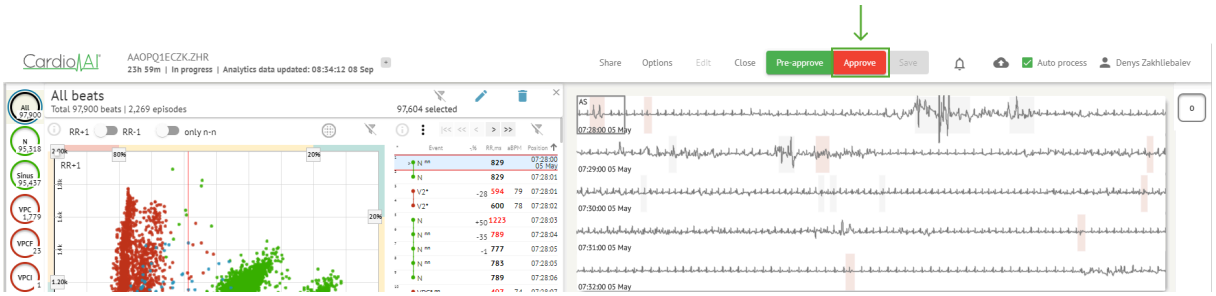
- Summary - provides a comprehensive and structured overview of the key findings and metrics derived from the cardiac monitoring session. It serves as a consolidated report that healthcare professionals can reference to quickly assess the patient's cardiac health and identify any notable deviations from the norm.
- Daily BPM - provides a BMP (beats per minutes), including ectopic beats.
- BMP (sinus) - provides a BMP on sinus beats, excluding ectopic beats;
- PQRST (sinus) - provides a information about PQ interval, QRS complex, QT/QTc intervals
- Annotations list - provides details of different annotations, according to the timeline. The explanation of the abbreviations is placed below the list. Every annotation has it's own features.
- Heart Rate Variability (sinus) - provides various aspects of heart rate variability and sinus rhythm. They provide insights into the health of the cardiovascular system and the variability in time between successive heartbeats.
- ST-segment and T-wave type - provides the length and direction of ST segment and determines the type of T-wave.
- Strip Index table - contains information about specific cardiac events, including their labels, notes, associated heart rates, and timestamps;
- Strips section - provide additional details or data related to specific events or conditions mentioned earlier. It includes heart rate measurements (in BPM) and timestamps for each event.
- Patient's diary index table - contains information about specific cardiac events highlighted by the patient, including their labels, notes, associated heart rates, and timestamps;
- Patient's diary strips - provides additional details or data related to specific events highlighted by the patient, or conditions mentioned earlier. It includes heart rate measurements (in BPM) and timestamps for each event.

The option to approve report is available under **Approve** button:



The option to export the report is available under Organization view after approving the report > **Download report** button:

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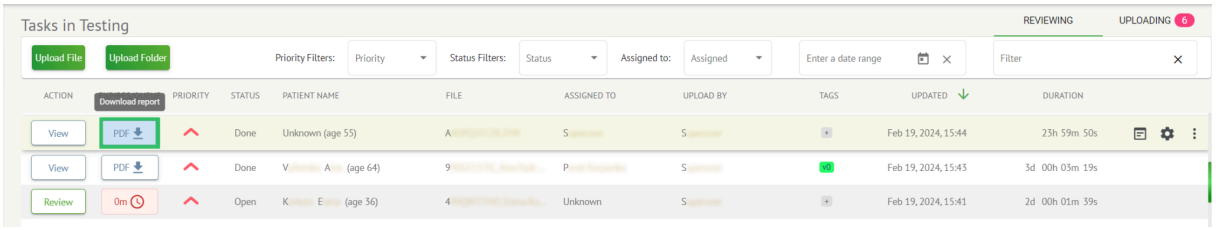

The user is able to navigate to heartbeat sections of interest by clicking on cells in the report:

The user is able to observe the data from the ECG channels under **Strips** section of the report > Labels. The table of labels is available under **Strip Index** section:

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Strip Index

Label	Note	BPM	Time
Sinus BPM Max			17 Aug 22:14:30
Sinus BPM Min			18 Aug 10:16:31
Atrial Premature Contraction			17 Aug 21:17:26
Junctional (Nodal) Premature Contraction			18 Aug 09:56:16
Aberrated Beat			18 Aug 10:18:05
Non-Conducted P-Wave (Blocked)			18 Aug 17:45:23
Ventricular Premature Contraction			17 Aug 19:52:02
Junctional (Nodal) Escape Beat			18 Aug 14:11:21
Sinus Arrhythmia			17 Aug 19:59:23
Wandering Sinus Pacemaker Within The Sinus Node			18 Aug 13:25:21
Wandering Sinus Pacemaker Within The Sinus Node			18 Aug 13:26:00
Atrial Ectopic Rhythm			18 Aug 14:51:05
Atrial Ectopic Rhythm			18 Aug 14:52:10
Atrial Bigeminy			18 Aug 17:44:41
Atrial Flutter			18 Aug 11:19:03
Atrial Flutter			18 Aug 11:19:34
Atrial Flutter			18 Aug 11:22:15
Atrial Flutter			18 Aug 11:23:42
AV Junctional (Nodal) Escape Rhythm			18 Aug 09:45:47
First Degree AV Block			18 Aug 10:28:29
Second Degree SA Block Type I			18 Aug 17:31:50
Lown-Ganong-Levine Syndrome			18 Aug 11:15:54
Lown-Ganong-Levine Syndrome			18 Aug 11:16:07
Pause			18 Aug 07:55:47
Atrial Couplet			17 Aug 22:32:36
Atrial Triplet			18 Aug 14:07:40
Nonsustained Atrial Flutter			18 Aug 11:17:49
Nonsustained Atrial Flutter			18 Aug 11:18:18
Nonsustained Atrial Flutter			18 Aug 11:18:29
Nonsustained Atrial Flutter			18 Aug 11:27:14

The user is enabled to navigate to the strip by clicking on strip under **Strip Index** table of labels.

By default, the data under **Labels** is being shown from the **ES, AS, AI** channels.

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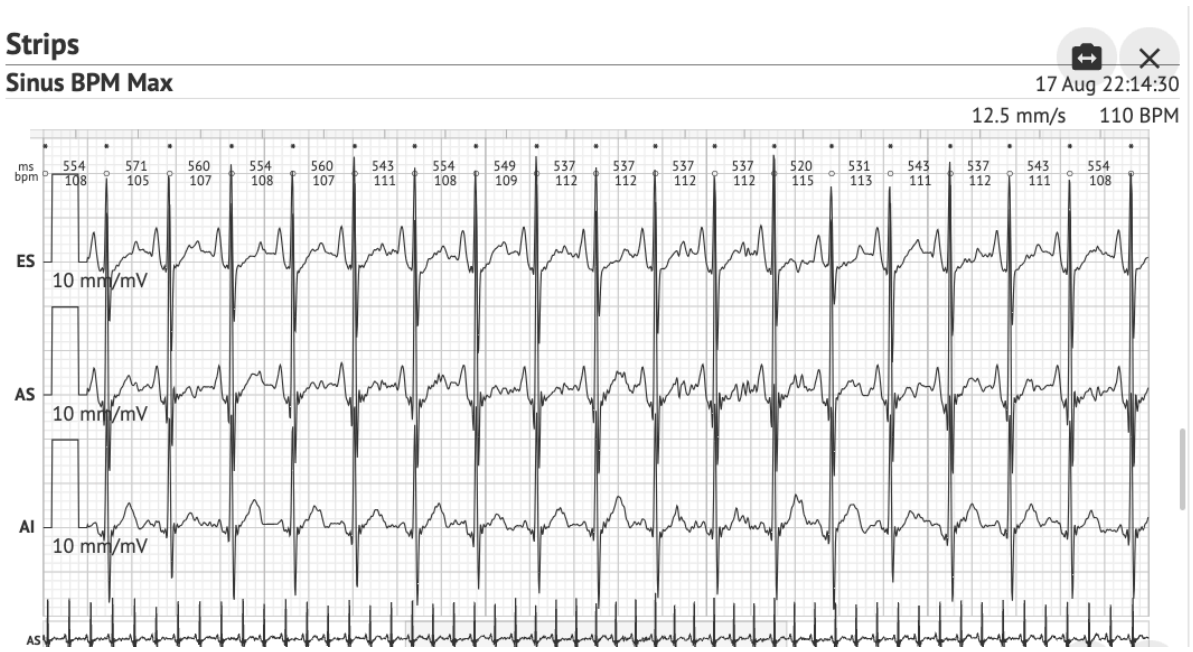

The option to expand the data from all channels is available under button:

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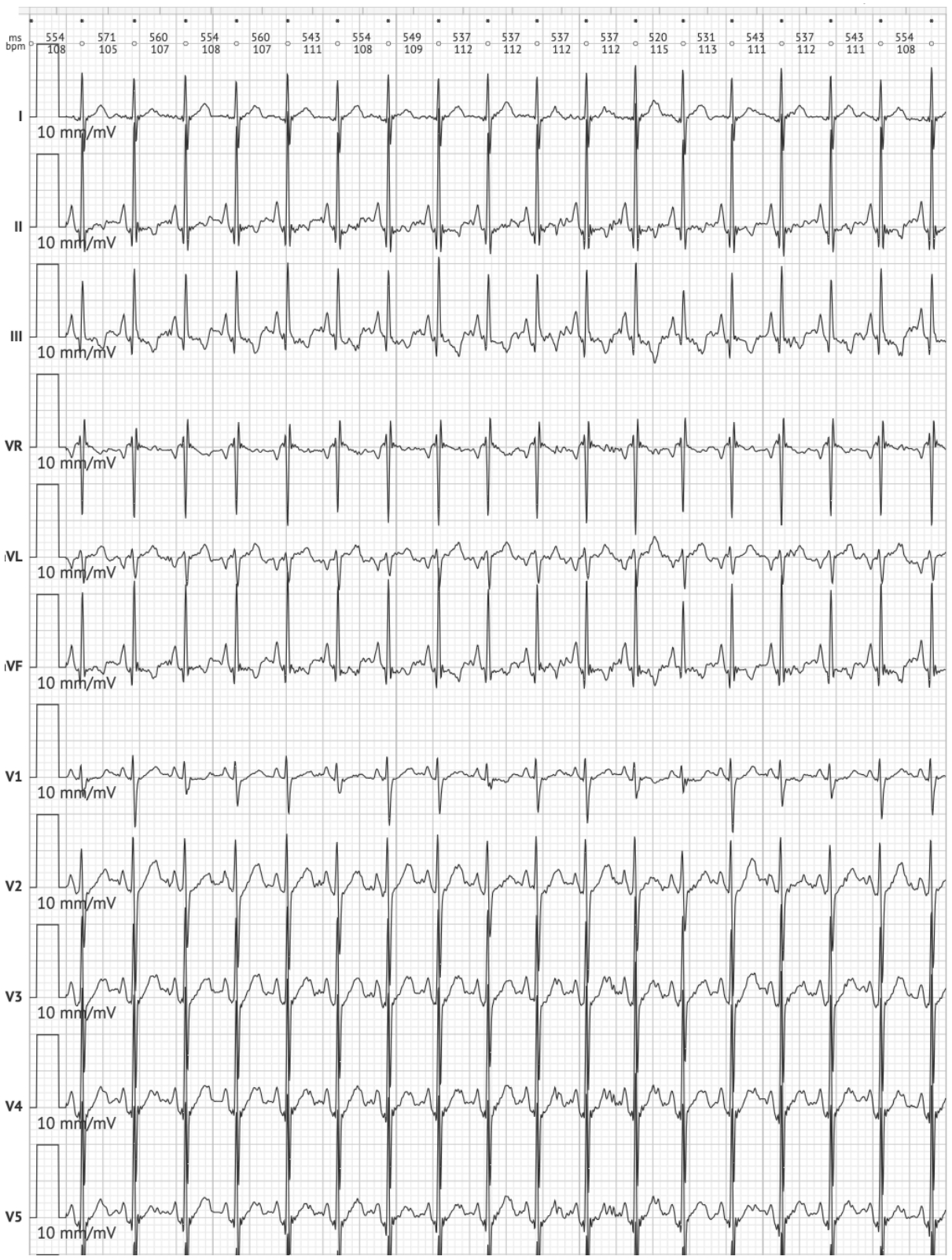
ms
bpm
554 108
571 105
560 107
554 108
560 107
543 111
554 108
549 109
537 112
537 112
537 112
537 112
520 115
531 113
543 111
537 112
543 111
554 108
I
II
III
VR
VL
VF
V1
V2
V3
V4
V5
10 mm/mV

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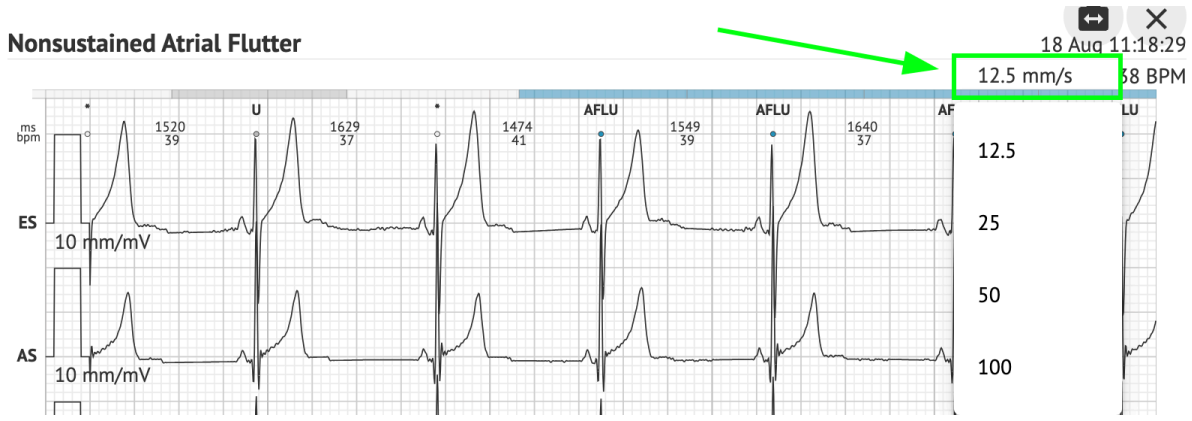
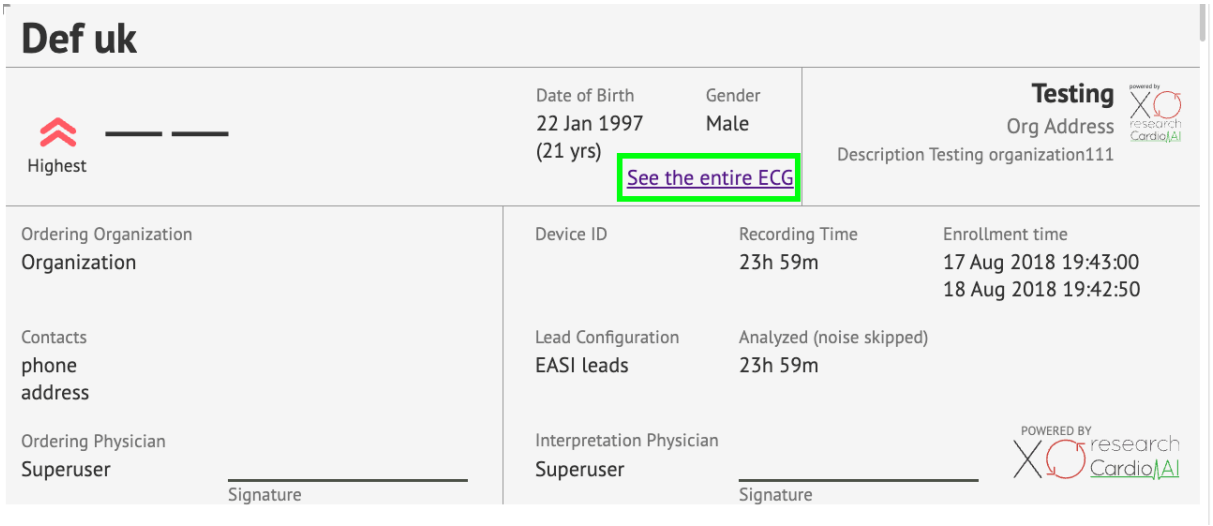
Note. The option to expand the channels is depend on the ECG data source and the availability of channels from the ECG recording device.
By default, the speed is 12.5mm/s. The option to expand the amplitude is available by clicking the entry:



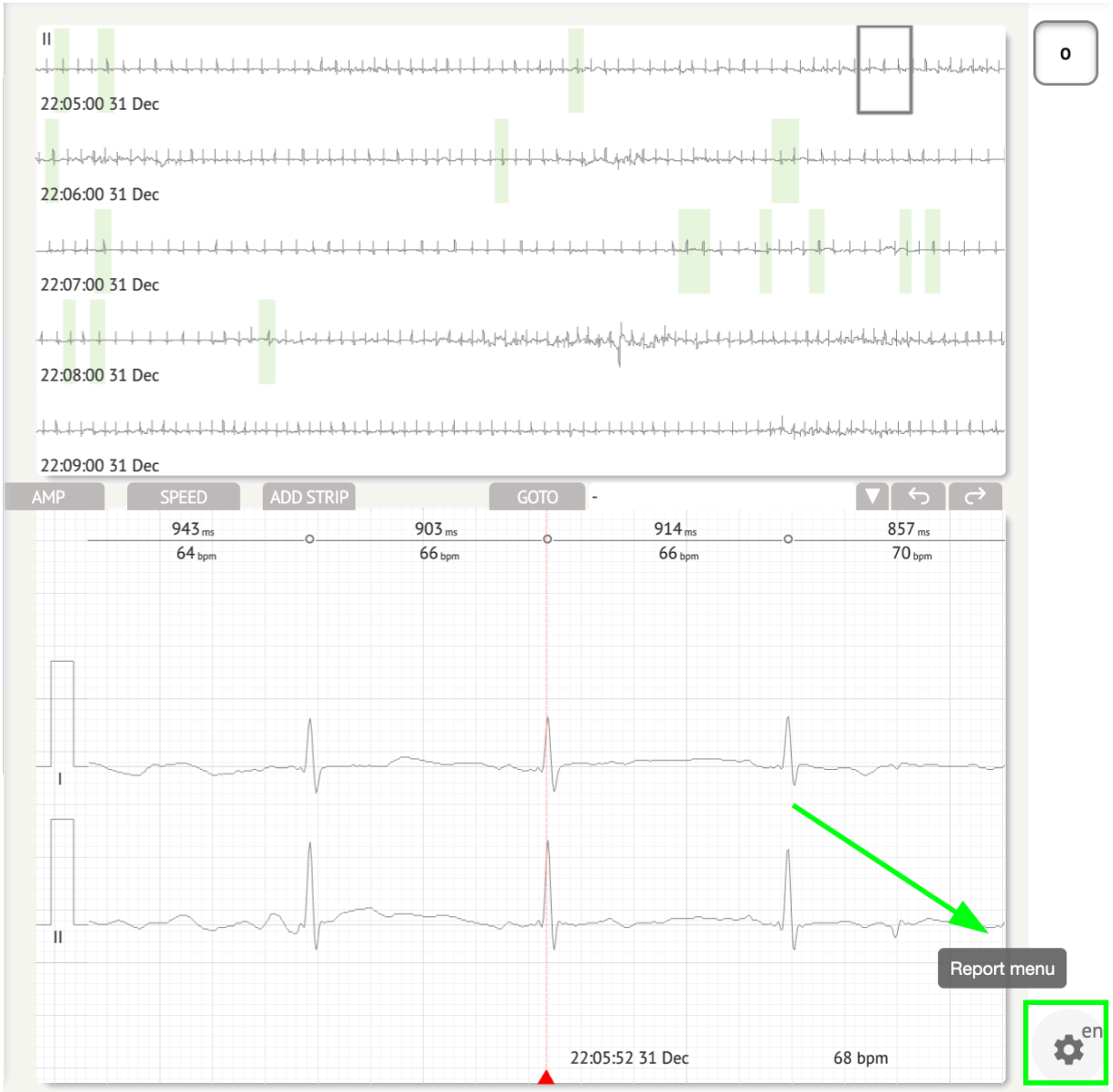
The option to access and share the entire ECG record to observe for the 3rd party person is available under **See the entire ECG** link:



Note. The link is workable within the 90 days since report generation.

11.6.2 ECG data report sections managing

The option to manage ECG data report sections is available under the **Report menu** section:



XOresearch Cardio.AI™ shows the following screen when successful:

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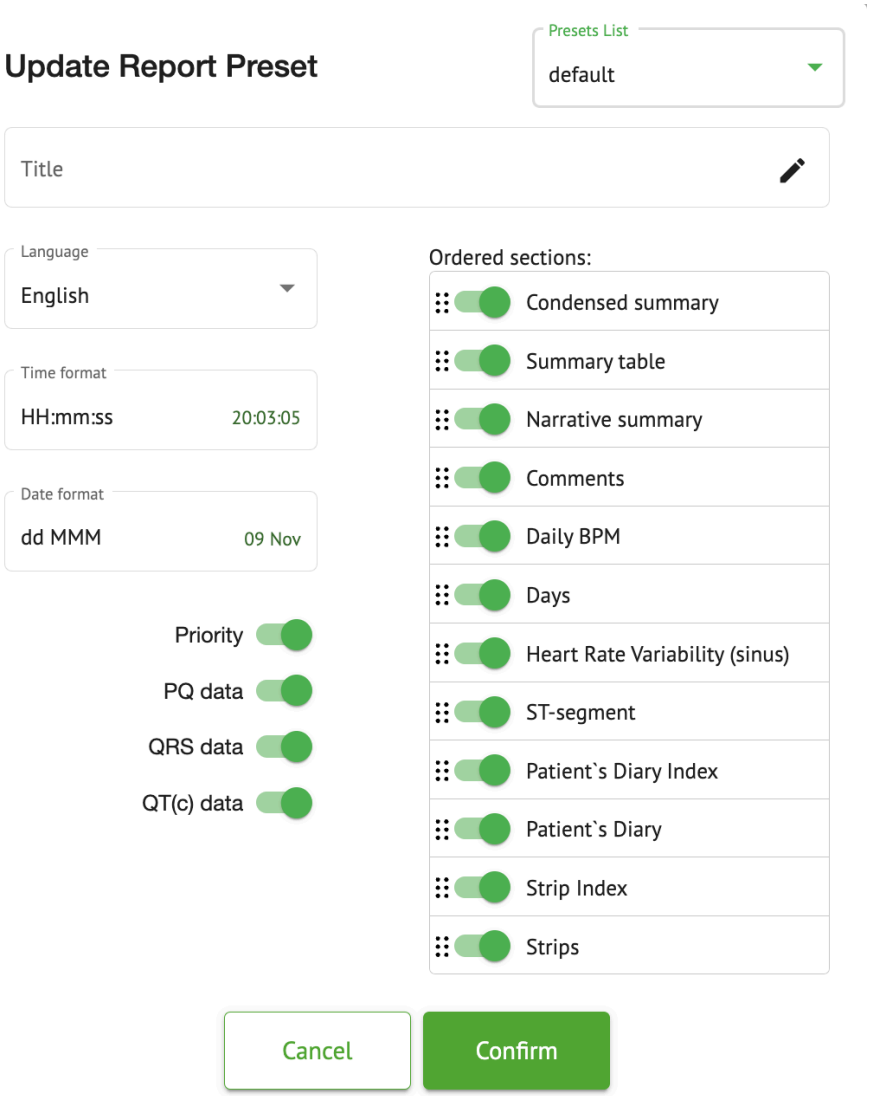

The settings under **Report menu** correspond to the settings under [Report preset configuration](#).

11.6.3 ECG data report editing

XOresearch Cardio.AI™ enables a user to edit the following sections of the report inside the ECG task:

- Condensed summary;
- Narrative summary;
- Comments.

The option to edit the sections above is avalble by clicking the section, or by clicking the **Edit** button:

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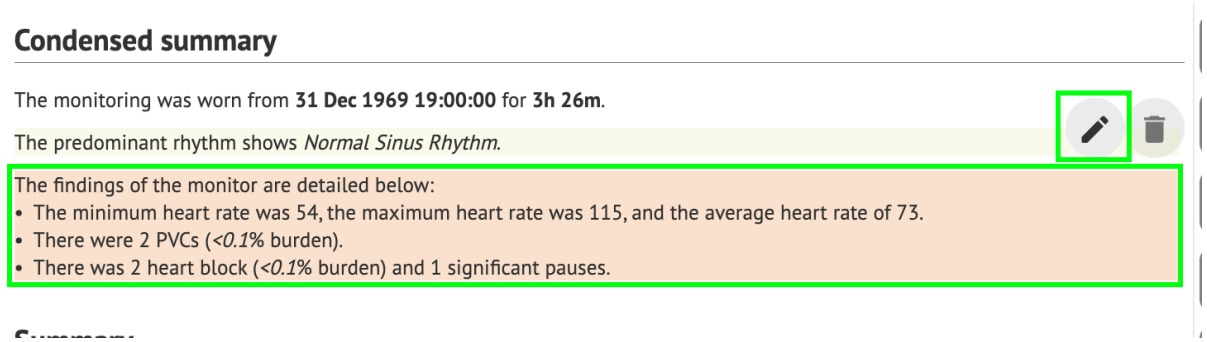
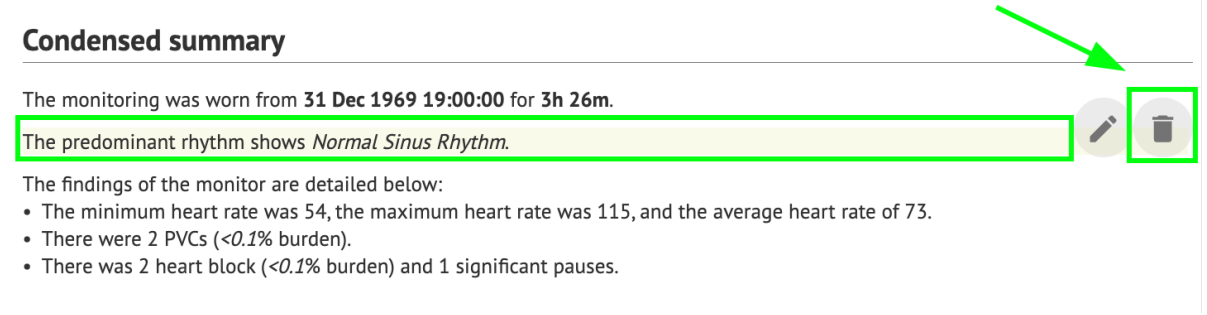


The option to remove the data entry is available by clicking the **Remove** button:



12. Data Input and Output:

Data Input:

- XOresearch Cardio.AI™ accepts ECG file data in the following formats: EDF, BDF.
- Ensure that all input data is accurate and complete;

Data Output:

- XOresearch Cardio.AI™ generates reports based on analysed ECG data and displays it on the screen on purpose. The user is enabled to export this report as a PDF report for sharing with other healthcare professionals.

13. User Authentication and Access Control:

User Authentication: Each authorized user is required to log in using their unique username and password. It is essential to keep login credentials confidential. Login credentials are being provided by the XOresearch SIA directly, via the contact email, or via the contact webform under XOresearch Cardio.AI™ website.

Access Control: The software offers role-based access control, ensuring that users only have access to the features and patient data relevant to their role. Administrators can manage user permissions.

There are 4 types of users to access XOresearch Cardio.AI: Support, Administrator, Editor, and Uploader. A brief description of each of them is given below.

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Support: This is the user responsible for managing organizations (hospitals or clinical settings) and user profiles within these organizations. Only XOresearch personnel can have this type of access.

Uploader: This is a user who can upload ECG data and download the report to be delivered to a patient inside the organization.

ECG Editor: This is a user with Uploader access and a few more permissions.

Administrator: This is the user with an admin role inside a given organization.

User Type	User permissions
Uploader	● Upload ECG records; ● Create tasks based on uploaded ECG records; ● Manage metadata for the created tasks; ● View only the created tasks;
ECG Editor	● Upload ECG records; ● Create and manage tasks based on uploaded ECG records; ● View, edit ECG, create, manage and export reports for the ECG tasks within the organization; ● Manage metadata for the tasks within the organization.
Admin	● Upload ECG records; ● Create and manage tasks based on uploaded ECG records; ● View, edit ECG, create, manage and export reports for the ECG tasks available within the organization; ● Manage metadata for the tasks within the organization; ● Manage users, roles and permissions within the organization.
Support	● Upload ECG records; ● Create and manage tasks based on uploaded ECG records; ● View, edit ECG, create, manage and export reports for the ECG tasks available within the organizations; ● Manage metadata for the tasks within the organizations;

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	• Manage users, roles and permissions within the organization; • Managing the organizations, users, roles and permissions within the software.

Note: allocation of 'customizable' permissions is the responsibility of the health institution's admin.
The Support role is intended to be used only by the XOresearch Cardio.AI™ staff members.

14. Data Security and Privacy:

XOresearch SIA places the utmost importance on the security and privacy of patient data. We employ industry-standard encryption protocols to ensure the confidentiality and integrity of patient data during both transmission and storage. Additionally, our software complies with all relevant data privacy regulations, including but not limited to the Regulation (EU) 2016/679 (General Data Protection Regulation - GDPR) and the Health Insurance Portability and Accountability Act of 1996 (HIPAA). These measures are in place to safeguard patient privacy and data security.

Additional User Security Recommendations:

In addition to the security measures we have implemented, we strongly recommend that users take the following steps to enhance cybersecurity while using XOresearch Cardio.AI™:

Keep Your Login Information Secure: Never share your login credentials, and ensure they remain confidential. Avoid writing down login information or storing it near your computer.

Access Control: Always log out of XOresearch Cardio.AI™ when not actively using it, especially when in shared or public environments.

Regularly Change Your Password: Change your password at the first login and periodically thereafter. Use strong passwords that include a minimum of 8 characters, comprising special characters, numbers, uppercase letters, and lowercase letters.

Avoid Common Passwords: Refrain from using easily guessable passwords, such as simple combinations or common words. Never use the same password for multiple devices or accounts.

Verify Website URLs: Always verify the URL address before logging into any site. Secure websites start with "https," and a green lock symbol should be displayed in the URL bar.

Install Antivirus and Antispyware Software: Protect your computer by installing and regularly updating antivirus and antispyware software.

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Report Suspicious Activity: If you notice any unexpected behavior on your system while using XOresearch Cardio.AI™, please contact our support team. If necessary, we will notify you via email and/or our website if the system faces potential threats that require downtime for resolution.

System Updates: Regularly update your browser used to access the XOresearch Cardio.AI™ and any associated systems to apply the latest security patches. This is crucial to safeguard against newly identified vulnerabilities.

Data Consent: Obtain explicit patient consent before storing or processing data with XOresearch Cardio.AI™, especially for long-term storage or data sharing with other entities. Document consent as part of the patient's medical record.

Anonymization Best Practices: For all identifiable patient data, follow anonymization protocols to prevent unauthorized access. This includes restricting access to only authorized personnel and applying anonymization techniques where applicable, especially when data is shared outside the organization.

Continuous Improvement and User Notifications:

As part of our commitment to security, we continuously monitor cybersecurity threats and make necessary improvements. We will keep you informed of software updates, revisions, or additional security measures through email notifications, ensuring that you have access to the latest safeguards and enhancements.

15. Troubleshooting:

If you encounter technical issues or unexpected errors while using XOresearch Cardio.AI™, please contact our technical support team at getintouch@xoresearch.com.

16. Availability of the Instructions for Use (IFU):

The Instructions for Use (IFU) for XOresearch Cardio.AI™ is provided in electronic format.

The electronic version (eIFU) is available for observation from the official SIA XOresearch Support Centre website at: https://support.cardio.ai/ifu/index.html.

Users can request an additional copy by contacting XOresearch Support via email at getintouch@xoresearch.com.

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It is the responsibility of the user to ensure that they are referring to the latest version of the IFU, which can be verified on the XOresearch website.

17. Limitations

Limitations
XOresearch Cardio.AI™ is a clinical decision support software designed to assist healthcare professionals in ECG data analysis. While using, the following limitations should be considered:

Clinical Decision Support Only
XOresearch Cardio.AI™ does not provide a definitive diagnosis and is not intended to replace clinical judgment. It serves as an aid to qualified healthcare professionals who must interpret the results in the context of the patient's clinical presentation.

Dependence on Input Data Quality
The accuracy of analysis depends on the quality and integrity of the ECG data. Incorrect lead placement, signal noise, or incomplete recordings may affect performance and lead to misinterpretation.

No Real-Time Monitoring or Emergency Alerts
The software processes ECG data retrospectively and does not support real-time monitoring or automated alerts for critical cardiac events. It is not intended for use in emergency decision-making.

Pacemaker Signal Limitations
The software does not reliably detect or differentiate ECG signals originating from implanted pacemakers or defibrillators. It should not be used as a primary tool for patients with these devices.

ECG Format Compatibility
XOresearch Cardio.AI™ supports ECG data import in EDF and BDF formats only. ECG recordings in other proprietary formats may not be compatible unless converted to a supported format.

Regulatory Scope and Intended Use
The software is classified as a Class IIa medical device under MDR (EU) 2017/745 (Rule 11). Its intended use is limited to the scope defined in the regulatory documentation and certification. Any use beyond this scope is not covered by the manufacturer’s intended purpose.

System and Environmental Requirements

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XOresearch Cardio.AI™ is a web-based application requiring stable internet connectivity and a compatible browser (Google Chrome 116+, Microsoft Edge 126+, or Opera 113+). Performance may be affected if system requirements are not met.

User Training Requirement
The software should only be used by qualified healthcare professionals who have reviewed the Instructions for Use (IFU) and completed appropriate training. Improper use may result in misinterpretation of ECG data.

Risk of False Positives/Negatives
Despite rigorous validation, the software may produce false-positive or false-negative classifications. Clinical verification of AI-generated annotations is **required** before making patient management decisions.

Data Storage and Retention
ECG data is stored for a limited period per the manufacturer's data retention policy. Users must comply with applicable data protection regulations regarding the storage, processing, and transfer of patient information.

18. Manufacturer's Declaration

We, SIA XOresearch, declare that this Instructions for use accurately represents the use and troubleshooting procedures for XOresearch Cardio.AI™.

Any serious incident related to the device must be reported to SIA XOresearch and to the competent authority of the Member State in which the users and/or patients are established.

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