PMcardio®
for Individuals

Core AI ECG Model

Instructions for Use

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Read the Instructions for Use before using Core AI ECG Model

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1. Introduction

The Core AI ECG Model is an artificial intelligence-based model designed to provide accurate diagnostics for a specific range of cardiovascular diseases based on ECG input data. The device leverages deep learning algorithms trained on thousands of ECGs containing various cardiovascular diagnoses and can be integrated into medical devices or other IT healthcare solutions. The device is only intended to analyze ECG recordings generated from adults.

2. Warnings and precautions

2.1. Warnings

1. DO NOT use for analyzing other waveform data such as electroencephalograms (EEGs) depicting the electrical activity of the brain.
2. The device has not been tested for pediatric patients or patients under the age of 18.
3. Read instructions for use before using the device.

2.2. Precautions

1. The Core AI ECG Model only detects the indications listed in the section 'Supported ECG diagnoses' in the instructions for use. Other indications that are not identified by Core AI ECG Model might nevertheless be present.
2. Additional diagnostic investigations may be necessary.
3. Powerful Medical makes no warranty for any data or information that is collected erroneously by the device, or misuse or malfunction as a result of abuse, accidents, alteration, misuse, neglect, failure to update, or install the application as instructed.
4. DO NOT use the Core AI ECG Model for analyzing ECG recordings of low quality.
5. DO NOT use the Core AI ECG Model for analyzing ECG recordings that do not satisfy the device's input requirements.
6. DO NOT use the Core AI ECG Model for analyzing ECGs of patients with an active pacemaker.
7. DO NOT use the Core AI ECG Model for analyzing ECGs with flatlines (disconnected leads).
8. DO NOT use the Core AI ECG Model for analyzing exercise stress test ECG recordings.
9. DO NOT use the Core AI ECG Model for analyzing ambulatory/Holter ECG recordings.
10. Powerful Medical does not guarantee that the patient is not experiencing a cardiovascular event, abnormal rhythm or other health conditions when no serious diagnoses are detected.
11. The overall average values of the ECG intervals may be inaccurate for ECG recordings of low quality.
12. The Core AI ECG Model may incorrectly identify cardiovascular conditions.
13. Always ensure correct placements of the leads to avoid limb lead reversal.

3. Intended purpose, Indications for use, Contra-indications and exclusions, intended users and patients

3.1. Intended purpose (EU MDR)

The product is intended to be used by qualified healthcare professionals for the assessment of cardiovascular diseases using ECG data. The application provides diagnostic recommendations for patients aged 18 years and above.

3.2. Indications for use

Core AI ECG Model is designed to assist qualified healthcare professionals in interpreting 12-lead resting ECGs in subjects over 18 years of age. Core AI ECG Model is intended for use by healthcare professionals trained in ECG interpretation in a professional healthcare environment such as hospitals, emergency medical services and other healthcare facilities.

Indications for use include patients presenting with common cardiovascular symptoms, such as Chest pain, Palpitations, Shortness of breath, Syncope. Additionally, Core AI ECG Model can be used in all situations when an ECG exam is performed or gathered by the intended users including routine examinations, pre-operative testing, sport exams and vitals testing in the urgent care setting.

Core AI ECG Model interpretation results are not intended to be the sole means of diagnosis. The device's output is to be considered advice only and to be interpreted in conjunction with the health care professional's knowledge of ECG patterns, patient background, clinical history, symptoms, and other diagnostic information. The device is designed to be integrated into medical devices or other IT healthcare solutions by a healthcare solution operator to build web, mobile or other types of applications.

3.3. Contra-indications and exclusions

- The use of the Core AI ECG Model is not allowed for ECGs of pediatric patients or patients under the age of 18, due to different normal ranges for electrocardiographic measurements.
- The use of the Core AI ECG Model is not allowed for the analysis of stress test ECG recordings and Holter recordings.
- It is not allowed to use Core AI ECG Model for the assessment of other waveform data such as electroencephalograms (EEGs) depicting the electrical activity of the brain, due to different features of the waveform.
- The Core AI ECG Model is not for use in life-supporting or sustaining systems or ECG monitor and Alarm devices.
- The Core AI ECG Model results are not intended to be the sole means of diagnosis, and they shall not be used in environments without qualified healthcare professionals present to make the final diagnosis. It is to be offered to qualified healthcare professionals on an advisory basis in conjunction with the physician's knowledge of ECG patterns, patient background, clinical history, symptoms, and other diagnostic information.
- The Core AI ECG Model shall not be used in autonomous IT systems that rely on the device's input for further medical decisions.

3.4. Intended users

The device is intended to be used by qualified healthcare professionals trained in ECG interpretation, such as:

- Non-Cardiologist Physicians, e.g., General Practitioners (GP)
- Cardiologists (General Cardiologist, Specialized Cardiologist)
- Nurses
- Emergency Medical Service (EMS) Workers / Paramedics
- Medicine students during clinical rotations

As the device is intended to be integrated into other medical devices or other IT healthcare solutions, we consider Operators who intends to integrate the Core AI ECG Model to also be the users of the device.

Based on a use-case analysis, the intended users are grouped to the following user groups:

- Healthcare professionals
- Operators of the device

3.5. Characterization of Patients

Core AI ECG Model is intended to be used as a standard tool to analyze and interpret standard 12-lead electrocardiograms recorded by qualified healthcare professionals for patients over 18 years of age. The following types of adult patients can be considered:

- Healthy patients presenting to the GP for routine examination
- Asymptomatic patients

- Symptomatic patients presenting to the GP, emergency department, ambulance
- Patients with known chronic cardiovascular disease followed up by GPs or internal medicine physicians

3.6. Environmental specification

The Core AI ECG Model is intended to be integrated into medical devices or other IT healthcare solutions by a healthcare solution operator to build web, mobile, or other types of applications, and is intended for use by qualified healthcare professionals trained in ECG interpretation in hospitals, outpatient clinics, emergency departments, and out-of-hospital sites such as ambulances and patients' homes.

4. Supported Diagnoses, Clinical Safety, and Performance

4.1. Supported ECG diagnoses

Using the proprietary Core AI ECG Model algorithm, the subject device is able to assist in the detection and interpretation of the following ECG-based diagnoses:

- Sinus bradycardia
- Sinus rhythm
- Sinus tachycardia
- Paced rhythm
- Atrial fibrillation
- Atrial fibrillation - rapid
- Atrial fibrillation - slow
- Atrial flutter
- Atrial flutter - rapid
- Atrial flutter - slow
- Supraventricular tachycardia
- Suspected junctional rhythm
- Suspected junctional bradycardia
- Suspected accelerated junctional rhythm
- Wide QRS rhythm
- Idioventricular rhythm
- Wide QRS tachycardia
- Premature complex
- 1st degree AV block
- 2nd degree AV block, type Wenckebach
- Higher degree AV block
- Complete right bundle branch block
- Incomplete right bundle branch block
- Complete left bundle branch block
- Incomplete left bundle branch block
- Nonspecific intraventricular conduction delay
- Left anterior fascicular block
- Left posterior fascicular block
- Bifascicular block (RBBB + LAFB)
- Bifascicular block (RBBB + LPFB)
- Trifascicular block (RBBB + LAFB + AVBLOCK1)
- Trifascicular block (RBBB + LPFB + AVBLOCK1)
- Suspected long QT syndrome
- Suspected short QT syndrome
- Suspected atrial enlargement

- Suspected ventricular hypertrophy

4.2. Supported ECG measurements

Using the proprietary Core AI ECG Model algorithm, the subject device is able to assist in the detection of the following ECG measurements:

- P Wave
- PR Interval
- QRS Complex
- QT Interval
- RR Interval
- Heart Rate
- PP Interval
- QTc Time - based on the Framingham formula
- Cardiac Axis - each of the ECGs has exactly one class for R-axis defined. Options are Normal, Left, Right, and Extreme.

4.3. Unsupported diagnoses by the AI-algorithms

The Core AI ECG Model does not support any other indications than the indications listed in the 'Supported ECG diagnoses' section.

As such, Core AI ECG Model currently does not support the following diagnoses:

- Asystole
- Movement artefact
- Suspected Electrode Reversal
- Sino-Atrial Exit Block (and its different types)
- Sick sinus syndrome
- Sinus pause
- Digitalis intoxication
- Pericarditis
- Pericardial effusion/tamponade
- Myocarditis, Pulmonary embolism
- Brugada Syndrome
- Bundgaard syndrome
- Ashman Phenomenon
- Electrolyte imbalances (including: Hyperkalemia, Hypokalemia, Hypercalcemia, Hypocalcemia, Hypermagnesemia and Hypomagnesemia)
- Hyperthyroidism
- Hypothyroidism
- Hypothermia (Osborn wave)
- Raised intracranial pressure
- Arrhythmogenic cardiomyopathy (ACM, arrhythmogenic right ventricular cardiomyopathy (ARVC) - epsilon waves)
- Tako Tsubo cardiomyopathy
- Wellens syndrome
- De Winter ST-T
- Low QRS voltage
- Poor R-wave progression
- Persistent S-waves

- Dextrocardia
- Other medication intoxication

Also, any other diagnosis not listed is not supported by default.

4.4. Clinical benefits of Core AI ECG Model

ID	Clinical Benefit	Explanation
CB1	Patients receive prompt ECG diagnostic from a spectrum of 38 cardiac pathologies while in a primary or emergency care setting.	Automatic and fast analysis of 38 ECG diagnoses commonly found in the use environments.
CB2	Patients receive list of diagnoses with a high degree of accuracy.	Diagnostic performance was evaluated using industry five industry-standard metrics, significantly outperforming general practitioners in diagnostic performance.
CB3	Patients receive improved ECG diagnostics at the primary care level.	General practitioners represent the state-of-the-art in ECG diagnostics at the primary care level. In a head-to-head benchmark comparison, the evaluated technology significantly outperformed general practitioners in the diagnostic performance.

4.5. Device performance

The performance testing methodology for the Core AI ECG Model was constructed to evaluate the machine learning based algorithm's performance in detecting various cardiovascular diagnoses and its operational robustness across a range of clinical scenarios. The final Test dataset consists of 4,122 ECGs, each diagnostics pattern is covered by at least 50 positive and negative cases. The data was labeled by 3 expert annotators and 2 cardiologists to obtain the reliable labels. Performance of the Morphology Measurements was evaluated on the CSE ECG dataset. The CSE Multilead dataset is an official dataset for morphology measurement assessment.

Performance evaluation metrics:

Metric	Description	Formula
Sensitivity	The ability of a test to correctly identify patients with a specified disease.	$\mathrm{TPR} = \frac{\mathrm{TP}}{\mathrm{P}} = \frac{\mathrm{TP}}{\mathrm{TP}+\mathrm{FN}} = 1 - \mathrm{FNR}$
Specificity	The ability of a test to correctly identify people without a specified disease.	$\mathrm{TNR} = \frac{\mathrm{TN}}{\mathrm{N}} = \frac{\mathrm{TN}}{\mathrm{TN}+\mathrm{FP}} = 1 - \mathrm{FPR}$
Positive Predictive Value (PPV)	The positive predictive value is the probability that following a positive test result, that individual will truly have the specified disease.	$\mathrm{PPV} = \frac{\mathrm{TP}}{\mathrm{TP}+\mathrm{FP}} = 1 - \mathrm{FDR}$
Negative Predictive Value (NPV)	The negative predictive value is the probability that following a negative test result, that individual will truly not have the specified disease.	$\mathrm{NPV} = \frac{\mathrm{TN}}{\mathrm{TN}+\mathrm{FN}} = 1 - \mathrm{FOR}$

Patterns evaluation

The final performances and evaluation of the Core AI ECG Model on patterns are presented below:

	Cases	TP	FN	FP	TN	PPV	NPV	Sensitivity	Specificity	MCC	F1
sinrhy_p	1161	385	4	27	745	0.934 (0.92-0.949)	0.995 (0.99-0.999)	0.99 (0.984-0.996)	0.965 (0.954-0.976)	0.942 (0.935-0.948)	0.961 (0.95-0.972)
pacerhy_p	1161	258	17	7	879	0.974 (0.964-0.983)	0.981 (0.973-0.989)	0.938 (0.924-0.952)	0.992 (0.987-0.997)	0.942 (0.936-0.948)	0.956 (0.944-0.967)
afib_p	1161	185	7	3	966	0.984 (0.977-0.991)	0.993 (0.988-0.998)	0.964 (0.953-0.974)	0.997 (0.994-1.0)	0.969 (0.965-0.972)	0.974 (0.964-0.983)
aflut_p	1161	153	6	4	998	0.975 (0.965-0.984)	0.994 (0.99-0.998)	0.962 (0.951-0.973)	0.996 (0.992-1.0)	0.963 (0.959-0.967)	0.968 (0.958-0.978)
otherhy_p	1161	128	18	9	1006	0.934 (0.92-0.949)	0.982 (0.975-0.99)	0.877 (0.858-0.896)	0.991 (0.986-0.997)	0.892 (0.88-0.903)	0.905 (0.888-0.921)
pcom_p	368	175	9	1	183	0.994 (0.987-1.0)	0.953 (0.932-0.975)	0.951 (0.929-0.973)	0.995 (0.987-1.0)	0.947 (0.935-0.956)	0.972 (0.955-0.989)
avblock2w_p	504	66	21	11	406	0.857 (0.827-0.888)	0.951 (0.932-0.97)	0.759 (0.721-0.796)	0.974 (0.96-0.988)	0.769 (0.731-0.803)	0.805 (0.77-0.839)
avblockhd_p	504	134	51	15	304	0.899 (0.873-0.926)	0.856 (0.826-0.887)	0.724 (0.685-0.763)	0.953 (0.934-0.971)	0.715 (0.67-0.756)	0.802 (0.768-0.837)
rbbb_p	538	177	1	21	339	0.894 (0.868-0.92)	0.997 (0.992-1.0)	0.994 (0.988-1.0)	0.942 (0.922-0.961)	0.913 (0.898-0.926)	0.941 (0.922-0.961)
lbbb_p	538	179	10	3	346	0.984 (0.973-0.994)	0.972 (0.958-0.986)	0.947 (0.928-0.966)	0.991 (0.984-0.999)	0.947 (0.937-0.955)	0.965 (0.949-0.98)
lafb_p	476	139	16	8	313	0.946 (0.925-0.966)	0.951 (0.932-0.971)	0.897 (0.869-0.924)	0.975 (0.961-0.989)	0.884 (0.863-0.902)	0.921 (0.896-0.945)
lpfb_p	476	138	24	6	308	0.958 (0.94-0.976)	0.928 (0.904-0.951)	0.852 (0.82-0.884)	0.981 (0.969-0.993)	0.859 (0.833-0.881)	0.902 (0.875-0.929)

	Cases	TP	FN	FP	TN	PPV	NPV	Sensitivity	Specificity	MCC	F1
atrenl_p	403	268	2	9	124	0.968 (0.95-0.985)	0.984 (0.972-0.996)	0.993 (0.984-1.0)	0.932 (0.908-0.957)	0.938 (0.925-0.949)	0.98 (0.966-0.994)
venhyp_p	328	167	4	12	145	0.933 (0.906-0.96)	0.973 (0.956-0.991)	0.977 (0.96-0.993)	0.924 (0.895-0.952)	0.903 (0.881-0.921)	0.954 (0.932-0.977)
extreme_r	302	53	1	0	248	1.0 (1.0-1.0)	0.996 (0.989-1.0)	0.981 (0.966-0.997)	1.0 (1.0-1.0)	0.989 (0.986-0.991)	0.991 (0.98-1.0)
left_r	302	70	21	1	210	0.986 (0.973-0.999)	0.909 (0.877-0.942)	0.769 (0.722-0.817)	0.995 (0.988-1.0)	0.827 (0.788-0.86)	0.864 (0.826-0.903)
normal_r	302	102	1	24	175	0.81 (0.765-0.854)	0.994 (0.986-1.0)	0.99 (0.979-1.0)	0.879 (0.843-0.916)	0.836 (0.799-0.867)	0.891 (0.856-0.926)
right_r	302	51	3	1	247	0.981 (0.965-0.996)	0.988 (0.976-1.0)	0.944 (0.919-0.97)	0.996 (0.989-1.0)	0.954 (0.943-0.964)	0.962 (0.941-0.984)

Table - Test set performance; `5000` model; digitized signal

	Cases	TP	FN	FP	TN	PPV	NPV	Sensitivity	Specificity	MCC	F1
sinrhy_p	1161	385	4	32	740	0.923 (0.908-0.939)	0.995 (0.99-0.999)	0.99 (0.984-0.996)	0.959 (0.947-0.97)	0.933 (0.925-0.94)	0.955 (0.943-0.967)
pacerhy_p	1161	248	27	10	876	0.961 (0.95-0.972)	0.97 (0.96-0.98)	0.902 (0.885-0.919)	0.989 (0.983-0.995)	0.911 (0.9-0.92)	0.931 (0.916-0.945)
afib_p	1161	186	6	17	952	0.916 (0.9-0.932)	0.994 (0.989-0.998)	0.969 (0.959-0.979)	0.982 (0.975-0.99)	0.93 (0.922-0.938)	0.942 (0.928-0.955)
aflut_p	1161	146	13	5	997	0.967 (0.957-0.977)	0.987 (0.981-0.994)	0.918 (0.902-0.934)	0.995 (0.991-0.999)	0.933 (0.926-0.94)	0.942 (0.928-0.955)
otherhy_p	1161	119	27	11	1004	0.915 (0.899-0.931)	0.974 (0.965-0.983)	0.815 (0.793-0.837)	0.989 (0.983-0.995)	0.846 (0.828-0.861)	0.862 (0.842-0.882)
pcom_p	368	158	26	2	182	0.988 (0.976-0.999)	0.875 (0.841-0.909)	0.859 (0.823-0.894)	0.989 (0.979-1.0)	0.855 (0.825-0.88)	0.919 (0.891-0.947)

	Cases	TP	FN	FP	TN	PPV	NPV	Sensitivity	Specificity	MCC	F1
avblock2w_p	504	16	71	0	417	1.0 (1.0-1.0)	0.855 (0.824-0.885)	0.184 (0.15-0.218)	1.0 (1.0-1.0)	0.396 (0.32-0.468)	0.311 (0.27-0.351)
avblockhd_p	504	154	31	63	256	0.71 (0.67-0.749)	0.892 (0.865-0.919)	0.832 (0.8-0.865)	0.803 (0.768-0.837)	0.618 (0.561-0.669)	0.766 (0.729-0.803)
rbbb_p	538	178	0	13	347	0.932 (0.911-0.953)	1.0 (1.0-1.0)	1.0 (1.0-1.0)	0.964 (0.948-0.98)	0.948 (0.938-0.956)	0.965 (0.949-0.98)
lbbb_p	538	184	5	3	346	0.984 (0.973-0.995)	0.986 (0.976-0.996)	0.974 (0.96-0.987)	0.991 (0.984-0.999)	0.967 (0.961-0.972)	0.979 (0.967-0.991)
lafb_p	476	132	23	8	313	0.943 (0.922-0.964)	0.932 (0.909-0.954)	0.852 (0.82-0.884)	0.975 (0.961-0.989)	0.85 (0.823-0.873)	0.895 (0.867-0.922)
lpfb_p	476	159	3	7	307	0.958 (0.94-0.976)	0.99 (0.982-0.999)	0.981 (0.969-0.994)	0.978 (0.964-0.991)	0.954 (0.945-0.961)	0.97 (0.954-0.985)
atrenl_p	403	260	10	5	128	0.981 (0.968-0.994)	0.928 (0.902-0.953)	0.963 (0.945-0.981)	0.962 (0.944-0.981)	0.917 (0.9-0.931)	0.972 (0.956-0.988)
venhyp_p	328	168	3	12	145	0.933 (0.906-0.96)	0.98 (0.964-0.995)	0.982 (0.968-0.997)	0.924 (0.895-0.952)	0.91 (0.889-0.927)	0.957 (0.935-0.979)
extreme_r	302	40	14	1	247	0.976 (0.958-0.993)	0.946 (0.921-0.972)	0.741 (0.691-0.79)	0.996 (0.989-1.0)	0.824 (0.784-0.857)	0.842 (0.801-0.883)
left_r	302	63	28	6	205	0.913 (0.881-0.945)	0.88 (0.843-0.917)	0.692 (0.64-0.744)	0.972 (0.953-0.99)	0.726 (0.667-0.775)	0.788 (0.741-0.834)
normal_r	302	102	1	31	168	0.767 (0.719-0.815)	0.994 (0.985-1.0)	0.99 (0.979-1.0)	0.844 (0.803-0.885)	0.797 (0.752-0.835)	0.864 (0.826-0.903)
right_r	302	50	4	9	239	0.847 (0.807-0.888)	0.984 (0.969-0.998)	0.926 (0.896-0.955)	0.964 (0.943-0.985)	0.86 (0.827-0.887)	0.885 (0.849-0.921)

Table - Test set performance; 2500 model; digitized signal

	Cases	TP	FN	FP	TN	PPV	NPV	Sensitivity	Specificity	MCC	F1

	Cases	TP	FN	FP	TN	PPV	NPV	Sensitivity	Specificity	MCC	F1
sinrhy_p	1161	386	3	30	742	0.928 (0.913-0.943)	0.996 (0.992-1.0)	0.992 (0.987-0.997)	0.961 (0.95-0.972)	0.939 (0.931-0.945)	0.959 (0.948-0.97)
pacerhy_p	1161	250	25	10	876	0.962 (0.95-0.973)	0.972 (0.963-0.982)	0.909 (0.893-0.926)	0.989 (0.983-0.995)	0.916 (0.906-0.924)	0.935 (0.92-0.949)
afib_p	1161	186	6	16	953	0.921 (0.905-0.936)	0.994 (0.989-0.998)	0.969 (0.959-0.979)	0.983 (0.976-0.991)	0.933 (0.925-0.94)	0.944 (0.931-0.957)
aflut_p	1161	142	17	6	996	0.959 (0.948-0.971)	0.983 (0.976-0.991)	0.893 (0.875-0.911)	0.994 (0.99-0.998)	0.914 (0.905-0.923)	0.925 (0.91-0.94)
otherhy_p	1161	121	25	12	1003	0.91 (0.893-0.926)	0.976 (0.967-0.985)	0.829 (0.807-0.85)	0.988 (0.982-0.994)	0.851 (0.834-0.866)	0.867 (0.848-0.887)
pcom_p	368	158	26	1	183	0.994 (0.986-1.0)	0.876 (0.842-0.909)	0.859 (0.823-0.894)	0.995 (0.987-1.0)	0.861 (0.832-0.886)	0.921 (0.894-0.949)
avblock2w_p	504	17	70	1	416	0.944 (0.924-0.964)	0.856 (0.825-0.887)	0.195 (0.161-0.23)	0.998 (0.993-1.0)	0.393 (0.317-0.464)	0.324 (0.283-0.365)
avblockhd_p	504	154	31	68	251	0.694 (0.653-0.734)	0.89 (0.863-0.917)	0.832 (0.8-0.865)	0.787 (0.751-0.823)	0.601 (0.542-0.654)	0.757 (0.719-0.794)
rbbb_p	538	178	0	13	347	0.932 (0.911-0.953)	1.0 (1.0-1.0)	1.0 (1.0-1.0)	0.964 (0.948-0.98)	0.948 (0.938-0.956)	0.965 (0.949-0.98)
lbbb_p	538	183	6	3	346	0.984 (0.973-0.995)	0.983 (0.972-0.994)	0.968 (0.953-0.983)	0.991 (0.984-0.999)	0.963 (0.957-0.969)	0.976 (0.963-0.989)
lafb_p	476	138	17	8	313	0.945 (0.925-0.966)	0.948 (0.929-0.968)	0.89 (0.862-0.918)	0.975 (0.961-0.989)	0.879 (0.857-0.898)	0.917 (0.892-0.942)
lpfb_p	476	159	3	6	308	0.964 (0.947-0.98)	0.99 (0.982-0.999)	0.981 (0.969-0.994)	0.981 (0.969-0.993)	0.958 (0.95-0.965)	0.972 (0.958-0.987)
atrenl_p	403	258	12	6	127	0.977 (0.963-0.992)	0.914 (0.886-0.941)	0.956 (0.935-0.976)	0.955 (0.935-0.975)	0.901 (0.88-0.918)	0.966 (0.949-0.984)
venhyp_p	328	168	3	12	145	0.933 (0.906-0.96)	0.98 (0.964-0.995)	0.982 (0.968-0.997)	0.924 (0.895-0.952)	0.91 (0.889-0.927)	0.957 (0.935-0.979)

	Cases	TP	FN	FP	TN	PPV	NPV	Sensitivity	Specificity	MCC	F1
extreme_r	302	44	10	0	248	1.0 (1.0-1.0)	0.961 (0.939-0.983)	0.815 (0.771-0.859)	1.0 (1.0-1.0)	0.885 (0.858-0.907)	0.898 (0.864-0.932)
left_r	302	69	22	5	206	0.932 (0.904-0.961)	0.904 (0.87-0.937)	0.758 (0.71-0.807)	0.976 (0.959-0.993)	0.784 (0.736-0.824)	0.836 (0.795-0.878)
normal_r	302	101	2	25	174	0.802 (0.757-0.847)	0.989 (0.977-1.0)	0.981 (0.965-0.996)	0.874 (0.837-0.912)	0.822 (0.782-0.855)	0.882 (0.846-0.918)
right_r	302	51	3	7	241	0.879 (0.843-0.916)	0.988 (0.975-1.0)	0.944 (0.919-0.97)	0.972 (0.953-0.99)	0.891 (0.865-0.912)	0.911 (0.879-0.943)

Table - Test set performance; 2500 model; digitized signal with Cabrera lead order

Based on the comparison of the model's performances to the benchmark performances, the models meet quality criteria, and the Core AI ECG Model is suitable for its intended purpose.

Morphology measurement performance evaluation

The performance results are presented below:

	Cases	Mean difference [ms]	Standard deviation [ms]
PRInterval	92	-2.859	7.198
QTInterval	92	-5.207	11.346
RRInterval	92	1.076	7.89
QRSDuration	92	0.489	6.38
PDuration	92	3.413	5.92

Table - CSE performance; 5000 model; digitized signal

	Cases	Mean difference [ms]	Standard deviation [ms]
PRInterval	92	-1.359	7.536
QTInterval	92	-1.543	11.232
RRInterval	92	4.315	14.137
QRSDuration	92	2.033	5.629
PDuration	92	3.609	5.833

Table - CSE performance; 2500 model; digitized signal

	Cases	Mean difference [ms]	Standard deviation [ms]
PRInterval	92	-1.391	7.577
QTInterval	92	-1.533	11.144

	Cases	Mean difference [ms]	Standard deviation [ms]
RRInterval	92	4.359	14.408
QRSDuration	92	2.207	5.539
PDuration	92	3.565	5.775

Table - CSE performance; 2500 model; digitized signal with Cabrera lead format

Both 5000 and 2500 models have all metrics within the acceptance criteria for the digitized signals. Based on the comparison of the model's performances to the IEC standard, the models meet quality criteria, and the Core AI ECG Model is suitable for its intended purpose.

5. Residual risks and undesirable side-effects

1. **Misclassification:** As per the reported performances, a misclassification or misinterpretation of the ECG, resulting in under- or overdiagnosis, cannot be excluded.
2. **Loss of service:** The Core AI ECG Model's functionality may be interrupted or unavailable due to technical problems (e.g. cybersecurity attacks, system errors, unavailability due to server downtime), or incorrect use. In case of time-critical decisions in an environment with poor availability, the analysis of an ECG recording may be delayed or even fail altogether.

6. User interface description

No specific training other than the instructions for use is intended for this medical device.

6.1. View diagnostics result

6.1.1. Example screen flow

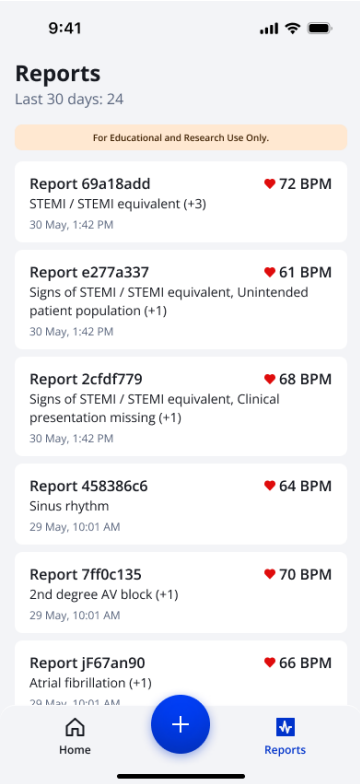

Figure 1: Reports list

1. Reports list
Select a specific report to see the diagnostics result of the Core AI ECG Model.

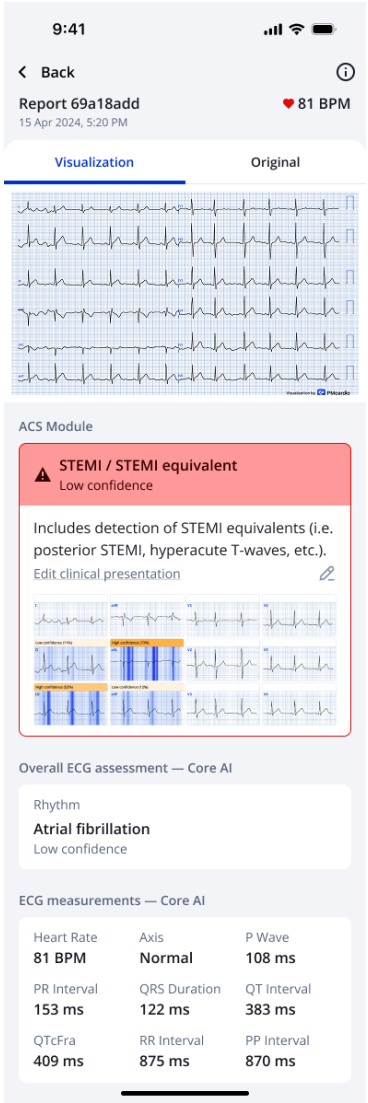

Figure 2: Report detail, success

2. Report detail

The report detail is shown.

Note: The diagnostics result screen is shown also during the new report creation flow.

6.1.2. Report detail screen elements

1. **Report ID and timestamp**

   The report ID and timestamp area of the user interface shows the unique ID of the ECG report and the exact time and date at which it was recorded.

2. **Diagnosis area**

   The analysis results of the Core AI ECG Model are displayed in the diagnosis area. Each element representing detected diagnosis includes diagnosis name.

   Further, in case of any error, no diagnostic output will be displayed. Instead, the respective error statement will be displayed in this area (see section 7 Error messages for details).

3. **Measurements area**

   The measurements detected within the ECG are displayed in the measurements area.

4. **Waveform area**

   The waveform area displays the exact 12-lead resting ECG recording that was analyzed by the Core AI ECG Model.

6.2. View information about the Core AI ECG Model

Information about the medical device can be accessed through Report detail screen by tapping on **Info** button.

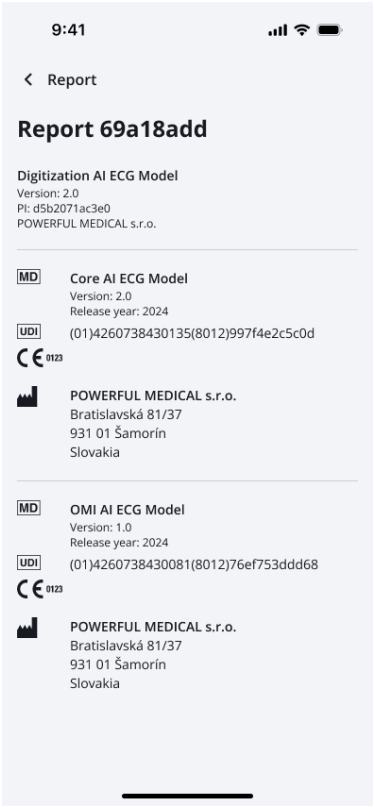

Figure 3: About screen

7. Error messages

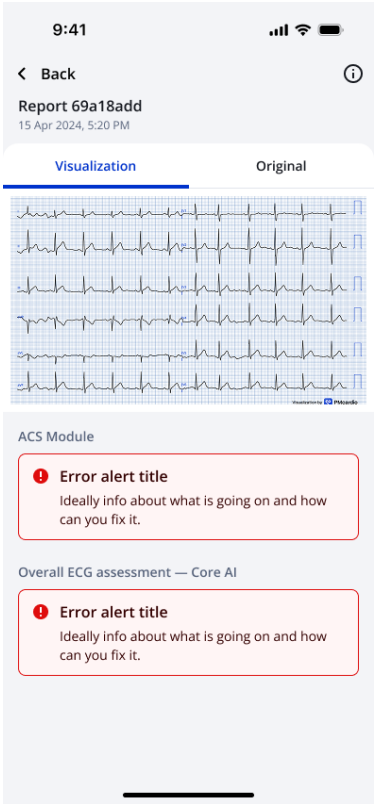

Figure 4: Report detail, error

If the processing of the ECG was unsuccessful, one of the following error messages will be displayed in the diagnosis area of the GUI:

1. `Insufficient signal error`
    - Title: "*Leads have too many missing parts.*"
    - Message: "*The provided leads have too many missing parts. Please ensure the input ECG is valid.*"

    This error will be displayed if more than five leads have over 70% of `null` values in the signal.

2. `Leads too short error`
    - Title: "*Leads are too short.*"
    - Message: "*All input leads should have at least 2500ms.*"

    This error will be displayed if any of the leads of the input ECG recording is shorter than 2.5 seconds.

3. `Leads too long error`
    - Title: "*Leads are too long.*"
    - Message: "*All input leads should have at most 15000 ms (15 s).*"

    This error will be displayed if any of the leads of the input ECG recording is longer than 15 seconds.

4. `Outlier measurements error`
    - Title: "*ECG measurement is out of the expected range.*"
    - Message: "*Outlier ECG measurements have been detected. Please double-check ECG settings (paper speed, voltage gain).*"

    This error will be displayed if some measurement value was calculated outside of its expected range.

5. `Unknown error`
    - Title: "*Code 500*"
    - Message: "*An unexpected exception occurred.*"

    This error will be displayed in case an unexpected error occurred. For example, this could be due to unavailability of the Core AI ECG Model. Please contact your system operator in case this error keeps occurring.

8. Reporting

8.1. Reporting according to EU MDR (EU only)

The user must report a suspected medical device-related serious incident to both the competent authority of the Member State in which the user and/or patient is established and the manufacturer. In the case of an event, please contact Powerful Medical via support@powerfulmedical.com.

9. Printed version of the Instructions for Use

The user can contact manufacturer at support@powerfulmedical.com to request a printed copy of this document. The manufacturer will provide a printed copy within 7 days at no additional costs.

10. Labels

The following symbols are used in the labeling of the Core AI ECG Model:

Symbol	Description
CE 0123	CE Mark
	Consult instructions for use
	Manufacturer of the medical device
MD	Medical device
UDI	Unique device identifier
CH REP	Swiss representative

Note: The Instructions for Use document is accessible through the menu in the User Interface.

11. Device and manufacturer information

Name of the medical device	Core AI ECG Model
Manufacturer of the medical device	 POWERFUL MEDICAL s.r.o. Karadžičova 8/A, 821 08 Bratislava, Slovakia www.powerfulmedical.com
Corresponding version of the the medical device	2.0
Date of the publication of Instructions for Use	April 2025
Release year of the medical device	2024
Basic-UDI-DI	426073843PMcardio0003H6
UDI-DI	4260738430135
Contact manufacturer	www.powerfulmedical.com support@powerfulmedical.com
Swiss authorized representative	CH REP Johner Medical Schweiz GmbH Tafelstattstrasse 13a, CH-6415 Arth, Switzerland